xspray
PHARMA

Xspray Pharma Annual Report 2018

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Xspray Pharma AB in brief

Xspray Pharma AB (publ) is a product development Company with multiple product candidates in clinical development. Xspray uses its innovative, patented RightSize® technology to develop improved and generic versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. The segment is the second largest in oncology, and drug prices are very high.

The Company's innovative RightSize® technology allows Xspray Pharma to gain entry as the first competitor to today's original drugs before the secondary patents expire. Xspray's goal is to become the leader in the development of improved drugs or generic versions of PKIs already marketed for the treatment of cancer, which numbered 39 in 2018. The Company's leading product candidates, HyNap-Dasa, HyNap-Sora and HyNap-Nilo, are stable amorphous versions of the three blockbuster cancer drugs Sprycel® (dasatinib), Nexavar® (sorafenib) and Tasigna® (nilotinib), respectively. The launch of the first product candidate, HyNap-Dasa, is planned to take place in 2021. The substance patent for the original drug Sprycel® (dasatinib) expires at the end of 2020, and the secondary patents in 2026, which offers Xspray's HyNap-Dasa a period of five years of semi-exclusivity before other competitors gain access to the market. The Company has patented the manufacturing technology, the equipment and the resulting products.

Xspray has been listed on Nasdaq First North Stockholm since 2017 with Redeye as its Certified Adviser.

Launch under a current patent

- The ability to launch product candidates after the expiration of the original drug's primary substance patent but before the expiration of the secondary product patents
- The original drug's secondary patents also give Xspray protection against the launch of competing products

Low development cost

- Development cost is lower than one third of the normal cost for drug development
- Total development cost is between 7 and 15 million dollar per product candidate

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Limited risk

- Proof-of-concept demonstrated
- Short development process with limited capital investment
- Clear regulatory pathway to approval
- Unique technology and active patent strategy significantly reduces risk of losing patent disputes

Short development time

- Only 2–4 years from development to market launch
- Clinical studies on healthy volunteers sufficient for registration of generics

2018 – one year closer to market launch

Xspray's focused efforts during 2018 have resulted in significant progress toward market launch of the Company's leading product candidate, HyNap-Dasa.

Significant events during the full year 2018

- Charlotta Liljebris was engaged as the new Head of R&D in January.
- In January, Xspray completed a targeted new share issue totaling 1,350,000 shares, raising approximately SEK 88 million for the Company before transaction expenses.
- In August, Xspray and NerPharMa announced that they had delivered test material for a clinical Phase 1 study with the Company's primary product candidate HyNap-Dasa, which was duly initiated.
- In September, Xspray presented positive data from the Company's clinical Phase 1 study with HyNap-Dasa which confirmed the study's primary purpose – to demonstrate bioequivalence of an optimized formulation of HyNap-Dasa compared with Sprycel®.
- The final analysis of the complete data set from the clinical Phase 1 study with HyNap-Dasa was presented in October. The study results confirmed bioequivalence of an optimized formulation of HyNap-Dasa and reinforced the conclusions that could be drawn from the preliminary data.
- Xspray's Board resolved in October to apply within 12 months for listing of the Company's shares on Nasdaq Stockholm's main list. As a result of the planned switch in listing, the Company changed its accounting policies as of the fourth quarter 2018 in order to comply with IFRS and RFR 2, and it will also simultaneously switch to a layout classified by function for the income statement.
- In November, LTI 2018, an incentive program in Xspray linked to the Company's long-term value growth was adopted.
- In December, another product patent for HyNap-Dasa was granted in the United States.
- The planned pilot study with HyNap-Sora was begun in December.
- With the aim of expanding the product portfolio, Xspray completed a targeted new share issue in December totaling 1,370,000 shares, raising approximately SEK 92 million before transaction expenses.
- In December, Xspray acquired a newly incorporated subsidiary in December in order to meet a possible future need for an expanded group structure.

Significant events after the reporting period

- In February 2019, Xspray presented positive data from a clinical Phase 1 pilot study with the Company's product candidate, HyNap-Sora.

Important milestones

2003

- ☑ Xspray Microparticles was founded, based on the development of a new nozzle that enables a unique scaling up of particle technology with supercritical carbon dioxide, financed by Karolinska Development

2004–2006

- ☑ Development of RightSize® technology with the fundamental method and design of the nozzle.

2007

- ☑ Technology scale-up demonstrated in a new pilot installation that is 10 times larger than the laboratory system

2007–2010

- ☑ Evaluation of the technology in collaboration with e.g. Roche, Novartis and Lilly

2009

- ☑ Construction of a GMP classified equipment for manufacturing of clinical test materials

2011

- ☑ Xspray switches business model from being a drug-delivery company to developing improved drugs against cancer, with a patented product portfolio

2012

- ☑ Development of the company's hybrid nanoparticle technology (HyNap)
- ☑ Focus on protein kinase inhibitors (PKIs)
- ☑ Patent applications submitted for 10 of a total of 18 marketed PKIs

2013

- ☑ Clinical proof-of-concept demonstrated for the product candidate HyNap-Nilo

2015

- ☑ Clinical proof-of-concept demonstrated for the product candidate HyNap-Dasa
- ☑ Freedom-to-operate (FTO) for HyNap-Dasa confirmed by the Swedish and US patent attorneys

2016

- ☑ Results from three clinical studies with the product candidate HyNap-Dasa
- ☑ FDA confirms that the Company's clinical trial program for HyNap-Dasa can be implemented on healthy subjects and that no studies on cancer patients are required

2017

- ☑ Xspray is listed on Nasdaq First North
- ☑ Product scale-up begins
- ☑ HyNap-Dasa demonstrates bioequivalence in clinical study
- ☑ Clinical results show that HyNap-Dasa can have less interaction between dasatinib and other drugs compared to the original

2018

- ☑ Production scale-up with the conversion and development of a new manufacturing equipment with an Italian partner
- ☑ Demonstrated bioequivalence with the product formulation of HyNap-Dasa

2019

- ☑ Finalization of the pilot bioequivalence study with HyNap-Sora
- ☐ Switched listing to Nasdaq Stockholm
- ☐ First GMP batch of HyNap-Dasa manufactured in commercial scale
- ☐ Start of registration studies with HyNap-Dasa

2020

- ☐ Results from the registration studies with HyNap-Dasa
- ☐ Submission of the FDA dossier for market approval of HyNap-Dasa
- ☐ Pilot bioequivalence study with HyNap-Nilo to establish product formulation
- ☐ Start registration studies with HyNap-Sora

2021

- ☐ FDA market approval and the launch of HyNap-Dasa in the USA
- ☐ Start registration studies with HyNap-Nilo
- ☐ Submission of the FDA dossier for market approval of HyNap-Sora

A message from the CEO

The past year was a very eventful one in the Company's history. The organization was strengthened with employees with solid experience of late phase drug development. We now have 15 employees with cutting-edge skills in our in-house developed HyNap technology and extensive experience in important areas such as regulatory affairs, quality and commercial production.

In November, we moved into new premises that allows us to develop tablets under our own management. During the year, our Italian partner NerPharMa produced GMP material for both HyNap-Sora and HyNap-Dasa bioequivalence studies using pilot-scale equipment. At the same time, they converted the premises for production equipment that will be validated and qualified for commercial production during 2019.

During October, we were able to present the results from the clinical bioequivalence study of HyNap-Dasa, our product candidate that has progressed furthest and which is an amorphous stable formulation of Sprycel® for the treatment of chronic myeloid leukemia (CML). It was a pilot study using healthy volunteers and compared two formulations of HyNap-Dasa with Sprycel®. The results were very positive and showed formal bioequivalence for one of the formulations.

"We're all looking forward to implementing the plans we have established for 2019 and becoming, in due course, a leading player in improved versions of protein kinase inhibitors that address clinically relevant needs and increase the availability of cancer drugs."

The study also showed reduced variation between the subjects. It's extremely gratifying that the study data provided such strong support for our technology and opened the way for further product candidates in our product portfolio. Preparations for the studies necessary for submission of the HyNap-Dasa dossier are now in full swing.

HyNap-Sora also enjoyed successes during the year. HyNap-Sora is a stable amorphous version of Nexavar® (sorafenib) for the treatment of liver, kidney, and thyroid cancer. The study was carried out on 14 healthy subjects with the aim to investigate the bioavailability of two different formulations of HyNap-Sora in comparison with Nexavar®. The results were positive and the study achieved its primary objective of demonstrating significantly improved bioavailability compared to the reference product. This study also showed reduced variation between subjects.

We have strengthened our patent rights, and at year-end an additional US patent for HyNap-Dasa was granted. This new HyNap-Dasa patent has the widest scope of all our composition patents in the USA, which makes it much more difficult for other companies to launch a dasatinib product based on amorphous solid dispersion in the USA over the term of the patent, i.e. until January 2033. It is Xspray's third product patent in the USA, our most important market.

On two separate occasions during the year, we were able to secure our financial position through two targeted share issues in the amounts of SEK 88 and 92 million before transaction expenses, respectively. These were undersigned mainly by a number of Swedish and international institutional investors,

including the Third and Fourth Swedish National Pension Funds and Nyenburgh.

In October, the Board resolved to apply for listing on the Nasdaq Stockholm main list. This is a logical step in our progress toward enhancing prospects for a broader shareholder base. We're ready for the task, and look forward to the change in listing planned for the end of 2019.

Bringing a finished product to market is a complicated process and I'm happy to note that the Company is characterized by great team spirit where every employee chose to purchase share options in the incentive program. Together, we're looking forward to implementing the plans we have established for 2019 and becoming, in due course, a leading player in improved and generic versions of protein kinase inhibitors that address relevant needs and increase the availability of cancer drugs.

During the year, we created excellent basis for carrying through our business plan. Together with our collaborative partners, we continue our focused efforts on creating new cancer products from well-documented protein kinase inhibitors, and becoming a profitable Company.

Solna, April 2019

Per Andersson
CEO

The Business

Xspray's objective is to become a profitable, leading Company in the development and commercialization of already marketed protein kinase inhibitors for targeted cancer therapy, of which there were 39 on the US market in 2018. The first market launch is planned for 2021 with the product candidate HyNap-Dasa.

Business idea

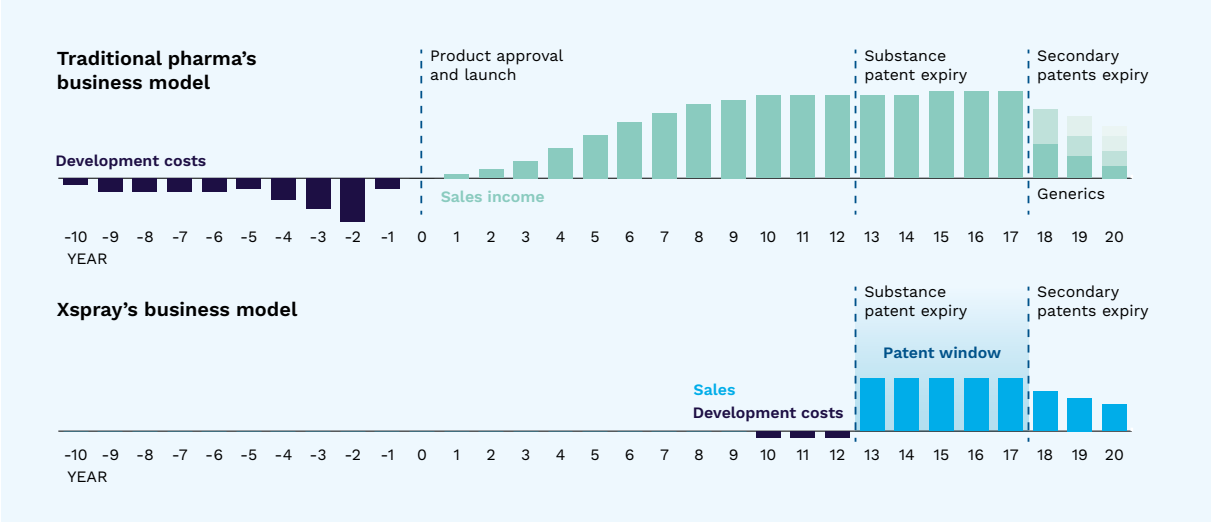
Xspray Pharma's business idea is to create value by developing and commercializing proprietary drugs based on well-documented substances that offer significant benefits for patients, and which have significant commercial potential.

Goal

The Company's goal is to become the leader in the development of improved drugs or generic versions of protein kinase inhibitors already marketed for the treatment of cancer, which numbered 39 in 2018. This will take place mainly through the use of the Company's patented technology for improving existing drugs and creating a commercially favorable patent situation. The primary business objective is to introduce the Company's products in the US market and work to prepare selected product candidates ready for launch at favorable, patent-specific times. The launch of HyNap-Dasa, the Company's first product candidate, is planned for 2021.

Vision

Xspray's vision is to use its unique technology to establish itself as the world's leading company for generic and/or improved versions of established protein kinase inhibitors for targeted cancer therapy and thus increase the patient's quality of life and chance of survival. An aggressive pricing and patent strategy will allow Xspray to take market share and create long-term profitability for the Company and its owners while improving patient access to what, to date, has been extremely expensive drugs.



Xspray's business model differs substantially from that of traditional drug companies. In general, drug development entails very large initial investments in the form of development expenses that are then recovered through high sales revenues during the remaining years of the patent. It is a risky business model. Xspray's business model is significantly less risky as development costs are limited while sales revenues continue to be good for a number of years known in advance.

Business model

Xspray's technology enables the Company's products to gain entry as the first competitor to today's original drugs before the secondary patents expire. The products can be sold semi-exclusively in selected markets in parallel with the original drugs and where attractive pricing will enable rapid market penetration and high market shares. The technology also creates relevant medical benefits for the patients. Furthermore, the Company can license the technology to partners to evaluate and improve drug candidates that are in clinical development or already launched.

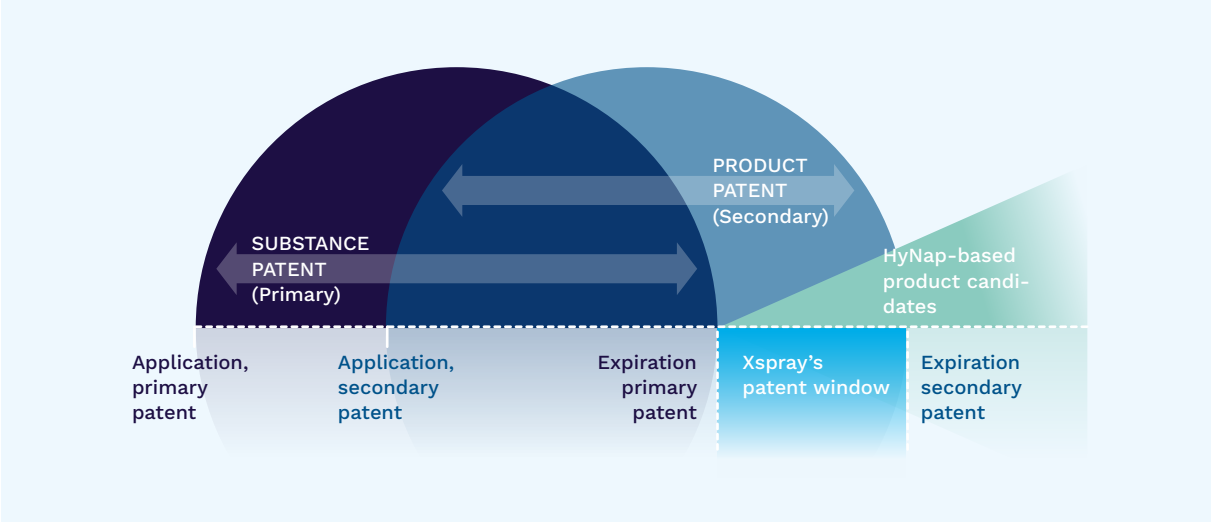
Xspray's business model is based on licensing its product candidates to bigger pharmaceutical companies with original drugs on the market, or to generic drug companies to market Xspray's products. The out-licensing will take place immediately before or after a product candidate is approved as a drug. Out-licensing is expected to provide the Company an initial payment and royalties on sales upon commercialization of the drug.

In time, the Company may establish its own sales in selected markets and thus enjoy a greater proportion of the revenues when the products come to market.

Strategy

Xspray's main strategy is to apply the Company's technology platform to its product portfolio, which comprises carefully selected product candidates with significant market potential and where Xspray is expected to have an advantageous competitive position. The technology will allow the launch of products whenever a so-called patent window arises, i.e. the time between the expiry date of the primary substance patent for the original drug and relevant secondary patents. Because Xspray's technology and products are based on amorphous formulations (HyNap), and the original drug contains a crystalline drug substance, Xspray's products are not affected by the secondary patents, which means that launch can take place with the original drug as the only competitor. This gives Xspray a unique position compared to e.g. various generic drugs that are prevented from launching during the patent window due to the valid secondary patents.

Xspray is actively engaged in seeking new patent windows by analyzing patents and business opportunities in the PKI field. Selected product candidates are planned to be ready for launch in connection with the opening of each individual PKI's patent window.



Because Xspray's technology enables the use of amorphous instead of crystalline materials, a patent window is created between the expiration of the original drug's primary substance patent and the secondary product patents. Within the patent window, Xspray is able to launch a product on semi-exclusive basis in an existing market without infringing upon the original substance's secondary product patents.

Commercialization

When Xspray began operations, the Company entered into an agreements with other drug companies where Xspray's technology was used for the partners' drug candidates. Today, the Company develops its own drug candidates by combining well-known and well-documented cancer drugs with its own innovative patented technology. The Company's primary product candidates are in different stages of development and are based on Xspray's RightSize® technology.

The Company is of the opinion that the pharmaceutical industry in general has difficulty in developing new drugs at the rate at which important drug patents expire. This is expected to increase demand for efficient lifecycle management of successful products and access to external projects.

Xspray seeks to build revenues by progressing the Company's product candidates to registration by itself in order to subsequently conclude licensing agreements with external partners who will manage marketing and sales. Xspray has identified three different potential licensee categories:

- **Original drug companies** who are thus able to both prevent significant revenue losses and gain the opportunity to launch new versions of the original drug through so-called lifecycle management. The original Company would then be in a stronger position with a patented version of the product and automatically mitigate generic replacements in pharmacies when these are brought to market.
- **Generic drug companies** who can enter the market and launch a product immediately when the primary substance patent expires and sell the product without competition from other generic drug companies. This puts them in a strong position when other generic drug companies enter the market.
- **Other drug companies in the field of oncology** who need to fill their product portfolios and launch a product before competition from generic drugs.

Xspray will also investigate opportunities for commercializing selected products itself in cases where a product is provided as a targeted specialist treatment and has orphan drug status on the US market.

Xspray intends primarily to address markets where the Company's technology and patents situation can provide Xspray's products with the so-called patent window, i.e. the period comprising the time between the expiration date of the primary substance patent for the original drug and the expiration date of the relevant secondary patents. Within this window, Xspray's products can be sold without any, or only limited, competition except from the original drug. The products are expected to take significant market shares from the original drugs through attractive pricing.

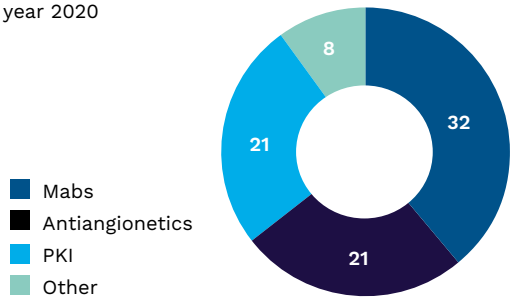
Initially, the Company intends to focus on the US market and thereafter on the European market. The strategy of focusing on one market at a time is aimed essentially at reducing the initial capital requirement. Commercial profit margins are also estimated to be higher in the USA since protein kinase inhibitors have much higher prices on the US market.


VWR

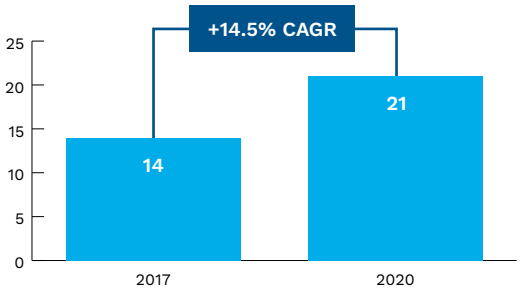
The Market

Xspray develops improved generic versions of patented cancer drugs based on protein kinase inhibitors (PKIs). The segment is the second largest within the field of oncology with more than 300 drug candidates in clinical development and 39 approved drugs on the US market. Xspray's technology has the potential to be applied to the majority of these drugs.

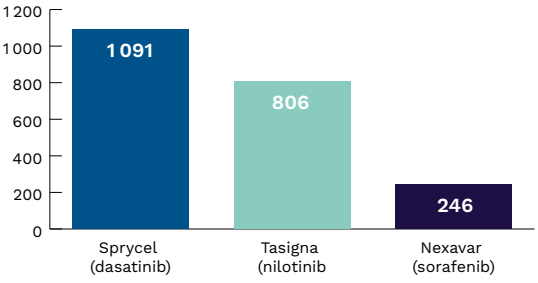
US Oncology Product Sales
Sales forecast distribution year 2020



US PKI Sales Forecast
Year 2017–2020, USD billion



US Sales 2018
(MUSD)



Source: Evaluate Pharma.

According to Global Oncology Trends 2018, IQVIA Institute, a total of 17 million people around the world became ill with cancer in 2018. According to WHO, this figure is anticipated to rise by 62 percent in 20 years and afflict almost 27 million people. In the USA alone, 2.1 million people were diagnosed with cancer in 2018.

Total global sales of cancer drugs in 2017 amounted to USD 133 billion. Of this amount, USD 24 billion went to supporting care when no alternative treatment remains. Since 2012, the market for cancer drugs in the USA has increased to almost USD 50 billion, of which two thirds of the growth concerns new drugs developed during the past five years. Global sales of cancer drugs are anticipated to increase on average by 10–13 percent to USD 200 billion by 2022. In the USA, the market is expected to increase to USD 100 billion by 2022 with an average growth of 12–15 percent.

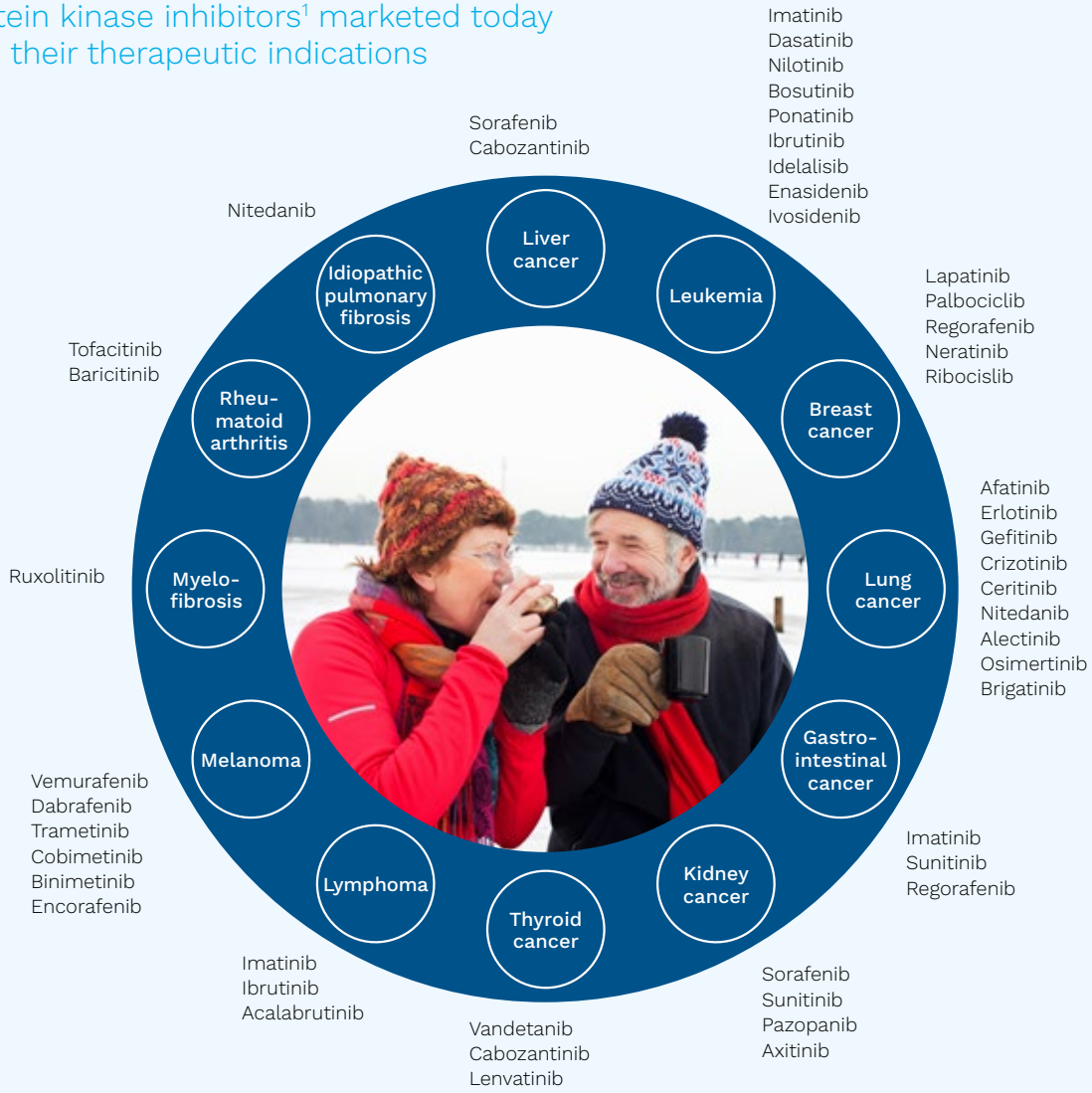
Protein kinase inhibitors

With annually increasing sales figures, protein kinase inhibitors constitute the second biggest segment for targeted cancer therapies. All of the PKI-based drugs marketed today are intended for the treatment of patients with various forms of cancer. Only one PKI product (Xeljanz®, tofacitinib) is indicated for the treatment of patients with rheumatoid arthritis.

In 2017, sales of PKIs on the US market were almost USD 14 billion, and are anticipated to increase to more than USD 21 billion by 2020. Protein kinase inhibitors are a growing segment with more than 300 drug candidates in clinical development, of which around 250 are in late clinical phases (Phases 2 or 3).

Of the 39 protein kinase inhibitors marketed today in the field of cancer treatment, 25 substance patents are expected to expire in the USA until 2030. These include many blockbuster drugs such as Sprycel®, Tasigna® and Nexavar®, which are also the original

Protein kinase inhibitors[1] marketed today and their therapeutic indications



[1] Substance name

drugs upon which those of Xspray's product candidates closest to launch are based.

The original drugs Tasigna®, Sprycel® and Nexavar® had combined sales of USD 2 billion in the USA alone during 2018. Tasigna® and Sprycel® are both indicated for the treatment of patients with newly diagnosed Philadelphia chromosome positive (Ph+) chronic myeloid leukemia (CML) in its chronic phase. Sprycel® is also indicated for the treatment of patients with Ph+ acute lymphocytic leukemia (ALL) and lymphoblastic leukemia CML with resistance or intolerance toward previous treatment. Nexavar® is used for treatment of patients with hepatocellular carcinoma, renal cell cancer and differentiated thyroid cancer.

Xspray will continue to grow its product portfolio with new product candidates through the use of its unique in-house developed technology.

Industry trends

During the next few years, it is estimated that drugs worth more than USD 267 billion will be exposed to generic competition. The pharmaceutical industry has difficulty in developing new drugs at the rate at which patents for many important drugs expire. This will increase demand for the efficient lifecycle management of successful products and access to external projects, which will result in more license agreements and acquisitions.

Technology, production & patents

Xspray's projects are based on the Company's patented RightSize® technology. Clinical trial materials for Xspray's clinical studies and finished products for future commercial sale are supplied by the Company's strategic pharmaceutical production partner, NerPharMa S.r.l. in Milan, Italy.

Xspray's products are entirely amorphous

Many new and existing drug molecules display low or almost no solubility, which can be a challenge when developing formulations and result in a product with low oral absorption. One way of improving oral absorption is to use an amorphous form of the active substance as it has higher energy and dissolution rate than the crystalline substance. The crystalline form is defined by a specific three-dimensional organized structure, while the amorphous form is defined as lacking such a structure.

The most important aspect in the development of an amorphous product is its stability during storage. Amorphous products tend to revert to a more stable, crystalline state during storage, which can lead to the loss of its therapeutic effect.

Because Xspray's products are entirely amorphous without any crystallinity, and since this is crucial for the Company's business model, Xspray uses the most sensitive methods of analysis available today to ensure its product candidates are 100 percent amorphous.

The most common technique for stabilizing an amorphous form in a fixed state is to include an excipient to form a so-called solid dispersion, which protects the active substance from crystallization during storage. Even if this method has been known for many years, there are only a small number of formulations on the market based on this principle, which illustrates the difficulties inherent in this formulation strategy.

RightSize® technology

Purely amorphous substances tend to revert to crystalline forms over time. Xspray's RightSize® technology forms a solid dispersion of the active substance (HyNap). Today, Xspray has stability data regarding several substances confirming that the Company's HyNap material remains amorphous and without traces of crystals for more than two years at room temperature, and can therefore become products with long shelf lives.

The technology is scalable

Molecules in a supercritical state can move quickly as in a gas, while the ability to dissolve substances is good, such as in a liquid. The supercritical liquid is used as an antisolvent for controlled particle precipitation of the active pharmaceutical ingredient (API) with or without the addition of excipients. Supercritical fluid (SCF) technology was developed in the pharmaceutical industry during the 1990s. Despite major investments in SCF installations and its known advantages, it was not possible to convert the technology for commercial production due to scale-up problems. Xspray has overcome this obstacle with its own technology. In one example, productivity was increased a hundredfold compared to the previously published results.

Xspray's technology enables robust production of solid dispersions according to a bottom-up process (the formation of particles from a solution). There is currently no [other] production-scale technology that produces amorphous PKI formulations in this way. The established top-down process in which large particles are ground to form smaller ones has many disadvantages in the subsequent separation and processing.

Manufacturing

In 2018, Xspray engaged NerPharMa S.r.l. to produce material for Xspray's clinical program and finished product for future commercial sales. NerPharMa is an established Contract Manufacturing Organization (CMO) located outside of Milan, Italy, and a subsidiary of Nerviano Medical Sciences S.r.l.

NerPharMa has extensive experience in producing drugs for clinical trials and commercial sales in both the USA and Europe. NerPharMa's production facility is GMP classified and approved by the US Food and Drug Administration (FDA). NerPharMa's focus on cancer drugs makes it well suited as a collaborative Xspray's partner.

Xspray's unique commercial-scale HyNap equipment is in place and installed in NerPharMa's premises. Before production of amorphous material begins for the crucial clinical studies, stability studies and commercial production, the equipment must undergo an extensive validation and qualification process, which is progressing according to plan.

A stable solid dispersion of the drug substance is made at NerPharMa's production facility. The material is then shipped to a CMO in the USA for final tablet production. As part of the collaboration, NerPharMa has delivered e.g. clinical trial material for Xspray's Phase 1 studies with HyNap-Dasa and HyNap-Sora.

Patents and other intellectual property rights

Xspray's intellectual property rights are protected mainly through patents and patent applications. Submitted patent applications provide protection equivalent to a patent, given that a patent is subsequently granted. The Company's patent portfolio includes five patent families with granted patents and patent applications. Patents and patent applications apply in commercially important countries such as the USA, Europe, Japan, China and Canada. The granted patents provide protection until 2024–2033.

Xspray pursues an active, well-planned patent strategy based on protecting its ownership position by applying for patents at the international level related to the Company's proprietary technology, inventions and improvements that are important for development and the business operation. The Company is currently not dependent on licenses but uses its own patented and patent pending technologies and products.

Product platform

Xspray is a product development Company with multiple product candidates in clinical development. Xspray's primary business objective is to introduce the Company's products in the US market and work to prepare selected product candidates ready for launch at favorable, patent-specific times. The first product candidates are of the protein kinase inhibitors HyNap-Dasa, HyNap-Sora and HyNap-Nilo, of which HyNap-Dasa is planned for launch in 2021.

Two product development strategies

Xspray has two product strategies. The first is to develop generic drugs, i.e. pharmaceutically and therapeutically equivalent versions of previously approved products for which there is a patented window allowing semi-exclusive product sales in parallel with the original drug. In the US market, such products may be registered through abbreviated new drug registration procedure (ANDA) under section 505(j) of the Federal Food, Drug and Cosmetic Act.

The other strategy is to develop improved versions of previously approved products for which there exist patent windows and where the products can be sold semi-exclusively alongside the original drugs. In the US market, such products may be registered under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act.

Xspray exploits the advantage the Company's amorphous product candidates have regarding significantly lower development cost and development times where both product strategies mean that the Company only need carry out Phase 1 studies in healthy subjects before product registration.

The Company also endeavors to invest in drugs with orphan drug designation (ODD). This type of drugs often have high , for which reason the effect of attractive pricing can be expected to have a major impact on the captured market share and rapid market penetration.

Multiple product candidates under development

Xspray's product portfolio is under constant development and hitherto comprises seven product candidates based on the Company's HyNap platform, of which four have not been made public. All of them are generic versions of established, marketed drugs (protein kinase inhibitors) for the treatment of cancer. The original drugs underlying Xspray's product candidates have secondary patents that expire between 2026–2029, and their total combined annual sales in 2018 exceeded USD 2 billion in the US market.

Protein kinase inhibitors are remarkably effective in the treatment of various forms of cancer. Unfortunately, many patients suffer side effects from PKIs, in some cases fatal. PKIs are generally known for their toxicity, depending on the sub optimal formulations,

Orphan Drugs

The term orphan drugs is applied to those used for treating conditions that are so rare that drug companies are unwilling to develop them as the revenues from the limited market will not cover the drug's high research and development costs. Because orphan drugs are frequently used to treat rare and often life-threatening illnesses, they are generally priced higher than drugs that lack orphan drug status. In recent years, the average annual cost per patient has been almost 4 times higher for orphan drugs than for other drugs.

Xspray's first three product candidates under development, HyNap-Dasa (dasatinib), HyNap-Sora (sorafenib) and HyNap-Nilo (nilotinib) are all improved versions of cancer drugs with orphan drug status intended for several indications. The original drugs Sprycel® (dasatinib) and Tasigna® (nilotinib) are both orphan drugs for the treatment of chronic myeloid leukemia. Sprycel® is also an orphan drug for the treatment of Philadelphia positive acute lymphocytic leukemia and Tasigna® for the treatment of gastrointestinal stromal tumors. Nexavar® (sorafenib) is an orphan drug for the treatment of kidney cancer, liver cancer and several forms of thyroid cancer.

Announced product candidates

Xspray product-candidate	Drug substance	Product	Original manufac-turer	Indication	Substance patent expiration	Patent window
HyNap-Dasa	Dasatinib	Sprycel®	Bristol-Myers Squibb (BMS)	chronic myeloid leukemia (CML) and acute lympho-blastic leukemia (ALL)	Dec 2020	Dec 2020 – Sep 2026
HyNap-Sora	Sorafenib	Nexavar®	Bayer	liver, kidney and thyroid cancer	Jan 2020	Jan 2020 – Dec 2027
HyNap-Nilo	Nilotinib	Tasigna®	Novartis	chronic myeloid leukemia (CML)	Jan 2024	Jan 2024 – Feb 2029

and variable bioavailability inter alia because of low solubility and pH-dependent absorption Xspray's technology can solve many of the above problems with PKI product formulations, and the Company has already successfully developed product candidates with improved pharmacokinetic characteristics that provide a more beneficial therapeutic profile than existing products.

The three announced product candidates, HyNap-Dasa, HyNap-Sora and HyNap-Nilo, are stable amorphous versions of the blockbuster cancer drugs Sprycel® (dasatinib), Nexavar® (sorafenib) and Tasigna® (nilotinib) and all are indicated for targeted cancer therapy.

The original drugs have all orphan drug designations where the annual treatment cost is extremely high with a price per tablet of up to SEK 3,000. This makes aggressive pricing possible and can enable Xspray to achieve high market shares and rapid market penetration with good margins.

Launch of HyNap-Dasa in 2021

HyNap-Dasa is based on BMS's Sprycel® (dasatinib) for the treatment of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL). HyNap-Dasa is Xspray's primary product candidate with its market launch planned for 2021. The substance patent for Sprycel® expires in December 2020, and the secondary patents in 2026, which offers Xspray's HyNap-Dasa a period of five years in an semi-exclusive position before other competitors gain access to the market.

In a bioequivalence study in 2018, Xspray demonstrated formal bioequivalence for HyNap-Dasa in comparison with Sprycel®. The results from the study will form the basis for the design of the upcoming registration study for HyNap-Dasa and for the abbreviated new drug application (ANDA), the US simplified approval procedure for generic drugs.

Xspray is developing HyNap-Dasa both as a full replacement version of Sprycel® for registration in the US under an ANDA 505(j) application, or alternatively by submitting an application for an improved product under the 505(b)(2) procedure.

Xsprays products provide significant benefits

Xspray's technology results in products that can offer clear clinical advantages by:

- increasing the drug's water solubility and thus its bioavailability
- reducing variability in absorption
- reducing or eliminating the drug's pH-dependent absorption
- reducing or eliminating food-drug interaction, i.e. the effect on the drug's absorption resulting from existence of food in the stomach
- minimize drug interactions, i.e. negative interactions with other drugs taken simultaneously.

Clinical Phase 1 study with HyNap-Dasa

In a clinical bioequivalence study completed during 2018, HyNap-Dasa's bioavailability was evaluated compared with the dasatinib-based cancer drug marketed today as Sprycel® for the treatment of chronic myeloid leukemia (CML). The bioavailability of two different HyNap-Dasa tablet formulations was tested compared to Sprycel® tablets in 16 healthy subjects.

Even though the study was not planned to demonstrate formal bioequivalence, a formal bioequivalence with Sprycel® was achieved for one of the HyNap formulations. The results indicate a very high level of probability that formal bioequivalence will be achieved in an upcoming registration study with an adequate number of subjects.

Clinical Phase 1 pilot study with HyNap-Sora

In a clinical Phase 1 pilot study carried out in 2019 in 14 healthy subjects, the bioavailability of two different HyNap-Sora formulations was studied in comparison with the cancer drug sorafenib, marketed as Nexavar® for the treatment of inoperable liver cancer and advanced renal cell cancer. The results were positive and the study achieved its primary objective of demonstrating improved bioavailability compared to the original product. The study also showed reduced variation between subjects.

Shorter pathway to market

Because Xspray focuses on established drug substances, generic or improved versions of the originaldrug already evaluated in clinical Phase 2 and Phase 3 studies, the formal process toward approval is significantly less complex than when developing an entirely new drug candidate. A product candidate that is exactly like the original drug does not need to be evaluated in the major Phase 2 and Phase 3 studies, but only demonstrate bioequivalence and food-drug interaction in a clinical study on healthy subjects. The product candidate may then proceed directly to registration and thus enjoy a faster, simpler and more cost-effective pathway to the market.

Xspray's clinical test program solely in healthy subjects has been found satisfactory by the US Food and Drug Administration, which is of great importance to Xspray as it entails lower development cost and shorter development times. Clinical studies on patients are significantly more expensive and take substantially more time. Thus, Xspray's product candidates can be expected to enjoy clear, short pathways to market. Initially, Xspray's primary goal is to introduce its first product candidates on the US market.

Market potential for Xspray's product candidates

Analyses of current market values, prognoses based on calculations by analysts and the future competitive situation of the three Xspray product candidates closest to launch, were carried out by Globe Life Sciences Ltd., a renowned, independent British market survey company. The report from an evidence-based evaluation of HyNap-Dasa (dasatinib), which is under development, suggests a sales potential during the top year, i.e. the last year of the patent window, of between SEK 2.8 and 3.3 billion.

The report is based on data from the completed launch and sales of another PKI drug, Gleevec® (imatinib), a generic product whose sole competition is the original drug with the same cancer indication, CML. Xspray's share of the sales will be dependent on the royalty levels the Company can succeed to negotiate in its collaboration agreements. When Sun Pharmaceuticals introduced its generic product imatinib on the US market in 2016, it very quickly took around 60 percent market share (total USD 2.2 billion per year) from Novartis' original drug, Gleevec. This was in spite of an initial price discount of only 17 percent.

Competitors

Xspray's product candidates are stable amorphous versions of Sprycel® (dasatinib), Nexavar® (sorafenib) and Tasigna® (nilotinib). The Company intends to introduce its product candidates to the market in parallel with the original drug and will therefore compete mainly with those.

Because other possible competitors are products that could be introduced in the patent window between the original drug's primary and secondary patents, the Company has carried out a thorough competitive landscape analysis with the aid of renowned Swedish and US patent firms. The results of these analyses show that there are only a few technologies that would be able to lead to the development of similar products, and the Company does not feel such a scenario to be likely. The Company has no knowledge of any other development projects in progress with the same objectives as the Company's own product candidates.

The Share & Shareholders

Xspray was formed in 2003 and its shareshares have been listed on Nasdaq First North since September 2017. With the aim of improving conditions for a broader owner base, Xspray's Board resolved during the fall of 2018 to apply for listing of the Company's shares on Nasdaq Stockholm's main list.

About the share
Since September 28, 2017 Xspray Pharma's share has traded on the Nasdaq First North under the ticker XSPRAY with the ISIN code SE0009973563. It was introduced at a price of SEK 22.00 per share. On 31 December, 2018, the number of shares in the Company totaled 15,076,460. The share forms part of the following index: OMX Stockholm Pharma & Biotech PI.

Xspray intends to apply for listing of its shares on Nasdaq Stockholm's main list in 2019.

Share turnover and trends
In 2018, Xspray's share price increased by 10.0 percent from SEK 64 to SEK 70.40.

At year-end 2018, Xspray's market value totaled SEK 1,061 million based on the year's latest price paid of SEK 70.40. In 2018, 7,890,940 shares for a total value of SEK 571.7 million were traded on Nasdaq First North Stockholm.

Certain rights associated with the share
The Company only has one class of shares. The rights associated with shares in the Company, including rights derived from the articles of incorporation, may only be amended in compliance with the provisions of the Swedish Companies Act (2005:551). Each share in the Company entitles its holder to one vote at shareholders' meetings. At shareholders' meetings, each shareholder is eligible to vote all the shares he or she holds in the Company.

Certified Adviser
Companies belonging to Nasdaq First North Stockholm must have a Certified Adviser whose duties involve exercising certain supervision. Redeye AB is Xspray's Certified Adviser.

New share issues
During the first quarter of 2018, the Company carried out a targeted new issue of 1,350,000 new shares at an issue price of SEK 65 per share, which resulted in a share capital increase of SEK 1,350,000. The new share issue was aimed at a limited number of strategic and institutional investors and provided the company with around SEK 88 million before transaction expenses.

In the beginning of December 2018, an additional targeted issue of 1,370,000 new shares was carried out at an issue price of SEK 67 per share, which meant a share capital increase of SEK 1,370,000. This new issue was also aimed at a limited number of strategic and institutional investors. The new issue provided the Company with around SEK 92 million before transaction expenses.

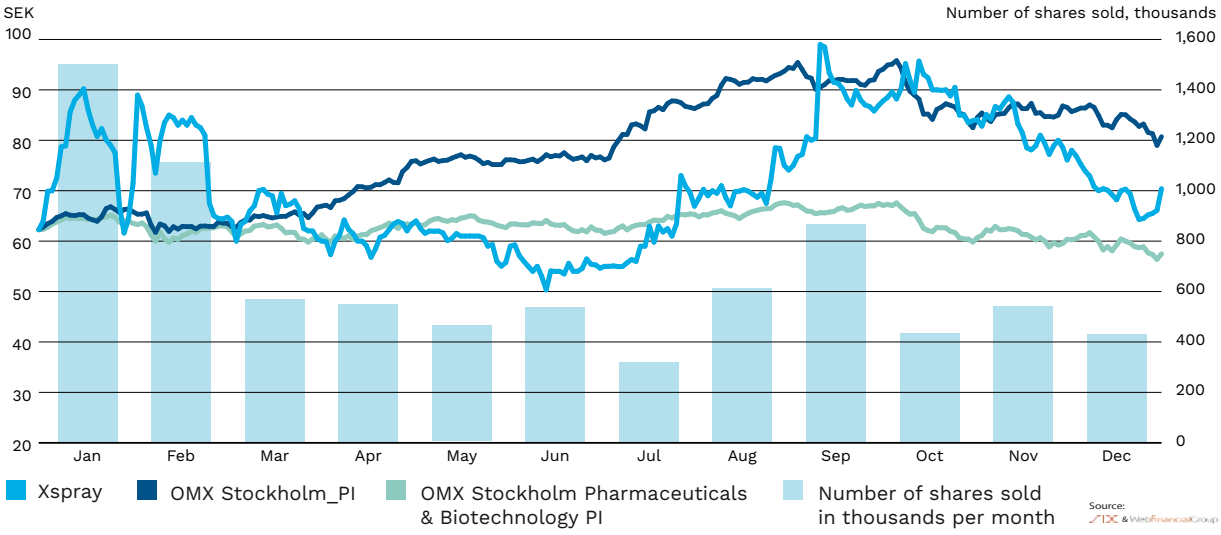
Stock-related compensation program
The Company has conducted a total of three incentive programs in the form of share warrants to senior executives and key individuals. For further information, see page 24 in the Report of the Board of Directors.

Analysts monitoring the Company
Mathias Spinnars, Redeye
Jacob Svensson, Redeye

Owners as of December 31, 2018	Number of shares	Percentage of shares & votes
Östersjöstiftelsen	2,500,826	16.6%
Ribbskottet AB	1,382,399	9.2%
Niclas Eriksson family	1,342,082	8.9%
Swedbank Robur Fonder	1,250,000	8.3%
Catella Fonder	1,141,904	7.6%
Avanza Pension	695,035	4.6%
Fjärde AP-fonden	670,000	4.4%
Unionen-Svenska	520,000	3.5%
Danica Pension	363,227	2.4%
Kåre Gilstring	310,000	2.1%
Total, ten largest owners	10,175,473	67.5%
Total, other shareholders	4,900,987	32.5%
Total number of shares	**15,076,460**	**100.0%**

Year	Event	Increase in number of shares	Total number of shares	Change in capital (SEK)	Capital after increase (SEK)	Quota value
2014	New share issue	104,768	1,243,783	104,768	1,243,783	1.00
2014	New share issue	80,323	1,324,106	80,323	1,324,106	1.00
2015	New share issue	43,354	1,367,460	43,354	1,367,460	1.00
2015	New share issue	1,849,000	3,216,460	1,849,000	3,216,460	1.00
2015	New share issue	100,000	3,316,460	100,000	3,316,460	1.00
2016	New share issue	660,000	3,976,460	660,000	3,976,460	1.00
2016	New share issue	2,380,000	6,356,460	2,380,000	6,356,460	1.00
2017	New share issue	6,000,000	12,356,460	6,000,000	12,356,460	1.00
2018	New share issue	1,350,000	13,706,460	1,350,000	13,706,460	1.00
2018	New share issue	1,370,000	15,076,460	1,370,000	15,076,460	1.00

Share price and number of shares sold



Report of the Board of Directors

The Board of Directors and Chief Executive Officer of Xspray Pharma AB (publ), domiciled in Solna, Sweden, hereby submits the Annual Report for the financial year 2018. The Annual Report has been prepared in Swedish crowns (SEK) and rounded to the nearest thousand unless otherwise indicated. Figures within parentheses refer to the corresponding period for the previous financial year.

Information about the business

Xspray Pharma AB (publ) is a product development Company with multiple product candidates in clinical development. Using its innovative RightSize® technology, Xspray is develops improved and generic versions of drugs already marketed drugs, primarily protein kinase inhibitors for the treatment of cancer. Protein kinase inhibitors make up the second largest segment in cancer drugs and are anticipated to enjoy strong growth in the years ahead. Today, there are 39 approved protein kinase inhibitors on the market, and Xspray's technology has the potential to be used on the majority of these drugs.

The business model is based on licensing Xspray's product candidates to bigger pharmaceutical companies with original drugs on the market, or to generic drug companies to market Xspray's products. The out-licensing takes place immediately before or after a product candidate is approved as a drug.

Xspray has been listed on Nasdaq First North Stockholm since 2017 with Redeye as its Certified Adviser. The Company is domiciled in Solna, Sweden; during the year, it moved into new, more suitable premises.

Important events during the year

- Xspray Pharma completed a targeted new share issue during the first quarter totaling 1,350,000 shares, raising approximately SEK 88 million before issue expenses.
- The Company hired Charlotta Liljebris as the new head of R&D.
- Xspray Pharma and NerPharMa (collaborative partner and supplier) delivered trial materials for the clinical HyNap-Dasa study, which was duly initiated. The study was completed according to plan and the promising preliminary results were presented on September 9.
- The final analysis of the complete data from the clinical Phase 1 study with HyNap-Dasa was presented on October 10. The study results confirmed bioequivalence of an optimized formulation of HyNap-Dasa and reinforced the conclusions that could be drawn from the preliminary data.
- Xspray Pharma's Board of Directors resolved to apply for listing of its shares on Nasdaq Stockholm's main list. The change in listing is expected to take place within 12 months and is being carried out in order to enhance prospects for a broader shareholder base. As a result, the Company will be changing its accounting policies in order to comply with IFRS and RFR 2, and it will also switch to an income statement layout classified by function. See below for further information.
- In November, LTI 2018 – an incentive program in Xspray linked to the Company's long-term value growth – was adopted.
- An additional product patent for HyNap-Dasa was granted in the United States.
- The planned pilot study with HyNap-Sora was begun in December.
- In order to expand the product portfolio, Xspray Pharma completed a targeted new share issue in early December totaling 1.37 million shares, raising approximately SEK 92 million before issue expenses.
- In December, Xspray Pharma acquired a newly incorporated subsidiary in order to meet a possible future need for an expanded group structure.

Accounting policies and valuation principles

During the last quarter, the Company switched to applying IFRS with the adjustments required by RFR 2 Accounting for Legal Entities. The Company will also switch to an income statement layout classified by function.

The effects of these changes and further information about the accounting policies are described in more detail in note 24. During previous periods, financial statements were prepared in accordance with the Swedish Annual Accounts Act and K3.

At the end of December 2018, Xspray Pharma AB (publ) acquired a newly incorporated subsidiary, dormant for the time being, to prepare the Group for possible future structural needs. No business activity has taken place in the subsidiary; all business is pursued in the parent Company Xspray Pharma AB (publ). Accordingly, Xspray is presenting consolidated financial statements for the first time. Because the acquisition date is at the end of 2018 and no business activities have been pursued in the subsidiary, no consolidated income statement is presented for 2018. This provides a more accurate picture of the operations as the number of transactions is limited and 2018 operations as a whole are reported in the parent Company's statements. The consolidated balance sheet will be prepared as per the closing date 12/31/2018.

Significant events after the reporting period

No events leading to adjustments in the income statement and balance sheet have occurred between the closing date and

the date of approval of this report. In February 2019, Xspray presented positive data from a pilot clinical Phase 1 study with the Company's product candidate, HyNap-Sora.

Revenues and profit/loss, (Parent company)
Net sales for the full year totaled SEK 277 thousand (332). Sales are not expected to increase before 2021, when the Company plans to launch the first product on the market under the current business plan.

Total expenses for the full year amounted to SEK -23,494 thousand (-14,228). The increase is attributable to the planned increase in expenses for the Company's clinical program and its stronger organization.

For 2018 as a whole, the Company reported an operating loss of SEK -23,217 thousand (-13,896). The net loss for 2018 totaled SEK -23,098 thousand (-13,817). Earnings per share amounted to SEK -1.70 (-1.74) for 2018 as a whole.

Financial position (Parent company)
As of December 31, 2018 total equity amounted to SEK 301,716 thousand (154,355) and the equity/assets ratio was 97% (96%). As of December 31, 2018, the number of shares totaled 15,076,460.

The Company's operations are financed mainly through equity and its financial position is deemed to be good in relation to the Company's future development plans.

Given that the business is currently in a pre-commercial stage without sales revenues, the Board resolved to propose to the AGM that no dividend will be paid to shareholders in 2019.

In general, the Group's financial position corresponds to that of the parent company as the Group was not formed until December 31 in connection with the Company's acquisition of a newly incorporated subsidiary, which is dormant for the time being.

Cash flow and investments (Parent company)
Total cash flow for 2018 resulted in a net inflow of SEK 105,704 thousand (86,709). Cash flow from operating activities totaled SEK -17,746 thousand (-11,658). The effect from working capital totaled SEK 1,251 thousand (993).

Cash flow from investments totaled SEK -47,008 thousand (-24,016). The major part consists of expenditures for developments in progress that were capitalized according to plan. Activated development expenses during the last quarter amounted to SEK 9,520 thousand (6,874), and for the full year to SEK 31,965 thousand (21,247). As of December 31, 2018, capitalized expenditures for development and similar works amounted to SEK 71,850 thousand (39,885). This is where the greatest effect associated with switching accounting policies to IFRS occurs, as certain indirect expenses previously capitalized are now reported as an expense. However, the adjustments do not constitute significant amounts; see note 22 for further info.

Investments were also made in new premises as the company moved during the latter part of 2018 into new, more suitable premises.

Cash flow from financing activities totaled SEK 170,458 thousand (122,384). A targeted new share issue aimed at a limited number of strategic and institutional investors was carried out during the first quarter of 2018 and brought in proceeds of around SEK 88 million before transaction costs. In the beginning of December 2018, a further targeted new share issue was carried out, and this was also aimed at a limited number of strategic and institutional investors. The new issue provided the Company with around SEK 92 million before transaction costs.

Xspray had SEK 221,216 thousand (115,512) in cash and cash equivalents as of December 31, 2018.

Parent company
At the end of 2018, the parent company acquired a newly incorporated subsidiary, dormant for the time being, to prepare the Group for possible future structural needs. No business activity took place in the subsidiary during the year; all business is pursued in the parent company Xspray Pharma AB (publ).

Personnel & compensation to senior executives
The organization continued to grow and by the end of the financial year, the number of employees in the Group totaled 15 (6). The average number of employees totaled 11 (6). The subsidiary had no employees as of the closing date.

Xspray must offer levels of compensation and employment conditions on market terms to enable the recruitment and retention of senior executives and key expertise.

All pension commitments must be based on defined contributions.

See below for further information about compensation and incentive programs.

Agreements under market terms between the Company and Board representatives are in place. See also note 22.

Nomination committee
The nomination committee for the 2019 AGM consists of:
- Gillis Cullin, appointed by Östersjöstiftelsen
- Anders Bladh, appointed by Ribbskottet AB
- Niclas Eriksson, appointed by the Niclas Eriksson family with companies
- Michael Wolff Jensen (Chairman of the Board)

Before the 2019 AGM, the nomination committee must prepare proposals regarding the election of the chairman and other members of the Board, the election of the chairman for the AGM, the election of auditors, and resolutions on fees and related matters.

Compensation to senior executives is presented in note 7. No new amendments to job descriptions or policies concerning compensation to senior executives were adopted.

Environment
Xspray is actively engaged in reducing any negative environmental impact and to develop as a sustainable company. As the Company does not have any product sales, it has no environmental impact in this regard; its focus is instead on exercising responsibility in its purchases of goods, services and production and the way it uses energy and transportation.

Xspray uses an environmentally friendly production technique in which organic solvents are replaced in one

stage by carbon dioxide collected from a different emissions source e.g. brewery products, biogas or fertilizer production. Because the technique replaces a great quantity of solvents with carbon dioxide it is considered to be green manufacturing.

The work of the Board

The Company's Board comprises five members including the Chairman, who were elected at the AGM until the end of the 2019 AGM.

During 2018, the Board met 18 times. Among other things, the Board is responsible for setting objectives and strategies, ensuring the adoption of procedures and systems for evaluating objectives; the ongoing evaluation of the Company's financial performance and position, and evaluating its operational management.

The Board follows written rules of procedure that are revised and adopted at the statutory annual board meeting. The rules of procedure govern such things as Board practice, the Board's functions and the allocation of work between the Board and the CEO, and where appropriate between the Board and various committees.

The share and ownership structure

The share has been traded on Nasdaq First North under the name XSPRAY since September 28, 2017. It was introduced at a price of SEK 22.00 per share. On 31 December, 2018, the number of shares in the Company totaled 15,076,460.

The share forms part of the following index: OMX Stockholm Pharma & Biotech PI

All shares are common shares and have equal rights to the Company's profit, and each share entitles the holder to one vote at the AGM. At the AGM, each shareholder is entitled to vote the full number of shares, owned or represented, without limitation to the number of votes.

Östersjöstiftelsen (The Foundation for Baltic and East European Studies) is the only shareholder whose proportion of shares and votes is greater than 10%. As of December 31, 2018 its holding amounted to 16.6%.

New share issues

During the first quarter of 2018, the Company carried out a targeted new issue of 1,350,000 new shares at an issue price of SEK 65 per share, which resulted in a share capital increase of SEK 1,350,000. The new share issue was aimed at a limited number of strategic and institutional investors and provided the Company with around SEK 88 million before transaction expenses.

In the beginning of December 2018, an additional targeted issue of 1,370,000 new shares was carried out at an issue price of SEK 67 per share, which meant a share capital increase of SEK 1,370,000. This new issue was also aimed at a limited number of strategic and institutional investors. The new issue provided the Company with around SEK 92 million before transaction costs.

Incentive program

The Company has previously issued share options in two series, made out to senior executives.

The first share option program comprises 255,000 options at an exercise price of SEK 25.00 per share. These may be exercised no later than January 21, 2021. Fully exercised, the options result in a maximum dilution of 1.69 percent based on the current number of shares.

The second option program comprises 199,591 share options that may be exercised no later than August 2020 at an issue price of SEK 49.30. The program will result in a maximum dilution effect of 1.30 percent based on the current number of shares. The second program is conditional upon the holder remaining an employee of the Company. Both programs were subscribed on market terms determined on the basis of estimated market value.

The extraordinary shareholders' meeting of November 28 resolved to introduce an incentive program (LTI 2018) comprising a maximum of 234,505 share options linked to the Company's value growth with the purpose of creating a stronger link between the interests of key employees and those of shareholders. LTI 2018 comprised 17 persons. LTI 2018 did not apply to the Company's Board of Directors. The right to subscribe share options, in the case of deviation from shareholders' preferential rights, fell to the CEO, senior executives and other Company employees or persons who during the underwriting period have concluded an employment contract with Xspray Pharma. The share options was subscribed on market terms to a price (premium) determined on the basis of estimated market value for the options with the application of Black & Scholes valuation model and calculated by an independent valuation Institute. The value was estimated at SEK 5.83 per option based on a price per share of SEK 116.50. The Company subsidized the participants' premiums with an amount equivalent to earned premiums, which was reported as personnel costs in its entirety.

Given the full exercise of the options already issued during incentive programs previously adopted, LTI 2018 is equivalent to a maximum of around 1.5 percent of the share capital and votes after dilution (subject to any translation according to the option terms).

Business activities and prospects

Xspray Pharma is a product development company with multiple product candidates in clinical development. Xspray's technology enables the Company's products to be launched semi-exclusively in selected markets alongside the original drug immediately after the expiration of the original drug's primary patent. Because the original drug is protected from competition by secondary patents, Xspray achieves an exceptionally attractive market position since other products cannot be launched until the applicable secondary patents expire. Because Xspray focuses on established drug substances already evaluated in clinical studies, the formal process toward approval is substantially less complex than when developing an entirely new drug candidate, Xspray's drug candidates can be expected to enjoy a fast and clear pathway to the market.

The Company's first product candidates comprise HyNap-Dasa, HyNap-Sora and HyNap-Nilo. The goal is to become the leader in the development of protein kinase inhibitor products already marketed for the treatment of cancer, which numbered 39 in 2018. The launch of HyNap-Dasa, the first product candidate, is planned for 2021. The substance patent for Sprycel (dasatinib) expires at the end of 2020, and the secondary patents in 2026, which offers Xspray Pharma's

HyNap-Dasa a period of five years in a semi-exclusive position before other competitors gain access to the market. The Company has patented the manufacturing technology, the equipment and the resulting products.

The business model is based on licensing Xspray's product candidates to bigger pharmaceutical companies with original drugs on the market, or to generic drug companies to market Xspray's products. The out-licensing takes place immediately before or after a product candidate is approved as a drug.

The Company's operation and development have proceeded according to plan and prospects for achieving its business plan targets are good. Sales are not expected to increase before 2021, when the Company plans to launch the first product on the market under the current business plan.

Risks and uncertainty factors

Commercial risks

In addition to financial risks, commercial risks are primarily linked to research and development efforts. In general, the development of drugs is associated with very high risk. The R&D efforts necessary for a drug candidate to gain approval for use as a drug carry many risks including delays in development delays, higher-than-anticipated costs, failure of the drug candidates to meet efficacy xpectations and other.

The pharmaceutical industry is characterized by global competition, rapid technological development and extensive investment requirements.

When a drug is approved, there is still a risk that national or international sales fail to meet expectations and the product does not become commercially successful. A drug's market acceptance and sales are dependent on a number of factors including product characteristics, clinical documentation and outcomes, competing products, distribution channels, availability, price, subsidies/reimbursements, and sales and marketing initiatives. These circumstances can have a negative effect on the Company's future operations, financial position and profitability.

Xspray is at risk of a lawsuits for patent infringement by original companies with the additional risk of a block of up to 30 months stay on the launch of its products. Xspray is actively engaged in strengthening its patent portfolio to protect itself against such delays.

Financial risk management and the Company's procedures for asset management

The Company's activities expose it to various financial risks such as market risk, credit risk and liquidity risk.

Market risk consists mainly of currency risks. The Company collaborates with international parties and has some exposure to fluctuations in different currencies, in particular USD and EUR. Currency risk arises through future business transactions and the carrying amount of assets and liabilities. The current extent of the Company's operations means that its net exposure in foreign currencies is limited.

The credit risk for cash and cash equivalents is considered to be negligible as the counterparties are reputable banks with high credit ratings from external evaluators.

Financing risk constitutes the ability to finance projects to commercialization.

Liquidity risk is the Company's potential inability to meet its obligations. The Company manages this risk by constantly monitoring cash flow to reduce liquidity risk and ensure its ability to pay.

The Company does not pursue active trade in financial assets for the purpose of speculation.

The objective of asset management is to ensure that operations are financed through equity.

Multi-year overview, Parent Company	**2018**	**2017**	**2016**
Net sales (SEK thousand)	277	332	792
Earnings after financial items (SEK thousand)	-23,098	-13,817	-4,782
Earnings per share before dilution	-1.7	-1.74	-1.15
Earnings per share after dilution	-1.64	-1.64	-1.08
Research and development expenses as % of operating expenses	23.6	29.0	38.3
Cash and cash equivalents (SEK thousand)	221,216	115,512	28,803
Balance sheet total (SEK thousand)	312,485	160,109	51,176
Equity/assets ratio (%)	96.6	96.4	89.5
Number of employees	11	6	6

See note 23 for key ratio definitions.
The above figures refer to the parent company as the Group was not formed until December 31 in connection with the Company's acquisition of a newly incorporated subsidiary, which is dormant for the time being. The parent company's figures are therefore reported above to make comparisons between the periods easier. Figures for the Group will be reported in 2019.

Proposed appropriation of earnings

The Board and the Chief Executive Officer propose that the available earnings of (SEK):

Retained earnings	236,911,119
Loss for the year	-23,097,896
	213,813,223
be appropriated and carried forward	213,813,223

Dividend policy

The Company is currently in an expansive growth phase where any capital surpluses in the operation are invested in the operation and/or acquisitions. The Company has hitherto not allocated any dividends to its shareholders since its formation. Consequently, Xspray has not adopted any dividend policy.

The Company's performance and position is otherwise set forth in the below income statement, balance sheet and statement of cash flows with supplementary disclosures.

Corporate governance report

Xspray Pharma AB is a Swedish public limited liability Company whose shares have been traded on Nasdaq First North Stockholm since 2017. At the end of December 2018, Xspray Pharma AB (publ) acquired a newly incorporated subsidiary, dormant for the time being, to prepare the Group for possible future structural needs. No business activity has taken place in the subsidiary; all business is pursued in the parent Company Xspray Pharma AB (publ). Since its listing on First North, the Company's corporate governance is mainly based on Swedish legislation, the Company's articles of incorporation, internal rules and regulations, best securities market practices, and where relevant for the Company, the Swedish corporate governance code (**the Code**).

The Board of Xspray resolved to apply for listing of the Company's shares on Nasdaq Stockholm's main list. Consequently, the Company's accounting policies have changed as of the fourth quarter 2018 in order to meet IFRS and RFR2 regulations. Because there is no requirement for the Code to be applied by companies whose shares are admitted for trading on the First North, the Company has not applied for Code in 2018 other than in parts where it was considered relevant for the Company. The Company intends to apply the Code in full in 2019.

Shareholders

Xspray share is listed on Nasdaq First North. Share capital as of December 31, 2018 amounted to SEK 15,076,460 distributed across 15,076,460 shares with the quota value of SEK 1.00. As of December 31, 2018, Östersjöstiftelsen is the only shareholder with a holding in Xspray that represents at least one tenth of the votes of all shares in the Company. At year-end, Östersjöstiftelsen's shares and votes amounted to 16.6 percent.

All shares are common shares and have equal rights to the Company's profit, and each share entitles the holder to one vote at the AGM. At the AGM, each shareholder is entitled to vote the full number of shares, owned or represented, without limitation to the number of votes.

Shareholders' meeting

Under the Swedish Companies Act (2005:551), the shareholders' meeting is the Company's highest decision-making body. Shareholders exercise their voting rights at the shareholders' meeting. An Annual General Meeting (AGM) must be held within six months of the end of each financial year. In addition to the AGM, extraordinary shareholders' meetings may also be convened. Under Xspray's articles of incorporation, the Company's shareholders' meetings may be held in Stockholm in addition to Solna, where the Company has its registered office.

In accordance with the Company's articles of incorporation, notice convening the AGM is announced through the Official Swedish Gazette (Post- och Inrikes Tidningar) and by making the notice available on the Company's website. At the same time, an announcement that notice has been given must be placed in the Swedish business daily, Dagens Industri. Under the provisions of the Swedish Companies Act, notice to attend a shareholders' meeting or an extraordinary shareholders' meeting that will address amendments to the articles of incorporation, must be given no earlier than six weeks and no later than four weeks before the meeting. Notice to attend other extraordinary shareholders' meetings must be given at the earliest six weeks and at the latest three weeks before the meeting.

Shareholders who are registered in the shares ledger five days before the shareholders' meeting and who register with the Company no later than the date and time indicated in the notice to attend, are eligible to participate in the meeting. This day may not be a Sunday, public holiday, Saturday, Midsummer's Eve, Christmas Eve or New Year's Eve and may not fall earlier than five working days before the meeting.

Annual General Meeting 2018

Xspray's AGM for 2018 was held on May 14 in Stockholm. In addition to the usual agenda items, the AGM resolved the following:

- to reelect Michael Wolff Jensen, Hans Arwidsson, Maris Hartmanis, Carl-Johan Spak and Torbjörn Koivisto as board members until the end of the next AGM;
- to reelect Michael Wolff Jensen as Chairman of the Board until the end of the next AGM, and
- to reelect registered auditors Grant Thornton Sweden AB as the Company auditor.
- to establish, prior to the AGM, a nomination committee tasked with preparing resolutions in matters concerning elections and fees and, where appropriate, procedural matters for the next nomination committee, and to establish instructions for said committee's work and ensure that the nomination committee be established before the 2019 AGM and that it comprise the three largest shareholders in terms of votes on September 30, and who wish to participate in the nomination committee's work.
- to authorize the Board before the next AGM to pass on one or more occasions resolutions concerning new share issues equivalent to no more than ten percent of the total number of shares in the Company at the time of the AGM's resolution, and which deviate from the preferential rights of shareholders.

Extraordinary shareholders' meeting, 2018

Xspray held two extraordinary shareholders' meetings in 2018.

In accordance with the Board's proposal concerning a targeted new share issue of no more than 1,350,000 new shares, the extraordinary shareholders' meeting of February

20, 2018 resolved to increase share capital by no more than SEK 1,350,000. For further information about the new issue, see page 24 in the Report of the Board of Directors.

In accordance with the Board's proposal to introduce an incentive program (LTI 2018), Xspray's extraordinary shareholders' meeting of November 28, 2018 resolved to issue no more than 234,505 warrants involving, when fully exercised, an increase in share capital of no more than SEK 234,505, For further information about the incentive program (LTI 2018), see page 24 in the Report of the Board of Directors.

Annual General Meeting 2019

The Annual General Meeting (AGM) will take place in Stockholm on Thursday, May 23, 2019. Notice to attend will be announced by press release and publication in the Official Gazette, the Svenska Dagbladet newspaper and on the Xspray website.

Shareholders who would like an issue addressed at the AGM must submit a written request to the Board in good time before the AGM. The Board can be contacted by letter addressed to The Board of Directors, Xspray Pharma AB, Råsundavägen 12, SE 169 67 Solna, Sweden or by email to generalmeeting@xspray.com

Nomination committee

The 2018 AGM resolved to establish a nomination committee tasked with preparing resolutions prior to AGMs on matters concerning elections and fees and, where appropriate, procedural matters for the next nomination committee, and to establish instructions for said committee's work. The nomination committee must comprise the three largest shareholders as of September 30 in terms of votes, and who wish to participate in the nomination committee's work.

Instruction concerning the nomination committee's composition and work.

The Chairman of the Board must contact the Company's three largest shareholders in terms of votes according to a transcript of Euroclear Sweden AB's shares ledger on September 30, and allow each to appoint a representative, who together with the Chairman of the Board, will constitute the nomination committee. Should any of them not exercise the right to appoint a member, the right to appoint such a member will be transferred to the next biggest shareholder in terms of votes who does not already have the right to appoint a member to the nomination committee. This procedure must continue until the nomination committee comprises three members excluding the Chairman of the Board. Unless otherwise agreed, the member representing the biggest shareholder in terms of votes must be appointed chairman of the nomination committee. The Chairman of the Board may not be chairman of the nomination committee.

The Chairman of the Board must convene the nomination committee's first meeting and also, as part of the nomination committee's work, present the conditions regarding the work of the Board and the requirement for special skills etc. that may be of importance for the nomination committee's work.

The names of nomination committee members must be published as soon as the nomination committee is appointed, but no later than six months before the next AGM. The nomination committee's term of office runs from the date when its composition is made public until such time as a new nomination committee is appointed.

If any change in the Company's ownership structure takes place after September 30 but before the nomination committee's complete motions have been made public, and if a shareholder, who following this change has become one of the Company's three biggest shareholders in terms of votes, expresses a wish to the nominating committee chairman to become a member of said committee, the shareholder has the right to appoint an additional member to the nomination committee. Furthermore, the nomination committee may resolve that a member, who in terms of votes has become significantly smaller than the third biggest Company shareholder in terms of votes, must resign from the nomination committee if this is deemed appropriate.

If a member of the nomination committee resigns during the term of office or if said member is prevented from fulfilling the assignment, the nomination committee must urge the shareholder who appointed the member to appoint a new member within a reasonable time.

Should any shareholder not exercise the right to appoint a new member, the right to appoint such a member will be transferred to the next biggest shareholder in terms of votes who has not already appointed, or who has declined the right to appoint, a member to the nomination committee. Changes to the composition of the nomination committee must be made public as soon as they take place.

The nomination committee must put forth proposals on the matters listed below for presentation to the AGM for resolution:

- proposed Chairman of the meeting,
- proposed Board of Directors,
- proposed Chairman of the Board,
- proposal for Board fees and their distribution between the Chairman and other members of the Board,
- proposals for fees to members of the remuneration and audit committees (where applicable)
- proposal for auditors,
- proposal for auditor's fee, and
- to the extent considered necessary, proposals for amendments in current nomination committee regulations.

There are no special provisions in the articles of incorporation concerning the appointment and removal of Board members or changes to the articles of incorporation.

No fees will be paid to members of the nomination committee.

The nomination committee for the 2019 AGM

The Company's nomination committee for the 2019 AGM consists of: Gillis Cullin, appointed by Östersjöstiftelsen, Anders Bladh, appointed by Ribbskottet AB, Niclas Eriksson, appointed by Niclas Eriksson family with companies, and Michael Wolff Jensen (Chairman of the Board).

Board of Directors

The Boards assignments

Behind the shareholders' meeting, the Board of Directors is the Company's highest decision-making body and its highest executive body. The responsibilities of Xspray's board are governed by the Swedish Companies Act and the articles of incorporation. The Board is responsible for the Company's organization and the administration of its affairs. The Board must continually assess the Company's financial situation and ensure that its organization is designed such that the Company's accounting, asset management and its financial circumstances in general are satisfactorily controlled.

The work of the Board includes setting goals and strategies for the Company's activities, endeavoring to ensure that the organization and operation of the Company's activities are characterized by internal governance and control. Furthermore, the Board is tasked with appointing the CEO, adopting instructions for the work of the CEO and monitoring the CEO's performance.

The composition of the Board

According to its articles of incorporation, Xspray's Board must consist of no fewer than three and no more than seven members with between nil and no more than two alternates, all appointed by the shareholders' meeting. The Board currently consists of five members and no alternates. All members were elected at the AGM held on May 14, 2018 for a term until the end of the 2019 AGM. Profiles of Board members are given on pages 30–31.

Chairman of the Board

The Chairman of the Board must ensure that the work of the Board is conducted efficiently and that the Board fulfills its obligations. The Chairman of the Board is also responsible for ensuring that the Board is provided with satisfactory documentation in support of its work, and that its work is reviewed annually. The Chairman of the Board is responsible for contacts with shareholders on ownership matters and for conveying the views of the owners to the Board. The Chairman of the Board is elected by the shareholders' meeting.

Board procedures

The Board follows written rules of procedure that are reviewed annually and adopted by the statutory board meeting held in connection with the AGM. Among other things, the rules of procedure govern the Board's functions, assignments, decision-making process and procedures, and the Chairman's assignments and the allocation of work between the Board and the CEO. Instructions regarding financial reporting and the CEO instructions are also set forth in connection with the statutory board meeting.

Board committees

The Board had no committees during 2018.

Compensation to Board members

Compensation to Xspray's board members is resolved by the shareholders' meeting. The AGM of May 14, 2018 resolved that a fee be paid in the amount of SEK 182,000 to the Chairman of the Board and SEK 91,000 to each of the other Board members who are not employees of the Company.

The work of the Board, 2018

The Board held 18 minuted meetings in 2018. The attendance of individual members at meetings is shown in the table below. All of the meetings during the year followed approved agendas that were provided, together with documentation for each agenda item, to Board members prior to Board meetings. The CEO participates in the majority of the Board meetings. Each scheduled Board meeting includes a review of the current business situation, the Company's economic performance and financial position and the outlook for the rest of the year. During the year, the Board's work focused mainly on:

- Developing the project portfolio.
- The Company's clinical Phase I study with HyNap-Dasa and the start of the pilot study with HyNap-Sora.
- Strategy and business intelligence analysis.
- Financial development and the procurement of capital.
- Interim reports, year-end report and Annual Report.
- The upcoming application for listing of the Company's share on Nasdaq Stockholm's main list.

The CEO and other senior executives

The CEO's and Company management's assignments

The CEO reports to the Board and is responsible for the Company's day-to-day operations. The allocation of work between the Board and the CEO is set forth in the Board's rules of procedure and the CEO's instructions. The CEO is also responsible for preparing reports and compiling

Name	Position	Elected	Independent in relation to		Attendance, Board meetings
			The Company and Company management	Major shareholders	
Michael Wolff Jensen	Chairman of the Board	2013	No	Yes	18 (18)
Hans Arwidsson	Board member	2016	Yes	Yes	18 (18)
Maris Hartmanis	Board member	2015	Yes	Yes	18 (18)
Carl-Johan Spak	Board member	2015	Yes	Yes	17 (18)
Torbjörn Koivisto	Board member	2017	Yes	Yes	18 (18)

information from Company management prior to Board meetings. The CEO must keep the Board continually informed about the development of the Company's operations, its economic performance and financial position, important business events and every other event, circumstance or condition that can be considered to have material importance for the Company's shareholders. Company management, under the leadership of Company CEO Per Andersson, consists of individuals responsible for important areas of activity within Xspray. The CEO and other senior executive are profiled in more detail on page 32.

The CEO's employment conditions

When termination is on the part of the CEO, the period of notice is six months. When termination of the CEO is on the part of the Company, the period of notice is nine months. If the CEO is relieved of his duties during the period of notice, he is not eligible for variable compensation; other regular compensation will be paid during the period of notice. The CEO is not entitled to severance pay.

Compensation to the CEO and senior executives

Xspray must offer levels of compensation and employment conditions on market terms to enable the recruitment and retention of senior executives and key expertise. There are currently no agreements regarding severance pay for senior executives.

Compensation to senior executives consists of basic salary, share-related compensation, pension provisions and other benefits. For further information concerning compensation to the CEO and senior executives, see note 7.

Other information about Board members and the CEO

All members of the board and the CEO can be contacted at the Company's address, Råsundavägen 12, SE 169 67 Solna, or by telephone on +46 8 730 37 00.

Stock-related compensation program

The Company has conducted a total of three incentive programs in the form of share warrants to senior executives and key individuals. For further information, see page 24 in the Report of the Board of Directors.

Audit and control

External audits

The auditor must examine the Company's annual report, its accounts and the Board of Directors' and the Chief Executive Officer's administration. Following each financial year, the auditor must submit an auditor's report to the AGM. According to the Company's articles of incorporation, it must have one or no more than two auditors and no more than two alternate auditors.

The AGM of May 14, 2018 resolved to reelect registered auditors Grant Thornton Sweden AB as auditor for the period until the end of the next AGM. Thomas Lindgren is auditor-in-charge. The Company's auditor is presented in more detail on page 31.

Compensation to auditors

Resolutions concerning compensation to auditors are passed by the shareholders' meeting. The AGM of May 14, 2018 resolved that the auditor's fee be paid against approved invoice. For further information regarding compensation to auditors, see note 6.

Internal audits and control

The overall objective of the internal control is to reasonably ensure that the Company's operational strategies and goals are followed up and that the owners' investment is protected. The internal controls must also ensure that external financial reporting is with reasonable certainty reliable and prepared in compliance with good accounting practice, that applicable legislation and regulations are followed and that the requirements for listed companies are abided by. The Board of Directors bears overall responsibility for internal controls. Provisions in the Swedish Companies Act and the Swedish Annual Accounts Act require the inclusion of information about the most important features in Xspray's system for internal control and risk management in the Company's Corporate Governance Report. In order to maintain good internal control, the Board has established a number of policy documents such as the Board's rules of procedure, the CEO instruction, instructions for financial reporting and information policy.

Each year, the Board evaluates the need to establish a special internal audit department. Based on analyses in 2018, the Board has resolved not to establish such a department. The day-to-day responsibility for internal control and risk management has been delegated to the Company's CEO, who must regularly report to the Board in accordance with instructions. Internal controls and risk management is monitored and evaluated on an ongoing basis through internal and external checks and evaluations of the Company's policy documents.

The Corporate Governance Report is available on the Company's website.

Board and auditor

Michael Wolff Jensen

Member of the Board and Chairman of the Board since 2013
Born 1971
Education: Master of Laws (LL.M.), University of Copenhagen
Other current assignments: Chairman of the boards of Ascendis
Pharma A/S, Eurocine Vaccines AB, VANX ApS and chairman of the board and owner of MWJ Partners ApS.
Previous assignments (past five years): -
Holding in the Company on December 31, 2018: 35,864 shares and 25,000 warrants.

Hans Arwidsson

Board member since 2006
Born 1958
Education: Ph.D. in Pharmaceutical Science and Pharmacist's Degree, University of Uppsala; Master of Business Administration, Executive MBA, Stockholm School of Economics.
Other current assignments: Member of the boards of Healthy Bizniz Europe AB, Eurocine Securities AB; Chairman of the board of Nanexa AB and CEO of Eurocine Vaccines AB.
Previous assignments (past five years):
Member of the board of Nanexa AB.
Holding in the Company on December 31, 2018: -

Maris Hartmanis

Board member since 2015
Born 1953
Education: Dr. of Technology and Associate Professor, KTH Royal Institute of Technology.
Other current assignments: CEO and chairman of the board of Hartmanis & Partners AB and a member of the boards of Xbrane Biopharma AB and BioLamina AB.
Previous assignments (past five years): CEO of Medivir Aktiebolag, member of the board and CEO of BioPhausia AB and member of the boards of Vitrolife AB, Karolinska Institutet Innovations AB, Glycovisc Biotech AB, Medivir Personal AB, Altesse AB, Astor Pharma AB, Medivir HIV Franchise AB and Applied Photophysics Ltd and chairman of the board of Cross Pharma AB.
Holding in the Company on December 31, 2018: 28,619 shares.

Carl-Johan Spak

Board member since 2015
Born 1956
Education: Dr. of Odontology, Degree in Dentistry, Karolinska Institutet
Other current assignments: Member of the boards of Pharmanest AB, Symcel Sverige AB, Cobra Biologics Holding AB, Empros Pharma AB, Inject Pharma Sweden AB, Atrogi AB, Prokarium Ltd, Synthonics Inc, Kahr Medical Ltd, SwedenBIO Service AB and Bostadsrättsföreningen Smultronhyllan, and member of the boards and CEO of Recipharm Venture Fund AB.
Previous assignments (past five years): Chairman of the boards of Recipharm OT Chemistry AB, Recipharm Pharmaceutical Development AB, Cobra Biologics Matfors AB and Cobra Biopharma Matfors AB; member of the board of Recipharm Strängnäs AB; CEO of Empros Pharma AB and alternate board member of Cormorant Pharmaceuticals AB and Cobra Biologics AB; member of the board and CEO of RPH Pharmaceuticals AB.
Holding in the Company on December 31, 2018: -

Torbjörn Koivisto

Board member since 2017
Born 1969
Education: Master of Laws (LL.M.), Uppsala University
Other current assignments: Member of the boards of Hemcheck Sweden AB, Cinclus Pharma Holding AB and IARU Institutet för Affärsjuridisk Rådgivning i Uppsala AB; partner in KOL Arts & Craft Handelsbolag and alternate member of the board of RJC Roger Johansson Consulting AB.
Previous assignments (past five years): Member of the boards of Moberg Pharma AB (publ), NOSTER System AB, Kibion AB, KIBACQ AB, Apoteksamariten AB and chairman of the board of Forslid & Co AB.
Holding in the Company on December 31, 2018: 4,000 shares via the Company IARU.

Auditor

Registered auditors Grant Thornton Sweden AB (Sveavägen 20, SE 111 57 Stockholm) have been the Company's auditor since 2015 and were reelected as Company auditor at the AGM of May 14, 2018 for the period until the end of the 2019 AGM. Thomas Lindgren (authorized public accountant and member of FAR, the Swedish Institute for authorized accountancy professionals) has been auditor-in-charge since 2015.

Management

Per Andersson

CEO since 2006
Born 1967
Education: Doctorate in analytical chemistry, Stockholm University.
Other current assignments: Chairman of the board of Robotic Lawn Care Sweden AB and alternate member of the board of Journeyman Stockholm AB.
Previous assignments (past five years): Alternate member of the board of Shing AB.
Holding in the Company on December 31, 2018: 127,437 shares and 154,857 warrants

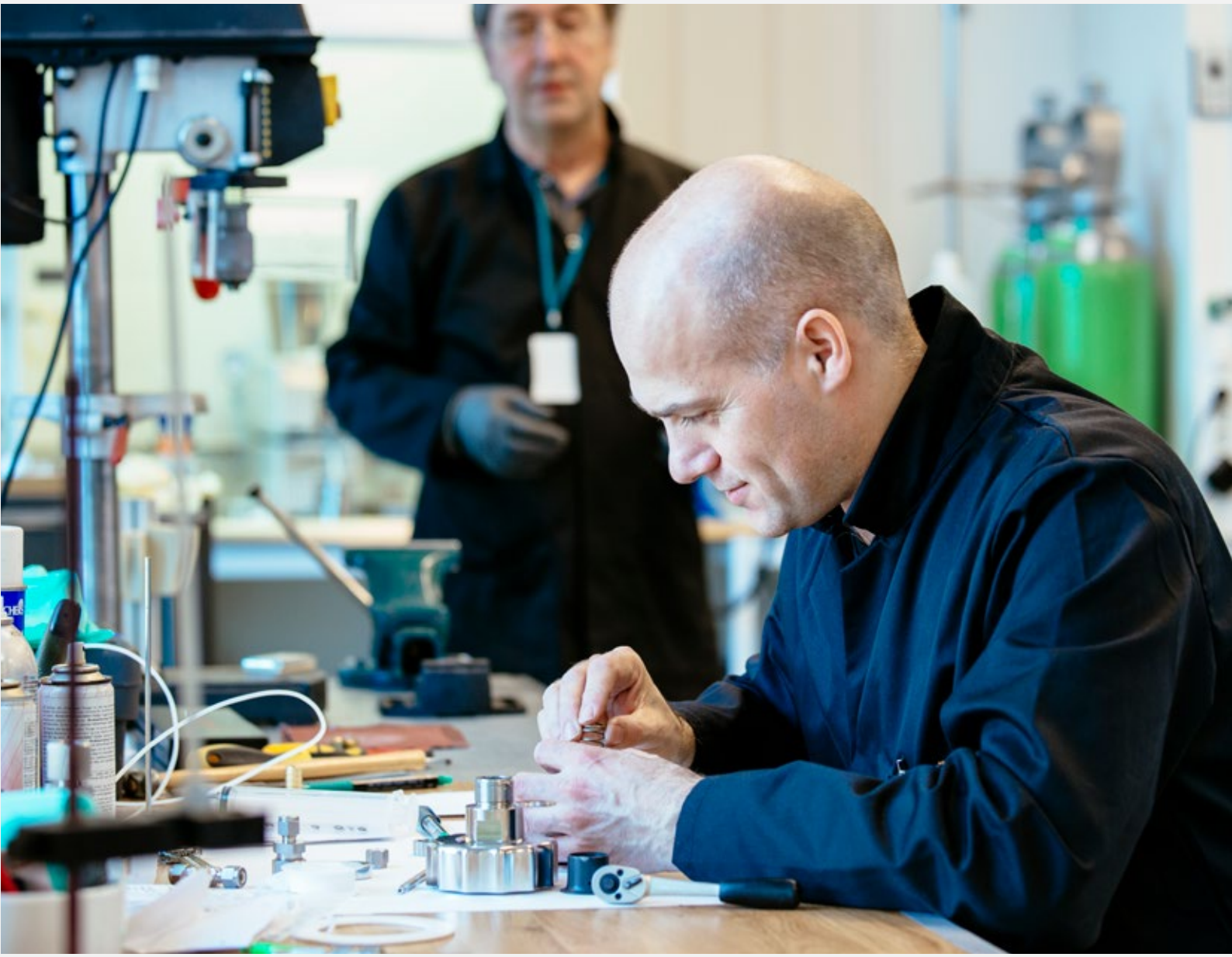
Andreas Konar

Business development since 2010
Born 1949
Education: Associate professor in organic chemistry, Lund University; Doctorate in organic chemistry, Lund University; Master of science in engineering, Chalmers University of Technology, Gothenburg.
Other current assignments: Member of the board of Ground Zero Pharmaceuticals Inc.
Previous assignments (past five years): -
Holding in the Company on December 31, 2018: 73,555 shares and 19,091 warrants

Charlotta Liljebris

Head of R&D since 2018
Born 1964
Education: Doctorate in medicinal chemistry, Uppsala University.
Other current assignments: Member of the board of Sprint
Bioscience.
Previous assignments (past five years): Member of the boards of Connect Uppsala and Recipharm OT Chemistry.
Holding in the Company on December 31, 2018: 752 shares and 23,437 warrants.

Financial statements



Consolidated balance sheet

Amount in SEK thousands	Note	12/31/2018
ASSETS		
Fixed assets		
Intangible assets		
Capitalized development costs	9	71,850
Patent	10	43
		71,893
Property, plant and equipment		
Equipment and other technical facilities	11	12,447
Inventories, tools and installations	12	1,283
		13,730
Financial fixed assets		
Other non-current securities holdings	14	1
		1
Total fixed assets		**85,624**
Current assets		
Current tax assets		201
Other current receivables		1,474
Prepaid expenses and accrued income	15	3,920
Cash and cash equivalents		221,266
Total current assets		**226,861**
TOTAL ASSETS		**312,485**
EQUITY AND LIABILITIES		
Equity	16	
Share capital		15,076
Other contributed capital		337,967
Other equity (including loss for the year)		-51,327
Total equity attributable to parent Company shareholders		**301,716**
Current liabilities		
Trade accounts payable		7,780
Other current receivables		1,301
Accrued expenses and deferred income	17	1,688
Total current liabilities		**10,769**
TOTAL EQUITY AND LIABILITIES		**312,485**

At the end of December 2018, Xspray Pharma AB (publ) acquired a newly incorporated subsidiary, dormant for the time being, to prepare the Group for possible future structural needs. No business activity has taken place in the subsidiary; all business is pursued in the parent Company Xspray Pharma AB (publ). Accordingly, Xspray is presenting consolidated financial statements for the first time. Because the acquisition date is at the end of 2018 and no business activities have been pursued in the subsidiary, no consolidated income statement is presented for 2018, only a consolidated balance sheet on the closing date 12/31/2018. This provides a more accurate picture of the operations as the number of transactions is limited and 2018 operations as a whole are reported in the parent Company's statements.

Parent Company income statement

Amount in SEK thousands	Note	1/1/2018 12/31/2018	1/1/2017 12/31/2017
Operating income etc.			
Net sales		277	332
		277	**332**
Operating expenses	4, 5, 6, 7		
Sales and administration expenses		-16,967	-10,779
Research and development expenses		-5,536	-4,132
Other operating income	2	86	824
Other operating expenses	3	-1,077	-141
Operating loss		**-23,217**	**-13,896**
Earnings from financial items			
Interest income and similar income statement items		150	80
Interest expenses and similar profit/loss items		-31	-1
Earnings from financial items		**119**	**79**
Loss before income tax		**-23,098**	**-13,817**
Tax	8	0	0
Loss for the year		**-23,098**	**-13,817**

Parent Company statement of comprehensive income

Amount in SEK thousands	1/1/2018 12/31/2018	1/1/2017 12/31/2017
Loss for the year	**-23,098**	**-13,817**
Other comprehensive income	0	0
Comprehensive income for the year	**-23,098**	**-13,817**
Average number of shares before dilution	13,593,172	7,945,622
Average number of shares after dilution	14,055,472	8,400,213
Earnings per share for the year before dilution, SEK	-1.70	-1.74
Earnings per share for the year after dilution, SEK	-1.64	-1.64

Parent Company balance sheet

Amount in SEK thousands	Note	12/31/2018	12/31/2017
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development costs	9	71,850	39,885
Patent	10	43	420
Total intangible assets		**71,893**	**40,305**
Property, plant and equipment			
Equipment and other technical facilities	11	12,447	2,180
Inventories, tools and installations	12	1,283	281
Total property, plant and equipment		**13,730**	**2,461**
Financial fixed assets			
Participations in subsidiaries	13	50	0
Other non-current securities holdings	14	1	1
Total financial fixed assets		**51**	**1**
Total fixed assets		**85,674**	**42,767**
Current assets			
Current receivables			
Accounts receivable		0	23
Current tax assets		201	201
Other receivables		1,474	825
Prepaid expenses and accrued income	15	3,920	781
Total current receivables		**5,595**	**1,830**
Cash and bank		221,216	115,512
Total current assets		**226,811**	**117,342**
TOTAL ASSETS		**312,485**	**160,109**

Parent Company balance sheet *cont.*

Amount in SEK thousands	Note	12/31/2018	12/31/2017
EQUITY AND LIABILITIES			
Equity	16		
Restricted equity			
Share capital		15,076	12,356
Fund for development charges		71,850	39,886
Statutory reserve		976	976
Total restricted equity		**87,902**	**53,218**
Non-restricted equity			
Share premium reserve		336,991	169,253
Accumulated earnings		-100,079	-54,299
Loss for the year		-23,098	-13,817
Total non-restricted equity		**213,814**	**101,137**
Total equity		**301,716**	**154,355**
Current liabilities			
Trade accounts payable		7,780	2,890
Other current receivables		1,301	253
Accrued expenses and deferred income	17	1,688	2,611
Total current liabilities		**10,769**	**5,754**
TOTAL EQUITY AND LIABILITIES		**312,485**	**160,109**

Statement of changes in equity in the parent company

Amount in SEK thousands	Capital share	Fund for dev. costs	Statutory reserve	Share premium reserve	Accumu-lated earnings	Profit for the year	Total equity
Opening balance as of January 1, 2018	**6,356**	**19,324**	**976**	**52,869**	**-28,954**	**-4,097**	**46,474**
Adjustment for transition to IFRS		-686			686	-686	-686
Adjusted balance as of January 1, 2017	**6,356**	**18,638**	**976**	**52,869**	**-28,268**	**-4,783**	**45,788**
Transfer of loss for the year					-4,783	4,783	0
New share issue	6,000			116,384			122,384
Fund for development costs		21,866			-21,866		0
Loss for the year						-13,199	-13,199
Adjustment for transition to IFRS		-618			618	-618	-618
Adjusted balance as of December 31, 2017	**12,356**	**39,886**	**976**	**169,253**	**-54,299**	**-13,817**	**154,355**
Adjusted balance as of January 1, 2018	**12,356**	**39,886**	**976**	**169,253**	**-54,299**	**-13,817**	**154,355**
Transfer of loss for the year					-13,817	13,817	0
New share issue	2,720			176,820			179,540
Transaction expenses				-9,082			-9,082
Fund for development costs		31,964			-31,964		0
Loss for the year						-23,098	-23,098
Closing balance as of December 31, 2018	**15,076**	**71,850**	**976**	**336,991**	**-100,080**	**-23,098**	**301,715**

Conditional shareholder contributions amounted to SEK 50,000 (50,000).

Parent company statement of cash flows

Amount in SEK thousands	Note	1/1/2018 12/31/2018	1/1/2017 12/31/2017
Operating activities			
Operating loss before financial items		-23,217	-13,896
Non-cash adjustments	18	4,101	1,166
Received interest		150	80
Interest paid		-31	-1
Cash flow from operating activities before change in working capital		**-18,997**	**-12,651**
Change in working capital			
Change in accounts receivable		23	-4
Change in current receivables		-3,788	632
Change in trade accounts payable		4,890	-1,453
Change in current liabilities		126	1,818
Cash flow from operating activities		**-17,746**	**-11,658**
Investment activities			
Investments in intangible assets		-31,965	-21,247
Capital expenditures in property, plant and equipment		-14,993	-2,769
Investments in other financial assets		-50	0
Cash flow from investment activities		**-47,008**	**-24,016**
Financing activities			
New share issue		170,458	122,384
Cash flow from investment activities		**170,458**	**122,384**
Cash flow for the year		**105,704**	**86,709**
Cash and cash equivalents at beginning of year		115,512	28,803
Cash and cash equivalents at year-end		**221,216**	**115,512**

Notes – applicable to both consolidated and parent company financial statements

Note 1 Accounting and valuation principles

General information
This annual report and consolidated financial statements concerns the Swedish parent Company Xspray Pharma AB (publ), corporate ID number 556649-3671 and the start-up subsidiary Xspray Pharma Futurum AB, corporate ID number 559178-7642.

The parent Company is a public limited Company whose shares are listed on the ABC, registered and domiciled in Stockholm, Sweden The Company's head office is located on Råsundavägen 12, SE 169 67 Solna.

At the end of December 2018, Xspray Pharma AB (publ) acquired a newly incorporated subsidiary, dormant for the time being, to prepare the Group for possible future structural needs. No business activity has taken place in the subsidiary; all business is pursued in the parent Company Xspray Pharma AB (publ).

The nature of the business
Xspray Pharma AB has developed a patented technology, RighSize, for the production of hybrid nano particles, HyNap.

Xspray's technology allows new and existing drug substances to be developed with better properties. It can be used to produce improved versions of established drugs, to extend a product's lifetime or in certain cases produce a variant comparable to an established product.

Xspray's technology has been applied to both new and existing drug substances. The Company is close to the commercialization of the product platform through an application for an established drug for the treatment of cancer.

General Information, compliance with IFRS and the going concern principal.
The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS), published by the International Accounting Standards Board (IASB) as adopted by the European Union (EU). The consolidated financial statements also comply with recommendations from the Swedish Financial Reporting Board RFR1, Supplementary rules for consolidated financial statements. In addition, the Company follows Swedish Financial Reporting Board RFR2, Accounting for Legal Entities.

The Parent Company has prepared its annual report in compliance with the Swedish Annual Accounts Act and Swedish Financial Reporting Board recommendation RFR 2 Accounting for Legal Entities.

The differences between the consolidated and parent Company accounting policies are described below.

Xspray does not divide its operations into different lines of business, This reflects the Company's organization and reporting system. The chief operating decision maker is the Chief Executive Officer. The Group is not anticipated to have any direct revenues until its products are launched on the market.

The financial statements have been prepared under the proviso that the Group conduct its business according to the going concern principle.

The financial statements for Xspray Pharma for the financial year ending on December 31, 2018 have been approved by the Board of directors and Chief Executive Officer and will be presented to the Annual General Meeting on May 23, 2019 for adoption. The parent Company Xspray Pharma AB (publ) is a Swedish public limited Company, domiciled in Stockholm, Sweden.

Change of accounting policies and valuation principles
During the last quarter, the Company switched to applying IFRS with the adjustments required by RFR 2 Accounting for Legal Entities. The Company will also switch to an income statement layout classified by function.

The effects of these changes and further information about the accounting policies are described in more detail below and in note 24. During previous periods, financial statements were prepared in accordance with the Swedish Annual Accounts Act and K3.

At the end of 2018, the parent Company acquired a newly incorporated subsidiary, dormant for the time being, to prepare the Group for possible future structural needs. No business activity has taken place in the subsidiary; all business is pursued in the parent Company Xspray Pharma AB (publ). Accordingly, Xspray is presenting consolidated financial statements for the first time. Because the acquisition date is at the end of 2018 and no business activities have yet been pursued in the subsidiary, no consolidated income statement has been prepared for 2018. This provides a more accurate picture of the operations as the number of transactions is limited and 2018 operations as a whole are reported in the parent Company's statements. The consolidated balance sheet will be prepared as per the closing date 12/31/2018.

Standards, changes and interpretations of standards that have not yet come into force or been applied in advance by the Group
A number of new or amended IFRSs have not yet come into force and have not been applied in advance when preparing the consolidated and parent Company financial statements. The new IFRS thought to affect the Group's accounting in the future is IFRS 16 Leases. According to the new standard, lessees must report the obligation to pay lease charges as a leasing liability in the balance sheet. The right to use the underlying asset during the term of

the lease is reported as an asset. Depreciation of the asset is reported in the income statement as interest on the leasing liability. Paid lease charges are reported partly as payment of interest, and partly as an amortization of the leasing liability. The standard exempts leases with a lease term shorter than 12 months (short-term leases) and leases in respect of low-value assets. The new standard does not entail any major differences for lessors. IFRS 16 comes into force in the financial year beginning January, 2019 or later and will be applied by the Group as of January 1, 2019.

The Group applies the simplified transition method.

It is thought the standard will initially entail reporting leases as assets and liabilities in the balance sheet, especially those reported as operational leases in these financial statements. This will also mean splitting their reported expenses between interest expense and depreciations.

The exemptions in RFR 2 concerning leases will be applied in the parent company. All leases are reported in the parent Company under the rules for operational leasing. This means the parent company's accounting policies for leases will remain unchanged. See also note 5.

Important accounting policies

The Group's financial statements were prepared using the accruals concept and based on cost. Monetary amounts are expressed in Swedish crowns (SEK) and rounded to the nearest thousand unless otherwise indicated.

Non-current assets and non-current liabilities consist in all material respects of amounts that are expected to be recovered or settled more than twelve months from the closing date. Current assets and current liabilities consist in all material respects of amounts that are expected to be recovered or settled within twelve months of the closing date.

Basis for consolidation

Subsidiaries

Subsidiaries are companies in which Xspray Pharma AB has a controlling influence. An investor has a controlling influence over a company when said investor is exposed to, or has the right to, variable rates of return from his participation in the company and is able to affect the rate of return through his influence.

Subsidiaries are reported according to the acquisition method, wherein the acquisition of a subsidiary is regarded as a transaction through which the Group indirectly acquires the subsidiary's assets and assumes its liabilities. In the acquisition analysis, the fair value of the acquired identifiable assets and assumed liabilities and any holdings without a controlling influence are determined on the day of acquisition. Transaction expenditures, with the exception of transaction expenditures attributable to the issuance of equity instruments or debt instruments that arise, are reported directly in profit/loss for the year. In a business combination where the transferred compensation exceeds the fair value of acquired assets and assumed liabilities reported separately, the difference is reported as goodwill.

A subsidiary's financial statements are included in the consolidated financial statements from the acquisition date until the date when controlling influence no longer exists.

Participations in subsidiaries are reported in the parent Company according to the cost method. This means transaction expenditures are included in the carrying amount for holdings in subsidiaries.

Transactions eliminated on consolidation

Intra-group receivables and liabilities, income or expenses, as well as unrealized gains or losses arising from transactions between Group companies, are eliminated in their entirety when preparing the consolidated financial statements. Unrealized losses are eliminated in the same way, but only to the extent that no impairment loss is necessary

Currency translations

Transactions in foreign currency

Foreign currency transactions are translated into the functional currency at the exchange rate prevailing on the transaction date. Monetary assets and liabilities in foreign currency are translated to the functional currency at the exchange rate prevailing on the closing date. Exchange rate differences that arise from translations are reported under profit/loss for the year. Exchange-rate gains and losses on operating receivables and liabilities are reported under operating profit/loss while exchange-rate gains and exchange-rate losses on financial receivables and liabilities are reported as financial items.

Revenues

Because the Group does not enter into contracts with its customers where the Group's right to payment, when performance of the contract is completed, is dependent upon anything other than the passage of time, the Group does not currently report any contract assets.

Xspray does not divide its operations into different lines of business, and this reflects the Company's organization and reporting system. The chief operating decision maker is the Chief Executive Officer. The Group does not anticipate having any direct revenues until its products are launched on the market.

Revenue is recognized when the amount can be measured reliably and it is probable that future economic benefits will flow to the Group and the Company. Revenue comprises the fair value of what is received or will be received for services sold in day-to-day operations. Revenue is recognized exclusive of value-added tax, returns and discounts, and after elimination of intra-group sales.

Xspray Pharma is a product development Company with multiple product candidates in clinical development. Xspray Pharma uses its innovative, patented RightSize® technology to develop improved and generic versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. The segment is the second largest in oncology, and drug prices are very high. Thanks to its innovative technology, Xspray Pharma is able, through licensing to suitable pharmaceutical companies, gain entry as the first competitor to today's original drugs before their secondary patents expire. The Company's first product candidates comprise HyNap-Dasa, HyNap-Sora and HyNap-Nilo. The goal is to become the leader in the development of protein kinase inhibitors already marketed for the treatment of cancer, which numbered 39 in 2018. The launch of HyNap-Dasa, the first product candidate, is planned for 2021. The

substance patent for Sprycel® (dasatinib) expires at the end of 2020, and the secondary patents in 2026, which offers Xspray Pharma's HyNap-Dasa a period of five years in a semi-exclusive position before other competitors gain access to the market. The Company has patented the production technology, the equipment and the resulting products.

Sales are not expected to increase before 2021, when the Company plans to launch the first product on the market under the current business plan.

Financial income

Financial income consists of interest income and exchange rate gains. Interest income is reported in accordance with the effective interest method. Effective interest is the interest that discounts estimated future receipts and payments during the anticipated term of the financial instrument to the financial asset's or liability's reported net value. The calculation comprises all charges paid or received by contractual parties that form part of the effective interest, transaction expenses and all other premiums and discounts.

Dividends received are reported when the right to receive the dividend is determined. Exchange rate gains and losses are reported net.

Operating expenses

Operating expenses are reported in the income statement when the service is used or when the event has occurred.

Borrowing costs

Borrowing costs that are directly attributable to the acquisition, erection or manufacture of qualifying assets, are capitalized during the time period necessary for completing and preparing the asset for its intended use or sale. Other borrowing costs are expensed in the period during which they occur and are reported under Financial expenses. The Group currently has no borrowing costs.

Leasing

Leases in which the lessor in principle retains all risks and benefits associated with the rights of ownership are classed as operational in the legal entity. Leasing charges are expensed on a straight-line basis in the income statement during the leasing period. Initially, any incentives received upon signing the lease are taken into account.

Employee benefits

Current employee compensation

Current employee compensation such as pay, social security charges, vacation pay and bonuses are expensed during the period when the employees perform the services.

Pensions

The Group's pension commitments only include defined contribution plans. A defined contribution pension plan is one where the Group pays fixed premiums to a separate legal entity. The Group has no legal or informal obligation to pay additional fees if the legal entity does not have sufficient assets to pay all employee benefits associated with the employee's service during the current or earlier periods. Thus the Group has no additional risk. The Group's obligations in respect of the fees to the defined contribution plan are reported as expenses in profit/loss for the year as they are earned by employees in the performance of services for the Group during a period.

Stock-based compensation

For certain key individuals, the Group has share-related compensation that is settled using shares in the parent Company (warrants) which are thus booked against equity. The option price in all option programs was determined at fair value according to the Black & Scholes valuation model. See also note 7.

Taxes

Income taxes consist of current tax and deferred tax. Income taxes are reported in the income statement except when the underlying transaction is reported in equity, in which case the associated tax effect is reported under other comprehensive income and equity.

Current tax is tax that must be paid or received in respect of the current year by applying the tax rates that were enacted, or announced, as of the closing date. Adjustments current tax attributable to prior periods are also reported under current tax.

Deferred tax is reported in its entirety according to the balance sheet method on all temporary differences arising between the taxable value of assets and liabilities and its carrying amount. Temporary differences attributable to participations in subsidiaries that are not expected to be reversed in the foreseeable future are disregarded.

Valuation of deferred tax is based on how the underlying assets or liabilities are expected to be realized or settled. Deferred tax is calculated according to the tax rates and regulations adopted or announced as of the closing date and which are expected to apply when the deferred tax asset concerned is realized or the deferred tax liability settled. Deferred tax assets are reported net against deferred tax liabilities only if they can be paid with a net amount.

Deferred tax assets in respect of deductible temporary differences and loss carryforwards are reported only to the extent that it is likely they will be utilized. The value of deferred tax assets is reduced when it is no longer considered likely that they can be utilized. Because of the connection between reporting and taxation, deferred tax assets are not disclosed as being attributable to untaxed reserves.

Public subsidies

Subsidies received refers to awarded or previously accrued EU subsidies for the financial year.

Fixed assets

Intangible assets

Intangible assets with a limited lifetime are reported at cost less depreciations and any impairment charges. Intangible fixed assets are depreciated systematically over the asset's estimated useful life. Useful life is reviewed at every balance sheet date and adjusted as necessary. Depreciation commences upon completion. When the depreciable amounts of the assets are determined, the asset's residual value is taken into account where applicable.

Development expenditures are capitalized when they fulfill IAS 38 criteria and amount to significant sums for the

development investment as a whole.

Otherwise, development expenditures are expensed as normal operating expenses. The most important criteria for capitalization are the demonstrable future earnings (market), cost-saving or cash flow potential of the end product under development and the existence of technological and financial conditions for completing development work once started. The Group only has internally developed intangible assets. Cost includes consists chiefly of direct personnel costs arising in the work and relevant invoiced development costs.

The following useful lifetimes are applied:	
Expenditures for development and similar work brought forward	5 years
Concessions, patents, licenses, brands and similar rights	5 years

Property, plant and equipment

Property, plant and equipment comprises fixtures and fittings and is reported in the consolidated accounts at cost less accumulated depreciations and any impairment charges. Cost includes the purchase price and expenditures directly attributable to an asset in order to bring it to the position and condition necessary for use in accordance with the purpose of the acquisition.

The carrying amount of an asset is removed from the balance sheet when the asset is retired or disposed of or when no future economic benefits are anticipated from the use or retirement/disposal of the asset. Gains and losses that arise from the disposal or retirement of an asset consist of the difference between the sales price and the asset's carrying amount less deductions for direct selling expenses. Profit and loss are reported as other operating income/expense.

Depreciation is calculated on a straight-line basis over the asset's calculated useful life. The estimated useful life of the Group's property, plant and equipment is five years. The depreciation methods, residual values and useful lifetimes are reviewed at the end of each year.

Impairment of non-financial assets

Assets with an indefinite useful life such as the Group's intangible assets where depreciation has not yet begun as they are not yet in use, are reviewed at least annually with regard to any need for impairment and when an indication for impairment is present. Assets are considered for impairment whenever events or changes in circumstances indicate that the asset's carrying amount is not recoverable.

An impairment loss is reported in the amount by which the asset's carrying amount exceeds its recovery value. The recoverable value is the asset's fair value less selling expenses or its value-in-use, whichever is the higher. When assessing the need to recognize impairment, assets are grouped at the lowest levels at which there are separately identifiable cash-flows (cash generating units).

The Company uses the cash flow model to test the value of intangible assets. The value of development projects in progress is derived by calculating anticipated future cash flows at present value to take development risks into account. The valuation considers cash flow for the next five years and does not include calculation of any residual value thereafter.

Previously reported impairments are reversed if the recoverable value is considered to exceed the carrying amount. However, reversal does not take place at an amount greater than that which the carrying amount would have been, had the impairment not been reported in earlier periods. However, impairment of any goodwill is never reversed.

See also note 9.

Financial instruments

Reporting and valuation at initial recognition

Financial assets and liabilities are reported when the Group becomes party to an agreement in respect of the financial instrument's agreed conditions.

Financial assets are removed from the statement of financial position when the contractual rights in respect of the financial asset expire, or when the financial asset and all significant risks and benefits are transferred.

A financial liability is removed from the statement of financial position when it is extinguished, i.e. when it is discharged, canceled or expires.

Classification and valuation of financial assets upon initial recognition

Except for accounts receivable that do not include a significant financing component and which are measured at the transaction price under IFRS 15, all financial assets are measured at fair value adjusted for transaction expenses (where applicable).

Financial assets other than those identified and effective as hedging instruments, are classified in the following categories:

- Accrued acquisition cost
- Fair value via the income statement
- Fair value via other comprehensive income

During the periods covered by the financial statements, the Company has had no financial assets categorized as measured at fair value via profit/loss or fair value via other comprehensive income.

The classification is determined by:

- the Company's business model for the administration of the financial asset, and
- the properties of the contractual cash flows from the financial asset

All revenues and expenses in respect of financial assets reported in the income statement are classified as Financial expenses, Financial income or Other financial items except when it concerns the impairment of accounts receivable classified as Other expenses.

Because of the relationship between reporting and taxation, the IAS 39 rules on financial instruments are not applied in the parent company as a legal entity. Instead, the parent company applies the cost method in accordance with the Swedish Annual Accounts Act. Non-current financial assets are thus measured in the parent company at cost less any impairments, or as current financial assets, whichever is the lower.

Subsequent valuation

Financial liabilities appraised at amortized cost

Financial assets are measured at amortized cost if the assets meet the following conditions and are not reported at fair value via the income statement:

- they are held within the framework of the business model whose objective is to hold the financial assets and collect the contractual cash flows, and
- the contractual conditions for the financial assets give rise to cash flows that are only payments for the capital amount and not interest on the outstanding principal.

After initial recognition, they are measured at amortized cost using the effective interest method. Discounting is omitted if its effect is insignificant. The Group's cash and cash equivalents, accounts receivable and most other receivables belong to this category of financial instrument.

Impairment of financial assets

IFRS 9's impairment rules use more forward-looking information to report anticipated credit losses using the expected credit loss (ECL) model. It replaces IAS 39's earlier impairment model. The financial assets subject to the new model for expected credit losses are bonds and debt instruments measured at amortized cost or fair value via other comprehensive income; accounts receivable, contract assets reported and measured according to IFRS 15, loan obligations and certain financial guarantees (for the issuer) not measured at fair value via the income statement.

The Group no longer needs to first identify a credit loss event to report a credit loss. Instead, the Group considers more comprehensive information when assessing credit risk and evaluating expected credit losses such as previous occurrences, current circumstances and reasonable, well-founded prognoses that affect the anticipated ability to obtain future cash flows from the asset.

When taking a more forward-looking approach, a distinction is made between:

- financial instruments that have not deteriorated significantly in credit quality since initial recognition or which have low credit risk (Stage 1) and
- financial instruments that have deteriorated significantly in credit quality since initial recognition or whose credit risk is not low (Stage 2).

Stage 3 refers to financial assets where the Company on the reporting date has objective evidence of a reduction in value (that a credit loss event has taken place). In the first category, the expected credit losses for 12 months are reported, while in the second category, the anticipated credit losses for the remaining term are reported. The expected credit losses are evaluated on the basis of probability-weighted amounts of estimated credit losses over the anticipated term of the financial instruments.

Accounts receivable, other receivables and contract assets

The Group uses a simplified method for reporting accounts receivable, other receivables and contract assets and reports expected credit losses for the remaining term. This is where the anticipated shortcomings in contractual cash flows are found given the risk of nonpayment at some time during the lifetime of the financial instrument. The Group uses its historical experience, external indications and forward-looking information to calculate the expected credit losses with the aid of a provision matrix. Because they have common credit attributes, the Group assesses the impairment of accounts receivable collectively where the receivables are grouped based on the number of overdue days.

Classification and valuation of liabilities

The Group's financial liabilities include loans, trade accounts payable, other liabilities and derivative instruments. Financial liabilities are initially measured at fair value adjusted for transaction expenses. Following initial recognition, financial liabilities are valued at amortized cost with the aid of the effective interest method.

Cash and cash equivalents

Cash and cash equivalents consist of bank balances and current investments with an original due date of three months or less.

Dividends

Dividends to the parent company's shareholders are reported as liabilities in the consolidated financial statements during the period in which the dividend is approved.

Provisions

A provision differs from other liabilities due to uncertainty about the payment date or the amount required to settle the provision. A provision is reported in the balance sheet when there is an existing legal or informal obligation as a result of an event that has occurred and it is probable that an outflow of financial resources will be required to settle the obligation and a reliable estimate of the amount can be made. A provision is made in an amount that is the best estimate of what is required to settle the existing obligation on the closing date. If the point in time when payment takes place has a material effect, the provision is calculated by discounting the anticipated future cash flows.

Contingent liabilities

A contingent liability is reported when there is a possible obligation that arises from past events and whose existence is confirmed only by the occurrence of one or more uncertain future events or when there is an obligation that is not reported as a liability or provision because it is not likely that an outflow of resources will be required.

Equity, reserves and dividends

Equity consists of the following items:

Equity representing the nominal value of issued and registered shares.

Other contributed capital consists of premiums received for new issues of capital share. Any transaction expenses associated with the new share issue are deducted from the capital contribution with account taken of any income tax effects.

The parent company also has a *Fund for development expenditures*, which is grown annually by the amount

capitalized in respect of the Company's own development efforts. The fund is reduced annually by depreciation of the capitalized development work.

The statutory reserve, which originated when there was a requirement under the Swedish Companies Act to make provisions to a reserve fund.

Retained earnings/accumulated deficit, i.e. all gains/losses brought forward and capitalized compensation for the current and earlier periods, and the acquisition of own shares.

Significant estimations

Preparing the financial statements in accordance with IFRS, requires Company management to make estimations, assessments and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, revenues and expenses. Actual outcomes may deviate from these estimations.

Uncertainty in estimations

The estimations and assumptions are evaluated on an ongoing basis. Changes in estimations are reported in the period in which the change is made if the change only affects that period, or in the period in which the change is made and future periods if the change affects both the current and future periods.

The source of uncertainties in estimations that entail a significant risk of substantial adjustment to the value of an asset or liability during the coming financial year are impairment tests for intangible assets with a non-determined period of use.

Assessment is necessary to determine whether or not requirements for the capitalization of development expenditures have been met. After capitalization, compliance with the accounting requirements for development expenses will continue to be monitored as well as if there are indications that the capitalized expenditures may be exposed to diminution of value. The Company has capitalized intangible assets that are not yet completed. At a minimum, such assets must be tested for impairment annually in order to calculate their recovery value. To do this, an estimation must be made of future cash flows attributable to the asset or the cash-generating unit to which the asset is attributable when it is completed. These estimates and assessments relate to such things as the anticipated sales price for the product, anticipated market penetration, anticipated development, sales and marketing expenses and the anticipated probability that the product will proceed through the remaining development stages. The assumptions are based on industry and market-specific data and are prepared by Company management and reviewed by the Board. For further information about testing intangible assets with an indefinite useful life for impairment, refer to note 9.

A further source of uncertainty is the assessment of the extent to which deferred tax assets may be reported based on an assessment of the likelihood of the Company's future taxable revenues against which deferred tax assets may be exercised. Furthermore, important considerations are necessary when assessing the effect of certain legal and financial limitations or uncertainties in different jurisdictions.

Risks and uncertainty factors

Commercial risks

n addition to financial risks, commercial risks are primarily linked to research and development efforts. In general, the development of drugs is associated with very high risk. The R&D efforts necessary for a drug candidate to gain approval for use as a drug carry many risks including delays in product development, higher-than-anticipated expenses, failure of the drug candidates to meet efficacy expectations and other.

The pharmaceutical industry is characterized by global competition, rapid technological development and extensive investment requirements. There are competitors with significant financial resources and there is a risk that competitors develop drugs that have a negative impact on the Company's competitive situation.

When a drug is approved, there is still a risk that national or international sales fail to meet expectations and the product does not become commercially successful. A drug's market acceptance and sales are dependent on a number of factors including product characteristics, clinical documentation and outcomes, competing products, distribution channels, availability, price, subsidies/reimbursements, and sales and marketing initiatives. These circumstances can have a negative effect on the Group's future operations, financial position and profitability.

Xspray is at risk of a lawsuits for patent infringement by original companies with the additional risk of a up to 30 months stay on the launch of its products. Xspray is actively engaged in strengthening its patent portfolio to protect itself against such delays.

Financial risks and procedures for asset management

The Group's activities expose it to various financial risks such as market risk (currency risk in cash flow), credit risk and liquidity risk.

Market risk consists mainly of currency risks. The Company collaborates with international parties and has some exposure to fluctuations in different currencies, in particular USD and EUR. Currency risk arises through future business transactions and the carrying amount of assets and liabilities. The current extent of the Company's operations means that its net exposure in foreign currencies is limited.

The credit risk for cash and cash equivalents is considered to be negligible as the counterparties are reputable banks with high credit ratings from external evaluators.

Financing risk constitutes the ability to finance projects to commercialization.

Liquidity risk is the Company's potential inability to meet its obligations. The Company manages this risk by monitoring and forecasting payments and receipts in day-to-day operations. The Company does not pursue active trade in financial assets for the purpose of speculation.

The objective of asset management is to ensure that operations are financed through equity.

Note 2 Other operating income

SEK thousand	2018	2017
EU subsidy	0	806
Exchange rate gains	86	18
Total	**86**	**824**

Note 3 Other operating income

SEK thousand	2018	2017
Exchange rate losses	-589	-141
Loss from the disposal of assets	-74	0
EU subsidy	-414	0
Total	**-1,077**	**-141**

Note 4 Expenses classified by type

SEK thousand	2018	2017
Other external expenses	-10,145	-8,206
Employee expenses	-4,602	-3,290
Depreciation	-4,027	-1,166
Other operating expenses	-4,806	-2,390
Total	**-23,580**	**-15,052**

Note 5 Leases – Operational leasing, lessees

Leasing expenses for the year in respect of operational leases consists mainly of rent for premises. Rental agreements for premises in the parent Company are valid until 10/31/2023 with a possible extension of three years. Total leasing charges amounted to SEK 701 thousand (291).

Future lease charges for non-cancelable leases fall due for payment as follows:

SEK thousand	2018	2017
Within 1 year	1,974	209
Later than one year but within five years	12,600	72
Later than 5 years	0	54
Total	**14,574**	**335**

In the case of IFRS 16 Leases, which comes into force in January 2019, the Company applies the simplified transition method. When reviewing the Company's various lease obligations, the rental agreement concerning premises on Råsundavägen 12 was identified as significant. Recalculation according to IFRS 16, affects the balance sheet such that right-of-use assets increase by SEK 8,769 thousand and liabilities increase with the lease liability of SEK 8,769 thousand. Marginal loan interest as of January 1, 2019 is assessed at 5%. SEK 1.6 million of the lease liability refers to current liability. Key ratios such as the equity/assets ratio are affected as the balance sheet total increases by just over SEK 8 million.

Note 6 Compensation to the auditors

Audit assignment refers to the auditor's work regarding the statutory audit, and audit activities refers to various kinds of quality assurance services. Other services are such that are not included in the audit assignment, audit activities or tax advice.

SEK thousand	2018	2017
Grant Thornton Sweden AB		
Audit assignments	224	103
Other services	79	0
Total	**303**	**103**
Öhrlings Pricewaterhouse-Coopers AB		
Other services	325	200
Total	**325**	**200**

Note 7 Employees and personnel costs

SEK thousand	2018	2017
Average number of employees		
Women	4	0
Men	7	6
Total	**11**	**6**
Salaries and other compensation		
Board and CEO	2,626	2,028
Bonuses and similar compensation to the Board and CEO	554	414
Other employees	7,513	4,083
Total	**10,693**	**6,525**
Social security expenses		
Pension expenses for the Board and CEO	349	263
Pension expenses for other employees	981	569
Other statutory and contractual social security charges	2,753	1,736
Total	**4,083**	**2,568**
Total pay, compensation, social security expenses and pension expenses	**14,776**	**9,093**

Compensation to senior executives

Compensation 2018, SEK thousand	Basic salary/ board fee	Other compensation	Variable compensation	Other benefits	Pension expenses	Total compensation
Chairman Michael Wolff Jensen	182	400				582
Member Hans Arwidsson	91					91
Member Maris Hartmanis	91					91
Member Carl-Johan Spak	91					91
Member Torbjörn Koivisto	91					91
CEO Per Andersson	1,528		553	49	349	2,479
Other senior executives	927	1,932			178	3,037
Total	**3,001**	**2,332**	**553**	**49**	**527**	**6,462**

Cont. Note 7

Compensation to senior executives

Compensation 2017, SEK thousand	Basic salary/ board fee	Other compensation	Variable compensation	Other benefits	Pension expenses	Total compensation
Chairman Michael Wolff Jensen	179	612				791
Member Hans Arwidsson	90					90
Member Maris Hartmanis	90					90
Member Carl-Johan Spak	90					90
Member Torbjörn Koivisto	90					90
CEO Per Andersson	1,484			67	263	1,814
Other senior executives		1,624				1,624
Total	**2,023**	**2,236**	**-**	**67**	**263**	**4,589**

There are no pension obligations for the Board members.

At year-end, the following senior executives had shares in the Company:
Michael Wolff Jensen 29,378 shares, Per Andersson 115,403 shares, Maris Hartmanis 28,619 shares, Torbjörn Koivosto 4,000 shares, other senior executives 74,307 shares.

The number of warrants issued to senior executives in the Company at year-end:
Michael Wolff Jensen 25,000, Per Andersson 186,124, other senior executives 42,528.

Agreements on severance pay and notice of termination

There are currently no agreements regarding severance pay for senior executives.

When termination is on the part of the CEO, the period of notice is six months. When termination of the CEO is on the part of the Company, the period of notice is nine months. If the CEO is relieved of his duties during the period of notice, he is not eligible for variable compensation; other regular compensation will be paid during the period of notice.

Gender distribution among senior executives	2018	2017
Proportion of women on the Board	0 %	0 %
Proportion of men on the Board	100 %	100 %
Proportion of women among other senior executives	33 %	0 %
Proportion of men among other senior executives	67 %	100 %

Note 8 Tax on profit for the year

Tax on current year earnings, SEK thousand	2018	2017
Current tax	0	0
Total reported tax	**0**	**0**

Reconciliation of effective tax, SEK thousand	2018 Percent	Amount
Reported loss before income tax		-23,098
Tax according to applicable tax rate	22.00	5,082
Non-deductible expenses		-19
Tax-exempt income		0
Loss carryforward exercised this year		0
Loss carryforward arising this year		-5,063
Reported effective tax		**0**

Reconciliation of effective tax, SEK thousand	2017 Percent	Amount
Reported loss before income tax		-13,817
Tax according to applicable tax rate	22.00	3,040
Non-deductible expenses		-19
Tax-exempt income		5
Loss carryforward exercised this year		0
Loss carryforward arising this year		-3,026
Reported effective tax		**0**

The Company has tax items in respect of emissions expenses reported directly against equity.

It has tax-related loss carryforwards in the amount of SEK 173 million (139) for which deferred tax assets have not been reported in the balance sheet and which have no time limitation. Deferred tax assets have not been reported for these items as the Company in all likelihood will continue to make losses next year. Furthermore, significant parts of the loss carryforward may be lost owing to the special limitation and blocking rules that apply when there are changes in ownership, e.g. new share issues. The size of the remaining loss carryforward is analyzed every year and the likelihood of their ability to be used against future gains is assessed.

Note 9 Capitalized development costs

SEK thousand	12/31/2018	12/31/2017
Acquisition costs brought forward	39,885	18,638
Purchases	31,965	21,247
Closing accumulated acquisition costs	**71,850**	**39,885**
Closing residual value according to plan	**71,850**	**39,885**

Impairment tests

Intangible assets with an indefinite useful life or which are not yet in use, are reviewed at least annually with regard to any need for impairment. Furthermore, value is also reviewed if there are indications that the carrying amount is not recoverable.

Xspray uses a probability-weighted cash flow model to test the value of intangible assets. The value of development projects in progress is derived by calculating anticipated future cash flows at present value probability-weighted to take development risks into account. The valuation considers cash flow for the five years, but with an increase in sales of 2% thereafter (equivalent to inflation). The valuation model refers to level II according to IFRS 13 and consists of the material assumptions listed below:

- Revenue and expense forecasts covering five years of the development project.
- The revenues are calculated based on forecasts for total market size, anticipated market share, estimated price level, royalty level and in certain cases also so-called milestone payments. The size of the market and the level of royalties on prices etc. are obtained from secondary sources, accepted assumptions within the industry and our own assumptions.
- The expenses consist of development expenses and direct and indirect project expenses based on the Company's business plan.
- Any investments deemed necessary are also taken into account.
- Cash flows are calculated at present value and weighted for the probability of project success. The weighted average cost of capital after tax is estimated at 31.3%.

The most critical assumptions are mainly those made about market size, market share and price levels. The Company remains in the development phase and the assessments cannot be confirmed with historical data, and this entails difficulties in assessing the reasonableness of forecasts. However, the Company can relate to relevant products on the market today.

The Group has conducted sensitivity analyses based on lower margins, displacements in time regarding estimated sales and the size of estimated sales, and none of the analyses give indications that any impairment is necessary.

Cont. Note 9

The weighted average cost of capital after tax can even be doubled without any indication of a need to recognize impairment.

The capitalized development costs will begin depreciation according to plan once the product concerned is launched on the market.

Note 10 Patent

SEK thousand	12/31/2018	12/31/2017
Acquisition costs brought forward	2,699	2,699
Purchases	0	0
Closing accumulated acquisition costs	**2,699**	**2,699**
Depreciations brought forward	-2,279	-1,902
Depreciations for the year	-377	-377
Accumulated depreciations carried forward	**-2,656**	**-2,279**
Closing residual value according to plan	**43**	**420**

Note 11 Equipment and other technical facilities

SEK thousand	12/31/2018	12/31/2017
Acquisition costs brought forward	8,791	6,280
Purchases	13,584	2,511
Closing accumulated acquisition costs	**22,375**	**8,791**
Depreciations brought forward	-6,611	-5,881
Depreciations for the year	-3,317	-730
Accumulated depreciations carried forward	**-9,928**	**-6,611**
Closing residual value according to plan	**12,447**	**2,180**

Depreciations on machinery and other technical facilities are included in the income statement under the items Sales and administration expenses in the amount of SEK 0 thousand (0), and Research and development expenses in the amount of SEK 3,317 thousand (730).

Note 12 Equipment, tools, fixtures and fittings

SEK thousand	12/31/2018	12/31/2017
Acquisition costs brought forward	718	459
Purchases	1,409	259
Disposals/retirements	-148	0
Closing accumulated acquisition costs	**1,979**	**718**
Depreciations brought forward	-437	-378
Depreciations for the year	-333	-59
Disposals/retirements	74	0
Accumulated depreciations carried forward	**-696**	**-437**
Closing residual value according to plan	**1,283**	**281**

Depreciations on machinery and other technical facilities are included in the income statement under the items Sales and administration expenses in the amount of SEK 247 thousand (11), and Research and development expenses in the amount of SEK 86 thousand (48).

Note 13 Shares in subsidiaries

	12/31/2018	12/31/2017
Acquisition value brought forward	0	0
Purchases	50	0
Accumulated cost carried forward	**50**	**0**
Closing carrying amount	**50**	**0**

Specification, shares in subsidiaries

Name	Proportion of equity	Proportion of voting rights	Number of participations	Book value
Xspray Pharma Futurum AB	100	100	50,000	50
				50

Name	Corporate ID number:	Domicile	Equity	Earnings
Xspray Pharma Futurum AB	559178-7642	Stockholm	50	0

Note 14 Other non-current securities holdings

SEK thousand	12/31/2018	12/31/2017
LFF Service AB nom value SEK 10	1	1
Closing number	**1**	**1**
Closing carrying amount	**1**	**1**

Note 15 Prepaid expenses and accrued income

SEK thousand	12/31/2018	12/31/2017
Prepaid rent	3,491	0
Other prepaid expenses	429	781
Total	**3,920**	**781**

Note 16 Equity

st	2018	2017
Number/value at beginning of year	12,356,460	6,356,460
New share issue	2,720,000	6,000,000
Number at end of year	**15,076,460**	**12,356,460**

The share has been traded on Nasdaq First North under the name XSPRAY since September 28, 2017. It was introduced at a price of SEK 22.00 per share. On 31 December, 2018, the number of shares in the Company totaled 15,076,460.

The Company has previously issued share options in two series, made out to senior executives.

The first share option program comprises 255,000 options at an exercise price of SEK 25.00 per share. These may be exercised no later than January 21, 2021. Fully exercised, the options result in a maximum dilution of 1.99 percent based on the current number of shares.

The second option program comprises 199,591 share options that may be exercised no later than August 2020 at an issue price of SEK 49.30. The program will result in a maximum dilution effect of 1.56 percent based on the current number of shares. The second program is conditional upon the holder remaining an employee of the Company.

The extraordinary shareholders' meeting of November 28 resolved to introduce an incentive program (LTI 2018) comprising a maximum of 234,505 share options linked to the Company's value growth with the purpose of creating a stronger link between the interests of key employees and

Cont. Note 16

those of shareholders. LTI 2018 comprised 17 persons. LTI 2018 did not apply to the Company's Board of Directors. The right to subscribe share options, in the case of deviation from shareholders' preferential rights, fell to the CEO, senior executives and other Company employees or persons who during the underwriting period have concluded an employment contract with Xspray Pharma. The share options was subscribed on market terms to a price (premium) determined on the basis of estimated market value for the options with the application of Black & Scholes valuation model and calculated by an independent valuation Institute. The value was estimated at SEK 5.83 per option based on a price per share of SEK 116.50. The Company subsidized the participants' premiums with an amount equivalent to earned premiums, which was reported as personnel costs in its entirety.

Given the full exercise of the options already issued during incentive programs previously adopted, LTI 2018 is equivalent to a maximum of around 1.5 percent of the share capital and votes after dilution (subject to any translation according to the option terms).

Note 17 Accrued expenses and deferred income

SEK thousand	12/31/2018	12/31/2017
Accrued vacation pay	658	391
Accrued special payroll tax	323	202
Accrued payroll-related expenses	179	1,128
Other accrued expenses	528	890
Total	**1,688**	**2,611**

Note 18 Adjustment for items not included in cash flow

SEK thousand	2018	2017
Depreciation	4,027	1,166
Earnings from asset disposals	74	0
Total	**4,101**	**1,166**

Note 19 Pledged assets

There were no assets or liabilities for which securities were pledged.

Note 20 Contingent liabilities

There are no contingent liabilities or contingent liabilities in favor of legal entities.

Note 21 Significant events after the close of the financial year

No events leading to adjustments in the income statement and balance sheet have occurred between the closing date and the date of approval of this report. In February 2019, Xspray presented positive data from a clinical phase I pilot study with the Company's product candidate, HyNap-Sora.

Note 22 Transactions with related parties

SEK thousand	12/31/2018	12/31/2017
Purchase of services from Board members	400	612
Total	**400**	**612**

The purchase of services from Board members refers to MWJ Partners Aps, which is owned by Chairman of the Board Michael Wolff Jenssen. The following Board members own share in the Company: Michael Wolff Jensen 29,378 shares, Per Andersson 115,403 shares, Maris Hartmanis 28,619 shares and Torbjörn Koivosto 4,000 shares.

Note 23 Definition of key ratios

Earnings per share is calculated as net income divided by the average number of shares during the period.

The equity/assets ratio is equity, and where applicable untaxed reserves (less deferred tax), in relation to total assets.

Research and development expenses as a percentage of operating expenses comprise the former divided by the latter, which include selling and administrative expenses and other operating expenses.

Note 24 Effect of changed accounting policies

During the year, Xspray Pharma changed its accounting policies. The Company switched to applying IFRS with the adjustments required by RFR 2 Accounting for Legal Entities. Because the Company has also switched its accounting to reflect functions instead of the type of expense, a function-based income statement is presented. The Q4 interim report was the first prepared according to IAS 34 Interim reports. At the end of December, Xspray Pharma AB (publ) acquired a newly incorporated subsidiary, dormant for the time being, and thus reports as a group. In addition to IFRS, the Group also complies with Swedish Financial Reporting Board recommendations, RFR 1. During previous periods, financial statements were prepared in accordance with the Swedish Annual Accounts Act and K3.

The Group uses cost for balance sheet item valuation unless otherwise stated.

The consequences of the switch to the new accounting standard are shown below. The left column shows the outcome following the switch.

Cont. Note 24

Income statement and report of comprehensive income

Amount in SEK thousands	Restated 1/1/2016 12/31/2016	Reclass-ification	1/1/2016 12/31/2016
Operating income etc.			
Net sales	792		792
Capitalized work on own account	-	-19,324	19,324
Total operating income etc.	**792**	**-19,324**	**20,116**
Operating expenses			
Sales & administration expenses	-4,078		-4,078
Research and development expenses	-2,531	18,638	-21,169
Other operating income	1,078		1,078
Other operating expenses	-6		-6
Total operating expenses	**-5,537**	**18,638**	**-24,175**
Operating loss	**-4,745**	**-686**	**-4,059**
Earnings from financial items	**-37**		**-37**
Earnings after financial items	**-4,782**	**-686**	**-4,096**
Loss before income tax	**-4,782**	**-686**	**-4,096**
Earnings for the year & comprehensive income	**-4,782**	**-686**	**-4,096**

Amount in SEK thousands	Restated 1/1/2017 12/31/2017	Reclass-ification	1/1/2017 12/31/2017
Operating income etc.			
Net sales	332		332
Capitalized work on own account	-	-21,865	21,865
Total operating income etc.	**332**	**-21,865**	**22,197**
Operating expenses			
Sales & administration expenses	-10,779		-10,779
Research and development expenses	-4,132	21,247	-25,379
Other operating income	824		824
Other operating expenses	-141		-141
Total operating expenses	**-14,228**	**21,247**	**-35,475**
Operating loss	**-13,896**	**-618**	**-13,278**
Earnings from financial items	**79**		**79**
Earnings after financial items	**-13,817**	**-618**	**-13,199**
Loss before income tax	**-13,817**	**-618**	**-13,199**
Earnings for the year & comprehensive income	**-13,817**	**-618**	**-13,199**

The adjustments also have an impact on earnings per share

	Restated 1/1/2017 12/31/2017	Reclass-ification	1/1/2017 12/31/2017
Number of shares before dilution	12,356,460		12,356,460
Number of shares after dilution	12,811,051		12,811,051
Average number of shares before dilution	7,945,622	-4,410,838	12,356,460
Average number of shares after dilution	8,400,213	-4,410,838	12,811,051
Earnings per share before dilution, SEK	-1.74	-0.61	-1.07
Earnings per share after dilution, SEK	-1.64	-0.56	-1.03

Cont. Note 24

The Company has also switched from a cost-based to a function-based income statement. The way the converted income statement, following adjustment due to the change in accounting policies, has affected the income statement is shown below. In all, 99% of the depreciations are reported under the item Research and development expenses during 2017 (100% 2016).

Income statement and report of comprehensive income

Amount in SEK thousands	Restated 10/1/2017 12/31/2017	Reclass-ification	10/1/2017 12/31/2017
Operating income etc.			
Net sales	20		20
Capitalized work on own account	-	-6,992	6,992
Other operating income	-	-806	806
Total operating income etc.	**20**	**-7,798**	**7,818**
Operating expenses			
Goods for sale	-	6,190	-6,190
Other external expenses	-	2,475	-2,475
Employee expenses	-	3,484	-3,484
Amortization & impairment of tangible & intangible fixed assets	-	595	-595
Sales & administration expenses	-4,128	-4,128	-
Research and development expenses	-1,624	-1,624	-
Other operating income	806	806	-
Other operating expenses	-118	-118	-
Total operating expenses	**-5,064**	**7,680**	**-12,744**
Operating loss	**-5,044**	**-118**	**-4,926**
Earnings from financial items	**80**	**118**	**-38**
Earnings after financial items	**-4,964**	**0**	**-4,964**
Loss before income tax	**-4,964**	**0**	**-4,964**
Earnings for the year & comprehensive income	**-4,964**	**0**	**-4,964**

Amount in SEK thousands	Restated 1/1/2017 12/31/2017	Reclassifica-tion	1/1/2017 12/31/2017
Operating income etc.			
Net sales	332		332
Capitalized work on own account	-	-21,247	21,247
Other operating income	-	-824	824
Total operating income etc.	**332**	**-22,071**	**22,403**
Operating expenses			
Goods for sale	-	17,731	-17,731
Other external expenses	-	8,618	-8,618
Employee expenses	-	8,785	-8,785
Amortization & impairment of tangible & intangible fixed assets	-	1,165	-1,165
Sales & administration expenses	-10,779	-10,779	-
Research and development expenses	-4,132	-4,132	-
Other operating income	824	824	-
Other operating expenses	-141	-141	-
Total operating expenses	**-14,228**	**22,071**	**-36,299**
Operating loss	**-13,896**	**0**	**-13,896**
Earnings from financial items	**79**	**0**	**79**
Earnings after financial items	**-13,817**	**0**	**-13,817**
Loss before income tax	**-13,817**	**0**	**-13,817**
Earnings for the year & comprehensive income	**-13,817**	**0**	**-13,817**

Cont. Note 24

Balance sheet and financial position

Amount in SEK thousands	Restated 12/31/2016	Adjustment	12/31/2016
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development costs	18,638	-686	19,324
Patent	797		797
	19,435	**-686**	**20,121**
Property, plant and equipment			
Equipment & other technical facilities	399		399
Equipment, tools & installations	81		81
	480	**0**	**480**
Financial fixed assets			
Other non-current securities holdings	1		1
	1	0	1
Total fixed assets	**19,916**	**-686**	**20,602**
Current assets			
Current receivables			
Accounts receivable	19		19
Current tax asset	201		201
Other receivables	2,075		2,075
Prepaid expenses & accrued income	162		162
	2,457	**0**	**2,457**
Cash and bank balances			
Cash and bank balances	28,803		28,803
	28,803	**0**	**28,803**
Total current assets	**31,260**	**0**	**31,260**
TOTAL ASSETS	**51,176**	**-686**	**51,862**
EQUITY & LIABILITIES			
Equity			
Restricted equity			
Share capital	6,357		6,357
Fund for development costs	18,638	-686	19,324
Statutory reserve	976		976
Total restricted equity	**25,971**	**-686**	**26,657**
Non-restricted equity			
Profit or loss brought forward	24,600	686	23,914
Loss for the period and the year	-4,783	-686	-4,097
Total non-restricted equity	**19,817**	**0**	**19,817**
Total equity	**45,788**	**-686**	**46,474**
Current liabilities			
Trade accounts payable	4,343		4,343
Other liabilities	217		217
Accrued expenses and deferred income	828		828
Total current liabilities	**5,388**	**0**	**5,388**
TOTAL EQUITY & LIABILITIES	**51,176**	**-686**	**51,862**

Cont. Note 24

Balance sheet and financial position

Amount in SEK thousands	Restated 12/31/2017	Adjustment	12/31/2017
ASSETS			
Fixed assets			
Intangible assets			
Capitalized development costs	39,885	-1,304	41,189
Patent	420		420
	40,305	**-1,304**	**41,609**
Property, plant and equipment			
Machinery & other technical facilities	2,180		2,180
Equipment, tools & installations	281		281
	2,461	**0**	**2,461**
Financial fixed assets			
Other non-current securities holdings	1		1
	1	**0**	**1**
Total fixed assets	**42,767**	**-1,304**	**44,071**
Current assets			
Current receivables			
Accounts receivable	23		23
Current tax asset	201		201
Other receivables	825		825
Prepaid expenses & accrued income	781		781
	1,830	**0**	**1,830**
Cash and bank balances			
Cash and bank balances	115,512		115,512
	115,512	**0**	**115,512**
Total current assets	**117,342**	**0**	**117,342**
TOTAL ASSETS	**160,109**	**-1,304**	**161,413**
EQUITY & LIABILITIES			
Equity			
Restricted equity			
Share capital	12,356		12,356
Fund for development costs	39,886	-1,304	41,190
Statutory reserve	976		976
Total restricted equity	**53,218**	**-1,304**	**54,522**
Non-restricted equity			
Profit or loss brought forward	114,954	618	114,336
Loss for the period and the year	-13,817	-618	-13,199
Total non-restricted equity	**101,137**	**0**	**101,137**
Total equity	**154,355**	**-1,304**	**155,659**
Current liabilities			
Trade accounts payable	2,890		2,890
Other liabilities	253		253
Accrued expenses and deferred income	2,611		2,611
Total current liabilities	**5,754**	**0**	**5,754**
TOTAL EQUITY & LIABILITIES	**160,109**	**-1,304**	**161,413**

Signatories to the Annual Report

We affirm that, to the best of our knowledge, the annual accounts have been prepared in accordance with generally accepted accounting principles. The Annual Report provides a true and fair view of the Company's financial performance and position and the Report of the Board of Directors provides a true and fair view of the activities, financial position and earnings of the Company and describes the significant risks and uncertainties to which the Company is exposed.

The consolidated financial statements were prepared in accordance with international accounting standards as referred to in Regulation (EC) No 1606/2002 of the European Parliament and of the Council of 19 July 2002 on the application of international accounting standards. The Consolidated Financial Statements provide a fair and true view of the Group's position, and the Report of the Group's Directors gives a true and fair view of the Group's activities and financial position and describes the significant risks and uncertainties to which the companies that form the Group are exposed.

Solna
April 29, 2019

Michael Wolff Jensen
Chairman

Hans Arwidsson

Maris Hartmanis

Torbjörn Koivisto

Carl-Johan Spak

Per Andersson
Chief Executive Officer

Our auditor's report was submitted on April 29, 2019

Grant Thornton Sweden AB

Thomas Lindgren
Authorized Public Accountant

Auditor's report

To the shareholders' meeting of Xspray Pharma AB • Corp ID no. 556649-3671

Report on the annual accounts and consolidated financial statements

Opinion

We have carried out our audit of the annual accounts and consolidated financial statements for XSpray Pharma AB for the financial year 2018 with the exception of the corporate governance report on pages 26–29. The Company's annual accounts and consolidated financial statements are included on pages 22–57 of this document.

In our opinion the annual accounts have been prepared in accordance with the Swedish Annual Accounts Act and provide in all material respects a true and fair view of the parent Company's financial position as of December 31, 2018 and its financial performance and cash flow for the year in accordance with the Swedish Annual Accounts Act. The consolidated financial statements were prepared in accordance with the Swedish Annual Accounts Act and in all material respects fairly represent the Group's balance sheet for the year as of December 31, 2018 in accordance with International Financial Reporting Standards as adopted by the EU, and the Swedish Annual Accounts Act. Our opinion does not cover the corporate governance report on pages 26–29. The administration report is consistent with the other sections of the annual accounts and consolidated financial statements.

We therefore recommend that the shareholders' meeting adopt the income statement and balance sheet for the parent Company and the balance sheet for the Group.

Basis for our opinion

We conducted our audit in accordance with International Standards on Auditing (ISA) and good auditing practice in Sweden. Our responsibility under these standards is described in more detail in the section entitled Auditor's responsibility. In accordance with generally accepted auditing standards in Sweden, we are independent in relation to the parent Company and Group and have fulfilled our ethical responsibility under these standards.

We believe that the audit evidence we have obtained in our audits is sufficient and appropriate to provide a basis for our audit opinion.

Information additional to the annual accounts and consolidated financial statements

This document also includes information additional to the annual accounts and consolidated financial statements, which can be found on pages 2–21. The Board and CEO are responsible for this additional information.

Our statement concerning the annual accounts and consolidated financial statements does not cover this information and we make no assurance in respect of said additional information.

As part of our audit of the annual accounts and consolidated financial statements, it is our responsibility to read the information identified above and consider whether it is incompatible to a substantial degree with the annual accounts and consolidated financial statements. In our review, we also consider other information gathered during the audit and assess whether this information in other regards appears to include material misstatements.
If, based on the work conducted with regard to this information, we conclude that the other information contains material misstatements, we are obliged to report this. We have nothing to report in this respect.

Responsibilities of the Board of Directors and the Chief Executive Officer

The Board and the CEO are responsible for ensuring that the annual accounts and consolidated financial statements are prepared and that they provide a fair and true view according to the Swedish Annual Accounts Act, and according to IFRS as adopted by the EU in the case of the consolidated financial statements. The Board and CEO are also responsible for the internal controls they deem necessary for the preparation of annual accounts and consolidated financial statements and to ensure they do not include any material misstatements, whether or not these be due to fraud or error.

When preparing the annual accounts and consolidated financial statements, the Board and CEO are responsible for assessing the Company's and Group's ability to continue operations. Where appropriate, they provide information about circumstances that can affect the ability to continue operations and to apply the going concern assumption. However, the going concern assumption is not applied if the Board and CEO intend to liquidate the Company, cease operations or do not have some other realistic alternative to either of these options.

Auditor's responsibility

Our objective is to achieve a reasonable degree of certainty as to whether the annual accounts and consolidated financial statements as a whole contain any material misstatements, whether or not these be due to fraud or error, and to submit an auditor's report that includes our opinions. Reasonable certainty is a high degree of certainty but no guarantee that an audit carried out according to ISA and generally accepted auditing standards in Sweden will always be able to detect material misstatements if such are present. Misstatements can arise due to fraud or error and they are considered material if they singly or severally can reasonably be anticipated to affect the financial decisions that users

make on the basis of the annual accounts and consolidated financial statements.

As part of an audit in accordance with ISA, we use professional judgement and take a professionally skeptical approach throughout. Furthermore:

- we identify and assess the risks of material misstatements in the annual accounts and consolidated financial statements, whether or not these be due to fraud or error, and we establish and perform audit procedures based inter alia on these risks and obtain audit evidence that is sufficient and appropriate to constitute the basis of our statements. The risk of failing to detect material misstatements as a result of fraud is higher than for a material misstatement that stems from error, as fraud can include actions in collusion, forgery, deliberate omissions, erroneous information or the disregard of internal controls.
- we gain an understanding of the part of the Company's internal controls that is important for our audit and for establishing appropriate audit procedures with regard to circumstances, but not to express an opinion on the effectiveness of internal controls.
- we assess the suitability of the accounting policies used and the reasonableness of the estimations made by the Board and CEO in the accounts and associated disclosures.
- we draw a conclusion concerning the suitability of the Board's and CEO's use of the going concern assumption when preparing the annual accounts and consolidated financial statements. We also draw a conclusion based on audit evidence gathered as to whether there is any material uncertainty factor that relates to such events or circumstances as can lead to significant doubts about the Company's and Group's ability to continue operations. If we conclude that a material uncertainty factor is present, we must draw attention in the audit report to the information in the annual accounts and consolidated financial statements about the material uncertainty factor or, if such information is insufficient, modify our statement on the annual accounts and consolidated financial statements. Our conclusions are based on the audit evidence gathered up until the date of the auditor's report. However, future events or circumstances may mean that a Company or a group no longer can continue operations.
- we evaluate the overall presentation, structure and content of the annual accounts and consolidated financial statements, including disclosures and whether the annual accounts and consolidated financial statements reflect the underlying transactions and events in a way that provides a fair and true view.
- we gather sufficient and appropriate audit evidence related to the financial information in the units or the business activities within the Group in order to provide an opinion concerning the consolidated financial statements. We are responsible for control, supervision and execution of the Group's audit. We are solely responsible for our statements of opinion.

We must inform the Board about e.g. the audit's planned scope, direction and date. We must also provide information about important observations during the audit, including any significant shortcomings we identify in the internal controls.

Report on other legal and regulatory requirements

Opinion

During our audit of the annual accounts and consolidated financial statements, we also carried out a review of the Board's and CEO's administration of XSpray Pharma AB for 2018 and the proposed allocation of the Company's profit or loss.

We recommend to the shareholders' meeting that the profit be appropriated in accordance with the proposal in the administration report and that the members of the Board and the CEO be discharged from liability for the financial year.

Basis for our opinion

We conducted the audit in accordance with auditing standards generally accepted in Sweden. Our responsibility under these standards is described in more detail in the section entitled Auditor's responsibility. In accordance with generally accepted auditing standards in Sweden, we are independent in relation to the parent Company and Group and have fulfilled our ethical responsibility under these standards.

We believe that the audit evidence we have obtained in our audits is sufficient and appropriate to provide a basis for our audit opinion.

Responsibilities of the Board of Directors and the Chief Executive Officer

The Board is responsible for proposing the allocation of the Company's profit or loss. Dividend proposals include e.g. assessing whether the dividend is justifiable with regard to the demands placed on the Company's and Group's equity, solvency requirements, liquidity and general position by the nature of the Company's and Group's operations, scope and risks.

The Board is responsible for the Company's organization and the administration of its affairs. This means the Board

must for example continually assess the Company's and the Group's financial situation and ensure that the Company's organization is designed such that the Company's accounting, asset management and its financial affairs in general are satisfactorily controlled. The CEO is responsible for day-to-day administration according to the Board's guidelines and instructions and his duties include taking the necessary measures to ensure the Company's accounting records are completed in compliance with the law and that asset management is conducted in a satisfactory manner.

Auditor's responsibility

Our goal concerning the review of the administration and thus our statement concerning the discharge from liability, is to gather audit evidence to enable a reasonable degree of certainty in our assessment if any Board member or the CEO in any material respect

- has taken any action or is guilty of any omission that can lead to liability for damages on the part of the Company, or
- has in any other way acted in contravention of the Swedish Companies Act, Annual Accounts Act or articles of incorporation.

Our goal in regard to reviewing the proposed allocation of the Company's profit or loss and thus our statement of opinion on this, is to assess with a reasonable degree of certainty whether the proposal is in compliance with the Swedish Companies Act.

Reasonable certainty is a high degree of certainty but no guarantee that an audit carried out in accordance with generally accepted auditing standards in Sweden will always detect measures or omissions that can lead to liability for damages on the part of the Company, or that a proposal for the allocation of the Company's profit or loss is not in compliance with the Swedish Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we use professional judgment and take a professionally skeptical approach throughout. The review of the administration and proposed allocation of the Company's profit or loss is based primarily on an audit of the accounts. Any additional review measures carried out are based on our professional assessment with respect to risk and materiality. This means our focus is on reviewing such measures, areas and circumstances that are important for the operation and where departures and noncompliance would be of particular importance for the Company's situation. We review and test decisions made, supporting documentation, measures taken and other circumstances relevant for our opinion concerning discharge from liability. As a basis for our opinion on the Board's proposed allocation of the Company's profit or loss, we examined the proposal to see if it is in accordance with the Swedish Companies Act.

Auditor's review of the corporate governance report

The Board of Directors is responsible for the corporate governance report on pages 26–29 and ensuring that it is prepared in accordance with the Swedish Annual Accounts Act. Our review was conducted in accordance with FAR's RevU 16 Auditor's review of the corporate governance report. This means our examination of the corporate governance report is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and auditing standards generally accepted in Sweden. We believe that this audit provides us with sufficient grounds for our opinion.

A corporate governance report has been drawn up. Disclosures in compliance with Chapter 6 section 6 second paragraph items 2–6 of the Swedish Annual Accounts Act and Chapter 7 section 31 second paragraph of the same enactment are consistent with the other parts of the annual accounts and consolidated financial statements and with the Swedish Annual Accounts Act.

Uppsala April 29, 2019

Grant Thornton Sweden AB

Thomas Lindgren
Authorized Public Accountant

Glossary

Amorphous • Amorphous structure is a chemical term that describes substances whose molecules lack an organized structure.

API • Active Pharmaceutical Ingredient

Bioavailability • i.e. biological availability, is a pharmacological term that shows what proportion of the drug reaches the blood.

Blockbusters • Drugs with annual global sales in excess of USD 1 billion.

Clinical phase • The various stages in the study of a drug's effects in humans (see also 'clinical study'). Phase 1 investigates safety in healthy subjects; Phase 2 investigates the effects in patients with the disease concerned, and Phase 3 is a larger study to verify earlier achieved outcomes. Once a drug is sold on the market, Phase 4 studies are conducted to discover e.g. unusual side effects.

Clinical study • A study of healthy test subjects (Phase 1) or patients (Phases 2 through 4) in order to study safety and the effect of the drug or method of treatment.

CMO • Contract Manufacturing Organization

CRO • Contract Research Organization. A service company that performs assignment research and drug development services.

Crystalline • Crystalline structure is a chemical term that describes substances whose molecules have an organized structure.

Drug candidate • A substance chosen during a pre-clinical phase for further testing in healthy subjects and later on, in patients.

Excipient • Excipients facilitate/enable handling and use of a drug formulation; they include binding agents, fillers and stabilizing agents and other.

FDA • Food and Drug Administration. The USA's food and drug authority whose responsibilities cover food, dietary supplements, drugs, cosmetics, medical equipment, radiation emission products and bio products.

Formulation • In the pharmaceutical industry, formulation is synonymous with preparation.

Generic • Generic drugs are replacement drugs with the same function, quality and safety as the original drug.

GMP • Good Manufacturing Practice. Good Manufacturing Practice rules describe how the drug industry must produce medications such that patients can always be sure they are getting thevorrect and high-quality product. The rules govern the production, including packaging, of drugs, foods – and nutritional supplements. GMP is a system for ensuring that products are always manufactured and controlled for compliance with current quality standards. They are designed to minimize the risks in drug production that cannot be eliminated through testing of the end product.

Indication • In medical contexts an indication is a symptom, illness or a condition that requires treatment.

Oncology • The study of cancer and also a medical specialization that focuses on cancers and their treatment.

Orphan Drug • An individual drug for the treatment of a single serious or chronic illness where no more than 200,000 patients in the USA have the indication.

Patent window • The time between the start date of the primary substance patent for the original drug and the expiration date of the relevant secondary patents.

Pharmaceutical equivalence • The product has the same active ingredients as the original product, with the same strength, dosage form and route of administration. However, it may differ from the original product where in excipients, size, shape and packaging, etc.

Preclinical • Part of drug development that takes place before a drug candidate is tested on humans.

Primary and secondary patents • The primary patent protects the active substance (API) in a drug. The secondary patent describes modified compounds, formulations, dosages, special medical uses etc.

Protein kinase • An enzyme that acts as a messenger in a cell. Protein kinases are crucial when a cell's functions are to be controlled by external signals e.g. hormones, by helping to pass on signals inside the cell. Protein kinases help cancer cells grow and spread.

Protein kinase inhibitors • Drugs that block protein kinases. Protein kinase inhibitors act by blocking the activity of enzymes that drive the development and growth of cancer cells.

SCF • Super Critical Fluid

SEK billion • Billions of Swedish kronor.

SEK million • Millions of Swedish kronor.

SEK thousand• Thousands of Swedish kronor.

Shareholder information

Financial calendar 2019	Date
Interim Report Q1, Jan–March 2019	May 16, 2019
Annual General Meeting 2019	May 23, 2019
Interim Report Q2, Apr–Jun 2019	August 29, 2019
Interim Report Q3, Jul–Sep 2019	November 7, 2019
Year-end report, 2019	February 13, 2020

All financial reports are available on Xsprays website, www.xspraypharma.com

The English version is a translation from Swedish. In case of discrepancy, the Swedish version shall prevail.

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Annual General Meeting 2019

The AGM will take place at 11:00 on Thursday, May 23, 2019 in Vinge's premises at Stureplan 8 in Stockholm.

To be eligible to attend the AGM, shareholders must:

- be registered as shareholders in the shares ledger maintained by Euroclear Sweden AB regarding circumstances on Friday, May 17, 2019
- have notified the Company of their intention to participate in the AGM by no later than Friday, May 17, 2019. Notification must be in writing to Xspray Pharma AB, Råsundavägen 12, SE 169 67 Solna, Sweden or by email to generalmeeting@xspray.com

For complete information regarding the 2019 AGM, we refer to the notice to attend posted on Xspray's website, www.xspraypharma.com

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