sobi

Pioneer in Rare Diseases

ANNUAL REPORT 2016

*The audited annual report includes pages 72–122.

This is Sobi

Sobi is an international biotechnology company dedicated to rare diseases.

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

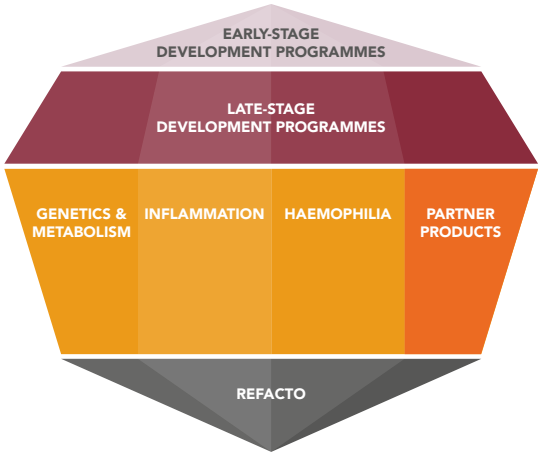
sarah loves animals

WHY

Pioneers in rare disease

Our strong commitment to improving the quality of life for patients with rare diseases guides us throughout our operations. We strive to be pioneers in creating a world where patients are diagnosed at birth, receive effective and sustainable therapy, and go on to live full and healthy lives.

Read more on page 16



WHAT

Strong and growing portfolio

We are an integrated biotechnology company dedicated to rare diseases. Our research and product portfolio is primarily focused on haemophilia, inflammation and genetic and metabolic diseases. Our in-house capabilities encompass the entire value chain with a focus on protein engineering and biologics development and supply.

Read more on page 24

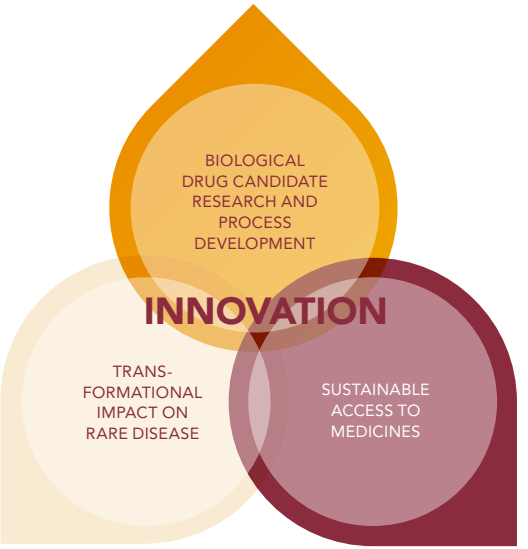
WHERE

Growing international presence

With our head office in Stockholm, Sweden, the organisation now spans 24 countries, delivering treatments to patients in over 60 countries across the globe. Europe is the core market for our haemophilia franchise.

Read more on page 12

Sobi affiliates
Sobi's other sales areas



HOW

Collaborative approach

We put the needs of patients first, in the belief that this will create long-term, sustainable value for everyone. We have developed a patient and customer-centric commercialisation model (PC3) to ensure that we are guided by patient needs. By working in a collaborative way, 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 – delivering new treatments to patients.

Read more on page 44

The financial year in brief

- Total revenues increased to SEK 5,204 M (3,228), an increase of 61 per cent.
- Total product revenues increased to SEK 4,548 M (2,568), an increase of 77 per cent.
- Gross margin increased to 70 per cent (62).
- EBITA amounted to SEK 1,543 M (433).
- Ended the year with a cash position of SEK 786 M (904).

Key figures

SEK M	2012	2013	2014	2015	2016
Total revenues[1]	1,923	2,177	2,607	3,228	5,204
Gross profit	1,040	1,284	1,548	2,007	3,651
Gross margin, %	54	59	59	62	70
Operating expenses	1,096	1,351	1,873	1,861	2,518
EBITA	367	211	–43	433	1,543
EBIT	–55	–67	–325	146	1,133
Profit/loss for the year	–105	–93	–266	65	809
Earnings per share, SEK	–0.40	–0.35	–1	0.24	3.01
Cash flow from operations	406	185	234	507	343
Equity per share, SEK	17.8	17.5	16.6	17.2	19.8
Equity assets ratio, %	76	73	71	56	54
Dividend	0	0	0	0	0
No. of employees	514	546	589	702	760

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.

REVENUES, %

+61

GROSS MARGIN, %

70

EBITA, SEK M

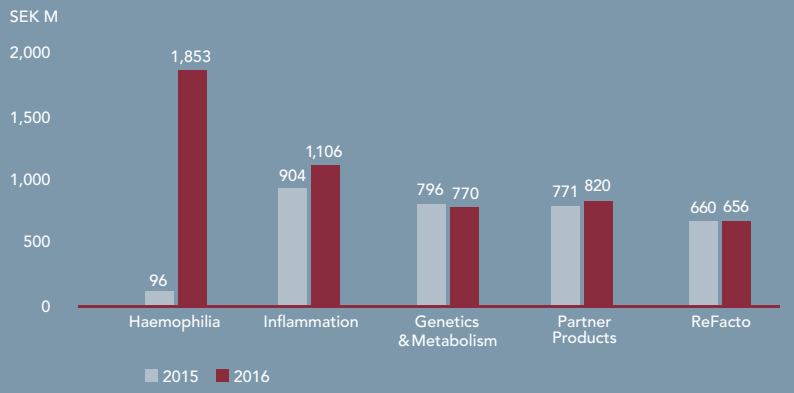
1,543

PROFITABLE GROWTH

During 2016, Sobi delivered strong financial performance across the portfolio. For the second year in a row, we over-delivered on raised financial targets and set down a strong platform for future ventures in our marketing, sales and development projects.

Read our CFO comments on our 2016 financial results on page 71

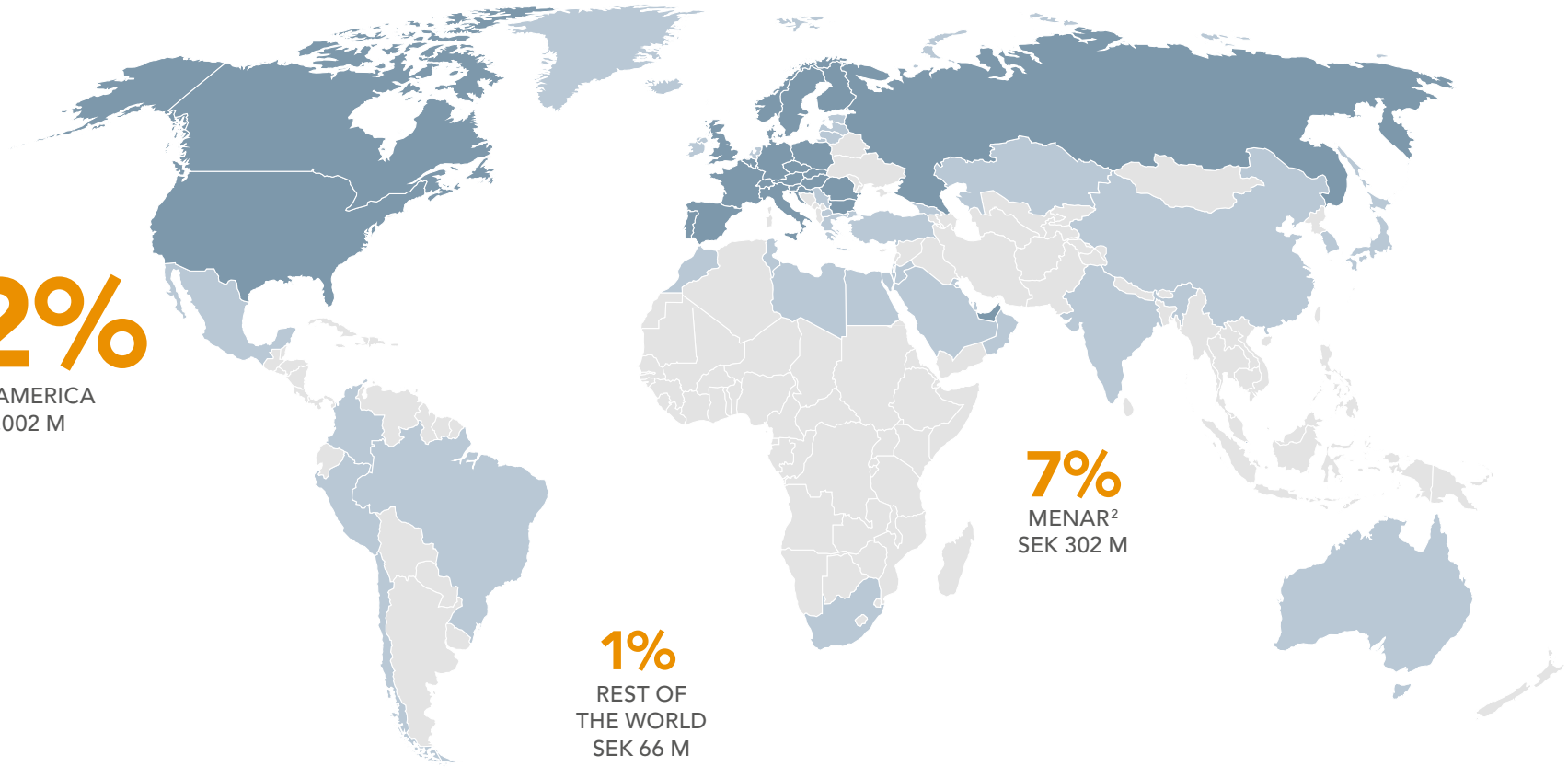
REVENUES BY BUSINESS AREA



Product revenues per region[1]

Excluding revenues from ReFacto.

70%
EUROPE SEK 3,178 M



22%
NORTH AMERICA
SEK 1,002 M

7%
MENAR[2]
SEK 302 M

1%
REST OF
THE WORLD
SEK 66 M

- Sobi affiliates
- Sobi's other sales areas

1. Revenues from legal companies registered in each region.
2. Middle East, North Africa, Russia.

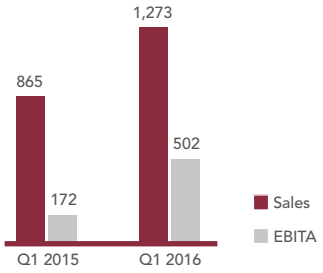
An eventful 2016

This is Cerys

Q1

- Signed agreement on commercial rights[1] for Relistor®, Deflux® and Solesta®.
- Commercial launch of Elocta® in first countries in Europe.
- Orfadin® Oral Suspension granted European patent.
- Clinical development programmes in acute gout and Still's disease announced.
- Market authorisation for Elocta transferred to Sobi.

SALES AND EBITA, SEK M



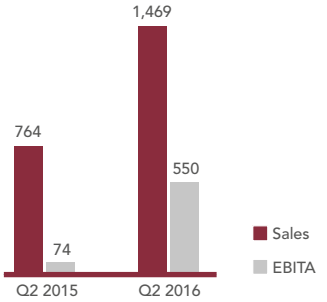
We received a one-time credit of SEK 322 M related to the first commercial sales of Elocta.

Q2

- US and European patent granted on new formulation of Kineret®.
- Licensing agreement signed with Affibody for development of treatments in IL-1 driven diseases.
- Orfadin Oral Suspension approved in the US.
- Extended the existing manufacturing agreement with Pfizer for ReFacto until 2023.
- Decision to move the production of Kineret drug substance to Pfizer in Strängnäs, Sweden.
- Alprolix® approved in the EU with maintained orphan designation for the treatment of haemophilia B.
- First Alprolix sales in the EU.
- Orfadin 20 mg capsule approved in the US.

Håkan Björklund elected new Chairman of the Board as Bo Jesper Hansen stepped down

SALES AND EBITA, SEK M

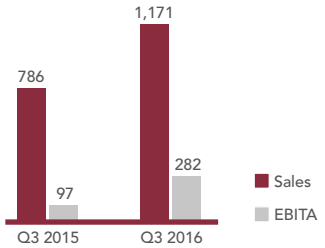


We received a one-time credit of SEK 386 M related to the first commercial sales of Alprolix.

Q3

- Orfadin capsule application validated by Health Canada.
- Elocta reimbursed in the United Kingdom, Italy, Spain and France.
- Alprolix reimbursed across the United Kingdom.

SALES AND EBITA, SEK M

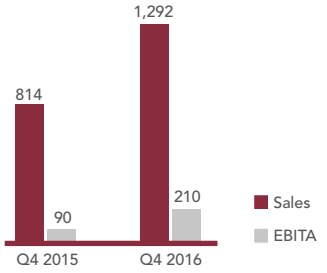


Revenues for Kineret increased by 23 per cent, supported by growth in all markets.

Q4

- Market authorisation for Alprolix transferred to Sobi.
- SOBI003 granted orphan designation by the European Commission for the treatment of MPS IIIA.
- Elocta approved in Kuwait for the treatment of haemophilia A.
- Five-year distribution agreement[2] for Ravicti® and Ammonaps®.

SALES AND EBITA, SEK M



Strong performance across the entire portfolio.

Milan Zdravkovic joined Sobi as Senior Vice President, Head of Research & Development

1. Commercial rights in a territory including Western Europe, Czech Republic, Slovakia, Hungary and also for Relistor in Russia.
2. Ravicti in all 28 member states of the EU and in three member states of the EEA. Ammonaps in the same European countries and certain Middle Eastern countries.

Reaching our strategic goals 2016 – a pivotal year

In 2011 we set three strategic priorities to develop Sobi in the years ahead.

Strategic priorities

1

Diverse, growing, and profitable base business in Europe and North America focused on rare diseases.

2

Launching first-to-market extended half-life haemophilia factor treatments in Sobi territory – providing forward cash flow to continue to build the company.

3

Growing the business organically with new products and with a pipeline of early stage rare disease biologics.

Sobi established in the Middle East and the US

Expanded partner portfolio with Xiapex® and Pharmaswiss portfolio

2011

REVENUE SEK 1,911 M

- Geoffrey McDonough appointed CEO.
- Focus on making the Sobi platform sustainable.

2012

REVENUE SEK 1,923 M

- Operational focus on key therapeutic areas.
- Pivotal phase 3 studies completed and paedia-tric trials initiated for Elocta and Alprolix.
- Research agreement signed with Affibody AB.
- ReFacto agreeement extended and Nordic commercial rights sold to Pfizer.

2013

REVENUE SEK 2,177 M

- New momentum in operating business.
- Aquired full rights for Kineret and received approval for CAPS indication in the EU.

Eloctate® and Alprolix launched in the US by our partner Bioverativ

REVENUE SEK 2,607 M

- Positive contributions from all parts of the business.
- Development pipeline setbacks as Kiobrina phase 3 study did not meet primary end-points.
- Orfadin direct sales in the US.

2014

Elocta approved in the EU

REVENUE SEK 3,228 M

- Haemophilia launch organisation in place.
- Implemented new distribution model for Kineret in the US.

2015

Launch of Elocta and Alprorix

REVENUE SEK 5,204 M

- Alprolix approved in the EU.
- Launch of two next-generation haemophilia products – Elocta and Alprolix in Europe and the Middle East.
- Pipeline strengthened with two candidate drugs in early stage development and new planned clinical pro-grammes.
- ReFacto agreeement extended to 2023.

2016

Objectives for 2017

- Exercise personal leadership by taking crisp decisions and acting with urgency in serving patients.
- 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.
- Ensure key pipeline inflection points are met:
  - complete enrolment in anaGo study;
  - initiate anaStill's study;
  - initiate two Elocta immune tolerance studies in collaboration with Bioverativ; and
  - SOBI003 on track for first patient in clinical trials in early 2018.
- Clear priority setting to ensure sustainable growth.

A strong platform for new and transformative treatments

Thank you for taking time to engage with our annual report for 2016. This volume captures a unique moment in securing the sustainable development of the collaborative, innovative, and patient-centred community that is Sobi today.

"Throughout the year we have come to understand the positive impact that these therapies can bring to patients and physicians."

We are inspired by our vision of contributing to a world in which people with rare diseases are diagnosed early and can access life-changing therapies to achieve sustained transformation over a lifetime. From a business perspective this has led our company to focus on achieving a growing, diverse, and profitable base business as a platform for translating our rare disease expertise into new therapeutic areas.

Strategic decisions are forming our future

We took a major step in this direction in 2016 by launching Elocta and Alprolix, two first in class extended half-life Fc fusion clotting factors to people with haemophilia in Europe and in parts of the Middle East. Throughout the year we have come to understand the positive impact that these therapies can bring to patients and physicians, and as these therapies find their place in this important field they will also set the foundation for a period of significant growth for Sobi. In addition they may significantly advance the standard of care in the field. In particular we plan to explore in 2017 their potential application to eradicating the antibodies to clotting factors which remain a major challenge faced by many people with haemophilia.

It was an active year for our research and development portfolio. We initiated two important programmes in the Inflammation area to explore the potential for Kineret to be applied to acute gout and to Still's disease. In the Genetics & Metabolism field we demonstrated that Orfadin can be administered once daily, and launched both the Orfadin 20 mg capsule and the oral suspension – broadening our ability to support a growing population of patients with tyrosinaemia throughout all stages of life. Importantly we also were granted an orphan drug designation for our internally developed enzyme replacement therapy to treat the lysosomal storage disease Sanfilippo A and we are on track to begin a phase 1 clinical trial in early 2018.

Working sustainably

Our progress is driven by the energy, passion, and skills of a great variety of people working in 24 countries to move Sobi forward. Our commitment to quality and sustainability begins with our people, and is

reflected in the values which characterise our working environment: collaboration, accountability, respect, and engagement. Our strategy is guided by prioritising access to treatment for patients. By collaborating with our stakeholders we have advanced sustainable pricing models for our new haemophilia treatments, and are working to ensure that our pipeline candidates reach the patients who need them in a similar fashion. In addition, we continue to focus on upholding the highest standards for ethics and compliance through individual accountability, training, and support.

We are also especially happy with the progress during the year on our shared commitment with our partner Bioverativ to support global access to our haemophilia therapies. Our journey to donate 1 billion international units of Elocta and Alprolix to the developing world became actual during the year. Our donations to date totalling 190 million International Units have enabled the treatment of 11,000 people in 40 countries and doubled the number of children treated in the countries where the programme is active today.

Future perspectives

We enter the year ahead with a sense of confidence based on the platform we have created, balanced by the determination and humility required to bridge the gap between where we are today and the remaining needs of the communities we serve. It has been a privilege to have worked with the amazing individuals that make up Sobi over the past six years, and I am certain that the contributions that Sobi will bring to the rare disease community in the years to come will continue with unchanged determination and dedication. Thank you again for your support and interest in our work here.

Yours sincerely,
Geoffrey McDonough
CEO and President
Solna, Sweden

scan the QR-code to see an interview with our CEO

"Our donations to date have doubled the number of children receiving haemophilia treatment within the programme."


This is Quinn,
she is one in a million

Bringing value to the patients we serve with a clear vision for our business.

Finding a treatment for rare diseases

Legislation in the European Union, United States and other regions aims to stimulate research and development and the availability of treatments for rare conditions.

A rare disease affects a small percentage of the population, and is often serious, life-treathening or chronically debilitating. Many rare diseases appear early and are present throughout a person's life. To date, the cause remains unknown for many rare diseases.

In Europe and North America, an estimated 60 million people are impacted by one of approximately 7,000 known rare diseases. Although more and more therapies are becoming available, the majority of rare diseases are without treatment.

The history of orphan drugs developed to treat rare diseases is one of shared responsibility and community collaboration to achieve legislation and incentives to support the research and development of treatments. In 2016, the European Commission authorised 16 medicines with an orphan designation and the US Food and Drug Administration (FDA) approved 9 new orphan drugs. The main driver of this growth is successful legislation, combined with technological and scientific advancements, academic partnerships, the increasing availability of infrastructure, together with patient-led international and cross-border collaborations, which have helped to spur momentum worldwide.

Responsible pricing

An effective treatment is one that not only gives 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 important 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. A number of multi-stakeholder initiatives to support dialogue and collaboration have been presented and are in place, with the objective of finding shared sustainable solutions or frameworks to include rare disease treatments in the healthcare systems. Examples of patient and authority- driven initatives can be seen on the facing page.

A competitive landscape

Although the rare disease sector might appear less competitive than the pharmaceutical sector in general, we are exposed to competition in various areas. The market for haemophilia treatments – in terms of value and size – is both larger and more competitive than those for most rare diseases, with several conventional treatment options available. In the Genetics & Metabolism therapy area, we see emerging competition from generics.

As well as developing our own early stage programmes, we are also looking to strengthen our mid-stage portfolio over the coming years, via acquisitions or partnership agreements for early to mid-stage assets. Other pharmaceutical companies are also seeking to strengthen their research portfolios and to compete for the best assets we must show the benefits of our approach.

APPROXIMATELY

7,000

DIFFERENT RARE DISEASES IDENTIFIED TODAY

A rare disease affects a small percentage of the population and is often serious, life-threatening or chronically debilitating. The vast majority of rare diseases have no treatments.

RARE DISEASES IMPACT **1 IN 14**

60 MILLION

EU AND US CITIZENS ARE DIAGNOSED WITH A RARE DISEASE

80%

OF RARE DISEASES ARE GENETIC IN ORIGIN

Pioneering sustainable pricing models

Yann le Cam
Chief Executive Officer, EURORDIS Rare Diseases Europe

One of the biggest challenges from the patient perspective is delayed and inequitable access to new, approved treatments.

Decentralised national pricing and reimbursement processes after EU approval makes Europe an unequal continent. Some innovative medicines approved for use in Europe are considered so highly priced compared with their perceived value that they are not reimbursed by individual national healthcare systems and, therefore, are not available to the patients who need them.

National authorities are increasingly reluctant to reimburse orphan drugs due to uncertainties regarding their long-term efficacy. Patients and payers are willing to pay for clinical value, for instance if the patient can return to work after treatment. The added value of an orphan drug can only be demonstrated through the continuous generation of real-life evidence in the years following approval.

We hope to see more collaboration between national and European authorities and the pharmaceutical industry in order to streamline the pricing process and to overcome the delay and inequity in access issue.

We would also like companies to be daring, adaptive and forward-looking; and to remember that they are handling small populations where knowledge is limited due to the rarity; but the urgency and medical need is very real. Daring means involving patients from the very beginning and at all stages. And, of course, setting a fair price, aiming to create value from long-term, sustainable development of new medicines rather than short-term, quick returns in pursuit of maximum profit.

Ri de Ridder
Director General, RIZIV-INAMI, Belgian National Institute for Health and Disability Insurance

A 'static' reimbursement model is no longer relevant. The number of innovation breakthroughs, particularly related to orphan drugs, is increasing. These new treatments are perceived to have an unsustainable budget impact in the current system.

Belgium has demonstrated a strong willingness to further develop existing systems by adapting them to new requirements for drug development and the timely and sustainable reimbursement of innovative technologies. One example is Belgium's leading role in the MoCA[1], a voluntary open dialogue on the development of new technologies, which has led to very early partnerships between payers, patients and companies. The MoCA dialogue offers a forum outside formal reimbursement processes and has enabled the creation of a trusting environment between all parties, allowing truly important issues to be addressed.

Triggered by the need to negotiate high-priced drugs with a bigger share of voice, authorities in Belgium, Austria, Luxembourg and the Netherlands have also created a formal collaboration platform to share capacity and expertise in new therapeutic fields. The aim is to leverage areas of mutual interest such as HTA, registries and horizon-scanning.

Early diagnosis and collaborations play a role to reach sustainable pricing. Companies willing to collaborate early in their development programmes will be able to make investment decisions that are sustainable in the long term. Money will be directed towards innovations targeting real unmet medical needs.

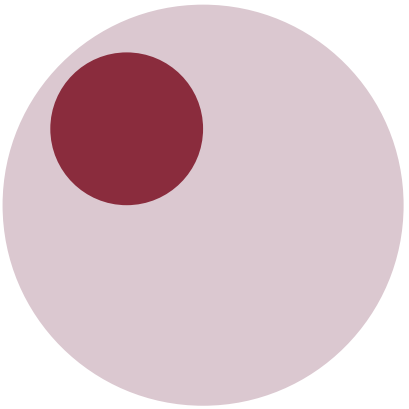
1. Mechanism of Coordinated Access to orphan medicinal products.

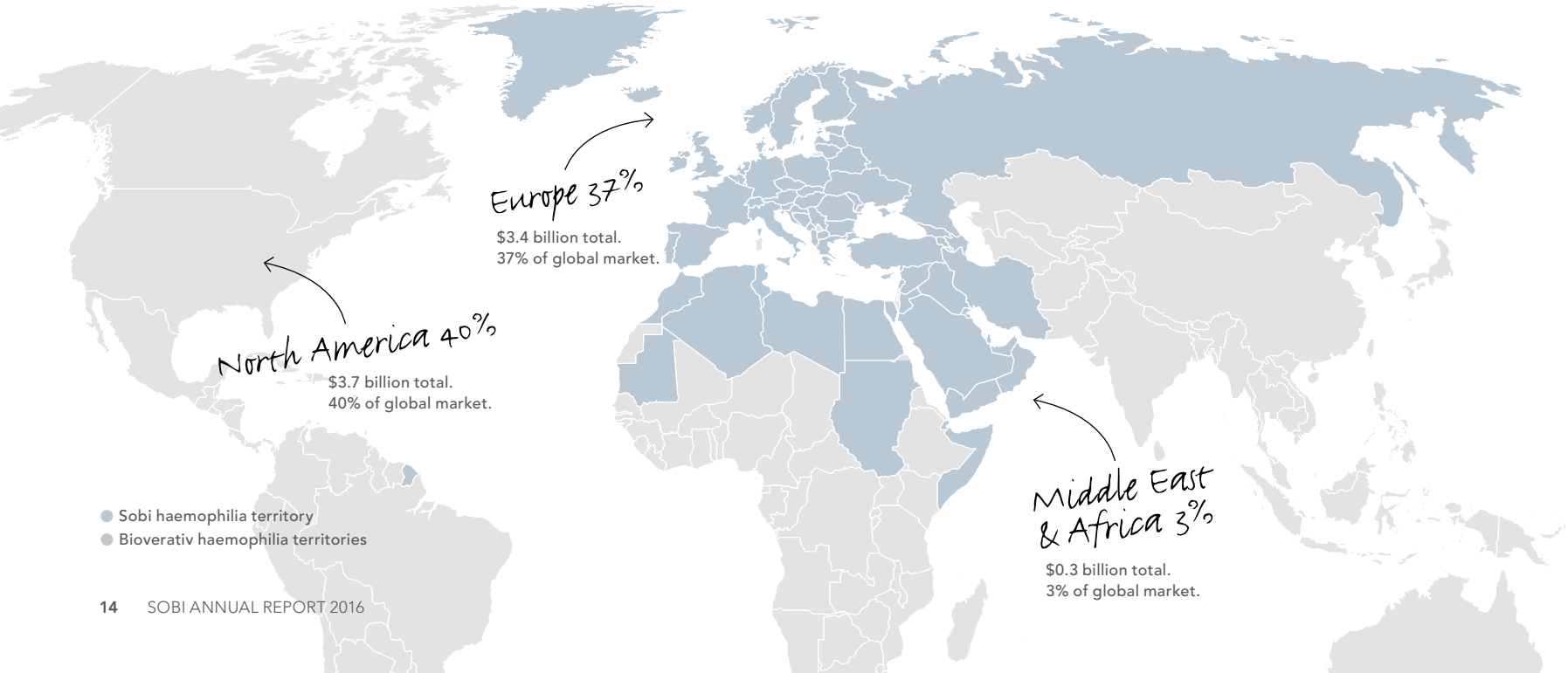
Haemophilia is the most common rare disease in the world

Only an estimated 25 per cent of the people living with haemophilia across the globe have been correctly diagnosed and have access to satisfactory treatment. The availability of treatment is concentrated to Europe and North America, with 37 and 40 per cent of the market, respectively.

Sobi makes recombinant extended half-life (EHL) coagulation factor concentrates available in Europe and certain parts of the Middle East. In addition to the EHL products currently offered by Sobi, other EHL products are expected to receive EU-wide authorisation over the next one to two years, while the field of gene therapy and other technologies is maturing and may offer treatment alternatives in the future.

Coagulation factor concentrates are the treatment of choice and are either recombinant or plasma-derived. Treatment is provided as prophylaxis (preventive) or on demand to stop a bleed. The use of prophylactic therapy is roughly similar in both haemophilia A and haemophilia B in countries with developed health systems. The estimated use of prophylaxis in haemophilia is 40–60 per cent in Europe and North America.





ABOUT

1 IN 10,000

IS BORN WITH HAEMOPHILIA A

ABOUT

1 IN 50,000

IS BORN WITH HAEMOPHILIA B

PEOPLE LIVING WITH HAEMOPHILIA

	Haemophilia A population	Haemophilia B population
Germany	3,800	680
France	5,600	1,270
United Kingdom	6,400	1,450
Italy	4,000	820
Spain	1,670	280
Other Europe (outside EU/EEA)	4,700	840
TOTAL EUROPE	**35,000**	**7,300**
Middle East	13,100	2,730
North Africa	7,400	1,690
Russia	5,800	990

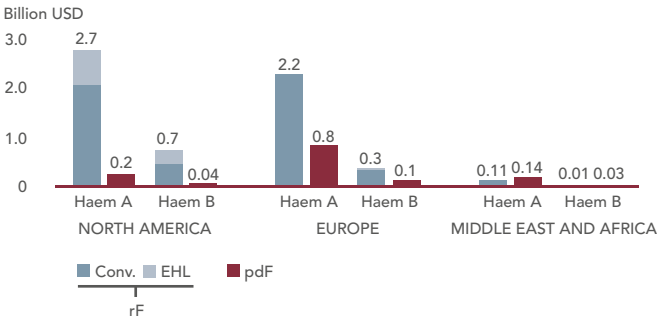
OF AN ESTIMATED
400,000 PEOPLE AFFECTED WITH
HAEMOPHILIA WORLDWIDE
ONLY

25%

HAVE ACCESS TO TREATMENT

FACTOR MARKET

Recombinant coagulation factors (rF) dominate the market compared to plasma-derived (pdF). Extended half-life (EHL) treatments were first made available to the market in 2014 in North America and in 2016 in Europe. Conventional treatments (Conv) still dominate the market.



Source: MRB Sept 2016 and 2016 WFH Annual Global Survey

Humanitarian aid donation report

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

In 2014, Sobi and Biogen (now Bioverativ), committed to produce one 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 systems to plan in a way that fosters better care. Surgeries can be planned and prophylactic treatment becomes a real possibility.

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

By year end 2016, Sobi and Bioverativ had donated 203 million IUs of Elocta/Elocate and Alprolix – enabling the treatment of 11,000 people in 40 countries by addressing 12,500 bleeds and almost 700 surgeries. Importantly the percentage of children who receive treatment trough the donation programme in these countries has doubled from 14 to 28 per cent.

PERCENTAGE OF CHILDREN RECEIVING TREATMENT IN THESE COUNTRIES HAS DOUBLED FROM

14% TO 28%

A patient-centric strategy

Our strategy is based on our vision – to pioneer a world in which rare disease patients are diagnosed at birth, receive effective and sustainable therapy, and go on to live full and healthy lives.

We believe the key ingredients to pioneering are the ability to listen to and to understand the needs of patients, to choose the precise application of technologies, to co-create an efficient path to approval with regulators, patients and physicians, and our willingness to jointly author sustainable commercial solutions with budget holders that can allow therapies to be included in the healthcare system and available for a lifetime.

Crucially, we believe that the culture of pioneering in the service of patients with rare diseases requires a small, agile, and human scale organisation that can stay responsive to the changing landscape of patient needs, science and society.

Our expertise ranges from preclinical development, process development and manufacturing of protein drugs, through to market entry ensuring patient access and commercialisation. Our operations are structured to allow for integrated engagement at all stages of the development, authorisation and commercialisation phases. This allows us to take advantage of our extensive in-house expertise at every stage of the process.

Gearing for growth

In 2016, we believe that we have reached the strategic priorities that we set out in 2011 – establishing a diverse, growing and profitable base business in Europe and North America focused on rare diseases; launching first-to-market long-acting haemophilia factors in our territory and providing forward cash flow to continue to build our company; and growing the business organically with new partner products and with a pipeline of early stage rare disease biologics. We now stand ready to bring Sobi to the next level and the next stage in our development. Drawing on more than 35 years of experience in developing biopharmaceutical products and 25 years of experience in commercialising those products for patients with rare diseases, we are well-positioned to continue to build value for patients, society and shareholders in a collaborative and sustainable way.

Read more about our vision on page 18

Cassius enjoys playing football

Vision

We are inspired to pioneer a world in which rare disease patients are diagnosed at birth, receive effective and sustainable therapy, and go on to live full and healthy lives.

Mission

To develop and deliver innovative therapies and services to improve the lives of patients.

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.

Input

Patient journey insights
Insights into patient needs provide input from research and development to commercialisation.

Capital provided by investors
Sobi is listed on Nasdaq Stockholm, with 32,397 shareholders as of 31 December 2016.

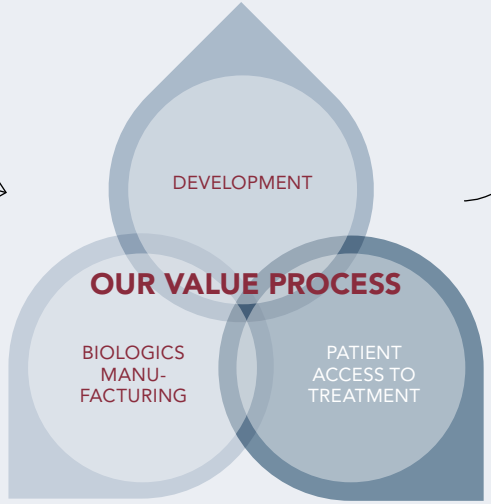
Partner Products
Innovative specialty care treatments from small and medium-sized partner companies.

Manufacturing facilities
Biologics manufacturing facilities for contract production and development scale-up.

Skilled workforce
760 highly skilled and engaged employees.

Intellectual property
Six proprietary products and a number of patents in development pipeline.

Raw materials and natural resources
Input to production of biologics.



Read more about our sustainability work on page 52

Outcome

Patient value
Patient access to rare disease and specialty care treatments in areas with a high medical need.

Product
Commercialisation of core products: Alprolix, Ammonaps, Elocta, Kepivance®, Kineret and Orfadin. Production of drug substance for ReFacto.

Return to partner companies
A cost-efficient distribution platform, to make niche medicines available in treatment areas with high unmet medical need in Europe, the Middle East, North Africa and Russia.

Return to investors
Over the past five years, the share price has risen 611 per cent.

Job creation & productivity
International workforce with employees in 24 countries.

Competence building
- Employees
- Broadened understanding of rare diseases in the community.

Our vision – to change the course of a disease for a lifetime

Sobi's goal is to pioneer a world in which rare-disease patients can live full and healthy lives. This vision is clearly demonstrated by Orfadin, our orphan drug that for more than 25 years has been used to treat the severe rare disease, hereditary tyrosinaemia type-1 (HT-1).

Children born with HT-1 are unable to break down the amino acid tyrosine. As a result, toxic substances build up in the blood, causing liver, kidney and neurological complications. 25 years ago, before treatment was available, the survival rate for children with HT-1 who developed symptoms before the age of two months was 29 per cent after two years. After the introduction of Orfadin, the survival rate is 93 per cent after two years in patients with treatment initiation before two months of age.[1] Early treatment with Orfadin and a closely managed diet have increased the survival probability rate and can change the course of this rare disease.[2]

New medical needs throughout the patient journey have inspired us to continuously develop and provide new solutions.

The patient's journey guides us

Childhood

1

Diagnosis at birth and early treatment
Orfadin Oral Suspension, approved in both Europe and the US, has been specially developed for infants and small children, and for those who have difficulty swallowing capsules or tablets.

1. van Spronsen FJ, et al. Hepatology. 1994;20(5):1187-1191.
2. Orfadin SmPC June 2015.

2

Addressing adherence challenges
"Let's Talk Tyrosinaemia" is one of several programmes developed together with the rare-disease community to increase knowledge about the importance of HT-1 treatment, and to support people with HT-1 through their life-long journey.

OUR DREAM IS THAT THEY ONE DAY BECOME

GRAND-PARENTS

4

Support programmes
Orfadin4U™ – a comprehensive support programme in the US for people living with HT-1 and their caregivers, is aimed at following them through life transitions, from product and reimbursement support to nurse assistance.

Mature adulthood

Mid-life

Adolescence

3

Flexible doses
For the first time, people with HT-1 who are diagnosed and start treatment early are now growing up to become teenagers and adults. Since dosing is weight-based, the doses are adjusted as they grow. The 20 mg capsule facilitates treatment regimens that support adherence in adolescents and adults and reduces the pill burden.

1,000

HT-1 PEOPLE AROUND THE WORLD ARE GROWING UP

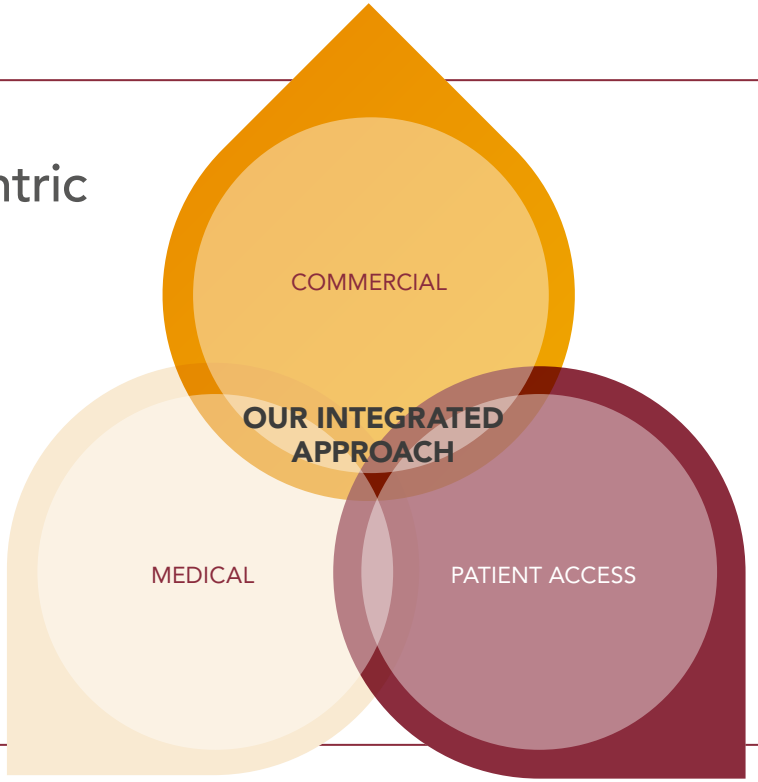
How we pioneer rare diseases

We believe that a company's ability to develop and deliver new and effective therapies for rare disease patients is determined by its success in terms of collaborative, patient-centric and sustainable practices.

PC3 – Patient and Customer-Centric Commercialisation

We put the needs of patients first, in the belief that this will create long-term, sustainable value for everyone. Medical needs throughout the patient journey inspire us to continuously develop and provide new solutions. We believe that a close collaboration between all stakeholders, all focusing on the needs of patients and our customers, no matter where they are in the process, is a crucial element to secure the best outcomes for patients and their families. Our teams are integrated and cross-functional. They listen and interact in a way that mirrors how our external customers and the communities we serve are also collaborating.

Involving stakeholders in all stages of the development process allows us to deliver the most meaningful value for patients, the healthcare system, the community and our shareholders.



"Our focus on collaboration and truly listening to the perspectives of patients, treaters, reimbursement agencies and payers is unique – this is the foundation for creating real effective treatments, which are accessible for patients to use and affordable to the health care systems."

Karin,
Patient Access Lead
Haemophilia, Nordics

"At Sobi, we work each day to deliver innovative therapies and services to improve the lives of patients, and we are touched each time we can bring the 'sun in our hands' of hope and happiness to those who need it most."

Ashraf,
Business Unit Manager
Global Brands, Middle East

Collaborative

The pharmaceutical arena is highly regulated and subject to decisions by external stakeholders at all stages – research, development and availability within a healthcare system.

OUR APPROACH

Only by listening to the community can we establish authentic collaborations and partnerships. Each rare disease is often an uncharted area. Patients, disease information, expertise and specialist treaters are few and may be scattered geographically, meaning that multi-stakeholder and cross-boarder collaboration is an essential and core element of our ability to be successful in developing potential therapies. We want to accelerate development times and generate robust and compelling evidence and data; and it makes sense to seek these collaborative solutions as early as possible. This requires long-term commitment and collaboration from the earliest phases of development through every stage.

Patient-centric

People living with rare diseases and the patient organisations that represent them are vital stakeholders in the patient journey, and are often experts in their own conditions.

OUR APPROACH

Our focus on bringing value to end-users – the patient – improves our chances to sucessfully develop and provide a meaningful treatment. For us, listening to people living with rare diseases and the community around them is an integral part of learning more about their experience, and what it means to be living with a rare condition. The ability to listen gives us insightful knowledge and creates understanding that is the foundation for future innovation.

Patient access to treatment guides our operations. We consider that a treatment that does not reach a patient in need is a lost opportunity for everyone. We believe that access to patient-centred treatment will always bring more sustainable results for all.

Sustainable

Ideally, patients will receive an early diagnosis and have access to effective treatment starting as early as needed and available sustainably over the course of their lifetime. Effective treatment is a treatment that is both available and affordable in the country or region where the patient lives.

OUR APPROACH

Our aim is to secure early and sustainable access to treatment. That means both being a sustainable company and a sustainable part of the healthcare system. A key factor is responsible pricing, which increases the possibility of patients having access to treatment and, thus, to our sustainability as a company.

We believe that people with a rare disease should have access to lifesaving treatment no matter where they are born. For this reason, we have created a sustainable access programme to secure that people with significant medical needs have access to innovative and effective treatments from our portfolio.


Through cooking,
Uwais is learning
about his disease

Access to treatment
is more than just
providing a product.

Laying the ground for the future

In line with our priorities, the base business and launch of the haemophilia treatments has provided a forward cash flow to continue to build the company. All therapeutic areas grew during the year and we increased access to our treatments in all regions.

	Actual 2016	Outlook 2017*
Revenues, SEK M	5,204	5,800–6,000
Gross margin, %	70	66–68
EBITA, SEK M	1,543	1,600–1,700

* The outlook was published on 16 February 2017.

Our performance in 2016 exceeded the outlook that we gave in February 2016 and based on strong performance across the portfolio and an earlier than expected launch for Alprolix, we raised guidance for the full year after the Q3 earnings in October 2016.

Sales increased by 61 per cent. The main contributor to the sales growth compared to last year was the launch and introduction of our extended half-life products within haemophilia in our territory.

Haemophilia

Total revenue for the Haemophilia franchise was SEK 1,853 M, with royalty revenue amounting to SEK 1,525 M. We are re-entering the haemophilia space after 20 years and this is the first year with product sales. By launching Elocta and Alprolix, Sobi has taken the first steps into the haemophilia market, valued at approximately SEK 30 billion in our territory.

Product sales were SEK 327 M, whereof SEK 267 M was from Elocta and SEK 60 M was from Alprolix.

We made significant progress during the year toward securing timely patient access to Elocta and Alprolix. Our pricing model has been met with a good reception from budget holders and by year end, Elocta had been approved for reimbursement in 13 countries in Europe and the Middle East and Alprolix in six countries.

Investments to support the launch of Elocta and Alprolix have been made during the year.

Inflammation

Kineret reached an important milestone with sales of SEK 1 billion and growth of 24 per cent. Growth in the EMENAR region was driven by the successful launch of Kineret for the CAPS indication and North America continues to see positive impact from the new US specialty distribution model and patient support programme.

Genetics & Metabolism

Revenue for Orfadin was SEK 770 M, a decrease of 3 per cent. The business continued to grow in EMENAR supported by the continued launch of the oral suspension and 20 mg formulations, however, the entrance of a local generic in Turkey and Canada negatively impacted the sales in 2016.

Partner Products

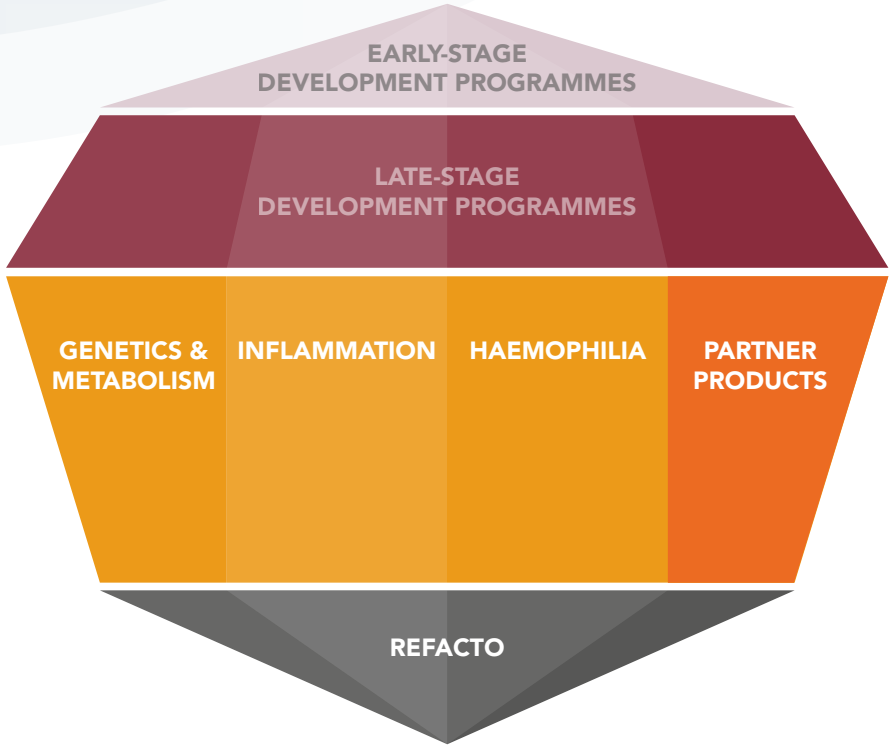
Revenue for Partner Products was SEK 820 M, an increase of 6 per cent. The growth was mainly due to continued growth for Xiapex and to the partnership with PharmaSwiss.

ReFacto

ReFacto manufacturing revenue and royalty totalled SEK 656 M. While manufacturing revenues increased, a changed royalty structure meant reduced royalties contribution, resulting in an overall decrease of 1 per cent.

A growing portfolio of innovative therapies

Our portfolio includes proprietary products, focused on haemophilia, inflammation and genetic and metabolic diseases, and approximately 30 products from 20 partners. We also contract manufacture the drug substance for Pfizer's recombinant haemophilia treatment, ReFacto AF.



HAEMOPHILIA
In 2016, we launched our extended half-life haemophilia treatments, Elocta and Alprolix, in Europe and the Middle East. We see a clear potential for these therapies to become the new standard of care and transform the lives of people living with haemophilia. Read more on pages 26–31.

INFLAMMATION
The launch of Kineret for the CAPS indication was completed in Europe during 2016. Read more on pages 32–34.

GENETICS & METABOLISM
Our commitment to patients living with the disease HT-1 includes active participation in the community to understand the continued medical need. Read more on pages 35–37.

PARTNER PRODUCTS
Sobi offers small and mid-sized pharmaceutical and biotech companies a cost-efficient and integrated platform for the commercialisation of their specialty care products in Europe, the Middle East, North Africa and Russia. Read more on pages 38–39.

REFACTO
We have been manufacturing the active ingredient in the haemophilia A product ReFacto AF for the global market on behalf of Pfizer for many years. Read more on page 40.

Elocta and Alprolix build our haemophilia platform

The launches of Elocta and Alprolix gave us the rare opportunity to present two innovative state-of-the-art treatments for haemophilia to Europe and the Middle East within one year.

In 2016, the launches of Elocta and Alprolix brought our pioneering approach in rare diseases to the area of haemophilia. We are committed to working with the community to improve standards of care for all people with haemophilia, and believe that extended half-life (EHL) therapies are uniquely capable of achieving this goal.

The European Commission's authorisation of Elocta and Alprolix covers all 28 EU member states, as well as Iceland, Liechtenstein and Norway. Both products were also approved in Switzerland.

Country-by-country

Marketing authorisation in the EU is granted at central level, but each country decides individually whether a treatment is to be reimbursed and included in their national healthcare system.

We have been working to achieve timely access and engaging at national, as well as local or regional level, to understand the specific challenges and opportunities in each country. This is supported by individual plans that reflect the local evaluation, pricing and reimbursement regulations and health system needs.

When bringing our new therapies to market, we did not want the cost of treatment to limit access to only a privileged few. This led to a collaborative dialogue with the community in each individual country, which then guided our overall pricing approach. The products have subsequently been launched on a country-by-country basis.

The actual rate of uptake in each of our markets varies and depends on such factors as national and regional budget holder negotiations, hospital listing, health technology assessments and a willingness among doctors and patients to change their existing treatments. Pages 30–31 give a summary of countries where Elocta and Alprolix are reimbursed. Our work is now continuing in the remaining countries to work with governments and healthcare systems to make Elocta and Alprolix available to all people with haemophilia who wish to use these therapies.

A competitive landscape

Compared with most other rare diseases served by Sobi, the haemophilia market is larger – in terms of both value and size – and more competitive, with several conventional treatment options approved for people with haemophilia. In addition to the EHL products currently offered by Sobi and Bioverativ, other EHL products and, potentially, other therapies for haemophilia, are expected to receive marketing authorisation in Europe over the next decade. At the end of 2016, Elocta was the only Fc-fusion EHL treatment for haemophilia A with EU authorisation. Both Alprolix and Idelvion[1], EHL treatments for haemophilia B, were granted EU authorisation in 2016.

Elocta and Alprolix use Fc technology to extend the half-life. These treatments are engineered by fusing factor VIII and IX, respectively, to the Fc portion of immunoglobulin G subclass 1, or IgG1 (a protein commonly found in the body), enabling Elocta and Alprolix to use a naturally occurring pathway to extend the time the therapy remains in the body. Elocta and Alprolix are manufactured by Bioverativ using a human cell line in an environment free of animal and human additives. Using both Fc technology and a human cell line is a unique approach in the field of haemophilia.

1. Idelvion is a trademark of CSL Behring.

Mélanie and Marc are working to ensure access to treatment in France.

OVER

4,800

PATIENTS TREATED

With more than two years of post-authorisation real-world experience with Elocta (marketed as Eloctate in the US and other regions), over 4,800 patients have been treated in countries where the product is commercially available.

CORRESPONDING TO ABOUT

3,000

PATIENT-YEARS OF EXPERIENCE

The Sobi way

While new products are authorised in Europe on the basis of quality, safety & efficacy, the European Commission and the European Medicines Agency have no influence on the availability of treatments within the national healthcare systems, nor on the prices and conditions under which products are purchased by national healthcare providers. This is carried out country by country and, in some countries, region by region or even at a hospital level. Bringing therapies to patients – true access – requires a collaborative and concerted effort in each national market.

ITALY

In Italy, the conditions for reimbursement are established on a national level and then implemented at a regional level, as the country has seen a move to regionalising the provision of healthcare.

Some treatments can be designated for "fast track" at a national level, if it is decided that they meet a particular medical need or if they bring a significant therapeutic value. Without this priority status, the process of pricing and reimbursement decision may take over a year.

In preparing for the launch of Elocta, we spent a lot of time listening to the needs of the haemophilia community in Italy. This gave us a deep understanding of what was important for the healthcare providers as well as fostering a strong network.

We prepared a comprehensive presentation of Elocta based on our learnings, with a strong focus on transparency, fair pricing and realistic budget impact approaches. Elocta was included in the fast track at national level, much due to our preparations and despite it not being automatically qualified for such a review. The national price and reimbursement negotiations were, thus, successfully completed six months earlier than usual for a treatment of this type. Elocta's potential to improve the standard of care was a factor that strongly supported the national negotiations.

After the national process was completed, we continued our collaborative dialogue with the regional authorities in their work to decide when Elocta is made available to patients locally. Again, the "listening tour" that we performed before the launch, made this process easier. We had and continue a close dialogue with the regional commissions, providing them with the evidence they need. This has facilitated earlier provision and availability of Elocta to patients across the country. At year-end Elocta was available in eleven of Italy's twenty regions.

"Our way of seeking co-creative approaches together with the community comes from our rare disease background. The approach has been valuable initially and we hope that it will continue to serve the community well going forward."

Paul,
Business Unit Director
Haemophilia, UK

"The supply of products is a life line for many people living with a rare disease. Coming from a rare disease company the focus and dedication by our teams to ensure uninterrupted supply of high quality products is part of our DNA."

Christine,
Senior Manager,
External Manufacturing

Haemophilia therapies

EHL treatments can achieve higher factor levels for longer than conventional factor in the blood.[1] For EHL treatments such as Elocta and Alprolix, this allows an opportunity to individualise prophylaxis treatment which can meet the individual patient's needs and thus improve the clinical outcome while at the same time reducing the treatment burden.

The key to a successful long-term treatment outcome in children and adults with severe haemophilia is an effective prophylactic regimen that patients are willing and able to adhere to. Prophylactic treatment offers significant protection, minimising the number of bleeding episodes and reducing the risk of joint arthropathy and life-threatening soft-tissue bleeds.[2]

We expand the knowledge of the benefits of Elocta and Alprolix through continued analysis of the data from our development programme as well as studying the safety and efficacy of treatment in previously untreated patients. We are also working to further develop the body of literature from our pivotal and extension clinical studies.

MILESTONES 2016

January

Commercial launch of Elocta; first sales reported in Germany.

February

Positive opinion from Committee for Medicinal Products for Human use (CHMP) at EMA for Alprolix for the treatment of haemophilia B.

March

Transfer of marketing authorisation for Elocta from Bioverativ to Sobi.

Elocta granted reimbursement in the Netherlands and Ireland.

April

Positive opinion from the Committee for Orphan Medicinal Products (COMP) at EMA recommending the European Commission to maintain the orphan designation for Alprolix.

May

Alprolix authorised in the EU; first sales reported in Germany.

Elocta obtains positive pricing and reimbursement decision in Sweden.

June

Elocta authorised in Switzerland.

A European retrospective study[3] that assessed haemophilia care in seven countries, showed that treatment practice varied widely between countries and that patients treated both on-demand and prophylactically experienced bleeds, emphasizing the need for further improvement of standard of care.

Even when prophylaxis is the norm, it appears that prophylactic treatment is left at a minimal acceptable level or even lower, which increases the risk of joint injury and limits the ability to live a full and active life. Intensifying prophylactic treatment with conventional clotting factors could also potentially reduce the number of bleeding episodes, but barriers such as increased treatment burden, compliance, higher factor consumption and associated cost implications prevent widespread adoption.

A patient-centric organisation with a strong culture

Based on a strong patient-centric culture, we have built the infrastructure and capabilities to ensure initial and sustained access to Elocta and Alprolix in our territory. The culture is collaborative with co-creational approaches and where the different functions work in an integrated way. Today, the organisation consists of a team of professionals who are leaders in their field as clinical and academic specialists, as well as professionals in pricing and reimbursement, marketing, regulatory, logistics and many more.

We engage at all stages of our work with patient organisations that operate both globally and in Europe, as well as local organisations representing people with haemophilia, to fully understand patient and medical needs in the community. This work spans across European, Middle Eastern, North African and Russian haemophilia organisations and includes the World Federation of Hemophilia (WFH) and the European Haemophilia Consortium (EHC) as well as the EHC national member organisations and other, regional associations representing people with haemophilia and their families.

About the Sobi and Bioverativ collaboration

We collaborate with Bioverativ, a US based biotechnological company, on the development and commercialisation of Elocta/Eloctate and Alprolix. We have final development and commercialisation rights in our territory (Sobi territory is essentially Europe, North Africa, Russia and most Middle East markets). Bioverativ has manufacturing responsibility for Elocta/Eloctate and Alprolix, and final development and commercialisation rights in North America and all other regions in the world excluding the Sobi territory.

The financial terms of the agreement between the companies are described in more detail in Note 19.

Bioverativ was created as a spin-off from Biogen's haemophilia business and separated from Biogen on 1 February 2017. Bioverativ is an independent, publicly-traded company, headquartered in Waltham, Massachusetts, USA, focussed on the discovery, research, development and commercialisation of treatments for haemophilia and other rare blood disorders. Bioverativ will continue to collaborate with Sobi on our joint development programmes.

1. Berntorp E, et al. Haemophilia. 2016;(1-8)
2. Carcao M. Haemophilia. 2014;20(4):99-105
3. Berntorp E, et al. Haemophilia. 2017;23(1):105-114

July

Long-term efficacy and safety data from EHL haemophilia therapies showcased at World Federation of Hemophilia (WFH) 2016 World Congress.

September

Elocta received national reimbursement in the United Kingdom, Italy, France and Spain.

October

Alprolix authorised in Switzerland.

Transfer of marketing authorisation for Alprolix from Bioverativ to Sobi.

November

Elocta authorised in Kuwait.

Retrospective European study of haemophilia treatment emphasises the need to improve the standard of care.

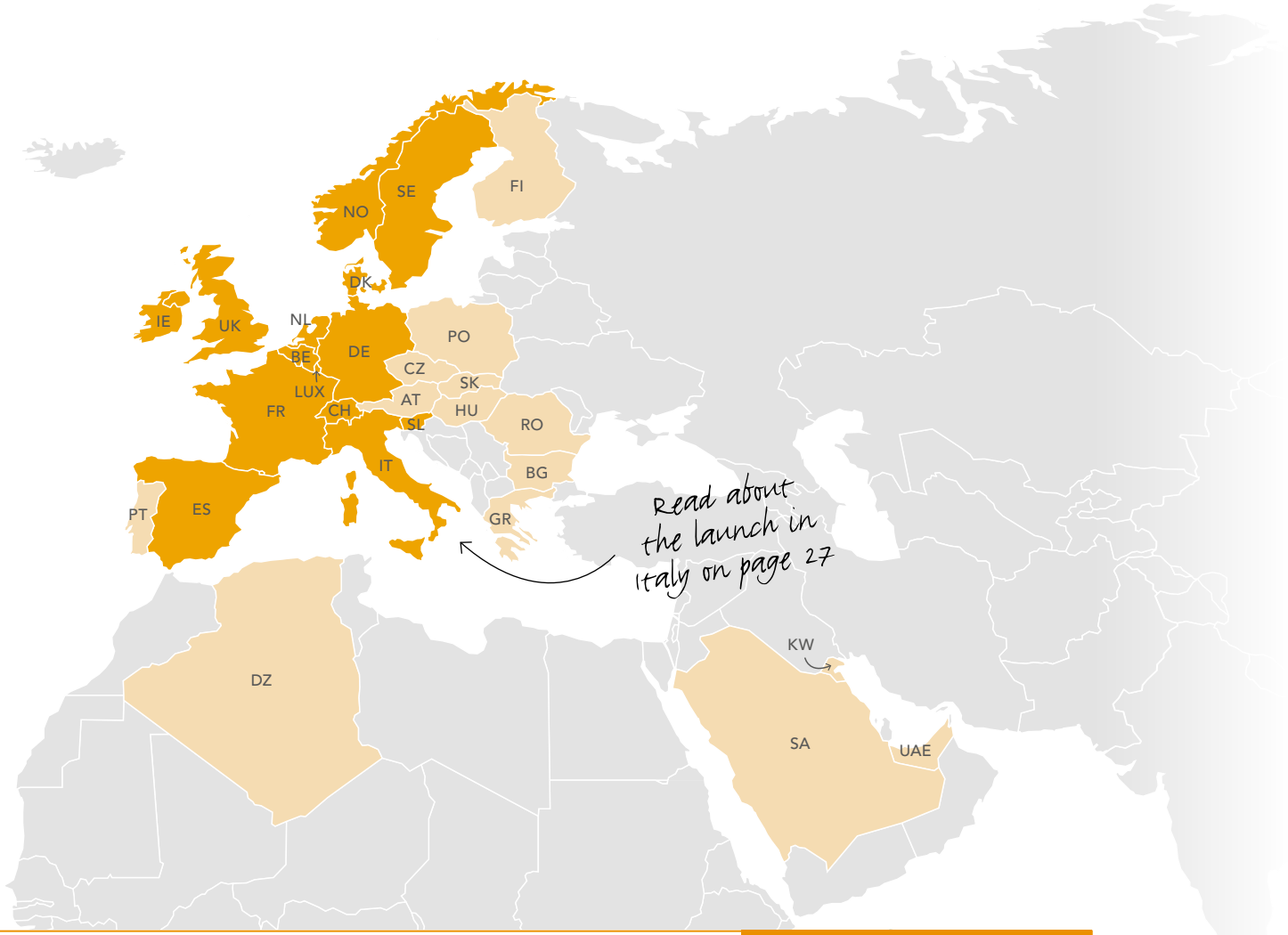
December

Long-term data shows long-term prophylactic use of Elocta/Eloctate resulted in effective target joint resolution and improved quality of life measures.

The launch of Elocta
An update

Commercial access to Elocta for people with haemophilia A in Sobi's territory was first achieved in January 2016.

The clinical benefit of Elocta reflected in our value proposition has been well received and, despite challenges unique to each market, we have stayed ahead of schedule in the national reimbursement process for Elocta by between 4 and 14 months. Germany was the first country to make Elocta available on a reimbursed basis. By the end of September 2016, Elocta had been approved for reimbursement in the five largest EU markets – Germany, UK, Italy, France and Spain.



- Reimbursement granted, treatment available
- Pricing and reimbursement decision-making in progress

"Dialogue works. Our collaborative dialogues with healthcare authorities have helped to reduce time to positive pricing and reimbursement decisions for Elocta by an average of 4.5 months across our first 8 markets, ranging from 1.5 to 8.9 months earlier than normal."

Wills Hughes-Wilson
SVP, Chief Patient Access Officer

ABOUT 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 the European Union, Iceland, Liechtenstein, Norway, Switzerland and Kuwait and marketed by Sobi. Eloctate is approved for the treatment of haemophilia A in the United States, Japan, Canada, Australia, New Zealand, Brazil and other countries, and marketed by Bioverativ.

As with any factor replacement therapy, allergic-type hypersensitivity reactions and development of inhibitors may occur in the treatment of haemophilia A. Inhibitor development has been observed with Elocta.

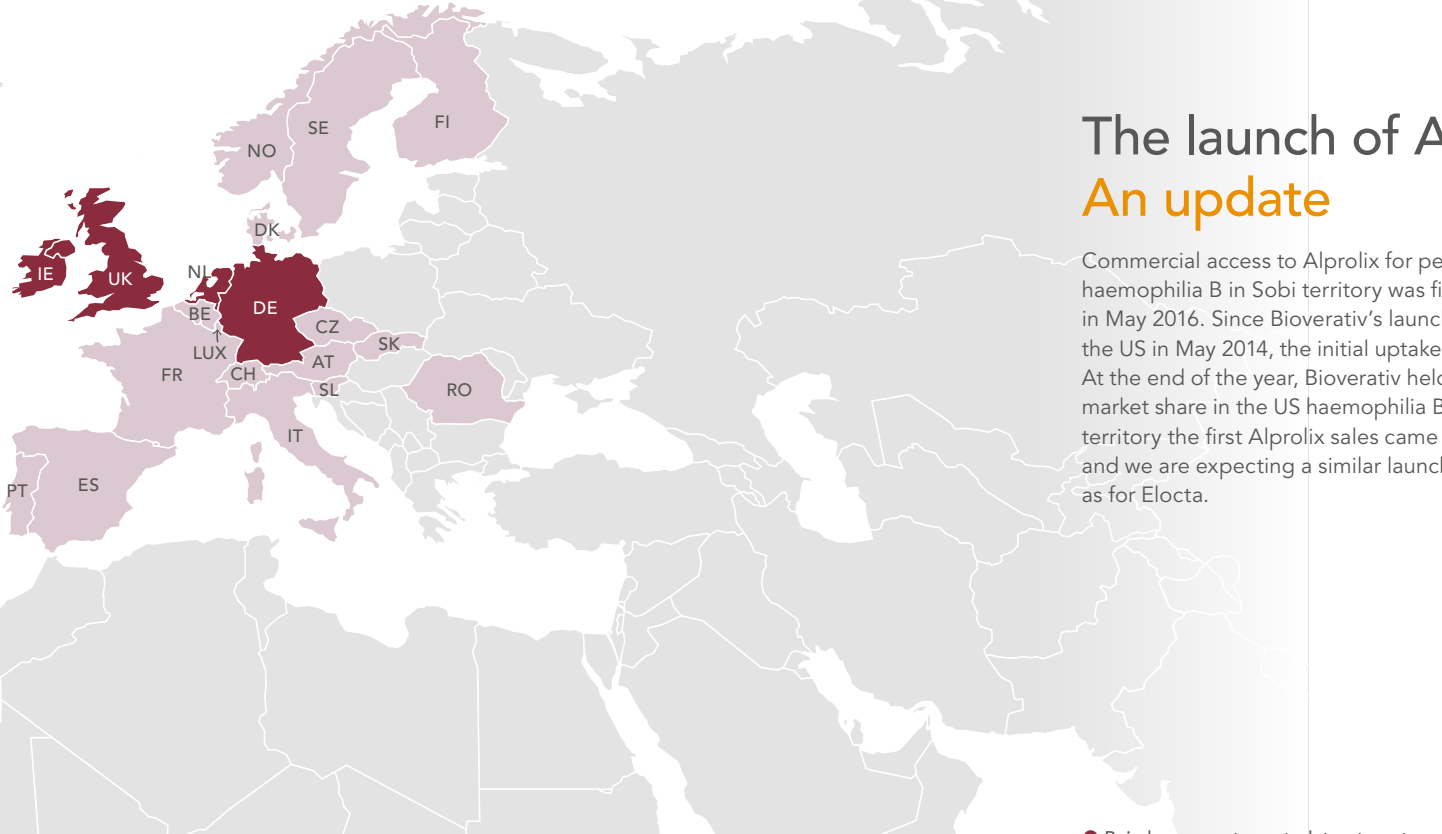
ELOCTA®
efmoroctocog alfa
(recombinant human coagulation factor VIII Fc fusion protein)

IDENTIFIED PEOPLE IN SOBI TERRITORY WITH HAEMOPHILIA A

59,000

The launch of Alprolix
An update

Commercial access to Alprolix for people with haemophilia B in Sobi territory was first achieved in May 2016. Since Bioverativ's launch of Alprolix in the US in May 2014, the initial uptake has been high. At the end of the year, Bioverativ held a 25 per cent market share in the US haemophilia B market. In our territory the first Alprolix sales came in Germany and we are expecting a similar launch sequence as for Elocta.



- Reimbursement granted, treatment available
- Pricing and reimbursement decision-making in progress

IDENTIFIED PEOPLE IN SOBI TERRITORY WITH HAEMOPHILIA B

12,000

ABOUT 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 the European Union, Iceland, Liechtenstein, Norway and Switzerland and is marketed by Sobi. Bioverativ holds the marketing rights for the United States, Canada, Japan, Australia, New Zealand, Brazil and other countries.

Allergic-type hypersensitivity reactions and development of inhibitors have been observed with Alprolix in the treatment of haemophilia B.

ALPROLIX®
eftrenonacog alfa
(recombinant human coagulation factor IX, Fc fusion protein)

Read about the Alprolix approval and risk management on page 63

Kineret – expanding awareness for the benefit of patients

Kineret (anakinra) is a biologic that can reduce the activity of IL-1, a key driver of inflammation in several diseases. In 2016, Kineret continued to grow across all major regions supported by new indications and our efforts to facilitate access and raise awareness of the treatment.

Kineret is a recombinant protein drug first approved in 2001 to ease the symptoms and to slow the progression of structural joint damage in moderate to severe rheumatoid arthritis (RA) in adults. In recent years, Sobi has focused on expanding the indications for Kineret to include paediatric auto-inflammatory diseases because an increasing body of work and the feedback from the treating community has led us to believe that Kineret can play a key role in addressing many diseases.

In 2012, Kineret became the first and only drug approved by the US Food and Drug Administration (FDA) for the treatment of neonatal-onset multisystem inflammatory disease (NOMID) in children and adults. In 2013, the European Commission approved Kineret for the treatment of cryopyrin-associated periodic syndrome (CAPS) in adults, and in children from eight months of age. The approval of these indications is a key milestone for Sobi, and for the company's efforts to make innovative products available to patients with debilitating and often life-threatening diseases.

Long-term growth

In 2016, Kineret recorded sales over 1 billion crowns for the first time and a growth of 24 per cent. In the last three years sales have increased by 78 per cent. This has been driven by the expansion of indications and an increased collaboration with the rheumatology community, which has provided opportunities for innovative educational programmes and greater accessibility of Kineret to healthcare professionals and patients. The launch of Kineret for the treatment of CAPS is now completed, with all EU markets covered.

Sustainable access

Building on the needs of the community, based on feedback from the patient communities, we continue to seek to increase the awareness of Kineret, with the objective of improving the lives of patients with paediatric rheumatic and auto-inflammatory diseases. In Europe and the US, we are engaged in continuous dialogue with many stakeholders to facilitate access to treatment for CAPS and NOMID by patients in need.

We have continued our collaboration with patient organisations, such as the Auto-inflammatory Alliance, dedicated to improve the diagnosis, treatment and care for people with auto-inflammatory diseases. We also collaborate with academic research consortia such as the Childhood Arthritis and Rheumatology Research Alliance (CARRA) in the US and the Single Hub and Access point for paediatric Rheumatology (SHARE) in Europe, to support research into prevention, treatment and cures for paediatric rheumatic diseases.

We continue to invest in patient support programmes. Kineret On TRACK is a robust US-based programme designed to help patients navigate their treatment experience from initiation, through follow-up and adherence as well as providing support for product reimbursement.

In July 2016, we held our first patient advisory board for RA patients in the US, in order to understand the patient journey and the challenges around drug administration and long-term use. The input has given us insights into how we can continue to improve patient offering and patient support.

This is Quinn, she likes to dance

Transfer of production for growth

We will move the production of Kineret drug substance to Pfizer's manufacturing site in Strängnäs, Sweden. The technology transfer will significantly expand capacity to support the growth of Kineret. The transfer was initiated in 2016 and is expected to be completed in time to support the launch of Kineret in potential new indications currently under exploration.

1 IN 1,000,000

CAPS mutations are believed to occur in 1 out of 1 million people worldwide, however, this is only an estimate. Some believe that these diseases may be more prevalent, but may be misdiagnosed.

Source: Cuisset, L, et al. An. J. Hum. Genet. 1999;65(5):1054-59.

ABOUT KINERET

Kineret (anakinra) is approved for the treatment of rheumatoid arthritis (RA) in adults, neonatal-onset multisystem inflammatory disease (NOMID) in children and adults (US)[1], cryopyrin-associated periodic syndrome (CAPS) in adult patients, and in children from eight months and older (EU)[2].

Kineret is a recombinant protein drug that blocks the biological activity of IL-1a and IL-1b by binding to 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.

GEOGRAPHIC MARKET: Global

Kineret® (anakinra)

1. Kineret PI USA September 2015.
2. Kineret Summary of Product Characteristics January 2016.

A NETWORK OF SUPPORT

The Kineret On TRACK program is staffed by a team of experts who will support patients and healthcare providers from prescription through injection and beyond.

KINERET CASE MANAGERS
- Benefits investigation
- Insurance verification
- Prior authorisation
- Appeals support

KINERET-TRAINED NURSES
- In-home injection training
- Advice on management
- Questions about Kineret

KINERET PHARMACY SUPPORT SPECIALISTS
- Refill reminders
- Delivery to your home
- Emergency shipments

Returning investments to the community

"We appreciate Sobi's willingness to include the patient community in collaborating and co-creating trials that more directly respond to and answer the needs of the community."

Laura Schanberg,
Professor, Duke Clinical
Research Institute

The Childhood Arthritis and Rheumatology Research Alliance (CARRA) is a network of academic paediatric rheumatologists based in the United States and Canada that are dedicated to conducting collaborative research on the prevention, treatment and cure of paediatric rheumatic diseases. Professor Laura Schanberg is part of the Duke Clinical Research Institute and is also former President of CARRA. She is heading the clinical trials collaboration between CARRA and Sobi for Still's disease.

"Our work in general is aimed at bringing real-world questions to research. We find that the scientific agenda is often driven by companies whose aim is to support an application for marketing authorisation and is, therefore, not always aimed at helping the doctors answer questions that the community and the patients might have.

In paediatric rheumatology, the patients are so few in number that it is important for us to ensure the trials being conducted are responsive to what physicians and patients actually need to know. By doing this, the resources invested in treatments and trials are used as wisely as possible and are put to use in more areas. I find that the openness and willingness of companies to conduct studies centred on the needs of the patients and the community is a culture thing. Some companies understand, others don't.

We also actively support patient involvement in clinical trial design. One approach is for patients and parents to read protocols and patient-focussed material to ensure that the trials are adapted to meet their needs and take into account issues that patients care about. By partnering with CARRA and academia, companies like Sobi can receive patient input to ensure that the trial is both feasible and attractive to patients. Unfortunately we do not yet see the authorities being as receptive to the needs of the patients as one would hope, which may impact the design of the trial, against our input.

The CARRA network also works to strengthen and broaden research infrastructure to make more paediatric rheumatology sites able to participate in clinical research. CARRA has established a registry for efficacy- and safety-data generation, responding to the regulatory demands for post-marketing monitoring. The idea is that, instead of each company having a *drug-specific* registry, CARRA has created a *disease-specific* registry. This registry will provide valuable information to the community – bringing together a larger number of patients than each company or treatment is capable of doing individually; and also monitoring participants over a longer period of time. We are also looking to do trials within the registry. This will make it easier for physicians with a small number of patients, as is the case with rare paediatric rheumatology diseases, to focus on the trial, instead of learning how to use numerous registries and protocols. A joint registry and infrastructure will make it easier to find patients and investigators who are willing to participate. By making the registry available to the entire community, we can bring the return on investment in this research and follow-up back to the community."

Orfadin – a mission to further improve lives

Our close collaboration with the HT-1 community over the years has helped us to understand the ongoing medical needs of people living with tyrosinaemia. We are committed to adding value along the entire patient journey, investing in the development of our products and supporting treatment adherence.

For many years, we have been engaged in the delivery of treatment for hereditary tyrosinaemia type 1 (HT-1). Orfadin was developed for clinical use by two Swedish scientists in the early 1990s and subsequently commercialised by Sobi. The launch of Orfadin signalled the beginning of our commitment to developing innovative therapies for children with life-threatening rare diseases. Orfadin is approved in the EU, US, Canada and several other countries and, in combination with the appropriate diet, is a key component of effective HT-1 treatment. Before Orfadin was available, the survival rate for HT-1 was 29 per cent after two years for children who developed symptoms before two months of age. After the introduction of Orfadin, the survival rate for the same group rose to 93 per cent.

Long-term effort

In 2016, Orfadin generated revenues of 770 million crowns, a decrease of 3 per cent compared to 2015. The EMENAR business was negatively impacted by loss of sales due to the approval of a generic formulation in Turkey, and to ordering patterns in the Middle East and Russia. This follows after a period where sales have increased over the past three years. The main driver of this trend is our decision to assume direct responsibility for the distribution of Orfadin in North America. Although we see generic competition entering in some markets, we have continued to invest in value-added support and expanded markets, driven by our long-term commitment to patients and the community.

Community commitment

A strong patient-centric approach is crucial to our mission to further improve the lives of people living with HT-1. The HT-1 patient population is small – approximately 1,000 people are currently living with the disease worldwide. We continuously solicit feedback from patient and healthcare stakeholders to ensure that we understand the patient journey. By listening to their needs, we are able to develop educational resources, support services and new formulations, empowering them to take control of their treatment. The course of HT-1 has changed dramatically in recent decades, and most people who are diagnosed with the disease and receive therapy are now growing up to become teenagers and adults.

ABOUT 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.

Orfadin®
nitisinone

Scientific partnerships and relationships help us to further identify, understand and meet the gaps, and the new medical needs of individuals who are now growing up to become adults, to increase their knowledge of optimal treatments and care. This includes continued investment in Orfadin, in both the new oral suspension formulation and 20 mg capsule strength, and a strong focus on treatment adherence to ensure that patients follow their treatment plans.

While treatment adherence is vital for chronic life-threatening diseases, this can be a challenge for patients. By understanding the situational causes of poor adherence, our aim is to support them with relevant, practical and timely resources to achieve the best treatment outcomes and live up to our vision of providing therapy that can sustainably improve their lives over the long term.

"Let's talk Tyrosinaemia" is a comprehensive patient education programme. The campaign offers a variety of printed and online educational resources for patients and caregivers. We have worked together with the rare disease community to create a disease education package with a lifestyle-oriented approach.

Orfadin4U is a comprehensive support programme for patients and their caregivers in the US, aimed at following the patient through life transitions. Orfadin4U provides direct-to-patient pharmacy services, including home delivery, reimbursement support and financial assistance.

Global access programme

We believe that access to safe, effective and reliable treatment is a shared societal responsibility. Under the umbrella of our global sustainable access programme, we bridge access to Orfadin for children living with HT-1 in India. We are working to set up shared commitments to secure real access to treatment for patients in partnership with all of the system's stakeholders. In 2016, several meetings were held with representatives from the Indian government, which have given us insights into how we can continue to explore creating and nurturing more sustainable, long-term approaches to treatment of HT-1 in India.

LOW PROTEIN DIET

A special low protein diet must be followed in conjunction with treatment.

The four low protein diet rules:

1. Avoid high-protein foods, such as meat, fish, cheese, eggs, milk, seeds, nuts and ordinary bread.
2. Have daily protein substitutes as prescribed to ensure healthy growth and development.
3. Have a calculated number of protein exchanges every day.
4. Eat plenty of low protein foods.

The mission – no one living with tyrosinaemia should feel alone

Jon Miller, President of N.O.T.A. The Network of Tyrosinemia Advocates

As is the case for all new parents, Jon Miller's life changed the day his son was born. But he could not imagine just how much it would change when a few days after birth, his son became ill. It took a long time, almost too long a time, for the correct diagnosis to be made. This is not uncommon in rare diseases where knowledge about an individual disease is scarce. The experience of having a child born with a rare disease has had a huge impact on the work that Jon is passionate about: in addition to being a mechanic and managing his car-care centre, Jon Miller is also President of the Network of Tyrosinemia Advocates (N.O.T.A).

What kind of organisation is N.O.T.A.?
N.O.T.A. is a not-for-profit organisation and our aim is to be the "glue" for every person living with tyrosinaemia across the world. We work to spread information and to build a stronger community. People need to know that they are not alone and if there are resources available to them, then they deserve also to know about it.

It started with a simple Facebook group and it keeps growing. N.O.T.A. has now turned into a worldwide community of families and friends who are, or who know someone who is affected by tyrosinaemia. We represent about 70 patients around the world and have 400 members in our Facebook group, including families and children, as well as dieticians and other experts.

Why is it important to have a community when living with a rare disease?
Together everyone can feel strong. Every parent needs to know that they are not alone in their struggle and to feel that they have the support they need at critical times. By sharing stories, resources and recipes we can make some parts of life easier to handle. Peer support is vital because there are so many questions about everyday life that cannot be answered by doctors. And for medical questions that can be answered, the materials needs to be available in language that is understandable to all parents. You should not need to have a medical degree to understand them.

We support and connect local organisations across the world to make a stronger community, bringing small groups that have already found each other together with others. Our network stretches from the US, Canada to India and Australia.

What has been your most important mission for 2016?
Early diagnosis is the most important factor for survival in this disease and effective new-born screening can, if correctly applied, find affected babies in the first days of their lives. My son's diagnosis was missed in the new-born screening and he was finally diagnosed with HT-1 just hours before it would have been too late. My mission in 2016 has been to reform the standards of screening across the US and ensure that they are using the correct biomarkers because there is an outdated screening method still being used, both in the United States and worldwide, that can miss a correct diagnosis of HT-1. I have not yet fully succeeded: I have six states left, but my mission goes on. Next year's mission will be to organise a patient conference. I look forward to meeting many of the families I have had contact with over the years.

Our partner platform provides access to niche medicines

Sobi offers small and medium-sized pharmaceutical and biotechnology companies a cost-efficient and integrated platform for the commercialisation of their products in Europe, the Middle East, North Africa and Russia.

Based on more than 25 years of experience, Sobi offers our partners an efficient distribution capacity and extensive market knowledge. These partnerships span over many years and include strategies for regulatory approval, pricing and reimbursement, as well as preparations for the launch of additional and/or subsequent marketing activities, tender management and efficient logistics. The main objective is to meet important medical needs in various therapeutic areas to ensure that each patient may access optimal treatment.

Long-term growth

While the continued strong growth of Partner Products is partly due to new agreements signed in 2013 and 2014, such as the PharmaSwiss portfolio and Xiapex, all parts of the product portfolio have contributed to the positive trend. The portfolio comprised approximately 30 different medicinal products from a total of 20 partners. For the full-year, total revenues for Partner Products amounted to 820 million crowns, representing annual growth of 6 per cent.

Continued launch of Xiapex

During the year, we continued the European launch of Xiapex for the treatment of Dupuytren's contracture and Peyronie's disease. Treatment with Xiapex can offer patients an alternative to surgery. Peyronie's disease is a hidden condition, not spoken about publicly, and by raising awareness about the disease more men were given access to treatment. The increased use in these two indications resulted in an 11 per cent sales increase year-on-year.

New and terminated partnerships

At the beginning of the year, we acquired commercial rights from the Swiss-based company, PharmaSwiss SA, to distribute Relistor, Deflux and Solesta in a territory including Western Europe, Czech Republic, Slovakia, Hungary, and to distribute Relistor in Russia. Since June 2013, we have been marketing four other PharmaSwiss products: Megace®, Monopril®, Cefzil® and Duracef®, approved for treatments in the therapeutic areas of oncology, cardiovascular medicine and anti-infectives.

In May 2016, we extended our distribution agreement with LFB for an additional four years for the products Betafact® , IVheBex® and Wilfact®. The contractual terms for these products remain unchanged. In addition, LFB has developed a new product, Fibclot®. Fibclot was recently been approved for treatment of congenital fibrinogen deficiency in patients at risk of complications during surgery because of a rare genetic bleeding disorder. The distribution of Fibclot in Sweden, Denmark and Norway is included in the agreement.

In mutual agreement with TiGenix, we decided to return the distribution rights of ChondroCelect®. Reimbursement for ChondroCelect was denied in several key countries and TiGenix subsequently decided to withdraw the product from the market in November 2016.

Also in November, the distribution rights for Cometriq® was returned to Exelixis Inc. The commercialisation agreement was signed in 2013 to support the placement of Cometriq on the European market.

At the end of the year, a five-year distribution agreement with Horizon Pharma plc was signed for Ravicti and Ammonaps. Under the agreement, we received exclusive marketing, sales and distribution rights for the two medications in certain European countries and for Ammonaps, also the Middle East. This complements the already existing distribution agreement for Ravicti in the Middle East and Ammonaps in Europe and the Middle East. Ravicti and Ammonaps have received marketing authorisation from the European Commission and are used to treat urea cycle disorders (UCD).

ABOUT XIAPEX

Xiapex (collagenase clostridium histolyticum), 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.

XIAPEX®
collagenase clostridium histolyticum

Jenny is Brand portfolio Director for Partner Products

SOBI PARTNER PRODUCTS – A SUSTAINABLE BUSINESS MODEL

The European market consists of nearly 40 countries with a broad range of supply-chain demands, patient needs, healthcare traditions and medical standards. Companies entering Europe are often faced with two difficult options: to charge more for their product, which might slow down or even eliminate their opportunities to receive reimbursement, or to not make the medication available at all in certain countries. Either of these decisions will impact those in need of the medication – the patients. A cost-efficient platform for the provision of products for a limited number of patients is important, and has a direct impact on the availability of niche medications to European patients.

- Costs/capital
- Regulatory
- Pricing & Patient Access
- Pharmacovigilance
- Compliance
- Supply network
- Marketing capabilities
- Quality assured release
- Expert network
- IT structure
- Insurances

"Smaller companies cannot effectively launch their product in 28 markets. It can take up to six years before the product is available to patients in all markets. This makes Europe an unequal continent."

Yann le Cam,
Chief Executive Officer,
EURORDIS, Rare Diseases Europe

ReFacto – a long-term partnership

We have been manufacturing the drug substance for the haemophilia treatment ReFacto AF on behalf of Pfizer for many years. In 2016, we initiated preparations to increase the capacity of Sobi's biologics facility.

In the 1980s, Sobi was a pioneer in the development and manufacturing of biopharmaceuticals using recombinant protein technologies. One of these products was a recombinant factor VIII, which we have been manufacturing for Pfizer since 1998. As the global supplier, Sobi receives manufacturing revenues as well as royalties on Pfizer's sales of ReFacto AF. The collaboration with Pfizer is based on our extensive experience and expertise in the development and manufacture of recombinant protein drugs. The active ingredient is produced in our Good Manufacturing Practice (GMP) biologics facility in Stockholm, Sweden. In April 2016, we announced a three-year extension to our existing supply agreement with Pfizer, which will now run until 31 December 2023.

In 2016, the royalty agreement reached a milestone, meaning that the global royalty agreement – ex-US – changed as of May 2016. This will affect about 80 per cent of the royalties generated by ReFacto. The agreement for the US market remains valid and unchanged until January 2018.

Consistent growth

ReFacto has continuously contributed to Sobi's overall revenues. In 2016, total revenues for ReFacto from manufacturing and royalties amounted to 656 million crowns. While manufacturing revenues increased, a changed royalty structure meant reduced royalties contribution, resulting in an overall decrease of 1 per cent.

Capacity increase

To meet higher demand, we increased production and deliveries of the ReFacto drug substance in 2016 and are planning a significant increase in production capacity of our manufacturing facility from 2017. We have also recruited and trained new employees and restructured our manufacturing team to meet the demand as well as to support manufacturing of active ingredients for our future programmes. For example, the active ingredient for our candidate drug SOBI003 will be manufactured in the same site as ReFacto and will supply the planned clinical trials to evaluate the potential of this compound.

Sales

SEK M	2012	2013	2014	2015	2016
Manufacturing revenues	436	492	466	504	569
Royalty revenues	130	127	152	156	88
TOTAL	566	619	618	660	656

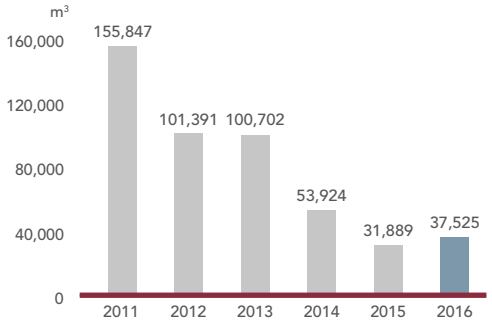
Read more about SOBI003 on page 48

SOBI'S COMMITMENT TO SUSTAINABLE MANUFACTURING

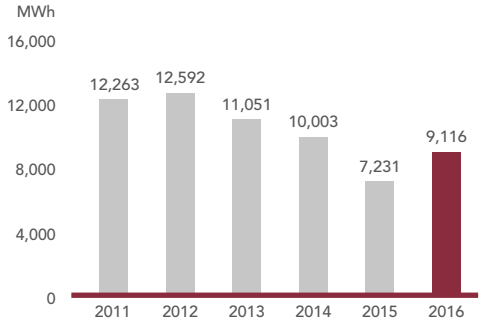
Sobi has ongoing projects to continually improve the energy efficiency of our site and we regularly review and monitor the operating costs of the buildings in which we operate. A programme to review and reduce water consumption at the production facility in Stockholm was launched in 2011. An energy management plan for the facility was launched in 2012. Measures include heating/cooling recovery and the optimisation of running times for heating and ventilation.

During 2016, energy and water consumption increased due to increased production volumes.

WATER CONSUMPTION



ENERGY CONSUMPTION



SWEDISH GOVERNMENT INVESTS IN NEXT-GENERATION BIOLOGICS

The Swedish government has presented a strategic programme in life sciences to support the future development and production of biologics in Sweden, aimed at positioning Sweden as a leading nation. The programme will extend over a period of eight years, starting in 2016, with government funding of 320 million crowns. Sobi is working jointly with academia and in 2016, two projects involving Sobi were selected for inclusion in the programme.


Cerys lives an active life thanks to early diagnosis

A patient-centric approach to R&D will ideally result in **faster development of innovative treatments.**

Making a difference

With a firm philosophy that innovation is an idea successfully commercialised, our R&D organisation is seeking to transform our new innovations into commercially available treatments for patients.

Our innovation pipeline as per 31 December 2016

Therapeutic area/Indication	Product/Project	Pre-clinical	Phase 1	Phase 2	Phase 3
Haemophilia A	Elocta/ASPIRE[1]				On-going
Haemophilia A	Elocta/PUP[2]				On-going
Haemophilia A	BIVV001[3]/XTEN	On-going	On-going		
Haemophilia B	Alprolix/B-YOND[1]				On-going
Haemophilia B	Alprolix/PUP[2]				On-going
Acute gout	Kineret/anaGO			On-going	
Still's disease	Kineret/anaSTILLS[4]				Planned
Alkaptonuria	Orfadin/SONIA2				On-going
MPSIIIA	SOBI003	On-going	On-going		
C5 driven diseases	SOBI005	On-going	On-going		
IL-1 driven diseases	SOBI006	On-going	On-going		

On-going Planned

1. Extension trial for an already approved indication.
2. PUP = Previously Untreated Patients.
3. Bioverativ development programme. Sobi has elected to add the programme to the collaboration agreement but not yet opted-in.
4. Planned start in second half of 2017.

Our R&D model is not linear but rather cyclical, as the knowledge we gain throughout the process is continuously fed back into development. By working cross-functionally and identifying the stakeholders at each stage, we aim to streamline the time it takes to bring treatments to patients, while also ensuring optimal outcomes and sustainable access.

Driving the portfolio forward

In 2015/2016, a number of projects aimed at developing approved products and late-stage projects, such as our haemophilia products, were successfully brought to market. These innovations will lay the foundation for building Sobi, a research-based biotech company, in the years to come.

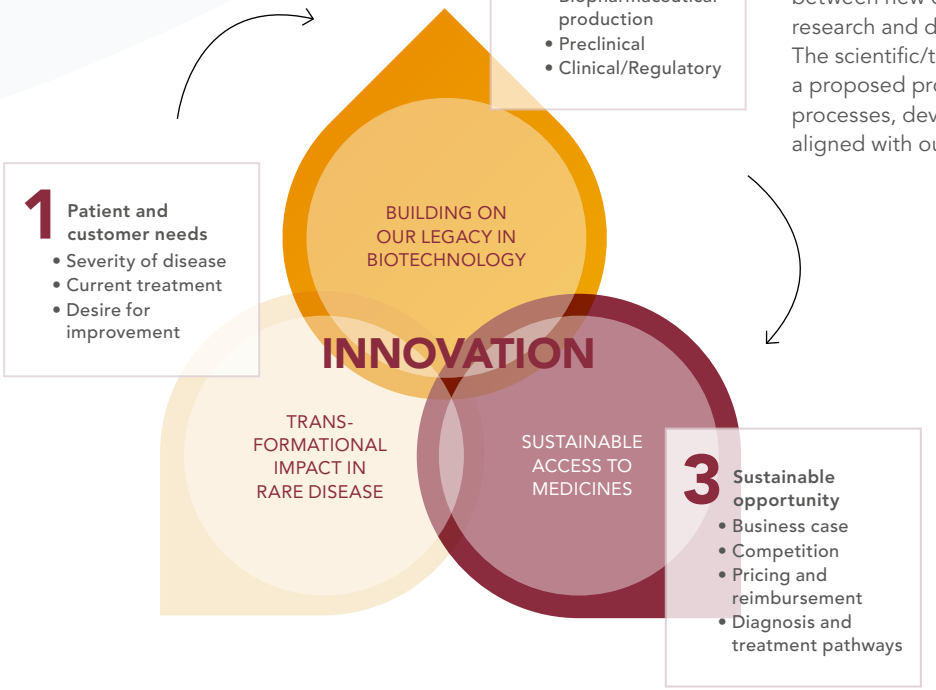
We achieved substantial in-house accomplishments in our early-stage pipeline during the year by focusing on our capabilities in protein engineering and biologics production. We have now begun to seek collaboration with patient communities and authorities at the pre-clinical stage to ensure access to treatments once the development process has been successfully completed.

Sobi's innovation model

Using a multi-disciplinary approach, cross-functional teams map and evaluate new R&D projects by applying the three lenses of our innovation model. This ensures that new projects are aligned with our corporate strategy, that we successfully utilise our strengths, and assures that only projects with favourable risk profiles will be pursued.

A transformational impact on rare diseases

Our innovation model revolves around the patient journey for people with rare diseases. We aim to define the real unmet needs by collaborating with patients, their families, care-givers, and the medical community; and by continuously studying treatment outcomes. By doing so, we aim to achieve a transformative impact with our programmes – to substantially improve the lives of people living with rare diseases.



Expertise in biologics and process development

Our R&D approach provides an interface between new discoveries and integrated research and development processes. The scientific/technological aspects of a proposed programme (drug molecule, processes, development plans) should be aligned with our capabilities and skill sets.

Providing sustainable access to medicines

By identifying the relevant stakeholders at each stage of the patient journey we aim to co-create and secure optimal outcomes along the development pathway. When we collaborate we believe that we are able to facilitate each step, resulting in smoother, and ideally faster development and delivery to patients.

Our R&D capabilities

Our in-house capabilities encompass the entire R&D value chain, from gene to patient, and our aim is to build a balanced portfolio of new biological entities and projects to develop our existing products according to patient insight.

Biologics development and supply – a strategic asset

The close collaboration and integration within our project teams, and with our biologics manufacturing unit in Stockholm, Sweden, is a key success factor for both the development of our candidate drug SOBI003 and our other programmes.

Our in-house competences provides an understanding of the elements needed in order to successfully scale up and prepare for commercial-scale 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. In 2016, we invested in new cell culture technology, which enables greater flexibility and shorter set-up times to accelerate lead times.

Process development and optimisation of manufacturing is resource intensive, requiring high investment by drug developers throughout the process. Our end-to-end perspective on research, development, manufacturing and product maintenence is a strategic asset, and our ability to access in-house manufacturing facilities creates a competitive advantage. The combination of biologics production know-how and manufacturing under license to Pfizer generates synergies and reduces costs, which benefits Sobi as well as our partners and patients.

Protein engineering

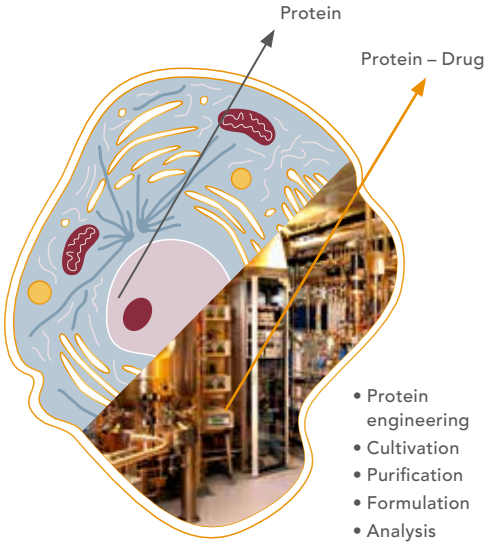
Pharmaceutical protein engineering is the process of developing proteins that can be useful in the treatment of diseases. The aim is to optimise and tailor the key properties of new investigational leads and products, in an effort to create differentiated products in an increasingly competitive pharmaceutical landscape and, even more importantly, to design proteins that are suitable for effectively targeting rare diseases.

This technique has made it possible to develop new therapeutic proteins with improved properties. Many of the key attributes that determine the future success of a protein lead can be modulated by protein engineering. Sobi has more than 30 years of experience in protein engineering and were one of the pioneers in using recombinant technologies to develop biopharmaceuticals in the 1980s. Together with our partner companies, we use protein engineering to design and produce therapeutic proteins with the potential to transform the lives of rare disease patients.

Extending the half-life of proteins

Extending the half-life of a therapeutic protein means that it can stay in the bloodstream for longer. The advantages of extending the half-life can include increased efficacy of a single dose, as well as increased concentration of drug substance, which can lead to enhanced uptake and reduced treatment burden. The Fc-fusion technology platform is already being used in haemophilia and the IL-1 inflammation (SOBI006) and complement C5 (SOBI005) development programmes. In addition to the Fc-fusion technological platform to extend the half-life of products, we are currently exploring a number of other platforms, both our own and those of partners.

THE PROTEIN FACTORY



In our biopharmaceutical production, we mimic the natural process in the cell by using cells from different species as a "protein factory". We employ recombinant DNA technology to produce an optimised protein. In the bioreactors, we grow a large number of cells – each producing our biopharmaceutical, which is then isolated and purified. Throughout, our protein is analysed and characterised to verify that the production process produces our biopharmaceutical at consistent quality, to ensure the safety and efficacy of the product. The production process must also be robust, scalable and cost-effective.

Responding to patient insights

Influenced by the patient journey and based on the needs of patient representatives and caregivers, we continuously explore the potential to further develop authorised medications for new indications.

Orfadin (nitisinone) – delivering on our promise to patients

We have developed a new dosage form and new strengths of Orfadin to meet changing needs. The two new formulations – an oral suspension and a 20 mg capsule – were authorised by the European Commission in 2015 and approved by the Food and Drug Administration (FDA) in 2016. The oral suspension formulation is a result of our commitment to the needs of infants and children diagnosed with HT-1 early in life, to provide a formula that is suited for a population that is growing and where treatment is given relative to body weight. The 20 mg capsule facilitates adherence to treatment regimens by reducing treatment burden. With a continued strong patient-centric approach we aim to improve the treatment, care and ultimately, lives of people living with HT-1 in the coming years.

Safety first

Sobi is sponsoring a long-term safety study of Orfadin treatment in HT-1 in standard clinical care (the OPAL study). The participants are using Orfadin according to normal clinical practice. The study is in response to demands from the Committee for Medicinal Products for Human Use (CHMP) who have looked at the data for approximately 400 patients and found the benefit-risk ratio to be positive.

Patient-driven development

Alkaptonuria (AKU) is a genetic disease that damages the bones and cartilage, causes severe pain and leads to health problems such as osteoarthritis, heart and kidney disease. It is extremely rare and approximately 950 people worldwide are living with AKU.

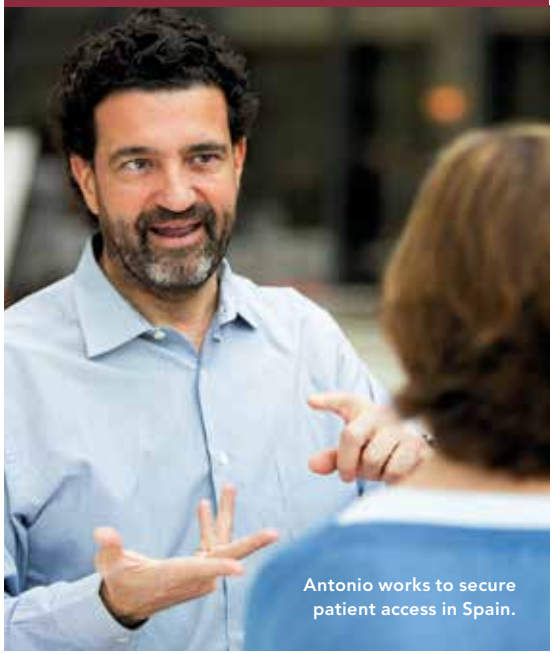
DevelopAKUre[1] is a clinical development programme for the drug nitisinone, the first potential treatment for AKU, run by a European consortium, which was initiated by a patient group. Sobi is an equal partner in this consortium of 12 member organisations; hospitals, pharmaceutical companies and consultancies, universities, biotech companies and national AKU patient organisations are all working towards the development of nitisinone as a treatment for AKU.

Kineret (anakinra) – exploring the full potential

Interleukin-1 (IL-1) is a key mediator of local and systemic inflammation and a significant contributor to autoinflammatory diseases. Many autoinflammatory diseases, such as CAPS (cryoprin-associated periodic syndrome) and NOMID (neonatal-onset multisystem inflammatory disease) one of three forms of CAPS, have symptoms that are chronic from childhood or infancy. Blocking IL-1 activity in autoinflammatory syndromes results in a rapid and sustained reduction in disease severity. We are determined to continue exploring the full potential of Kineret in auto-inflammatory diseases, such as Still's disease, as well as other more common inflammatory diseases, such as acute gout. In 2016, we expanded our strategic development activities for the product in an effort to meet the needs the of the medical and patient communities.

ABOUT STILL'S DISEASE

Still's disease is an autoinflammatory disease that affects both children and adults, and is characterised by high spiking fevers, intermittent rash and arthritis. Still's disease is also referred to as systemic juvenile idiopathic arthritis or adult-onset Still's disease. For patients with Still's disease, there remains a high unmet need for a short-acting treatment option with a quick onset of efficacy and a well-established benefit:risk profile. The total number of people in the US with Still's disease, is an estimated 40,000.



Antonio works to secure patient access in Spain.

1. This project has received funding from the EU's Seventh Framework Programme for Research and Technological Development under grant agreement no 304985

Exploring unmet need

Two new clinical programmes

Clinical programmes with Kineret have been designed with the aim of evaluating two new potential indications where a significant need for alternative treatment options exists: acute gout and Still's disease. The clinical trials will take place in North America.

The acute gout programme – anaGO – was initiated in 2016 and will include a dose-finding phase 2 study, followed by a planned phase 3 study designed to evaluate the efficacy and safety of Kineret treatment in resolving the auto-inflammatory driven pain of acute flares.

The planned Still's disease study – anaSTILLS – is a phase 3 study designed to evaluate the efficacy and safety of Kineret in newly diagnosed adult and paediatric patients. The trial is planned to start in the second half of 2017. Sobi received Orphan Drug Designation in the US in September 2015 for anakinra for the treatment of Still's disease including systemic juvenile idiopathic arthritis and adult-onset Still's disease.

Product maintenance

We are committed to addressing all kinds of patient and caregiver needs.

For the administration of Kineret, we have introduced a new syringe with a thinner, 29-gauge, needle and components not made from natural rubber latex. The new syringe was launched in all markets during the year. In addition, we have been granted both a European and US patent for a citrate-free formulation of anakinra.

Our world-class capabilities in protein biochemistry and biologics manufacturing allow us to develop next-generation biological products. Our patient-access oriented approach from early development and onwards generates the evidence needed to support early and sustainable access to treatment.

Lysosomal storage disorders – a Sobi candidate

In 2016, the European Commission granted orphan drug status to our product candidate SOBI003, a modified human recombinant sulfamidase enzyme for the treatment of mucopolysaccharidosis type IIIA (MPS IIIA), or Sanfilippos disease.

In MPS IIIA, the body is unable to break down long chains of sugar molecules called heparan sulfate, resulting in heparan sulfate accumulation in lysosomes. MPS IIIA affects the whole body, especially the central nervous system where it causes severe progressive degeneration.[1] SOBI003 is an enzyme replacement therapy, intended to reduce accumulated heparan sulfate in the affected cells.

Our entire approach has been built on elements that have been identified by representatives of the patient community, starting from the earliest phases. Development of SOBI003 is currently in late preclinical stage and to date, preclinical studies with repeated systemic infusions have demonstrated reduced substrate levels in the brain of mice with resulting disease-modifying effects. We are preparing for clinical studies with a planned start in 2018. In 2016, we established advisory boards with patient representatives and experts to promote a collaborative approach to clinical study design.

Rare diseases require a creative and collaborative approach to overcome the challenges along the way. Our emphasis on patient-access oriented R&D is actively guiding the SOBI003 programme and co-creation with all stakeholders is, and will remain, a critical success factor for this work. There are many decision points along the path to real patient access for a novel treatment for a rare disease, particularly when there has been no treatment available to date. Evidence is required for each decision point and our collaborative and co-creative approach with our stakeholders aims at supporting the availability of good decisions based on as solid evidence as possible at each step along the way.

ABOUT MPS IIIA

MPS IIIA – or Sanfilippo A syndrome – is a progressive, life-threatening and rare inherited metabolic disorder that affects children from a young age. MPS IIIA belongs to a group of diseases known as Lysosomal Storage Disorders (LSDs).

An estimated 1,000-2,000 people live with MPS IIIA in the EU and the US. The disease is usually identified at around four years of age and the lifespan of an affected child does not usually extend beyond early twenties. There is no effective treatment for MPS IIIA at present.

Exploring a novel technological platform

We have continued to capitalise on proprietary and partner platform technology, with the aim of developing new molecules with sustained effect and improved utility.

We have been working with Affibody AB on various programmes over the years, exploring a novel technological platform. Affibody molecules are a class of

protein-targeting biological molecules that can be considered an alternative to antibodies. We have used this technology to develop highly potent inhibitors to complement factor C5. The complement system is an important part of the immune system involved in the pathology of many severe diseases. Complement factor C5 is one of the central components in the complement cascade and has a clear therapeutic potential to target diseases such as PNH (paroxysmal nocturnal haemoglobinuria) and aHUS (atypical haemolytic uraemic syndrome). In 2016, we chose a new drug candidate, SOBI005, within this programme.

In 2016, we also signed a licensing agreement with Affibody AB to exploit Affibody molecules as a potential new interleukin-1 (IL-1) pathway modulators for the development of novel treatments for inflammatory diseases where IL-1 is involved. We nominated our second new drug candidate for the year, SOBI006, within this IL-1 programme. SOBI006 is directed against a specific target in the IL-1 pathway and is aimed at further strengthening our presence in the inflammation field with the objective to provide additional opportunities to address unmet medical needs in the field of autoinflammatory diseases.

Building next-generation treatments

BIVV001 (rFVIIIFc-XTEN) is a drug candidate developed by Bioverativ. The molecule has the potential to further extend the half-life of factor VIII for the treatment of haemophilia A. The XTEN technology is proprietary to Amunix Operating, Inc. The collaboration agreement with Bioverativ has similar terms to those of Elocta and Alprolix and we have not yet exercised our opt-in right to this programme.

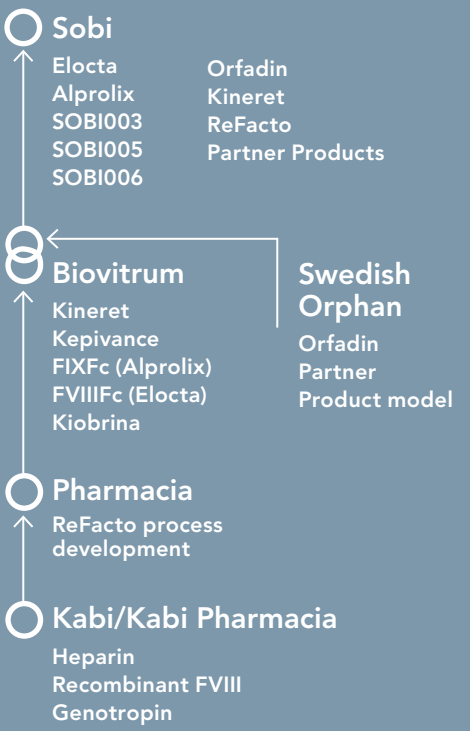
1. Valstar MJ et al. J Inhert Metab Dis. 2008;31:204-252

A legacy of innovation
Pioneers in recombinant biotechnology

Sobi and our predecessors contributed to a major transformational stage in haemophilia treatment. In 1985 Kabi-Vitrum started a project in the early stages of DNA cloning with the ambition to create a new recombinant form of coagulation factor VIII. We have brought the recombinant treatments from gene to patient - both for ReFacto and now for Elocta and Alprolix.

Understanding recombinant protein expression was an evolving new areas of research and the latest advancements in the field were applied. We continue to work in this pioneering and explorative way today.

In 2006, Biovitrum signed an agreement with Syntonix regarding extended half-life haemophilia development programmes. This was the beginning of today's collaboration between Sobi and Bioverativ. A number of our current development programmes are in collaboration with partners, an approach that strengthens our innovation capacity.




Garrett's mother has been able to see her son grow up to become a teenager

Access to healthcare and medicine has been identified as our primary priority.

Sustainable access to high-quality patient care

Our collaborative, patient-centric and sustainable way of developing new and effective therapies is the heart of our operations, aimed at improving quality of life for people who live with a rare disease all over the world.

> "Persons living with a rare disease tend to remain a marginalised and invisible population, with little information available about their diseases and very few treatment options. They suffer inequality in accessing healthcare services and treatment, and in the prices they have to pay, due to their social status or their country of origin."
>
> The NGO Committee for Rare Diseases (United Nations, New York)

Human rights

As recognised by the newly formed UN NGO Committee for Rare Diseases, rare-disease patients can be seen as "the most vulnerable of the vulnerable" due to the combined rare, complex and disabling nature of their disease. Our work with health initiatives, bridging programmes and awareness raising of rare diseases and their treatments represents a key contribution to addressing health as a human right. We agree that businesses have a responsibility to respect human rights and to act in accordance with internationally applicable standards, such as the UN Declaration of Human Rights.

At Sobi, we are committed to addressing human rights concerns if they are a consequence of our own actions, or the actions of our suppliers. Human rights are addressed in several of our stakeholder policies. Our Code of Conduct and Ethics sets out the principles for respecting the rights of employees, patients and participants in clinical trials. In procurement processes we require our suppliers to respect human rights as described in the UN Declaration of Human Rights. We believe there is a strong link between respecting human rights and promoting access to healthcare and medicines.

Access to healthcare and medicines

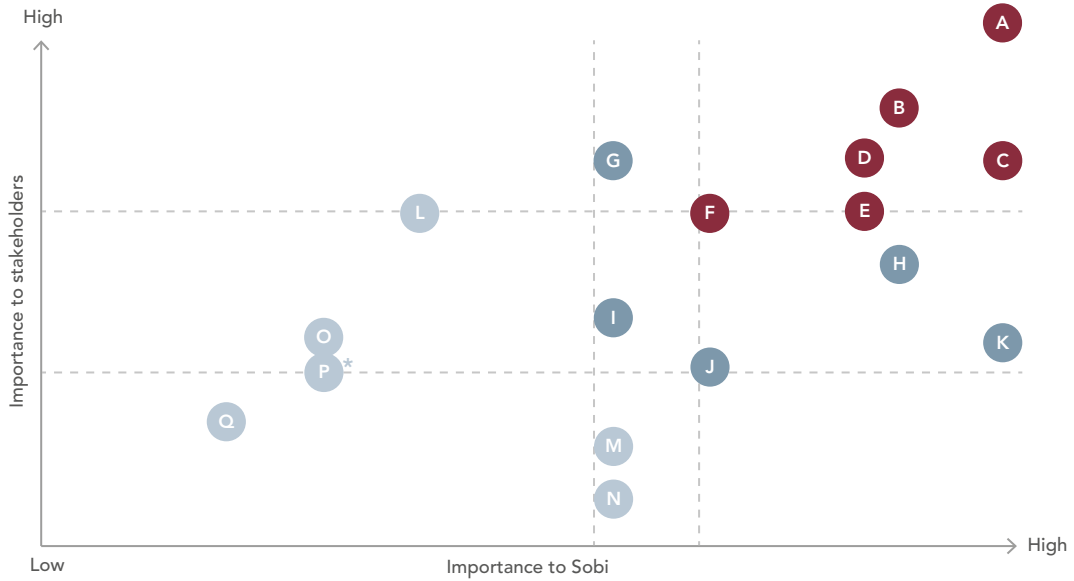
We understand the need for an integrated approach to ensure that patients can access the medicinal products we develop and to assure the best-possible treatment outcomes. This requires a comprehensive and sustainable set of solutions: access to early diagnosis and treatment, a long-term commitment to the community and healthcare systems, and responsible pricing. This ensures the sustainability of both the treatments and our company. Read more about responsible pricing on page 13.

Smaller and mid-sized companies seeking to bring their innovative treatments to Europe face a variety of challenges. Through our Partner Product platform we

Identifying strategic issues

Sobi's materiality analysis is a key tool for identifying and prioritising issues in the business strategy, communication and stakeholder dialogue. The materiality analysis is based on the standard disclosures for stakeholder engagement in the GRI Sustainability Reporting Guidelines, combined with our own analysis of issues raised by the media and other industry players. In 2013, a broader group of internal and external stakeholders was invited to prioritise the relevant aspects and themes identified via a survey and targeted interviews. This process resulted in a number of relevant aspects that reflect our financial, environmental and social impact and/or that affect judgments and decisions made by key stakeholder groups. These priorities remained unchanged during the 2016 financial year and a new materiality analysis was conducted at year-end to capture the issues that will become most important for us in the coming years. Access to healthcare and medications remains our most important aspect. A sustainable supply chain was also identified as critical, as well as responsible marketing and sales activities, and the advancement of our research and development in an ethical way.

SOBI MATERIALITY MATRIX 2016



A Access to healthcare and medicines
B Sustainable and secure supply-chain
C Responsible marketing and sales activities
D Ethics in research
E Engagement with patient groups
F Research and development incl pipeline-programs
G Regulatory and legal environment
H Product safety and quality
I Anti-corruption
J Diversity and equal opportunity
K Sustainable workforce
L Environmental management regarding water, chemicals and pharmaceuticals
M Anti-competetive practices
N Protecting personal information
O Counterfeit drugs prevention
P Greenhousegas emissions
Q Tax transparency and responsibility

The materiality analysis was performed in 2016.

The vertical axis shows the importance that stakeholders attach to various aspects relating to Sobi and the pharmaceutical industry. The horizontal axis shows Sobi's own assessment in relation to the actual business strategy and operations.

* Identified as an area of high general interest. We will increase focus on this aspect in the years to come.

provide a structure that enables access to niche products for patients across Europe, patients that otherwise may be without treatment. Read more on page 38.

Bridging and access programmes

We believe that people with rare diseases should have access to treatment regardless of where they were born. In recent years, we have been laying the foundation for a sustainable access approach to provide people in great medical need with access to innovative and effective treatments from our portfolio no matter where they live. Our ambition is to work with local health communities in order to improve local health policies, and to ensure sustainable access to treatment globally. In India, we support access to Orfadin treatment and in the US, we provide financial assistance for people in need of treatment with Orfadin and Kineret, to bridge access until reimbursement is in place. In collaboration with Bioverativ we have pledged to donate one billion international units of clotting factor to humanitarian aid programmes in developing countries between 2015 and 2025. Read more about our humanitarian aid on page 15.

Engagement with patient organisations

We recognise the importance of learning from patients and their families about the challenges they face, and the success and limitations of their current treatment options, in order to develop and deliver treatments that help meet their needs.

Collaboration is an integral part of our research, clinical programmes, patient access and pricing model. We support and partner with a wide range of patient organisations, both nationally and regionally, to reach the common goal of achieving the best patient outcomes. We do this by conducting research and raising awareness, and by working collaboratively with all stakeholders, including governments and healthcare systems. By working this way, we believe that we can not only bring treatments that will make a difference but that will reach the patients in a timely and sustainable way. All interactions with patient organisations are made public on our website.

Product safety and quality

Patient safety throughout the life-cycle of our products is one our most important tasks. With a robust pharmacovigilance system in place, we continuously oversee the benefit/risk profiles of our products. We provide annual training for all of our employees to ensure 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 for regulators, healthcare professionals and patients.

Counterfeit pharmaceuticals are a growing worldwide problem. To combat this hazardous and highly illegal business, governments all over the world are introducing regulations and systems to detect and prevent the distribution of counterfeit products.

Our products have not yet been subject to falsification, but all our products will be serialised from 2018.

Research ethics

We strive to maintain the highest ethical, technical and scientific standards in all of our research.

Protecting the safety of individuals who take part in our clinical trials is of utmost importance, and build on rigorous and scientifically based evaluations by our clinical experts in cooperation with regulatory authorities, independent ethics committees and stakeholders. We apply the Declaration of Helsinki's principles for medical researchers to guide the ethical conduct of our research involving human participants, and all clinical studies that we sponsor are conducted and reported in accordance with applicable law and the international Good Clinical Practice (GCP) standard.

UN'S SUSTAINABLE DEVELOPMENT GOALS

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

We collaborate to a large extent with contract research organisations (CROs) when conducting clinical trials. This collaboration is governed by mutual high standards and procedures.

We follow the Principles for Responsible Clinical Trial Data Sharing published by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), as well as the European Medicines Agency's (EMA) policy on the publication of clinical trial data.

Our employees

Our employees are our most important asset. To continue our process of building a company that remains innovative and high-performing in a period of growth, we have identified the importance of retaining a strong culture. Creating and sustaining a learning organisation supports us in these efforts.

Sobi is a knowledge-intensive company. We continue to establish, create and nurture a learning organisation. We seek to engage our people in high-performing teams in order to perform and deliver in a competitive market and to reach challenging goals in an appropriate manner that is aligned with our values. This calls for a culture that encourages and supports continuous learning, critical thinking and collaborative new idea generation, to lay the ground for a sustainable future. Efforts to share and provide training in our Sobi culture and values have played a key role in building our new, strong haemophilia business.

Labour rights

We are committed to providing a safe and healthy workplace for our 760 employees around the world. Our activities to protect labour rights are based on our responsibilities as an employer and we encourage our suppliers and partners to adopt socially responsible labour practices as well.

We respect the international labour standards set forth by the International Labour Organisation (ILO) and comply with national labour laws. Our 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.

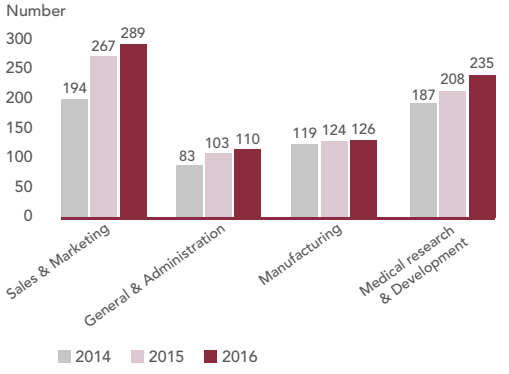
"Sobi's culture of collaboration and inclusion spans globally so that we, in the US and Canada, join other affiliates and headquarters in Sweden in learning and leading together."

Christine,
VP Finance, North America

"I like working at Sobi because here I can combine my interest in protein characterisation and analytical sciences with our goal to develop high quality drugs to improve the life of patients."

Jörgen,
Senior Scientist,
Protein Characterisation

EMPLOYEES 2014–2016



Full-time equivalent (FTE) development for the company: 589 (2014) to 760 (2016)

COLLABORATIVE Contributing to innovations and to the results-oriented work of our teams – both within and between various company functions, and with external partners.

ACCOUNTABLE Taking responsibility for results and focussing on consistently meeting commitments.

RESPECTFUL Having an approach to colleagues and customers alike, based on reliability and trust, where the integrity of the person's relationships is supported by candid feedback.

ENGAGED Making a positive contribution to the company's results through the energy that this person puts into their work, by sharing experiences, and by actively making the most of our opportunities.

SELF DEVELOPMENT → TEAM DEVELOPMENT → COMPANY DEVELOPMENT

100%

Our UK affiliate entered the Great Place to Work® ranking in 2016. We achieved the rare ranking that 100 per cent of Sobi employees said "Sobi is a great place to work". We also received 93 per cent in the Trust Index, an increase of 9 per cent versus the previous year. As a result Sobi is now in the running to be one of the UK's top 20 places (Small companies) to work. The results will be presented in May 2017.

New at Sobi

We continued to grow in 2016, and we reached a total of 760 employees by year end. During the year, we focused not only on strengthening our commercial teams, as in previous years, but also on our aim to become a leading biotechnology company. Recruitment was also, therefore, strong in the manufacturing, research and development, and clinical operations.

Our efforts to on-board new employees take place at both local and central levels. At our head office in Stockholm, Sweden, we arrange induction days to create an understanding of Sobi's history, our strategy and organisation and, most importantly, our patient and customer-centric commercialisation (PC3) and the Sobi CARE (Collaborative, Accountable, Respectful, Engaged) values. Nine events have been held since the first induction days in February 2014, involving 346 people, or 46 per cent of the current workforce.

Personal leadership

Our environment is highly regulated and constantly changing, requiring an adaptive and agile approach to respond to our evolving requirements as well as to stimulate innovation. Continuous scientific, regulatory and compliance training is part of our people development strategy. Through different learning activities, we also aim to develop a change-ready mind-set across our organisation, a learning process that is dependent on individuals across Sobi being engaged and committed in our shared day-to-day operations. Providing professional development for all employees is crucial to both the development of the product portfolio as well as the organisation as a whole.

Building leadership is a critical success factor for a modern biotechnology company. In 2016, we expanded our leadership development programme, which is designed to unleash personal leadership potential and to promote team leadership. Leaders also have access to training and e-learning courses addressing specific managerial topics or skills. All employees have been

given the opportunity to take part of this leadership philosophy and all our training programmes are closely aligned with our culture and CARE values.

In 2016, we implemented a training programmes system, to serve as a platform for creating and sharing e-learning courses across the organisation and to monitor the impact and results of training and development.

Culture-supported performance

We strive for a performance-based culture based on individual accountability, which we believe supports our ability to successfully address our competitive market and to achieve ambitious objectives collectively. A critical factor in this work is to set, and continuously support, individual goals linked to our strategic business objectives. However, performance is not only about *what* individuals achieve but *how* the objectives are achieved. Employees are therefore expected to achieve the individual and team performance results in line with the CARE values.

Sobi's business relies on the knowledge and competences of our employees. Competitive terms of employment are a prerequisite for recruiting and retaining high-calibre employees. We endeavour to offer competitive salaries and benefits, which are individually determined, and adapted to the local labour market.

Actions based on employee feedback

An effective tool for in-depth analysis and long-term action planning is our employee survey, which we conduct every two years, most recently in September 2015. The results showed that Sobi performed on par with, or above, the global average[1] in most comparable areas. For example, Sobi's score was 28 per cent above par in the area of 'Values' compared with other companies. In the biopharmaceutical industry, a value-driven organisation is a key driver of engagement. Employees also highlighted Sobi "as a great place to work", which means we should continue working the way we do to support the overall high levels of engagement. But there were also areas for improvement. Sobi scored on par with the global average for 'Career Opportunities', 'Performance Management' and 'Compensation & Benefits'. We have used the results of the employee survey to develop the company in areas identified as having the most potential for improvement. We are now devoting more attention to setting clear objectives and expectations, giving continuous feedback and having in-depth long-term development dialogues. The performance management and reward systems have also been simplified. The next employee survey will be conducted in the second half of 2017.

Increased diversity

In recent years, we have expanded internationally and the successful incorporation of new knowledge and influences is building our future company. The combination of rare-disease competencies and specific therapeutic knowledge has guided our recruitment process.

We are committed to providing equal employment opportunities regardless of race, age, gender, religion, national origin, sexual orientation or physical ability. We believe that diversity among our employees contributes to our progress and mutual enrichment. We offer equal opportunities for men and women across the organisation, in accordance with our employee policies and guidelines.

Of the total number of employees in 2016, 42 per cent were men and 58 per cent women. The corresponding figures for the executive leadership team and Board of Directors were 75/25 per cent and 62/38 per cent respectively (excluding employee representatives).

1. CEB survey database: 85 per cent match to Sobi (similar company size/population/industry), consists of data from >300.000 employees globally.

GENDER DISTRIBUTION OF EMPLOYEES

♀ 58% ♂ 42%

Environment

We accept environmental responsibility by performing risk assessments, managing chemicals and waste and working with energy and water consumption plans in our production facilities.

Proactive environmental management is part of creating a sustainable business. Environmental considerations are integrated into our 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 Environment and Safety Training, covering risk assessment, greenhouse gas emissions and the management of chemicals and waste in the environment.

Chemicals management

Chemical regulations, aimed at eliminating adverse effects on the environment and human health, are vast and continuously increasing. The handling of chemicals in R&D and manufacturing processes is subject to the applicable guidelines, as well as annual risk assessments, internal reviews and audits.

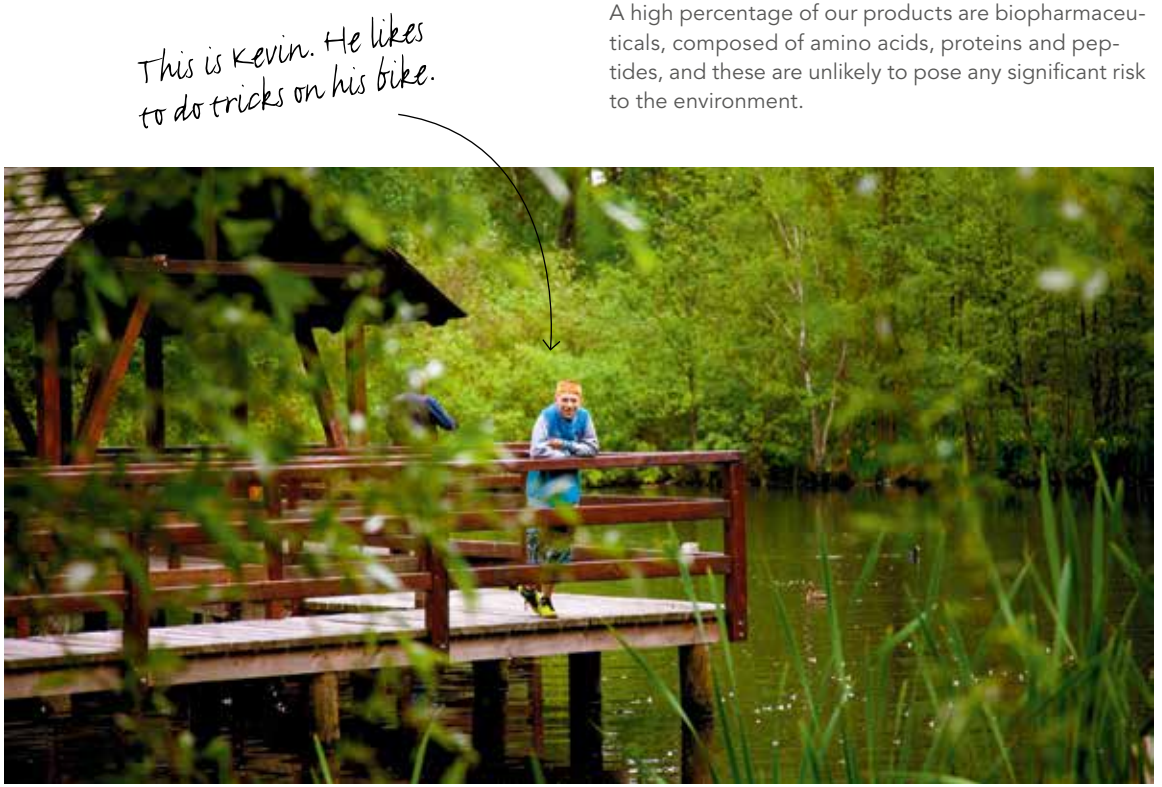
Energy and resource consumption

Business travel is one of the largest sources of greenhouse gas emissions from our activities. As we expand our operations, face-to-face meetings with the multidisciplinary teams across the organisation are invaluable for implementing our Patient and Customer-centric approach to Commercialisation. We continuously emphasize the importance of complying with the Travel Policy, which calls for consideration of virtual meetings when possible. We provide several tools for virtual meetings.

We are committed to improving the energy efficiency of our sites, and regularly review and monitor the operating costs of our buildings. An energy management plan for our production facility in Stockholm has contributed to reduce our energy and water consumption relative to production capacity. As we have increased production during 2016, consumption has increased. For data on energy and resource consumption, see sobi.com.

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 – including 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.



Anti-corruption

We promote business ethics by enforcing compliance with our corporate principles, and by supporting a culture that promotes the open discussion of ethics in both our own operations and among key stakeholders.

We work actively to prevent all forms of corruption and to ensure compliance with our ethical standards across the value chain. We have a zero tolerance policy towards bribery, which is 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 our interactions with healthcare professionals and organisations. An open dialogue on ethical issues is the foundation of our efforts to prevent corruption. This dialogue is supported by annual training for all employees, which translates our Code of Conduct and Ethics and other related procedures into a business context.

Regulatory and legal environment

We operate in a highly regulated environment and are subject to laws and regulations governing production, research and marketing. There is a general trend today towards greater awareness of liability issues and legal risk, as well as increased transparency requirements.

In the rare-disease community, collaboration between authorities, healthcare professionals, companies and patient organisations has always been a cornerstone of the development of new and better treatments and this needs to be done in the right way. Increased transparency provides an even stronger basis for continued collaboration and can positively impact the quality of research, development and manufacturing across the industry. In order to secure future collaboration and to raise public awareness, 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. In June 2016, we implemented the EFPIA Disclosure Code and made all payments and transfers of value to healthcare professionals and healthcare organisations in Europe from 2015 publicly available, including sponsorships to attend meetings, grants and donations, speaker fees, consultancy and advisory boards.

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 the Sobi 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.

Our 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 own governing documents and procedures, followed by continuous assessments. In the second category, we procure goods at the best terms and balance price and quality, with consideration for the relevant industry's standards of responsibility. We have also continued our work with due diligence to ensure that service providers comply with our anti-corruption standards.

99%

OF ALL SOBI EMPLOYEES COMPLETED AND PASSED THE ANNUAL ANTI-CORRUPTION REFRESHER TRAINING.

"A quality culture is instrumental in driving a company in this field. We have strengthened our ability to share knowledge and deepen competence in this area of anti-corruption. In order to emphasise that how we do things is equally important as what we do, a mandatory compliance objective was added to the performance evaluation for all employees during 2016."

Lars Dreiøe,
SVP Chief Quality & Compliance Officer

Our global supply chain

We market and sell a wide range of products to over 60 countries, typically in small volumes to a limited number of patients. Our single most important responsibility is to ensure that patients never risk being without their medication, which could cause a life-threatening situation. Therefore, we have built up a robust supply chain covering all our markets. Through strong focus on patient access, manufacturing partners and an extensive and efficient distribution network we work continuously to shorten the time it takes for the products to reach our patients.

The manufacture of our commercial products is performed by 15 contract manufacturing organisations (CMOs) in Europe and the US. Our unit External Manufacturing is responsible for managing the CMO network globally to ensure uninterrupted, reliable and sustainable supply of our products.

The manufacturing process itself contains three steps – manufacturing of the drug substance, manufacturing of the drug product and finally the packaging of finished goods. Depending on product, there can be different partners for each step or the same partner for several steps. All manufacturers must meet the Sobi Code of Conduct and Ethics. Manufacturers are normally contracted long-term and are continuously monitored.

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 chain – from manufacturing, all the way to when the product reaches the patient.

We interpret sales patterns and prepare long-term forecasts for each product in order to place timely orders with the manufacturers, with whom we have close partnerships and long-term contracts. The entire supply chain is characterised by collaboration and strong commitment to patient health. We take responsibility to ensure the right products of specified quality in the right quantities at our distribution units, and we ensure their quick and efficient physical delivery to the patient when the order arrives.

Our unit for Transport and Trade Compliance ensure that trade laws and regulations are followed. Routines and processes are in place to ship the correct product to the correct place and to ensure that proper approval is in place for each shipment.

In the US, home delivery is an important part of patient support programmes.

Drug Substance

- Manufacturing of active pharmaceutical ingredient
- Biological or chemical synthesis manufacturing process

Drug Product

- Manufacturing of final dosage form
- Aseptic/sterile production and injectable manufacturing: pre-filled syringes, vials, etc.
- Tablets, capsules, liquids/suspensions

Finished Goods

- Labelling and packaging into sales pack

Europe

In Europe, when pharmacies and clinics order products, these orders are normally managed by our logistics partners who ship the products within 24 hours.

Trade compliance

Transport and Trade compliance governs orders to sanctioned countries and their approval.

- Manufacturing network
- Distribution infrastructure

SERIALISATION

To ensure that products are not subject to falsification, a global initiative is being implemented to ensure that all pharmaceuticals will be serialised. That means that a product can be traced from the point of packaging to the point of dispense.

WE DISTRIBUTE TO

60

COUNTRIES WORLDWIDE

EUROPEAN CENTRAL WAREHOUSE

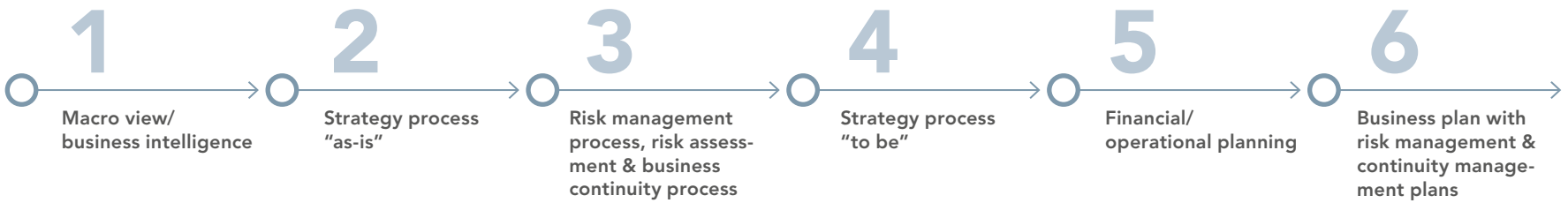
Small volumes drive the need for one large central warehouse. The location is logistically ideal to provide service all over Europe and to the US. Smaller local warehouses support quick service to the countries.

"During all the years, we have never been out-of-stock regarding Orfadin. We understand the difference it can make for patients and are committed to provide Orfadin treatment without delay, all over the world."

Annika, Head of Global Supply Chain

Risk management for successful strategy execution

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



We have a business-integrated risk management process. Our business intelligence, risk management and business continuity management are all integrated into the strategy and business planning process in the regular corporate planning procedure. This process needs to be linked to all other divisions and processes – quality evaluation, financial planning and strategy – within the company, in an integrated and seamless way.

During the year, some areas became increasingly important to address in order to reduce the potential risk impact. One such area was the growing competition in our commercial markets, especially for Haemophilia and Orfadin. Our development portfolio has also been identified needing more balance in terms of the developmental stages of our programmes.

We strive to balance financial investment in our R&D portfolio by spreading investments between the development and re-purposing of already approved products, where the risk is limited; and potential future products in pre-clinical and clinical phase where the inherent risk is higher but where there is a strong potential for future returns if successful. We made substantial in-house achievements during the year in our early-stage pipeline and in order to support our aim of having an increasingly balanced portfolio, we announced our intention to expand our late-stage clinical programmes through partnerships, in-licencing or acquisition.

Our assessment of business risks

We review all identified risks and assess them on the basis of their likelihood to occur, and the impact should they occur. We conduct this assessment from both a one-year and a three-year perspective, enabling the identification of both operational and strategic risks in order to implement timely risk management measures and activities. Risks with a high likelihood and high impact require urgent and decisive action to ensure that they are properly managed.

Case study of successful risk management

Alprolix approval

THE RISK: Working towards the EU marketing approval of Alprolix, our filing came three months behind that of a competing recombinant factor IX candidate.

CONSEQUENCE: Late access to Europe for the product, possibly with less compelling positioning in the haemophilia community and a greater uncertainty about the orphan drug exclusivity treatment for Alprolix.

A critical milestone for us and Bioverativ in 2016 was to receive EU marketing authorisation for Alprolix for the treatment of haemophilia B. We were aware of competing drug programmes under development by other companies. Both products sought to maintain their orphan designation and to achieve approval first.

Bioverativ and Sobi built on their long-standing relationship and assembled an agile and highly collaborative team to address this challenge. By working in the fastest possible time while maintaining quality, we were ready for an authorisation decision significantly earlier than the time-frame allowed in the process.

We successfully managed to reduce the timeline for our application by three months and both candidate applications were reviewed at the same time. Both products received a positive opinion on the maintenance of orphan designation and both received a marketing authorisation for the same indication on the same day. This was a highly successful outcome, as it meant we could move on to focus on the most important aspect for everyone – bringing the product to patients.


This is Amina. She takes good care of her younger brother

Smart investments create
long-term value for patients
and shareholders.

The share's development

The share (STO:SOBI) is listed on Nasdaq Stockholm, under the company name of Swedish Orphan Biovitrum, and is included in the Large Cap Index and the Pharmaceuticals & Biotechnology Sector Index, which rose 2 and 3 per cent, respectively, during the year. Sobi's market capitalisation at year-end 2016 was SEK 29 billion.

Over the past five years, the share price has risen 611 per cent. In 2016, the highest price paid was SEK 133.30 on 4 January 2016, and the lowest was SEK 89.50 on 2 November 2016.

Share capital

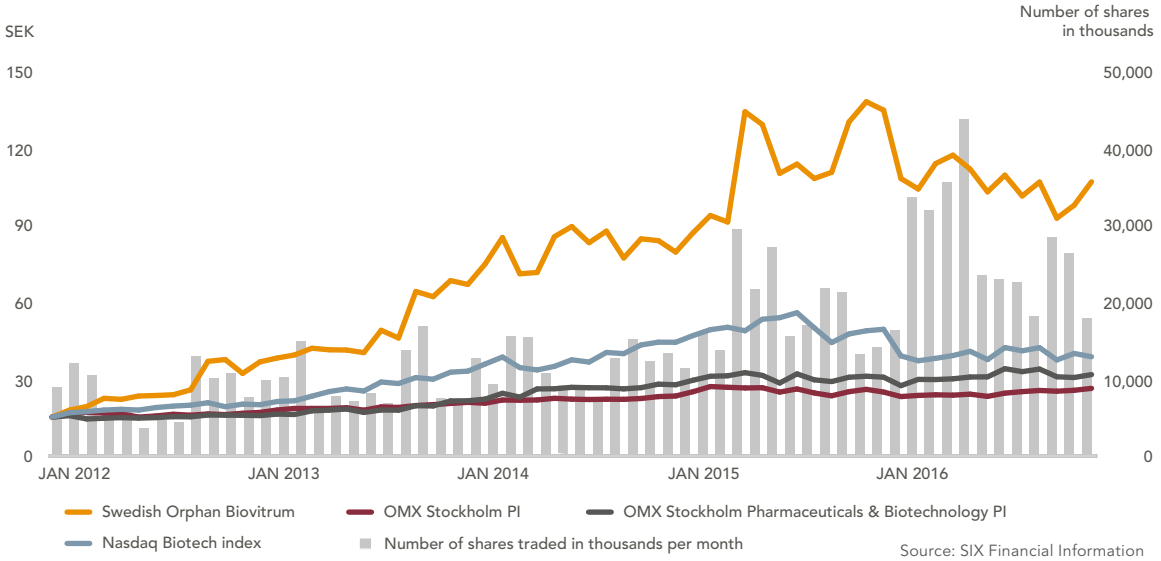
At year-end, the total number of shares outstanding in Sobi was 272,010,948, of which 270,389,770 were ordinary shares and 1,621,178 Class C shares, representing a total of 270,551,888 votes. Each ordinary share carries one vote, while Class C shares carry 1/10 of a vote. The increased number of shares and votes is due to a new issue of 188,142 Class C shares, which will be used to secure obligations under Sobi's incentive programmes. At year-end, the share capital was SEK 149,254,136, distributed between 272,010,948 shares with a par value of approximately SEK 0.55.

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.

SOBI SHARE PRICE AND TRADING VOLUME 2012–2016



Source: SIX Financial Information

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

SEK 1,000	2012	2013	2014	2015	2016
A shares	10,726	22,446	43,445	100,369	131,644

In 2016, the average daily trading volume in number of shares for the Sobi share on Nasdaq Stockholm was 1,240,305 shares.

Source: di.trader

Shareholders

At year-end, the number of shareholders was 32,397 (2015: 21,096). The largest shareholder, Investor AB, held 39.6 per cent (39.6) of the shares. Swedish legal entities, including institutions and funds, held 77.2 per cent (65.6).

Treasury shares held by Swedish Orphan Biovitrum AB (publ) at year-end totalled 1,610,086 A shares and 1,621,178 C shares. During the year, 940,588 shares were used for allotment under the performance-based long-term share programme. Sobi has launched several share-based incentive programmes for senior executives and our employees. For more information, see Note 12.

Dividend

The Board proposes no dividend for the 2016 financial year. For more information about Sobi's dividend policy, please refer to the Corporate Governance Report.

Market price for the Sobi share, SEK

	2016		2015	
	High	Low	High	Low
1st quarter	133.30	92.60	95.85	76.30
2nd quarter	128.80	96.75	145.90	89.45
3rd quarter	115.50	98.00	125.00	100.30
4th quarter	108.90	89.50	140.30	109.10

Shareholder categories

31 December 2016	% of capital
Foreign shareholders	13.8
Swedish shareholders	86.2
Of which:	
Institutions	90.9
Private persons	9.1

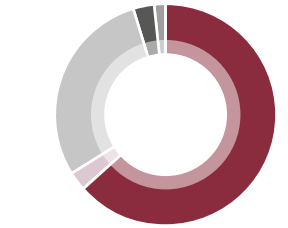
Source: Euroclear

Recommendations from analysts, %

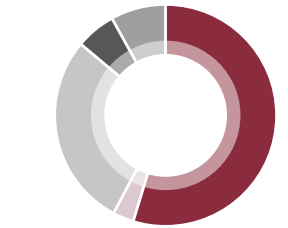
	2014	2015	2016
Buy	70	75	73
Hold	20	25	9
Sell	10	0	18

Source: Based on analyst reports

TRADING PLACES 2015



TRADING PLACES 2016



Source: Fidessa

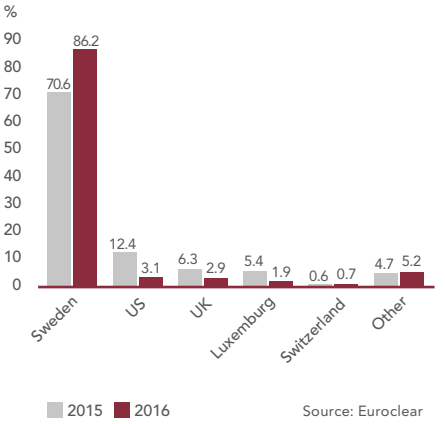
Analyst coverage

Carnegie	Erik Hultgård
Danske Bank	Lars Hevreng
Deutsche Bank	Richard Parkes
Goldman Sachs	Eleanor Fung
Handelsbanken	Peter Sehested
Jefferies	Eun K. Yang
Nordea	Hans Mähler
Pareto Securities	Finlay Heppenstall
RX Securities	Samir Devani
SEB	Richard Koch
Swedbank	Johan Unnérus

Brief facts, the Sobi share

Listing	Nasdaq Stockholm
Number of shares (A + C shares)	272,010,948
Market capitalisation, at year end	SEK 29 billion
Ticker	SOBI
ISIN	SE0000872095
CUSIP	870321106

SHAREHOLDERS BY COUNTRY



Source: Euroclear

Largest shareholders at 31 December 2016[1]

Shareholders	Number of A shares	Number of C shares	Share capital, %	Share votes, %
Investor AB	107,594,165	0	39.56	39.77
Swedbank Robur Funds	11,158,600	0	4.10	4.12
Fourth Swedish National Pension Fund	10,909,958	0	4.01	4.03
Lannebo Funds	10,523,683	0	3.87	3.89
AMF – Insurance + Funds	9,441,827	0	3.47	3.49
Handelsbanken Funds	6,140,568	0	2.26	2.27
SEB Investment Management	5,213,435	0	1.92	1.93
Gladiator	4,470,000	0	1.64	1.65
Biotech Target N.V.	4,449,334	0	1.64	1.64
Afa Insurance	3,376,684	0	1.24	1.25
Swedish Orphan Biovitrum AB (publ)	1,610,086	1,621,178	1.19	0.66
Länsförsäkringar Fondförvaltning AB	2,994,870	0	1.10	1.11
Catella Fondförvaltning	2,253,309	0	0.83	0.83
Försäkringsaktiebolaget, Avanza Pension	2,183,615	0	0.80	0.81
Nordea Investment Funds	1,801,482	0	0.66	0.77
Total 15 largest shareholders	**184,121,616**	**1,621,178**	**68,29**	**68,22**
Other	86,268,154	0	31,71	31,78
Total	**270,389,770**	**1,621,178**	**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

FOR MORE INFORMATION ABOUT SOBI'S AMERICAN DEPOSITARY RECEIPT (ADR), CONTACT:

US Depositary
BNY Mellon Shareowner services
P.O. Box 30170, College Station, TX 77842-3170, USA
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

	2012	2013	2014	2015	2016
Income statement, SEK M					
Total revenues[1]	1,923	2,177	2,607	3,228	5,204
Gross profit	1,040	1,284	1,548	2,007	3,651
EBITDA[2]	400	241	–12	465	1,574
EBITA[2]	367	211	–43	433	1,543
EBIT[2]	–55	–67	–325	146	1,133
Profit/loss for the year	–105	–93	–266	65	809
Capital, SEK M					
Total assets	6,313	6,524	6,376	8,315	9,974
Capital employed	5,725	5,842	5,588	5,795	6,667
Equity	4,814	4,745	4,497	4,660	5,354
Cash and cash equivalents	457	445	519	904	786
Net cash (–)/debt (+)[2]	143	352	298	–82	–282
Cash flow, SEK M					
Cash flow from operating activities before changes in working capital	368	166	299	411	643
Cash flow from operating activities	406	185	234	507	343
Cash flow from investing activities	–67	–405	–184	–143	–158
Cash flow from financing activities	–100	207	20	22	–308
Change in cash and cash equivalents	238	–13	70	386	–123
Key figures, %					
Gross margin	54	59	59	62	70
Return on capital employed	–1.0	–1.1	–5.8	2.5	17.0
Return on equity	–2.2	–2.0	–5.9	1.4	15.1
Equity ratio[2]	76	73	71	56	54
Debt/equity ratio	30	37	41	77	86
Share ratio, SEK					
Earnings/loss per share	–0.40	–0.35	–1.01	0.24	3.01
Equity per share[2]	17.8	17.5	16.6	17.2	19.8
Dividend	0	0	0	0	0
Cash flow per share	0.9	0.0	0.3	1.4	–0.5
Cash flow from operating activities per share	1.5	0.7	0.9	1.9	1.3

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.

Table of Contents

Profitable growth

The financial results during 2016 show that Sobi continues on a path of strong development. For the second year in a row, we over-delivered on raised financial targets and set down a strong platform for future ventures in our marketing, sales and development projects.

Sobi is today a profitable and rapidly growing international leader in rare diseases. During 2016, the turnover increased with 61 per cent to just over 5.2 billion Swedish crowns, the gross margin was strengthened with 8 percentage points to 70 per cent and the EBITA increased from 433 to 1,543 million crowns and our net cash position increased to 282 million crowns by year end. We can now see a definite financial impact from the strategic initiatives that we have implemented and followed through upon during the past five years.

Impact of one time credits

A more balanced product portfolio had a positive impact on revenue, margin and operating profit, especially from the launches of Elocta® and Alprolix® in our territory. According to our agreement with Bioverativ, Sobi received one time credits totalling 708 million crowns during the year, whereof 322 million crowns are related to Elocta and 386 million crowns are related to Alprolix.

Change in Bioverativ royalty structure

The one time credits represent 10 per cent of the sales of Eloctate® and Alprolix in Bioverativ territories, up until the first commercial sale of the respective products in our territories. Sobi has previously received 2 per cent royalty on Bioverativ sales. With the launch of Elocta and Alprolix, Sobi now receives 12 per cent royalty on Bioverativ sales and equally pays 12 per cent to Bioverativ on our sales of the respective products. In total, Sobi recognised revenues of 1,511 million crowns from Bioverativ (whereof 708 million crowns were one time credits).

Adjustment of debt relating to development costs

Sobi has assumed a liability towards Bioverativ for half of the past development costs for Elocta and Alprolix. These will be settled through a cross royalty payment mechanism. At year end, the debt for Elocta totalled 138 million US dollars and for Alprolix 115 million US dollars (For full details, please refer to Note 19 of this report).

Strong finances provide opportunities

Building on the positive impact of the Haemophilia launches was the growth and momentum of the commercial business more broadly. Kineret® sales increased by 24 per cent to over one billion crowns, which corresponds to a doubling over three years. Combined with the positive development of other segments of our business, this influenced cash flow positively to over 343 million crowns during 2016. We have also been able to strengthen our financial position by recalling our bond totalling 800 million crowns, and replacing it with a more flexible and capital efficient debt structure.

With strong finances and a continued positive profit development from both our haemophilia products as well as the other parts of the business we are set to contribute to a world where more people have access to treatment and thereby increase our sales and drive our development programmes in order to strengthen our position as a rapidly growing international player in the rare disease field.

Mats-Olof Wallin, CFO

"We can now see a definite financial impact from the strategic initiatives that we have implemented and followed through upon during the past five years."

Directors' Report

Highlights 2016

Financial highlights

- Total revenues were SEK 5,204 M (3,228), an increase of 61 per cent.
- Revenues from Key Therapeutic Areas amounted to SEK 3,729 M (1,797), up more than 100 per cent.
- The gross margin was 70 per cent (62).
- EBITA was SEK 1,543 M (433). Profit for 2016 included non-recurring revenue of SEK 322 M related to the first commercial sales of Elocta in the first quarter, and non-recurring revenue of SEK 386 M related to the first commercial sales of Alprolix in the second quarter.
- Profit for the year totalled SEK 809 M (65), representing earnings per share of SEK 3.01 (0.24).
- Cash flow from operating activities amounted to SEK 343 M (507).

Business highlights

- Elocta was launched in the first European countries.
- Agreement with PharmaSwiss regarding commercialisation of three products.
- Orfadin oral suspension and 20 mg capsule approved in the US.
- Extended supply agreement with Pfizer for ReFacto AF until 2023.
- Alprolix approved in the EU.
- Elocta reimbursed in the UK, Italy, France and Spain
- Alprolix reimbursed in the UK.
- Market authorisation for Alprolix transferred to Sobi.
- Sobi and Horizon Pharma sign five-year distribution agreement for Ravicti® and Ammonaps® outside the US.

Sobi's operations

Sobi is an international healthcare company dedicated to rare diseases. Our mission is to develop and deliver innovative therapies and services to improve the lives of patients. The product portfolio is primarily focused on haemophilia, inflammation and genetic diseases. Sobi also markets a portfolio of specialty and orphan drugs in Europe, the Middle East, North Africa and Russia, in collaboration with various partner companies.

In 2016, the company generated revenues through:

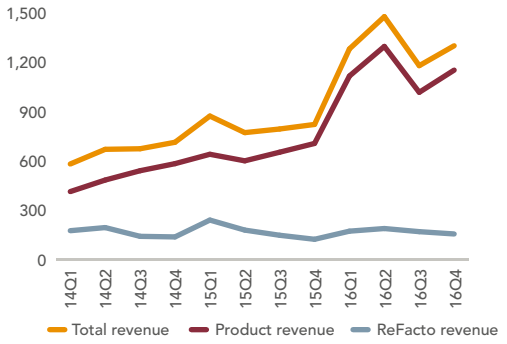
- Sales of proprietary products, marketing rights for Elocta and Alprolix, and royalty revenue from Bioverativ's sales of Eloctate and Alprolix.
- Sales in Europe, the Middle East, North Africa and Russia of products for which Sobi holds the distribution and/or licensing agreements.
- The sales of the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

Key figures

SEK M	2016	2015
Operating revenues	5,204	3,228
Gross profit	3,651	2,007
Gross margin, %	70	62
EBITA	1,543	433
EBIT	1,133	146
Profit for the year	809	65
Earnings/loss per share, SEK	3,01	0.24

See page 69 for a five-year summary of revenues, expenses and earnings.

Revenue trend, SEK M



Revenues by product category

SEK M	2016	2015
Key Therapeutic Areas	3,729	1,797
Partner Products	820	771
ReFacto	656	660
Total revenues	5,204	3,228

Operating revenues
In 2016, revenues rose to SEK 5,204 M (3,228). Sales of products in Key Therapeutic Areas increased by more than 100 per cent, and in Partner Products by 6 per cent. Revenues related to ReFacto declined 1 per cent.

Gross margin
The gross margin was 70 per cent (62). The improvement was mainly attributable to the launch of Elocta and Alprolix and strong sales of Kineret.

Expenses
Operating expenses increased to SEK 2,518 M (1,861). The increase was partly attributable to higher R&D expenditure, due to early pipeline programmes and the start-up of pipeline programmes for Kineret, for acute gout and Still's disease. R&D expenditure for the year also reflects Sobi's responsibility for 50 per cent of Bioverativ's ongoing development expenditure for Elocta from 1 March, and for Alprolix from 1 August.

Operating expenses also include costs of SEK 36 M (45) for the long-term incentive programmes. Cash flow was not impacted by these programmes.

Selling and administrative expenses increased to SEK 1,776 M (1,345). The increase mainly reflected the continued investments to support the launch of Elocta and Alprolix. Research and development expenditure rose to SEK 778 M (513), with increased costs in the haemophilia operations.

Other operating revenues amounted to SEK 36 M (–3). Operating revenues and expenses for both 2016 and 2015 pertain to exchange-rate effects.

Profit/loss
EBITA was SEK 1,543 M (433). Amortisation of intangible fixed assets amounted to SEK 410 M (287). EBIT was SEK 1,133 M (146).

Net financial items
In 2016, net financial items amounted to an expense of SEK –85 M (–61), including exchange-rate gains of SEK 5 M (–4). Net financial items comprised financial income of SEK 8 M (4) and financial expense of SEK 93 M (65). In addition to exchange-rate effects, net financial items consisted of interest income and interest expense.

Taxes
Current tax expense during the year amounted to SEK –32 M (–22) and deferred tax to an amount of SEK –206 M (4). Total tax recognised for the Group amounted to SEK –239 M (–19). The increase in deferred tax pertained to a change in accounting requirements for the amortisation of intangible assets, appropriations in the Parent Company and acquisitions of intangible assets.

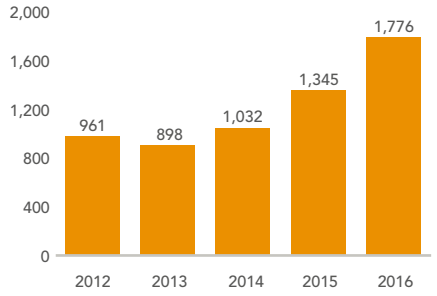
Other comprehensive income
Other comprehensive income amounted (net) to SEK –170 M (53) comprising cash-flow hedges attributable to future inflows in USD, deferred tax on these, exchange-rate differences and revaluation of the pension obligation.

Cash flow and investments
Cash flow from operating activities was SEK 343 M (507). Cash flow from investing activities was SEK –158 M (–143). During the year, net investment in Alprolix totalled SEK 1,348 M, but had no impact on cash flow (for more information, see Note 19).

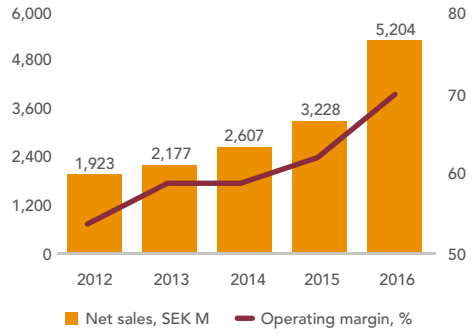
An increase in working capital had a negative impact of SEK –300 M (96) on cash flow. The increase was mainly attributable to higher accounts receivable due to increased sales and accrued income derived from royalties from Bioverativ. Working capital also improved due to an increase in operating liabilities related to production.

Financial position
At 31 December 2016, cash and cash equivalents and current investments amounted to SEK 786 M (904). In June 2016, Sobi redeemed a bond loan with a nominal value of SEK 800 M. The bond loan was replaced by a three-year credit facility of SEK 1,000 M, of which SEK 500 M has been utilised. The transaction lowered the company's interest expense, increased financial flexibility and reduced refinancing risk.

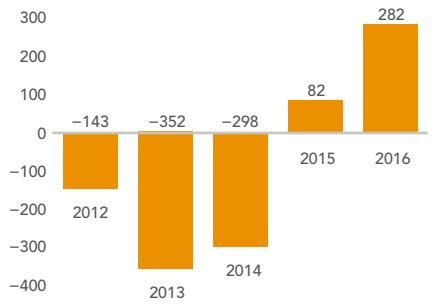
Selling and administrative expenses, SEK M



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



Net cash (+)/debt (–), SEK M



At 31 December 2016, net cash was SEK 282 M, compared with SEK 82 M at 31 December 2015.

The debt to Bioverativ is a non-interest-bearing liability and therefore not included in net cash/debt.

Equity

At 31 December 2016, consolidated equity amounted to SEK 5,354 M (4,660). In addition to profit for the year, the change comprised sales of own shares, costs related to share programmes and hedge accounting. In 2015, the opening balance was adjusted by a negative amount of SEK 26 M, related to a restoration provision for leased premises. The provision is attributable to earlier periods but recognised during the year.

Sales

Key Therapeutic Areas

Sales in Sobi Key Therapeutic Areas – Inflammation, Genetics & Metabolism and Haemophilia – with the products Kineret, Orfadin, Elocta and Alprolix, grew more than 100 per cent to SEK 3,729 M (1,797). Sales for 2016 included non-recurring revenue of SEK 322 M related to the first commercial sales of Elocta in the first quarter, and non-recurring revenue of SEK 386 M related to the first commercial sales of Alprolix in the second quarter. The products Ammonaps, Ammonul® and Ravicti, which were included in Genetics & Metabolism in 2015, are now included in Partner Products.

Sales of Kineret rose 24 per cent to SEK 1,001 M (805), driven by growth in most markets.

Despite healthy sales in the US, sales of Orfadin declined 3 per cent to SEK 770 M (796), negatively impacted by the authorisation of generic drugs in Canada. EMENAR operations were adversely impacted by lower sales due to the authorisation of generic drugs in Turkey, and by order patterns in the Middle East and Russia.

In 2016, total revenues for the haemophilia operations were SEK 1,853 M (96), including non-recurring revenues of SEK 708 M for the first sales of Elocta and Alprolix. Of revenues, royalty revenue accounted for SEK 803 M (95) of Bioverativ's sales of Eloctate and Alprolix. Furthermore Sobi obtained a milestone revenue of SEK 14 M.

In 2016, product sales related to haemophilia amounted to SEK 327 M (2), of which sales of Elocta accounted for SEK 267 M (1). Revenues for sales of Elocta were mainly derived from Germany, France and the UK. The year also included sales in Italy, Denmark, Belgium, Spain, Poland, Slovenia, the Netherlands, Austria, Switzerland and Kuwait.

In 2016, sales of Alprolix amounted to SEK 60 M (1). Revenues for Alprolix were mainly derived from Germany and the UK.

At year-end, Elocta was reimbursed in 13 European countries, including the UK, France, Italy, Germany and Spain, and in Kuwait. At year-end, Alprolix was reimbursed in six European countries.

Partner Products

Total sales for Partner Products amounted to SEK 820 M (771), up 6 per cent, including a non-recurring payment of SEK 24 M from Exelixis related to the transfer of Cometriq® to Ipsen. The operations continued to show favourable growth, mainly driven by Xiapex® and the new PharmaSwiss products. Sales for Partner Products now include sales of Ammonaps, Ammonul and Ravicti which were previously recognised under Genetics & Metabolism: The figures for preceding years have been adjusted.

Sales for the three largest products increased as follows: Xiapex rose 11 per cent to SEK 153 M (138), Yondelis® rose 4 per cent to SEK 88 M (85) and the Valeant portfolio rose 40 per cent to SEK 88 M (63).

ReFacto

Total revenues for the ReFacto business area from manufacturing and royalties amounted to SEK 656 M (660), of which manufacturing revenue rose 13 per cent to SEK 569 M (504) and royalty revenue declined 44 per cent to SEK 88 M (156) due to the expiration of Sobi's rights to royalty revenue on sales outside the US on 1 June. In April 2016, Sobi and Pfizer extended their supply agreement for ReFacto AF/XYNTHA until 31 December 2023, with an option to renew. Sobi´s royalty agreement for ReFacto in the US remains valid until January 2018.

Parent Company

The Parent Company's business model is to develop, register, distribute and market drugs for rare diseases. In 2016, Parent Company revenues totalled SEK 4,594 M (2,750). Operating profit was SEK 1,206 M (309). Profit for the year totalled SEK 59 M (214), including additional depreciation of SEK 1,154 M and Group contributions of SEK 105 M. At 31 December 2016, cash and cash equivalents amounted to SEK 662 M (750) and equity amounted to SEK 5,744 M (5,803). The change was attributable to profit for the year, costs linked to the company's share programmes, sales of Treasury shares and hedge accounting including deferred tax. In 2015, the opening balance was adjusted by a negative amount of SEK 26 M, related to a restoration provision for leased premises. The provision is attributable to earlier periods but recognised during the year.

Five-year summary (Group)

SEK M	2016	2015	2014	2013	2012
Operating revenues	5,204	3,228	2,607	2,177	1,923
Cost of goods and services sold	–1,554	–1,221	–1,059	–893	–883
Research and development expenditure	–778	–513	–501	–456	–402
Operating income (EBIT)	1,133	146	–325	–67	–55
Financial items, net	–85	–61	5	–56	–54
Profit for the year	809	65	–266	–93	–105
Earnings/loss per share, SEK	3,01	0.24	–1.01	–0.35	–0.40
Earnings/loss per share after dilution, SEK	3,01	0.24	–1.01	–0.35	–0.40
Number of shares, 000s	270,390	270,390	270,390	270,390	265,227
Equity/assets ratio	54%	56%	71%	73%	76%

Revenues by product category (Group)

SEK M	2016	2015
Inflammation: Kineret	1,001	805
Inflammation: Other	105	99
Genetics & Metabolism: Orfadin	770	796
Haemophilia	1,853	96
Key Therapeutic Areas	**3,729**	**1,797**
Partner Products	**820**	**771**
Manufacturing revenue	569	504
Royalty revenue	88	156
ReFacto	**656**	**660**
Total revenues	**5,204**	**3,228**

Product sales by region (Group)

(Excluding ReFacto manufacturing and royalty revenue and Haemophilia royalty revenue.)

SEK M	2016	2015	Change
Europe	1,654	1,296	28%
MENAR[1]	302	231	31%
North America	1,002	861	16%
RoW[2]	66	85	–22%
Total	**3,023**	**2,473**	**22%**

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

Products per business line (Group)

Key Therapeutic Areas	Partner Products	ReFacto
Inflammation	Aloxi®/Akynzo®	Manufacturing
Kineret	Ammonaps	Royalty
Kepivance®	Ammonul	
Genetics & Metabolism	Betapred	
Orfadin	Cometriq	
Haemophilia	Defitelo	
Elocta	Ferriprox®	
Alprolix	Ravicti	
Eloctate (From Bioverative)	Ruconest®	
	PharmaSwiss portfolio	
	Xiapex	
	Yondelis	
	Other	

Development

Sobi development projects include pipeline programmes in the areas of haemophilia, inflammation, genetic diseases and lysosomal diseases. In 2016, Sobi selected two new product candidates, SOBI005 and SOBI006, for continued development in the preclinical development portfolio. Sobi is also conducting a number of projects focused on further development of our existing products.

In Haemophilia, development consists of an expanded clinical trial activity to strengthen the already extensive evidence for Sobi's authorised haemophilia products. Sobi is also conducting preclinical development of XTEN technology in partnership with Bioverativ.

In Inflammation, efforts to design two clinical programmes have commenced, with the aim of studying new applications for Kineret – acute gout and Still's disease. In the phase 2 trial (anaGO) to evaluate the safety and efficacy of Kineret for the treatment of acute gout, the first patient has been randomised for treatment. The earlier pipeline programme explored potential new product candidates for the treatment of inflammatory conditions involving IL-1. During the year, the SOBI006 product candidate, based on the Affibody platform, was presented.

In Genetics, the clinical development programme consists of a collaboration study designed to examine the use of nitisinone in patients with alkaptonuria (AKU). Surveillance studies to assess the long-term efficacy and safety of Orfadin in HT-1 are ongoing.

In 2016, progress was made in the preclinical programme and in the development of an industrial manufacturing process to develop a modified sulfamidase, SOBI003, for the treatment of MPS IIIA, a lysosomal storage disease. In the programme for complement-related diseases, the SOBI005 product candidate was selected.

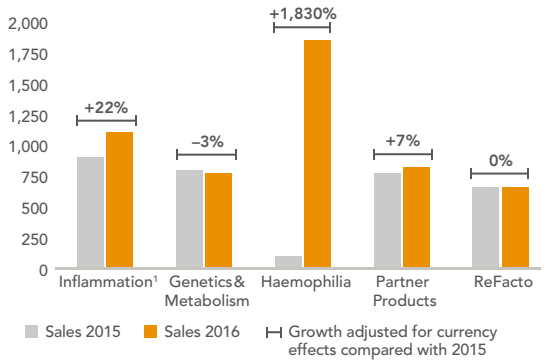
Orfadin Oral Suspension formulation granted a European patent

The European Patent Office (EPO) granted a European patent for the Orfadin Oral Suspension formulation, which was authorised by the European Commission in 2015 for the treatment of HT-1.

Clinical development programmes for acute gout and Still's disease initiated

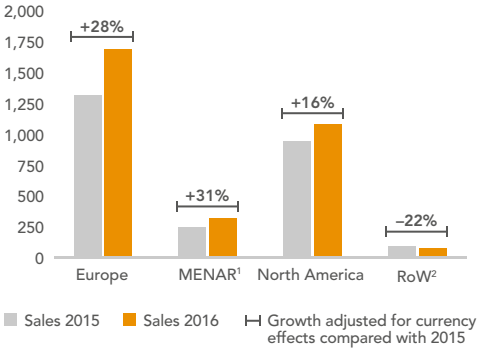
Sobi announced its intention to commence two clinical development programmes for Kineret, with the goal of evaluating two potentially new applications – acute gout and Still's disease.

Revenues per product category, SEK M



1. Includes both *Inflammation: Kineret* and *Inflammation: Other*

Product revenue per region (excluding ReFacto and Haemophilia royalty, SEK M)



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

Alprolix authorised in the EU
The European Commission authorised Alprolix for the treatment of haemophilia B in all 28 member states, plus Iceland, Lichtenstein and Norway. Alprolix was granted orphan designation in line with a recommendation by the European Medicines Agency's Committee for Orphan Medicinal Products (COMP).

US and European patents granted for new Kineret formulation
Sobi was granted patents for a citrate-free formulation of Kineret in the US and Europe. The patents expire in February 2032.

Licensing agreement for IL-1 signed with Affibody
Sobi signed a licensing agreement with the biotech company Affibody AB. The agreement governs the development of new treatments for inflammatory diseases involving interleukin-1 (IL-1). In 2012, Sobi entered into a research collaboration agreement with Affibody, which included an option to sign an exclusive licensing agreement for IL-1. The research has been based on Affibody's patented technology platform and is focused on selected proteins involved in regulating the body's immunological reactions and inflammatory processes.

Data from long-term treatment with Elocta and Alprolix were presented at the WFH 2016 World Congress
Sobi and Bioverativ presented updated results for the long-term safety and efficacy of Elocta/Eloctate and Alprolix. Data from the continuing phase 3 trials, B-YOND (haemophilia B) and ASPIRE (haemophilia A), were presented orally and with posters at the World Federation of Hemophilia (WFH) 2016 World Congress in Orlando, Florida, on 24–28 July 2016.

European Commission granted orphan designation to SOBI003 for the treatment of MPS IIIA
The European Commission granted orphan designation to SOBI003, Sobi's product candidate in the development phase SOBI003 is a chemically modified human recombinant sulfamidase for the treatment of mucopolysaccharidosis type IIIA (Sanfilippo syndrome type A). SOBI003 will be included in the EU register of designated Orphan Medicinal Products.

European study on clinical outcomes for haemophilia therapy clarifies the need for better haemophilia care
Sobi presented the results of a new European study that evaluated clinical outcomes associated with haemophilia care. The study was fully financed by Sobi and showed that treatment practices varied greatly between countries, and that patients treated both intermittently and prophylactically had bleeding episodes, which highlights the need to further improve the standard for haemophilia care.

Sobi and Bioverativ presented long-term safety and efficacy data for Elocta and Alprolix
Sobi and Bioverativ presented new data for Elocta and Alprolix at the 58th American Society of Hematology (ASH) Annual Meeting and Exposition, including new follow-up data related to safety and efficacy from the phase 3 and continuation trials.

Other information

Change in management
In September 2016, Milan Zdravkovic was appointed Senior Vice President, Head of Research & Development. Milan joined Sobi from Novo Nordisk, where he was involved in the research and development organisation for 18 years, and responsible for therapeutic areas including diabetes, growth hormones, obesity and immunology.

Environmental information
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 is available 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, Sweden, 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. In 2016, no breaches of the conditions were reported by any of the facilities. The company also has an import permit for animal by-products from the Swedish Board of Agriculture, and a permit for handling flammable products. In 2016, a permit from the Swedish Radiation Safety Authority for working with radioactive substances was terminated, since no such activities take place any more. While adaptation to current regulations has not, to date, had any adverse impact on Sobi's competitiveness or operations, the company cannot predict the impact of future regulations.

Share capital and ownership

Sobi's share capital amounted to SEK 149,254,136, distributed between 272,010,948 shares, with a par value per share of about SEK 0.55. On 31 December 2016, the total number of shares outstanding was 270,389,770 ordinary shares, which carry one vote per share, and 1,621,178 Class C shares, which carry 1/10 of a vote per share. On 31 December 2016, Investor AB was Sobi's single largest shareholder with a total of 107,594,165 shares, representing 39.77 per cent of the votes and 39.56 per cent of the capital.

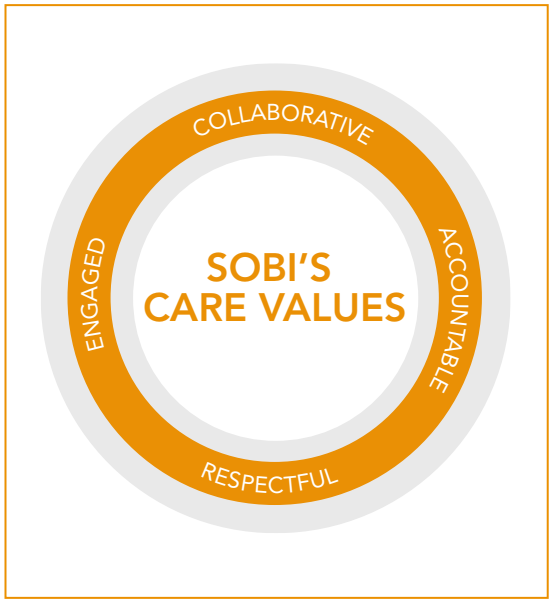
Share conversions

At the Annual General Meeting on 24 May 2016, Sobi's Board of Directors was authorised to issue Class C shares and to repurchase the issued Class C shares, for hedging of the long-term incentive programme. The AGM also resolved to approve the Board's proposed transfer of shares. On 31 December 2016, Sobi held 1,610,086 ordinary shares and all 1,621,178 Class C shares in treasury. For more detailed information about the total number of shares in the company, the number of different classes of shares and the number of votes carried by the company's shares, refer to the section on shares on page 66.

Sobi's values

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

Sobi's values are appropriately reflected by the word "CARE":
Collaborative – I contribute to an innovative and results-oriented way of working in our teams – both in and between the various company functions and with external partners.
Accountable – I take responsibility for my results and focus on consistently meeting my commitments.
Respectful – My approach to employees and customers is based on reliability and trust, where the integrity of my relationships is supported by candid feedback.
Engaged – I make a positive contribution to the company's results through the energy I put into my work, by sharing my experience, and by actively making the most of our opportunities.



Compliance with the company's values is evaluated every year in Sobi's performance appraisal process. Sobi acknowledges and rewards performances above and beyond the ordinary by individual employees and teams who put the company's values into practice in various ways.

Employees

At 31 December 2016, the number of full-time employees was 760 (672), of which 433 (406) were based in Sweden. Salaries and other remuneration amounted to SEK 793 M (678), of which the Parent Company accounted for SEK 367 M (344).

Of the total number of employees in 2016, 58 per cent were women and 42 per cent were men. All employees are treated equally and offered the same opportunities regardless of age, gender, religion, sexual orientation, disability or ethnicity.

Guidelines and remuneration 2017

The Board of Directors proposes that the Annual General Meeting 2017 resolves on principles for remuneration to Management as set forth below which shall apply until the Annual General Meeting 2018. The Management is defined as the managing director of Swedish Orphan Biovitrum AB (publ) and the executives who report to the managing director and are members of the senior management, as well as members of the Board of Directors if employment or consulting agreements are entered into.

Objective

The objective 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 to the Management should be built 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 principles should enable international hiring and should support diversity within the Management. The remuneration may consist of the following components:

- A, Fixed base pay
- B, Variable pay – so-called Short Term Incentives
- C, Long term incentives
- D, Pensions
- E, Other benefits

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

Fixed base pay

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

Variable pay

The annual Short Term Incentive plan is based on the achievement of annual performance objectives (corporate, departmental[1] and individual). No payment will be made unless these objectives are achieved. 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 may not amount to more than 75 per cent of the annual gross salary for the managing director and not more than 50 per cent of the fixed annual salary for the other members of the management (pension compensation for the managing director may be included in the annual gross salary and therefore also be included as 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 talents, to offer participants 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 programs, see Note 12.

1. Departmental objectives are not applicable for the managing director.

Pensions
Sobi's preferred pension plan design is defined contribution[1]. If the operating environment requires the establishment of a defined benefit pension plan by law or other regulations, such a plan may be established. The defined benefit level should in such cases be limited to the mandatory level.

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

Additional compensation may also be paid out in extraordinary circumstances, provided that such arrangements are made for management 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, including for example if the Board of Directors is of the option that a deviation is necessary or appropriate for the purpose of recruiting the most competent individual as the new managing director.

Deviations from the 2016 guidelines
In connection with the implementation of the company's long-term incentive program 2016 (LTI 2016) several employees, including members of the management, were legally prohibited from participating in the program due to them, at that point in time, being in possession of inside information. In light of the 2016 Annual General Meeting's resolution to approve the proposal for the LTI 2016, which meant that, amongst others, members of management were envisaged to participate in the LTI 2016, and since the Board of Directors considers that a long-term incentive program is a crucial component of a competitive total remuneration package with which to attract and retain executives who are critical to the company's long-term success, the Board of Directors resolved on a deviation from the guidelines to allow the employees who were legally prohibited from participating in the LTI 2016 to instead participate in a long-term cash-based incentive program (LCI). The deviation was made in accordance with the provision in the remuneration guidelines approved by the 2016 Annual General Meeting. Similar to the LTI 2016, the LCI has a three-year term with certain performance measures which must be satisfied in order for any compensation to be payable to management. For the management, the performance measures are related to profitability and revenue growth. The company's maximum costs for the LCI cannot on an individual basis exceed the maximum costs that otherwise may have arisen under the LTI 2016.

Furthermore, since the CEO, Geoffrey McDonough will leave the company in July 2017, the company has entered into an agreement with him which deviates from the remuneration guidelines approved by the Annual General Meeting 2016. 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 salaries, i.e. more than the maximum two years that is stipulated in the guidelines. Given that it is in both the company's and the shareholders' interest to keep the CEO for as long as possible while the company is recruiting a successor and that Geoffrey McDonough intends to be in service during the entire notice period up until 1 July 2017, the Board of Directors resolved to deviate from the remuneration guidelines approved by the Annual General Meeting 2016 in this individual case.

For the guidelines and remuneration that applied in 2016 and up until the 2016 AGM, see Note 12.

1. A defined contribution pension plan defines the level of contribution that will be paid into the pension plan for each employee.

Proposed appropriation of profit

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

SEK	
Share premium reserve	4,191,748,633
Profit carried forward	544,244,952
Profit for the year	58,694,262
Total	**4,794,687,847**

The Board of Directors proposes that no dividend be distributed for the 2016 financial year.

The Board proposes that the funds at their disposal, SEK 4,794,687,847 be carried forward.

Significant events after the reporting period, as per 28 March 2017

Health Canada approved Orfadin capsules
Health Canada approved Orfadin capsules for the treatment of hereditary tyrosinaemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenylalanine.

Armin Reininger joined Sobi as Senior Vice President, Head of Global Medical and Scientific Affairs
Armin Reininger, MD, PhD was appointed Senior Vice President, Head of Global Medical and Scientific Affairs. Armin will lead Sobi's cross-functional Medical & Scientific Affairs team, supporting Sobi's patient centric approach.

CEO Geoffrey McDonough to leave Sobi
Sobi announced that Geoffrey McDonough will leave Sobi on 1 July 2017, and that a search for a new Chief Executive Officer has been initiated to identify his successor, see Note 12 for further information.

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

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

Sobi and Bioverativ revealed new long-term safety and efficacy data of Elocta and Alprolix at EAHAD
Sobi and Bioverativ presented nine posters with data on long-term safety and efficacy for Elocta and Alprolix at the 10th Annual Congress of the European Association for Haemophilia and Allied Disorders (EAHAD).

Sobi obtained approval from the EC for new dosing frequency for Orfadin
Sobi received confirmation by the European Commission approving a reduced dosing frequency for Orfadin from twice daily to once daily, in people with HT-1 with a body weight >20 kg.

Long-term safety and efficacy data for Alprolix 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.

Discussions regarding a possible sale of Partner Products
Sobi confirmed discussions with a private equity firm regarding a possible sale of the Partner Products business area. The discussions may or may not lead to an agreement. In realtion to these discussions the financial Statements in this report have not been prepared in accordance with IFRS 5 Non-current Assets Held for Sale and Discontinued Operations, since the conditions specified in the standard are not met yet.

Haemophilia development portfolio expanded with XTEN-molecule
Haemophilia B development portfolio expanded by adding BIVV002 (rFIXFc-XTEN) to collaboration agreement with Bioverativ.

New distribution agreement entered with Valeant for Ammonul
3-year agreement with Valeant Pharmaceuticals for the distribution of Ammonul in Europe, the Middle East and North Africa.

EMA approves higher capacity drug substance manufacturing for Elocta
The variation involves the approval of Elocta drug substance manufacturing in 15,000 litre scale bioreactors.

Long-term safety and efficacy extension study data of Alprolix
Interim results from the B-YOND extension trial, which studies Alprolix in previously treated subjects with severe haemophilia B, were published in Thrombosis and Haemostasis.

FDA approves in-use storage at room temperature for Orfadin capsules
FDA approved in-use storage at room temperature (25°C or less) for up to 45 days for all strengths of Orfadin capsules, in line with the already existing approval by EMA for in-use storage at room temperature.

Outlook for 2017[1]

For the full-year 2017, Sobi expects revenues within the range of SEK 5,800–6,000 M. The gross margin is expected to range from 66–68 per cent. Sobi expects EBITA for the full-year to be within the range of SEK 1,600–1,700 M.

Risk management

We work according to a fully integrated business-risk-management process that contributes to our ability to achieve defined objectives and pursue the strategy adopted for the operations. Each operational unit works actively to identify any uncertainties surrounding the ability to achieve defined objectives. These are assessed even when they could potentially disrupt the operations in the short or long term. The risks are quantified against the relevant values for the operations in order to prioritise and handle the risks in a commercial manner. By identifying risks and allowing the Leadership Team to determine strategic priorities for risk management, we achieve a dynamic process in which uncertainties and untapped opportunities around the company's strategy can be identified and managed. Our Risk Manager reports the current risk status to the Leadership Team and a review of this process is presented to the Board of Directors every quarter.

As part of the strategic work with risk management, the company's critical flows are identified and business continuity plans are established. If circumstances arise that fall within the framework of our definition of a crisis, there is a crisis management policy and a crisis management group composed of members of the company's Leadership Team. The strategic crisis management group works alongside of established operational crisis management groups 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, and 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
Drug development
Sobi currently has a number of projects in clinical development and several projects in preclinical development. Drug development is a capital-intensive, complex and risk-filled 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 trials, while costs increase at a faster rate when the project moves into the later clinical phases.

Before receiving authorisation to launch any drug candidates, a company must be able to demonstrate that the drugs 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 impacted by a variety of factors, including those beyond the company's control, such as changing regulatory requirements. Sobi's innovation model is used to determine how attractive a project is, and its risk profile.

Obtain and retain authorisation for new products
Before initiating any launch of a drug, Sobi and its business partners must demonstrate that the drug meets the stringent proof of quality, safety and efficacy requirements imposed by authorities in the countries or regions where Sobi plans to market the drug.

Even when drugs in Sobi's product portfolio receive marketing authorisation, there is no guarantee that these products will be granted reimbursement and pricing approval by the national or regional healthcare systems, nor market acceptance by physicians, patients or procurement organisations. 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 both internally and together 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, budgetary restraints and prescribers in the event of a potential 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.

1. The outlook was published on 16 February 2017.

Collaboration and partnerships
The strategy for a balanced product portfolio includes entering into collaborative agreements for joint development and/or authorisation with other pharmaceutical and biotech companies, for example, for the development and launch of some of Sobi's products. Collaborations may also refer to patient organisations, academic institutions or other relevant groups. The success of such collaborations will largely depend on the work of Sobi's partners or licensees, since these still have considerable discretion when it comes to determining the efforts and resources to be put into the projects, depending on the nature of the agreement between the parties.

Intellectual property protection and patent risks
Sobi's success will largely depend 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 has a number of technology licences that are important for the operations, and the company is expected to obtain additional licences 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.

Biologics manufacturing and quality
Sobi manufactures protein drugs and recombinant protein drugs and is dependent on the company's production facility in Stockholm being maintained and available. Sobi also collaborates on drug development with other pharmaceutical companies, as both supplier and customer.

The manufacture of Sobi's products requires that all manufacturing processes, methods and equipment are compliant with Good Manufacturing Practice (GMP) guidelines. The GMP guidelines apply to Sobi as well as its distributors, contract laboratories and suppliers.

The GMP guidelines control all aspects of the pharmaceutical manufacturing process, including quality control and quality assurance, manufacturing processes and documentation. Furthermore, Sobi must conduct extensive audits of its distributors, contract laboratories and suppliers who are also covered by these requirements.

Sobi's production facilities may be inspected at any time by the regulators or the company's customers.

The company's production and R&D also involve controlled use of biological and hazardous materials and waste. Sobi is subject to laws and regulations governing the use, manufacture, storage, handling and disposal of such hazardous materials 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.

Any significant decline in revenues from Sobi's key products could have a material adverse effect on Sobi's operations, earnings and financial position – regardless of whether this is due to reduced demand, increased competition or other reasons, such as policy changes for the national drug reimbursement scheme.

Furthermore, there is always the risk that the company's products under development will be exposed to competition from similar products, or entirely new product concepts, that can demonstrate better value. Sobi therefore initiates collaborations with external research groups at the forefront of medical development, to increase opportunities for gaining access to target proteins that can be developed into competitive medical treatment options.

The market in which Sobi operates is increasingly impacted by cost-consciousness due to the growing cost of healthcare in many countries. In most markets where Sobi operates, regulators exercise some control over the pricing of pharmaceuticals.

Sobi's success depends on whether the products developed by the company are covered by, and eligible for, reimbursement under private or national reimbursement systems in the healthcare sector. Legislation and regulatory proposals in some European countries and in the US include measures that could potentially restrict or prevent payment for treatment with certain medications.

The use of medications could also be affected by the treatment guidelines, recommendations and studies published by regulators and other bodies.

In order to ensure optimal and sustainable results for everyone, relevant stakeholders in the various stages of the patient journey are identified, which in the best of worlds, could lead to faster development and availability, or the discovery of new opportunities.

Product counterfeiting
Prescription drugs are increasingly being challenged by illegally produced pharmaceutical products (and by access to pirated products in some distribution channels.) This phenomenon has been observed in an increasing number of geographical markets and via the Internet.

Sobi's products have not yet been subject to pirating, but we are constantly on our guard, and participate in global efforts initiated to investigate product traceability. To minimise the risk of counterfeiting, all of Sobi's distribution processes comply with Good Distribution Practice.

Ethical and compliance risks
Issues such as social responsibility and sustainable business play an increasingly significant role in a company's competitiveness and profitability. Sobi's Risk and Regulatory Compliance Committee continuously monitors the development and implementation of Sobi'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 are identifying risks, promoting clear messages, establishing clear guidelines and processes, training and continuous monitoring.

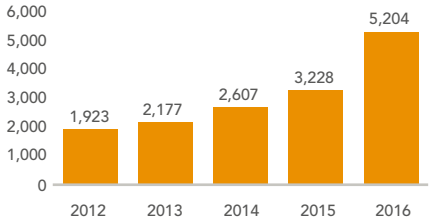
Financial risks
The company's operations are exposed to foreign-exchange risk. Most of the company's expenses are incurred in SEK, while a significant portion of revenues are generated in other currencies. Due to the company's international expansion, lower exchange rates for the USD and EUR in particular, but also for other currencies in which revenues are generated, could have an adverse effect on Sobi's earnings and financial position. For more information about financial risks, refer to Note 3.

Consolidated statement of comprehensive income

SEK 000's	Note	2016	2015
	1–4		
Operating revenue	5–6	5,204,340	3,227,867
Cost of goods and services sold		–1,553,823	–1,220,968
Gross profit		**3,650,517**	**2,006,899**
Selling and administrative expenses	13	–1,776,261	–1,344,860
Research and development expenditure		–777,587	–513,370
Other operating revenue	8	118,191	14,783
Other operating expenses	9	–81,746	–17,929
Operating profit	7, 10, 12, 14, 17, 19, 20, 32	**1,133,114**	**145,523**
Financial revenue	15	7,925	4,326
Financial expense	16	–93,060	–65,639
Financial items, net		**–85,135**	**–61,313**
Profit before tax		**1,047,979**	**84,210**
Income tax for the year	18	–238,907	–19,297
Profit for the year[3]		**809,072**	**64,913**
Other comprehensive income[1]			
Items that will not be reclassified to profit or loss			
Actuarial gains/losses on defined-benefit plan		1,231	–3,340
Items that may be reclassified subsequently to profit or loss			
Translation differences		4,869	–1,505
Cash flow hedges		–226,019	74,736
Tax effect of cash flow hedges		49,724	–16,442
Other comprehensive income		**–170,195**	**53,449**
Comprehensive income for the year[3]		**638,877**	**118,362**
Earnings per share, SEK[2]		3.01	0.24
Earnings per share after dilution, SEK[2]		3.01	0.24
Number of shares (ordinary)		270,389,770	270,389,770
Average number of shares		268,362,041	267,278,339
Number of Class C shares held in treasury		1,621,178	1,433,036
Number of ordinary shares held in treasury		1,610,086	2,763,768
Number of shares after dilution		269,252,883	270,389,770
Average number of shares after dilution		269,218,052	267,278,339

1. In accordance with the revised version of IAS 1, all changes in equity other than those resulting from transactions with owners are to be presented in the consolidated statement of comprehensive income. Translation differences are entirely related to shares in foreign subsidiaries.
2. For calculation, refer to Consolidated statement of change in equity.
3. Everything attributable to the Parent Company's shareholders.

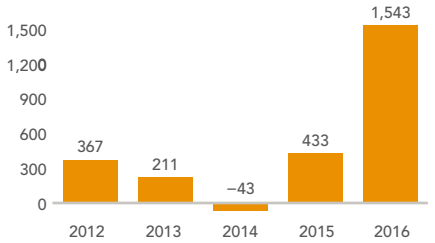
Operating revenue, SEK M



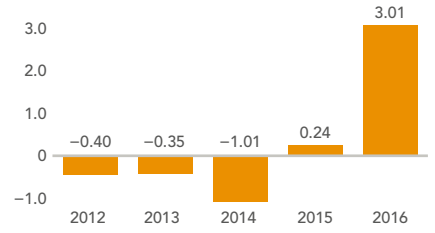
Operating revenue

Revenues for the full-year amounted to SEK 5,204 M (3,228), an increase of 61 per cent.

EBITA, SEK M



Earnings/share, SEK M

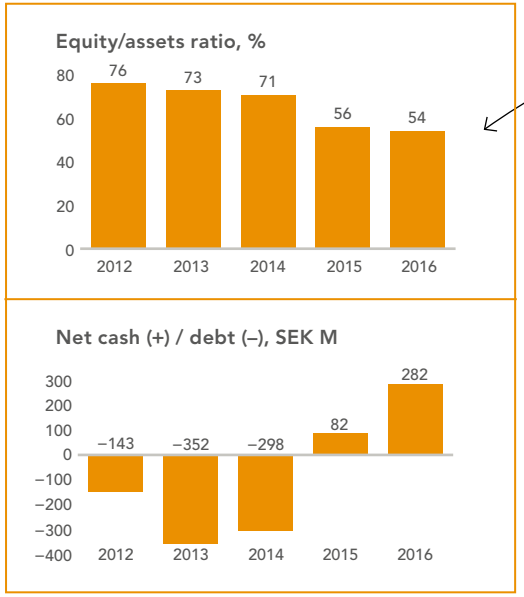


Consolidated balance sheet

SEK 000's	Note	31 Dec 2016	31 Dec 2015
ASSETS	1–4		
Fixed assets			
Intangible assets	19	6,806,010	5,787,036
Tangible assets	20	121,023	112,676
Financial assets	22	1,956	1,791
Deferred tax assets	23	133,897	97,219
Total fixed assets		**7,062,886**	**5,998,722**
Current assets			
Inventories	24	870,046	775,854
Accounts receivable	25, 28	768,765	451,229
Other receivables	25	75,543	67,576
Prepaid expenses and accrued income	26	411,109	117,847
Cash and cash equivalents	27, 28	785,790	903,660
Total current assets		**2,911,253**	**2,316,166**
TOTAL ASSETS		**9,974,139**	**8,314,888**

SEK 000's	Note	31 Dec 2016	31 Dec 2015
EQUITY AND LIABILITIES			
Equity			
Share capital		149,254	149,150
Other contributed capital		4,983,959	4,928,765
Reserves		–167,734	2,461
Profit/loss carried forward		–420,273	–485,082
Profit for the year		809,072	64,913
Equity attributable to owners of the Parent		**5,354,278**	**4,660,207**
Liabilities			
Non-current liabilities			
Deferred tax liabilities	23	506,246	312,809
Bond loans	28, 29	—	795,158
Debt to Bioverativ	28, 30	1,808,916	1,179,468
Liabilities to credit institutions	28, 30	502,216	5,178
Provision for pension commitments	32, 33	44,389	41,966
Total non-current liabilities		**2,861,767**	**2,334,579**
Current liabilities			
Accounts payable	28	280,173	183,193
Tax liabilities		15,801	12,197
Debt to Bioverativ	28, 31	496,697	459,818
Other liabilities	28, 31	156,123	115,026
Accrued expenses and deferred income	34	809,300	549,868
Total current liabilities		**1,758,094**	**1,320,102**
TOTAL EQUITY AND LIABILITIES		**9,974,139**	**8,314,888**

Related to pledged assets and contingent liabilities, see Note 35.

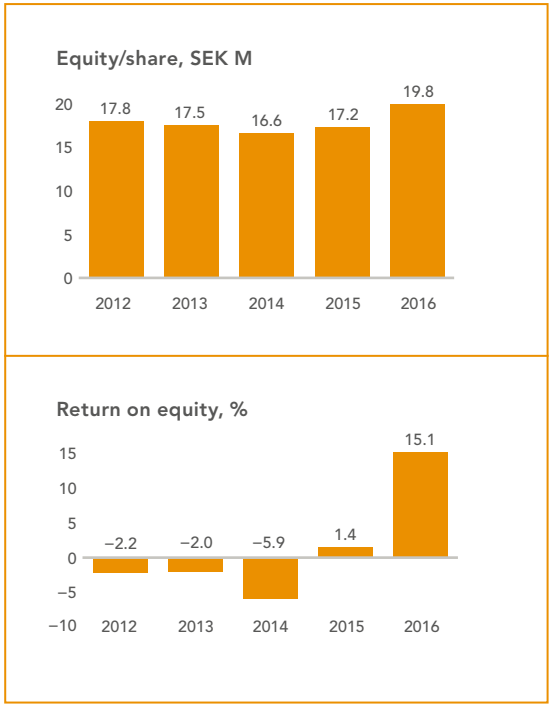


The decline the last two years is mainly due to the acquisition of Elocta and Alprolix

Consolidated statement of changes in equity

SEK 000's	Share capital	Other contrib-uted capital	Other reserves	Profit/loss carried forward	Total equity
Opening equity, 1 Jan. 2015	**148,580**	**4,883,930**	**–50,785**	**–484,512**	**4,497,213**
Comprehensive income					
Profit for the year	—	—	—	64,913	64,913
Other comprehensive income					
Cash flow hedges	—	—	58,294	—	58,294
Actuarial loss/gain	—	—	–3,340	—	–3,340
Exchange-rate differences	—	—	–1,505	—	–1,505
Total comprehensive income	**—**	**—**	**53,449**	**64,913**	**118,362**
Transactions with shareholders					
Issue/repurchase of shares	570	—	—	–570	—
Sale of ordinary shares	—	22,230	—	—	22,230
Share-based remuneration	—	22,605	—	—	22,605
Other	—	—	–203	—	–203
Total transactions with shareholders	**570**	**44,835**	**–203**	**–570**	**44,632**
Closing equity, 31 Dec. 2015	**149,150**	**4,928,765**	**2,461**[1]	**–420,169**	**4,660,207**
Opening equity, 1 Jan. 2016	**149,150**	**4,928,765**	**2,461**	**–420,169**	**4,660,207**
Comprehensive income					
Profit for the year	—	—	—	809,072	809,072
Other comprehensive income					
Cash flow hedges	—	—	–176,295	—	–176,295
Actuarial loss/gain	—	—	1,231	—	1,231
Exchange-rate differences	—	—	4,869	—	4,869
Total comprehensive income	**—**	**—**	**–170,195**	**809,072**	**638,877**
Transactions with shareholders					
Issue/repurchase of shares	104	—	—	–104	—
Sale of ordinary shares	—	23,500	—	—	23,500
Share-based remuneration	—	31,694	—	—	31,694
Total transactions with shareholders	**104**	**55,194**	**—**	**–104**	**55,194**
Closing equity, 31 Dec. 2016	**149,254**	**4,983,959**	**–167,734**	**388,799**	**5,354,278**

1. At 31 December 2016, other reserves consists of translation differences of SEK –20,195 K (–25,064), pensions according to IAS 19 of SEK –25,231 K (–26,462), cashflow hedges (see table on right) of SEK –122,105 K (54,190), related to cash flow hedging of the liability to Bioverativ for Elocta and Alprolix.

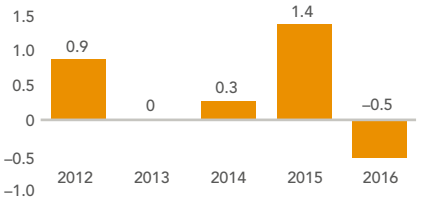


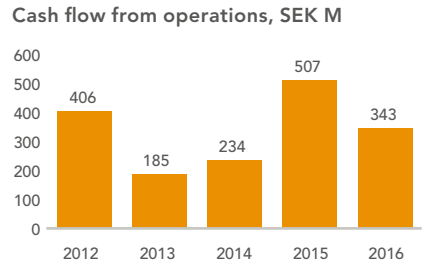
Cash flow hedges, SEK 000's	2016	2015
Opening balance, cash-flow hedges	54,190	–4,104
Change in value for the year, hedging instruments	–176,295	58,294
Closing balance, cash-flow hedges	–122,105	54,190

Consolidated cash flow statement

SEK 000's	Note	2016	2015
Operating activities			
Profit for the year		809,072	64,913
Adjustments for non-cash items		–166,612	346,323
Cash flow from operating activities before changes in working capital		**642,460**	**411,236**
Cash flow from changes in working capital			
Decrease (+) / Increase (–) in inventories		–94,192	–11,919
Decrease (+) / Increase (–) in operating receivables		–618,765	14,588
Increase (+) / Decrease (–) in operating liabilities		413,354	93,300
Cash flow from operating activities		**342,857**	**507,205**
Investing activities			
Acquisition of intangible assets[1,2]	19	–118,657	–118,728
Acquisition of tangible assets	20	–45,808	–27,374
Acquisition of financial assets	22	–100	—
Divestment of tangible assets	20	6,555	2,250
Divestment of financial assets	22	—	435
Cash flow from investing activities		**–158,010**	**–143,417**
Financing activities			
Sale of shares		23,500	22,230
Raising of loans[3]	30	496,914	—
Payment of loans[3]	29	–828,000	—
Cash flow from financing activities		**–307,586**	**22,230**
Change in cash and cash equivalents		**–122,739**	**386,018**
Cash and cash equivalents at 1 January		**903,660**	**519,147**
Exchange-rate differences in cash flow		**4,869**	**–1,505**
Cash and cash equivalents at 31 December		**785,790**	**903,660**

1. The largest investment of the year is the Kineret Milestone of SEK 72 M, see Note 19.
2. The debt to Bioverative is not included in the cash flow since it doesn't affect the cash flow.
3. Payment of loans pertains to repayment of a loan of SEK 20 M from AB Svensk Exportkredit and redeem of the bond loan of SEK 800 M, which was replaced by a three year revolving facilities agreement of SEK 1,000 M, of which SEK 500 M have been used.





Supplemental disclosures to the consolidated cash flow statement

SEK 000's	Note	2016	2015
Interest paid and received			
Interest received		874	4,342
Interest paid		85,927	56,206
Tax paid		10,812	21,081
Adjustments for non-cash items			
Depreciation and impairment of fixed assets	7, 19, 20	440,710	319,507
Revaluation of long term debt		670	2,960
Pensions	32	2,851	–6,679
Cost of share programmes[1]		31,694	22,605
Deferred tax	23	156,759	12,462
Elocta and Alprolix[2]		–811,832	–10,208
Other items		12,536	5,676
Total		**–166,612**	**346,323**

1. IFRS expenses associated with the share programmes that is recognised in equity.
2. Refers to the net of the investment, the debt to Bioverativ, royalty revenues used to settle the debt to Bioverativ and the cash flow hedge for the debt to Bioverativ.

Parent Company income statement

SEK 000's	Note	2016	2015
	1–4		
Operating revenue	5–6	4,593,940	2,750,027
Cost of goods and services sold		–1,469,991	–1,167,702
Gross profit		**3,123,949**	**1,582,325**
Selling and administrative expenses	13	–1,218,391	–814,173
Research and development expenditure		–729,241	–472,285
Other operating revenue	8	111,553	27,623
Other operating expenses	9	–81,631	–14,757
Operating profit	7, 10, 12, 14, 17, 19, 20	**1,206,239**	**308,733**
Financial revenue	15	21,883	29,507
Financial expense	16	–94,819	–65,555
Financial items, net		**–72,936**	**–36,048**
Profit after financial items		**1,133,303**	**272,685**
Group contributions		105,334	—
Accelerated depreciation		–1,154,000	—
Appropriations		**–1,048,666**	—
Profit before tax		**84,637**	**272,685**
Income tax for the year	18	–25,943	–58,625
Profit for the year		**58,694**	**214,060**

Parent Company statement of comprehensive income

SEK 000's	2016	2015
Profit for the year	58,694	214,060
Items that may be reclassified subsequently to profit or loss		
Cash flow hedges	–226,019	74,736
Tax effect of cash flow hedges	49,724	–16,442
Other comprehensive income	**–176,295**	**58,294**
Comprehensive income for the year	**–117,601**	**272,354**

Parent Company balance sheet

SEK 000's	Note	31 December 2016	31 December 2015
ASSETS	1–4		
Fixed assets			
Intangible assets	19		
Patent, licenses and product rights		4,261,999	2,656,257
Advance payments for intangible assets		—	82,400
Tangible assets	20		
Land and buildings		—	3,927
Plant and machinery		58,536	41,824
Equipment, tools, fixtures and fittings		29,891	39,796
Construction in progress		14,770	10,902
Financial assets			
Participations in Group companies	21	3,882,138	3,882,138
Receivables from Group companies		—	16,604
Other long-term financial receivables	22	1	21
Total fixed assets		**8,247,335**	**6,733,869**
Current assets			
Inventories	24		
Raw materials and consumables		25,557	14,991
Work in progress		433,243	316,001
Finished goods and goods for resale		307,584	342,563
Current receivables			
Accounts receivable	25	280,249	184,035
Other receivables	25	54,532	47,623
Receivables from Group companies		725,626	670,947
Prepaid expenses and accrued income	26	399,373	109,406
Cash and cash equivalents	27	662,110	750,398
Total current assets		**2,888,274**	**2,435,964**
TOTAL ASSETS		**11,135,609**	**9,169,833**

SEK 000's	Note	31 December 2016	31 December 2015
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital		149,254	149,150
Statutory reserve		800,257	800,257
Total restricted equity		**949,511**	**949,407**
Non-restricted equity			
Share premium reserve		4,191,749	4,156,272
Profit carried forward		544,245	483,084
Profit for the year		58,694	214,060
Total non-restricted equity		**4,794,688**	**4,853,416**
Total equity		**5,744,199**	**5,802,823**
Untaxed reserves			
Accelerated depreciations		1,154,000	—
Untaxed reserves		**1,154,000**	—
Liabilities			
Non-current liabilities			
Deferred tax liabilities	23	35,582	59,371
Bond loans	29	—	795,158
Debt to Bioverativ	30	1,808,916	1,179,468
Liabilities to credit institutions	30	496,914	—
Other provisions	33	33,060	32,390
Total non-current liabilities		**2,374,472**	**2,066,387**
Current liabilities			
Accounts payable		257,038	165,093
Liabilities to Group companies		549,753	307,221
Tax liabilities		40	40
Debt to Bioverativ	31	496,697	459,818
Other liabilities	31	100,484	85,389
Accrued expenses and deferred income	34	458,926	283,062
Total current liabilities		**1,862,938**	**1,300,623**
TOTAL EQUITY AND LIABILITIES		**11,135,609**	**9,169,833**

Related to pledged assets and contingent liabilities, see Note 35.

Parent Company statement of changes in equity

	Restricted equity		Non-restricted equity		
SEK 000's	Share capital	Statutory reserve	Share premium reserve	Profit/loss brought forward and profit/loss for the year	Total equity
Opening equity, 1 Jan. 2015	**148,580**	**800,257**	**4,132,928**	**403,130**	**5,484,895**
Cash flow hedges	—	—	—	58,294	58,294
Issue/repurchase of shares	570	—	—	–570	—
Sales of own shares	—	—	—	22,230	22,230
Share-based remuneration to employees	—	—	23,344	—	23,344
Profit for the year	—	—	—	214,060	214,060
Closing equity, 31 Dec. 2015	**149,150**	**800,257**	**4,156,272**	**697,144**[1]	**5,802,823**
Opening equity, 1 Jan. 2016	**149,150**	**800,257**	**4,156,272**	**697,144**	**5,802,823**
Cash flow hedges	—	—	—	–176,295	–176,295
Issue/repurchase of shares	104	—	—	–104	—
Sales of own shares	—	—	—	23,500	23,500
Share-based remuneration to employees	—	—	35,477	—	35,477
Profit for the year	—	—	—	58,694	58,694
Closing equity, 31 Dec. 2016	**149,254**	**800,257**	**4,191,749**	**602,939**[1]	**5,744,199**

At year-end, Sobi's share capital was SEK 149,254,136, distributed between 272,010,948 shares with a par value of approximately SEK 0.55. Issued shares are distributed between 270,389,770 ordinary shares and 1,621,178 Class C shares. Ordinary shares carry one vote per share, and Class C shares 1/10 votes per share. All Class C shares are held as treasury shares. Class C shares are intended to be used for the hedging of commitments under the company's incentive programmes. The company held 1,610,086 ordinary shares in treasury at the balance-sheet date. The Equity item represents 1.2 per cent of the total number of shares in the company.

[1] Cash flow hedges	2016	2015
Opening balance, cash-flow hedges	54,190	–4,104
Change in value for the year, hedging instruments	–176,295	58,294
Closing balance, cash-flow hedges	–122,105	54,190

Parent Company cash flow statement

SEK 000's	Note	2016	2015
Operating activities			
Profit for the year		58,694	214,060
Adjustments for non-cash items		297,672	220,737
Cash flow from operating activities before changes in working capital		**356,366**	**434,797**
Cash flow from changes in working capital			
Decrease (+) / Increase (–) in inventories		–92,829	6,713
Decrease (+) / Increase (–) in operating receivables		–431,145	25,768
Increase (+) / Decrease (–) in operating liabilities		537,676	2,719
Cash flow from operating activities		**370,068**	**469,997**
Investing activities			
Acquisition of subsidiaries		—	–69
Acquisition of intangible assets[1,2]	19	–118,657	–118,644
Acquisition of tangible assets	20	–36,315	–16,390
Divestment of tangible assets		4,202	850
Cash flow from investing activities		**–150,770**	**–134,253**
Financing activities			
Raising of loans[3]	30	496,914	—
Payment of loans[3]	29	–828,000	—
Sale of shares		23,500	22,230
Cash flow from financing activities		**–307,586**	**22,230**
Change in cash and cash equivalents		**–88,288**	**357,974**
Cash and cash equivalents at 1 January		**750,398**	**392,424**
Cash and cash equivalents at 31 December		**662,110**	**750,398**

1. The largest investment of the year is Kineret Milestone of SEK 72 M, see Note 19.
2. The debt to Bioverative is not included in the cash flow since it doesn't affect the cash flow.
3. Payment of loans pertains to repayment of a loan of SEK 20 M from AB Svensk Exportkredit and the redemption of the bond loan of SEK 800 M, which was replaced by a three year revolving facilities agreement of SEK 1,000 M, of which SEK 500 M have been used.

Supplemental disclosures to cash flow statement – Parent Company

SEK 000's	Note	2016	2015
Interest paid			
Interest received		874	4,065
Interest paid		34,975	56,364
Tax paid		—	85
Adjustments for non-cash items			
Depreciation/amortisation and impairment of assets	7, 19, 20	269,323	121,573
Revaluation of long term debt		670	2,960
Deferred tax	23	–23,789	78,367
Cost of share programmes[1]		35,477	23,344
Untaxed reserves		1,154,000	—
Elocta and Alprolix[2]		–1,150,850	–10,208
Other items		12,841	4,701
		297,672	**220,737**

1. IFRS expense associated with the share programmes that is recognised in equity.
2. Refers to the net of the investment, the debt to Bioverativ, royalty revenues used to settle the debt to Bioverativ and the cash flow hedge for the debt to Bioverativ.

Note 1

General information

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

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

The company has been listed on the Stockholm Stock Exchange (now Nasdaq Stockholm) since 15 September 2006, and as a Large Cap company since 2 January 2014.

Note 2

Significant accounting policies and basis for preparation of 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.

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

New standards, amendments to, and interpretations of, existing standards not yet applied by the Group
IFRS 9 Financial Instruments will be effective for financial years commencing on or after 1 January 2018 and will replace IAS 39 Financial Instruments: Recognition and Measurement.

The greatest change relates to liabilities measured at fair value. The portion of change related to the fair value attributable to own credit risk is to be recognised in other comprehensive income rather than profit or loss, unless this causes inconsistencies in the accounts.

The second section relates to hedge accounting and requires additional disclosures on risk management and the impact of hedge accounting. Finally, new principles were introduced for impaired financial assets, based on the premise of providing for expected losses. Sobi still analyses the effects of the standard on the company's accounts in more depth.

The IFRS 15 Revenue from Contracts with Customers standard will become effective for financial years commencing on or after 1 January 2018. The standard will replace all standards and interpretations previously used for revenue. IFRS 15 provides a single model for revenue recognition to be applied to all contracts with customers.

The idea is that everything begins with a contract between two parties for the sale of a product or a service. Initially, a contract with a customer is to be identified, which generates performance obligations for an entity (rights, an entitlement to consideration) and a liability (an undertaking, a promise to transfer goods or services). The entity then recognises a revenue according to the model to show that it has satisfied the performance obligation of transferring the promised goods or services to the customer.

The Group will apply the new standard in its entirety. In 2016, a thorough review of IFRS 15 and its effects on the company's financial statements was performed, and shows that no material change will occur in relation to the company's revenue recognition.

The company is also evaluating IFRS 16 Leases, with an effective date of 1 January 2019. The standard addresses leases, and the current separation of operating and finance leases will be replaced by a model in which the assets and liabilities for all leases will be recognised in the balance sheet. A first analysis indicates that the company's assets and liabilities in the balance sheet are expected to increase when IFRS 16 becomes effective.

CONSOLIDATED ACCOUNTS
General information
The consolidated financial statements include the Parent Company and the subsidiaries.

Subsidiaries
Subsidiaries are all entities (including special purpose entities) in which Sobi has the power to govern the financial and operating strategies in a manner normally associated with a shareholding of more than one-half of the voting rights. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are deconsolidated from the date on which that control ceases.

The Group has applied the acquisition method for business combinations. The cost of acquisition is comprised of the total of the fair value of the assets transferred as compensation, equity instruments issued and liabilities incurred or assumed from the previous owner of the acquired company on the transfer date. Each contingent payment is measured at fair value on the acquisition date. Subsequent changes to the fair value of a contingent consideration classified as a provision are recognised in the statement of comprehensive income. All transaction costs attributable to an acquisition are expensed. Identifiable assets acquired, as well as liabilities and contingent liabilities assumed through a business combination are measured at fair value on the acquisition date.

The excess of the cost of acquisition over the fair value of the Group's share of the acquired assets, and liabilities and contingent liabilities is recognised as goodwill. In step acquisitions, goodwill is determined at the acquisition date when control is obtained, and not in connection with previous acquisitions. To determine goodwill in step acquisitions, the previous holding of equity interests in the acquired company are included, adjusted to fair value, and any gains or losses resulting from the revaluation are recognised in profit or loss. For each acquisition, the Group determines whether the non-controlling -interest in the acquiree is measured at fair value or at the proportionate share of the acquiree's net assets. Goodwill is not amortised according to plan, but tested annually for impairment. If the net fair value of the acquiree's identifiable assets, liabilities and contingent liabilities exceeds the cost, the surplus (negative goodwill) is recognised directly in profit or loss.

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

Segment reporting
Operating segments are presented from a management perspective, which means they are presented on the same basis used for internal reporting. The basis for identifying reportable segments is the internal reporting as reported to, and monitored by, the highest executive decision-maker. The Group has identified the highest executive decision maker as the CEO. In internal reporting to the CEO, only one segment is used. For more information, see Note 6.

Currency
Functional and reporting currency
Items included in the financial statements for each of the

Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in Swedish kronor (SEK), which is the company's functional and reporting currency.

Transactions and balance-sheet items
Foreign currency transactions are translated into the functional currency using the exchange rate that applies on the transaction date. Exchange rate differences resulting from the settlement of such transactions and from the translation of monetary assets and liabilities in foreign currency at the closing day rate, are recognised in the statement of comprehensive income. Operating items are recognised in operating profit, while other items are recognised as financial income or expense.

Translation of foreign subsidiaries
The assets and liabilities of foreign subsidiaries are established in the respective functional currency, meaning the primary economic environment in which the company operates. For Sobi's foreign subsidiaries, all assets, provisions and other liabilities are translated at the closing day rate into the Group's presentation currency (SEK) and any exchange-rate differences arising are recognised directly 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 entity are treated as assets and liabilities of the entity and translated at the closing day rate.

Revenues
Revenues comprise the fair value of goods and services sold, excluding value-added tax, rebates, returned goods and after eliminated intra-Group sales. Revenues are recognized as follows:

Operating revenues
Revenue from the sale of pharmaceuticals is recognised when risks and control have been transferred to the buyer, which 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 responsibility for the risk associated with the goods has been transferred to the customer.

Co-promotion revenue from partners is recognised as the service is performed and the revenue can be measured reliably and it is considered probable that the economic benefits will accrue to the Group.

Revenues also include 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 collaborative agreement, such as the regulatory approval of a jointly developed product.

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

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

When the Group has undertaken to carry out research and development assignments and receives payment for services provided by the Group, this is recognised as work is carried out. Revenue from research collaborations is recognised in the period in which the work is performed.

Government grants
Government grants are recognised when the company meets the conditions associated with the grants and when it can be established with certainty that the the grants will be received. Grants received are recognised in the balance sheet as deferred income and recognised in the period in which the cost associated with the grant is recognised.

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

Other operating revenue/expense
Other operating revenue is revenue from activities outside the normal operations. The item includes exchange-rate effects on operating receivables and liabilities. Other operating expenses are expenses from activities outside the normal operations. The item includes exchange rate differences on operating receivables. The accumulated gains or losses from cash flow hedges recorded in equity are returned to other operating revenue/expenses in the periods in which the hedged item affects profit/loss. For more information, see Notes 8 and 9.

Classifications
Within the Group, assets and liabilities are classified as either current or non-current. Current receivables and liabilities fall due within one year of the balance-sheet date. Non-current receivables and liabilities essentially consist of amounts expected to be settled later than one year from the balance-sheet date.

Intangible assets
Amortisation of intangible assets
Amortisation of product rights and acquired R&D is charged to sales and administrative expenses. Software and IT projects in progress are also charged to selling and administrative expenses. For more information, see note 7.

Goodwill
Goodwill consists of the amount by which the cost exceeds the fair value of the Group's share of the acquired subsidiary/associated company's net identifiable assets at the acquisition date. Goodwill on acquisition of a subsidiary is recognised as an intangible asset. In connection with the acquisition of associated companies, goodwill is included in the value of the holding in the associated company. Goodwill is tested annually for impairment and carried at cost less accumulated impairment write-downs. Gains or losses on the disposal of an entity include the residual carrying amount of goodwill pertaining to the disposed entity.

Product and marketing rights
Product and marketing rights are recognised at cost less accumulated depreciation. They have a limited useful life and are depreciated to spread the cost over this period (5 to 20 years). Straight-line depreciation is carried out over the useful life, after the expected earnings of each respective product and marketing right. Depreciations are classified as selling expenses. For more information see Note 4.

Research and development expenditure
Expenditure for development projects is recognised as intangible assets if the company can demonstrate that it is technically possible to complete and profitably commercialise the results, and only if the expenditure for 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 at the acquisition date. Amortisation is carried out to allocate the cost of development projects over their estimated useful lives, and is implemented once the development project starts to generate revenue. Other research and development expenditures that do not meet the accounting requirements according to IAS 38 are recognised as incurred.

>> Note 2, cont.

Software and IT projects in progress
Acquired software licenses are capitalised on the basis of the costs incurred when the software in question is acquired and put into operation. These costs are amortised over the estimated useful life of the software.

Costs associated with developing or maintaining software are expensed as incurred. Costs directly associated with identifiable software products developed specifically for Sobi that are controlled by the company and will probably generate economic benefits exceeding costs beyond one year, are recognised as intangible assets. Direct costs include the costs for employees working on software development and a reasonable proportion of overhead costs.

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

Amortisation according to plan for software recognised as fixed assets is performed using the straight-line method over its useful life up to a maximum of three years.

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

All tangible assets are stated at cost less depreciation. Cost includes expenditure that can be directly attributed to the acquisition of the asset. Additional expenditure increases the carrying amount of the asset or is recognised as a separate asset, depending on which is appropriate, only when it is probable that the future economic benefits associated with the asset will accrue to the Group and the initial cost of the asset can be measured reliably. All other forms of repair and maintenance are recognised as an expense in profit or loss in the period they occur.

Depreciation of tangible assets
Depreciation according to plan of tangible assets is based on their useful life. Depreciation is calculated on a straight-line basis over the asset's estimated useful life and with consideration for residual value. The following depreciation /amortisation 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, fixtures and 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 residual value and useful life of the assets are assessed at each closing date and adjusted as needed.

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

The gain or loss arising on the disposal or retirement of tangible assets is determined by comparing the difference between the selling price and the carrying amount less direct selling expenses. The profit/loss item is recognised as other operating revenue and other operating expense, respectively.

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

Impairment of tangible and intangible assets
Goodwill, with an indeterminable useful life, and intangible assets not yet taken into operation, are not depreciated but tested annually for impairment or when there are indications that an asset has decreased in value. Product rights that are depreciated are also tested annually for impairment since the carrying amount is significant for the Group. Other assets that are subject to amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An asset is impaired if its carrying amount exceeds the recoverable amount. Impairment thus comprises the difference between the carrying amount and the recoverable amount where the recoverable amount is defined as the greater of the asset's net realisable value and its value in use. When calculating the recoverable amount, future cash flows that the asset is expected to generated are discounted at a rate equivalent to Sobi's weighted average cost of capital (WACC).

When assessing the impairment of goodwill, this is grouped at the lowest levels for which there are separately identifiable cash flows. Sobi has made the assessment that the Group's operations as a whole comprise a cash-generating unit. Any impairment of goodwill is not reversed. Impairment of assets other than goodwill is reversed if there has been any change in the conditions used to determine the recoverable amount. Reversal amounts do not exceed the carrying amount that would have been recognised, less depreciation, if no impairment had been performed. Impairment testing of goodwill, product rights and development projects is described in Note 19.

Financial instruments
A financial instrument is a contract that gives rise to a financial asset in a company and a financial liability or an equity instrument in another company. Financial instruments also include, for example, contract-based rights to receive cash, such as accounts receivable. See also Note 3.

The Group classifies its financial instruments in the following categories:
1. *Loans and accounts receivable*
2. *Financial instruments measured 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 depends on the purpose for which the instruments were acquired. Management determines how the instruments will be classified in connection with initial recognition and reviews this decision on each reporting date.

Financial instruments are measured on the trading date at 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 in the balance sheet include such assets as cash and cash equivalents and accounts receivable. Financial liabilities include accounts payable, equity instruments and borrowings.

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

Loan receivables and accounts receivable are measured at amortised cost less any impairment. The maturities of accounts receivable are short and are therefore initially recognised at nominal amounts without discounting. Any impairment of bad debts, which are assessed on an individual basis, is recognised in operating expenses.

2. Financial instruments measured 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 fixed 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 recognised in net financial items.

Derivatives are either 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 a manner corresponding to the assets.

3. Other financial liabilities
This category contains loans and accounts payable. Liabilities in this category are measured at amortised cost using the effective interest method.

Borrowings are initially measured at fair value, net after transactions costs. Borrowings are subsequently measured at amortised cost and any difference between the amount received and the repayment amount is recognised in profit or loss over the term of the loan, using the effective interest method.

Borrowings are classified as current liabilities unless there is an unconditional right to defer settlement of the liability until at least twelve months after the balance-sheet 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 not classified in any other category. They are included in fixed assets unless management intends to dispose of the asset within twelve months of the balance-sheet 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 of equity are transferred to the income statement as gains and losses from financial instruments. This category includes financial instruments identified as hedges. These are either recognised as assets or liabilities depending on whether the fair value is positive or negative. Hedge accounting of financial instruments is specified in the paragraph below.

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

The entire fair value of a derivative that is a hedging instrument is classified as a fixed asset or non-current liability when the hedged item's remaining maturity is longer than twelve months, and as a current asset or current liability if the hedged item's remaining maturity is 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 fair value of a derivative instrument identified as a cash flow hedge is recognised in other comprehensive income. The gain or loss pertaining to the ineffective portion is recognised immediately in profit or loss. Accumulated gains or losses in equity are returned to profit or loss in the periods in which the hedged item affects profit/loss. If a hedging instrument expires or is sold, or when a hedge no longer meets the criteria for hedge accounting and accumulated gains or losses from the hedge are recognised in equity, the gains or losses on the hedge remain as a separate component of equity and are recognised when the the hedged item is ultimately recognised in profit or loss. If a loan is designated a hedging instrument for foreign-exchange risk, the effective portion of the revaluation effect pertaining to exchange rate fluctuations is recognised in the same way as for derivatives, while other parts of the loan are recognised as a loan not included in a hedge.

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 expected selling price in operating activities less selling expenses. Obsolescence risk and established obsolescence are taken into account.

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

Equity
Ordinary shares are classified as equity. Transaction costs directly attributable to the issue of new shares or options are recognised in equity, net after tax, as a deduction from the proceeds.

>> Note 2, cont.

Provisions
Provisions are recognised in the balance sheet when Sobi has a legal or constructive obligation as a result of an event that has occurred and where it is probable that an outflow of resources will be required to settle the obligation. It must also be possible to make a reliable estimate of the amount. Provisions are recognised in the amount corresponding to the best estimate of the payment required to settle the obligation. If the outflow of resources is expected to take place at a point far in the future, the expected future cash flow is discounted and the provision is recognised at its present value. The discount rate corresponds with the market rate before tax, and the risks associated with the liability. Provisions are recognised in the balance sheet under other current and non-current liabilities.

Provisions for restructuring which substantially change the way in which the Sobi Group works are recognised when a detailed and formal restructuring plan has been established and publicly announced, at which point clear expectations are created that the plan will be implemented. Provisions for restructuring often include benefits at termination, which can be either voluntary or involuntary. Termination benefits are recognised as described above, except in those cases in which a requirement for service is linked to the benefit, in which case cost is distributed over the period during which the services are carried out. Restructuring provisions entail estimates of the time and cost of planned future activities. The most significant estimates relate to 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 cost of withdrawal. Such estimates are based on the relevant situation in negotiations with the affected parties and/or their representatives. Salaries relating to periods following the termination of duty to work are expensed when the decision is made and communicated.

Taxes
Taxes in the statement of comprehensive income consist of current tax and deferred tax. Current tax is tax to be paid or received regarding 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 regulations enacted or substantively enacted at the balance-sheet date.

Deferred tax is not recognised for consolidated goodwill, nor for differences attributable to participations in subsidiaries where the Parent Company can control the timing of the reversal of the temporary differences and it is probable that such a transfer will not take place in the foreseeable future. In the consolidated accounts, however, untaxed reserves are divided between deferred tax liabilities and equity. Deferred tax assets for deductible temporary differences and loss carryforwards are only recognised to the extent it is probable they will be utilised. The value of deferred tax assets is reduced when it is no longer deemed likely they can be utilised. Tax is recognised under the Income tax item in the statement of comprehensive income except for those items recognised under other comprehensive income or shareholders' equity. See also Notes 18 and 23.

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 and when the employees perform their duties. Pension commitments are calculated without discounting, as payments for these plans fall due within twelve months.

In the case of 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 and is responsible for ensuring that the established benefits are paid out.

The net amount of the estimated present value of the commitments and fair value of the plan assets in defined-benefit pension commitments are recognised in the balance sheet as either a provision or a non-current financial receivable.

Regarding defined-benefit plans, pension costs and pension commitments are calculated according to the applicable principles of IAS 19. This calculation is performed annually by independent actuaries.

The company's commitments have been valued at the present value of expected future payments. When discounting commitments in Sweden, a discount rate equal to the interest on mortgage bonds with a maturity corresponding to the commitments is applied. The most important actuarial assumptions are described in Note 32.

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

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

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

Commitments for retirement pensions and family pensions for white-collar employees in Sweden are insured through Alecta. According to a statement issued by the Swedish Financial Reporting Board, UFR3, this is a defined benefit plan covering multiple employers. For the 2005-2016 financial years, the company did not have access to the information required to recognise this plan as a defined-benefit plan. The ITP pension plan insured through Alecta is therefore recognised as a defined contribution plan.

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

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 the conditions that are market-related. 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 profit or loss, distributed over the vesting period, and corresponding adjustments are made in equity. At the end of every quarter, the Group reviews its assessments of how many shares are expected to be vested based on the service requirement. The shares are delivered to the employee when vested under the framework of the programmes.

The Group also has three long-term cash-based incentive programmes covering all employees in the US, which do not constitute share-based remuneration. Since remuneration under these programmes is contingent on continued employment at the company, the costs are recognised continuously over the vesting period. A liability is calculated at each balance-sheet date taking into account the time value, new assessments of target fulfilment and the amount earned. The net of these effects is recognised as a personnel cost in consolidated profit or loss.

Costs for social security contributions are treated as cash-settled share-based remuneration that is remeasured at each balance-sheet date until settlement occurs and 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 12.

Remuneration in connection with terminated employment
A provision is recognised in connection with termination only if the company is demonstrably obliged to terminate a position before the normal period of service has ended or when remuneration is offered in order to encourage voluntary resignation, e.g. retirement packages. In cases where the company terminates employment, a detailed plan is prepared that, as a minimum, contains information on the workplace, positions and approximate number of individuals involved, as well as the remuneration due to each employee category or position and the schedule for the plan's implementation.

Contingent liabilities
Contingent liabilities are recognised when there is a possible commitment arising from past events and whose existence is confirmed by only one or more uncertain future events, or when there is a commitment that is not recognised as a liability or a provision because it is unlikely that an outflow of resources will be required.

Parent Company's Accounting Principles
The annual report for Swedish Orphan Biovitrum AB (publ), the Parent Company, has been prepared according to the Swedish Annual Accounts Act, the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities and statements from the Financial Reporting Board. The Parent Company applies the same accounting policies as the Group with the following exceptions:

Employee benefits/defined-benefit plans
In the calculation of defined-benefit pension plans, the Parent Company complies with the Swedish Pension Obligations Vesting Act and the Swedish Financial Supervisory Authority's instructions, which is a prerequisite for tax deductibility. The most significant differences compared with the requirements under IAS 19 are how the discount rate is established, that the calculation of the defined-benefit commitment is based on current salary levels without assumptions on future salary increases, and that all actuarial gains and losses are recognised in the income statement as they occur. Refer to Note 32 for more information.

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

Taxes
For legal entities, untaxed reserves including deferred tax liabilities are recognised.

Subsidiaries
Participations in subsidiaries are recognised under the cost method of accounting. Testing of the value of subsidiaries occurs 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 recognised as part of the cost. Contingent considerations are recognised as part of the cost if it is probable that they will produce results. If, in subsequent periods, it turns out that the initial assessment needs to be revised, the cost should be adjusted.

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

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

All amounts are stated in thousands of Swedish kronor (SEK 000s) unless otherwise stated. Assets and liabilities are measured at historical cost, except for certain financial assets and liabilities, which are measured at fair value.

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

Assessments made by management in conjunction with the implementation of IFRS that have a significant influence on the financial statements and estimations made have not involved any significant adjustments in the financial statements of the subsequent year. The accounting policies stated above are used consistently in the preparation of the financial statements that are published and are based on IFRS.

Previous periods have been restated with respect to a restoration reserve for rented premises regarding previous years, that were identified during 2016.

The stated amounts and figures in parenthesis indicate comparative figures for 2015. See also Note 4.

Note 3
Financial risk management

Financial risks and risk management
Through its operations, Sobi is exposed to various kinds of risks that may impact the company's results and financial position. The risks can be divided into operational risks and financial risks. Financial risks refer to a potentially negative impact on the financial position resulting from changes in the financial risk factors. Below is a description of the financial risk factors that are deemed the most significant for Sobi, and the management of them. Operational risk is also described in a separate section of the Directors' Report.

Financial risk is managed at the central level by Sobi's treasury department, which is also responsible for providing solutions for liquidity management and supporting the business in finance-related issues.

The finance 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 tasked with, among other things, working on the structure and content of the finance policy and, if necessary, suggesting changes to the Board. The main objective of the finance policy is to maintain a low level of financial risk and to manage risk in a reliable 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. Since 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, primarily the EUR and USD.

This risk is managed by matching all transactions in their respective currencies, and by limiting any nominal net exposure of a sufficiently large amount, compared with a fixed measure, by entering into financial instruments, such as currency futures. During the year, no financial instruments were concluded for managing this risk.

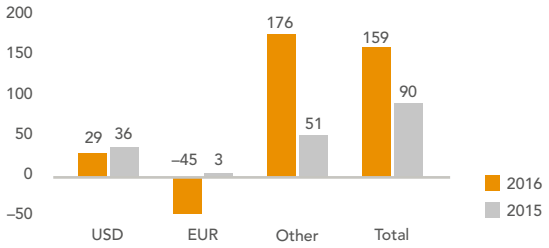
>> Note 3, cont.

However, some transaction risk for the products Elocta and Alprolix is managed by using hedge accounting through cash flow hedges from highly probable inflows regarding these products. This means that the result from the revaluations of the liabilities for Elocta and Alprolix to Bioverativ is recognized in other comprehensive income and accumulated gain or loss from these revaluations is reclassified into profit or loss when the mentioned inflows affects profit or loss. See note 19 and note 30 for further information regarding these liabilities.

The currencies with the largest net exposures (including currency derivatives) are shown in the graph below. The amounts shown in the graph correspond to the net amounts restated in operating profit. At 31 December 2016, the exposure was linear and amounted to SEK 159 M (90). An instantaneous and permanent change in all rates against the SEK of +/– 10 per cent would have an impact of +/– SEK 16 M (9) on operating profit before tax.

Commercial transaction exposure

SEK M



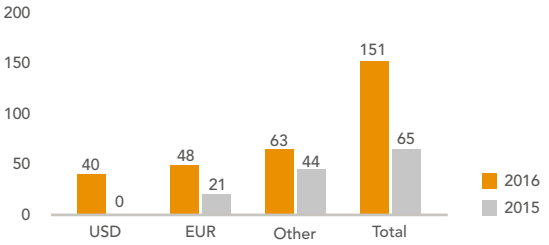
Currency risk – Financial transaction risk

Financial transaction risk refers to the risk of changes in exchange rates having a negative impact on net financial items. The loans and investments of subsidiaries are managed by the company's treasury department and are generally transacted in the local currencies of the subsidiaries. Financial transaction risk is thus centralised in the Parent Company.

This risk is managed by matching all transactions in their respective currencies, including assets, liabilities and other items restated in net financial items, and by limiting any nominal net exposure of a sufficiently large amount, compared with a fixed measure, by entering into financial instruments, such as currency futures. The currencies with the largest net exposures are shown in the graph below. The amounts shown in the graph correspond to the net amounts (including derivatives) restated in net financial items. At 31 December 2016, the exposure was linear and amounted to SEK 151 M (65). An instantaneous and permanent change in all rates against the SEK of +/– 10 per cent would have an impact of +/– SEK 15 M (7) on financial profit before tax. The derivatives outstanding on the balance-sheet date are shown in the table below.

Financial transaction exposure

SEK M



Outstanding derivatives (nominal amounts in millions, local currency)

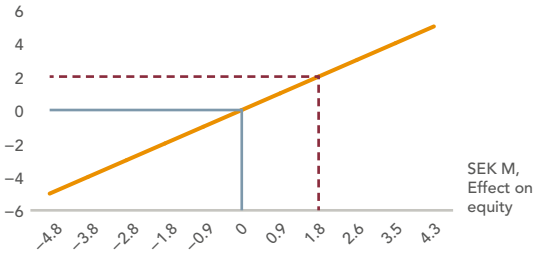
	2016	2015
EUR	–23	–20
USD	–21	–22
GBP	–1	–1
CZK	–24	—

Currency risk – Translation risk

Translation risk is the risk that fluctuations in exchange rates will have a negative impact on shareholders' equity when balance sheets and income statements of the 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 the SEK weakened, and vice versa. If, for example, the SEK weakened 2 per cent against other currencies, the translation effect on consolidated equity would be SEK 1.8 M (1.1).

Translation risk

Currency change in SEK, %



Interest-rate risk

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

Sobi's 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 a three-year credit facility agreement of SEK 500 M and a revolving credit facility of SEK 500 M with Svenska Handelsbanken AB (publ) and Danske Bank A/S (Sweden), where only a credit facility of SEK 500 M with a variable interest rate has been utilised. On 27 June 2016, this facility plus own funds were used to prematurely redeem the bond loan of SEK 800 M. During the year, the loan of SEK 20 M to AB Svensk Exportkredit (SEK) was also repaid. There were no interest-rate derivatives outstanding on the balance-sheet date. The liability to Bioverativ is non-interest bearing by agreement, but is discounted in the financial statements and therefore recognised as an interest expense.

The sensitivity to interest-rate changes on profits is measured by assuming a sustained interest-rate change of 1 percentage point. At 31 December 2016, such a change would have had an annual impact of SEK 3 M (6) on net financial items. At 31 December 2016, Sobi's interest-bearing liabilities amounted to SEK 504 M (822).

Credit risk

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

Sobi's credit risk is primarily related to accounts receivable. At the balance-sheet date, these amounted to SEK 769 M (451), of which SEK 272 M (127) was due for payment, see Note 25 for information regarding overdue accounts receivable. Sobi's customers are primarily hospitals and government agencies, which means that the governments in the respective countries provide a substantial portion of the financing. If Sobi deems that a receivable will not be paid, provisions must be made, and at 31 December 2016, these provisions amounted to SEK 49 M (25). Normally there is no collateral for the credit risk in accounts receivable.

Credit reports are taken up both in distribution agreements and in individual transactions when the customer is not previously known or when other circumstances cause uncertainty regarding credit worthiness. Credit reports should be obtained from a market-recognised rating agency.

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

Liquidity risk

Liquidity risk is the risk that Sobi cannot raise financing on acceptable terms, or meet its payment obligations due to factors beyond Sobi's control. How the liquidity risk should be managed is described in the finance policy. Both short and long-term forecasts of the Group's liquidity are compiled on an ongoing basis to ensure the availability of sufficient cash funds to meet the needs of operating activities. Investment of any surplus liquidity should be made in instruments with low credit risk and a high level of liquidity. Investments should 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. A high level of liquidity means that the investments can be converted into liquid funds at any given time. According to the policy, there must also be a liquidity reserve the size of which should be based on a proportion of annual sales. The liquidity reserve comprises bank balances, current investments and the unutilised portion of granted credit facilities. At 31 December 2016, the company had unutilised granted credit facilities totalling SEK 635 M (315).

The long-term financing consists of a three-year credit facility agreement of SEK 500 M and a revolving credit facility of SEK 500 M with Svenska Handelsbanken AB (publ) and Danske Bank A/S (Sweden). The credit agreement contains customary terms regarding limitations in the Group's 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 limitations with regard to a change of control.

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

Maturity analysis

At 31 December 2016	Less than 1 year	Between 1–2 years	Between 2–5 years	More than 5 years
Bond	—	—	—	—
Derivatives	—	—	—	—
Borrowings	7,351	7,531	502,920	—
Accounts payable	280,173	—	—	—
Other liabilities[2]	1,800	3,502	2,426,195	0
Total	**289,323**	**10,853**	**2,929,115**	0

At 31 December 2015	Less than 1 year	Between 1–2 years	Between 2–5 years	More than 5 years
Bond[1]	37,181	818,030	—	—
Derivatives	—	—	—	—
Borrowings	20,039	—	—	—
Accounts payable	183,193	—	—	—
Other liabilities[2]	1,766	2,602	1,724,247	0
Total	**242,179**	**820,632**	**1 ,724,247**	0

1. The interest rate 2015 has been calculated using an interest rate of 4.6 per cent, the interest rate is undiscounted.
2. Other liabilities mainly pertain to the liability to Bioverativ. Repayment of the liability to Bioverativ in USD will mainly take place via royalty revenue in USD, see Note 19.

Capital risk

The goal of Sobi's capital structure is to generate high returns for shareholders, benefits for other stakeholders, and to maintain an optimal capital structure in order to keep capital costs at a reasonable level. The capital structure can be adapted to the needs arising by changing the dividend to shareholders, repaying capital to shareholders, issuing new shares or selling assets to reduce debt.

The Group's equity/assets ratio forms the basis of the Group's capital structure assessment. The company's target is an equity/assets ratio of at least 40 per cent. At 31 December 2016, the equity/assets ratio was as follows:

	2016	2015
Equity	5,354,278	4,660,207
Total assets	9,974,139	8,314,888
Equity/assets ratio, %	53,7	56.0

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:** Data for the asset or liability that is not based on observable market data.

At 31 December 2016	Level 1	Level 2	Level 3	Total
Financial assets measured at fair value through profit or loss				
Derivatives held for trade	—	3,901	—	3,901
Total assets	**—**	**3,901**	**—**	**3,901**

At 31 December 2015	Level 1	Level 2	Level 3	Total
Financial liabilities measured at fair value through profit or loss				
Derivatives held for trade	—	9,255	—	9,255
Total liabilities	**—**	**9,255**	**—**	**9,255**

All derivatives are measured at fair value based on market data in accordance with IFRS. At 31 December 2016, the carrying amount of derivatives in the balance sheet was SEK 4 M (9), see also Note 28.

Note 4

Important estimates and assumptions, and judgements for accounting purposes

The Group makes estimates and assumptions about the future, and judgements for accounting purposes. Key judgments for accounting purposes, estimates and assumptions that have a significant risk of material adjustments in the carrying amounts of assets and liabilities within the next fiscal year are described below.

Judgements for accounting purposes

Revenues

The Group assesses the likelihood of future economic benefits accruing to the Group on the basis of a number of factors, including a customer's payment history and credit rating. If a receivable is deemed doubtful by the Group, a provision is made for the receivable until it is possible to determine whether the Group will receive payment or not. According to the Group's routine 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 commitments.

Revenues are recognised when control is transferred to the buyer. Revenues are calculated as invoiced gross revenue with deduction for actual and estimated rebates to public and private customers, adjustments for deliveries where the control has not yet been transferred to the buyer, royalty costs to partners as well as payments to wholesalers and distributors. As actual and final conditions relating to rebates on sales in the current period may not be known at closing date, some of the deductions from gross income are based on estimates.

See also Note 2 on revenue recognition of license fees and milestones.

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, maintenance, etc.

Calculation of the indirect production costs is based on a method for calculating standard costs. This method is revised on a regular basis to ensure a reasonable calculation of the degree of usage, lead times and other relevant factors. Changes in the method of calculating the indirect production costs, including the degree of usage, lead times, etc., may have an impact on gross margins and the overall valuation of inventories.

Research and development costs

The company conducts research and development in internal projects as well as 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 deductions reconciled with the external partner. The calculation is assessed and updated regularly. In some collaborative agreements, the company agrees to pay milestone payments. This payment is capitalised as research and development, and amortisation does not commence until the project has reached the commercialisation phase and meets requirements under IAS 38. Evaluation of the project's progress and impairment testing is performed regularly, at least once a year.

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 Intangible assets. Standards 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 possible and profitable to commercialise the results. For a sensitivity analysis, see Note 19.

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 important assumptions such as sales growth, margins and discount rates, see below as well as note 19.

Goodwill

The Group conducts regular impairment testing of goodwill, in accordance with the policy described in Note 2.

The recoverable amount of the cash-generating unit is determined by a calculation of value in use. When calculating the value of use, certain estimates must be made, see Note 19. At 31 December 2016, Sobi's goodwill amounted to SEK 1,554 M (1,554). Impairment testing did not result in any impairment.

Acquired development projects

The Group assesses periodically for impairment of acquired development projects in accordance with the policy described in Note 2. The evaluation of impairment requires that certain estimates must be made. These assumptions are specified in Note 19.

Product and marketing rights

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

Since 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 this depreciation is attributable to selling expenses, since the intangible assets classified as product rights primarily relate 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. These rights enable Sobi to market and sell certain products. Usefulness of rights is not consumed in a manufacturing process but rather over a period of use that relates to how long the related product is relevant to the market.

The assumption that has the greatest impact on the future value is the projected sales growth. It is based on assumptions about the underlying growth, as well as future product development and expanded indications for the drug. In the event that the company's assumptions regarding product development and the expansion of the applicable areas for a pharmaceutical prove to be incorrect, this may imply that the impairment of this product right is required. Other assumptions included in impairment testing of product rights are presented in Note 19.

Taxes

Deferred tax is calculated using the liability method based on temporary differences between the carrying amounts and tax bases of assets and liabilities. The amounts are calculated using the tax rates and regulations enacted or substantively enacted at the balance-sheet date. Tax loss carry-forwards never mature, under current Swedish tax legislation.

Assumptions for the calculation of pension benefits

The actuarial calculation of pension commitments and pension costs is based on the actuarial assumptions specified in Notes 2 and 32.

Inventories

Obsolescence

Stock consists of raw materials for production, manufactured semi-finished and finished products of Alprolix, Ammonaps, Elocta, Kepivance, Kineret, Orfadin and Xiapex, and stocks of finished goods for other products. For this stock, there is no provision for obsolescence. 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. The 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. Also, 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	2016	2015
Operating revenue by major revenue type		
Product sales	2,990,343	2,432,424
Manufacturing and contract development	568,684	503,841
Royalty revenue	1,598,887	250,589
Out-licensing and milestone revenue	13,783	69
Service fee	32,643	40,944
Total	**5,204,340**	**3,227,867**

GROUP	2016	2015
Revenues by geographic market[1]		
Europe[2]	2,221,801	1,800,016
MENAR[3]	301,513	231,396
North America	1,002,050	861,058
RoW[4]	66,306	84,739
Total	**3,591,670**	**2,977,209**
Royalty revenue[5]	1,598,887	250,589
Out-licensing and milestone revenue	13,783	69
Total	**5,204,340**	**3,227,867**

In 2016, revenues for the Parent Company, Swedish Orphan Biovitrum AB (publ), amounted to SEK 4,594 M (2,750) of which sales to Group companies accounted for SEK 1,472 M (1,136).

PARENT COMPANY	2016	2015
Operating revenue by major revenue type		
Product sales	2,379,943	1,954,584
Manufacturing and contract development	568,684	503,841
Royalty revenue[5]	1,598,887	250,589
Out-licensing and milestone revenue	13,783	69
Service fee	32,643	40,944
Total	**4,593,940**	**2,750,027**
Revenues by geographic market[1]		
Europe[2]	1,882,846	1,705,070
MENAR[3]	200,862	86,160
North America	830,642	623,400
RoW[4]	66,920	84,739
Total	**2,981,270**	**2,499,369**
Royalty revenue[5]	1,598,887	250,589
Out-licensing and milestone revenue	13,783	69
Total	**4,593,940**	**2,750,027**

1. The geographic distribution is based on where end-customers are located.
2. Sales in Sweden amounted to SEK 128 M (113).
3. Middle East, North Africa and Russia.
4. Rest of the world
5. Royalty revenues pertains to Bioverativ's sales of Eloctate and Alprolix in their regions of SEK 803 M, one time credits from Bioverativ relating to the approval of Elocta and Alprolix of SEK 708 M and royalty revenues of SEK 88 M from Pfizer relating to their sales of ReFacto.

Revenues by product category

GROUP	2016	2015
Inflammation: Kineret	1,001,302	805,361
Inflammation: Other	104,538	99,402
Genetics & Metabolism: Orfadin	769,992	795,714
Haemophilia	1,852,699	96,252
Key Therapeutic Areas	**3,728,531**	**1,796,728**
Partner Products	**819,530**	**771,207**
Manufacturing revenue	568,684	503,841
Royalty revenue	87,595	156,092
ReFacto	**656,279**	**659,932**
Total	**5,204,340**	**3,227,867**

Note 6

Segment reporting

The Group reports one operating segment, sales of pharmaceuticals. The basis for identifying reportable segments is the internal reporting as reported to, and monitored by, the highest executive decision-maker. The Group has identified the highest executive decision-maker as the CEO. Sobi reports revenues by geographic areas. See Note 5 for more information regarding the distribution of major revenue types and geographic areas.

Sobi's largest customers 2016 are Bioverativ, which account for sales of SEK 1,176 M, and Pfizer, which account for sales of SEK 707 M, representing 23 and 14 per cent of the company's total revenues. In 2016 and 2015, Sobi did not have any other customer for whom revenues exceeded 10 per cent of the company's total revenues. Most of the company's fixed assets are in Sweden.

Note 7

Depreciation/amortisation and impairment of intangible and tangible assets

GROUP	2016	2015
Depreciation/amortisation according to plan by type of asset		
Capitalised software expense	–14,458	–8,399
Patents and licenses	–39,200	–54,925
Product and marketing rights	–356,479	–223,816
Land and buildings	–56	–334
Plant and machinery	–10,241	–8,970
Equipment, tools, fixtures and fittings	–17,571	–20,390
Other assets	–2,705	–2,673
Total	**–440,710**	**–319,507**
Depreciation/amortisation according to plan by function		
Cost of goods and services sold	–13,995	–17,651
Selling and administrative expenses	–422,848	–299,236
Development expenditure	–3,867	–2,620
Total	**–440,710**	**–319,507**

PARENT COMPANY	2016	2015
Depreciation/amortisation according to plan by type of asset		
Capitalised software expense	–14,458	–8,115
Patents and licenses	–5,193	–3,254
Product and marketing rights	–224,747	–82,503
Land and buildings	–56	–334
Plant and machinery	–10,241	–8,970
Equipment, tools, fixtures and fittings	–14,108	–17,877
Other assets	–520	-520
Total	**–269,323**	**–121,573**
Depreciation/amortisation according to plan by function		
Cost of goods and services sold	–13,938	–17,594
Selling and administrative expenses	–251,733	–101,533
Development expenditure	–3,652	–2,446
Total	**–269,323**	**–121,573**

Note 8

Other operating revenues

GROUP	2016	2015
Sale of real estate	4,166	—
Exchange rate gains on operating receivables/liabilities	112,328	14,547
Other	1,697	236
Total	**118,191**	**14,783**

PARENT COMPANY	2016	2015
Sale of real estate	4,166	—
Exchange rate gains on operating receivables/liabilities	105,887	8,119
Invoiced expenses to Group companies	—	19,504
Other	1,500	—
Total	**111,553**	**27,623**

Note 9

Other operating expenses

GROUP	2016	2015
Exchange rate losses on operating receivables/liabilities	–81,521	–17,873
Other	–255	–56
Total	**–81,746**	**–17,929**

PARENT COMPANY	2016	2015
Exchange rate losses on operating receivables/liabilities	–81,631	–14,757
Other	—	—
Total	**–81,631**	**–14,757**

Note 10

Leasing fees for operational leasing

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

	Group		Parent Company	
	2016	2015	2016	2015
Within 1 year	68,476	64,947	58,119	57,052
Between 1–5 years	263,663	204,723	222,225	183,899
Later than 5 years	103,450	88,120	103,450	88,120
Total	**435,589**	**357,790**	**383,794**	**329,071**
Leasing costs for the year	62,942	65,836	52,980	58,621

Future minimum lease payments under non-cancellable contracts, due for payment as follows:

	Group		Parent Company	
	2016	2015	2016	2015
Within 1 year	8,215	6,727	324	331
Between 1–5 years	8,742	13,013	—	324
Total	**16,957**	**19,740**	**324**	**655**
Leasing costs for the year	10,552	7,490	279	349

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. As regards properties, assessments of the lease agreement must be made both for the building and the land. Sobi mainly bases its position on the fact that the present value of the minimum lease payments does not amount to a significant portion of the fair value of the property and that there is no compelling evidence of a financial lease.

Note 11

Profit/loss from participations in Group companies

No dividends or write-downs pertaining to subsidiaries have been taken during 2016 or 2015.

Note 12

Personnel, personnel costs and remuneration to Board members and senior executives

Number of employees[1]

GROUP	2016	% of whom women	% of whom men	2015	% of whom women	% of whom men
Sweden	433	63	37	406	62	38
Denmark	16	64	36	14	77	23
Finland/Baltics	13	54	46	12	54	46
Norway	7	71	29	7	71	29
United Kingdom	47	44	56	34	43	57
France	36	71	29	27	66	34
Germany	33	58	42	32	55	45
Italy	30	50	50	21	54	46
Spain	25	48	52	18	57	43
Belgium	15	45	55	15	45	55
Russia	6	67	33	6	71	29
Switzerland	5	26	74	2	36	64
Austria	6	87	13	4	74	26
Central and Eastern Europe	18	51	49	16	53	47
USA	47	48	52	43	38	62
Canada	4	44	56	3	68	32
United Arab Emirates	19	17	83	11	20	80
Total	**760**	**58**	**42**	**672**	**58**	**42**

1. At 31 December 2016, the number of full-time employees was 760, while the amount of hired employees at the same date was 797.

GENDER DISTRIBUTION OF EMPLOYEES

♀ 58% ♂ 42%

Gender composition of the Board and management

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

GROUP	2016	2015
Board of Directors		
Men	5	5
Women	3	3
Total	**8**	**8**
CEO and other senior executives		
Men	9	7
Women	3	3
Total	**12**	**10**

Salaries, other remuneration and social security costs

	2016		2015	
GROUP AND PARENT COMPANY	Salaries and remunera-tions	Social security costs	Salaries and remunera-tions	Social security costs
Parent Company	366,986	198,808	343,914	199,572
(of which pension cost)		*(65,047)*		*(65,510)*
Subsidiaries	426,043	79,102	333,595	55,312
(of which pension cost)		*(25,100)*		*(11,277)*
Group, total	793,029	277,910	677,509	254,884
(of which pension cost)		*(90,147)*		*(76,787)*

>> Note 12, cont.

Salaries and other remuneration by Board members and CEO, and other employees

	2016		2015	
	Board and CEO	Other employees	Board and CEO	Other employees
Parent Company				
Salaries and other remuneration	6,565[1]	360,421	6,368[1]	337,546
(of which bonus)	*(—)*	*(44,711)*	*(—)*	*(43,390)*
Subsidiaries				
Salaries and other remuneration	10,090[1]	415,953	8,827[1]	324,768
(of which bonus)	*(3,862)*	*(70,340)*	*(2,701)*	*(63,627)*
Group, total	**16,655**	**776,374**	**15,195**	**662,314**
(of which bonus)	*(3,862)*	*(115,051)*	*(2,701)*	*(107,017)*

1. The CEO's salary has mostly been paid by the US subsidiary, where the CEO also has his domicile.

Guidelines and remuneration 2016

The 2016 Annual General Meeting (AGM) adopted the following guidelines for the remuneration of senior executives.

Guidelines for remuneration of senior executives
The Board of Directors recommended and the AGM decided to approve the Board's proposal regarding guidelines for remuneration of the company's senior executives as follows, for the period until the 2017 AGM. Senior executives, in this context, refers to Sobi's CEO and the managers currently reporting to the CEO, who are also included in company management, and any Board members who have signed employment or consulting contracts.

Motives
Sobi aims to ensure that the company can attract and retain the best employees to support the company's vision and strategy. The basis for remuneration of senior executives is to be the total remuneration. Total remuneration is to be competitive, but not leading in relation to competitors in each local market. Market comparisons should be made in relation to a peer group of companies of similar size, operating in a similar sector and with similar complexity. The guidelines shall enable international employments and support diversity among the senior executives. Remuneration may include the following components:

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

	Basic salary/fees	Variable remuneration	Pension cost	Other benefits	Financial instruments, etc.	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
Chief Executive Officer						
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 people in addition to the CEO at 31 December 2016. The table shows the company´s costs (excluding social securities). For more information about the Board fees, see the Corporate Governance Report.
2. Håkan Björklund was elected new Chairman of the Board at the Annual General Meeting 2016, while former Chairman Bo Jesper Hansen resigned.
3. The fee includes the Board fee excluding social security contributions. In 2016 the gross payment to the Chairman's company was SEK 1,113 K, which includes compensation for social security contributions.
4. Bo Jesper Hansen's employment and his monthly salary during his Chairman period was not linked to his position as Chairman of the Board.
5. The Annual General Meeting 2016 elected Jeffrey Jonas and Theresa Heggie as new Board members to replace outgoing Adine Grate Axén and Hans Wigzell.
6. The fee includes the Board fee excluding social security contributions. In 2016 the gross payment to the Board member's company was SEK 234 K, which includes compensation for social security contributions.
7. The fee includes the Board fee and additional remuneration of SEK 200 K for extraordinary work performed during 2015, as decided at the Annual General Meeting 2016 excluding social security contributions. In 2016 the gross payment to the Board member's company was SEK 658 K, which includes compensation for social security contributions.
8. Refer also to allotment and fulfilment of long-term incentive programmes for the 2013 share programme.

- Basic salary
- Variable remuneration – or "short-term incentives"
- Long-term incentives
- Pensions
- Other benefits

If a Board member performs assignments on behalf of the company or another Group company alongside of Board duties, consulting fees and/or other remuneration may be payable for such work.

Basic salary
The basic salaries of senior executives are determined on the basis of their expertise, responsibilities and performance. The company uses an international system to evaluate the scope and responsibilities of each position.

Variable remuneration
The annual short-term incentive programme is based on the achievement of annual performance targets (company-specific, department-specific and individual). There is no payment unless these targets are met. The annual performance targets are determined in advance by the Compensation & Benefits Committee and adopted by the Board.

Long-term incentive programmes
Sobi may introduce long-term incentive programmes to all, or some, of its employees. The aim of such programmes would

be to harmonise the interests of employees and shareholders, to create long-term commitment to the company, to provide a tool for attracting and retaining managers and top talent, to give participants an opportunity to share Sobi's long-term success and value creation and to help provide competitive total remuneration.

Pensions
The preferred form of pension plans at Sobi is defined-contribution plans. Defined-benefit pension plans may be established if required by law or other regulations. In such cases, the defined-benefit level is not to exceed the required level.

Other benefits
Fixed salary during notice periods and for severance pay, including compensation for possible restrictions on competition, shall not exceed a total amount equivalent to the basic salary for two years. In addition to this limitation, the total severance pay is to be limited to the existing monthly salary for the remaining months up to 65 years of age.

Additional remuneration may also be paid in extraordinary circumstances, provided that such arrangements are designed to recruit or retain senior executives, and that they are only agreed on a case-by-case basis. Such extraordinary arrangements may for example include a one-time cash payment, a benefit package in the form of relocation assistance, tax filing assistance, a retention bonus or severance pay in the event of changed ownership, or similar.

Deviations from the guidelines
The Board may decide to deviate from the above guidelines if it considers the guidelines inappropriate in a specific case.

Incentive programmes
Sobi currently has five active share programmes. To participate in the share programmes, employees must be permanently employed and invest in Sobi shares. The company also has three cash-based programmes for employees in the US. All programmes have a vesting period of three years. The performance conditions are related to Sobi's share price trend.

Conditions and remuneration for senior executives
Sobi aims to offer competitive terms, enabling the company to recruit and retain competent personnel. (For complete guidelines, see the Directors' Report).

AGM-elected Board members receive remuneration as adopted by the 2016 AGM. No pension is paid to Board members.

The CEO's remuneration is reviewed and proposed by the Chairman and the Compensation & Benefits Committee, and approved by the Board. Remuneration of other members of Group management is proposed by the CEO in close consultation with the Compensation & Benefits Committee and is approved by the Board. Remuneration of the CEO and other senior executives comprises fixed salary, short and long-term variable salary, benefits and pension. "Other senior executives" refers to the individuals who, together with the CEO, make up the Leadership Team. In 2016, there was a total of eleven other senior executives.

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

Short-term variable remuneration
For the CEO, the short-term variable remuneration in 2016 amounted to 50 per cent of the annual gross salary, with effect from 1 July 2015 for the period January to June (50), and 75 per cent of the revised annual gross salary (50) from July 1 2016. Variable remuneration is based on targets at Group level as well as individual targets established by the Board. For other senior executives, short-term variable remuneration is capped at 50 per cent (40) of fixed salary and is based on targets at Group and division level, as well as individual targets. The expected outcome is reconciled regularly throughout the year and reserves are adjusted monthly. On each reporting date, an assessment is made of the variable salary.

Pension terms and conditions
The CEO has a defined-contribution pension agreement, for which Sobi paid a contribution of SEK 272 K (135) in 2016. In 2016, gross salary including pension provisions amounted to SEK 6,109 K (5,534), in addition to the revised wage increase of 8 per cent the increase reflects exchange rate effects, since most of the CEO salary is paid out in USD. The age of retirement is 65.

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

	Basic salary/fees	Variable remuneration	Pension cost	Other benefits	Financial instruments, etc.	Total
2015[2]						
Chairman of the Board						
Bo Jesper Hansen[3]	2,408					2,408
Other Board members[4]						
Helena Saxon	388					388
Hans GCP Schikan	410					410
Adine Grate Axén[5]	410					410
Lennart Johansson	398					398
Hans Wigzell	360					360
Matthew Gantz	364					364
Annette Clancy	382					382
Chief Executive Officer						
Geoffrey McDonough	5,399	2,701	135	1,835	4,263[6]	14,333
Other senior executives[1]	18,243	8,780	4,941	968	5,746[6]	38,678
Total	**28,764**	**11,481**	**5,076**	**2,803**	**10,009**	**58,133**

1. Other senior executives refers to Sobi´s Leadership Team, comprising nine people in addition to the CEO at December 2015.
2. The table shows the Company´s costs (excluding social security costs).
3. Bo Jesper Hansen´s employment and his monthly salary is not linked to his position as Chairman of the Board.
4. For more information about Board fees, see the Corporate Governance Report.
5. The fee includes the Board fee excluding social security contributions. The gross payment to the Board member´s company was SEK 539 K, which includes compensation for social security contributions.
6. Refer also to allotment and fulfilment of long-term incentive programmes for the 2012 share programme, in the Annual Report 2015.

>> Note 12, cont.

Other senior executives employed in Sweden are covered by the ITP plan with a retirement age of 65. They are also covered by a supplementary defined-contribution pension commitment of 27 per cent of pensionable salary including ITP. The pensionable salary is limited to 50 income base amounts.

In conjunction with the transition from defined-benefit to defined-contribution plans, separate agreements were reached with individuals with contribution percentages exceeding 27 per cent. Members of the Leadership Team employed in other countries receive pension conditions according to market practice in their country of employment.

CEO's severance pay 2017

9 January 2017 Sobi announced that CEO Geoffrey McDonough will leave Sobi on 1 July 2017, and that a search for a new Chief Executive Officer has been initiated to identify his successor. A fixed salary will be payed during the notice period together with the severance pay, which will total an amount of approximately SEK 15 M (calculated at SEK/USD exchange rate 6 January 2017). This is equivalent to the fixed salary for approximately 27 months.

Given that it is in both the company's and the shareholders' interest to keep the CEO for as long as possible while the company is recruiting a successor and that Geoffrey McDonough intends to be in service during the entire notice period up until 1 July 2017, the Board of Directors resolved to deviate from the remuneration guidelines approved by the annual general meeting 2016 in this individual case.

Long-term incentive programmes

Annual General Meetings in 2013–2016 resolved in accordance with the Board's proposals to establish long-term incentive programmes. The aim has been to create a 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 2013–2016 are structured according to similar principles.

- The programmes have a three-year vesting period.
- The programmes also require investment in Sobi shares.
- Employees are entitled to matching shares free of consideration. Some employees may also be entitled to potential performance shares if the performance criteria are met. The number of potential performance shares that employees are entitled to receive differs between the organisational levels.
- 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 increases by a certain percentage over a three-year period.
- Who the eligible employees are differs between the programmes, as well as how the performance target has been formulated.

2013 Share Programme (paid 2016)

The 2013A and 2013B share programmes expired in 2016. For 2013A, the Board decided that the following performance conditions and other vesting terms were fully met when the 2013A Share Programme was redeemed on 19 May 2016. In the Leadership Programme for managers and key employees, 694,317 shares with a market value of SEK 76.2 M were thereby allotted, of which the CEO's proportion comprised 135,103 shares with a market value of SEK 14.8 M. In the Employee Programme, 215,622 shares with a market value of SEK 23.7 M were allotted.

For 2013B, the Board decided that the following performance conditions and other vesting terms were met by up to 57.98 per cent when the 2013B Share Programme was redeemed on 16 November 2016. In the Leadership Programme for managers and key employees, 25,253 shares with a market value of SEK 2.4 M were thereby allotted. In the Employee Programme, 5,396 shares with a market value of SEK 0.5 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.

2014 Share Programme

The 2014 AGM approved a long-term share programme covering the CEO, senior executives and managers, and a programme for other employees. 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.

2014 Cash-Based Programme

The 2014 AGM approved a long-term cash-based programme comprising 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 remain 95–105 per cent relative to the average budget over a three-year period.

2014 Share Programme

	No. of performance shares	No. of matching shares	Value in SEK
CEO and other senior executives in the Group, 10	160,610	40,276	8,952,824
Total	**160,610**	**40,276**	**8,952,824**

2015 Share Programme

The 2015 AGM approved a long-term share programme covering the 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:

The CEO is allotted performance shares (no matching shares), contingent on the achievement of a certain share price performance. Performance shares are allotted in the CEO Programme provided that the share price, with adjustment for any dividends, has exceeded the threshold value of 20 per cent. If the share-price performance increases 20–100 per cent, the proportional number of performance shares is allotted. The maximum possible allotment of performance shares is 400,000.

Participants in the Leadership 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 a 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, the programme participants will receive a straight-line allotment of performance shares. The maximum possible allotment of performance shares is 108,975.

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 is 443,746 shares.

2015 Cash-Based Programme
The 2015 AGM approved a long-term cash-based programme comprising 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. The turnover should also 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
CEO and other senior executives in the Group, 9	494,722	6,798	19,525,438
Total	**494,722**	**6,798**	**19,525,438**

2016 Share Programme
The 2016 AGM approved a long-term share programme covering the 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 Leadership 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 a 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, the programme participants will receive a straight-line allotment of performance shares. The maximum possible allotment is 205,731 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 is 104,799 shares.

2016 Cash-Based Programme
The design of the Cash Programme covering all employees in North America was adjusted in 2016. The programme consists of two components; one time-based component (50 per cent) and one performance based component (50 per cent) based on two performance metrics. The first performance metric (50 per cent) is Total Shareholder Return, which must increase by at least 10 per cent per year over a four year period. The second performance metric (50 per cent) is North America Net revenue as a percentage of budget, which must meet a threshold of at least 95 per cent per year over a four year period.

2016 Share Programme

	No. of performance shares	No. of matching shares	Value in SEK
CEO and other senior executives in the Group, 9	0	0	0
Total	**0**	**0**	**0**

In connection with the introduction of Sobi's Share Programme 2016, a number of employees, including the CEO and other senior executives of the Group, were legally prohibited from attending the programme because that they at the time were in possession of inside information. In light of the legal obstacles, and to ensure Sobi's ability to attract and retain senior management, the board instead decided to set up a long-term cash-based incentive programme to take effect from 1 January 2017.

Expensing of the 2014–2016 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	Expected employee turnover, %	Max. allotment of shares	Forfeited shares 2016
2014:1 Share Programme	9 May 2014	9 May 2017	125,521	236,127	36	81.78	37.41	5	361,648	7,253
2014:2 Share Programme	17 November 2014	17 November 2017	37,771	137,478	36	83.34	34.03	5	175,249	3,486
2015 Share Programme	19 August 2015	19 August 2018	113,287	402,949	36	116.40	43.20	5	541,727	36,485
2015 Share Programme CEO	24 September 2015	24 September 2018	n/a	400,000	36	n/a	36.60	—	400,000	—
2016 Share Programme	28 October 2016	28 October 2019	104,799	205,731	36	94.05	33.34	5	310,530	—

Volatility is measured as the standard deviation of the expected return on the share price, based on a statistical analysis of daily share prices for Sobi's ordinary share over the past three years. 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 13
Remuneration of auditors

GROUP	2016	2015
EY		
Auditing assignments[1]	–3,914	–2,773
Audit activities in addition to the auditing assignment	–968	–2,302
Tax consultancy	–1,299	–636
Other services	–285	–391
Total EY	**–6,466**	**–6,102**
Other		
Auditing assignments[1]	—	–178
Tax consultancy	—	–464
Total other	**—**	**–642**
Total	**–6,466**	**–6,744**

PARENT COMPANY	2016	2015
EY		
Auditing assignments[1]	– 1,776	–1,310
Audit activities in addition to the auditing assignment	–864	–2,302
Tax consultancy	–1,287	–496
Other services	—	–391
Total EY	**–3,927**	**–4,499**
Other		
Other services	—	—
Total other	**—**	**—**
Total	**–3,927**	**–4,499**

1. Audit assignment refers to the statutory audit in order to submit the audit report and audit consultancy.

Note 14
Costs according to type of cost

GROUP	2016	2015
Raw materials and consumables	–1,228,611	–966,540
Other external costs	–1,265,018	–774,560
Costs for remuneration of employees	–1,173,332	–1,018,591
Depreciation	–440,710	–319,507
Other operating expenses	–81,746	–17,929
Total	**–4,189,417**	**–3,097,127**

PARENT COMPANY	2016	2015
Raw materials and consumables	–1,144,774	–913,268
Other external costs	–1,387,869	–837,193
Costs for remuneration of employees	–615,657	–582,126
Depreciation	–269,323	–121,573
Other operating expenses	–81,631	–14,757
Total	**–3,499,254**	**–2,468,917**

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

Note 15
Financial revenue

GROUP	2016	2015
Other interest income	1,427	2,929
Exchange-rate gains[1]	6,498	—
Other	—	1,397
Total	**7,925**	**4,326**

PARENT COMPANY	2016	2015
Interest income, Group companies	16,329	26,637
Other interest income	923	1,695
Exchange-rate gains	4,631	—
Other	—	1,175
Total	**21,883**	**29,507**

1. Exchange rate effects are reported net and are a gain for 2016, and a loss last year that is reported under Note 16. Included in these are realised and unrealised currency effects from derivates, that amounted to SEK –17 M (–2).

Note 16

Financial expenses

GROUP	2016	2015
Interest expense, borrowings	–27,722	–51,903
Other interest expense	–50,824	–5,767
Exchange rate losses[1]	—	–3,581
Administrative expenses	–2,319	–3,464
Other	–12,194	–924
Total	**–93,060**	**–65,639**

PARENT COMPANY	2016	2015
Interest expense, Group companies	–3,100	–784
Interest expense, borrowings	–27,722	–51,903
Other interest expense	–50,824	–5,140
Exchange rate losses[1]	—	–3,340
Administrative expenses	–2,319	–3,464
Other	–10,854	–924
Total	**–94,819**	**–65,555**

1. Exchange rate effects are reported net and are a gain for 2016, see Note 15.

Note 17

Exchange rate differences affecting operating profit/loss

GROUP	2016	2015
Exchange rate differences affecting operating profit/loss	30,807	–3,326
Total	**30,807**	**–3,326**

PARENT COMPANY	2016	2015
Exchange rate differences affecting operating profit/loss	24,256	–6,637
Total	**24,256**	**–6,637**

See Note 8 and 9.

Note 18

Income tax

GROUP	2016	2015
Current tax expense (–) / tax income (+)		
Tax expense/income for the period	–30,269	–25,665
Adjustment of tax attributable to previous years	–2,161	3,300
Total current tax for the Group	**–32,430**	**–22,365**
Deferred tax related to:		
Provision for pensions	636	–272
Change in tax allocation reserve and excess depreciation	–111,684	–39,546
Return to amortisation according to plan	–28,773	—
Intercompany profit in inventory	43,327	18,455
Amortisation of intangible assets	38,148	19,765
Acquisition of marketing rights	–144,367	—
Cash flow hedging, financial instruments	2,840	–2,840
Other	–6,604	7,506
Total deferred tax for the Group	**–206,477**	**3,068**
Total tax for the Group	**–238,907**	**–19,297**

PARENT COMPANY	2016	2015
Current tax expense (–) / tax income (+)		
Tax expense/income for the period	—	—
Adjustment of tax attributable to previous years	–10	3,300
Total current tax for the Parent Company	**–10**	**3,300**
Deferred tax related to:		
Cash flow hedging, financial instruments	2,840	–2,840
Return to amortisation according to plan	–28,773	–59,085
Total deferred tax for the Parent Company	**–25,933**	**–61,925**
Total tax for the Parent Company	**–25,943**	**–58,625**

Reconciliation of effective tax

GROUP	2016	2015
Profit before tax	**1,047,979**	**84,210**
Tax according to the applicable tax rate for the Parent Company	–230,555	–18,526
Effect of foreign tax rates	7,699	–2,210
Return to amortisation according to plan	–63,512	—
Cash flow hedge	52,564	—
Non-deductible expenses	–8,761	–1,495
Non-taxable income	3,648	399
Adjustment of tax attributable to previous years	–2,161	3,300
Taxable profit, not recognised	–1,571	—
Deductable costs, not recognised	7,274	—
Loss carry-forward, not recognised	–60	—
Other	–3,471	–765
Recognised effective tax	**–238,907**	**–19,297**

PARENT COMPANY	2016	2015
Profit before tax	**84,637**	**272,685**
Tax according to the applicable tax rate for the Parent Company	–18,620	–59,991
Non-deductible expenses	–2,026	–1,490
Adjustment of tax attributable to previous years	–10	3,300
Non-taxable income	17	321
Return to amortisation according to plan	–63,511	—
Cash flow hedge	52,564	—
Taxable profit, not recognised	–1,571	—
Deductable costs, not recognised	7,274	—
Loss carry-forward, not recognised	–60	—
Other	—	–765
Recognised effective tax	**–25,943**	**–58,625**

The applicable tax rate for the Parent Company is 22 per cent (22).

Note 19

Intangible assets and impairment testing

GROUP	Goodwill	Licenses & patents	Product & marketing rights	Advance payments	Capitalised software expenditure	IT software in progress	Total
1 January–31 December 2015							
Opening accumulated cost	1,554,158	609,477	3,432,433	73,503	72,393	24,405	5,766,369
Initiation of construction in progress	—	—	—	—	31,794	–31,794	—
Acquisitions	—	750[1]	1,706,088[1]	82,400[1]	—	33,178[1]	1,822,416
Reclassification	—	–63,994	137,497	–73,503	600	3,671	4,272
Closing cost	**1,554,158**	**546,233**	**5,276,018**	**82,400**	**104,787**	**29,460**	**7,593,056**
Opening accumulated depreciation and impairment losses	—	–253,316	–1,205,356	—	–60,209	—	–1,518,881
Depreciation	—	–54,925	–223,816	—	–8,399	—	–287,140
Closing accumulated depreciation and impairment losses	**—**	**–308,241**	**–1,429,172**	**—**	**–68,608**	**—**	**–1,806,021**
Closing carrying amount	**1,554,158**	**237,992**	**3,846,846**	**82,400**	**36,179**	**29,460**	**5,787,036**
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	—	15,067[2]	1,382,384[2]	—	—	31,196[2]	1,428,647
Reclassification	—	11,797	79,988	–82,400	–8,945	—	440
Exchange rate differences	—	—	25	—	—	—	25
Closing cost	**1,554,158**	**573,097**	**6,738,415**	**—**	**126,426**	**30,072**	**9,022,168**
Opening accumulated depreciation and impairment losses	—	–308,241	–1,429,172	—	–68,608	—	–1,806,021
Depreciation	—	–39,200	–356,479	—	–14,458	—	–410,137
Reclassification	—	–1,592	—	—	1,592	—	—
Closing accumulated depreciation and impairment losses	**—**	**–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 Acquisitions in 2015 pertain to Elocta (SEK 1,704 M), Alprolix recognised as an advance payment (SEK 82 M), IFS ERP-system (SEK 17 M), and other (SEK 19 M), divided among all intangible items.
2 Acquisitions in 2016 pertain to Alprolix opt-in SEK 1,348 M, Kineret milestone SEK 72 M, and other SEK 8 M, divided among all intangible items.

PARENT COMPANY	Licenses & patents	Product & marketing rights	Advance payments	Capitalised software expenditure	IT software in progress	Total
1 January–31 December 2015						
Opening accumulated cost	113,165	1,147,733	73,503	66,084	24,405	1,424,890
Initiation of construction in progress	—	—	—	31,794	–31,794	—
Acquisitions	750[1]	1,706,088[1]	82,400[1]	—	33,093[1]	1,822,331
Reclassification	–63,994	137,497	–73,503	—	3,672	3,672
Closing cost	**49,921**	**2,991,318**	**82,400**	**97,878**	**29,376**	**3,250,893**
Opening accumulated depreciation and impairment losses	–8,409	–353,308	—	–56,647	—	–418,364
Depreciation	–3,254	–82,503	—	–8,115	—	–93,872
Closing accumulated depreciation and impairment losses	**–11,663**	**–435,811**	**—**	**–64,762**	**—**	**–512,236**
Closing carrying amount	**38,258**	**2,555,507**	**82,400**	**33,116**	**29,376**	**2,738,657**
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	15,067[2]	1,721,037[2]	—	—	31,196[2]	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 depreciation and impairment losses	–11,663	–435,811	—	–64,762	—	–512,236
Depreciation	–5,193	–224,747	—	–14,458	—	–244,398
Reclassification of accumulated depreciation	–1,592	—	—	1,592	—	—
Closing accumulated depreciation and impairment losses	**–18,448**	**–660,558**	**—**	**–77,628**	**—**	**–756,634**
Closing carrying amount	**58,337**	**4,131,785**	**—**	**41,889**	**29,988**	**4,261,999**

1. Acquisitions in 2015 pertain to Elocta (SEK 1,704 M), Alprolix recognised as an advance payment (SEK 82 M), IFS ERP-system (SEK 17 M), and other (SEK 19 M), divided among all intangible items.
2. Acquisitions in 2016 pertain to Alprolix Opt-in SEK 1,348 M, Factor IX SEK 339 M, Kineret milestone SEK 72 M, and other SEK 8 M, divided among all intangible items.

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Testing for impairment of intangible fixed assets

Goodwill

The assessment of the value of the Group's goodwill is based on value in use of 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 established based on past performance, experiences and expectations in the market. The plans includes assumptions about the current product development and future product launches. The financial plans also include assumptions of the development of price, sales and expenses. Cash flows beyond the five- to ten-year period have been extrapolated using an estimated growth rate of 2 per cent. At 31 December 2016, Sobi's goodwill amounted to SEK 1,554 M (1,554). There is no indication of goodwill impairment at Group level.

The following table shows the growth rate and discount rate used before and after tax:

PARAMETER, %	2016	2015
Growth rate beyond the initial five-year period	2	2
Discount rate before tax	11,8	11,3
Discount rate after tax	9,2	8,8

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:* 6.1 per cent (5.7).
- *Beta coefficient:* Sobi's beta coefficient is calculated at 1.30 (1.25).
- *Interest expense:* according to Sobi's borrowing costs.
- *Tax rate:* according to tax rates in Sweden.

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

Development projects and product rights

Development projects and product rights are tested annually for impairment. Impairment testing has been carried out for each product or project separately. The assessment of the value of development projects and product rights is based on the value in use of 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 of future cash flows, the discount rate is used as described above.

For impairment testing of development projects, key parameters are future cash flows from the individual asset, the probability to achieve positive outcomes in clinical trials, and assumptions of the best commercial outcome. Future cash flows are estimated with respect to project development in the short- and long-term and adjusted for the probability that the project will be commercialised. The earlier in the chain of development that the project is, the higher the risk. As it passes through the defined development phases, the likelihood of reaching the market increases. The assessment of the likelihood for a proposal to implement the current development phase successfully is made on the basis of an assessment of the scientific potential of the project to have a positive outcome at the individual phase of the development. A best-case assumption is made on the basis of the parameters that affect whether the project will develop a drug with the highest commercial potential, and is based on what is reasonable to assume about the project's scientific profile using the information available today. The forecast period is based on the product's estimated market life.

In the impairment testing of product and market rights, a number of assumptions are made. The assumptions are forecasts of future sales, costs attributable to each product, product life and discount rate. In cases where the contract or patent rights to the product exceed five years, the contract or the patent term is used as the remaining lifetime. Implemented impairment testing of product and market rights does not indicate any impairment.

Impairment losses in 2016

Sobi did not make any impairments in 2016.

Contractual commitments for acquisitions of intangible assets

In connection with certain acquisitions and licensing agreements, Sobi agreed to pay additional payments (often called milestone payments) linked to certain pre-determined objectives. Listed below are the most significant agreements.

Agreement with Bioverativ

Bioverativ was created as a spin-off from Biogen's haemophilia business and seperated from Biogen on 1 February 2017. Bioverativ is an independent, publicly traded company, headquartered in Waltham, Massachusetts, USA. Bioverativ will continue to collaborate with Sobi on their joint development programmes.

According to the agreement between Sobi and Bioverativ regarding the development and commercialisation of Elocta, Alprolix and BIVV001, Bioverativ takes full responsibility for development and production, plus the associated costs, until Sobi exercises its opt-in right to the programmes.

Sobi has opt-in rights to take over final development and commercialisation in 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 in the respective company's territory according to the royalty rates set out in the table below.

Under the terms of the opt-in right and following Bioverativ's submission of a marketing authorisation application (MAA) to the European Medicines Agency (EMA) for Elocta and Alprolix, 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 for each programme.

Liability arising from pipeline programmes

When granted regulatory approval by the EU, Sobi became liable to reimburse Bioverativ for 50 per cent of the total development and production costs for clinical manufacturing of Elocta and Alprolix, development costs for the product as of 1 October 2009 until the date on which Sobi is registered as the marketing authorisation holder (MAH), or, 90 days after approval, as well as some shared expenses related to regulatory approval, costs for final development and commercialisation, and 100 per cent of some development costs that only benefitted Sobi's territory.

Liability settlement
Sobi's reimbursement to Bioverativ for each pipeline programme takes the following three forms:

- When regulatory approval is granted in the EU, the deposit of USD 10 M is transferred to Bioverativ and offset against Sobi's liability.
- With the first commercial sales of each of its products, Sobi will be able to credit a retroactive royalty revenue on the difference between the base rate and the 2 per cent already received on Bioverativ's sales. This amount is offset against the liability. The amount will be recorded as a revenue but have no cash effect.
- 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 reimbursement has not been achieved 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 the first commercial sales.

Elocta
In October 2014, Sobi's partner Bioverativ submitted an MAA for Elocta to the EMA. The MAA, together with the delivery of data from Bioverativ to Sobi, triggered Sobi's exclusive opt-in right to assume the final development and commercialisation of Elocta in Europe, North Africa, Russia and most Middle Eastern countries. On 21 November 2014, Sobi exercised its opt-in right and paid a deposit of USD 10 M, in accordance with the agreement. Total payment is expected to be about USD 216 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 set off against the liability. In connection with its first commercial sales in January 2016, Sobi credited a retroactive royalty revenue of SEK 322 M against the liability. As of 31 December 2016, the remaining liability totals SEK 1,258 M (USD 138 M) and corresponded to the discounted value of the nominal liability, which amounted to USD 144 M.

Alprolix
In June 2015, Sobi's partner Bioverativ submitted an MAA for Alprolix to the EMA. The MAA, together with the delivery of data from Bioverativ to Sobi, triggered Sobi's exclusive opt-in right to assume the final development and commercialisation of Alprolix in Europe, North Africa, Russia and most Middle Eastern countries. On 16 July 2015, Sobi exercised its opt-in right and paid a deposit of USD 10 M, in accordance with the agreement. The deposit was recognised in the balance sheet as an advance payment under intangible fixed assets. 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 set off against the liability. In connection with its first commercial sales in June 2016, Sobi credited a retroactive royalty revenue of SEK 386 M against the liability. As of 31 December 2016, the remaining liability totals SEK 1,048 M (USD 115 M) and corresponded to the discounted value of the nominal liability, which amounted to USD 123 M.

BIVV001 (rFVIIIFc-XTEN)
In September 2014, Sobi decided to include the preclinical development programme for the potentially long-acting haemophilia A treatment BIVV001 (rFVIIIFc-XTEN), in the agreement with Bioverativ. Under the agreement between Sobi and Bioverativ, Sobi will thus have an exclusive opt-in right to the programme, and the possibility to obtain 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	Rate before first commercial sales in Sobi's territory, %	Base rate[4],%	Adjusted royalty rate during repayment period[4]	Net royalty payment during repayment period[5], %
From Sobi to Bioverativ based on net sales in Sobi's territory	Royalty on sales	N/A	12	Base rate plus 5%	17
Bioverativ to Sobi based on net sales in North America	Royalty on sales	2	12	Base rate plus 5%	7
Bioverativ to Sobi based on net sales in Bioverativ's territory outside North America	Royalty on sales	2	17	Base rate plus 5%	12
Bioverativ to Sobi based on the net profit[1] from Bioverativ's distribution territory[2]	Royalty on sales	10	50	Base rate plus 15%	35

1. Net profit pertains to Bioverativ's revenues before tax from distributors (third-party), less expenses incurred by Bioverativ for supporting these sales.
2. Bioverativ's distribution territory pertains to the territory in which sales are conducted through a third party.
3. Sobi will receive credit from Bioverativ against the payment that Sobi will make according to its opt-in right, in an amount equal to the difference between the royalty payments that Bioverativ made to Sobi on sales in Bioverativ's territory during certain periods before the first sales in Sobi's territory, and the rate that would otherwise have been payable on such sales.
4. Base rate impacts the results. Repayment of the liability is based on the difference between the base rate and the adjusted royalty.
5. Actual payments that impact cash flow.

Note 20

Tangible assets

GROUP	Land & buildings	Plant & machinery	Equipment, tools, fixtures & fittings	Other fixed assets	Construction in progress	Total
1 January–31 December 2015						
Opening accumulated cost	6,728	405,487	206,705	14,069	7,130	640,119
Acquisitions	—	9,106	9,812	4,581	3,875	27,374
Reclassification	—	—	—	—	–103	–103
Disposals	—	–5,049	—	–3,211	—	–8,260
Closing cost	**6,728**	**409,544**	**216,517**	**15,439**	**10,902**	**659,130**
Opening accumulated depreciation and impairment losses	–2,467	–364,225	–150,107	–3,400	—	–520,199
Depreciation	–334	–8,970	–20,390	–2,673	—	–32,367
Disposals	—	4,475	—	1,905	—	6,380
Exchange-rate differences	—	—	–268	—	—	–268
Closing accumulated depreciation and impairment losses	**–2,801**	**–368,720**	**–170,765**	**–4,168**	**—**	**–546,454**
Closing carrying amount	**3,927**	**40,824**	**45,752**	**11,271**	**10,902**	**112,676**
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-rate differences	—	—	789	—	—	789
Closing cost	**—**	**435,449**	**225,281**	**15,361**	**14,770**	**690,861**
Opening accumulated depreciation and impairment losses	–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-rate differences	—	—	–365	—	—	–365
Closing accumulated depreciation and impairment losses	**—**	**–377,473**	**–187,929**	**–4,436**	**—**	**–569,838**
Closing carrying amount	**—**	**57,536**	**37,792**	**10,925**	**14,770**	**121,023**

PARENT COMPANY	Land & buildings	Plant & machinery	Equipment, tools, fixtures and fittings	Other fixedassets	Construction in progress	Total
1 January–31 December 2015						
Opening accumulated cost	6,728	400,510	191,331	5,210	7,130	610,909
Acquisitions	—	9,106	3,409	—	3,875	16,390
Reclassification	—	—	—	—	–103	–103
Disposals	—	–4,895	—	—	—	–4,895
Closing cost	**6,728**	**404,721**	**194,740**	**5,210**	**10,902**	**622,301**
Opening accumulated depreciation and impairment losses	–2,467	–357,973	–141,237	–520	—	–502,197
Depreciation	–334	–8,970	–17,877	–520	—	–27,701
Disposals	—	4,046	—	—	—	4,046
Closing accumulated depreciation and impairment losses	**–2,801**	**–362,897**	**–159,114**	**–1,040**	**—**	**–525,852**
Closing carrying amount	**3,927**	**41,824**	**35,626**	**4,170**	**10,902**	**96,449**
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 losses	–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 losses	**—**	**–371,650**	**–173,222**	**–1,560**	**—**	**–546,432**
Closing carrying amount	**—**	**58,536**	**26,241**	**3,650**	**14,770**	**103,197**

Note 21

Participations in Group companies

PARENT COMPANY	2016	2015
Accumulated cost		
At 1 January	4,059,573	4,059,504
Purchasing	—	69
Total	**4,059,573**	**4,059,573**
Accumulated impairment losses		
At 1 January	–177,435	–177,435
Impairment losses for the year	—	—
Total	**–177,435**	**–177,435**
Carrying amount at end of period	**3,882,138**	**3,882,138**

>> Note 21, cont.

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

SUBSIDIARY/CORP. REG. NO./ DOMICILE	No. of partic-ipations	Participa-tions in %[1]	Carrying amount
Swedish Orphan Biovitrum International AB (publ), 556329-5624, Stockholm, Sweden	100	100	3,655,588
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, Martinsreid, Germany			
SOBI Middle East FZ-LLC, 91193, Dubai, United Arab Emirates	1,000	100	132
Arexis AB, 556573-5130, Stockholm, Sweden	1,000	100	225,137
Sobi, Inc EIN 68-0682244, Delaware, USA	1,000	100	7
Swedish Orphan Biovitrum s.r.o., 28171276, Prag, 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, Luzern, 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
Total			3,882,138

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.

Note 22

Financial assets

GROUP	2016	2015
Accumulated cost		
At 1 January	1,791	2,862
Divestment of Akinion	–20	—
Divestment of Agrisera	—	–600
Financial receivables	158	282
Returned deposit	–67	–717
Other	95	–36
Accumulated cost	**1,956**	**1,791**
Carrying amount at end of period	**1,956**	**1,791**

PARENT COMPANY	2016	2015
Accumulated cost		
At 1 January	21	621
Divestment of Akinion	–20	—
Divestment of Agrisera	—	–600
Accumulated cost	**1**	**21**
Carrying amount at end of period	**1**	**21**

Note 23

Deferred tax assets and deferred tax liabilities

Recognised deferred tax assets and liabilities

GROUP 2016	Deferred tax assets	Deferred tax liabilities	Net
Stock	120,260	—	120,260
Acquired product rights	—	–290,054	–290,054
Pensions	2,805	—	2,805
Excess depreciation	—	–253,880	–253,880
Change of depreciation method	—	–69,475	–69,475
Cash flow hedging, financial instruments	34,439	—	34,439
Other intangible assets	72,333	—	72,333
Restoration reserve	—	–803	–803
Loss carry-forwards	258	—	258
Other	11,768	—	11,768
Total	**241,863**	**–614,212**	**–372,349**
Offsetting	–107,966	107,966	—
Tax assets/ liabilities, net	**133,897**	**–506,246**	**–372,349**

GROUP 2015	Deferred tax assets	Deferred tax liabilities	Net
Stock	76,933	—	76,933
Acquired product rights	—	–328,202	–328,202
Pensions	2,500	—	2,500
Excess depreciation	—	–182,898	–182,898
Cash flow hedging, financial instruments	—	–18,125	–18,125
Other intangible assets	216,700	—	216,700
Restoration reserve	—	–803	–803
Loss carry-forwards	258	—	258
Other	18,161	–114	18,047
Total	**314,552**	**–530,142**	**–215,590**
Offsetting	–217,333	217,333	—
Tax assets/liabilities, net	**97,219**	**–312,809**	**–215,590**

For the Parent Company, a deferred tax liability/receivable of SEK –35.6 M (–59.4) remains of which the largest items relates to the change of depreciation method SEK –69.5 M and cash flow hedges financial instruments of SEK 34.4 M. The closing balance for tax loss carry-forwards pertains to Swedish companies. Deficits never mature, under current tax legislation. Deficits are capitalised since the Group assesses it likely that the remaining deficit will be offset against future taxable profits. The value of deferred tax after year-end is calculated on a tax rate of 22 per cent (22).

Change in deferred tax on temporary differences and loss carry-forwards

GROUP 2016	Amount at 1 January	Recognised in profit or loss	Recognised in other comprehensive income	Translation difference	Amount 31 December
Stock	76,933	43,327	—	—	120,260
Acquired product rights	–328,202	38,148	—	—	–290,054
Pensions	2,500	636	–331	—	2,805
Tax allocation reserves/Excess depreciation	–182,898	–111,684	—	—	–253,880
Change of depreciation method	—	–28,773	—	—	–69,475
Cash flow hedging, financial instruments	–18,125	2,840	49,724	—	34,439
Other intangible assets	216,700	–144,367	—	—	72,333
Restoration reserve	–803	—	—	—	–803
Capitalised loss carry-forwards	258	—	—	—	258
Other	18,047	–6,604	325	—	11,768
Total	**–215,590**	**–206,477**	**49,718**	—	**–372,349**

GROUP 2015	Amount at 1 January	Recognised in profit or loss	Recognised in other comprehensive income	Translation difference	Amount 31 December
Stock	58,442	18,455	—	36	76,933
Acquired product rights	–347,967	19,765	—	—	–328,202
Pensions	3,251	–272	–479	—	2,500
Tax allocation reserves/Excess depreciation	–143,352	–39,546	—	—	–182,898
Cash flow hedging, financial instruments	—	–2,840	–15,285	—	–18,125
Other intangible assets	216,700	—	—	—	216,700
Restoration reserve	–803	—	—	—	–803
Capitalised loss carry-forwards	258	—	—	—	258
Other	10,343	7,506	198	—	18,047
Total	**–203,128**	**3,068**	**–15,566**	**36**	**–215,590**

Note 24

Inventories

GROUP	2016	2015
Raw materials and consumables	25,557	14,991
Work in progress	433,244	316,001
Finished goods and goods for resale	411,245	444,862
Total	**870,046**	**775,854**

The cost of inventories that was expensed is included in the cost of goods sold item and amounted to SEK 1,145,708 K (914,467).

PARENT COMPANY	2016	2015
Raw materials and consumables	25,557	14,991
Work in progress	433,244	316,001
Finished goods and goods for resale	307,583	342,563
Total	**766,384**	**673,555**

The cost of inventories that was expensed is included in the cost of goods sold item and amounted to SEK 1,144,773 K (913,267).

Note 25

Accounts receivable and other receivables

GROUP	2016	2015
Accounts receivable	818,043	476,509
Minus: Provision for bad debts	–49,279	–25,280
Accounts receivable, net	**768,765**	**451,229**
Tax assets	35,011	20,634
Other receivables	40,532	46,942
Total other receivables	**75,543**	**67,576**
Total accounts receivable and other receivables	**844,307**	**518,805**

PARENT COMPANY	2016	2015
Accounts receivable	293,048	197,206
Minus: Provision for bad debts	–12,799	–13,171
Accounts receivable, net	**280,249**	**184,035**
Tax assets	27,203	16,924
Other receivables	27,329	30,699
Total other receivables	**54,532**	**47,623**
Total accounts receivable and other receivables	**334,781**	**231,658**

Profit for the year was not charged with any bad debt losses.

At 31 December 2016, overdue accounts receivables in the Group amounted to SEK 272 M (127), of which 49 SEK M (25) was written off as bad debt.

Changes in the provision for bad debts are as follows:

Bad debts

GROUP	2016	2015
At 1 January	–25,280	–12,424
Provision for bad debts	–25,219	–12,856
Reversed provisions	1,220	—
At 31 December	**–49,279**	**–25,280**

PARENT COMPANY	2016	2015
At 1 January	–13,171	–8,801
Provision for bad debts	–849	–4,370
Reversed provisions	1,220	—
At 31 December	**–12,799**	**–13,171**

Past due accounts receivable

GROUP	2016	2015
Undue	497,161	324,586
Past due 1–30 days	150,588	68,073
Past due 31–90 days	70,830	19,819
Past due 91–120 days	21,981	12,944
Past due > 121 days	28,204	25,807
Total	**768,765**	**451,229**

PARENT COMPANY	2016	2015
Undue	212,234	177,120
Past due 1–30 days	28,906	2,972
Past due 31–90 days	38,383	1,895
Past due 91–120 days	128	390
Past due > 121 days	598	1,658
Total	**280,249**	**184,035**

Recognised amount per currency for accounts receivable and other receivables

GROUP	2016	2015
AUD	12,720	6,451
CHF	8,414	2,359
CZK	5,033	5,236
DKK	95,962	9,307
EUR	310,339	224,678
GBP	58,223	32,118
NOK	16,246	9,732
PLN	5,942	6,232
RON	13,405	15,201
SEK	152,400	75,555
USD	161,123	128,079
Other currencies	4,500	3,857
Total	**844,307**	**518,805**

PARENT COMPANY	2016	2015
AUD	12,720	6,451
CHF	8,414	2,359
CZK	1,640	1,440
DKK	16,425	9,188
EUR	84,446	66,093
GBP	887	1,568
NOK	15,745	9,232
PLN	5,942	6,232
RON	13,405	15,201
SEK	152,400	75,555
USD	20,555	35,668
Other currencies	2,202	2,671
Total	**334,781**	**231,658**

Note 26

Prepaid expenses and accrued income

GROUP	2016	2015
Accrued royalty revenue	285,858	57,844
Prepaid leasing fees	88	258
Prepaid rents	17,412	15,943
Prepaid insurance expenses	12,233	12,734
Accrued interest income	144	2,120
Other accrued income	—	5,552
Other prepaid expenses	95,374	23,396
Total	**411,109**	**117,847**

PARENT COMPANY	2016	2015
Accrued royalty revenue	285,858	57,844
Prepaid rents	15,134	14,161
Prepaid insurance expenses	10,360	11,518
Accrued interest income	—	2,120
Other accrued income	—	5,526
Other prepaid expenses	88,021	18,237
Total	**399,373**	**109,406**

Note 27

Current investments and cash equivalents

	2016		2015	
GROUP	Fair value	Carrying amount	Fair value	Carrying amount
Cash and equivalents	785,790	785,790	903,660	903,660
Total	**785,790**	**785,790**	**903,660**	**903,660**

	2016		2015	
PARENT COMPANY	Fair value	Carrying amount	Fair value	Carrying amount
Cash and equivalents	662,110	662,110	750,398	750,398
Total	**662,110**	**662,110**	**750,398**	**750,398**

Note 28

Financial assets and liabilities per category (Group)

	Loans and receivables	Assets measured at fair value through profit or loss	Assets held for sale	Total
31 December 2016				
Assets in the balance sheet				
Accounts receivable	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**
31 December 2015				
Assets in the balance sheet				
Accounts receivable	451,229	—	—	451,229
Derivatives	—	9,255	—	9,255
Cash and cash equivalents	903,660	—	—	903,660
Total	**1,354,889**	**9,255**	**—**	**1,364,144**

	Liabilities measured at fair value through profit or loss	Other financial liabilities	Liabilities held for sale	Total
31 December 2016				
Liabilities in the balance sheet				
Borrowings	—	496,914	—	496,914
Financial leasing	—	7,102	—	7,102
Accounts payable	—	280,173	—	280,173
Other liabilities	—	2,305,613	—	2,305,613
Total	**—**	**3,089,802**	**—**	**3,089,802**
31 December 2015				
Liabilities in the balance sheet				
Borrowings	—	815,158	—	815,158
Financial leasing	—	6,944	—	6,944
Accounts payable	—	183,193	—	183,193
Other liabilities	—	1,639,285	—	1,639,285
Total	**—**	**2,644,580**	**—**	**2,644,580**

See Note 2 for more information about what is included in the various categories. Advance payments are excluded from accounts receivable and other receivables since the analysis is only required for financial instruments. Accrued social security contributions, etc., are excluded from this table for the same reason.

Note 29
Bond loans

GROUP	2016	2015
Bond loan	—	795,158
Total	—	**795,158**

PARENT COMPANY	2016	2015
Bond loan	—	795,158
Total	—	**795,158**

During the year, the bond loans were prematurely redeemed and replaced with bank loans, see Note 30.

Note 30
Other liabilities, non-current

GROUP	2016	2015
Liability to Bioverativ	1,808,916	1,179,468
Liabilities to credit institutions	496,914	—
Other	5,302	5,178
Total	**2,311,132**	**1,184,646**

PARENT COMPANY	2016	2015
Liability to Bioverativ	1,808,916	1,179,468
Liabilities to credit institutions	496,914	—
Total	**2,305,830**	**1,179,468**

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. Since these liabilities will be repaid over a period of years, the discounted amounts after repayment are reflected in the balance sheet (USD 138 M for Elocta, and USD 115 M for Alprolix). The right to market the product in certain markets, which is recognised as intangible assets, is initially recognised at the same amount as the liabilities. The costs corresponds to the discounted liability, and the difference compared with the nominal amount leads to deferred tax in the financial statements. The risk associated with currency effects on these liabilities is reduced by applying hedge accounting by hedging highly probable inflows in the future in USD via cash flow hedges, and the effect of the revaluations of the liabilities is reflected in other comprehensive income. If full payment has not been made within six years of the first commercial sales of each respective product, Bioverativ is entitled to request that Sobi pay the remaining amount within 90 days of the sixth anniversary of the first commercial sales.

During the year, the loan of SEK 20 M from AB Svensk Exportkredit was repaid, and a three-year agreement for a credit facility of SEK 500 M and a revolving credit facility of SEK 500 M with Svenska Handelsbanken AB (publ) and Danske Bank A/S (Sweden) was signed. Only the credit facility of SEK 500 M was utilised in 2016.

Note 31
Other liabilities, current

GROUP	2016	2015
Liability to Bioverativ	496,697	459,818
Liabilities to credit institutions	—	20,000
Non-invoiced goods received	58,367	25,501
Other	97,756	69,525
Total	**652,820**	**574,844**

PARENT COMPANY	2016	2015
Liability to Bioverativ	496,697	459,818
Liabilities to credit institutions	—	20,000
Non-invoiced goods received	58,367	25,501
Other	42,117	39,888
Total	**597,181**	**545,207**

Liability to Bioverativ pertains to the current portion of the liability described in Note 30

For 2015, liabilities to credit institutions refers to the loan of SEK 20 M from AB Svensk Exportkredit, which was repaid in 2016.

Note 32
Post-employment benefits

Pension commitments are calculated annually, on the balance-sheet date, based on actuarial principles. Sobi has a defined-benefit pension plan for the subsidiary in Norway, and for two individuals in Sweden.

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

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

Risks

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

Life expectancy assumptions: Most of the pension commitments entail that the employees covered by the plan will receive life-long benefits and, accordingly, the longer life expectancy assumptions will result in higher pension liabilities. This is most significant in the Swedish plan, in which inflation increases result in higher sensitivity to changes in life expectancy assumptions.

Inflation risk: Some of the plan's pension commitments are linked to inflation. Higher inflation leads to higher liabilities (even though, in most cases, a ceiling has been set for the level of inflation to protect the plan against exceptional increases in inflation). Most of the plan assets are either unaffected by (fixed-rate bonds), or weakly correlated with (shares), inflation, which means that an increase in inflation will also increase the deficit.

Discount rate: A decrease in the interest rate on corporate bonds will increase the liabilities of the plan, although this will partially 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 commitments for retirement and family pensions are insured through Alecta. According to the Financial Reporting Board's statement UFR 10 Accounting for pension plans in ITP 2 *financed through insurance with Alecta,* this is a defined-benefit plan covering multiple employers. For the 2016 financial year, the company did not have access to information enabling a presentation of its proportionate share of the plan's commitments, plan assets or expenses, which meant it has not been possible to recognise the plan as a defined-benefit plan. The ITP 2 pension plan is therefore

recognised as a defined-contribution plan. The premium for the defined-benefit retirement and family pension is calculated on an individual basis, and dependent on such factors as salary, previously earned pension and expected remaining period of service. Expected contributions in the next reporting period for the ITP 2 pension plans insured through Alecta amount to SEK 21 M (20). 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 commitments calculated according to Alecta's actuarial methods and assumptions, which are not consistent with IAS 19. The collective funding ratio is normally allowed to vary between 125 and 155 per cent. If Alecta's collective funding ratio falls below 125 per cent, or exceeds 155 per cent, action should be taken to create the conditions for returning the ratio to the normal range. If the ratio is low, one measure could be to raise the contractual price for new policies and expand existing benefits. If the ratio is high, one measure could be to introduce premium reductions. At the end of 2016, Alecta's surplus in the form of the collective funding ratio was 149 per cent (153).

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

1 January–31 December 2016	Present value of commitments	Fair value of plan assets	Total
At 1 January	**–37,874**	**28,300**	**–9,576**
Current service cost	–1,866	—	–1,866
Interest expense	–1,094	—	–1,094
Gains/losses on settlements	—	—	—
Revaluations:			
Return on plan assets, excl. amounts included in interest expense	2,177	–135	2,041
Gain/loss from change in demographic assumptions	—	—	—
Changed financial assumptions	–2,350	–36	–2,386
Experience-based assumptions	–1,400	1,791	391
Contributions:			
employer	3,328	–712	2,616
settlements	—	–277	–277
Exchange-rate differences	–1,599	749	–810
At 31 December	**–40,639**	**29,679**	**–10,960**

1 January–31 December 2015	Present value of commitments	Fair value of plan assets	Total
At 1 January	**–41,285**	**28,371**	**–12,915**
Current service cost	–1,473	—	–1,473
Interest expense	–1,047	—	–1,047
Gains/losses on settlements	—	—	—
Revaluations:			
Return on plan assets, excl. amounts included in interest expense	—	611	611
Gain/loss from change in demographic assumptions	—	—	—
Changed financial assumptions	3,924	–35	3,889
Experience-based assumptions	–1,321	–227	–1,548
Contributions:			
employer	2,029	326	2,355
settlements	—	–291	–291
Exchange-rate differences	1,299	–455	844
At 31 December	**–37,874**	**28,300**	**–9,575**

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

Both the Swedish and Norwegian plans are based on final salary.

Breakdown of the net obligation per country

	2016	2015
Sweden	–3,088	–1,704
Norway	–7,872	–7,872
Total	**–10,960**	**–9,576**

Actuarial assumptions on the balance-sheet date

Swedish pension plan	2016	2015
Discount rate, %	2.8	3.3
Expected annual inflation, %	2.0	2.0
Remaining life expectancy after retirement age, men, years	20.8	19.6
Remaining life expectancy after retirement age, women, years	23.4	22.8

Norwegian pension plan	2016	2015
Discount rate, %	2.1	2.5
Expected annual inflation, %	1.5	1.5
Remaining life expectancy after retirement age, men, years	21.3	21.3
Remaining life expectancy after retirement age, women, years	24.4	24.4

Demographic assumptions

Mortality assumptions are the same as those proposed by the Swedish Financial Supervisory Authority in force from 31 December 2007 for the Swedish pension plans, while the K2013 BE mortality table has been used for the Norwegian plan. At the balance-sheet date, Norway had seven active employees and Sweden had one active employee and one retiree. The retirement age is set at 65 years.

>> Note 32, cont.

Breakdown of asset class

	2016	Quoted in %	2015	Quoted in %
Equity funds[1]	8,601	100	9,230	100
Interest-bearing securities	17,281	100	11,913	100
Properties	527	—	1,070	—
Other funds	3,243	—	5,898	—
Other	27	—	189	—
Total	**29,679**		**28,300**	

1. The assets are managed by Procordias Pensionsstiftelse. Some of their equity funds, for example the AMF Aktiefond Sweden, have holdings of Sobi shares.

Sensitivity analysis

	2016	2015
Pension commitment under current assumptions	40,639	37,874
Discount rate –0.5%	45,018	41,651
Discount rate +0.5%	36,767	34,539
Inflation +0.5%	43,558	39,265
Inflation –0.5%	37,839	34,988
Life expectancy after retirement –1 year	38,257	35,831
Life expectancy after retirement +1 year	42,403	39,344

The above sensitivity analyses are based on a change in one assumption, while all other assumptions remain 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 commitments to significant actuarial assumptions, the same method (present value of the defined-benefit commitment by 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 statement of financial position.

Other information

For the 2017 financial year, contributions to plans for post-employment benefits are expected to be SEK 1,336 K (1,056). The weighted average maturity of the commitment is an estimated 35.3 years.

Note 33

Provision for pension commitments

	Group		Parent Company	
	2016	2015	2016	2015
Provision at 1 January	9,576	12,915	—	—
Redemption of defined-benefit pension plan	—	—	—	—
Payments and actuarial revaluations	4,000	–984	—	—
Provisions for the year	–2,616	–2,355	—	—
Provisions at 31 December	**10,960**	**9,576**	**—**	**—**

See also the Consolidated statement of changes in equity, and Note 32.

	Group		Parent Company	
	2016	2015	2016	2015
Non-current	10,960	9,576	—	—
Current	—	—	—	—
Total provisions	**10,960**	**9,576**	**—**	**—**

Note 34

Accrued expenses and deferred income

GROUP	2016	2015
Provision for vacation pay and bonuses, incl. social security contributions	239,037	193,407
Accrued social security contributions	48,334	60,468
Accrued royalty expense	26,614	17,573
Discontinuation of Multiferon	—	9,848
Accrued manufacturing costs	41,143	27,406
Accrued R&D expenditure	45,782	18,088
Accrued interest expense	253	2,561
Accrued consulting and travel expenses	14,738	15,118
Accrued discounts	176,435	148,488
Accrued expenses for audit and Annual Report	3,762	3,418
Other accrued expenses	213,202	53,493
Total	**809,300**	**549,868**

PARENT COMPANY	2016	2015
Provision for vacation pay and bonuses, incl. social security contributions	134,958	125,997
Accrued social security contributions	34,676	52,700
Accrued royalty expense	26,189	16,926
Discontinuation of Multiferon	—	9,848
Accrued manufacturing costs	27,731	15,887
Accrued R&D expenditure	45,782	18,088
Accrued interest expense	253	2,561
Accrued consulting and travel expenses	4,893	5,659
Accrued expenses for audit and Annual Report	2,149	1,984
Other accrued expenses	182,294	33,412
Total	**458,926**	**283,062**

Note 35

Pledged assets and contingent liabilities

GROUP	2016	2015
Pledged assets		
Floating charges	—	200,000
Total	**—**	**200,000**

PARENT COMPANY	2016	2015
Pledged assets		
Floating charges	—	200,000
Total	**—**	**200,000**

	2016	2015
Contingent liabilities		
Guarantee commitment	19,915	6,000
Total	**19,915**	**6,000**

Floating charges consists of pledged assets and guarantee commitments consists of contingent liabilities. The parent company's guarantee commitment 2016 for the subsidiaries relates to a general guarantee up to a specifically stated amount for all types of credits, such as rental guarantees, credit cards etc. that the subsidiary has to the bank, in this case Handelsbanken.

Tax and legal disputes

Sobi is not involved in significant ongoing disputes.

Note 36

The share

At year-end, Sobi's share capital was SEK 149,254,136, distributed between 272,010,948 shares with a par value of approximately SEK 0.55. Issued shares are distributed between 270,389,770 ordinary shares and 1,621,178 Class C shares. Ordinary shares carry one vote per share, and Class C shares 1/10 votes per share. All Class C shares are held as treasury shares. The Class C shares are intended to be used for the hedging of commitments under the incentive programmes. The company held 1,610,086 ordinary shares in treasury at the balance-sheet date. The Equity item represents 1.2 per cent of the total number of shares in the company.

Earnings per share

Earnings per share before dilution are calculated by dividing the earnings/loss 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/loss per share after dilution, the weighted average number of ordinary shares outstanding has been adjusted for the dilutive effect of all potential ordinary shares.

	2016	2015
Earnings/loss attributable to Parent Company shareholders	809,072	64,913
Weighted average number of ordinary shares outstanding (000s)	268,362	267,278
Earnings per share before dilution (SEK per share)	3.01	0.24
Earnings per share after dilution (SEK per share)	3.01	0.24

Note 37

Transactions with related parties

The company Orfacare related to the previous Chairman of the Board, Bo Jesper Hansson, provides consultancy regarding marketing and distribution from Sobi to Switzerland and Austria. In 2016, consultancy expenses amounted to SEK 0.7 M (1).

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

Note 38

Proposed appropriation of profit

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

SEK	
Share premium reserve	4,191,748,633
Profit carried forward	544,244,952
Profit for the year	58,694,262
Total	**4,794,687,847**

The Board of Directors proposes that no dividend be distributed for the 2016 financial year.

The Board proposes that the funds at their disposal, SEK 4,794,687,847 be carried forward.

Note 39

Significant events after the reporting period, as per 28 March 2017

- Orfadin capsules approved by Health Canada for the treatment of hereditary tyrosinaemia type-1 (HT-1).
- Armin Reininger joined Sobi as Senior Vice President, Head of Global Medical and Scientific Affairs.
- CEO Geoffrey McDonough will leave Sobi on 1 July 2017, and a search for a new CEO has been initiated.
- The first patient was randomised in the phase 2 study anaGO to evaluate efficacy and safety of Kineret (anakinra) in the treatment of acute gout.
- First patients enrolled in 24 month real-world study evaluating effectiveness of Elocta.
- New long-term safety and efficacy data of Elocta and Alprolix revealed at EAHAD.
- The EC approved new dosing frequency for Orfadin.
- Long-term safety and efficacy data for Alprolix published in the Lancet Haematology.
- Discussions confirmed regarding a possible sale of Partner Products.
- Haemophilia B development portfolio expanded by adding rFIXFc-XTEN to collaboration agreement with Bioverativ.
- New distribution agreement entered with Valeant for Ammonul.
- EMA approves higher capacity drug substance manufacturing for Elocta.
- Long-term safety and efficacy extension study data of Alprolix for haemophilia B published in Thrombosis and Haemostasis.
- FDA approves in-use storage at room temperature for Orfadin capsules.

The Board of Directors and the CEO certify that the consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and provide a fair and true description of the Group's financial position and results. The annual accounts have been prepared in accordance with generally accepted accounting principles in Sweden and give a true and fair view of the Parent Company's financial position and results.

The Directors' Report for the Group and Parent Company provides a fair overview of the Group's and the Parent Company's operations, financial position and results, 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 to the Annual General Meeting on 4 May 2017 for adoption.

Stockholm, 28 March 2017

Håkan Björklund
Chairman

Annette Clancy
Board Member

Matthew Gantz
Board Member

Theresa Heggie
Board Member

Lennart Johansson
Board Member

Jeff Jonas
Board Member

Helena Saxon
Board Member

Hans GCP Schikan
Board Member

Catarina Larsson
Employee representative

Bo-Gunnar Rosenbrand
Employee representative

Geoffrey McDonough
Chief Executive Officer

Our audit report was submitted on 12 April 2017
Ernst & Young AB

Björn Ohlsson
Authorised Public Accountant

A platform for continued success

I am very pleased to be completing my inaugural year as Chairman of the Board at Sobi. Sobi has gone through transformational change over the past five years – delivering very strong operating results which have set the financial and strategic foundation for an exciting future.

The launches of Elocta and Alprolix mark a critical inflection point for the company, as these products are entering a multi-billion Euro market segment in our territory throughout Europe and the Middle East. The base business continues to gain momentum, with Kineret a particular highlight this year, and our development programmes aimed at serving important patient needs have also made significant progress during the year.

Strong corporate culture

The Sobi culture springs from an energy that people from different backgrounds and cultures find in working together to follow a patient-centric approach to the business. Our values of collaboration, accountability, respect and engagement are a key source of strength for the company and sets its work environment apart.

Important common ground

The dynamics and diversity that is needed to make the right decisions for a growing organisation can also be found in the Board of Directors. We have had a constructive and close strategic and operational dialogue within the Board and with the company leadership. There is a united vision regarding Sobi's strategy going forward and the members of the Board have long experience from leading positions within the pharmaceutical and biotechnology sector as well as well-established listed companies.

Sobi's next phase

The Board's most important task now is to create the right preconditions for the leadership to bring Sobi into the next phase. The most prioritised objective is to ensure a continued successful launch of Elocta and Alprolix so that we can build resources for the growing portfolio of innovative development programmes and for the expansion of our portfolio based on accessing external assets and programmes. The key to success is dedicated work from all parts of the organisation, with a strong focus on development, collaboration and competence building. With this as the platform, Sobi will be able to continue to create value for all stakeholders with sustainably changing patients' lives for the better at the centre of our work.

Håkan Björklund,
Chairman of the Board

"The dynamics and diversity that is needed to make the right decisions for a growing organisation can be found in the Board of Directors."

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 imposed by law or regulations, Sobi applies the Swedish Corporate Governance Code without any deviations. This report pertains to the 2016 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 members to the Board and the Chairman of the Board. The AGM must be held within six months of the end of the financial year in order to decide on adopting the income statement and balance sheet and the appropriation of profits. The AGM also elects the company's auditor.

The company does not apply any special arrangements relating to the function of the general meeting of shareholders, either due to provisions in the Articles of Association or, as far as is known to the company, shareholder agreements.

The Articles of Association stipulate that the AGM is to be held in Stockholm or Solna. Sobi has not found that the composition of shareholders motivates any particular 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. An announcement that such notice has been given is published in Svenska Dagbladet.

2016 AGM

The 2016 AGM was held on 24 May 2016 in Stockholm. The Meeting was attended by 208 shareholders (228), in person or by proxy, representing about 60 per cent (63) of the total votes. Lawyer Eva Hägg was elected Chairperson of the Meeting.

The minutes and information from the 2016 AGM are available at www.sobi.com.

2017 AGM

The AGM will be held on Thursday, 4 May 2017 in the Wallenberg Auditorium at the Royal Swedish Academy of Engineering Sciences (IVA) in Stockholm, Sweden. For more information about the AGM, refer to page 133.

Shareholders, share capital, the share and voting rights

At year-end, Sobi's shareholders totalled 32,397 (21,096). Investor AB was the largest shareholder, holding 39.6 per cent (39.6) of the share capital and 39.8 per cent (39.8) of the votes. The 15 largest shareholders accounted for 68.3 per cent (71.7) of the share capital and 68.2 per cent (71.6) of the votes. No owner other than Investor AB has a direct or indirect shareholding that represents at least one tenth of the voting rights of all shares in the company. Sobi's Articles of Association contain no restrictions on how many votes each shareholder may cast at a general meeting.

The Articles of Association do not have any specific provisions regarding the appointment and dismissal of directors or about amending the Articles.

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. The evaluation of future dividends by Sobi's Board is based on several factors, including:

- the company's sustainable earnings trend;
- the company's potential for expansion and access to capital;
- the company's operating risk;
- the dividend's impact on liquidity; and
- the company's equity ratio target.

The Board proposes that no dividend be paid for 2016. Short-term, the company intends to use profits to finance the continued development and expansion of its operations.

Major internal regulations

- Articles of Association
- Board of Directors' working procedures
- CEO instructions
- Policy documents

Major external regulations

- Swedish Companies Act
- Swedish and international accounting law
- Nasdaq Stockholm's rules and regulations
- Swedish Corporate Governance Code

2. Nomination Committee

The Nomination Committee represents Sobi's shareholders and has the sole task of preparing resolutions on election and reimbursement issues at the AGM.

According to the instructions and statutes adopted by the AGM on 26 April 2013, the Nomination Committee is to consist of four members, three of whom are to represent the company's three largest shareholders on the final banking day of August 2016, based on statistics from Euroclear Sweden AB. As stipulated in the same resolution, the fourth person is to 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 that apply to Board members' independence under the Swedish Corporate Governance Code.

The 2016 Nomination Committee held three (three) meetings and also maintained contact by telephone. As a basis for its work, the Nomination Committee has taken note of the Chairman's account of the Board's work, including interviews with four Board members. The Chairman of the Compensation and Benefits Committee has left a written report of the work of the auditors. The CEO was also interviewed about the performance of the operations. The Nomination Committee also prepared recommendations to the AGM regarding Board members, the remuneration of Board and Committee members, the appointment of auditors and auditor fees, and the Chairman of the AGM.

Nomination Committee prior to the 2016 AGM

Name/Represented	Percentage of votes 31 December 2016, %	Percentage of votes 31 August 2016, %
Petra Hedengren (Chair of the Nomination Committee) Investor AB	39.8	39.8
Lennart Francke Swedbank Robur Fonder AB	4.1	3.7
Tomas Ehlin Fourth Swedish National Pension Fund	4.0	3.7
Håkan Björklund Chairman of Swedish Orphan Biovitrum AB (publ)	0.0	0.0
Total	**47.9**	**47.2**

3. Board of Directors/Chairman of the Board

Sobi is a speciality pharmaceutical company with a focus on marketing, developing and producing pharmaceutical products to treat rare diseases. The product portfolio contains products that are both marketed, and 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 of Directors is responsible for the Group's organisation and management. The Board also makes decisions regarding overall objectives, strategies, the financial structure, policies, appointment of the CEO, the remuneration of management, acquisitions, divestments and major investments. The Board approves and adopts annual reports and interim reports, and proposes a dividend, if any, to the AGM.

The Board's work is based on its working procedures, CEO instructions and the principles for the division of duties between the CEO, the Chairman of the Board, Board members and various committees established by the Board. The Board's working procedures and the CEO instructions are revised and updated once a year.

Composition of the Board

The Board of the company shall comprise at least three, and not more than twelve, members. In the 2016 financial year, the Board consisted of eight members, of whom five were re-elected and three were newly elected at the AGM on 24 May 2016, as well as two employee representatives appointed by the trade unions, and two alternates. Four of the Board members, including the employee representatives, are women. For more information about the Board, refer to pages 130–131.

Chairman of the Board

The duties of the Chairman of the Board, apart from leading the Board in its work, include monitoring the performance of the company and ensuring that important matters, in addition to those already on the agenda, are brought up for discussion as necessary. The Chairman is to consult with the CEO in strategic matters, participate in important external relationships and represent the company in ownership issues. The Chairman is also responsible for ensuring that the work of the Board is regularly evaluated and that new Board members receive adequate instruction.

Håkan Björklund was elected to replace Bo Jesper Hansen, who decided to resign from his position as Chairman. Håkan Björklund is the former CEO of Nycomed, and a Board member of several international life science companies, including Alere, Coloplast, Danisco and Lundbeck. Håkan Björklund was also a Board member of Biovitrum from 2001-2007. Håkan Björklund also serves as Industry Executive at Avista Capital Partners.

Independence

The company complies with the independence requirements of the Swedish Corporate Governance Code in that a majority of the Board members elected at the AGM are independent of the company and management, and that at least two of them are independent of larger shareholders. The table on page 127 shows the independence of the Board members on the publication date of this report.

Number of meetings

The Board is to meet at least four to six times per year, usually in conjunction with the publication of interim and annual financial statements and the AGM. Additional meetings or teleconferences are convened as necessary. The Board performs an in-depth strategic review of operations during at least one Board meeting each year. The Board has scheduled a total of nine meetings for 2017.

RESOLUTIONS, 2016 AGM

The following matters were resolved at the 2016 AGM:

- Five Board members re-elected, three new Board members elected.
- New Chairman of the Board elected, Håkan Björklund.
- EY re-elected as auditors.
- Adoption of remuneration of the Board and auditor.
- Adoption of proposed guidelines for remuneration of senior executives.
- Board and CEO discharged from liability for the 2015 financial year.

The Board's work in 2016

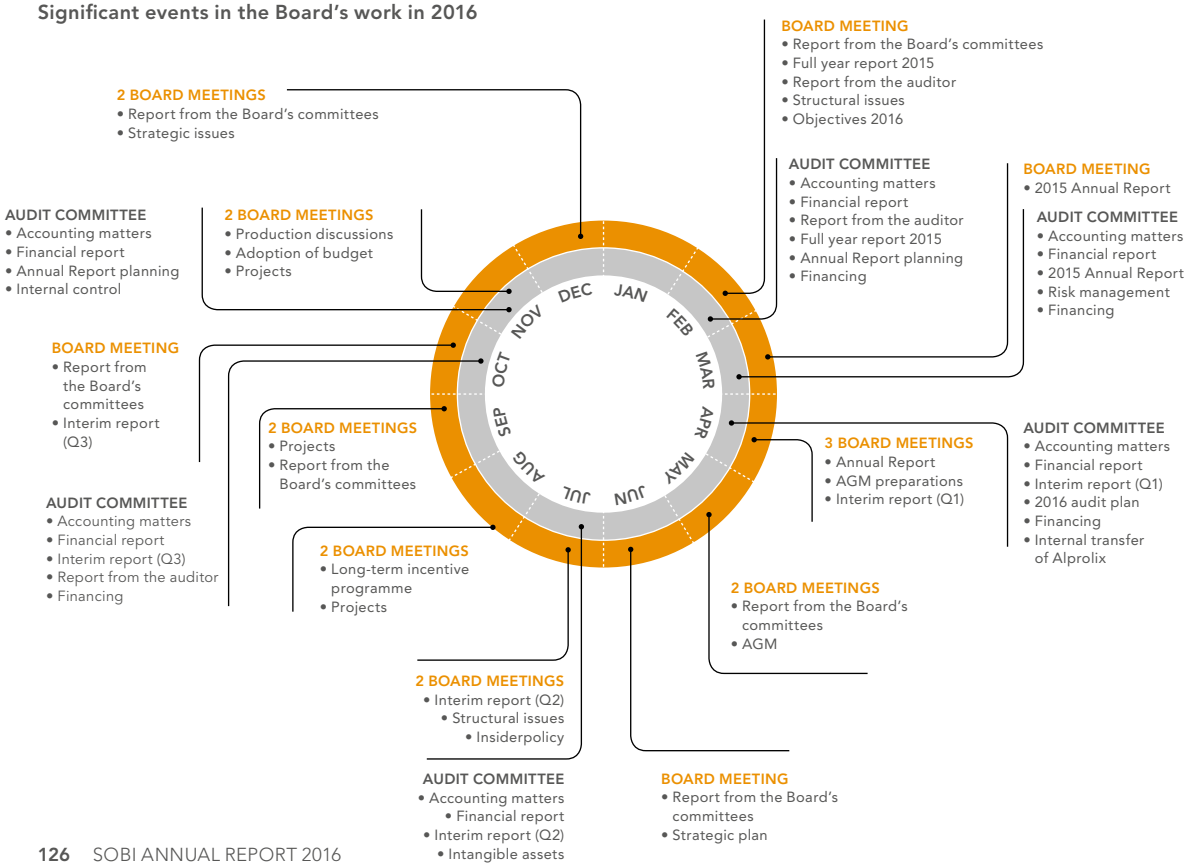
In 2016, the Board held a total of 19 meetings, of which 12 were scheduled and seven were extra meetings. Sobi's CEO and President participates in Board meetings, as does Sobi's General Counsel, who served as secretary at the meetings. Other Sobi employees presented reports. The number of extra Board meetings was motivated by discussions concerning strategic projects and extensions to product and distribution agreements. The agenda items are shown in the diagram opposite.

Board fees

The AGM on 24 May 2016 resolved that Board fees for the period until the next AGM would total SEK 4,290 K, of which a fee of SEK 365 K would be paid to each AGM-elected member except for the Chairman, who would be paid a fee of SEK 1,200 K. For Audit Committee work, the Chairman would be paid SEK 100 K and other members SEK 60 K each. For Compensation & Benefits Committee work, the Chairman would be paid SEK 70 K and other members SEK 35 K each. For Scientific Committee work, the Chairman would be paid SEK 70 K and other members SEK 35 K each. In 2016, Board fees totalled SEK 5,201 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 who live in Europe but outside the Nordic region, and SEK 20 K to Board members who live outside Europe.

For more information about the remuneration of Board members, refer to Note 12 and the table on page 127.

Significant events in the Board's work in 2016



4. Audit Committee

The Committee's main task is to address issues related to the accounting, auditing and financial reporting of the company. Sobi's Audit Committee consists of three members, all of whom are independent of management:

- Lennart Johansson (Chairman)
- Hans GCP Schikan
- Helena Saxon

Sobi's CFO serves as secretary to the Committee, but is not a member. The Committee held six meetings during the year. Sobi's elected auditors attended five of the meetings. The agenda items are shown in the diagram opposite. The attendance and remuneration of Board members at the Committee meetings are shown in the table on page 127.

5. Compensation & Benefits Committee

The Compensation & Benefits Committee's task is to recommend guidelines and principles for Sobi's remuneration programmes. This includes oversight of and proposals for the remuneration of senior executives and for long-term incentive programmes, pension plans and other issues relating to remuneration of the Company's employees. Sobi's Compensation & Benefits Committee consists of three members:

- Håkan Björklund (Chairman)
- Theresa Heggie
- Helena Saxon

All members are independent of management. Sobi's Senior Vice President Human Resources serves as secretary to the Committee, but is not a member. The Compensation & Benefits Committee held six meetings during the year. At these meetings, the Committee discussed and monitored annual salary revisions and bonus outcomes for the CEO and senior executives, and proposed guidelines and allocations for the long-term incentive programme. The proposed guidelines for remuneration of the CEO and senior executives will be presented at the AGM in May 2017 for adoption by the shareholders. The Board members' attendance at the Committee meetings is presented in the table below.

For information about salaries and remuneration of the CEO and senior executives, see Note 12.

6. Scientific Committee

The Scientific Committee's tasks include advising on scientific matters, evaluating the company's research strategies, and monitoring and reporting to the Board on scientific trends and new fields of research. The Scientific Committee consist of three members, all of whom are independent of management:

- Jeffrey Jonas (Chairman)
- Hans GCP Schikan
- Annette Clancy

Sobi's Head of Drug Design and Development serves as secretary to the Committee, but is not a member.

Jeffrey Jonas was Chairman of the Committee in 2016. Stefan Fraenkel, Senior Vice President Corporate Development, participated as a normal member at the Committee's meetings in addition to the Director of Drug Design & Development and the CEO. In 2016, the Committee's work revolved around a strategic overview of the company's research and development pipeline, especially the therapeutic areas of inflammation, and genetic and metabolic diseases. In 2016, more focus was dedicated to business development activities for the possible in-licensing of external research and pipeline programmes. The Committee held four meetings in 2016 and all members attended all or some of the meetings.

7. CEO/Leadership Team

Sobi has a functional organisation and the Leadership Team consists of the CEO and the heads of the most important functions. The Leadership Team has a broad composition of people with deep and extensive experience in R&D, and in the production and sales of drugs. In addition, members of the Leadership Team have the required skills in finance and business, law, human resources and communications. In 2016, Group Senior Management consisted of twelve members, including the CEO.

Each year, the Board determines the division of duties between the Board, the Chairman of the Board, and the CEO. Operational control is based on the decision-making procedure adopted by the Board, which is reflected in the organisational form and management model upon which Sobi works and is governed. At Board meetings, the CEO and, where appropriate, also the CFO, General Counsel and other senior executives present matters that require the attention of the Board. In 2016, the Leadership Team held one meeting every month.

For more information about the Leadership Team, refer to pages 132–133.

Remuneration of senior executives

To attract and retain talented and motivated employees, Sobi has established long-term incentive programmes. All employees receive a basic salary plus a variable salary component. The variable component, which is in accordance with a system adopted by the Board, is based on both overall company goals and individual goals. The variable salary component may not exceed 10–50 per cent of the annual salary.

For more information, see Note 12.

		Remuneration, (SEK 000s)						Attendance[1]			
	Independence	Fees	Audit Committee	Compensation & Benefits Committee	Scientific Committee	Other	Total	Board	Audit Committee	Compensation & Benefits Committee	Scientific Committee
Bo Jesper Hansen[3]	[2]	—	—	—	—	—	—	6/19	—	2/6	—
Håkan Björklund[3,4]	•	800	—	47	—	—	847	12/19	—	4/6	—
Hans Wigzell[5]	•	134	—	—	24	—	158	6/19	—	—	—
Lennart Johansson	[6]	377	107	—	—	—	484	18/19	6/6	—	—
Helena Saxon	[6]	377	64	35	—	—	477	17/19	6/6	5/6	—
Adine Grate Axén[5,7]	•	134	24	—	—	20	178	5/19	2/6	—	—
Hans GCP Schikan	•	377	40	12	35	40	505	17/19	3/6	2/6	3/4
Matthew Gantz	•	377	—	—	—	80	457	19/19	—	—	—
Annette Clancy[8]	•	377	—	—	35	240	653	15/19	—	—	3/4
Theresa Heggie[5]	•	243	—	23	—	30	297	12/19	—	4/6	—
Jeffrey Jonas[5]	•	243	—	—	47	40	330	8/19	—	—	4/4
Catarina Larsson	[9]	—	—	—	—	—	—	18/19	—	—	—
Bo-Gunnar Rosenbrand	[9]	—	—	—	—	—	—	19/19	—	—	—

1. The figures in the table show total attendance/meetings. In 2016, the Board held a total of 19 meetings, of which 12 were scheduled and seven were extra meetings.
2. Board member does not qualify as independent to the company and its management.
3. Håkan Björklund was elected new Chairman of the Board at the Annual General Meeting 2016, while former Chairman Bo Jesper Hansen resigned.
4. The fee includes the Board fee excluding social security contributions. In 2016 the gross payment to the Chairman's company was SEK 1,113 K, which includes compensation for social security contributions.
5. The Annual General Meeting 2016 elected Jeffrey Jonas and Theresa Heggie as new Board members to replace outgoing Adine Grate Axén and Hans Wigzell.
6. Board member does not qualify as independent to larger shareholders.
7. The fee includes the Board fee excluding social security contributions. In 2016 the gross payment to the Board member's company was SEK 234 K, which includes compensation for social security contributions.
8. The fee includes the Board fee and additional remuneration of SEK 200 K for extraordinary work performed in 2015, as decided at the Annual General Meeting 2016 excluding social security contributions. In 2016 the gross payment to the Board member's company was SEK 658 K, which includes compensation for social security contributions.
9. Employee representative.

8. Auditors

Sobi's auditor is the auditing firm Ernst & Young (EY), with Authorised Public Accountant Björn Ohlsson as auditor in charge. EY was elected auditor of Sobi until the end of the 2017 AGM and has been Sobi's auditor since the 2014 AGM. The external auditors discuss the external audit plan and risk management with the Audit Committee. The auditors perform a review of the interim report for the third quarter, and audit 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, 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, and a separate opinion on the Corporate Governance Report, in a presentation to the AGM. In addition, the auditors present detailed findings from their reviews to the Audit Committee three times per year, and to the Board in its entirety once per year.

For information regarding fees for the company's auditors, see Note 13.

Björn Ohlsson Authorised Public Accountant, EY

Internal control and risk management systems in relation to the financial reporting process

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. In 2016, efforts to streamline and develop procedures in the finance department continued.

The internal control environment at Sobi follows the established COSO Framework (Internal Control – Integrated Framework of the Committee of Sponsoring Organisations), comprising the following five components.

1. Control environment
2. Risk assessment
3. Control activities
4. Information and communication
5. Supervision

1. Control environment

The control environment constitutes the basis of Sobi's internal control. The control environment mainly comprises the culture on which the Board and management base their work and communication. It is the foundation for all other internal governance and control components, bringing order and structure in the form of manuals, processes and policies.

The basis for internal control of the financial reporting process consists of a clear organisational structure, decision-making processes, 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 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 issues and the regulatory environment in which the company operates.

2. Risk assessment

Effective risk assessment brings together Sobi's business opportunities and results with the requirements of shareholders and other interested parties for stable, long-term value growth and control. A prerequisite for effective risk assessment is that set targets are communicated. Risk assessment involves identifying and analysing relevant events and risks that could have a negative impact on Sobi's ability to achieve its set goals, and, as such, is the basis for risk management.

Structured risk assessment and risk management enable:

- identification and action plans for risks that may impact the adopted objectives for financial reporting; and
- identification and management of specific change-related risks.

Risk management aims to identify and minimise the number of risk factors in financial reporting, and to ensure that opportunities available within the company are used in the best possible way.

The operating units conduct risk analyses together with the controllers responsible for financial reporting. Within the framework of this process, the units are to identify and evaluate risks in the various accounting and reporting processes. In 2016, work included monitoring the units' efforts with process-based control and reporting on internal management and control. Risk management is reported quarterly to the Leadership Team, Risk Committee, Audit Committee and Board.

3. Control activities

Control activities are the manuals, processes and policies to ensure that directives and decisions are implemented. The aim of the control activities is to prevent and detect errors and deviations, and to propose corrective measures in the unlikely event that they occur. Activities include analytical monitoring and comparison of financial performance or items, account reconciliation, monitoring, checking Board decisions and Board-approved policies and procedures, approval and recognition of business transactions and partnership agreements, mandate and authorisation instructions, as well as accounting and valuation principles.

Controllers are responsible for maintaining internal control in each area and ensuring that this is developed as necessary. They follow up activities through a variety of control measures, including the monitoring of forecasts and budgets,

earnings and balance-sheet analyses, reconciliations, as well as trend analysis and market intelligence. The result of this work is reported to the management of each business area, and to management and the Board.

For information about manufacturing, refer to the general risk section.

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 of the company's employees. Guidelines for financial reporting are set out in policies, communicated to employees and 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, as well as several large meetings in which all employees participate.

The Board receives regular financial updates relating to the Group's financial position and performance.

Procedures for external information disclosure aim to provide the market with relevant, reliable and correct information about Sobi's development and financial position. Sobi has a communication policy that meets the requirements for a listed company.

To assess the relevance of information and ensure timely communication of important information to the market, a Disclosure Committee has been established, comprising the CEO, CFO, COO, General Counsel, Chief Patient Access Officer and Head of Communications.

Financial information is presented regularly in the form of:

- full-year and interim reports;
- the 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 day of publication of full-year and quarterly results and in conjunction with the release of other important information; and
- meetings with financial analysts and investors.

All reports, presentations and press releases are published on the Group's website at www.sobi.com at the same time as they are communicated to the market.

5. Supervision

Forms for supervision of the internal control are determined by the Board and the Audit Committee. Sobi's CFO is responsible for ensuring that internal control is performed in accordance with the Board's instructions. Monitoring takes place at various levels of the Group.

The Board deals with all quarterly and annual financial statements prior to publication, and follows the monitoring of internal control through the Audit Committee. The information provided is evaluated regularly. The company's auditors personally report their observations and assessment of internal controls to the Audit Committee.

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.

Activities 2016

- ERP system introduction and follow-up
- Establishment of internal control function
- Integration of Group reporting
- Visit to Sobi Middle East

Activities in focus in 2017

- Continued integration of Group reporting
- Continued work in the internal control function

Breaches

The company has not breached any of the regulations on the stock exchange on which its shares are traded, or acted contrary to generally accepted practices on the stock market.

Auditor's report on the corporate governance statement

To the general meeting of the shareholders of Swedish Orphan Biovitrum AB (publ), corporate identity number 556038-9321.

Engagement and responsibility

It is the Board of Directors who is responsible for the corporate governance statement for the year 2016 on pages 124–129 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.

Opinion

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, 12 April 2017
Ernst & Young AB

Björn Ohlsson
Authorised Public Accountant

Board of Directors

HÅKAN BJÖRKLUND

Born 1956.

Chairman and Board member since 2016. PhD, Karolinska Institutet, Stockholm, Sweden.

Other appointments: Industry Executive, Avista Capital Partners. Member of the Board of Directors, Bonesupport, Acino and Trimb.

Previous appointments: Extensive international background in the life science industry, from both R&D and sales and marketing. CEO, Nycomed. Member of the Board of Directors, Alere, Coloplast, Danisco, and Lundbeck. Board member, Biovitrum 2001-2007.

Shares: 15,800

ANNETTE CLANCY

Born 1954.

Board member since 2014.
BSc Pharmacology, Bath University, UK.

Other assignments: Non executive Chairman of the Board, Enyo SA and Lysogene SA. Member of the Board of Directors, Obseva SA. Senior European Advisor, Biopharmaceutical Team of Frazier Healthcare Ventures

Previous assignments: 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

MATTHEW GANTZ

Born 1965.

Board member since 2012.
BA, Princeton University, USA. MBA, Harvard Business School, USA.

Other assignments: Member, Life Science Pennsylvania Industry Board.

Previous assignments: Executive Vice President, BTG. Founder and CEO, Acureon Pharmaceuticals. President and CEO, Hydrabiosciences Inc.. VP Europe, Chiron's Biopharmaceutical Division. General Manager, PathoGenesis Europe. Variety of US sales and marketing roles, Abbott Laboratories Diagnostic Division.

Shares: 0

THERESA HEGGIE

Born 1960.

Board member since 2016.
BSc, Cornell University, Ithaca, NY, USA.

Previous appointments: Chief Strategy & Marketing Officer, Bupa. Senior commercial positions, Shire Human Genetic Therapies, formerly TKT, including the roles of Vice President & General Manager, EMEA, CEO, Jerini AG (a Shire acquisition) and Senior Vice President Global Commercial Operations. Vice President Marketing, Vice President Anaesthesia & Critical Care, Europe, and Vice President, Global Marketing Anaesthesia & Critical Care, Baxter – formerly Ohmeda PPD.

Shares: 0

LENNART JOHANSSON

Born 1955.

Board member since 2010.
MBA, Stockholm School of Economics, Sweden.

Other assignments: Member of the management team and Senior Advisor, Patricia Industries. Chairman of the Bord, Vectura AB. Board member, HI3G. Deputy board member, Mölnlycke.

Previous assignments: CEO, b-business partners and Emerging Technologies AB. Board member, SAAB AB, IBX Group AB and Gambro Holding AB.

Shares: 20,000

JEFFREY JONAS

Born 1953.

Board member since 2016.
MD from Harvard Medical School, USA

Other appointments: President and CEO, Sage Therapeutics. Board member, Decibel Therapeutics.

Previous appointments: Board member, Cara Therapeutics. Senior Vice President Research & Development Pharmaceuticals and President, Regenerative Medicine Division of Shire plc. Executive Vice President, ISIS Pharmaceuticals. Executive Vice President and Chief Medical Officer, Forest Laboratories. Various positions, Upjohn Laboratories. Founder, President, CEO and Chairman, AVAX Technologies. President and Chief Technology Officer, SCEPTOR Industries.

Shares: 0

HELENA SAXON

Born 1970.

Board member since 2011.
MBA, Stockholm School of Economics, Sweden.

Other assignments: CFO, Investor AB. Board member, SEB.

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

Shares: 15,500

HANS GCP SCHIKAN

Born 1958.

Board member since 2011.
PharmD, Utrecht University, Netherlands.

Other assignments: Chairman, Asceneuron, Interna Technologies and Complix. Member of the Board, Hansa Medical, Wilson Therapeutics, Therachon, and the Dutch Top Sector Life Sciences & Health. Advisor to various organisations in Life Sciences & Health.

Previous assignments: CEO, Prosensa. Director of the Supervisory Board, Prosensa. Board member, Top Institute Pharma. Chairman, Dutch Association of the Innovative Pharmaceutical Industry, Nefarma. Various senior management positions, Organon and Genzyme.

Shares: 4,000

CATARINA LARSSON

Born 1952.

Board member since 2001. Employee representative.

Laboratory engineer.

Representative of Federation of Salaried Employees in Industry and Services (PTK).

Shares: 2,983

BO-GUNNAR ROSENBRAND

Born 1963.

Board member since 2006. Deputy Board member 2001–2005. Employee representative.

Laboratory engineer.

Representative of Federation of Salaried Employees in Industry and Services (PTK).

Shares: 7,830[1]

BJÖRN OHLSSON

Authorised Public Accountant
Ernst & Young AB

1. Includes shareholdings of related physical and legal entitities.

Executive Leadership Team

GEOFFREY MCDONOUGH

Born 1970.

Chief Executive Officer.

Employed since 2011.

MD, Harvard Medical School, US, BSc Biology and BA Philosophy from University of North Carolina, US.

Other assignments: Board member of Zafgen and PTC Therapeutics.

Previous positions: Senior positions in Genzyme Corporation, CEO for Genzyme Europe, Middle East and Africa. SVP and General Manager, Personalized Genetic Health, Global Business Leader, LSD Therapeutics, US. Internist and paediatrician in the US.

Shares: 347,948

MATS-OLOF WALLIN

Born 1951.

Senior Vice President, Chief Financial Officer.

Employed since 2013.

BSc from Uppsala University, Sweden.

Previous positions: CFO, Biotage AB (publ). More than 30 years' experience in the life science industry in various executive positions at companies such as Pharmacia and Ortivus.

Shares: 76,619

ALAN RAFFENSPERGER

Born 1960.

Senior Vice President, Chief Operating Officer.

Employed since 2012.

BSc in Health Service Management, University of Maryland, Baltimore, US.

Other assignments: Chairman of the Board, Pharmanest AB.

Previous positions: CEO, Benechill Inc. Executive Director and General Manager of the Nordic and Baltic Region, Amgen. Sales and Marketing Director, Roche Pharmaceuticals. VP, Global Marketing Diabetes Care, Roche Diagnostics. CEO, SwedeMed. Pharmacia.

Shares: 153,694

LARS DREIØE

Born 1967.

Senior Vice President, Chief Quality & Compliance Officer.

Employed since 2016.

M. Sc. University of Southern Denmark, Executive MBA from Copenhagen Business School.

Previous positions: International Head of Quality at ALK. Senior postitions at Lundbeck and Novo Nordisk.

Shares: 4,732

STEFAN FRAENKEL

Born 1972.

Senior Vice President, Head of Corporate Development.

Employed since 2009.

PhD in International Economics and Management, MBA from the Copenhagen Business School, Denmark and an engineering degree from Chalmers University of Technology, Sweden.

Previous positions: Business Development and Commercial Operations, Wyeth. Management consultant.

Shares: 6,416

KIRSTI GJELLAN

Born 1963.

Senior Vice President, Head of Biologics Development & Supply.

Employed since 2014.

Pharmacist and PhD of Pharmaceutical Technology, University of Oslo, Norway.

Other assignments: Board member of Processindustriell IT and Automation (PiiA).

Previous positions: Factory Director, Biologics Manufacturing, Managing Director. Pfizer Health AB and Board member of Pfizer Health AB. Director of Quality Operations, Pfizer and AstraZeneca.

Shares: 1,292

WILLS HUGHES-WILSON

Born 1971.

Senior Vice President, Chief Patient Access Officer.

Employed since 2012.

LLB (Hons) from the University of Durham, UK.

Previous positions: Vice President Health/Market Access Policy EMEA at Genzyme Corporation. Executive Director of Emerging Biopharmaceutical Enterprises (EBE) at European Federation of Pharmaceuticals Industries & Associations (EFPIA). Government Affairs Lead in the European veterinary medicine industry association, and Ernst & Young Consulting.

Shares: 126,268[1]

DENNIS SCHMIDT PEDERSEN

Born 1970.

Senior Vice President, Human Resources.

Employed since 2013.

Trained officer from the Royal Danish Officers Academy, specialised in leadership development, analytical studies and tactics.

Previous positions: HR Director for Northern Europe at Takeda. Leading positions in international companies including Genzyme, Ferring Pharmaceuticals and A.P. Møller-Mærsk.

Shares: 11,180

MILAN ZDRAVKOVIC

Born 1970.

Senior Vice President, Head of Research & Development

Employed since 2016.

MD, PhD University of Aarhus, Denmark, MSc Pharmaceutical Medicine, University of Surrey, United Kingdom.

Other appointments: DIA Advisory Council Europe, Middle East and Africa. Board member and co-founder of Selma Diagnostics Aps.

Previous positions: Corporate Vice President, Novo Nordisk R&D organisation, responsible for diabetes, devices, growth hormone deficiency, obesity and immunology.

Shares: 0

FREDRIK BERG

Born 1955.

Vice President, General Counsel

Employed since 2001.

LLM from Stockholm University, Sweden.

Previous positions: Head of Legal/ Intellectual Property at Pharmacia AB and General Counsel for Pharmacia Europe, Middle East and Africa. Law firm Lindahl. Legal Counsel and various management positions at KabiVitrum, Procordia, Kabi Pharmacia and Pharmacia & Upjohn. Law firm Tisell & Co.

Shares: 32,352

STEPHEN JAMES

Born 1966.

Vice President, Head of Research & Translational Sciences.

Employed since 2001.

PhD in Biochemistry and Cell Biology, University of Leeds, UK. BSc (Hons) in Biochemistry and Microbiology, University of St. Andrews, UK.

Previous positions: Management positions in Research and Preclinical Development at Pharmacia & Upjohn, Pharmacia AB and Biovitrum AB. University of Dundee Research Fellow, UK.

Shares: 14,024

MARIANNE KEISU

Born 1951.

Vice President, Chief Medical Officer

Employed since 2009.

MD, PhD at Karolinska Institute, Stockholm, Sweden.

Previous positions: Clinical development and Pharmacovigilance, Astra and AstraZeneca. Swedish Medical Products Agency. Clinical haematologist by training.

Shares: 11,242

1. Includes shareholdings of related physical and legal entitities

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 2016. The annual accounts and consolidated accounts of the company are included on pages 72–122 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 2016 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 2016 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.

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.

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.

Valuation of product and marketing rights and goodwill

Per 31 December 2016 the majority of the Groups total assets were related to product rights, marketing rights and goodwill. Product rights and marketing rights are recorded at the historical acquisition value reduced by accumulated depreciation and, as applicable, impairments. Product rights and marketing rights are tested for impairment when an indication of impairment has been identified. Goodwill is recorded at a historical acquisition value and is annually tested for impairment. An impairment is recorded if the recoverable value of an asset is lower than its carrying value.

The recoverable value for the assets is based on the Company's future opportunity and ability to sell the products on the market and in that way generate cash flows. The Company's assessment is based on the internal forecast of future cash flows, interest rate, product life cycle and growth rate.

With respect to the material investments in product rights and marketing rights made during the year, the value of the assets in relation to the Company's total assets and the uncertainty connected with the calculation of the recoverable value we have determined valuation of the product rights, marketing rights and goodwill as a key audit matter in our audit.

We have in our audit evaluated the internal forecasts that the Company have based their valuation models on. The evaluation includes our assessment of the product life cycle and growth rate. The internal forecast was evaluated for reasonability in comparison to our knowledge of the Company's business and historical information as well as the Company's past accuracy in developing forecasts. We have in our audit included our internal valuation specialists for the evaluation of the valuation model and sensitivity analysis prepared by the Company.

Refer to note 2, 4 and 19 for the Company's description of the intangible assets and the impairment test. We have assessed if the disclosed information is suited for the purpose.

Accounting of liabilities to Bioverativ (Biogen)

The Company and Bioverativ collaborates regarding the development and commercialisation of the haemophilia products Elocta and Alprolix. The collaboration is regulated by agreement and defines the rights and obligations under the collaboration. According to the agreement the Company is obliged to compensate Bioverativ for half of the development costs that Bioverativ has incurred until the first commercialisation of the products on the Company's markets. The nominal value of the liabilities for development cost was USD 267 M per 31 December 2016.

The repayment of the liabilities for the 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 19 for a specification. The repayment period can therefore vary depending on the development of the two parties' sales under the period until end payment is required, which occurs six years after the first sale of each product.

The carrying value of the liabilities to Bioverativ is a net present value of the future repayments and is therefore depending on the Company's forecast of the repayment period and the net present value calculation. As the liabilities are nominated in USD the carrying value of the liabilities is also affected by revaluation into SEK. The Company has assessed that since the royalty income and expense also are nominated in USD an effective hedge relationship with the liabilities exists. Revaluation effects of the liabilities is therefore recorded in the other comprehensive income.

We have determined that accounting for the Bioverativ liabilities is a key audit matter in our audit due to (a) the significant amount that the liabilities represents in relation to the Company's financial position and (b) the complex agreement and accounting assessments required.

In our audit we have evaluated the Company's obligations and assessments made based on the agreement with Bioverativ. We have obtained the supporting documentation that the Company used to base their decisions regarding the timing of recognition of the liabilities and the timing of the repayments.

The Company's forecasts have been evaluated for reasonability by comparison to our knowledge of the Company's business, comparable companies and historical information as well as the Company's past accuracy in developing forecasts. We have evaluated the reasonability in the used discount rate.

The company's calculations have been audited by recalculation of the net present value using the assumptions evaluated by us.

We have evaluated the Company's own calculation of the hedge relationship effectiveness and audited the revaluation of the liabilities and the hedging effects in other comprehensive income.

Refer to note 2 and 19 for the Company's description of the Bioverativ 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 1–71, 123, 130–133 and 137–142. 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 also 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 scepticism 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 or when, in extremely rare circumstances, we determine that a matter should not be communicated in the auditor's report because the adverse consequences of doing so would reasonably be expected to outweigh the public interest benefits of such communication.

Report on other legal and regulatory requirements

Opinions
In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Managing Director of Swedish Orphan Biovitrum AB (publ) for the year 2016 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Director be discharged from liability for the financial year.

Basis for Opinions
We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Directors and the Managing Director
The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfil the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility
Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional 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.

Stockholm, 12 April 2017
Ernst & Young AB

Björn Ohlsson
Authorised Public Accountant

Global Reporting Initiative Index 2016

Specific disclosures – indicator overview

Aspect/Topic	Applied indicators
Customer health and safety	PR1; PR2
Access to health and medicine	EC8
Engagement with patient groups	PR5
Regulatory and legal challenges	SO4; SO5; SO8; PR2; PR4; PR9
Clinical trial ethics and safety	PR1; PR2
Employee recruitment and retention	LA1; LA6; LA11; LA12
Anti-corruption	G4-SO4, G4-SO5, G4-SO8

About this report

Sobi reports its sustainability efforts on an annual basis, as part of the Annual Report. Sobi prepares its Sustainability Report in accordance with the Core option of the latest GRI sustainability reporting guidelines, G4. The indicators below have been selected on the basis of a materiality analysis, which is further described on pages 53 of the Annual Report. The indicator overview above lists the GRI indicators that have been applied to reflect the aspects and topics considered most significant for Sobi. All page references below refer to pages in Sobi's 2016 Annual Report or at www.sobi.com

● = Fully reported ◐ = Partially reported

Standard disclosures		Page references	Reported	Comment
Strategy and analysis				
G4-1	CEO's statement	8–9, www.sobi.com	●	
G4-2	A description of key impacts, risks and opportunities	62–63, 79–80	●	
Organisational profile				
G4-3	Name of the organisation	90	●	
G4-4	Primary brands, products and services	1, 17, 24–25, 75	●	
G4-5	Location of organisation's headquarters	90		
G4-6	Countries where the organisation operates	101, 114	●	
G4-7	Nature of ownership and legal form	66–68, 76, 90, 124–125	●	
G4-8	Markets served	3, 14, 30–31, 101, 114	●	
G4–9	Scale of the organisation	68, 76	●	
G4-10	Total workforce by employment type, contract, region and gender	101	●	
G4-11	Percentage of employees covered by collective bargaining agreements		●	All employees in the Swedish operations (representing approximately 57 per cent of Sobi's employees) are covered by collective bargaining agreements.
G4-12	Describe the organisations' supply chain	60–61	●	
G4-13	Significant changes during the reporting period	4–5, 72	●	
G4-14	Whether and how the precautionary approach is applied	62–63, 78–79	●	Risk management is integrated into all strategic and operational work. There is a special procedure for the handling of hazardous chemicals, which describes the risks are identified, assessed and managed, including how the precautionary principle should be addressed.
G4-15	Endorsement of external charters, principles or initiatives	52–59, 90–94	●	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, the PhRMA & EFPIA's "Principles for Responsible Clinical Trial Data Sharing" and the EMA Policy on publication of clinical data. Sobi applies industry-specific codes of conduct (LIF and EFPIA).
G4-16	Memberships in associations	www.sobi.com	●	

Standard disclosures		Page references	Reported	Comment
Identified material aspects and boundaries				
G4-17	Organisational structure	124, 130–133	●	
G4-18	Process for defining report content	53	●	
G4-19	Material aspects identified in the process for defining report content	53	●	
G4-20	Aspect Boundaries within the organisation		●	Indicators cover all of Sobi's operations.
G4-21	Aspect Boundaries outside the organisation	53	●	
G4-22	Explanation of the effect of any re-statements of information provided in previous reports		●	There have been no re-statements of information since previous reports.
G4-23	Significant changes from previous reporting periods in the Scope and Aspect Boundaries		●	There have been no relevant changes in the Scope and Aspect Boundaries since previous reporting periods.
Stakeholder engagement				
G4-24	List of stakeholder groups	17, 53	●	
G4-25	Basis for identification and selection of stakeholders with whom to engage	17, 53	●	
G4-26	Approach to stakeholder engagement	17, 20–21, 54, 59	●	
G4-27	Key topics and concerns raised through stakeholder engagement	53	●	
Report profile				
G4-28	Reporting period		●	Calendar year 2016
G4-29	Date of most recent previous report		●	April 2016
G4-30	Reporting cycle		●	Annually
G4-31	Contact point for questions regarding the report		●	Morten Grøn, VP Head of Communications, morten.gron@sobi.com
G4-32	Table showing where information about all parts of the Standard Disclosures can be found	137–140	●	
G4-33	Policy and current practice with regard to seeking external assurance for the report		●	Sobi's Sustainability Report has not been subject to external assurance.
Governance				
G4-34	Governance structure	124	●	
Ethics and integrity				
G4-56	Values, principles, standards and norms of behaviour	16, 52–59, 77 www.sobi.com	●	Sobi's Code of Conduct and Ethics is available on www.sobi.com.

Indicators related to material aspects		Page references	Reported	Comment
ECONOMIC				
Indirect economic impacts				
Management approach		124–129, www.sobi.com	◐	
G4-EC8	Significant indirect economic impacts	15, 79–80, 95–97	●	Donation to the World Federation of Hemophilia
SOCIAL				
LABOUR PRACTICES AND WORKING CONDITIONS				
Employment				
Management approach		55–57, 77–78	●	
G4-LA1	Rate of employee turnover by age group, gender and region	101	◐	Turnover rate is not reported.

Indicators related to material aspects		Page references	Reported	Comment
Occupational health and safety				
Management approach		55–57, 77–78	●	
G4-LA6	Rates of injury, occupational diseases, lost days, absenteeism and total number of work-related fatalities, by region and by gender			In 2016, 21 incidents were reported, none of which led to sick leave.
Training and education				
Management approach		55–57	●	
G4-LA11	Employees receiving regular performance and career development reviews, by region and by gender	55–57, 77	●	All employees receive regular performance and career development reviews.
Diversity and equal opportunity				
Management approach		55–57	◐	
G4-LA12	Composition of governance bodies and employees according to diversity indicators	57, 101, 130–133	◐	
SOCIETY				
Anti-corruption				
Management approach		59 www.sobi.com	●	
G4-SO4	Communication and training on anti-corruption policies and procedures	59, 128–129	●	Issues related to anti-corruption are regulated in Sobi's Code of Conduct and Ethics and Global Policy on Anti-corruption. In Sweden, Sobi is a member of the Swedish Association of the Pharmaceutical Industry (LIF), and follows their "Ethical Rules for the Pharmaceutical Industry." These guidelines include specific rules on anti-corruption. The Sobi European organisation follows the European Federation of Pharmaceutical Industry and Associations (EFPIA) rules and standards. The rules are consistent with the WHO Code of Ethics for Pharmaceutical Marketing. The Sobi US organisation follows the Office of Inspector General, U.S. Department of Health & Human Services (OIG) and the Pharmaceutical Research and Manufacturers of America (PhRMA) rules and guidelines.
G4-SO5	Confirmed incidents of corruption and actions taken		●	In 2016, no cases of corruption involving Sobi or Sobi's employees were brought to the attention of the company's management.
Compliance				
Management approach		22–24, www.sobi.com	●	
G4-SO8	Significant fines and total number of non-monetary sanctions for non compliance with laws and regulations		●	During 2016 Sobi has not identified any non-compliance with laws and regulations, which possibly could have led to fines or non-monetary sanctions.

Indicators related to material aspects		Page references	Reported	Comment
PRODUCT RESPONSIBILITY				
Customer health and safety				
Management approach		52-54, 59 www.sobi.com	●	
G4-PR1	Percentage of significant product and service categories for which health and safety impacts are assessed for improvement	54	●	All products are assessed for health and safety impacts.
G4-PR2	Incidents of non-compliance with regulations concerning health and safety impacts of products		●	In 2016, Sobi did not identify any significant non-compliance issues. Ammonaps, for which Sobi is Market Authorisation Holder, was revoked from two markets due to shortcomings in the production at a third party. These shortcomings did not effect the health and safety impact of the product.
Products and services labeling				
Management approach		60-61 www.sobi.com	●	
G4-PR4	Incidents of non-compliance with regulations and voluntary codes concerning product and service information and labelling		●	In 2016, Sobi did not identify any non-compliance with laws, regulations or voluntary codes concerning product and service information and labelling.
G4-PR5	Results of surveys measuring customer satisfaction		●	Sobi's objective is to identify where value can be added for patients and their physicians. By creating and maintaining a dialogue with this community, and also with governments and budget holders, Sobi seeks to ensure that treatments are delivered in a sustainable way. At Sobi this is referred to as a Patient and Customer Centric Commercialisation (PC3). Sobi complies with the ethical rules of LIF (trade organisation for the research-based pharmaceutical industry in Sweden) that does not allow regular customer surveys to be conducted for prescribed pharmaceuticals.

Indicators related to material aspects		Page references	Reported	Comment
Marketing communications				
Management approach		59, www.sobi.com	●	
G4-PR7	Incidents of non-compliance with regulations and voluntary codes concerning marketing communications, including advertising, promotion, and sponsorship		●	In 2016, Sobi did not identify any non-compliance with laws, regulations or voluntary codes concerning promotion of its products.
Compliance				
Management approach		59, www.sobi.com	●	
G4-PR9	Significant fines for non-compliance with laws and regulations concerning the provision and use of products and services		●	In 2016, Sobi did not identify any non-compliance with laws, regulations or voluntary codes concerning the provision and use of its products.

2017 Annual General Meeting

2017 Annual General Meeting

Swedish Orphan Biovitrum AB (publ) will hold its Annual General Meeting on Tuesday, 4 May 2017 in Wallenberg-salen at Kungliga Ingenjörsvetenskapsakademien (IVA), Grev Turegatan 16, 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, 27 April 2017. Shareholders must notify the company of their intention to participate no later than Thursday, 27 April 2017 in one of the following ways:

- Visiting Sobi's website: www.sobi.com
- By phone: +46 (0)8-697 34 27
- 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, 27 April 2017. 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 web-site, www.sobi.com, and can also be sent to shareholders upon request.

Financial calendar 2017

January–March Interim Report	28 April 2017
Annual General Meeting	4 May 2017
January–June Interim Report	19 July 2017
January–September Interim Report	25 October 2017

The Annual Report can be downloaded in PDF format from www.sobi.com, as well as previous annual reports, interim reports and press releases.

Contact details

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Definitions

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.

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 in Australia, Canada, the EU, Japan, New Zealand, and the US for the treatment of haemophilia B, which can be used by people of all ages.

Bioverativ
Bioverativ was created as a spin-off from Biogen's haemophilia business and separated from Biogen on 1 February 2017. Bioverativ is an independent, publicly traded company, headquartered in Waltham, Massachusetts, USA. Bioverativ will continue to collaborate with Sobi on our joint development 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.

COMP
The Committee for Orphan Medicinal Products of 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.

EHL
Extended half-life.

Elocta
Elocta (efmoroctocog alfa) is a recombinant, extended half-life clotting factor VIII therapy approved in the EU and Switzerland for the treatment of haemophilia A and can be used by people of all ages. It is also approved in Australia, Canada, Japan, New Zealand, and the US where it is known as Eloctate.

EMA
European Medicines Agency.

EMENAR
A business region including Europe, Middle East, North Africa and Russia.

EURORDIS
A non-governmental patient-driven alliance of patient organisations representing 738 rare disease patient organisations in 65 countries covering over 4,000 diseases.

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 is a rare genetic disorder that can cause liver failure, kidney dysfunction and neurological problems and can be fatal if left untreated.

HTA
Health technology assessment is the systematic evaluation of the properties and effects of a health technology.

IFRIC
International Financial Reporting Interpretations Committé.

IL-1
Interleukin-1 (IL-1) is a key mediator of inflammation and driver of autoinflammatory diseases.

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 already 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).

PC3
Patient and Customer-Centric Commercialisation.

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.

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.

Solberg
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We believe that people with rare diseases should have access to treatment regardless of where they were born. This can only be achieved through multi-stakeholder dialogue and engagement, with the objective of finding shared and supportable solutions.

sobi

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