



Xspray Pharma Annual Report 2022

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## **About Xspray Pharma**

Xspray Pharma AB (publ) is a pharmaceutical company with multiple product candidates in clinical development. Xspray Pharma uses its innovative, patented HyNap-technology to develop improved versions of marketed protein kinase inhibitors (PKI) for treatment of cancer. The segment is the largest in oncology, and drug prices are very high.

The company's innovative technology provides a window of opportunity for Xspray Pharma to gain entry as the first competitor to the original drugs before the secondary patents expire and the market opens up to standard generics. Xspray Pharma's goal is to become a leading developer of improved versions of already marketed PKIs for cancer treatment, which amounted to a total of approximately 80 drugs on the US market in 2022.

## The year in brief

The financial year of 2022 began with an important milestone when FDA announced that they would initiate a full review of the application for market approval of Xspray Pharma's product candidate XS004. As expected, Bristol Myers Squibb filed a lawsuit against Xspray Pharma for patent infringement in February 2022. The development of the company's second product candidate, XS003, has progressed and clinical studies were initiated during the year.

## First quarter, January-March

- FDA initiated a review of Xspray Pharma's application for market approval of XS004.
- Anna-Karin Ekberg was appointed as Global Head of Marketing and Sales.
- Bristol Myers Squibb filed a lawsuit against Xspray Pharma in the US claiming patent infringement related to XS004.

## Second quarter, April-June

- The Annual General Meeting resolved, in accordance with the Nomination Committee's proposal, on the re-election of Board members Anders Ekblom, Anders Bladh, Maris Hartmanis, Torbjörn Koivisto, Christine Lind and Carl-Johan Spak as well as the election of new Board member Robert Molander for the period up until the end of the next Annual General Meeting. Anders Ekblom was elected Chairman of the Board.
- The company's long-term incentive program 2022 (LTI 2022), in the form of warrants and employee stock options, was fully subscribed and in total 421,875 employee stock options were issued. All members of the executive management team subscribed for their full allotment as part of the incentive program.
- Thomas Walz was appointed Chief Medical Officer and he assumed his position on September 1, 2022.
- FDA granted XS004 Orphan Drug Status for treatment of chronic myeloid leukemia.

## Third quarter, July-September

• No significant events during the third quarter.

### Fourth quarter, October-December

- The company made a directed issue of shares amounted to SEK 100 million. The proceeds will primarily be used for market preparations ahead of the coming launch of XS004 on the US market and for continued development of product candidate XS003.
- FDA granted XS004 Orphan Drug Status for treatment of acute lymphatic leukemia.

## Events after the period

- Xspray Pharma entered an agreement with EVERSANA ahead of the US-launch and commercialization of the company's product candidate XS004. Xspray Pharma keeps the financial and strategic control and gives EVERSANA exclusive commercial rights to execute the launch of XS004, which is expected in the second half of 2023.
- Xspray Pharma announced a new product candidate: XS008. The product candidate is based on the original substance axitinib which is used for treatment of kidney cancer.
- Xspray's manufacturing partner Nerpharma received approval by AIFA, Italy's medical product agency, for commercial production of XS004.
- Xspray Pharma founded a US subsidiary, Xspray Pharma Inc.

## History

With Xspray Pharma's unique technology platform HyNap and a focus on development of improved PKIdrugs for cancer treatment, the company has several exciting product candidates in development. Repeated studies show clear advantages with Xspray Pharma's products compared to currently marketed PKI-drugs.

When Xspray Pharma was founded in 2003, the company focused on development of particle technology in connection to production of drugs, which later became known as the company's HyNap-technology. In 2021, the company transitioned from development of improved and generic drugs to focusing on improved drugs. This was an important decision which resulted in increased focus on development of new product candidates with improved patient outcomes that are not limited by a requirement to be an exact copy of the original drug. An improved product also has a larger economic potential, both during and after the launch window.



#### 2022

In January 2022, the FDA announced that they will commence a full review of the application for market approval of XS004. Bristol Myers Squibb filed a lawsuit against Xspray Pharma for patent infringement in February 2022. The FDA granted XS004 Orphan Drug Status during the year for treatment of both chronic myeloid leukemia and acute lymphatic leukemia.

#### 2021

Bioequivalence is achieved in a study comparing Xspray Pharma's XS004 and the reference product Sprycel®. The study confirms that the dose of XS004 can be reduced by 30% and still achieve the same uptake in the body as the reference product. Xspray Pharma makes a final application to the FDA for market approval of XS004 according to the 505(b)(2) NDA process. The Company decides to exclusively focus its development efforts on improved PKIs instead of both improved and generic PKIs.

#### 2020

Xspray Pharma secures the supply chain for XS004, from production of active substance until production of a finished pill. A study shows that the body's absorption of XS004 is not impacted by the stomach's pH-value nor by comedication with pharmaceuticals for peptic ulcers such as omeprazol. Development also continues for the company's next product candidate XS003, a product candidate that has been granted Orphan Drug Status by the FDA for treatment of chronic myeloid leukemia. Planning for a manufacturing facility in Malta started.

#### 2017-2019

Xspray Pharma initiates a collaboration with an Italian partner Nerpharma which will manage production of XS004 in a new facility that is Good Manufacturing Practice-approved. The company successfully produces the amorphous material for XS004 at commercial scale.

#### 2011-2016

The Company's HyNap-technology is developed with a focus on protein kinase inhibitors (PKIs) for treatment of cancer patients. Positive results are shown from three clinical studies of an improved as well as a generic version of XS004. FDA approves that the company can initiate clinical trials of XS004 in healthy subjects.

#### 2003

Xspray Pharma was founded and focuses initially on the development of a new nozzle which enables larger production volumes for a specific particle technology.

## **CEO letter**

Dear Shareholder,

We made important progress during 2022 in completing our first product intended for launch and commercialization in the US. The product is XS004 brand-named Dasynoc, our amorphous version of dastinib intended for treatment of chronic myeloid leukemia (CML) and acute lymphatic leukemia (ALL) which are blood cancer diseases. During the year we were able to present new research data that shows that Dasynoc can have clear clinical benefits. We also made an application to the FDA, Federal Drug Administration, in the US for market approval of Dasynoc and received regulatory approval from the Italian Medicines Agency, AIFA, for commercial production of the product. We have thus initiated production of the required stock of Dasynoc ahead of a launch which is planned for the second half of 2023. After the financial year, we also presented our commercialization strategy by which we have signed an agreement with EVERSANA, a third party service provider giving us access to a specialized, established and scalable sales organization covering the entire US. EVERSANA has extensive experience in selling PKI-drugs and will be responsible for the US launch of Dasynoc at an optimized cost while Xspray Pharma maintains strategic and financial ownership of the product.

## Xspray to commercialize its first product

We are now working towards a launch of Dasynoc in the US in the second half of 2023, a decisive milestone for the company and something we have been working for many years. After the period we signed an agreement with EVERSANA to market and sell our product candidate Dasynoc throughout the US. According to the agreement, EVERSANA will provide a comprehensive solution with access to an experienced sales organization that manages marketing and sales of the product. As opposed to a solution whereby Xspray Pharma would build a sales organization on its own or a solution whereby we license the product to a third-party, this agreement with EVERSANA represents a middle-ground. This gives us exclusive access to an established and scalable marketing and sales organization for an optimized budget while we as owners retain the profits from the product's future sales. The EVERSANA-team covers the entire US, is dedicated to us and ready to begin their sales effort when all regulatory and legal requirements are in place.

During the year, our production partner Nerpharma was approved by the Italian Medecines Agency AIFA for commercial production of Dasynoc. We have now initiated commercial scale productions in order to build sufficient stock before the commercial launch in the US.

## Dasynoc is a unique product with clear patient benefits

In January 2022, the FDA announced that they are Initiating a full review of the company's application for market approval of Dasynoc. We expect that the FDA review of the application will be completed by the summer of 2023 and result in an approval to market Dasynoc as an improved version av dasatinib for treatment of CML and ALL.

During the year we presented new data on Dasynoc at ASH, the world's largest hematology conference is organized by the American Society of Hematology. Together with scientists from Uppsala University and Karolinska University Hospital we presented data showing that our patented HyNap-technology provides a more even uptake of Dasynoc in the body compared to the existing treatment. The reason for this is that the absorption of Dasynoc is less pH-sensitive than the existing treatment which is an important advantage, partly since it enables comedication of peptic ulcers.

Thus we have a patent which gives Dasynoc exclusive patient benefits beyond the launch window. We estimate that approximately 30-50% of all patients that are treated for CML with PKIs also comedicate for peptic ulcers. For these patients there is currently no other solution that can compete with Dasynoc.



At the same time, the lawsuit continues regarding an alleged patent infringement against the original product's secondary patent. A launch of Dasynoc is contingent upon a solution of the legal process. We are unable to speed up the process, it must run its course and we provide the courts with all the necessary documentation. However, we are optimistic of a resolution during the year.

## New product candidates based on the HyNap-technology

After the period we announced a new product candidate: XS008. The product candidate is based on the original substance axitinib which is used for treatment of kidney cancer. The PKI market for kidney cancer generated sales of approximately USD 3 billion in the US in 2022.

The development of XS003 progresses according to plan and clinical studies are ongoing. Following a careful evaluation, we have decided to discontinue the development of XS005 for the indication liver cancer, after a re-evaluation of the clinical needs and the product's market potential. The decision will result in a disposal of SEK 15 million during the year. We thus have three announced product candidates in different development stages all based on our patented HyNap-technology.

We are very pleased to have Nerpharma in Italy as our production partner since their facility will enable production of several of Xspray's future products. We therefore believe our new product candidates will have a shorter journey to commercialization since we can benefit from processes and agreements that have been established for Dasynoc.

I want to thank all shareholders, employees and partners for an eventful year and I look forward to keeping you updated on our continued progress.

Per Andersson, CEO Xspray Pharma

## Market

## Continuous demand for improved cancer treatments

Although significant improvements in the development of new cancer treatments have been made and the prognosis for many cancer diagnoses has improved, cancer remains a major healthcare challenge worldwide. According to The International Agency for Research on Cancer (IARC), 19.3 million new cases of cancer were diagnosed globally in 2020 and 10.0 million died as a result of their cancer. By 2040, the global incidence of new cancer cases is expected to grow to 28.9 million. Global sales of cancer drugs amounted to USD 156 billion in 2020, of which North America accounted for almost half. Over the next five years, the market for cancer drugs is expected to increase by an average of 11.5 percent per year.

## Protein kinase inhibitors

Protein kinase inhibitors (PKIs) have quickly become one of the most effective treatments of cancer and for certain types of cancer, PKIs are the only available option. This segment is the largest in the oncology area with over 600 drug candidates in clinical development, of which some 230 in late clinical phases (phases II or III), and approximately 80 PKIs are approved treatments on the American market.



## Marketed Protein kinase inhibitors and their therapeutic indications

Indication	Marketed PKIs	
Liver cancer and bile duct cancer	Sorafenib, Cabozantinib, Regofarein, Lenvatinib, Pemigatinib, Futibatinib, Infigratinib	
Leukemia	Imatinib, Dasatinib, Nilotinib, Ponatinib, Bosutinib, Asciminib, Ibrutinib, Idelalisib, Midostaurin, Ivosidenib, Duvelisib, Gilteritinib, Olutasidenib	
Rheumatoid arthritis	Tofacitinib, Baricitinib, Upadacitinib	
Lung cancer	Afatinib, Erlotinib, Gefitinib, Dabrafenib, Crizotinib, Ceritinib, Alectinib, Osimertinib, Brigatinib, Dacomitinib, Loratinib, Entrectinib, Capmatinib, Pralsetinib, Selpercatinib, Tepotinib, Mobocertinib, Trametinib	
Gastrointestinal cancer/ Gastrointestinal stromal cell tumor	Imatinib, Regorafenib, Ripretinib	
Kidney cancer	Sorafenib, Cabozantinib, Levatinib, Tivozanib, Sunitinib, Pazopanib, Axitinib	
Thyroid cancer	Sorafenib, Cabozantinib, Levatinib, Dabrafenib, Pralsetinib, Selpercatinib, Vandetanib	
Lymph node cancer	Imatinib, Idelalisib, Duvelisib, Crizotinib, Loratinib, Acalabrutinib, Copanlisib, Zanubrutinib, Pirtobrutinib	
Melanoma	Ibrutinib, Dabrafenib, Vemurafenib, Trametinib, Cobimetinib, Binimetinib, Encorafenib	
Breast cancer	Lapatinib, Palbociclib, Neratinib, Ribociclib, Abemaciclib, Alpelisib, Tucatinib	
Idiopathic pulmonary fibrosis	Nintedanib	
Glaucoma	Rhopressa	
Bladder cancer	Erdafitinib	
Pancreatic cancer	Erlotinib, Gefitinib	
Endometriecancer	Levatinib	
Neurofibrom	Erdafitinib, Selumetinib	
Other	Trilaciclib, Ruxolitinib, Fedratinib, Fostamatinib, Larotrectinib, Pexidartinib, Belumosudil, Pacritinib, Deucravacitinib, Tirbanibulin, Abrocitinib	





All Xspray Pharma's product candidates in development are currently PKIs.

The increased presence of cancer and autoimmune diseases are important factors that are expected to drive the growth of PKIs. PKIs have demonstrated an ability to prevent the growth of cancer which results in a lengthy treatment of the patient, in some cases an entire life time. Sales of PKI drugs amounts to approximately 37 percent of the total oncology market in the US, a segment in which drug prices are very high. In the end of 2022 there were approximately 80 marketed PKIs for cancer treatment in the US. As many as 23 of these substance patents are expected to expire in the US by 2030. Among the substance patents that expire include those original drugs whose active substance that Xspray Pharma's product candidates are based on. Total sales of the all 80 PKIs amounted to USD 33 billion in 2021, and the market is expected to continue to have high growth.

### Trends

## Demographic development

The demographic development results in an aging population due to increased life expectancy and less children being born primarily in Europe, US and Japan. For instance, the share of the population over the age of 80 is expected to double between 2016 and 2050 in Europe. This demographic development leads to increased needs for medication, innovative products and digital solutions.

#### Increased use of drugs

The use of more expensive and patented original drugs will increase, primarily driven by developing countries. At the same time, the use of generic drugs will be more prevalent when patents expire and demand for generica is primarily expected to increase in developing countries. Orphan drugs will account for a growing share of patented drugs since the prevalence of rare diseases increases which has led to increased interest in development of these drugs among both pharmaceutical companies and authorities.



## Annual sales of PKI-drugs in the US



# Strategy

Xspray Pharma uses its innovative and patented HyNap technology to develop amorphous product candidates which are improved versions av marketed protein kinase inhibitors (PKI) for treatment of cancer.

## Vision

Xspray Pharma's vision is to use its HyNap technology to become a world-leading actor in improved PKIs to give cancer patients a better life quality.

## Financial and operational vision

By 2030, the company will have:

- Net sales exceeding USD 400 million
- Profit margin exceeding 65 percent (profit before tax)
- 5 commercialized products
- 3 product candidates in development

The Company has updated its 2030 vision following a partnership agreement with EVERSANA for commercialization of XS004. The Company had previously estimated net sales based on a royalty agreement but since Xspray maintains financial and strategic control, the vision has been revised.

#### **Business model**

The first illustration below shows the typical product cycle for traditional pharmaceutical companies. A traditional pharmaceutical company initiates a long drug development process before the drug can be sold with market exclusivity during a number of years before the secondary patent expires and the market is opened up to generica. When a traditional pharmaceutical company develops a new drug, the development requires phase I, II and III studies, which take both a long time and require significant investments.

Xspray Pharma has a significantly shorter drug development cycle since the original substance has already been developed and the drug can be launched once the primary patent for the original substance has expired. With the HyNap technology as a foundation, Xspray Pharma improves already approved substances that have undergone clinical studies. Xspray Pharma's



studies are considerably shorter and require less capital.

When the primary patent has expired, Xspray Pharma has the right to launch its improved products. The time for the original substance's secondary patent is what Xspray refers to as launch window for its products. When it comes to PKIs, the primary patent protects the original substance and the secondary patent protects other aspects of the original drug, for instance crystalline forms of the active drug substance. Since Xspray Pharma through its HyNap technology develops drugs that are amorphous, Xspray Pharma is not affected by the original substance's secondary patent. This means that Xspray Pharma's products can be marketed directly after the original company's substance patent has expired, which leads to a favorable environment for a launch since competition is very limited. Also after the expiry of the secondary patent, Xspray Pharma's product candidates have advantages that are favorable to patients compared to generica which replicate the reference product.

## Strategic focus areas

#### Research and development

Xspray Pharma has chosen to develop its product candidates as improved versions of marketed protein kinase inhibitors and are registered according to the regulatory process 505(b)(2) New Drug Application of Federal Food, Drug and Cometic Act (FDCA). Xspray Pharma will not elect product candidates that require a complete new drug application since such a process is more costly and involves higher regulatory risk.

Of the approximately 80 PKIs that are currently marketed in the US, 23 have substance patents that are expected to expire before 2030. Xspray Pharma has to date tested its HyNap technology on approximately 20 PKIs that are marketed in the US, with positive results.

The HyNap technology is the foundation for Xspray Pharma's product portfolio. The product portfolio consists of carefully chosen product candidates for which Xspray Pharma see the greatest improvement and market potential.

## Production

The production strategy focuses on securing a supply chain, from production of the amorphous formulation of the active drug substance until a final pill, which secures sufficient production capacity for both clinical studies and commercial needs. Production of the amorphous substance material for commercial sales, has been outsourced to a well established external contractor, a so called CMO (Contract Manufacturing Organization). Xspray Pharma's CMO is Nerpharma, a well established Italian CMO that has also been approved by FDA. After the period, Nerpharma received approval from the Italian medical authorities AIFA for commercial production of XS004.

Even though production takes place with an external CMO, Xspray Pharma maintains full ownership of production units. In order to increase production capacity,



Xspray Pharma has also entered an agreement with Pharmacare Premium Ltd. regarding the construction of a new facility on Malta. The new facility will be located inside Pharmacare Premium's existing premises.

## Commercialization

Since Xspray Pharma's product candidates have an amorphous structure instead of a crystalline one, they can be launched after the expiry of the original drug's primary patent and thereby be marketed in parallel with the original drug. This gives Xspray Pharma's products limited competition. Also after the expiry of the secondary patent and the market opens up to generica, Xspray Pharma's products will continue to have strong and patented advantages based on the HyNap technology.

By offering clear patient benefits, Xspray Pharma's products are expected to gain sizeable market shares from the original drug. As a first step, Xspray Pharma wants to introduce its products on the American market. Profit margins are deemed higher in the US than in rest of the world since PKIs are highly priced on the American market. Xspray Pharma seeks to generate revenues by being granted market approvals on its own for the company's product candidates.

After the period, Xspray Pharma entered a partnership agreement with EVERSANA for the commercialization of XS004. Xspray Pharma maintains the financial and strategic control and gives EVERSANA exclusive commercial right to launch XS004 with the goal of launching during the second half of 2023. According to the agreement EVERSANA will provide Xspray with a dedicated commercialization team with long experience of successfully commercializing cancer drugs, including TKI products (tyrosine kinase inhibitors), which includes PKIs.

Facts: Launch of XS004					
Expected launch	Second half of 2023				
Place	US				
Commercialization parter	EVERSANA				
Market size	USD 1.5 billion (sales of original product in 2022)				



## Overview R&D status - product portfolio





## **Technology platform – HyNap**

All product candidates are developed based on the company's patented HyNap technology. This technology enables production of amorphous materials which provides advantages such as bio equivalence at lower dosages, not affected by the pH-value and a more even absorption of the drug in the body.

#### **HyNaps function**

Xspray Pharma's in-house developed HyNap technology is a particle technology that creates a so called amorphous solid dispersion of a drug's active substance. The HyNap technology is based on so called Super Critical Fluid.

Molecules in a super critical state can move quickly, similar to a fluid in the form of a gas, while there is an ability to dissolve elements. The Super Critical Fluid is used as a anti dissolvent for controlling the active pharmaceutical ingredient, with or without aiding elements.

Considerable research has taken place in the area since the early 1990's. Despite large investments in Super Critical Fluid facilities, the technology was not able to be commercialized due to difficulties upscaling production. Xspray Pharma has resolved these issues through the company's HyNap technology. The patented design enables upscaling of production from small quantities for laboratory needs to larger quantities for commercial purposes.

## Xspray produces amorphous drugs

Today's marketed PKI-drugs are produced in crystalline forms. A known problem with crystalline PKI-drugs is that they are difficult to dissolve and that the absorption can vary based on the stomach's pH-value. This often results in an uneven absorption of the drug in the body, especially combined with intake of food or pH-increasing drugs, for instance omeprazole. The variability in the body's ability to take up the drug reduces the therapeutic benefits. When the uptake is too low the benefits are likely to not materialize and as consequence the cancer can start to grow again and spread. When the uptake is too high the risk often increases for difficult side effects.



Xspray Pharma's amorphous formula based on its HyNap technology is of great significance to both the product candidates' improved qualities and for the legal possibility to launch products without being hindered by the original drug's secondary patent, which relates to their crystalline formula.



Xspray Pharma's innovative and patented HyNap technology means that many of the deficiencies existing PKIs generally have, can be resolved. The company produces amorphous drugs that are more easily dissolved and are not affected by the pH-value as opposed to today's marketed PKIs. This results in a better ability to absorb the drug, also when consuming food or in combination with pH-increasing drugs. In addition, the amorphous version of the drug leads to improved pharmacokinetic qualities that give the product a more advantageous therapeutic profile for patients. For instance, lower dosages can be provided with maintained therapeutic effects while side effects are reduced.

### Stability during storage

An important aspect of developing amorphous products is stability during storage. Amorphous formulas have higher energy and dissolve faster than crystalline formulas, but amorphous products tend to return to a crystalline state during storage and thereby eliminate the advantages with the amorphous drug. However, Xspray Pharma's products have demonstrated an ability to remain entirely amorphous during long storage periods.

The company's XS004 pills have been examined by sensitive instruments used to discover crystalline materials. In the conducted analysis there were no traces of crystalline material, which confirms earlier studies that have shown that the company's material, HyNap, remains amorphous during two years' storage in room temperature, which is a requirement from the FDA.

### New product candidates

The HyNap technology has been tested on approximately 20 PKIs with positive results and the company believes the technology can create patient benefits for a majority of the approximately 80 currently marketed PKIs. All of Xspray Pharma's product candidates are based on the HyNap technology which leads to product qualities that are advantagous for patients.

The selection of future product candidates is based on strategic considerations, market potential, launch window and patient benefits. The company thereby creates the greatest possible value for the company's product portfolio. The process from initiated development in laboratory until final market approval for the same product candidate is estimated at 3-4 years.

The development of future products occurs in the same way as for the company's first product XS004. Many parts of the process are replicable and effectively shortens the development time for future product candidates in the company's product portfolio.



# **Product portfolio**

Xspray Pharma's product portfolio so far includes three announced product candidates that are based on the company's HyNap technology: XS004 (previously known as HyNap-Dasa), XS003 (previously known as HyNap-Nilo) and XS008. The product candidates are developed to create increased patient benefits compared to marketed cancer drugs in the product category protein kinase inhibitors, so called PKIs. Additional product candidates are under review but have not yet been communicated.

The company's patented HyNap technology enables development of improved drugs that improve the life quality of cancer patients. In several of the indications that the company focuses on medication is life-long and Xspray's products can create increased benefit for these patients.

## Focus on improved patient outcome

Protein kinase inhibitors (PKIs) are effective in treatment of different forms of cancer but unfortunately many patient suffer from serious side effects. Xspray Pharma's HyNap technology has the potential of reducing or entirely eliminating some of these side effects.



PKIs are associated with a varying and pH-sensitive bioavailability, which means that the uptake in the body varies. The risk for insufficient therapeutic effects increases at too low absorption and the risk for serious side effects increases at too high absorption. Many PKIs demonstrate significant variability in absorption between patients and in the same patient, but also over time.

An additional problem associated with PKIs is the interaction with food and other medication. PKIs usually have an absorption that is affected by the stomach's pH-value, which in turn is affected by the patient's food intake and comedication. These factors can negatively affect the drug's security profile and efficiency which is why patients are recommended to not eat or take other medication for a period before and after intake of the PKI.

With Xspray Pharma's technology platform, drugs can be developed that lead to significant clinical benefits by:

- Increasing the drug's ability to dissolve and thereby its bioavailability.
- Reduce variability in absorption.
- Reduce or eliminate the impact of variability in pH-value on the uptake of the drug.

• Reduce or eliminate the drugs interaction with food, i.e. reduce the effect that food in the stomach has on the drug's uptake.

#### Product portfolio - overview

Xspray Pharma's product portfolio is continuously developed and includes three announced product candidates; XS004, XS003 and XS008. These product candidates are improved versions of already marketed PKIs. After the period, a decision was made to discontinue the development of XS005 for the indication liver cancer, following a re-evaluation of the clinical need and the product's market potential.

The original drugs have secondary patents that are effective during the period 2026-2029 and the combined annual sales for these three PKIs exceeded USD 3.4 billion in 2022 on the American market and USD 5.1 billion globally.

In December 2022 there were approximately 80 approved PKIs on the American market and Xspray Pharma has so far conducted initial tests.

Product candidate	Project	XS004	XS003	XS008	XSOOY
	Substance	dasatinib	nilotinib	axitinib	Not communicated
	Indication	Leukemia (CML, ALL)	Leukemia (CML)	Kidney cancer (RCC)	
	Regulatory path	505(b)(2)	505(b)(2)	505(b)(2)	
	Original product/company	Sprycel®/BMS	Tasigna®/Novartis	Inlyta®/Pfizer	
Patent	Substance patent expiry	Dec 2020	Jan 2024	Apr 2025	
	Secondary patent expiry	Sept 2026	Feb 2029	Dec 2030	
Development	New candidate evaluation				
phase	Formulation development				
	Pilot clinical study				
	Pivotal clinical study				
	Regulatory review FDA/EMA				

## XS004

Xspray Pharma has developed XS004, an improved version of Sprycel<sup>®</sup>, intended for treatment of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL). XS004 has achieved bioequivalence with a 30 percent lower dose against the original drug, Sprycel<sup>®</sup>. Conducted studies confirm that XS004:

- is unaffected by the pH value and can thus be used together with omeprazol without affecting the absorption of the drug. This enables simultaneous treatment of common diseases in the stomach such as peptic ulcers, with pharmaceuticals such as omeprazole while the patient is being treated for cancer.
- yields a more even and consistent uptake in the body without those variations in uptake seen for the original product in previous studies.
- can be administered at a lower dosage than the original product, which could potentially result in fewer side effects.

New data for XS004 was presented at ASH in December 2022, the world's largest hematology congress arranged by the American Society of Hematology. Together with scientists from Uppsala University and Karolinska University Hospital, Xspray Pharma presented data that shows that an amorphous version with our patented HyNap technology results in an absorption that is less pH sensitive than the crystalline version which sees



an uptake that is reduced by 40-60%. Simultaneous comedication with acid-inhibiting drugs is common when treating for CML and ALL. Studies presented at ASH showed that CML patients that take crystalline PKIs with acid-reducing agents have a 5-year survival rate of 79% compared to 94% for patients that did not use acid-reducing agents. XS004 uptake is not negatively impacted by comedication with acid-reducing agents.

The market value for XS004 is high both during and after the patent window. In November 2021, Xspray Pharma made an application for market approval in the US of the product candidate XS004 to FDA under the 505(b)(2) NDA process, the registration process used for improved drugs. In January 2022, FDA announced that they would initiate a full review of Xspray Pharma's application for market approval of XS004. In February 2022, Bristol Myers Squibb ("BMS") filed a lawsuit against Xspray Pharma in the US district court in New Jersey for patent infringement due to product candidate XS004. The company's view is that the company's amorphous products do not infringe on BMS patent and expects the court to rule in Xspray Pharma's favor. In 2022, XS004 was granted Orphan Drug Status for both CML and ALL by the FDA in US. Xspray Pharma expects to launch XS004 in the second half of 2023.

The primary patent for the original drug, Sprycel<sup>®</sup>, expired in December 2020 and the secondary patent expires in 2026. A secondary patent gives XS004 very limited competition. In 2022, the global market for Sprycel<sup>®</sup> amounted to approximately USD 2.2 billion, of which the US market accounted for approximately USD 1.5 billion.

After the period, Xspray Pharma entered a partnership agreement with EVERSANA for commercialization of XS004 in the US. EVERSANA has thereby exclusive commercial right to execute the launch of XS004, with the goal of launching the product in the second half of 2023. According to the agreement EVERSANA will provide Xspray with a dedicated commercialization team with long experience of successful commercialization of cancer drugs, including TKI products (tyrose kinase inhibitors). The collaboration gives Xspray access to EVERSANA's experience commercial team which creates prerequisites for a quick launch at an optimized budget.

The production facility that will produce XS004 in commercial scale is located in Milan, Italy.

### XS003

Xspray Pharma is also developing XS003, a product candidate that is an improved version of Tasigna<sup>®</sup> for treatment of chronic myeloid leukemia (CML).

Xspray Pharma has conducted a clinical study that investigated the pharmacokinetic properties and food interaction effects of a XS003 prototype. The study showed that XS003 significantly reduces food interaction compared with Tasigna® after a high-fat meals. XS003 is developed to reduce the effect of food intake and thereby potentially improve security for the patients that currently have to go without food for six hours every day when being treated with the crystalline product. Studies have also shown significantly higher bioavailability of XS003 compared with Tasigna®.

The FDA has previously granted Orphan Drug Status to XS003 for the treatment of CML. During the year, significant progress has been made in the development of XS003. The production process has been established in commercial scale and a clinical pilot study has been performed. The clinical pilot study showed that XS003 can achieve bioequivalence with a lower dose compared to the reference product Tasigna<sup>®</sup>. Pivotal clinical studies are in progress and the company expects to complete these by 2023.

In 2022, global sales of Tasigna<sup>®</sup> amounted to USD 1.9 billion, of which USD 0.9 billion in the US. Tasigna's substance patent expires in January 2024 and the secondary patent expires in February 2029.

### XS008

Xspray Pharma announced a new product candidate XS008. The product candidate is based on the original substance axitinib which is used for treatment of kidney cancer. The PKI market for kidney cancer had sales of approximately USD 3 billion in the US in 2022.

The currently marketed product which is based on axitinib is Inlyta<sup>®</sup> and its patent expiry creates an attractive launch window between April 2025 and December 2030 in the US.

Sales of Inlyta amounted to USD 0.6 billion in the US and USD 1.0 billion globally in 2022.



# Sustainability

UN's 17 global sustainability goals, Agenda 2030, aim to slow down global climate change and reduce world poverty by 2030. The most important goal for Xspray Pharma is the sustainability goal for "Good health and well-being". Below Xspray Pharma describes its sustainability work in relation to different stakeholders.

Xspray Pharma has an ambitious sustainability agenda that aims to minimize the company's environmental impact by taking action to increase energy efficiency and reduce waste from the company's work processes. In addition, Xspray Pharma as a R&D company in the pharmaceutical industry plays an important role in improving people's health and well-being. Through the company's patented HyNap technology, Xspray Pharma can develop drugs that have the potential of eliminating some of the challenges associated with protein kinase inhibitors for cancer treatment.

## For patients

Xspray Pharma must according to rules and regulations ensure that the company's product candidates fulfil demands on security and patient outcomes. Regulation affects everything from development of product candidates, clinical studies and how the finished product should be stored and handled.

National authorities frequently require information during inspections, revisions and reviews. Xspray Pharma works to continuously follow laws, regulations and guidelines, and always acts in a transparent and professional way when dealing with authorities. When required, Xspray Pharma works with external experts to fulfil regulatory demands. In the US, the authority is Food and Drug Administration (FDA), which is the responsible supervisory authority and it Europe it is the European Medicines Agency (EMA).

#### For suppliers and partners

Since Xspray Pharma has not sold any of its products during the year, focus has been on making responsible purchases of goods and services. Xspray Pharma set sustainability requirements on its suppliers, CMO and collaboration partners. Xspray Pharma tries to use environmentally friendly input goods, processes and transports, and when possible the company tries to find local suppliers that seek to reduce their climate footprint.

Good Manufacturing Practice (GMP) are rules to secure sufficient quality in production. The production standard means that there are regulatory demands on that the company must make frequent revisions to ensure that suppliers and CMOs fulfil the quality standards set by the pharmaceutical industry as well as good production standards. In order to live up to GMP-standards, Xspray Pharma has, through its production partner in Italy, received approval from the Italian medical authority (AIFA) for the full scale production facility in Milan. The approval relates to the use of amorphous material, based on the company's technology, in commercial scale. In line with the company's sustainability work, clean carbon dioxide is used in the production process.



### For empolyees

Since the company was founded in 2003, Xspray Pharma has continuously strengthened the organization with co-workers that have strong competencies and long experience of their respective areas. During 2022, Xspray Pharma has continued to recruit key competencies that will contribute to a successful commercialization of the company's first product candidate. In total, Xspray Pharma has increased its number of employees from 23 to 27 during the past financial year. In coming years, Xspray Pharma will additionally strengthen its organization in marketing and sales in the US.

Xspray Pharma's employees are the company's greatest asset and the company actively works to contribute to each individual's development. As the company has grown, work to strengthen the company's culture has intensified. Xspray Pharma seeks to be an attractive employer with professional and engaged co-workers.

#### Recruitment and introduction

Recruiting a new employee is a long-term investment. Gender equality and diversity are important factors in the recruitment process and aim to create a more competitive organization. All new employees are offered an introductory program adapted to their role, to learn the company and get to know new colleagues in the best possible way. During the year, the company was able to attract senior employees with specialist knowledge.

### Competence development

Xspray Pharma's goal is to have the best employees in the pharmaceutical industry. To achieve this goal, Xspray Pharma continuously reviews competences needed and encourage competence development among employees.

### Work environment

Without the skills and commitment of its employees, Xspray Pharma's operations cannot be conducted with high quality on a long-term basis. Therefore, a good work environment is prioritized, and Xspray Pharma works intensively to create an environment in which employees thrive and have good health.

Xspray Pharma will move to newly renovated offices in Campus Solna in November 2023. In order to make this move possible, Akademiska Hus will totally refurbing parts of the Scheele laboratory and in an empty space of 1,500 sqm create top modern offices and laboratories that Xspray Pharma needs in order to expand its operations.



# The share

Xspray Pharma was founded in 2003 and the company was listed on the Nasdaq First North Growth Market in 2017. Since 2020, the company is listed on the Nasdaq Stockholm, under the ticker XSPRAY.

## Share information

Xspray Pharma's share is traded on Nasdaq Stockholm. The company's share has the ticker XSPRAY with ISIN code SE0009973563 and belongs to the Small Cap segment. The number of shares in the company amounted to 22,680,408 (20,680,408) on December 31, 2022. The share is included in the healthcare sector of Nasdaq Stockholm.

### Share price performance and turnover

At the end of 2022, Xspray Pharma's share had a closing price of SEK 57.00 (closing price on December 31, 2022). In the beginning of the year the share was traded at SEK 64.10 (opening price on January 3, 2022), which means that the share price decreased by -11.1% during the full year 2022. At the end of 2022, Xspray Pharma's market capitalization amounted to SEK 1.3 billion based on the closing price of SEK 57.00. During the year, 4,564,382 shares were traded at a total value of SEK 259 million.

#### Number of shareholders

According to the shareholder register maintained by Euroclear Sweden AB, Xspray Pharma had 4,882 shareholders (5,305) on December 31, 2022. Information regarding shareholders and shareholdings is updated quarterly on the company's website.

#### Specific entitlements associated with shares

The company has one share class. The rights associated with the company's shares, including rights from the Articles of Association, may only be amended pursuant to provisions of the Swedish Companies Act (2005:551). Each share in the company entitles its holder to one vote at AGMs.

Largest shareholders (December 31, 2022)	Number of shares	Capital/ votes, %
Flerie Invest	3,439,378	15.16
Östersjöstiftelsen	2,742,626	12.09
Anders Bladh (private and through Ribbskottet AB)	2,591,800	11.42
Fjärde AP-fonden	1,995,806	8.80
Nordnet Pensionsförsäkring	852,858	3.76
Unionen	806,000	3.55
Tredje AP-fonden	800,000	3.53
Avanza Pension	739,359	3.26
Andra AP-fonden	622,320	2.74
TIN Fonder	404,241	1.78
Top 10 shareholders	15,017,038	66.21
Other shareholders	7,663,370	33.79
Total	22,680,408	100.00

### **Rights issues**

In October 2022, Xspray Pharma did a preferential rights issue of 2,000,000 new shares which resulted in proceeds of SEK 100 million before transaction costs. The subscription price amounted to SEK 50.00 per share and the rights issue increased share capital by SEK 2,000,000 and resulted in a dilution of 8.8% for existing shareholders. The rights issue was directed to Swedish institutional investors, including Tredje AP-fonden, Fleric Invest AB and Östersjöstiftelsen. Proceeds from the rights issue will primarily be used for:

- Preparations ahead of the coming launch on the US market.
- Continued development of the company's product portfolio with initial focus on the product candidate XS003 which is the next product to be launched on the American market.
- Strengthening of company's capital structure.

#### Incentive program

The Annual General Meeting on May 19, 2022, approved a new long-term incentive program LTI 2022. LTI 2022, in the form of warrants and employee stock options, was fully subscribed and in total 421,875 options were issued. All members in the management team subscribe for the full share of the incentive program. Strike price amounts to SEK 132.20 per share. Maximum dilution of share capital at full use of options amounts to 1.9% based on the current number of shares.

For more information on other incentive programs see page 68.

Year	Events	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
2019	New share issue	1,675,162	16,751,622	1,675,162	16,751,622	1.00
2020	Redemption of warrants	279,591	17,031,213	279,591	17,031,213	1.00
2020	New share issue	1,861,291	18,892,504	1,861,291	18,892,504	1.00
2021	Redemption of warrants	175,000	19,067,504	175,000	19,067,504	1.00
2021	New share issue	1,612 904	20,680,408	1,612,904	20,680,408	1.00
2022	New share issue	2,000,000	22,680,408	2,000,000	22,680,408	1.00

## **Corporate governance report**

Xspray Pharma AB is a Swedish public limited liability company and its shares are traded on Nasdaq Stockholm since March 27, 2020. Previously the company's shares were traded on Nasdaq First North Growth Market, Stockholm, since 2017. The company is governed by the Articles of Association, the Swedish Companies Act, the rules of Nasdaq Stockholm, the Swedish Corporate Governance Code (the Code) and other applicable laws and rules. There are no deviations from the Code's rules to report on for the financial year of 2022. The corporate governance report has been reviewed by the company's auditor in accordance with the Swedish Annual Accounts Act.

#### Principles for corporate governance

Corporate governance refers to the systems through which the shareholders, directly or indirectly, control Xspray Pharma. Good corporate governance is an essential component in the work to create value for Xspray Pharma's shareholders. The Company's corporate governance has been based on Swedish law, Nasdaq Stockholm's regulations for issuers and internal rules and regulations. The Company also applies the Swedish Code of Corporate Governance (the Code). The code applies to all Swedish companies whose shares are listed on a regulated market in Sweden. The Company does not have to follow all the rules in the Code as the Code itself provides the opportunity to deviate from the rules. If so, the Company needs to provided that such possible deviations, and the chosen alternative solution, are described and the reasons for this are explained in the corporate governance report. However, the Company has continued to fully apply the Code during the year.

## Steering documents

- Articles of Association
- The rules of procedure of the Board and the committees
- CEO intstruction
- Policy documents
- Important external regulations
- Swedish Companies Act
- Swedish Accounting Act
- Nasdaq Stockholm's rulebook
- Swedish code of corporate governance

## Shareholders

On March 18, 2020, Nasdaq Stockholm's Corporate Committee approved Xspray Pharma's application to list the Company's shares on Nasdaq Stockholm's main list. The first day of trading on the new list took place on March 27, 2020. The share capital amounted to 22,680,408 shares with a quota value of SEK 1.00 on December 31, 2022. Flerie Invest, Östersjöstiftlsen and Anders Bladh (in private and through Ribbskottet AB) were shareholders with holdings exceeding 10 percent of the votes for all shares of the Company. Flerie Invests share of capital and votes amounted ot 15.2 percent, Östersjöstiftelsen's holdings of shares and votes were 12.1%, and Anders Bladh (private and through Ribbskottet AB) holdings were 11.4% at year-end.

All shares are ordinary shares and carry equal rights to the Company's earnings, and to one vote at the AGM. All parties entitled to vote at the AGM may do so for the full number of shares held or represented, without limitation of the number of votes.

### Annual General Meeting (AGM)

Pursuant to the Swedish Companies Act (2005:551), the AGM is the Company's chief decision-making body. Shareholders exercise their voting rights at AGMs. AGMs must be held within six months of the end of each financial year. Extraordinary General Meetings (EGMs) may also be convened in addition to AGMs. Apart from Solna, where the Company has its registered office, the Articles of Association allow AGMs to be held in Stockholm. Pursuant to the Company's Articles of Association, invitations to AGMs should be through an announcement in the Swedish Official Gazette, and by an invitation being uploaded on the Company's website. Simultaneous with the invitation, the company should announce that the invitation has been made through an advertisement in Swedish daily newspaper Svenska Dagbladet.

Shareholders recorded in the share register six days prior to the AGM, and that have notified the Company by that date and time stated in the invitation to the Meeting, are entitled to participate. Such day may not be a Saturday, Sunday, other public holiday, Midsummer's Eve, Christmas Eve or New Year's Eve, and may not occur earlier than six days prior to the Meeting.

#### AGM 2022

Xspray Pharma's AGM 2022 was held on 19 May 2022 in Stockholm. Apart from customary business, the AGM made the following resolutions;

- To elect Robert Molander and re-elect Anders Ekblom, Anders Bladh, Maris Hartmanis, Torbjörn Koivisto, Christine Lind and Carl-Johan Spak as Board members for the period until the end of the following AGM.
- In accordance with the Nomination Committee's proposal, new principles were decided for election of a Nomination Committee. To summarize, the principles mean that the Nomination Committee shall consist of the Chairman of the Board and a representative of each of the four largest shareholders based on the ownership in the Company as of 31 August.
- In accordance with the Board of Directors' proposal, to adopt a long-term incentive program (LTI 2022-2025) and the issue of a maximum of 421,881 warrants.

• To authorize the Board of Directors to take decisions on new share issues on one or more occasions in the period until the following AGM, corresponding to a maximum of 20% of the total number of shares of the Company at the time of the AGM resolution.

## AGM 2023

The annual general meeting will be held on Thursday, 16 May 2023. The notice will be published in a press release and announced in Post och Inrikes Tidningar and in Svenska Dagbladet, and published on Xspray Pharma's website.

The Board of Directors has decided that shareholders may exercise their right to vote at the AGM through physical presence, proxies or pre-voting.

Shareholders wishing to have a matter considered by the AGM should make a written request to the Nomination Committee by no later than seven weeks prior to the AGM, March 28, 2023. The Nomination Committee can be contacted by email to: generalmeeting@ xspray.com, write "Valberedningen" in the subject line.

For entitlement to participate in the AGM, shareholders must:

- Be recorded as a shareholder in the share register maintained by Euroclear Sweden AB as of Monday 8 May 2023, and
- notify the Company of their intention to participate by voting in advance at the AGM no later than Wednesday 10 May 2023. The completed voting form may be submitted by post to Xspray Pharma, "General meeting", Råsundavägen 12, SE-169 67 Solna, Sweden, or via email to generalmeeting@xspray.com.

### Nomination committee

Companies that comply with the Code must have a Nomination Committee. Pursuant to the Code, the AGM should appoint the members of the Nomination Committee, or state how members are to be appointed. Pursuant to the Code, the Nomination Committee should have a minimum of three members, and a majority of them should be independent of the company and its management. At least one member of the Nomination Committee should also be independent of the largest shareholder in terms of the vote, or that group of shareholders that collaborate on the Company's administration.

The Nomination Committee has especially considered the need for diversity in terms of skills, experience and backgrounds, considering factors including the Company's strategic development, governance and controls. The Nomination Committee has discussed the diversity perspective based on its opinion that they are essential to the composition of the Board of Directors, and the Nomination Committee intends to attain equal gender balance.

## Instructions for the work and composition of the Nomination Committee

Pursuant to a resolution by the Company's AGM on 19 May 2022, the Chairman of the Board should make contact with the four largest shareholders of the Company in terms of votes according to Euroclear Sweden AB's printed register as of 31 August, who should each be offered the opportunity to appoint a member, who will make up the nomination committee jointly with the Chairman of the Board. If one of these shareholders does not exercise its right to appoint a member, entitlement to appoint such member defers to the next largest shareholder in terms of votes that has not already been entitled to appoint a member of the Nomination Committee. This process should continue until the Nomination Committee consists of four members apart from the Chairman of the Board. If the Nomination Committee does not decide otherwise, the Chairman of the Nomination Committee should be the member representing the largest shareholder in terms of the vote. The Chairman of the Board may not serve as Chairman of the Nomination Committee.

The names of the Nomination Committee members should be published as soon as the Nomination Committee is appointed, although by no later than six months prior to the following AGM. The Nomination Committee is appointed for a term of office from the time when its composition is published until a new Nomination Committee has been appointed.

If changes to the Company's ownership structure occur after 31 August, but before the Nomination Committee's complete proposals for resolution have been published, and if a shareholder, who after this change, is one of the four largest shareholders in terms of votes, expresses a wish to become a member of the Nomination Committee to the Chairman of the Nomination Committee, that shareholder shall be entitled to appoint one further member of the Nomination Committee. Additionally, the Nomination Committee can decide that a member that has become significantly smaller than the four largest shareholders in terms of the vote of the company should leave the Nomination Committee if considered appropriate.

If a member leaves the Nomination Committee during its term of office, or if such member is unable to render service, the Nomination Committee should require that shareholder that has appointed said member to appoint a new member in a reasonable time. If said shareholder does not exercise its right to appoint a new member, that right defers to the next largest shareholder in terms of the vote that has not already appointed or declined to appoint a member of the Nomination Committee. Alterations to the composition of the Nomination Committee should be published as soon as they have occurred. The Nomination Committee should consult on proposals on the following issues to be presented to the AGM for resolution:

- Proposal for a Chairman of the AGM,
- Proposal for a Board of Directors,
- Proposal for a Chairman of the Board,
- Proposal for Board members' fees, divided between the Chairman and other Board members,
- Proposal for fees for members of the Remuneration and Audit Committees (where applicable),
- Proposal for an auditor,
- Proposal for remuneration of the auditor, and
- where considered necessary, proposals for amending applicable rules for the Nomination Committee.

There are no specific provisions of the Articles of Association regarding appointing and dismissing Board members and on amending the Articles of Association.

#### Nomination committee for the AGM 2023

The members of the Company's Nomination Committee for the AGM 2023 are

- Thomas Eldered, appointed by Flerie Invest AB
- Gillis Cullin, appointed by Östersjöstiftelsen
- Johan Gyllenswärd, appointed by Ribbskottet AB
- Jan Särlvik, appointed by AP4
- Anders Ekblom, Chairman of the Board, Xspray Pharma AB

#### **Board of Directors**

**Board members** 

The Board of Directors is the Company's chief decision making body after the AGM. The Swedish Companies Act stipulates that the Board of Directors is responsible for the Company's administration and organisation, which means that the Board has duties including setting goals and strategies, ensuring procedures and systems for evaluating predetermined goals are in place, continuously evaluating the Company's results of operations and financial position, and appraising executive management. The Board of Directors is also responsible for ensuring that annual accounts and interim reports are prepared on time. The Board of Directors also appoints the Company's CEO.

Board members are normally appointed by the AGM for the period until the end of the following AGM. Pursuant to the company's Articles of Association, the Board of Directors, to the extent elected by the AGM, should have a minimum of three and a maximum of seven Board members, with a minimum of zero and maximum of two Deputies. The Chairman of the Board should be elected by the AGM and has special responsibility for leading the Board of Directors' work, and for this work being well organized and conducted efficiently.

The Board of Directors meets according to a predetermined schedule. In addition to these meetings, other meetings may be convened to consider issues that cannot be dealt with at scheduled Board meetings. The CEO and CFO participate in the majority of the number of Board meetings. In addition to Board meetings, the Chairman and CEO maintain a continuous dialogue on the Company's management. The Board of Directors complies with written rules of procedure that are revised yearly and adopted at the Board meeting following election in each year. The rules of procedure formalize activities including the Board's practices, functions and the segregation of duties between Board members and the CEO. At the Board meeting following election, the Board of Directors also adopts instructions for the CEO, and for financial reporting.

## Remuneration Committee

Xspray Pharma has established a Remuneration Committee with three members: Anders Ekblom (Chairman), Anders Bladh and Torbjörn Koivisto. The duties of the Remuneration Committee are formalized by the company's rules of procedure for the Remuneration Committee. This Committee consults on issues including the Board's decisions on remuneration principles, compensation and other employment terms for the CEO and senior executives.

			Independent		
Name	Position	Elected	Company and com- pany management	Major shareholders	Attendance, Board meetings
Anders Ekblom	Chairman of the Board	2021	Yes	No	18 (19)
Maris Hartmanis	Board member	2015	Yes	Yes	19 (19)
Torbjörn Koivisto	Board member	2017	Yes	Yes	19 (19)
Carl-Johan Spak	Board member	2015	Yes	Yes	18 (19)
Gunnar Gårdemyr	Board member (resigned May 19, 2022)	2019	Yes	Yes	7 (19)
Christine Lind	Board member	2019	Yes	Yes	16 (19)
Anders Bladh	Board member	2021	Yes	No	19 (19)
Robert Molander	Board member (appointed May 19, 2022)	2022	Yes	Yes	11 (19)

#### Audit Committee

Xspray Pharma has established an Audit Committee with three members: Maris Hartmanis (Chairman), Christine Lind and Carl-Johan Spak. The duties of the Audit Committee are formalized by the Company's rules of procedure for the Audit Committee. The Committee's duties include to support the Board of Directors in their work to ensure quality in the financial reporting, consider and prepare questions related to the Company's internal control and risk management. The Committee should also continuously monitor and appraise the work of the auditors, their independence and impartiality, as well as approve additional services that the Company acquires from its auditor.

## Remuneration for Board members

Remuneration to Xspray Pharma's Board members is resolved by the AGM. The AGM on 19 May 2022 approved the Nomination Committee's proposals that the following Board members' fees would be payable: SEK 420,000 to the Chairman of the Board, SEK 210,000 to each of the other Board members, SEK 100,000 to the Chairman of the Audit Committee and SEK 50,000 each to the Audit Committee's other members, and SEK 75,000 to the Chairman of the Remuneration Committee, and SEK 35,000 to the Remuneration Committee's other members.

## Work of the Board of Directors in 2022

In 2022, the Board of Directors held 19 meetings where minutes were taken. Individual Board members' participation at these meetings is stated in the table below. The meetings followed an approved agenda, which members received before Board meetings. The CEO and CFO participate at the majority of the Board meetings. The Board annually preforms a Self-assessment. The Self-assessment is designed to follow up the annual performance. Board meetings include a review of current business status, the Company's results of operations and financial position, and outlook for the remainder of the year. The work of the Board of Directors in the year largely focused on:

- Developing the project portfolio
- Strategy, business development and business intelligence
- Company's studies with XS003-nilotinib
- Financial performance and raising capital
- Interim reports, year-end report and the annual report.

#### Chief executive officer and other senior executives

The CEO is subordinate to the Board of Directors and is responsible for the Company's continuous administration and daily operation. The segregation of duties between the Board of Directors and CEO is stated in the rules of procedure for the Board of Directors and instructions for the CEO. The CEO is also responsible for preparing financial statements and compiling information from management for Board meetings, and presents this material at Board meetings. Pursuant to the instructions for financial reporting, the CEO is responsible for the Company's financial reporting, and consequently, should ensure that the Board of Directors receives sufficient information for the Board to be able to evaluate the Company's financial position continuously.

They CEO should keep the Board of Directors continuously informed on progress of the Company's operating activities, of its sales, the Company's results of operations and financial position, the liquidity and credit position, significant business events, and each other event, circumstance or relationship that could be assumed to be of material significance to the Company's shareholders.

The CEO and other senior executives are presented on page 38-39.

#### Audit

The auditor should review the Company's annual report and financials, and the Board of Directors' and CEO's administration of the business.

The auditor should present an audit report to the AGM after each financial year.

Pursuant to the Company's Articles of Association, the Company should have a minimum of one and a maximum of two auditors, and a minimum of zero and maximum of two Deputy Auditors. The Company's auditor is KPMG AB, with Duane Swanson as Auditor in Charge.

Total compensation to the company's auditors in 2022 was SEK 677 thousand (374), see note 6.

### **Internal controls**

Pursuant to the Swedish Companies Act and the Swedish Annual Accounts Act, the Board of Directors is responsible for internal controls. The purpose of internal controls is to achieve expedient and effective operating activities, ensure reliable financial reporting and information on operating activities, and compliance with applicable laws, regulations, policies and guidelines.

The Company's internal controls are based on principles produced by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

## Internal controls over financial reporting

Internal controls over financial reporting are designed to create reasonable reliability and assurance in financial reporting and to ensure that external financial reporting complies with applicable laws and accounting standards. The Board of Directors bears ultimate responsibility for internal controls, and continuously evaluates the Company's risk management controls through the Audit Committee.

The Company ensures internal controls over financial reporting through qualitative and quantitative analysis of the Consolidated Balance Sheet and Consolidated Income Statement. The purpose of the quantitative analysis is to identify risks associated with material and transaction-intensive items. The qualitative analysis is intended to identify risks associated with complexity and impropriety. Based on the outcome of this analysis, significant financial processes and risks have been identified.

The Company has designed procedures and activities to monitor financial reporting and ensure that any misstatements are discovered and rectified. Key controls have been designed and followed up as part of the work of maintaining good internal controls.

## Control environment and risk assessment

The Company's control environment sets a framework for the orientation and culture the Company's Board of Directors and Management communicate to the organization. To ensure expedient risk management and good internal controls, over and above policy documents such as the Board of Directors' rules of procedure, instructions for the CEO and associated delegation schedule and approvals list, the Company has adopted a number of internal guidelines, business processes and procedures.

The Audit Committee's main duty is to monitor the Company's financial position and effectiveness of the Company's internal controls, internal audit and risk management, and to stay informed on the audit of the annual report and consolidated accounts, and review and monitor auditor impartiality and independence, and this work has continued during the year. Responsibility for continuous work on internal controls over financial reporting has been delegated to the Company's CEO.

Each year, the company's group management should conduct a risk assessment regarding strategic, operational, legal and financial risks with the aim of identifying potential problem areas, and assess the company's risk exposure. The risk assessment includes identifying risks that may arise and could prevent the company from realizing its vision and achieving its goals, for example if the fundamental requirements of the Company's financial reporting are not satisfied. Within each risk segment, the individual responsible for each risk segment identifies risks and the potential consequences, as well as likelihoods, and proposes actions. The Audit Committee is responsible for continuously evaluating the Company's risk situation and should support the Board of Directors by making proposals for managing the Company's financial risk exposure and risk management.

#### Control activities

The Board of Directors has adopted a risk management policy to identify and manage the risks associated with the Company's operating activities. Risk management is a high priority within the company. The Board of Directors bears ultimate responsibility for risk management. The Company's risk situation is evaluated each year, including an action plan. The Company has based its control environment on the risks identified during the risk assessment process. The Company has also appointed process owners who are responsible for individual processes. The CEO and other senior executives all participate in ongoing work in managing risk associated with operating activities. The Company has formulated procedures and activities to monitor financial reporting and ensure that any misstatements are discovered and rectified. These activities include monitoring and comparing earnings performance with accounting items, account reconciliations and balance specifications, as well as approvals of banking transactions and collaborative agreements, powers of attorney and approvals lists, as well as accounting and valuation policies. The Company's CFO plays a key role in analyzing and monitoring the Company's financial reporting and results of operations. Access to the accounting system is limited by authority, responsibility and role.

## Information and communication

The Company has internal control functions for information and communication intended to ensure accurate financial and other corporate information is communicated to employees and other stakeholders. The Company's internal instructions and policies are available to all staff and offer detailed information on applicable procedures in all parts of the Company, and review the control functions and how they are implemented.

#### Monitoring

Compliance and effectiveness of internal controls is regularly monitored. The CEO ensures that the Board of Directors receives regular reports on progress of the Company's operating activities including progress of the Company's results of operations and financial position, and information on significant events, such as research outcomes and important agreements and contracts. The CEO reports on these issues to the Board of Directors. The Company's compliance with applicable policies and control documents, as well as the effectiveness of internal controls, are subject to annual review. The outcome of this evaluation is compiled by the Company's CEO and reported to the Board of Directors each year. The Board of Directors discusses all interim reports and annual accounts prior to their publication and monitors the review of internal controls through the Audit Committee. The Audit Committee supports the Board of Directors by consulting on issues and offering the Board of Directors support in its work on performing its duties within the segments of internal and auditing, as well as quality-assuring the Company's financial reporting.



## **Board and auditor**



#### Anders Ekblom

Board member and Chairman of the Board since 2021. Chairman of the Remuneration Committee. Born 1954

**Education:** M.D., Board certified in Anesthesiology and Intensive Care, D.D.S., Associate Professor in Physiology, Karolinska Institutet. **Other current assignments:** Chairman of the Board of Elypta AB, Deputy Chairman of the Board of LEO Pharma A/S, Board member in AnaMar AB, Alligator Bioscience AB and Mereo BioPharma Group plc., and Deputy Board member of Xspray Pharma Futurum AB.

**Previous assignments** (past five years): Board member of Infant Bacterial Therapy AB, Medivir AB, Chairman of the Board TFS International AB.

Holding in the Company on December 31, 2022: 3,000 shares, 13,214 warrants (LTIP2021/2026).

Independent in relation to the Company and its management, but not in relation to major shareholders.



#### Maris Hartmanis

Board member since 2015. Chairman of the Audit Committee. Born 1953

**Education:** Ph.D. in Biochemistry and Associate Professor, Kungliga Tekniska Högskolan (Royal Institute of Technology). **Other current assignments:** CEO and Chairman of the Board of Hartmanis & Partners AB, CEO and Chairman of the research foundation FINGERS Brain Health Institute and Affiliated Professor, Karolinska Institutet.

**Previous assignments** (past five years): Board member of BioLamina, board member of Xbrane Biopharma AB, Karolinska Institutet Holding AB and Applied Photophysics Ltd., England, and Deputy Chairman of the Board of ProNova, a VINNOVA Center of Excellence for protein technology at Kungliga Tekniska Högskolan.

Holding in the Company on December 31, 2022: 28,619 shares.



**Robert Molander** Board member since 2022. Born 1965

**Education:** MBA from Washington University as well as two Bachelor degrees from Miami University in Economics and International Studies.

Other current assignments: CCO in Infant Bacterial Therapeutics AB, CEO in Stratfox Healthcare Group LLC. Previous assignments (past five years): Board member in Infant Bacterial Therapeutics AB, CCO in Trialbee AB. Holding in the Company on December 31, 2022: None.



## Carl-Johan Spak

Board member since 2015. Member of the Audit Committee. Born 1956

**Education:** Dr. of Odontology, Degree in Dentistry, Karolinska Institutet.

Other current assignments: Board member in Provell Pharmaceuticals LLC, Atrogi AB, EpiEndo ehf, KAHR Medical Ltd., Pharmacolog i Uppsala AB and Symcel Sverige AB, and Deputy Board member in Buzzard Pharmaceuticals AB. **Previous assignments** (past five years): Chairman of the Board in Bostadsrättsföreningen Smultronhyllan, Cobra Biologics Matfors AB, Cobra Biopharma Matfors AB, Cobra Biologics Holding AB, Follicum AB, Recipharm OT Chemistry AB and Recipharm Pharmaceutical Development AB. Board member in Empros Pharma AB, Prokarium Ltd., SwedenBIO Service AB, Synthonics, Inc., Pharmanest AB, Inject Pharma Sweden AB, Binx Health Ltd., UK, Recipharm OT Chemistry AB and Recipharm Strängnäs AB. Board member and CEO in Recipharm Venture Fund AB. **Holding in the Company on December 31, 2022:** None.


#### Torbjörn Koivisto

Board member since 2017. Member of the Remuneration Committee.

Born 1969

Education: LL.M., Uppsala University.

**Other current assignments:** Board member of Cinclus Pharma Holding AB and IARU Institutet för Affärsjuridisk Rådgivning i Uppsala AB, Partner of KOL Arts & Craft Handelsbolag and Deputy Board member of RJC Roger Johansson Consulting AB and Virdings Allé Invest AB.

**Previous assignments** (past five years): Board member of Moberg Pharma AB (publ) and Hemcheck Sweden AB. **Holding in the Company on December 31, 2022:** 6,000 shares via the company IARU.



#### **Christine Lind**

Board member since 2019. Member of the Audit Committee. Born 1974

**Education:** B.Sc. Finance & Information Systems from New York University, Stern School of Business, and MBA in Finance and Organizational Management from Columbia Business School.

**Other current assignments:** VP Commercial of NDA Group AB, Chairman of the Board and CEO of Lind Growth Strategy AB, Chairman of the Board of Mendus AB,, Deputy Board member of Shinka Life Sciences AB.

**Previous assignments** (past five years): CEO as well as EVP Business Development of Medivir AB.

Holding in the Company on December 31, 2022: 4,000 shares.



#### Anders Bladh

Board member since 2021. Member of the Remuneration Committee.

Born 1958

**Education:** Bachelor of Science in Business Administration and Economics, University of Uppsala.

**Other current assignments:** Owner, member of the Board, as well as CEO of Intervalor AB, Ribbskottet AB, and Rimturs AB. Board member of DistIT AB.

Previous assignments (past five years): -

Holding in the Company on December **31**, **2022**: 2,450,519 shares via Ribbskottet AB and 140,200 shares in private.

Independent in relation to the Company and its management, but not in relation to major shareholders.

#### Auditor

KPMG AB (PO Box 382, 101 27 Stockholm, Sweden) were elected the Company's auditor at the AGM on 19 May 2022. Duane Swanson, Authorized Public Accountant and member of FAR (the Institute for the Accountancy Profession in Sweden) is Auditor in charge.

## Management



**Per Andersson** CEO since 2006. Born 1967

**Education:** Ph.D. in Analytical Chemistry, Stockholm University. **Other current assignments:** Chairman of the Board of Robotic Lawn Care Sweden AB and Board member of Xspray Pharma Futurum AB. Deputy Board member of Journeyman Stockholm AB.

**Previous assignments** (past five years): Deputy Board member of Innovation TBD AB.

Holding in the Company on December 31, 2022: 242,294 shares, 33,062 warrants and 28,124 employee stock options.



Kerstin Hasselgren CFO since 2019. Born 1961 Education: MBA, Stockholm School of Economics.

Other current assignments: Board member in SynAct Pharma AB.

Previous assignments (past five years): -

Holding in the Company on December 31, 2022: 5,500 shares and, 69,788 warrants and 22,500 employee stock options.



Andreas Konar Business Development since 2010. Born 1949

Education: Professor and Ph.D. in organic chemistry, Lund University; M.Sc. (Eng.) Chalmers University of Technology, Gothenburg.

**Other current assignments:** Board member of Ground Zero Pharmaceuticals Inc., Proprietor of Intercon Handelsbolag. **Previous assignments** (past five years): -

Holding in the Company on December 31, 2022: 72,055 shares and 13,500 warrants.



Charlotta Liljebris Head of R&D since 2018. Born 1964 Education: Ph.D. in Pharmaceutical Chemistry, M.Sc. in Organic Chemistry, Uppsala. Other current assignments: Deputy Board member of

**Other current assignments:** Deputy Board member of Liljebris Consulting AB.

**Previous assignments** (past five years): Board member of Recipharm OT Chemistry AB, Connect Uppsala and Sprint Bioscience.

Holding in the Company on December 31, 2022: 2,000 shares and 21,938 warrants and 16,876 employee stock options



#### Anna-Karin Ekberg

Global Head of Marketing and Sales since 2022. Born 1966

**Education:** Bachelor of science in Diagnostic Radiology and Nursing Science, Uppsala University, DIHM marketing, Stockholm Business School.

**Other current assignments:** CEO/owner TAKE-Life Science & Business partner AB and collaboration with STILLE AB – product STILLE-Ekberg Ergo Scissors.

**Previous assignments** (past five years): Board member Picture my Life AB.

Holding in the Company on December 31, 2022: No shares, 8,437 warrants and 16,874 employee stock options.



#### Thomas Walz

Chief Medical Officer since 2022. Born 1960

**Education:** Associate professor in Oncology at Linköping University and an MBA degree from Stockholm School of Economics.

#### Other current assignments: -

Previous assignments (past five years): -

Holding in the Company on December 31, 2022: No shares, 25,311 options of which 8,437 warrants and 16,874 employee stock options.

# **Board of Directors' Report**

The Board of Directors and Chief Executive Officer of Xspray Pharma AB (publ), with registered office in Solna, Sweden, hereby present the annual report for the financial year 2022. This annual report has been prepared in Swedish currency (SEK), and rounded to the nearest thousand unless otherwise stated. Figures in brackets are for the corresponding period of the previous financial year. Xspray Pharma AB (publ) is mentioned as "Xspray Pharma" alternatively "Company" below unless otherwise stated.

#### **Group structure**

The group structure consists of the parent company Xspray Pharma AB (publ), corp. ID no. 556649-3671, and its wholly owned subsidiary, Xspray Pharma Futurum AB, corp. ID no. 559178–7642, both with registered offices in Solna. The address of the head office is Råsundavägen 12, 169 67 Solna, Sweden. Figures in the following section apply to the parent company unless otherwise stated. Comparable figures have been presented in parenthesis and refer to the corresponding period 2021.

#### **Operations – general**

Xspray Pharma AB (publ) is a product development company with several product candidates in clinical development. Utilizing the Company's innovative HyNap technology, Xspray Pharma develops improved versions of already marketed pharmaceuticals, primarily protein kinase inhibitors for treating cancer. Protein kinase inhibitors (PKI) are the largest segment within cancer drugs, and continued high growth is forecast for them over the coming years. There are more than 80 approved protein kinase inhibitors on the US market in December 2022. Xspray Pharma's technology has the potential for application on the majority of these pharmaceuticals.

The Company has a partner, EVERSANA, for commercializing product candidate XS004 in the US. The agreement means that EVERSANA will provide Xspray with services in market access, medicine and commercial sales organization, patient supporting programs and compliance.

Xspray Pharma has been listed on Nasdaq Stockholm since March 27, 2020. Prior to that, the shares were listed on Nasdaq First North Growth Market, Stockholm.

#### Significant events during the year

- In January, FDA announced that they will conduct a full review of the company's application for market approval of XS004.
- In February, the Company announced that it had hired Anna-Karin Ekberg as Global Head of Marketing and Sales. Anna-Karin took office on March 15, 2022 and is now part of the company's management group.

- In February, it was announced that Bristol Myers Squibb ("BMS") had filed a lawsuit against Xspray Pharma in the US claiming patent infringement in relation to the submission of Xspray Pharma's 505(b)
   (2) New Drug Application to the FDA.
- In May, the Annual General Meeting resolved, in accordance with the Nomination Committee's proposal, on the re-election of Board members Anders Ekblom, Anders Bladh, Maris Hartmanis, Torbjörn Koivisto, Christine Lind and Carl-Johan Spak as well as the election of new Board member Robert Molander for the period up until the end of the next Annual General Meeting. Anders Ekblom was elected Chairman of the Board. Gunnar Gårdemyr declined re-election.
- In June, it was announced that the company's new long-term incentive program had been fully subscribed. The plan, LTIP 2022-2025, which was offered to all employees including senior executives, consists of both warrants and employee stock options.
- In June, the company announced that it had appointed Thomas Walz as Chief Medical Officer. Thomas will take up the new position on September 1, 2022 and will become part of the company's management team.
- In June, it was announced that the US Food and Drug Administration (FDA) had granted XS004 dasatinib orphan drug designation for the treatment of chronic myeloid leukemia (CML).
- In June, Xspray Pharma supplemented its applications to the FDA for XS004 dasatinib with the lower dosages. As a result of and in line with expectations, the originator supplemented its previous litigation with a new application for the lower dosages.
- In early August, BMS added a further patent regarding crystalline compounds to the ongoing dispute concerning XS004. BMS has previously asserted this patent against other parties in similar cases, so this was not unexpected. Xspray Pharma has not applied for FDA approval for marketing a product that could infringe on the patent in question. Consequently, Xspray Pharma is still convinced of a positive outcome

in the legal dispute, and does not expect that this will result in any delays in the case.

- In October, a directed issue of shares was conducted to a number of Swedish institutional investors, including Third Swedish National Pension Fund, Flerie Invest and the Foundation for Baltic And East European Studies. The subscription price was set at SEK 50,00 per share and, the issue raised proceeds of SEK 100 million before transaction costs. The number of shares increased by 2,000,000 shares, from 20,680,408 to 22,680,408.
- In November, Xspray received an approval from FDA on Orphan Drug Status in the US for XS004 dasatinib for treatment of acute lymfatic leukemia (ALL).
- In December, Xspray presented new data for XS004 at the annual international American Society of Hematology Congress (ASH) in the US.

#### Significant events after the period

- Xspray Pharma entered an agreement with EVERSANA ahead of the US-launch and commercialization of the company's product candidate XS004. Xspray Pharma keeps the financial and strategic control but gives EVERSANA exclusive commercial right to execute the launch of XS004, with the goal of launching the product in the second half of 2023.
- Xspray Pharma announces a new product candidate: XS008. The product candidate is based on the original substance axitinib which is used for treatment of kidney cancer.
- Xspray's production partner Nerpharma received approval by AIFA, Italy's medical product agency, for commercial production of XS004.
- Xspray Pharma founded an American subsidiary, Xspray Pharma Inc.

No events causing restatements of the Income Statement and Balance Sheet have occurred between the reporting date and the date of approval of this Report.

#### **Research and development activities**

Xspray Pharma has three product candidates in development; XS004 dasatinib, XS003 niltinib and XS008 axitinib. All are improved versions of established PKIs for treating cancer. For the Company's leading product candidate, XS004 dasatinib, a decision on tentative market approval is expected in the summer of 2023, see further information under section *Product Portfolio*.

Xspray Pharma is constantly seeking new products with attractive patent windows by analyzing patent and business opportunities within the PKI area. Selected product candidates are planned to be ready for launch in connection to the opening of the respective PKI's patent window. Xspray Pharma's operational strategy is to first introduce the products in the US market and prepare selected product candidates for launch at favorable patent-specific timings.

For more information, please see section Strategy.

#### **Financial overview**

The Group's numbers are consistent with the Parent Company's, except for the Group adjustments that are submitted in accordance with IFRS, see further information in note 1, *Parent Company accounting policies*. The subsidiary consists solely of equity of SEK 50 thousand and remains dormant during 2022.

#### **Revenue and profit (Group)**

Net sales for the full year were SEK – thousand (–). Sales are not expected to increase until the Company according to the current business plan obtains market approval for its first product and a launch occurs in the US. Total expenses for the full year amounted to SEK-133,073 thousand (-97,953). Costs mainly consist of administration and sales expenses which amounted to SEK-109,601 thousand (58,384) of the total operating costs. Of these, personnel costs classificed as administrative and sales costs amount to SEK -29,177 thousand (-19,711). The cost increase is due to market preparations ahead of the coming launch in the US, legal counseling for XS004 and other development costs in order to broaden the product portfolio. Furthermore, the Company has made a number of key recruitments, including two members of the executive management. During the last quarter a disposal of SEK-15,472 thousand was made due to a decision to discontinue development of XS005-soratinib in order to focus on other products in the Company's product portfolio. This disposal does not impact cash flow. For 2022 overall, the Company reported an operating loss of SEK -133,073 thousand (-97,953). The net loss for 2022 was SEK-131,670 thousand (-96,698). Earnings per share for the full year were SEK -6.25 (-5.03). The corresponding figure for the parent company was -6.31(-5.05).

#### Financial position (Group)

Total equity amounted to SEK 556,019 thousand (591,752) as of December 31, 2022, and the equity/asset ratio was 95 % (95). The total number of shares as of December 31, 2022 was 22,680,408 (20,680,408).

In October 2022, the Company did a directed rights issue of shares to a number of Swedish institutional investors, including Tredje AP-fonden, Flerie Invest and Östersjöstiftelsen.

The issue raised proceeds of SEK 100 million before transaction costs. Xspray Pharma had SEK 120,166 thousand (271,881) in cash and cash equivalents on December 31, 2022.

Considering that operations are in a pre-commercial stage without sales revenue, the Board of Directors has decided to propose to the AGM that no dividends are paid to shareholders in 2023. For further information regarding the financial position, please see section *Financing risk and continued operations* on p. 46.

#### Cash flow and investments (Group)

Total cash flow for 2022 amounted to SEK –151,715 thousand (–53,717). Cash flow from operating activities was SEK –110,179 thousand (–51,607). The effect from working capital was SEK -3,575 thousand (4,375). Cash flow from investing activities was SEK –135,345 thousand (–105,818). The largest portion consisted of ongoing development expenditure that has been capitalized according to plan. Capitalized development expenditure for development activities, was SEK 385,597 thousand (296,236) as of December 31, 2022. The increase is related to the intensified work in the Company's projects. New investments have been made in a new production facility that is under construction.

Cash flow from financing activities was SEK 93,809 thousand (103,708). The increase is mainly attributable to the directed share issue which took place in October 2022, see the coming section *Share issues*.

#### **Corporate Structure**

The subsidiary Xspray Pharma Futurum AB continues to be non operational. All operations have been carried out in the parent company Xspray Pharma AB (publ). After the period, Xspray Pharma founded an American subsidiary, Xspray Pharma Inc., no transactions or events have taken place in the company.

### Human resources & remuneration of senior executives

The organization has continued to grow this year and at the end of the financial year the Group had 27 (23) employees. The average number of employees was 25 (22). The subsidiary had no employees as of the reporting date. Xspray Pharma offers remuneration levels and employment terms in line with the market that enable senior executives and core skills to be hired and retained.

All pension obligation should be defined contribution. For more information on remuneration and incentive programs, see below. Market level agreements between the Company and board members are in place. More information in note 7.

#### NOMINATION COMMITTEE

The Nomination Committee for the AGM 2023 has the following members:

- Thomas Eldered, appointed by Flerie Invest AB
- Gillis Cullin, appointed by Östersjöstiftelsen
- Johan Gyllenswärd, appointed by Ribbskottet AB
- Jan Särlvik, appointed by AP4
- Anders Ekblom, Chairman of the Board, Xspray Pharma AB

In its work ahead of the AGM, the Nomination Committee's goal has been to ensure that as a group, the Board of Directors possess the necessary skills and experience to lead Xspray Pharma's operations and development successfully. The Nomination Committee applies provision 4.1 of the Swedish Code of Corporate Governance (the "Code"). Accordingly in this context, the Nomination Committee has especially considered the need for diversity in terms of skills, experience and backgrounds, considering factors including the Company's strategic development, governance and controls. The Nomination Committee has discussed the diversity perspective based on its opinion that they are essential to the composition of the Board of Directors, and the Nomination Committee intends to attain equal gender balance.

The Nomination Committee believes that the proposed Board includes a broad and diversified group of qualified individuals, that are motivated and appropriate for the required work. The Nomination Committee also believes that Board members complement each other in terms of qualifications and experience.

Prior to the AGM 2023, the Nomination Committee should consult on proposals regarding the election of a Chairman and other Board members, the election of a Chairman of the AGM, the election of auditors, a decision on fees and other related matters. The remuneration of senior executives is stated in note 7.

#### Environment

Xspray Pharma works actively to alleviate negative environmental impact and to develop as a sustainable company. Because the Company has no product sales, this does not impact the environment, but instead, puts its focus on responsible procurement of goods and services, manufacture, and on the consumption of energy and transportation.

Consistent with the Company's sustainability work, pure  $CO_2$  is used in its manufacturing process, a residual product of other emission sources, such as brewing products, biogas or fertilizer manufacture. For more information, please see section *Sustainability*.

#### Work of the Board of Directors

The Company's Board of Directors has seven regular members including the Chairman, elected by the AGM for the period until the end of the AGM 2023. In May 2022, the AGM resolved, in accordance with the Nomination Committee's proposal, on the re-election of Anders Ekblom, Anders Bladh, Maris Hartmanis, Torbjörn Koivisto, Christine Lind and Carl-Johan Spak as well as the election of new Board member Robert Molander. Previous Board member Gunnar Gårdemyr declined re-election. The Board of Directors met 19 (25) times in 2022.

The Board of Directors has duties including formulating goals and strategies, internal controls, ensuring procedures and systems are in place for measuring predetermined goals, continuously evaluating the Company's results of operations and financial position, and appraising executive management. The Board of Directors follows written rules and procedures that are revised yearly and adopted at the Board meeting following election each year. The rules of procedure regulate items including the functions of the Board of Directors and segregation of duties between the Board of Directors and CEO, and where appropriate, between the Board of Directors and various Committees.

Action logs record the work of the Board of Directors. The Board of Directors appraises its own, its Committees and the CEO's work yearly, as well as the Company's internal controls and financial reporting.

#### The share and ownership

The share has been trading on Nasdaq Stockholm with the ticker XSPRAY since 27 March 2020. Prior to that, First North Growth Market since 28 September 2017. As of 31 December 2022, the Company had 22,680,408 (20,680,408) shares. The share is part of the sector Healthcare.

All shares are ordinary shares and have equal rights to the Company's earnings, and each share carries one vote at the AGM. All shareholders entitled to vote may vote at the AGM for the full number of shares held or represented, without limitation of the number of votes. Flerie Invest, Östersjöstiftelsen and Anders Bladh (in private and via Ribbskottet AB) are the shareholders with holdings of shares and capital that exceed 10%. Flerie Invest's holdings were 15.2%, Östersjöstiftelsen's holdings were 12.1%, and Anders Bladh (private and via Ribbskottet AB) were 11.4% as of 31 December 2022.

#### **Share issues**

The Company did a directed rights issue in the beginning of the fourth quarter 2022 of 2,000,000 new shares at a subscription price of SEK 50.00 per share, implying an increase of share capital by SEK 2,000,000. This rights issue was directed to a number of institutional investors, including Tredje Ap-fonden, Flerie Invest and Östersjöstiftelsen. The rights issue raised proceeds of SEK 100 million before transaction costs.

### The Board of Directors' proposal for guidelines for executive remuneration

These guidelines relate to the Company's executive management, including the CEO and board members. The guidelines are forward-looking, i.e. they are applicable to agreed remunerations, and amendments to remuneration after adoption of the guidelines by the annual general meeting 2023. These guidelines do not apply to any remuneration decided or approved by the general meeting.

#### The guidelines' promotion of the Company's business strategy, long-term interests and sustainability

### In short, the Company's business strategy is the following

Xspray Pharma AB is a product development company with multiple product candidates in clinical development. Xspray Pharma uses its innovative, patented HyNap technology to develop improved amorphous versions of marketed drugs, primarily PKIs for the treatment of cancer. The segment is the second largest in oncology, and drug prices are very high. Often the original companies have secondary patents that are based on the crystalline forms of the active substance. Since Xspray Pharma's products are amorphous, they can be marketed as soon as the original companies' drug substance patents expire.

For more information regarding the Company's business strategy, please see page 12-15.

A prerequisite for the successful implementation of the Company's business strategy and safeguarding of its long-term interests, including its sustainability, is that the Company is able to recruit and retain qualified personnel. To this end, it is necessary that the Company offers competitive remuneration. These guidelines enable the Company to offer the executive management a competitive total remuneration.

Long-term share and share-price related incentive programs have been implemented in the Company. The prorams include among others members of the executive management, including the CEO, employees in the Company and certain board members. Previous long-term share and share-price related incentive programs have been, and future long-term share and share-price related incentive programs will be, resolved upon by the general meetings and are therefore excluded from these guidelines.

Variable cash remuneration covered by these guidelines shall aim at promoting the Company's business strategy and long-term interests, including its sustainability.

#### Types of remuneration, etc

The remuneration shall be on market terms and may consist of the following components: fixed cash salary, variable cash remuneration, pension benefits and other benefits. Additionally, the general meeting may - irrespective of these guidelines - resolve on, among other things, share-related or share price-related remuneration. The satisfaction of criteria for awarding variable cash remuneration shall be measured over a period of one year. The variable cash remuneration may amount to not more than 50 per cent of the fixed annual cash salary. Further variable cash remuneration may be awarded in extraordinary circumstances, provided that such extraordinary arrangements are limited in time and only made on an individual basis, either for the purpose of recruiting or retaining executives, or as remuneration for extraordinary performance beyond the individual's ordinary tasks. Such remuneration may not exceed an amount corresponding to 100 percent of the fixed annual cash salary and may not be paid more than once each year per individual. Any resolution on such remuneration shall be made by the board of directors based on a proposal from the remuneration committee.

For the CEO, pension benefits, including health insurance (Sw. sjukförsäkring), shall be premium defined. Variable cash remuneration shall not qualify for pension benefits.

The pension premiums for premium defined pension shall amount to not more than 25 per cent of the fixed annual cash salary. For other executives, pension benefits, including health insurance, shall be premium defined. The pension premiums for premium defined pension shall amount to not more than 35 per cent of the fixed annual cash salary. Other benefits may include, for example, life insurance, medical insurance (Sw. sjukvårdsförsäkring) and company cars. Such benefits may amount to not more than 15 per cent of the fixed annual cash salary.

#### **Termination of employment**

If notice of termination of employment is made by the Company, the notice period may not exceed nine months. Severance pay may only be paid in case of certain specific and pre-defined events, whereby the severance pay may not exceed twelve months' fixed salary. If notice of termination of employment is made by the executive, the notice period may not exceed six months and the executive shall not be entitled to severance pay, unless in case of certain specific and pre-defined events in which case the Company shall be able to extend the notice period up to nine months and make severance payments up to twelve months' fixed salary. Additionally, remuneration may be paid for non-compete undertakings. Such remuneration shall compensate for loss of income and shall only be paid in so far as the previously employed executive is not entitled to severance pay. The remuneration shall amount to not more than 60 per cent of the average monthly income during the last twelve months before the termination and be paid during the time the non-compete undertaking applies, however not for more than twelve months following termination of employment.

### Criteria for awarding variable cash remuneration, etc.

The variable cash remuneration shall be linked to predetermined and measurable criteria which can be financial or non-financial. The performance criteria are recommended by the remuneration committee and decided by the board on an annual basis. The criteria can be linked to the development of the Company's share price and/ or the development and progression of the Company's product candidates. They may also be individualized, quantitative or qualitative objectives. The criteria shall be designed so as to contribute to the Company's business strategy and longterm interests, including its sustainability, by for example being clearly linked to the business strategy or promote the executive's long-term development.

When the performance review period for variable remuneration has ended, the remuneration committee and Board shall determine to which extent the criteria has been met.

The remuneration committee is responsible for the evaluation of the remuneration to the members of the executive management, including the CEO. For financial objectives, the evaluation shall be based on the latest financial information made public by the Company.

#### Salary and employment conditions for employees

In the preparation of the board of directors' proposal for these remuneration guidelines, salary and employment conditions for employees of the Company have been taken into account by including information on the employees' total income, the components of the remuneration and increase and growth rate over time, in the remuneration committee's and the board of directors' basis of decision when evaluating whether the guidelines and the limitations set out herein are reasonable. The development of the gap between the remuneration to executives and remuneration to other employees will be disclosed in the remuneration report. The report will be presented at the AGM and will be available on the company's website.

### The decision-making process to determine, review and implement the guidelines

The board of directors has established a remuneration committee. The committee's tasks include preparing the board of directors' decision to propose guidelines for executive remuneration.

The board of directors shall prepare a proposal for new guidelines at least every fourth year and submit it to the general meeting. The guidelines shall be in force until new guidelines are adopted by the general meeting. The remuneration committee shall also monitor and evaluate programs for variable remuneration for the executive management, the application of the guidelines for executive remuneration as well as the current remuneration structures and compensation levels in the Company. The members of the remuneration committee are independent of the Company and its executive management. The CEO and other members of the executive management do not participate in the board of directors' processing of and resolutions regarding remuneration-related matters in so far as they are affected by such matters.

#### Deviation from the guidelines

The board of directors may temporarily resolve to deviate from the guidelines, in whole or in part, if in a specific case there is special cause for the deviation and a if it is necessary to serve the Company's long-term interests, including its sustainability, or to ensure the Company's financial viability. As set out above, the remuneration committee's tasks include preparing the board of directors' resolutions in remuneration-related matters. This includes any resolutions to deviate from the guidelines.

#### **Incentive programs**

As of December 31, 2022, the Company has four series of warrants to senior executives and other key individuals. In 2022, warrants program 2018/2022 has expired. No warrants were exercised.

The four remaining warrant programs were measured at market value by applying the Black & Scholes valuation model as of their grant dates. See also information on note 7.

#### **Risks and uncertainty factors**

#### **Business risks**

Business risks are primarily associated with development work. If bioequivalence studies on healthy trial subjects that Xspray Pharma conducts do not demonstrate bioequivalence, or if their safety profile is not approved by regulators, there is a risk for delays. Manufacture by providers of clinical trial materials and materials for stability studies may also be delayed. These delays may depend on difficulties in securing the relevant permits from drug regulators for manufacturing pursuant to GMP standards, or technical problems with the manufacturing process. If the development of product candidates, or a pharmaceutical study, are delayed, this generally means projects becoming more costly because development expenses continue for longer than planned. This may mean expected revenues are not received on schedule, which may impact the Company's operations and financial position negatively.

When a pharmaceutical gains approval, the risk that sales do not meet expectations and that the product does not become commercially successful, remain. There is a risk that Xspray Pharma will be subject to lawsuits from original drug companies for patent infringement, and risks up to 30 months' prevention of launch of its products. Xspray Pharma works actively to reinforce its patent portfolio to protect itself against such lawsuits and delays.

#### Legal risks

The Company conducts its operations in an industry where legal proceedings occur to a large extent. Xspray Pharma's competitors are partly companies that currently have approved and fully developed drugs within the same area as Xspray Pharma's products, which entails an inherent risk that the companies owning the original drug will initiate legal proceedings against Xspray Pharma for patent infringement, or on other grounds, to prevent Xspray Pharma's operations. In February 2022, Bristol Myers Squibb filed a lawsuit against Xspray Pharma in the United States for patent infringement, something the company has expected and thoroughly prepared for. The lawsuit has progressed according to plan during 2022.

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

Through its operations, the Company is exposed to various financial risks such as currency risk, market risk, credit risk and liquidity risk. The Company collaborates with international parties and there is some exposure to fluctuations in different currencies, mainly the USD and EUR. Currency risk arises in future business transactions and in reported assets and liabilities. The scope of the Company's operations means that at present, its net foreign currency exposure is limited.

Credit risk in cash and cash equivalents is considered negligible, because counterparties are reputable banks with high credit ratings from external institutes. Financing risk is the ability to fund projects until commercialization. Liquidity risk is the Company being unable to meet its commitments. The Company manages this risk by continuously monitoring its cash flow to reduce liquidity risk and ensure solvency. The Company does not conduct active trading in financial assets for speculation. The goal of asset management is to generate reasonable returns on the company's investments.

#### Financing risk and going concern

The Company has determined that the Group's cash and cash equivalents are insufficient for the Group's liquidity needs during the coming 12 months. The Company's capital needs are dependent on a number of factors, including the launch timing for the company's first product candidate XS004, as well as outcome and costs associated with ongoing and future development studies. The Board therefor is monitoring the situation and evaluates different financial options including timing and size of capital raise that can be beneficial to the company. The Board has a positive outlook on completing a capital raise. However, if financing is insufficient, this indicates significant uncertainty which can lead to significant doubts on the Group's ability to continue its operations.

According to the Board's policy, the Group shall maintain a strong financial position, which helps the company to retain the confidence of its investors and the market. It also creates a foundation for further development of its operations, with continued long-term support for its goal of securing dividends for the company's owners. Until the company has achieved long-term, sustainable profitability, its policy is to maintain a low level of debt and a high level of equity.

Historical summary		0001	0000	0010
Group	2022	2021	2020	2019
Net sales (SEK thousand)	-	-	-	_
Loss before Income tax (SEK thousand)	-131,670	-96,698	-52,410	-45,771
Earnings per share before dilution (SEK)	6.25	-5.03	-3.05	-3.01
Earnings per share after dilution (SEK)	6.25	-5.03	-3.05	-3.01
Research and development expenses as % of operating expenses	16.4	39.1	11.7	7.2
Cash and cash equivalents (SEK thousand)	120,166	271,881	325,598	209,872
Total assets (SEK thousand)	585,430	622,903	605,303	400,672
Equity/assets ratio (%)	95	95	96	93
Average number of employees	25	23	20	17

For definitions of key figures, see note 26.

Historical summary					
Parent company	2022	2021	2020	2019	2018*
Net sales (SEK thousand)	_	_	-	_	277
Loss before Income tax (SEK thousand)	-133,017	-97,116	-52,333	-45,796	-20,691
Earnings per share before dilution (SEK)	-6.31	-5.05	-3.04	-3.01	-1.52
Earnings per share after dilution (SEK)	-6.31	-5.03	-3.04	-3.01	-1.52
Research and development expenses					
as % of operating expenses	16.6	39.1	11.7	7.2	14.8
Cash and cash equivalents (SEK thousand)	120,116	271,831	325,548	209,822	221,216
Total assets (SEK thousand)	581,592	619,305	600,472	395,316	315,306
Equity/assets ratio (%)	95.3	95.5	97.0	94.5	96.6
Average number of employees	25	23	20	17	11

\* Some comparative figures have been re-calculated due to mistakes made in 2019.

For more information on the re-calculations' effects, see note 21 in the Annual Report 2019.

#### **Dividend policy**

The Board of Directors does not intend to propose any dividends to shareholders until the Company can generate long-term sustainable profitability and a positive cash flow. The Board of Directors' opinion is that the Company should maintain its focus on continued development and expansion of its project portfolio. Accordingly, available financial resources and reported results of operations should be reinvested in operations to finance the Company's long-term strategy.

Future dividends and their scale will be determined on the basis of the Company's long-term growth, earnings performance and capital requirements considering adopted goals and strategies. Where proposed, dividends will be well-balanced in terms of the Company's goals, scope and business risk.

#### Proposed appropriation of profits (SEK):

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

Share premium reserve	907,419,625
Profit/loss brought forward	-628,697,425
Profit/loss for the year	-133,016,869
Total	145,705,331
Board of Directors proposes that these funds are appropriated as follows:	
Share premium reserve	907,419,625
Profit/loss brought forward	-761,714,294
Carried forward	145.705.331

# Financial statements



# **Consolidated Income Statement**

Amount in SEK thousand	Note	2022	2021
Net sales		-	_
		-	-
Other operating income	4	2,180	656
Research and development expenses		-22,219	-38,567
Administration and sales expenses	6	-109,601	-58,384
Other operating expenses	5	-3,433	-1,657
Operating loss	3	-133,073	-97,953
Finance income	8	1,415	1,259
Finance costs	8	-12	-4
Finance net		1,403	1,255
Loss before Income tax		-131,670	-96,698
Тах	9	-	-
Loss for the period*		-131,670	-96,698
Earnings per share for the period before dilution, SEK	27	-6.25	-5.03
Earnings per share for the period after dilution, SEK		-6.25	-5.03
Average number of shares before dilution		21,070,518	19,237,743
Average number of shares after dilution		21,070,518	19,237,743

# Consolidated Income Statement of comprehensive Income

Amount in SEK thousand	2022	2021
Loss for the year	-131,670	-96,698
Other comprehensive Income	-	-
Total comprehensive Income for the year*	-131,670	-96,698

\* The profit for the year and the profit of the comprehensive income are entirely attributable to the Parent Company's shareholders

# **Consolidated Balance Sheet**

Amount in SEK thousand	Note	Dec 31, 2022	Dec 31, 2021
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	10	385,597	296,236
Total intangible assets		385,597	296,236
Property, plant and equipment			
Machinery and installations	11	15,407	20,458
Right-of-use assets	12	2,477	3,526
Equipment	13	147	574
Fixed assets under construction	14	46,573	20,043
Total Property, plant and equipment		64,603	44,601
Financial assets			
Financial investments		1	1
Other long-term receivables	17	2,999	-
Total financial assets		3,000	1
Total non-current assets		453,200	340,838
Current assets			
Inventories	18	8,552	6,199
Current receivables		2,362	2,473
Prepaid expenses and accured income	19	1,150	1,513
Cash and cash equivalents	20	120,166	271,881
Total current assets		132,229	282,065
TOTAL ASSETS		585,430	622,903

# Consolidated Balance Sheet cont.

Amount in SEK thousand	Note	Dec 31, 2022	Dec 31, 2021
EQUITY AND LIABILITIES			
Equity	21		
Share capital		22,680	20,680
Other contributed capital		907,420	813,483
Reserves		976	976
Retained earnings including profit/loss for the period		-375,057	-243,387
Total equity attributable to the Parent Company's shareholders		556,019	591,752
Non–current liabilities			
Lease liabilities	12	560	1,185
Total non-current liabilities		560	1,185
Current liabilities			
Trade accounts payable	16	14,786	16,865
Lease liabilities	12	1,566	2,048
Other current liabilities		1,043	653
Accrued expenses and deferred income	22	11,456	10,401
Total current liabilities		28,851	29,966
TOTAL EQUITY AND LIABILITIES		585,430	622,903

# Consolidated Statement of Changes in Equity

Amount in SEK thousand	Share c capital	Other contributed capital	Reserves	Retained earnings including profit/ loss for the period	Total Equity
Opening balance as of January 1, 2021	18,893	709,407	976	-146,689	582,587
Loss of the year	-	-	-	-96,698	-96,698
Other comprehensive income of the year	-	-	-	_	-
Total comprehensive income for the year	-	-	-	-96,698	-96,698
Transactions with shareholders					
Warrant program	-	1,621	-	-	1,621
Redemtion of warrants / new shares	175	4,200	-	-	4,375
New share issue	1,612	98,388	-	-	100,000
Transaction costs	-	-134	-	-	-134
Total	1,787	104,075	-	-	105,862
Closing balance as of December 31, 2021	20,680	813,483	976	-243,387	591,752
Opening balance as of January 1, 2022	20,680	813,483	976	-243,387	591,752
Loss of the year	-	-	-	-131,670	-131,670
Other comprehensive income of the year	-	-	-	-	-
Total comprehensive income for the year	-	-	-	-131,670	-131,670
Transactions with shareholders					
Warrant program	-	813	-	-	813
New share issue	2,000	98,000	-	-	100,000
Transaction costs	-	-4,876	-	-	-4,876
Total	2,000	93,937	-	-	95,937
Closing balance as of December 31, 2022	22,680	907,420	976	-375,057	556,019

# **Consolidated Statement of Cash Flow**

Amount in SEK thousand Note	2022	2021
Operating activities		
Operating loss	-133,073	-97,953
Non-cash adjustments		
Depreciation	9,533	8,870
Capital gains	-	98
Disposal of intangible asset 10	15,472	31,128
Interest received	1,611	1,878
Interest paid	-147	-4
Cash flow from operating activities before changes in working capital	-106,604	-55,983
Changes in working capital		
Change in operating receivables	-2,942	-5,712
Change in operating liabilities	-633	10,087
Cash flow from operating activities	-110,179	-51,607
Investing activities		
Capitalized development costs	-103,820	-94,651
Acquisition of property, plant and equipment	-24,466	-1,313
Prepayments	-7,059	-9,854
Cash flow from investing activities	-135,345	-105,818
Financing activities		
New share issue	100,000	99,877
Capital raising costs	-4,876	-29
Payment of lease liability 12	-2,128	-2,154
Redemption of warrants 7	-	4,375
Repurchased warrants	-52	-54
Allocated warrants 7	865	1,694
Cash flow from financing activities	93,809	103,708
Cash flow for the period	-151,715	-53,717
Cash and cash equivalents at the beginning of the period 20	271,881	325,598

# **Parent Company Income Statement**

Amount in SEK thousand	Note	2022	2021
Net sales		-	-
		-	-
Other operating income	4	2,180	656
Research and development expenses		-22,592	-38,560
Administration and sales expenses	6	-109,710	-58,486
Other operating expenses	5	-3,500	-1,660
Operating loss	3	-133,622	-98,050
Finance income	8	617	938
Finance costs	8	-12	-4
Finance net		605	934
Loss before Income tax		-133,017	-97,116
Tax	9	-	_
Loss for the period		-133,017	-97,116

# Parent Company Comprehensive Income

Amount in SEK thousand	2022	2021
Loss for the year Other comprehensive Income	-133,017	-97,116
Total comprehensive Income for the year	-133,017	-97,116

# **Parent Company Balance Sheet**

Amount in SEK thousand Note	Dec 31, 2022	Dec 31, 2021
ASSETS		
Non-current assets		
Intangible assets		
Capitalized development costs 10	384,944	296,005
Total intangible assets	384,944	296,005
Property, plant and equipment		
Machinery and installations 11	15,407	20,458
Equipment 13	147	574
Fixed assets under construction 14	45,383	19,719
Total Property, plant and equipment	60,936	40,751
Financial assets		
Shares in subsidiaries 15	50	50
Financial investments 16	1	1
Other long-term receivables 17	2,999	-
Total financial assets	3,050	51
Total non-current assets	448,930	336,808
Current assets		
Inventories 18	8,552	6,199
Current receivables		
Other current receivables 17	2,362	2,473
Prepaid expenses and accured income 19	1,632	1,995
Total current receivables	3,994	4,467
Cash and bank 20	120,116	271,831
Total current assets	124,110	282,831
TOTAL ASSETS	581,592	619,305

# Parent Company Balance Sheet cont.

Amount in SEK thousand	Note	Dec 31, 2022	Dec 31, 2021
EQUITY AND LIABILITIES			
Equity	21		
Restricted equity			
Share capital		22,680	20,680
Statutory reserve		976	976
Development expenditure reserve		384,944	296,005
Total restricted equity		408,601	317,622
Non-restricted equity			
Other contributed capital		907,420	813,483
Accumulated earnings		-628,697	-442,642
Loss for the period		-133,017	-97,116
Total non-restricted equity		145,705	273,724
Total equity		554,306	591,386
Current liabilities			
Trade accounts payable	16	14,786	16,865
Other current liabilities		1,043	653
Accrued expenses and deferred income	22	11,456	10,401
Total current liabilities		27,285	27,919
TOTAL EQUITY AND LIABILITIES		581,592	619,305

# Parent Company Statement of Change in Equity

Amount in SEK thousand	Share capital	Statu- tory reserve	Deve- lopment expen- diture reserve	Total restricted equity	Other contri- buted capital	Retained earnings	Loss for the year	Total non- restricted equity	Total Equity
Opening balance as of January 1, 2021	18,893	976	231,512	251,381	709,407	-325,816	-52,333	331,259	582
Transfer of loss from	10,000	0.0	201,012	201,001	100,101	020,010	02,000	001,200	002
previous year	-	-	-	-	-	-52,333	52,333	-	-
Loss for the year	-	-	-	-	-	-	-97,116	-97,116	-97,116
Other comprehensive income for the year	-	-	_	_	-	-	-	_	-
Total comprehensive income for the year	_	_	_	-	-	_	-97,116	-97,116	-97,116
Transactions with shareholders									
Allocated warrants	-	-	-	-	1,621	-	-	1,621	1,621
Redemption of warrants/	475			475	4 0 0 0			4 0 0 0	4 075
new shares	175	-	-	175	4,200	-	-	4,200	4,375
New share issue Transaction costs	1,612	_	-	1,612 -	98,388 –134	_	-	98,388 –134	100,000 –134
Total	1,787	-	-	1,787	104,076	-	-	104,076	105,863
Development expenditure reserve									
Provisions for the year	-	-	64,493	64,493	-	-64,493	-	-64,493	-
Total	-	-	64,493	64,493	-	-64,493	-	-64,493	-
Closing balance as of December 31, 2021	20,680	976	296,005	317,662	813,483	-442,642	-97,116	273,724	591,386
Opening balance as of January 1, 2022	20,680	976	296,005	317,662	813,483	-442,642	-97,116	273,724	591,386
Transfer of loss from									
previous year	-	-	-	-	-	-97,116 -	97,116	-	-
Loss for the year Other comprehensive income for the year	_	_	_	-	_	_	-133,017	-133,017	-133,017
Total comprehensive income									
for the year	-	-	-	-	-	-	-133,017	-133,017	-133,017
Transactions with shareholders									
Allocated warrants	-	-	-	-	813	-	-	813	813
New share issue	2,000	-	-	2,000	98,000	-	-	98,000	100,000
Transaction costs	-	-	-	-	-4,876	-	-	-4,876	-4,876
Total	2,000	-	-	2,000	93,937	-	-	93,937	95,937
Development expenditure reserve									
Provisions for the year	-	-	88,939	88,939	-	-88,939	-	-88,939	-
Total	-	-	88,939	88,939	-	-88,939	-	-88,939	-
Closing balance as of December 31, 2022	22,680	976	384,944	408,601	907,420	-628,697	-133,017	145,705	554,306

# Parent Company Statement of Cash Flow

Amount in SEK thousand	Note	2022	2021
Operating activities			
Operating loss		-133,622	-98,050
Non-cash adjustments			
Depreciation		8,341	7,781
Capital gains		-	98
Disposal of intangible asset	10	15,472	31,128
Interest received		647	1,557
Interest paid		-12	-4
Cash flow from operating activities before changes in working capital		-109,174	-57,490
Changes in working capital			
Change in operating receivables		-1,911	-5,389
Change in operating liabilities		-631	10,087
Cash flow from operating activities		-111,716	-52,792
Investing activities			
Purchase of intangible assets		-104,411	-95,621
Acquisition of property, plant and equipment		-24,466	-1,313
Prepayments		-7,059	-9,854
Cash flow from investing activities		-135,936	-106,788
Financing activities			
New share issue		100,000	99,877
Transaction costs		-4,876	-29
Redemption of warrants		-	4,375
Repurchased warrants		-52	-54
Allocated warrants		865	1,694
Cash flow from financing activities		95,937	105,863
Cash flow for the period		-151,715	-53,717
Cash and cash equivalents at the beginning of the period	20	271,831	325,548
Cash and cash equivalents at the end of the period		120,116	271,831

# **Notes** – applicable to both consolidated and parent company financial statements

### Note 1 Accounting policies

### General information, consistency with IFRS and going concern assumptions

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB) and as endorsed by the European Union (EU).

The consolidated accounts also comply with recommendation RFR1 "Supplementary Accounting Rules for Groups" from the Swedish Financial Reporting Board.

The Parent Company applies the same accounting policies as the Group, apart from certain instances stated below in the section "Parent Company accounting policies."

The financial statements of Xspray Pharma for the financial year ending 31 December 2022 were approved by the Board of Directors and CEO on March 28, 2023 and will be presented for adoption by the Annual General Meeting (AGM) on May 16, 2023.

Assets and liabilities are recognized at historical cost.

#### New standards and interpretations

The Group's and the Parent Company's accounting principles are unchanged compared with the Annual Report 2021.

The changed standards that came info effect in 2022 have not had any significant effect on the Group. These new standards and interpretation statements are not expected to have a material impact on the consolidated financial statements in current or future periods. New and amended IFRSs with future application adopted by the IASB are not expected to have any significant effect on the Group's financial statements.

#### Functional currency and presentation currency

The Group and Parent company's functional currency is Swedish kronor, which is also the presentation currency of the Parent Company and the Group. All amounts are rounded to the nearest thousand unless otherwise indicated.

#### Classification

Non-current assets comprise of amounts that are expected to be recovered or the risks and rewards associated with ownership are expected to be realized after at least 12 months from the reporting date, whilst current assets comprise of amounts that are expected to be recovered or the risks and rewards associated with ownership are expected to be realized within 12 months of the reporting date. Non-current liabilities comprise of amounts that Xspray Pharma has an unconditional right to defer settlement until a time at least 12 months from the reporting date. If Xspray Pharma does not possess this entitlement as of the reporting date, or if the liability is expected to be settled within the normal business cycle, the liability amount is recognized as a current liability.

#### Basis of consolidation Subsidiaries

Subsidiaries are entities controlled by the Group. The Group 'controls' an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity.

Subsidiaries are recognized according to the acquisition method. The financial statements of subsidiaries are included in the consolidated financial statements from the date on which control commences until the date on which control ceases.

#### Transactions eliminated on consolidation

Intra-group receivables and payables, and any unrealized income and expenses arising from intra-group transactions, are eliminated entirely when consolidating accounts.. Unre-

alized losses are eliminated in the same way as unrealized gains, but only to the extent that there is no impairment.

#### Transactions in foreign currency

Transactions in foreign currency are translated to the functional currency at the rate of exchange ruling on the transaction date. Monetary assets and liabilities denominated in foreign currencies are translated to the functional currency at the reporting date. Exchange gains and exchange losses on trade receivables and trade payables are recognized in operating profit or loss, while exchange gains and exchange losses on financial receivables and liabilities are recognized in Finance net within the income statement.

#### Revenue from contracts with customers

Revenue is measured based on the compensation specified in the contract with the customer. The Group recognizes revenue when control over a product transfers to the customer. Control arises at a point in time, or over time, depending on the contract terms with the customer.

The Group does not expect to generate any revenues before the Group's products are launched on the market. Sales are not expected to increase until the Company according to the current business plan obtains market approval of its first product or a business agreement is made.

#### Segment reporting

Xspray Pharma does not divide its operations into different operating segments. This reflects the Group's organizational structure and reporting system. The Chief Operating Decision Maker (CODM) is the CEO.

The Group has no operating segments, but rather, has a single development operation that consists of developing protein kinase inhibitors for targeted cancer therapy. Within this narrow operational focus, there are three similar product candidates, all based on the same technology. Development operations are conducted as a single segment without any sub-groups or specialization into any of the three products. The Head of R&D is responsible for all development projects and reports to the Parent Company's CEO. The Parent Company's CEO is responsible for operational governance, monitoring and allocation of resources. Accordingly, these operations are reflected in the consolidated financial statements.

#### Finance income and expenses

Finance income consists of interest income and exchange gains on bank balances and other interest-bearing investments. Finance expenses consist of interest expenses relating to lease liabilities; for more information see below under "Leases".

Interest income and interest expenses are recognized in accordance with the effective interest method. The effective interest rate is the interest rate that discounts estimated future receipts and payments during the anticipated term of the financial instrument to the financial asset's recognized gross value or at the amortized cost of the financial liability. Interest income and interest expenses include allocated amounts of transaction expenses, and any discounts or premiums.

For financial assets that have been credit-impaired after first-time recognition, interest income is measured by applying the effective interest rate on the financial asset's amortized cost. If the asset is no longer credit-impaired, interest income is measured by applying effective interest on the recognized gross value.

Interest expenses are recognized in profit or loss in the period to which they relate, apart from to the extent that they are included in an asset's cost. An asset for which interest is included in cost is an asset that by necessity takes significant time to complete for intended use or sale. Interest is capitalized in the Group's capitalized development expenditure.

Exchange gains and exchange losses on financial items are recognized on a net basis as finance income or finance expenses, respectively.

#### Leases

Leases mainly relate to premises and vehicles. The Standard implies that identified leases are recognized in the Balance Sheet and classified as a right-of-use asset and a corresponding lease liability. Leases of low value are expensed as associated costs are incurred. The Group defines leases of low value as associated leased assets with a value as new condition of less than SEK 50 thousand. When the Group enters a lease, a judgement is made as to whether this arrangement confers entitlement to control use of the identified asset for a period in exchange for compensation paid to the lessor. An asset for right-of-use and a lease liability is recognized at the commencement date of the lease, which is the date that the Group gains access to and is able to commence use of the underlying asset. Initially, the right-of-use asset is of the same amount as the lease liability, adjusted for any lease payments made prior to the start date, plus any initial direct expenses, and an estimate of expenses to restore the underlying asset, less any discounts received.

The lease asset is subsequently amortized on a straightline basis over its useful life, which is assumed to correspond to the lease term.

The lease liability, divided into a long-term and short-term portion, is initially measured at the present value of remaining lease payments over the estimated lease term. The lease term consists of the irrevocable period plus additional periods in the lease arrangement, if at the start date, it is reasonably certain that they will be utilized. Lease payments are normally discounted at the Group's incremental borrowing rate, which in addition to the Group's credit risk, reflects the lease term of each arrangement and the quality of the underlying asset as intended security. However, in those cases where the implicit interest of the lease arrangement can be readily determined, this rate is applied. This is generally the case for leased vehicles. The value of the liability reduces with amortization over the term, which amounts to the net of the lease payments and interest expense over the term.

For premises leases, no distinction is made between lease and non-lease components included in lease payments. Instead, lease and non-lease components are recognized as a single lease component.

Rent payments are restated when changes to future lease payments arise through changes to indexes or altered judgements of the contract resulting from circumstances such as a purchase, contract extension or contract termination. A corresponding restatement of the right-of-use is recognized. For more information, see Note 12.

#### Employee benefits Short-term benefits

Short-term benefits to employees such as salary, social security contributions, vacation pay, and bonuses are expensed during the period in which the employees render services to the Group.

#### Pensions

The Group's pension obligations are comprised of defined contribution plans only. A defined contribution pension plan is a pension plan by which the Group pays fixed premiums to a separate legal entity. The Group has no legal or informal obligations to pay further premiums if this legal entity has insufficient assets to pay all benefits to employees associated with employee service during current or previous periods. Accordingly, the Group bears no further risk associated with pension obligations. The Group's obligations regarding premiums to defined contribution plans are recognized as an expense in profit or loss for the year at the rate that they are accrued by employees rendering services for the Group during the period.

#### Share-based payment

The Group has incentive programs that include warrants for all employees as well as key individuals. Warrants that are distributed to employees free of charge or subsidy, constitutes a share-based payment and is accounted for as employee cost in the Group's profit, considering the number of warrants that are expected to be exercised. The cost is expensed over the vesting period and is accounted for in equity. Social security contributions attributable to share-based remuneration are expensed over the vesting period. Warrants acquired by employees at market value are not reported as share-based compensation but as financial instruments. For all warrant programs, warrant prices have been determined at fair value through application of the Black & Scholes valuation model at the time of allocation. Please refer to Note 7 for further information on all incentive programs.

#### Termination benefits

A provision for benefits in connection with the termination of staff is only recognized if the Group is obligated to terminate employment before the normal time without any realistic possibility of withdrawal, and the affected groups of employees have been informed of the corresponding redundancy plan. A provision is made for that portion of termination benefits that will be paid without requiring employees to render services.

#### Тах

Income tax consists of current tax and deferred tax. Income tax is recognized in profit or loss for the year with the exception of when the underlying transaction is recognized in other comprehensive income or in equity; when the associated tax effect is recognized in other comprehensive income or equity, respectively.

Current tax is tax to be paid or received for the current period, including restatement of current tax attributable to previous periods. Current and deferred tax is computed by applying those tax rates and tax regulations that are enacted or substantively enacted on the reporting date.

Deferred tax is recognized according to the balance sheet method on all temporary differences arising between the taxable value of assets and liabilities and their carrying amounts. Deferred tax assets relating to deductible temporary differences and loss carry-forwards are recognized only to the extent it is likely that they can be utilized. The value of deferred tax receivables is impaired when it is no longer considered likely that they can be utilized.

As the Group is in a development phase and has yet to launch any products for sale, tax loss carry-forwards have been generated since the Group commenced operations. The underlying potential tax value of loss carry-forwards has not been recognized as a deferred tax asset because IFRS does not permit the recognition of deferred tax in deductible deficits if there are not convincing factors indicating that the loss carry-forwards can be utilized within the foreseeable future. The deferred tax receivable in loss carry-forwards is recognized in those cases where offset is possible against deferred tax liabilities. Deferred tax receivables are recognized on a net basis against deferred tax liabilities only if they can be settled on a net basis.

#### Non-current assets Intangible assets

Limited-life intangible assets are recognized at cost less amortization and any impairment. Intangible assets are amortized systematically over the asset's estimated useful life. The useful life is reassessed at each reporting date and adjusted as required. Amortization of the asset commences once economic benefits associated with the asset are realized by the entity.

When the asset's amortizable amount is determined, the asset's residual value is considered where appropriate.

Development expenditure is capitalized when it satisfies the criteria of IAS 38 "Intangible Assets." Otherwise, development expenditure is expensed as it occurs as operating expenses. The criteria for capitalization are:

- it is technically or commercially feasible to complete the product or process for use,
- the entity intends to complete development of the asset and use or sell it,
- the ability to sell the asset exists,
- the means by which the asset will generate future economic benefits can be demonstrated,
- adequate technical, financial and other resources to complete development to use the asset are available, and
- the costs related to the asset during its development can be measured reliably.

Expenditure directly related to the development of the asset that is capitalized as part of capitalized development expenditure includes expenditure for employees, external consultants, amortization of a right-of-use asset in the form of premises used, and interest.

The following useful lives are applied:	
Capitalized development expenditure	5-10 years
Patents	5 years

#### Property, plant and equipment

Property, plant and equipment consists of machinery and technical plant and is recognized in the Group at cost, less accumulated depreciation and any accumulated impairment losses. Cost includes the purchase price and any costs directly attributable to bringing the asset to the location and condition for it to be capable of operating in the manner intended by its acquisition. The carrying amount of an asset is derecognized from the balance sheet on disposal or sale, or when no future economic benefits are expected from use or disposal/sale of the asset. A gain or loss on the sale or disposal of an asset consists of the difference between the selling price and that asset's carrying amount less direct selling expenses. Gains and losses are recognized as other operating income/expenses.

The Group presents right-of-use assets in the balance sheet jointly with owned assets of the same class as the underlying leased asset. The leased assets are specified by asset class in Note 12.

d
3–10 years
3–5 years
Estimated lease term

The depreciation of owned property, plant and equipment is recognized on a straight-line basis over the asset's estimated useful life. The depreciation methods and useful lives applied are re-evaluated at each reporting date. Right-of-use assets from leases are amortized over estimated useful lives based on the irrevocable term of arrangements, plus extension options, initially assumed as reasonably certain.

#### Impairment of non-financial assets

Assets with indefinite useful lives such as the Group's intangible assets where amortization has not yet commenced because they are not yet in use are subject to impairment testing at least annually and when there are indications of impairment. Assets that are amortized are assessed for impairment at any time events or changes in circumstances indicate that the carrying amount is not recoverable.

Assets are impaired by the amount that its carrying amount exceeds its recoverable amount. The recoverable amount is the greater of the asset's fair value less selling expenses and its value in use. Impairment is recognized as an expense in profit or loss for the year.

If, during the impairment test, it is not possible to determine largely independent cash flows for an individual asset, assets are grouped at the lowest level where it is possible to identify largely independent cash flows, known as cash-generating units.

To test the value of intangible assets, XsprayPharma applies a discounted cash flow model. The measurement of current development projects is computed by measuring the present value of future cash flows. This measurement considers cash flow over the next five years and does not include measurement of any residual value.

Previously recognized impairment is reversed if the recoverable amount is judged to exceed the carrying amount. However, the reversal is not of an amount greater than the carrying amount would have been if no impairment had been recognized in previous periods. However, goodwill impairment is never reversed.

#### Inventories

The inventory is accounted for according to the lowest of cost and net realizable value. The value of cost is determined through the use of first in, first out method (FIFO). The cost of completed goods and ongoing work comprises av raw materials, direct salaries, other direct costs and associated indirect production costs (based on normal production capacity). The net realizable value is the estimated sales price in the ongoing business, deducting for variable sales costs. Tests for obsolete stock takes place on a quarterly basis based on future sales prognosis and the sustainability of material in inventory.

#### **Financial instruments**

Financial instruments recognized in the balance sheet as assets include cash and cash equivalents, financial investments, accounts receivable, contract assets (accrued operating income) and loans receivable. Financial instruments recognized in the balance sheet as liabilities consist of accounts payable. Lease liabilities are described above and do not constitute financial instruments.

#### Recognition and de-recognition from the Balance Sheet

Financial assets are recognized when the group becomes a contract party in the matter of the financial instrument's contracted terms. Receivables are recognized when the group has delivered and there is a contracted obligation for the counterparty to pay, even if no invoice has been sent. Accounts receivable are recognized in the Balance Sheet when an invoice has been sent to the counter party concurrent with the timing of goods or services rendered.

Financial liabilities are recognized when the counterparty has delivered a good or service and there is a contracted obligation to pay, even if no invoice has been received. Trade accounts payable are recognized when an invoice has been received from a counter party concurrent with the timing of goods or services rendered.

Financial assets are derecognized from the balance sheet when the contracted rights to cash flows ceases or if the right to cash flows transfers through a transaction where essentially, all risks and rewards are transferred to the counterparty.

A financial liability is derecognized from the balance sheet when it has been discharged, cancelled, or expired.

### Classification and measurement of financial assets on initial recognition

The Group initially classifies financial assets and financial liabilities in accordance with the following measurement categories

- Amortized cost
- Fair value through profit or loss
- Fair value through other comprehensive income

The classification by measurement category determines how the financial assets and liabilities are measured and recognized initially and subsequently thereafter.

The Group's policies for classifying and measuring financial assets are based on a judgement of both (i) the Group's business model for managing financial assets, and (ii) the characteristics of the contracted cash flows from the financial asset. The Group's financial assets, except from the item "financial investments" of SEK 1 thousand that belong to the valuation category financial assets valued at fair value through profit or loss, are valued at accrued acquisition value due to the assets being held within the auspices of a business model which aims to obtain financial assets with the purpose of collecting contracted cash flows, and at predetermined times, the contracted assets give rise to cash flows that are exclusively payment of principal and interest on the outstanding amounts.

Financial assets and financial liabilities are measured at fair value on initial recognition. For financial instruments not measured at fair value through profit or loss, transaction expenses directly attributable to the purchase or issuance are added to the value of the associated asset or liability. Accounts receivable are typically measured at transaction price.

#### Subsequent measurement

After initial recognition, financial assets and financial liabilities classified in the amortized cost category are measured at amortized cost by applying the effective interest method. Interest including allocated transaction expenditure, exchange gains or losses and gains or losses on de-recognition from the balance sheet are recognized in profit or loss as financial income and expenses, with the exception of impairment of accounts receivable and contract assets, which are classified as other operating expenses.

#### Set-off

A financial asset and financial liability are offset and recognized at a net amount in the balance sheet only when there is a legal right of set-off these amounts and there is an intention to settle the items with a net amount or simultaneously realize the asset and settle the liability.

#### Impairment of financial assets

Impairment of financial assets is recognized in accordance with the expected credit loss (ECL) model. Impairment calculations are also based on forward-looking information to report expected credit losses. The impairment rules in IFRS 9 cover all financial assets that are valued at accrued acquisition value and fair value via other comprehensive income.

When measuring expected credit losses, previous events, current circumstances and reasonable and substantiated forecasts that influence the expected likelihood of receiving future cash flows from the asset are considered.

When applying a forward-looking view, a distinction is drawn between:

• financial instruments whose credit quality has not materially deteriorated since initial recognition or have low credit risk (Step 1) and  financial instruments whose credit quality has deteriorated materially since initial recognition or whose credit risk is not low (Step 2).

Step 3 is for financial assets where, on the reporting date, the Company has objective evidence of impairment (that a credit loss event has occurred). For the first category, 12 months of expected credit losses are reported, while for the second category, expected credit losses for the remaining term are reported. Measurement of expected credit losses is based on a probability-weighted amount of estimated credit losses over the expected life of the assets.

#### Accounts receivable and other receivables

The Group applies a simplified methodology for recognizing accounts receivable, contract assets and lesing receivables and recognizes expected credit losses over remaining terms. In its measurement, the Group uses historical experience, external indications and forward-looking information to measure expected credit losses using a provision matrix. The Group judges impairment of accounts receivable collectively, where receivables are grouped on the basis of a number of overdue days, because they have shared credit characteristics. In 2022, the Company has reported no accounts receivable.

#### Cash and cash equivalents

Cash and cash equivalents in the statement of cash flows include cash and bank balances.

#### Earnings per share

The measurement of basic earnings per share is based on the Group's profit or loss for the year attributable to equity holders of the parent and the weighted average number of shares outstanding in the year. When measuring diluted earnings per share, earnings and the average number of shares are revalued to consider the effect of potential ordinary shares that are sourced from warrants issued to employees during the reporting period. The dilution from warrants is based on the measurement of how many shares could hypothetically have been purchased in the period at an exercise price and value of the remaining shares pursuant to IFRS 2 Share-based Payment. Those shares that could not be acquired result in dilution. That number of warrants, and thus shares, that would have been vested if that degree of satisfaction of the vesting conditions applicable at the end of the current reporting period also applied at the end of the vesting period are also included. Potential ordinary shares are only considered diluting in those periods when they result in a lower gain or loss per share.

#### Basic earnings per share

Basic earnings per share is calculated by dividing:

earnings attributable to equity holders of the parent by
the weighted average number of outstanding ordinary shares in the period, adjusted for the bonus issue component of ordinary shares issued in the year, and excluding repurchased shares held in treasury by the Parent Company.

#### Diluted earnings per share

For calculating diluted earnings per share, earnings and the average number of shares are adjusted to take into account the effects of potential ordinary shares, which during reported periods derive from warrants issued to employees and the Chairman of the Board. The dilution from the warrants are based on a calculation of how many shares could hypothetically have been purchased during the period with the exercise price and the value of the remaining services in



accordance with IFRS 2 Share-based Payment. The shares that could not have been purchased lead to dilution. Furthermore, the number of warrants, and thereby shares, that would be exercised if the degree of fulfillment of the vesting conditions that exist at the end of the current period would also exist at the end of the vesting period are included. Potential ordinary shares are seen as diluting only during periods when it leads to a lower gain or greater loss per share.

#### Provisions

A provision is recognized when there is uncertainty about the payment date or the amount to settle a future obligation of the Group. A provision is recognized in the balance sheet when there is an existing legal or informal obligation resulting from an event that has occurred, it is likely that an outflow of economic resources will be necessary to fulfil this obligation, and the amount can be measured reliably. Provisions are recognized at an amount that is the best estimate of what is necessary to settle the existing obligation on the reporting date. When the effect of the timing of payment is material, provisions are estimated by discounting the expected future cash outflows.

#### **Contingent liabilities**

A disclosure on contingent liabilities is presented when there is a potential obligation resulting from events that have occurred, and this occurrence is confirmed only by one or several uncertain future events, or when there is an undertaking that is not recognized as a liability or provision because it is not likely that an outflow of resources will be required.

#### Equity

Equity consists of the following items:

- Share capital that represents the nominal amount (par value) of issued and registered shares.
- Additional paid in capital includes premiums received on the new issue of share capital and shareholders' contributions from the Parent Company's owners. Any transaction expenses associated with the new share issue are deducted from Additional paid in capital.
- Statutory reserve originates from when the Swedish Companies Act stipulated provisions to a statutory reserve in the parent company. In the consolidated accounts, the statutory reserve is disclosed in the Reserves item.
- Retained earnings and losses relate to all earnings/losses brought forward for current and previous periods, and purchases of treasury shares.

#### Parent Company accounting policies

The Parent Company's annual accounts have been prepared in accordance with the Swedish Annual Accounts Act and RFR 2 "Accounting for Legal Entities." RFR2 stipulates that in its annual accounts for the legal entity, the parent company should apply all IFRS and statements as endorsed by the EU as far as possible within the auspices of the Swedish Companies Act and considering the relationship between accounting and taxation.

The Parent Company's annual accounts are presented in the Company's presentation currency, Swedish kronor.

#### **Revised accounting policies**

The Parent Company's accounting policies for 2022 are unchanged compared to those applied in the annual accounts for 2021.

#### Differences between the Parent Company and Group accounting policies

The Parent Company's accounting and valuation policies are consistent with the Group's equivalent policies with the exception of items stated below.

#### Format

The income statement and balance sheet comply with the Swedish Annual Accounts Act in the Parent Company. The statement of income and other comprehensive income, the statement of changes in equity and cash flow statement are based on IAS 1 Presentation of Financial Statements and IAS 7 Statement of Cash Flows. The differences in the Group's statements applying to the Parent Company's income statement and balance sheet primarily relate to the presentation of equity.

#### Participations in subsidiaries

Participations in subsidiaries are recognized at cost after deducting for any impairment. Cost includes acquisitionrelated expenses and any contingent considerations. When there is an indication that participations in subsidiaries are impaired, their recoverable amount is measured. If this is lower than the carrying amount, they are impaired. Impairment is recognized in the "Profit/loss from participations in group companies".

#### Leases

The Parent Company does not apply IFRS 16 Leases pursuant to the exemption in RFR 2. As lessee, lease payments are recognized as an expense on a straight-line basis over the lease term, and accordingly, right-of-use assets and lease liabilities are not recognized in the balance sheet.

#### **Financial instruments**

The Parent Company has elected not to apply IFRS 9 for its financial instruments. However, parts of the policies of IFRS 9 remain applicable to impairment, recognition/derecognition and the effective interest method for interest income and interest expenses.

Within the Parent Company, financial non-current assets are measured at cost less any impairment and financial current assets are measured at the lower of cost or market value. For financial assets recognized at amortized cost, the impairment regulations of IFRS 9 are applied in the same manner as in the consolidated accounts.

#### Eauitv

The Parent Company has a fund for development expenditure which is increased each year by the amount of the Company's own development work capitalized. The fund is reduced annually by amortization of capitalized development work.

#### Shareholders' contributions

Shareholders' contributions made to subsidiaries without issued shares or other equity instruments being received in exchange are recognized in the balance sheet as an increase in the carrying amount of the shares.

Shareholders' contributions received from owners without issued shares or other equity instruments being provided in exchange are recognized directly in equity.

Shareholders' contributions repaid to owners are recognized as a dividend paid (value transfer) in the balance sheet. Repaid shareholders' contributions from subsidiaries are recognized as a dividend received in financial income, concurrent with an impairment test of the carrying amount of shares in subsidiaries being conducted.

The above policies apply equally to conditional and unconditional shareholders' contributions.

### **Note 2 Judgements and estimates**

Preparing the financial statements in accordance with IFRS requires Management to make judgements and estimates, and to make assumptions that affect the application of accounting policies and the carrying amounts of assets, liabilities, revenues and expenses. Actual outcomes may differ from these estimates.

The estimates and assumptions are evaluated regularly. Changes to estimates are recognized in the period that the change is made.

The sources of uncertainty and estimates that in-volve a significant risk that the value of assets or lia-bilities may require restatement to a material extent during the forthcoming financial year are impairment testing of intangible assets with indefinite useful lives. Whether the requirements for capitalization of development expenditure is satisfied requires estimates. After capitalization, whether the accounting requirement for development expenses remain satisfied, and whether there are indications that the capitalized expenditure may have been exposed to impairment is assessments both initially and on an ongoing basis. There is an ongoing analysis of whether the capitalized expenses may be subject to a depreciation. The capitalized intangible assets that are not yet complete, which are subject to yearly impairment tests or as soon as there is an indication of impairment. Impairment tests involve estimates of future cash flows attributable to the asset or the cash-generating unit to which the asset relates when it is complete. These estimates and judgements involve expectations primarily regarding the selling price of products, market penetration, remaining development, sales and marketing expenses, and the likelihood that the product passes through the remaining development phases. These assumptions involve sector and marketspecific data, are made by Management, then reviewed by the Board of Directors. For more information on the impairment testing of intangible assets with indefinite useful lives, see Note 10.

Another source of uncertainty is the judgement of the extent to which deferred tax assets can be recognized based on a judgement of the likelihood of the Group's future taxable revenues that the deferred tax assets can be applied against. Additionally, significant consideration of judgements of the effect of certain legal and financial limitations, or uncertainty in differing jurisdictions is also necessary.

### Note 3 Expenses classified by type

Operating profit/loss, expenses classified by type

	Gro	up	Parent c	Parent company			
SEK thousand	2022	2021	2022	2021			
Net sales	-	_	-	_			
Capitalized work on own account	103,820	95,621	104,411	95,621			
Other operating income	2,180	656	2,180	656			
Other external expenses	-168,652	-120,324	-170,916	-121,508			
Personnel expenses	-41,984	-32,251	-41,984	-32,251			
Depreciation and amortization	-9,532	-8,870	-8,341	-7,781			
Write-down/disposal	-15,472	-31,128	-15,472	-31,128			
Other operating expenses	-3,433	-1,657	-3,500	-1,660			
Operating profit/loss	-133,073	-97,953	-133,622	-98,050			

### Note 4 Other operating income

	Gro	up	Parent company			
SEK thousand	2022	2021	2022	2021		
Exchange gains	1,742	656	1,742	656		
Other operating income	438	-	438	-		
Total	2,180	656	2,180	656		

Other remuneration relates to advisory and development work that Xspray has performed for an external party in 2022.

### Note 5 Other operating expenses

	Gro	up	Parent c	Parent company		
SEK thousand	2022 2021		2022	2021		
Exchange losses	-3,433	-1,657	-3,500	-1,660		
Total	-3,433	-1,657	-3,500	-1,660		

Other operating expenses consist entirely of exchange rate losses that arise in connection to foreign payments and re-calculation of currency accounts. Other operating expenses amounted to SEK –3,433 thousand (–1,657) in 2022.

### **Note 6 Remuneration to auditors**

	Gro	up	Parent c	Parent company			
SEK thousand	2022	2021	2022	2021			
KPMG AB							
Auditing	551	305	551	305			
Audit-related activities in addition to audit assignment	126	69	126	69			
Total	677	374	677	374			
Öhrlings Pricewaterhouse Coopers AB							
Other	141	205	141	205			
Total	141	205	141	205			

#### Auditing

Auditing means the statutory audit of annual accounts and consolidated accounts, as well as accounting records and the Board of Directors' and CEO's administration, and auditing and other reviews conducted in accordance with agreement or contract.

This includes the duties incumbent on the Company's auditor, as well as consulting or other services resulting from observations from such review or performing other such duties.

Audit-related activities in addition to audit assignment

Audit-related activities in addition to audit assignment refers to audit of submitted certificates.

#### Other services

Other services mainly relate to advisory in areas such as other insurances and internal processes.

In 2021 and 2022, the Company has received advisory services from Öhrings Pricewaterhouse Coopers AB, related to structuring of new incentive programs.

### Note 7 Employees and personnel expenses

	Gro	up	Parent company		
SEK thousand	2022	2021	2022	2021	
Average number of employees					
Women	11	8	11	8	
Men	15	14	15	14	
Total	25	22	25	22	
Salaries and other benefits					
Salaries for the Board of Directors and CEO	4,418	3,816	4,418	3,816	
Bonuses, etc. for the Board of Directors and CEO	520	264	520	265	
Other employees	20,891	18,268	20,891	18,268	
Total	25,829	22,349	25,829	22,349	
Social security expenses					
Pension expenses for the Board of Directors and CEO	540	506	540	506	
Pension expenses for other employees	4,367	2,712	4,367	2,712	
Other statutory or contractual social security charges	7,175	5,157	7,175	5 157	
Total	12,082	8,374	12,082	8,374	
Total salaries, benefits, social security expenses	07.014		07.044		
and pension expenses	37,911	30,723	37,911	30,723	

Remunerations to senior executives 2022, SEK thousand	Basic salary/ Directors' fee	Variable compen- sation	Other benefits	Pension expense	Other compen- sation	Total compen- sation
Chairman of the Board Anders Ekblom	485	_	-	_	-	485
Board member Gunnar Gårdemyr						
(resigned on May 19, 2022)	100	-	-	-	-	100
Board member Maris Hartmanis	305	-	-	-	-	305
Board member Carl-Johan Spak	255	-	-	-	-	255
Board member Torbjörn Koivisto	240	-	-	-	-	240
Board member Christine Lind	255	_	_	-	_	255
Board member Anders Bladh	240	_	_	-	_	240
Board member Robert Molander						
(Appointed on May 19, 2022)	105	-	-	-	-	105
CEO Per Andersson	2,433	520	58	540	-	3,552
Other senior executives (6)	5,722	673	197	1,369	1,008*	8,968
Total	10,140	1,193	255	1,909	1,008	14,505

#### Note 7 Employees and personnel expenses - cont.

Remunerations to senior executives 2021, SEK thousand	Basic salary/ Directors' fee	Variable compen- sation	Other benefits	Pension expense	Other compen- sation	Total compen- sation
Chairman of the Board Anders Ekblom	238					238
Former Chairman of the board Michael Wolff Jensen (Resigned May 20, 2021)	190					190
Board member Gunnar Gårdemyr	195					195
Board member Maris Hartmanis	260					260
Board member Carl-Johan Spak	223					223
Board member Torbjörn Koivisto	213					213
Board member Christine Lind	223					223
Board member Anders Bladh	118					118
CEO Per Andersson	2,011	264	39	506	109	2,929
Other senior executives (3)	2,646	265	60	652	1,229*	4,852
Total	6,317	529	99	1,158	1,338	9,441

\* Other compensation for other senior executives is consulting fees and expenses from senior executives.

There are no pension obligations to the Board of Directors. The Company's CEO has been allocated a pension solution via Skandia in the form of an occupational pension policy.

#### Warrant program

As per 2022-12-31, the Company has issued four series of warrants via incentive programs targeting all employees and certain key individuals with the aim of creating greater unity between employees' at shareholders' interests.

#### Warrant program LTIP 2018/2022 (Completed)

An Extraordinary General Meeting on 28 November resolved to introduce an incentive program (LTIP 2018) involving a maximum of 234,505 warrants. LTIP 2018 was offered to all employees and other key individuals. The Company's directors were not eligible for LTIP 2018. The warrants were subscribed on market terms at a price (premium) determined on the basis of computed market value of the warrants by an independent valuation institute applying the Black & Scholes valuation model. The value was computed at SEK 5.83 per warrant based on a subscription price per share of SEK 116.50. The Company subsidized the participants' premium with an amount corresponding to the premium paid, which has been reported as personnel costs in 2018. The warrants could be exercised until January 17, 2022. None of the outstanding warrants were exercised and they have therefor been forefeited.

#### Warrant program LTIP 2020/2023

The program was resolved at an Extraordinary General Meeting on March 26, 2020 and comprised 79,074 warrants. LTI 2020 involved five persons, including the CFO. The warrants were subscribed on market terms at a price determined on the basis of an estimated market valuation (Black & Scholes) by an independent valuation institute. The value of the warrant was calculated at SEK 4.86 based on a subscription price per share of SEK 89.10. The program provides a maximum dilution effect of 0.3% on the current number of shares. The warrants can be exercised in the period 1 April 2023 to 14 May 2023. The Company subsidized the participants' premium with an amount corresponding to the premium paid, which has been reported as personnel costs in 2020. If the warrant holder's employment ends during the program's term, warrant will be redeemed proportionately based on the remaining term in relation to the program's original terms. During 2021, 6,589 warrants have been returned and deregistered. No change has occured in 2022.

#### Warrant program LTIP 2021/2024

The warrant program encompasses 24 persons, including the company's CEO. The program involved 195,725 warrants and was subscribed under market terms at a price established by an independent appraisal institute using the Black & Scholes model. The value per option was calculated to be SEK 7.55 and the subscription price per share was calculated to be SEK 148.90. The warrant program runs for three years and is contingent upon the recipient remaining as a employee in the Company. The program results in a maximum dilution of 0.8 percent on the current number of shares.. The warrants can be exercised in the period 3 June 2024 to 15 July 2024. The Company subsidized the participants' premium with an amount corresponding to the premium paid, which has been reported as personnel costs in 2021. If the warrant holder's employment ends during the program's term, warrant will be redeemed proportionately based on the remaining term in relation to the program's original terms. During 2021, 6,385 warrants have been returned and deregistered. No change has occured in 2022.

#### Warrant program 2021/2026

The warrant program (Chairman LTIP 2021/2026) included the Company's new Chairman of the Board. The value per warrant was calculated to be SEK 16.38 and the subscription price per share to be SEK 129.00. The program runs for five years and involved 13,214 warrants. The warrants can be exercised in the period 25 May 2026 to 15 June 2026. If the warrant holder's assignment ends during the program's term, the warrants will be redeemed proportionately based on the remaining term in relation to the program's original terms. No subsidy was paid.

#### The share option program LTIP 2022/2025

The program was decided by an extraordinary general meeting on May 19, 2022. The program includes 140,625 warrants and 281,250 employee stock options that can be exercised from June 15, 2025 until July 15, 2025 with a subscription price of SEK 132.20. The program is connected to the company's growth in profits in order to create stronger ties between employees interests with that of shareholders. The employee stock options were issued at market terms and no subsidy was used. In 2022, 8,438 warrants and 16,876 employee stock options were returned and deregistered due to terminated employment. Maximum dilution of 1.7% on the current amount of shares.

#### Parent company and group

#### No. of warrants per incentive program,

2022	2018/2022	2020/2023	2021/2024	2021/2026	2022/2025
Outstanding at beginning of period, 1 Jan. 2022	213,922	72,485	189,340	13,214	-
Granted in the period	-	-	-	-	421,875
Forfeited in the period	-213,922	-	-	-	-
Exercised in the period	-	-	-	-	-
Redeemed in the period	-	-	-	-	-25,314
Outstanding at end of period	0	72,485	189,340	13,214	396,561
Exercisable at end of period, 31 Dec. 2022	0	72,485	189,340	13,214	396,561

#### No. of warrants per incentive program,

2021	2015/2021	2017/2020	2018/2022	2020/2023	2021/2024	2021/2026
Outstanding at beginning of period, 1 Jan. 2021	175,000	0	213,922	79,074	_	_
Granted in the period	-	-	-		195,725	13,214
Forfeited in the period	_	_	_	_	_	
Exercised in the period	-175,000	_	_		_	_
Redeemed in the period	-	-	-	-6,589	-6,385	_
Outstanding at end of period	-	0	213,922	72,485	189,340	13,214
Exercisable at end of period, 31 Dec. 2021	_	0	213,922	72,485	189,340	13,214

#### Fair value and assumptions at the time of granting warrants

	Incentive program						
Fair value at grant date	2018/2022	2020/2023	2021/2024	2021/2026	2022/2025		
Share price (SEK)	69.2	52.4	88.95	88.95	59.66		
Volume weighted share price at the exercise price (SEK)	70.61	52.41	87.57	85.97	60.1		
Exercise price (SEK)	116.5	89.1	148.9	129	132.2		
Expected volatility (%)	35	35	35	35	45		
Warrant term (years)	3.1	3.1	3.1	5.1	3.15		
Expected dividend	0	0	0	0	0		
Risk-free interest rate (%)	-0.28	-0.3	-0.15	-0.04	1.41		

Outstanding warrants as of 31 December 2022 have a subscription price in the interval SEK 89.10 (89.10) to 148.90 (148.90) and a weighted average remaining contracted term of 3.5 (3.6) years. The fair value of warrants has been estimated using the Black & Scholes model.

The input data stated in the above table is for valuation at the grant date. The expected volatility is based on historical volatility based on a weighted average maturity of warrants adjusted for any expected change in future volatility resulting from officially available information. The expected term of the warrant has been determined considering expected subscription prior to the end of each program's subscription period, and has been assumed at 3-5 years. The expected maturity has been completed by using historical data on how early individuals in different staff categories have exercised their warrants.

### The following executives held shares in the Company at the end of the year:

in the company at the end of the year.	
Anders Ekblom	3,000 shares
Per Andersson	242,294 shares
Maris Hartmanis	28,619 shares
Torbjörn Koivosto (via IARU)	6,000 shares
Christine Lind	4,000 shares
Carl-Johan Spak	– shares
Anders Bladh (private & via Ribbskottet)	2,591,800 shares
Robert Molander	– shares
Other senior executives	79,555 shares

### The number of warrants granted to senior executives

of the Company at the end of year					
Anders Ekblom	13,214 warrants				
Per Andersson	33,062 warrants				
	& 28,124 employee options				
Other senior executives	82,562 warrants				
	& 72,134 employee options				

#### Agreements on severance pay and notice periods

The notice period for termination initiated by the CEO is six months. For termination initiated by the Company, the CEO's notice period is nine months. If the CEO is discharged during the notice period, the CEO is not entitled to variable compensation, otherwise normal compensation is payable during the notice period.

At present, there are no agreements on severance pay for other senior executives.

#### Gender division on the Board of

Directors and senior executives	2022	2021
Share of women on the		
Board of Directors	14%	14%
Share of men on the Board of Directors	86%	86%
Share of women in other senior executives	60%	50%
Share of men in other senior executives	40%	50%

### Note 8 Financial income & expenses

	Group		Parent c	Parent company	
SEK thousand	2022	2021	2022	2021	
External interest income	1,415	1,259	617	938	
Total	1,415	1,259	617	938	

	Group		Parent company		
SEK thousand	2022	2021	2022	2021	
External interest income	-12	-4	-12	-4	
Total	-12	-4	-12	-4	

### Note 9 Tax

	Group		Parent company		
SEK thousand	2022	2021	2022	2021	
Current tax	-	-	-	-	
Total reported tax	-	-	-	-	
Reconciliation of effective tax					
Reported profit/loss before tax	-131,670	-96,698	-133,017	-97,116	
Tax at applicable rate 21.4% (22.0)	27,124	19,920	27,401	20,006	
Tax effect of deductible costs that are not included in the reported profit	1,004	31	1,004	31	
Tax effect of non-deductible expenses	-46	-52	-46	-52	
Tax effect of non-taxable revenues	-		-		
Other	278	86	-	-	
Increase in loss carry-forwards without the corresponding capitalization of deferred tax	-28,360	-19,985	-28,360	-19,985	
Reported effective tax	-	-	-	_	

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

In 2020, the Company started a case with the Swedish Tax Authority to get their opinion on the tax-related loss carry-forwards that have arisen from 2015. The potential effect can lead to reductions of previous tax-related loss carry-forwards in 2015 due to the special limitation rules for change of the Company's ownership. Tax-related loss carry-forwards that have arisen after the 2015 tax year are not considered to be affected, but may have an effect for the opening tax-related balances for each year. The Company, in consultation with its tax consultants, has chosen to correct the previous tax declarations and then claim back the losses carry-forward from previous years. Accumulated loss carry-forwards as of December 31, 2022 amounted to SEK 420,378 thousand (292,014), thus the tax loss for the current year amounted to SEK 128,364 thousand (96,984). Deferred tax assets have not been reported for these items as the Company most likely will continue to make losses next year. Furthermore, significant parts of the loss carry-forward may be lost owing to the special limitation and blocking rules that apply when there are changes in ownership. The size of the remaining loss carry-forward is analyzed every year and the likelihood of their ability to be used against future gains is assessed.

### **Note 10 Capitalized development costs**

	Group		Parent company		
SEK thousand	31 Dec. 2022	31 Dec. 2021	31 Dec. 2022	31 Dec. 2021	
Acquisition costs brought forward	296,236	231,618	296,005	231,512	
Purchases	104,834	95,746	104,412	95,621	
Reclassification	-15,472	-31,128	-15,472	-31,128	
Closing accumulated acquisition cost	385,597	296,236	384,944	296,005	
Closing residual value according to plan	385,597	296,236	384,944	296,005	

Costs for research and development expensed in the period is SEK 6,747 thousand (7,432) for the parent company and SEK 7,120 thousand (7,439) for the Group.

In 2022, interest payments have been activated of SEK 863 thousand (511) as capitalized development cost. The interest relates to the Group's leasing debt. The average interest rate during the period amounted to 5% (5).

In the fourth quarter 2022, SEK –15,472 thousand were disposed as the Company announced that it would discontinue development of XS005-sorafinib in order to focus on other product candidates in the Company's portfolio. The disposal of SEK –31,128 thousand in 2021 related to discontinued development of the generic version of XS004-dasatinib.

#### **Critical estimates and judgements**

Several critical estimates and judgements are made when Xspray Pharma conducts impairment tests of the group's and parent company's capitalized development expenditure. Primarily, the most critical assumptions are assumptions

guarding the size of the market, market share and pricing levels. The Company remains in the development phase, and judgements cannot be backed by financial history, which presents difficulties in assessing the reasonableness of forecasts. However, the Company can refer to relevant products on the market at present. The Company has conducted sensitivity analyses based on narrower margins, delays in time in terms of estimated sales, and the scale of estimated sales, these analyses offer indications that impairment is necessary. The weighted average cost of capital after tax could also double without any indication of impairment.

The impairment test is based on forecasted sales revenue based on current sales statistics, since no sales have been reported. Furthermore, cost of goods sold has been calculated based on cost estimates from suppliers, partners and personnel costs. Other external costs and personnel costs for the projects have been considered and included in the impairment test. The Company has applied a discount rate of 11.5% in the impairment test. Furthermore, consideration has also been made for depreciation of the intangible asset.

Capitalized development expenditure begins amortization when each product is launched on the market.

### Note 11 Machinery and other technical plant

	Group		Parent company		
SEK thousand	31 Dec. 2022	31 Dec. 2021	31 Dec. 2022	31 Dec. 2021	
Acquisition costs brought forward	44,503	37.446	44.503	37,446	
Purchases	2,862	7,057	2,862	7,057	
Scrapping	-	-	-	-	
Closing accumulated acquisition cost	47,365	44,503	47,365	44,503	
Depreciations brought forward	-24,045	-16,700	-24,045	-16,700	
Depreciations for the year	-7,913	-7,346	-7,913	-7,346	
Accumulated depreciations carried forward	-31,958	-24,045	-31,958	-24,045	
Closing residual value according to plan	15,407	20,458	15,407	20,458	

Depreciation of machines and other technical facilities, amounting to SEK 7,913 thousand (7,346), are reported in the income statement as part of research and development expenses.

### Note 12 Leases

The Group has rental agreements for premises and cars. The rental agreement for the Company's current premises was entered in the fourth quarter 2018 and is valid until October 31, 2023. In 2022, the Company entered a new rental agreement for the period November 2023 until October 2030. This has had no effect in addition to the deposition that was paid when signing the contract.

Extension options are included in the agreement related to the premises. When determining the length of the lease,

relating to vehicles newly acquired in the year.

management considers all available information that provides a financial incentive to exercise an extension option. The possibility of extending an agreement is only included in the duration of the lease if it is considered reasonably certain that the agreement will be extended. Possible future cash flows of SEK 17,993 thousand have not been included in the lease debt as it is not certain that the agreements will be extended or terminated. The Group also has a small number of leasing contracts for cars with lease periods of 3 years.

Right-of-use asset, SEK thousand	Real estate used in business operations	Vehicles	Total
Closing balance, 31 December 2022 Depreciations during the year	1,464 -878	1,014 -312	2,477 -1,191
Additional right-of-use assets in 2022 were SEK 1,020 thou- sand (287). This amount includes cost for right-of-use assets	-676	-312	-1,131

Lease liabilities,<br/>SEK thousand20222021Short-term lease liabilities1,5662,048Long-term lease liabilities5601,185Total lease liabilities2,1253,233
#### Not 12 Leasingavtal - forts.

Amounts recognized in profit or loss, SEK thousand	2022	2021
Depreciations of right-of-use assets	1,191	984
Interest on lease liabilities	-	_
Variable lease payments not included in measurement of lease liability	475	353
Expense for short-term leases	-	_
Expense for leases of low value, not short-term leases of low value	109	111

Future lease payments:	Group Parent comp		ompany	
SEK thousand	2022	2021	2022	2021
Within one year	2,861	2,117	2,861	2,117
Between one year and five years	24,575	1,746	24,575	1,746
After more than five years	17,243	-	17,243	-

The group's future lease payments for 2022 are disclosures pursuant to IFRS 16 including expected usage of extension options. Future lease payments from one year and further on, also the new lease agreement is included.

	Parent c	ompany
Expense payments for operating leases pursuant amount to, SEK thousand	2022	2021
Minimum payments	1,750	2,169
Variable payments	475	353
Total lease expenses		
Amounts recognized in the Statement of Cash Flows, SEK thousand	2022	2021
Total cash outflows attributable to leases	2,847	2,618

The above cash outflow includes amounts for leases recognized as lease liabilities, and amounts paid for variable lease payments, short-term leases and leases of low value.

### Note 13 Equipment

	Gro	up	Parent co	ompany
SEK thousand	31 Dec. 2022	31 Dec. 2021	31 Dec. 2022	31 Dec. 2021
Acquisition costs brought forward	2,458	2.419	2,458	2,419
Purchases	0	39	0	39
Disposals/scrapping	-	_	-	-
Closing accumulated acquisition cost	2,458	2,458	2,458	2,458
Depreciation brought forward	-1,884	-1,449	-1,884	-1,449
Depreciations for the year	-427	-435	-427	-435
Disposals/ scrapping	-	_	-	-
Accumulated depreciations carried forward	-2,311	-1,884	-2,311	-1,884
Closing residual value according to plan	147	574	147	574

Depreciation on equipment is reported in the Income Statement under administration and selling expenses at SEK 323 thousand (349), as well as research and development expenses, at SEK 104 thousand (86).

## Note 14 Fixed assets under construction and prepayments

	Gro	up	Parent co	ompany
SEK thousand	31 Dec. 2022	31 Dec. 2021	31 Dec. 2022	31 Dec. 2021
Acquisition costs brought forward	20,043	15,746	19,719	15,746
Investments in the year	21,604	1,275	21,604	1,275
Reclassification in the year	-	-7,155	-	-7,155
Prepayments in the year	4,926	10,177	4,060	9,853
Closing accumulated acquisition cost	46,573	20,043	45,383	19,719

In 2020, an agreement was signed with Pharmacare Premium Ltd. to construct a new manufacturing plant in Malta. The new plant will be placed in Pharmacare Premium Ltd's existing facility. In 2022, work has progressed. The Group's prepayments amounted to SEK 4,926 thousand (4,060) and of these SEK 865 thousand (324) relate to deferred interest.

## **Note 15 Shares in subsidiaries**

Parent company, SEK thousand	31 Dec. 2022	31 Dec. 2021
Acquisition costs brought forward	50	50
Purchases	-	_
Accumulated cost carried forward	50	50
Closing carrying amount	50	50

Name	Share of equity (%)	Share of votes (%)	No. of shares	Book value (SEK thousand)
Xspray Pharma Futurum AB	100	100	50,000	50
Name	Corp ID no.	Reg. office	Equity (SEK thousand)	Profit/loss for the year
Xspray Pharma Futurum AB	559178-7642	Stockholm	50	0

## Note 16 Financial instruments and financial risks

All financial assets and liabilities below are recognized at amortized cost or fair value depending on how the instrument is classified according to IFRS 9. The items that have been valued at fair value are financial investment in shares of SEK 1 thousand, which is in the financial assets at fair value through profit or loss measurement category. For non-interest-bearing asset and liability items such as; current receivables, cash and cash equivalents and other current liabilities, accounts payable with a residual life of less than six months, the reported value is considered to be a reasonable approximation of fair value.

Group		
SEK thousand	31 Dec. 2022	31 Dec. 2021
Financial assets in the Balance Sheet		
Financial investments	1	1
Current receivables	2,362	2,473
Accrued income	-	30
Cash and cash equivalents	120,166	271,881
Total	122,529	274,385
Total Financial liabilities in the Balance Sheet	122,529	274,385
Financial liabilities in the	<b>122,529</b> 14,786	<b>274,385</b> 16,865
Financial liabilities in the Balance Sheet	·	
Financial liabilities in the Balance Sheet Trade accounts payable	14,786	16,865

The carrying amounts of financial assets and liablities that are valued above are reasonable approximations of fair value. For lease liabilities in the consolidated accounts, see note 12.

#### Financial risks and asset management procedures

Through its operations, the Company is exposed to various financial risks such as market risk (currency risk in cash flow), credit risk and liquidity risk. The Board of Directors has adopted a finance policy for managing financial risks within the Group. The Board is responsible for the Group's long-term financing strategy and for any raising of capital. The CFO is responsible for managing financial risks in its day-to-day operations.

#### **Currency** risk

The Company collaborates with international counterparties and there is some exposure to fluctuations of different currencies, mainly USD, EUR and GBP. The currency risk and the Company's way of working to minimize the risk are managed in the Company's treasury policy. Exposure to currency risk arises in tandem with foreign currency payments and receipts, and in the translation of foreign currency receivables and liabilities. A weakening of the Swedish Krona against these currencies will lead to increased costs for the Group, if all else being equal.

The Company has actively chosen not to hedge any currencies since the Company's business means that there is a limited net exposure to foreign currencies. A change in the average exchange rate for USD, EUR and GBP by +/-10%, with all other variables constant, will have an impact on the Group's profit before tax by SEK +/-10,479 thousand, SEK +/-4,536 thousand and SEK +/-1,259 thousand. However, since foreign currency expenditures are mainly capitalized in machinery and capitalized development expenditure, currency risks are only exposed for the time between delivery and payment. The profit/loss for the year for the group and parent company include exchange differences in the operating profit/loss.

#### Credit- and interest risk

Credit is the risk of a counterparty of a financial transaction not fulfilling its obligations on the due date. Credit risk mainly relates to balances with reputable banks with credit ratings of A or higher, based on credit rating from Standard & Poor. These balances are available on demand. Considering their short maturity and banks' high credit ratings, the credit risk is considered low, and expected credit losses negligible.

To reduce financial credit risk and to have a high level of readiness for investments, liquidity is invested in bank accounts or interest-bearing securities with low interest rate risk, low credit risk and high liquidity. The Company has placed the cash and cash equivalents in a bank account or deposit account in Nordic banks where interest income can be obtained.

#### Liquidity risk/financing risk and going concern

As of December 31, 2022, the Group had available liquidity of SEK 120,166 thousand. Liquidity consists of bank balances. From a capital structure perspective, current investments and financial investments are also included in net debt even though they are not classified as cash and cash equivalents. At year-end, there were no external borrowings in the Group, as the Company's operations are mainly financed by equity. The objective regarding the capital structure is to maintain the Group's ability to continue its operations in order to generate returns for shareholders and benefits for other stakeholders, and to maintain an optimal capital structure to minimize the cost of capital. The Company believes that the Group's cash and cash equivalents are not sufficient to meet the liquidity needed to conduct the accelerating operations over the next 12 months. The Company's capital needs depend on several factors, including the launch timing for the Company's first product candidate, XS004, as well as profits and costs for ongoing and future pharmaceutical studies. In light of this, the Board is monitoring the situation and evaluates different financing options including timing and size of capital raise that can be beneficial to the company. The Board has a positive outlook on completing a capital raise. However, if financing is insufficient, this indicates significant uncertainty which can lead to significant doubts on the Group's ability to continue its operations. According to the Board's policy, the Group shall maintain a strong financial position, which helps the company to retain the confidence of its investors and the market. It also creates a foundation for further development of its operations, with continued long-term support for its goal of securing dividends for the company's owners. Until the company has achieved longterm, sustainable profitability, its policy is to maintain a low level of debt and a high level of equity.

#### **Capital structure**

The Group's goal regarding the capital structure is to ensure the Group's ability to continue its operations, so that it can continue to generate returns to shareholders and benefit other stakeholders, and maintain an optimal capital structure to keep low costs.

The goal for the capital structure is that operations are financed with equity. Debt financing is not seen as an appropriate financing form, other than temporarily, until the company has achieved profitability and positive cash flow.

In order to maintain a solid capital structure, the Group must raise capital through rights issues and other equity instruments to finance the development costs and launch of new projects.

## Note 17 Other long-term receivables

	Grou	up	Parent co	ompany
SEK thousand	31 Dec. 2022	31 Dec. 2021	31 Dec. 2022	31 Dec. 2021
Provided depositions	2,999	-	2,999	-
Total	2,999	-	2,999	-

In 2022, the Company signed a rental agreement with Akademiska Hus. A deposition of SEK 2,999 thousand was paid. The Company expects to move in in the fourth quarter 2023.

## Note 18 Inventories

	Gro	up	Parent co	ompany
SEK thousand	31 Dec. 2022	31 Dec. 2021	31 Dec. 2022	31 Dec. 2021
Goods in transit	3,116	6,199	3,116	6,199
Inventory of tradeable goods	3,907	-	3,907	-
Products in work	1,528	-	1,528	-
Total	8,552	6,199	8,552	6,199

Inventories relate to the Company's production of medical products.

## Note 19 Prepaid expenses and accrued income

	Gro	up	Parent co	ompany
SEK thousand	31 Dec. 2022	31 Dec. 2021	31 Dec. 2022	31 Dec. 2021
Prepaid rent	160	98	642	580
Other prepaid expenses	768	1,385	768	1,385
Other accrued income	223	-	223	-
Accrued interest income	-	30	-	30
Total	1,150	1,513	1,632	1,995

## Note 20 Cash and cash equivalents

	Group		Parent company	
SEK thousand	31 Dec. 2022	31 Dec. 2021	31 Dec. 2022	31 Dec. 2021
Bank balances	120,166	271,881	120,116	271,831
Total	120,166	271,881	120,116	271,831

Cash and cash equivalents in the Balance Sheet and Cash Flow Statement consist of cash and bank balances only. All outstanding bank balances are wholly invested with banks with high credit ratings from leading credit institutions. See note 16 for more detail on credit risk.

### Note 21 Equity

Antal aktier	2022	2021
Number/value at end of year	20,680,408	18,892,504
New share issue	2,000,000	1,612,904
Redemption of warrants	-	175,000
Number at the end of year	22,680,408	20,680,408

The share has been trading on Nasdaq Stockholm with the ticker XSPRAY since 27 March 2020. As of 31 December 2022, the Company had 22,680,408 (20,680,408) shares and the closing price for the period was SEK 57.00. All shares are ordinary shares and have equal rights to Xspray Pharma's profit, and each share entitles to one vote at the Annual General Meeting. The shares have a quota value of SEK 1 per share.

### Note 22 Accrued expenses and deferred income

	Group		Parent company	
SEK thousand	31 Dec. 2022	31 Dec. 2021	31 Dec. 2022	31 Dec. 2021
Accrued bonus incl. soc.security fee	3,632	1,474	3,632	1,474
Accrued research and development expenses	320	1,650	320	1,650
Accured legal cost	50	100	50	100
Accrued vacation pay incl. soc.security fee	4,108	3,311	4,108	3,311
Accrued special payroll tax	2,058	1,576	2,058	1,576
Accured consulting fee	120	344	120	344
Accrued Board fees	665	639	665	639
Other accrued expenses	503	1,306	503	1,306
Total	11,456	10,401	11,456	10,401

#### **Note 23 Pledged assets**

There are no pledged assets or liabilities for which collateral has been pledged.

### **Note 24 Contingent liabilities**

There are no contingent liabilities, or contingent liabilities in favor of a separate legal entity.

In February 2022, Bristol Myers Squibb ("BMS") filed a lawsuit against Xspray Pharma in the US district court in New Jersey for patent infringement due to product candidate XS004. The company's view is that the company's amorphous products do not infringe on BMS patent and expects the court to rule in Xspray Pharma's favor.

## Note 25 Transactions with related parties

The Management of the parent company, the Boards of Directors of the parent company and subsidiaries are defined as related parties. The subsidiary is fully dormant, and there have been no intra-group transactions, so no further disclosure will be made on this topic subject. The following transactions with related parties occurred during the financial year and comparative year.

Purchases of services from management in 2022 relate to consultancy fees to InterCon HB, owned by Andreas Konas, who is a member of the Company's management team. Disclosed figures in the table also include figures that have been invoiced. When these expenses are excluded, the figure amounts to SEK 1,008 SEK (1,008) for the full year. Transactions have occurred in line with market terms.

	Group		Parent company	
SEK thousand	31 Dec. 2022	31 Dec. 2021	31 Dec. 2022	31 Dec. 2021
Purchase of service from Senior Executives	1,246	1,036	1,246	1,036
Total	1,246	1,036	1,246	1,036

### Note 26 Definitions of key ratios

Earnings per share computed as profit/loss for the period divided by the average number of shares in the period.

This key ratio is useful for readers of the financial reports as a complement to other key ratios for assessing Xspray Pharma's profit position.

Equity/assets ratio equity in relation to total assets. This key ratio is useful for readers of the financial reports as a complement to other key ratios for assessing Xspray Pharma's capital position.

Research and development expenses as a percentage of operating expenses consists of research and development expenses divided by operating expenses, which include selling and administration expenses and other operating expenses.

This key ratio is useful for readers of the financial reports as a complement to other key ratios for assessing the degree of development of the Company's product candidates.

## Note 27 Significant events after the reporting period

- Xspray Pharma entered an agreement with EVERSANA ahead of the US-launch and commercialization of the company's product candidate XS004. Xspray Pharma keeps the financial and strategic control but gives EVERSANA exclusive commercial right to execute the launch of XS004, with the goal of launching the product in the second half of 2023.
- Xspray Pharma announced a new product candidate: XS008. The product candidate is based on the original substance axitinib which is used for treatment of kidney cancer.
- Xspray's production partner Nerpharma received approval by AIFA, Italy's medical product agency, for commercial production of XS004.
- . Xspray Pharma founded an American subsidiary, Xspray Pharma Inc.

No events causing restatements of the Income Statement and Balance Sheet have occurred between the reporting date and the date of approval of this Report.

### Note 28 Earnings per share

	Group		Parent company	
SEK thousand	31 Dec. 2022	31 Dec. 2021	31 Dec. 2022	31 Dec. 2021
Basic earnings per share	-6.25	-5.03	-6.31	-5.05
Diluted earnings per share	-6.25	-5.03	-6.31	-5.05

Amounts used in numerators are consistent with profit/ loss for the year of the group of SEK –131,670 thousand (–96,698), and SEK –133,017 thousand (–97,116) in the parent company. Amounts used in denominators are stated below.

The weighted average number of outstanding shares was 21,070,518 (19,803,830), which is affected by new share issues and exercising of employee stock options in the current and previous financial years. The number of outstanding shares at year-end was 22,680,408 (20,680,408).

## Instruments that can have a dilution effect and changes after the reporting date

The weighted average number of shares after dilution and profit/loss after dilution are the same before and after dilution. Because the group is reporting a loss for the current and previous financial years, potential ordinary shares cause no dilution of the average number of shares. There are incentive programs, which once the Company reports a profit, will have a dilution effect. For more information on the terms & conditions of incentive programs, and the number of outstanding warrants, see note 7. No change to the number of shares before and after dilution occurred after the reporting date.

### Note 29 Appropriation of profit/loss

SEK thousand	31 Dec. 2022
The following funds are at the disposal of the Annual General Meeting:	
Share premium reserve	907,420
Loss brought forward	-628,697
Loss for the year	-133,017
Total	145,705
Appropriated as follows:	
Share premium reserve	907,420
Loss carried forward	-761,714
Carried forward	145,705

# **Signatories to the Annual Report**

The Board of Directors and Chief Executive Officer certify that these annual accounts have been prepared in accordance with generally accepted accounting principles in Sweden, and the consolidated accounts have been prepared in in accordance with the international accounting standards as referred to in European Parliament and Regulation (EC) No 1606/2002 as of 19 July 2002 on the application of international accounting standards. The annual accounts and consolidated accounts give a true and fair view of the parent company's and the group's financial position and results of operations. The Report of the Board of Directors for the parent company and the group gives a true and fair view of the progress of the parent company and the group's operations, financial position and results of operations, and describes the significant risks and uncertainties faced by the parent company and group companies.

As stated above, the annual accounts and consolidated accounts were approved for issue by the Board of Directors and Chief Executive officer on 28-03-2023. The Consolidated Income Statement and Consolidated Statement of Comprehensive Income, the Balance Sheet and Other Comprehensive Income and Statement of Financial Position, and the Parent Company Income Statement and Balance Sheet will be subject for adoption at the Annual General Meeting on 16-05-2023.

Stockholm 2023-03-28

Anders Ekblom Chairman

Anders Bladh

Carl-Johan Spak

Christine Lind

Maris Hartmanis

Robert Molander

Torbjörn Koivisto

Per Andersson CEO

Our Audit Report has been provided on 2023-03-28

#### KPMG AB

Duane Swanson Authorized Public Accountant

# **Auditor's Report**

To the general meeting of the shareholders of XSpray Pharma AB (publ), corp. id 556649-3671.

#### REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS Opinions

We have audited the annual accounts and consolidated accounts of Xspray Pharma AB (publ) for the year 2022, except for the corporate governance statement on pages 30-35. The annual accounts and consolidated accounts of the company are included on pages 40-77 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all material respects, the financial position of the parent company as of 31 December 2022 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2022 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. Our opinions do not cover the corporate governance statement on pages 30-35. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet for the parent company and the group.

Our opinions in this report on the the annual accounts and consolidated accounts are consistent with the content of the additional report that has been submitted to the parent company's audit committee in accordance with the Audit Regulation (537/2014) Article 11.

#### **Basis for Opinions**

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements. This includes that, based on the best of our knowledge and belief, no prohibited services referred to in the Audit Regulation (537/2014) Article 5.1 have been provided to the audited company or, where applicable, its parent company or its controlled companies within the EU. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

#### Material uncertainty as to going concern

We bring to your attention the information in the administration report (page 46) and in note16 (page 75) which states that the cash and cash equivalents are insufficient for the Group's liquidity needs during the coming 12 months. It also states in the administration report and note 16 that Board of Directors are monitoring the situation and evaluating different financial options including timing and size of the capiital. This indicates if sufficient financing is not arranged that there are material uncertainties that may cast significant doubt on the Group's ability to continue as a going concern. We have not modified our opinions in regards to this.

#### **Key Audit Matters**

Key audit matters of the audit are those matters that, in our professional judgment, were of most significance in our audit of the annual accounts and consolidated accounts of the current period. These matters were addressed in the context of our audit of, and in forming our opinion thereon, the annual accounts and consolidated accounts as a whole, but we do not provide a separate opinion on these matters.

#### Intangible assets

See note 10 and accounting principles on pages 61-62 in the annual account and consolidated accounts for detailed information and description of the matter.

#### Description of key audit matter

The consolidated carrying value at 31 December 2022 of capitalized development costs amounted to 386 MSEK. These intangible assets equal approximately 66 % of the consolidated total assets and are subject to an impairment testing.

The impairment testing of these assets are dependent on management's estimates and judgments of future revenues, operating results, as well as required levels of working capital and investments. Another important assumption is the discount rate to be used in order to reflect the time value of money as well as the specific risks associated with the operations.

#### Response in the audit

We have assessed whether the impairment tests related to intangible fixed assets have been prepared in accordance with the prescribed method as well as assessed the reasonableness in the group's test of the carrying value of the intangible assets. Additionally, we have considered the reasonableness of the predicted future cash flows as well as the discount rates used through evaluation of the group's written documentation and forecasts. We have also examined the sensitivity analysis prepared by group management to evaluate how reasonable changes in the assumptions may impact the valuation.

We have also reviewed the compliance with the accounting principles and disclosures related to capitalized development costs as stated in the annual accounts and consolidated accounts.

#### Other information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-29, 36-38 and 85-86. The other information comprises also of the remuneration report which we obtained prior to the date of this auditor's report. The Board of Directors and the Chief Executive Officer] are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

## Responsibilities of the Board of Directors and the Chief Executive Officer

The Board of Directors and the Chief Executive Officer are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Chief Executive Officer are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts The Board of Directors and the Chief Executive

Officer are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Chief Executive Officer intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

The Audit Committee shall, without prejudice to the Board of Director's responsibilities and tasks in general, among other things oversee the company's financial reporting process.

#### Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Chief Executive Officer.
- Conclude on the appropriateness of the Board of Directors' and the Chief Executive Officer's, use of the going concern basis of accounting in preparing the annual accounts and consolidated accounts. We

also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's and the group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts and consolidated accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts and consolidated accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company and a group to cease to continue as a going concern.

- Evaluate the overall presentation, structure and content of the annual accounts and consolidated accounts, including the disclosures, and whether the annual accounts and consolidated accounts represent the underlying transactions and events in a manner that achieves fair presentation.
- Obtain sufficient and appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the consolidated accounts. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our opinions.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

We must also provide the Board of Directors with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, measures that have been taken to eliminate the threats or related safeguards.

From the matters communicated with the Board of Directors, we determine those matters that were of most significance in the audit of the annual accounts and consolidated accounts, including the most important assessed risks for material misstatement, and are therefore the key audit matters. We describe these matters in the auditor's report unless law or regulation precludes disclosure about the matter.

## REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS

#### Auditor's audit of the administration and the proposed appropriations of profit or loss. *Opinions*

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Directors and the Chief Executive Officer of Xspray Pharma AB (publ) for the year 2022 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Chief Executive Officer be discharged from liability for the financial year.

#### **Basis for Opinions**

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

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

## Responsibilities of the Board of Directors and the Chief Executive Officer

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner.

The Chief Executive Officer shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

#### Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Chief Executive Officer in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgment and maintain professional scepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgment with starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's situation. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

#### The auditor's examination of the Esef report *Opinion*

In addition to our audit of the annual accounts and consolidated accounts, we have also examined that the Board of Directors and the Chief Executive Officer have prepared the annual accounts and consolidated accounts in a format that enables uniform electronic reporting (the Esef report) pursuant to Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528) for Xspray Pharma AB (publ) for year 2022.

Our examination and our opinion relate only to the statutory requirements.

In our opinion, the Esef report has been prepared in a format that, in all material respects, enables uniform electronic reporting.

#### Basis for opinion

We have performed the examination in accordance with FAR's recommendation RevR 18 Examination of the Esef report. Our responsibility under this recommendation is described in more detail in the Auditors' responsibility section. We are independent of Xspray Pharma AB (publ) in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

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

## Responsibilities of the Board of Directors and the Chief Executive Officer

The Board of Directors and the Chief Executive Officer are responsible for the preparation of the Esef report in accordance with the Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), and for such internal control that the Board of Directors and the Chief Executive Officer determine is necessary to prepare the Esef report without material misstatements, whether due to fraud or error.

#### Auditor's responsibility

Our responsibility is to obtain reasonable assurance whether the Esef report is in all material respects prepared in a format that meets the requirements of Chapter 16, Section 4(a) of the Swedish Securities Market Act (2007:528), based on the procedures performed.

RevR 18 requires us to plan and execute procedures to achieve reasonable assurance that the Esef report is prepared in a format that meets these requirements.

Reasonable assurance is a high level of assurance, but it is not a guarantee that an engagement carried out according to RevR 18 and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of the Esef report.

The audit firm applies ISQC 1 Quality Control for Firms that Perform Audits and Reviews of Financial Statements, and other Assurance and Related Services Engagements and accordingly maintains a comprehensive system of quality control, including documented policies and procedures regarding compliance with professional ethical requirements, professional standards and legal and regulatory requirements.

The examination involves obtaining evidence, through various procedures, that the Esef report has been prepared in a format that enables uniform electronic reporting of the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement in the report, whether due to fraud or error. In carrying out this risk assessment, and in order to design procedures that are appropriate in the circumstances, the auditor considers those elements of internal control that are relevant to the preparation of the Esef report by the Board of Directors and the Chief Executive Officer, but not for the purpose of expressing an opinion on the effectiveness of those internal controls. The examination also includes an evaluation of the appropriateness and reasonableness of the assumptions made by the Board of Directors and the Chief Executive Officer.

The procedures mainly include a validation that the Esef report has been prepared in a valid XHMTL format and a reconciliation of the Esef report with the audited annual accounts and consolidated accounts.

Furthermore, the procedures also include an assessment of whether the consolidated statement of financial performance, financial position, changes in equity, cash flow and disclosures in the Esef report have been marked with iXBRL in accordance with what follows from the Esef regulation.

## The auditor's examination of the corporate governance statement

The Board of Directors is responsible for that the corporate governance statement on pages 30-35 has been prepared in accordance with the Annual Accounts Act.

Our examination of the corporate governance statement is conducted in accordance with FAR's auditing standard RevR 16 The auditor's examination of the corporate governance statement. This means that our examination of the corporate governance statement is different and substantially less in scope than an audit conducted in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. We believe that the examination has provided us with sufficient basis for our opinions.

A corporate governance statement has been prepared. Disclosures in accordance with chapter 6 section 6 the second paragraph points 2-6 of the Annual Accounts Act and chapter 7 section 31 the second paragraph the same law are consistent with the other parts of the annual accounts and consolidated accounts and are in accordance with the Annual Accounts Act.

KPMG AB, Box 382, 101 27, Stockholm, was appointed auditor of Xspray Pharma AB (publ) by the general meeting of the shareholders on the 19 May 2022. KPMG AB or auditors operating at KPMG AB have been the company's auditor since 2019.

Stockholm 28 March 2023

KPMG AB

Duane Swanson Authorized Public Accountant

# Glossary

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

**ANDA** • An Abbreviated New Drug Application is an application for a U.S. generic drug approval for an existing licensed medication or approved drug.

API • Active Pharmaceutical Ingredient

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

**Bioequivalence** • A term in pharmacokinetics used to assess the expected in vivo biological equivalence of two proprietary preparations of a drug. If two products are said to be bioequivalent it means that they would be expected to be, for all intents and purposes, the same.

**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 I investigates safety in healthy subjects; Phase II investigates the effects in patients with the disease concerned, and Phase II is a larger study to verify previously achieved outcomes. Once a drug is sold on the market, Phase IV studies are conducted to discover unusual side effects, for example.

**Clinical study** • A study of healthy test subjects (Phase I) or patients (Phases II through III) 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 provider 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, 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 regulator 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 the correct 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.

**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.

**505(b)(2)** • Application for US drug approval for a new version of an existing licensed drug or approved drug.

# **Shareholder information**

Financial calendar 2023	Date
Interim Report Q1, Jan-Mar 2023	4 May 2023
AGM 2023	16 May 2023
Interim Report Q2, Apr-Jun 2023	2 August 2023
Interim Report Q3, Jul-Sep 2023	8 November 2023
Year-end Report 2023	17 February 2024

All financial reports are available at Xspray Pharma's website, www.xspraypharma.com

For more information on Xspray Pharma, please contact Kerstin Hasselgren, CFO Tel: +46 (0) 70 311 16 83 email: kerstin.hasselgren@xspray.com www.xspraypharma.com

# **Annual General Meeting 2023**

The annual general meeting will be held on Tuesday, May 16, 2023 at CET 10.00 in Vinges premises on Smålandsgatan 20, Stockholm.

Registration will commence at CET 09.30. Shareholders may exercise their right to vote at the AGM through physical presence, proxies or pre-voting.

For entitlement to participate in the AGM, shareholders must:

- Be recorded as a shareholder in the share register maintained by Euroclear Sweden AB as of Monday 8 May 2023, and
- notify the Company of their intention to participate by voting in advance at the AGM no later than Wednesday 10 May 2023. The completed voting form may be submitted by post to Xspray Pharma, "General meeting", Råsundavägen 12, SE-169 67 Solna, Sweden, or via email to generalmeeting@xspray.com.

Complete information on the AGM 2023 is in the notice convening the meeting, which is at Xspray Pharma's website, www.xspraypharma.com





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