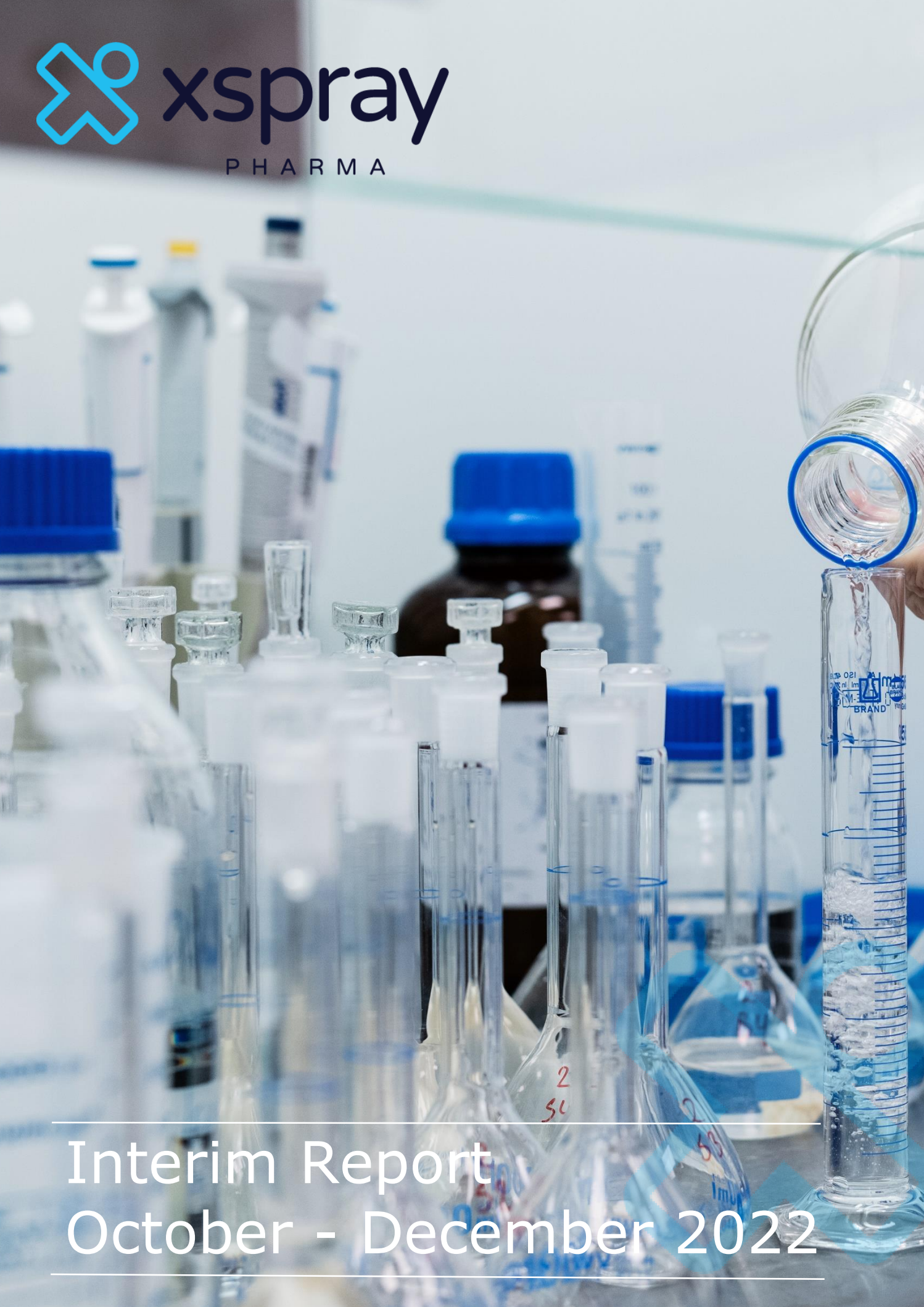
xspray PHARMA



# Interim Report
# October - December 2022

*Xspray Pharma AB (publ) is a pharmaceutical company with multiple product candidates in the clinical development phase. Xspray Pharma uses its innovative, patented technology to develop amorphous product candidates that are improved versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. They are formulated as hybrid nanoparticles ("HyNap") and are amorphous, patentable, and stable versions of crystalline original substances.*

Q4 2022

## October– December 2022, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -55,220 thousand (-51,944)
- Earnings per share before dilution amounted to -2.48 SEK (-2.62)
- Cash flow from operating activities amounted to SEK -35,003 thousand (-10,280)
- Cash flow from investing activities amounted to SEK -29,481 thousand (-33,691)

## January – December 2022, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -131,670 thousand (-96,698)
- Earnings per share before dilution amounted to -6.31 SEK (-5.03)
- Cash flow from operating activities amounted to SEK -110,179 thousand (-51,607)
- Cash flow from investing activities amounted to SEK -135,345 thousand (-105,818)
- Cash and cash equivalents at the end of the period amounted to SEK 120,166 thousand (271,881)

*Tal inom parentes avser motsvarande period föregående år.*

## Significant events during the quarter

- 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 quarter

- Xspray Pharma decided upon a commercialization strategy for future product launches and is negotiating with a partner to market and sell the product candidate XS004 in the entire US.
- 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.

# A message from the CEO

Dear shareholder,

We concluded 2022 with an eventful quarter for Xspray Pharma. One of the more important events was that we could present new data related to the product candidate XS004. These clearly demonstrate the advantages of our amorphous version of Dasatinib for the treatment of chronic myeloid leukemia, CML. Preparations ahead of a commercial launch in the latter part of 2023 progress and we began producing the first quantities of XS004 for commercial use. We have also decided upon a commercialization strategy for our first product, based upon which we will establish collaboration with a specialized commercialization partner, which provides access to a cost efficient and ready to go sales organization in the US. Following an extensive evaluation we have concluded that this is the most efficient and economically advantageous model to initially establish our product portfolio on the US market without limiting our right to future profits from our products.

**New data show clinical advantages in uptake and potential for concurrent treatment**

New data for XS004 was presented at ASH, the world's largest hematology congress arranged by American Society of Hematology. Together with scientists from Uppsala university and Karolinska University Hospital, we 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 makes XS004 more compatible for concurrent use with frequently used medications such as acid-reducing agents. Our 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. XS004 uptake is not negatively impacted by concurrent treatment with acid-reducing agents. In other research, XS004 demonstrated improved uptake and reduced variability in concentration of the drug in the body. This often leads to an improved effect and reduced risk profile for the patient.

This may bring a clear patient benefit which also has been verified by the FDA which has approved XS004 for Orphan Drug Status. The results show that when our regulatory applications are approved, we will be able to offer an improved second generation PKI product that can be taken together with frequently used acid-reducing agents. This is an important proof point of the product's clinical and commercial potential, not the least considering our estimation that 20-45% of patients that are treated with PKI for CML also take acid-reducing agents despite warnings. The presentation at ASH was well received and I would like to thank Chief Physician Gunnar Larfors and professors Hans Lennernäs and Leif Stenke for an important collaboration with the goal of improving life quality for chronically ill cancer patients.

**Launch with an integrated commercialization partner**

Ahead of launch in the US we continue to work intensively to make necessary market preparations. We have now chosen a commercialization strategy. Traditionally, the choice stands between time and resource heavy work to build a commercial organization on your own (with an associated risk) or to enter into an expensive license agreement with a well established life science company where a large part of the value and future profit goes to the licensee.

Following a detailed evaluation of our available options, we have gone for a third option with significant benefits. We aim to establish a collaboration with an existing market player which gives us access to a dedicated and qualified commercial organization, with people that have vast experience in selling PKI products to our target group of physicians, insurance companies and other payers.

**Continued work ahead of US launch in latter part of 2023**

Xspray's production partner NerPharma has now been approved by AIFA, Italy's medical products agency, for commercial production of XS004. We have thereby been able to begin production of XS004 in commercial scale with the purpose of building up sufficient stock prior to the commercial launch in the US. We are very pleased to have NerPharma as production partner since their facility enables supply of many of Xspray's future products that are based on the HyNap technology.

The legal proceedings concerning patent infringement against the original drug's secondary patent is proceeding according to plan. These patents relate to the product's crystalline formulation, and since our product candidate is built upon our own amorphous formulation it does not contain the crystalline substance that is patent protected. We still believe that this issue will be resolved during the year. We are also convinced that FDA's evaluation of Xspray Pharma's application for market approval of XS004 will be completed during the summer of 2023, and result in an approval, enabling marketing of XS004 as an improved version of Dasatinib for treatment of CML and ALL (acute lymphoblastic leukemia). When we reach these two milestones we will launch the product during the second half of 2023. We have been working for this goal a long time: to market our first product based on the HyNap technology and thereby create significant patient benefits.

**Update of product portfolio priorities**

In this report we are also pleased to announce a new product candidate: XS008. The product candidate is based on the original substance axitinib for treatment of kidney cancer. The PKI market for kidney cancer is estimated at USD 3 billion in 2022 in the US.

Since we have now made a successful upscaling, we believe that the HyNap technology can improve current PKI products and we see significant commercial potential. The only product on the market that uses axitinib is Inlyta® which has expiring patents, creating an attractive launch window that runs between April 2025 and December 2030 in the US.

Following a careful evaluation, we have decided to discontinue development of XS005 for liver cancer, following a re-evaluation of the clinical need and the product's market potential. The decision will result in a disposal of SEK 15 million in the quarter. The development of XS003 proceeds according to plan and pivotal studies are ongoing. As a result, we now have three announced product candidates in different phases.

The HyNap technology has high potential to improve PKI products but it is also important to carefully evaluate the original substances which we choose to improve, considering both clinical needs and market potential. This will be an exciting year for us and I really look forward to Xspray entering its next phase towards becoming a world leading provider of improved PKI products, bringing cancer patients a better quality of life.

*Per Andersson*
CEO, Xspray Pharma

## Financial overview, Group

| Key figures, Group | Q4 2022 | Q4 2021 | Jan-Dec 2022 | Jan-Dec 2021 |
|---|---|---|---|---|
| Net sales (SEK thousand) | - | - | - | - |
| Loss before Income tax (SEK thousand) | -55,220 | -51,944 | -131,670 | -96,698 |
| Earnings per share before dilution (SEK) | -2.48 | -2.62 | -6.25 | -5.03 |
| Earnings per share after dilution (SEK) | -2.48 | -2.62 | -6.25 | -5.03 |
| Research and development expenses as % of operating expenses | 30% | 63% | 16% | 39% |
| Cash and cash equivalents (SEK thousand) | 120,166 | 271,881 | 120,166 | 271,881 |
| Total assets (SEK thousand) | 585,430 | 622,903 | 585,430 | 622,903 |
| Equity/assets ratio (%) | 95.0% | 95.0% | 95.0% | 95.0% |
| Average number of employees | 27 | 23 | 25 | 23 |

Total expenditure for research and development amounted to SEK -26,191 thousand during the quarter, of which SEK -1,627 thousand has been expensed and SEK -24,564 thousand has been capitalized as development expenses. During the period a disposal of SEK -15,472 thousand was made since the company decided to discontinue development of XS005-sorafinib in order to focus on other product candidates in the company's product portfolio.

Total expenditure for research and development for the period January–December amounted to SEK -111,580 thousand, of which SEK -6,747 thousand has been expensed and SEK -104,834 thousand was capitalized as development expenditure.

## Comments on the report

Unless otherwise indicated, the comments below pertain to the Group. Comparison figures are presented in parentheses and pertain to the year-earlier period. Since the Group consists of the Parent Company and a dormant subsidiary, the differences between the Parent Company and consolidated statements consist of the existing differences between RFR2 and IFRS.

### Net sales

Net sales for the company amounted to SEK 0 thousand during the fourth quarter. The application for market approval of company's initial product, XS004 dasatinib, was filed in the fourth quarter 2021 and was supplemented with additional dosage strengths in the second quarter 2022. See further information under Research and Development on page 17.

### Other operating income and expenses

Other operating income for the period amounted to SEK 1,081 thousand (328). The increase was attributable to advisory services and development work performed by Xspray during the period. Other operating expenses amounted to SEK -745 thousand (-340) during the fourth quarter. For the full year, Other operating income amounted to SEK 2,180 thousand (656) and Other operating expenses amounted to SEK -3,433 thousand (-1,657). Other operating income and expenses consist of, in addition to advisory income, exchange rate gains and losses that arise in conjunction with international payments and translations of currency account.

### Research and development costs

During the fourth quarter, the company decided to discontinue development of XS005-sorafinib in order to focus on other product candidates in the portfolio. This disposal had an earning effect of SEK -15,472 thousand for which previously capitalized development costs were expensed. Apart from the item affecting comparability, the total expenditure for research and development amounted to SEK -26,191 thousand (-28,891) in the fourth quarter, of which SEK -1,627 thousand (-1,880) have been expensed in the income statement and SEK -24,564 thousand (-27,112) have been capitalized as an intangible fixed asset in the balance sheet. For the full year, total expenditure for the research and development amounted to SEK -111,580 thousand (-103,185), of which -6,747 thousand (-7,439) have been expensed and SEK -104,834 thousand (-95,746) have been capitalized as an intangible fixed asset in the balance sheet. The majority of the increased costs relates to the disposal and continued costs for the company's two product candidates, XS004-dasatinib and XS003-nilotinib.

### Administrative and sales costs

Administrative and sales costs amounted to SEK -38,824 thousand (-19,257) during the fourth quarter. Of these, personnel costs amounted to SEK-9,251 thousand (-4,050). For the full year, administrative and sales costs amounted to SEK -109,601 thousand (-58,384), of which SEK -29,177 thousand (-19,711) related to personnel costs. The increased costs for the fourth quarter are

primarily related to the company's continued market preparations ahead of a commercial launch in the US. Also legal advisory costs in the US have increased after the filing of law suit in the US in February 2022. In addition, the company has increased its workforce with four new employees compared to the corresponding period last year which also affects the cost base.

### Loss for the period

Loss for the fourth quarter amounted to SEK -55,220 thousand (-51,944) and loss for the full year amounted to SEK -131,670 thousand (-96,698). This corresponds to earnings per share before dilution of -2.48 SEK (-2.62) for the fourth quarter and -6.31 SEK (-5.03) for the full year. The worsening result for the quarter is primarily related to increased administrative and sales costs due to increased advisory costs which amounted to SEK -8,569 thousand (-2,938).

### Cash flow, investments, financial position and going concern

Cash flow from operating activities amounted to SEK -35,003 thousand (-10,280) during the fourth quarter, of which changes in working capital amounted to SEK 1,901 thousand (7,431). For the full year, cash flow from operating activities amounted to SEK -110,179 thousand (-51,607), of which changes in working capital amounted to SEK -3,575 thousand (4,375). The negative cash flow is in line with the company's plan and is primarily explained by a strengthened organization with key recruitments, project costs, legal advisory and other advisory for the company's future strategic positioning.

Cash flow from investment activities amounted to SEK -29,481 thousand (-33,691) during the fourth quarter and SEK -135,345 thousand (-105,818) for the full year. The item includes, among other things, capitalized development costs of SEK -24,317 thousand (-26,849) during the fourth quarter and SEK -103,820 thousand (-94,651) for the full year. The primary reason for the increase during the full year is high investments in fixed assets during the first quarter. Investments in fixed assets amounted to SEK -1,132 thousand (-838) during the fourth quarter and to SEK -24,466 thousand (-1,313) for the full year. During the fourth quarter, prepaid costs have been paid for the build up of the company's new production unit in Malta. Cash flow from investment activities are in line with expectations. Cash flow from financing activities amounted to SEK 94,816 thousand (99,309) during the fourth quarter and SEK 93,809 thousand (103,708) for the full year. Cash flow from financing activities is primarily related to the directed issue carried out in October which generated proceeds of SEK 100,000 thousand before transaction costs.

Total cash flow amounted to SEK 30,332 thousand (55,338) during the fourth quarter and to SEK -151,715 thousand (-53,717) for the full year. The group had SEK 120,166 thousand (271,881) in cash and cash equivalents at December 31, 2022.

Depending on the path and orientation the company chooses to take over the coming year, the Group's coverage of cash and cash equivalents may fall below the liquidity needed to pursue accelerated operations for the coming 12 months. In light of this, the Board of Directors is continually evaluating the company's financial requirements and position, and reviewing various financing alternatives. The equity/assets ratio for the Group amounted to 95.0 percent (95.0) at December 31, 2022.

### Intangible fixed assets

Development expenditures for projects have been capitalized according to plan. The group´s capitalized development costs amounted to SEK 24,564 thousand (27,112) during the fourth quarter. The group's total capitalized development costs amounted to SEK 385,597 thousand (296,236) on December 31, 2022. The item is associated with the company's product candidates XS004 dasatinib and XS003 nilotinib.

### Parent Company

All activities were pursued in the Parent Company, Xspray Pharma AB (publ). The Parent Company's cash and cash equivalents amounted to SEK 120,116 thousand (271,831) and the equity/assets amounted to 95.3 percent (95.5) on December 31, 2022.

### Employees

During the quarter, the organization increase by two full-time employees compared to the corresponding period last year. The average number of employees in the group amounted to 27 (23) at December 31, 2022.

### Related-party transactions

Related-party transactions are defined as the group management in the Parent Company and the Boards of Directors in the Parent Company and subsidiary. Purchase of services from senior executives in 2022 relates to consultancy fees from InterCon HB which is owned by Andreas Konar who is a member of group management. The fees amounted to SEK -252 thousand (-252) for the fourth quarter and SEK -1,008 thousand (-1,008) for the full year.

### Corporate Governance

The Audit and Remuneration Committees continued to assist the Board of Directors regarding monitoring assignments and remuneration issues.

# Financial statements and notes

All activities are pursued in the Parent Company, Xspray Pharma AB (publ).

## Consolidated income statement

| | Q4 | | Jan-Dec | |
|---|---|---|---|---|
| **SEK thousand** | **2022** | **2021** | **2022** | **2021** |
| Net sales | - | - | - | - |
| | | | | |
| Other operating income | 1,081 | 328 | 2,180 | 656 |
| Research and development expenses | -17,099 | -33,008 | -22,219 | -38,567 |
| Administration and sales expenses | -38,824 | -19,257 | -109,601 | -58,384 |
| Other operating expenses | -745 | -340 | -3,433 | -1,657 |
| **Operating loss** | **-55,587** | **-52,277** | **-133,073** | **-97,953** |
| | | | | |
| Finance income | 367 | 334 | 1,415 | 1,259 |
| Finance costs | -0 | -0 | -12 | -4 |
| **Finance net** | **367** | **333** | **1,403** | **1,255** |
| | | | | |
| Loss before Income tax | -55,220 | -51,944 | -131,670 | -96,698 |
| Tax | - | - | - | - |
| **Loss for the period** | **-55,220** | **-51,944** | **-131,670** | **-96,698** |
| | | | | |
| Earnings per share for the period before dilution, SEK | -2.48 | -2.62 | -6.25 | -5.03 |
| Earnings per share for the period after dilution, SEK | -2.48 | -2.62 | -6.25 | -5.03 |
| Average number of shares before dilution | 22,223,886 | 19,803,830 | 21,070,518 | 19,237,743 |
| Average number of shares after dilution | 22,223,886 | 19,803,830 | 21,070,518 | 19,237,743 |

## Consolidated statement of comprehensive income

| | Q4 | | Jan-Dec | |
|---|---|---|---|---|
| **SEK thousand** | **2022** | **2021** | **2022** | **2021** |
| Loss for the period | -55,220 | -51,944 | -131,670 | -96,698 |
| Other comprehensive income | - | - | - | - |
| **Total comprehensive income for the period** | **-55,220** | **-51,944** | **-131,670** | **-96,698** |

*Profit for the period and comprehensive income are attributable in their entirety to the Parent Company shareholders.*

## Consolidated balance sheet

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

| SEK thousand | 31 Dec 2022 | 31 Dec 2021 |
|---|---|---|
| **EQUITY AND LIABILITIES** | | |
| | | |
| **Equity** | | |
| 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 | 560 | 1,185 |
| **Total non-current liabilities** | **560** | **1,185** |
| | | |
| **Current liabilities** | | |
| Trade accounts payable | 14,786 | 16,865 |
| Lease liabilities | 1,566 | 2,048 |
| Other current liabilities | 1,043 | 653 |
| Accrued expenses and deferred income | 11,456 | 10,401 |
| **Total current liabilities** | **28,851** | **29,966** |
| | | |
| **TOTAL EQUITY AND LIABILITIES** | **585,430** | **622,903** |

## Consolidated report of changes in equity

| SEK thousand | Share capital | Other contributed capital | Reserves | Retained earnings incl. profit/loss for the period | Total Equity |
|---|---|---|---|---|---|
| **Opening balance as of Janary 1, 2021** | **18,893** | **709,407** | **976** | **-146,689** | **582,587** |
| Loss of the period | - | - | - | -96,698 | -96,698 |
| Other comprehensive income for the period | - | - | - | - | - |
| **Total comprehensive income for the period** | **-** | **-** | **-** | **-96,698** | **-96,698** |
| New share issue | 1,612 | 98,388 | - | - | 100,000 |
| Transaction costs | - | -134 | - | - | -134 |
| Redemption of warrants | 175 | 4,200 | - | - | 4,375 |
| Warrant program | - | 1,621 | - | - | 1,621 |
| **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 for the period | - | - | - | -131,670 | -131,670 |
| Other comprehensive income for the period | - | - | - | - | - |
| **Total comprehensive income for the period** | **-** | **-** | **-** | **-131,670** | **-131,670** |
| New share issue | 2,000 | 98,000 | - | - | 100,000 |
| Transaction costs | - | -4,876 | - | - | -4,876 |
| Redemption of warrants | - | -52 | - | - | -52 |
| Warrant program | - | 865 | - | - | 865 |
| **Closing balance as of December 31, 2022** | **22,680** | **907,420** | **976** | **-375,057** | **556,019** |

## Consolidated cash flow statement

| | Q4 | | Jan-Dec | |
|---|---|---|---|---|
| **SEK thousand** | **2022** | **2021** | **2022** | **2021** |
| **Operating activities** | | | | |
| **Operating loss** | **-55,587** | **-52,277** | **-133,073** | **-97,953** |
| Non-cash adjustments | | | | |
| Depreciation | 2,426 | 2,296 | 9,533 | 8,870 |
| Capital gains | - | - | - | 98 |
| Disposal of intangible fixed assets | 15,472 | 31,128 | 15,472 | 31,128 |
| Interest received | 812 | 1,141 | 1,611 | 1,878 |
| Interest paid | -27 | - | -147 | -4 |
| **Cash flow from operating activities before changes in working capital** | **-36,904** | **-17,712** | **-106,604** | **-55,983** |
| **Changes in working capital** | | | | |
| Change in operating receivables | -3,493 | -1,312 | -2,942 | -5,712 |
| Change in operating liabilities | 5,394 | 8,743 | -633 | 10,087 |
| **Cash flow from operating activities** | **-35,003** | **-10,280** | **-110,179** | **-51,607** |
| **Investing activities** | | | | |
| Capitalized development costs | -24,317 | -26,849 | -103,820 | -94,651 |
| Acquisition of property, plant and equipment | -1,132 | -838 | -24,466 | -1,313 |
| Prepayments | -4,032 | -6,004 | -7,059 | -9,854 |
| **Cash flow from investing activities** | **-29,481** | **-33,691** | **-135,345** | **-105,818** |
| **Financing activities** | | | | |
| New share issue | 100,000 | 99,877 | 100,000 | 99,877 |
| Transaction costs | -4,576 | -19 | -4,876 | -29 |
| Payment of lease liability | -556 | -538 | -2,128 | -2,154 |
| Redemption of warrants | - | - | - | 4,375 |
| Repurchased warrants | -52 | -10 | -52 | -54 |
| Allocated warrants | - | - | 865 | 1,694 |
| **Cash flow from financing activities** | **94,816** | **99,309** | **93,809** | **103,708** |
| **Cash flow for the period** | **30,332** | **55,338** | **-151,715** | **-53,717** |
| Cash and cash equivalents at the beginning of the period | 89,834 | 216,543 | 271,881 | 325,598 |
| **Cash and cash equivalents at the end of the period** | **120,166** | **271,881** | **120,166** | **271,881** |

## Parent Company income statement

| | Q4 | | Jan-Dec | |
|---|---|---|---|---|
| **SEK thousand** | **2022** | **2021** | **2022** | **2021** |
| Net sales | - | - | - | - |
| | | | | |
| Other operating income | 1,081 | 328 | 2,180 | 656 |
| Research and development expenses | -17,194 | -33,065 | -22,592 | -38,560 |
| Administration and sales expenses | -38,852 | -19,281 | -109,710 | -58,486 |
| Other operating expenses | -767 | -342 | -3,500 | -1,660 |
| **Operating loss** | **-55,733** | **-52,361** | **-133,622** | **-98,050** |
| | | | | |
| Finance income | 142 | 182 | 617 | 938 |
| Finance costs | -0 | -0 | -12 | -4 |
| **Finance net** | **142** | **181** | **605** | **934** |
| | | | | |
| Loss before Income tax | -55,591 | -52,180 | -133,017 | -97,116 |
| Tax | - | - | - | - |
| **Loss for the period** | **-55,591** | **-52,180** | **-133,017** | **-97,116** |

## Parent Company balance sheet

| SEK thousand | 31 Dec 2022 | 31 Dec 2021 |
|---|---|---|
| **ASSETS** | | |
| **Non-current assets** | | |
| **Intangible assets** | | |
| Capitalized development costs | 384,944 | 296,005 |
| **Total intangible assets** | **384,944** | **296,005** |
| | | |
| **Property, plant and equipment** | | |
| Machinery and installations | 15,407 | 20,458 |
| Equipment | 147 | 574 |
| Fixed assets under construction and prepayments | 45,383 | 19,719 |
| **Total Property, plant and equipment** | **60,936** | **40,751** |
| | | |
| **Financial assets** | | |
| Shares in subsidiaries | 50 | 50 |
| Financial investments | 1 | 1 |
| Other long-term receivables | 2,999 | - |
| **Total financial assets** | **3,050** | **51** |
| **Total non-current assets** | **448,930** | **336,808** |
| **Current assets** | | |
| **Inventories** | **8,552** | **6,199** |
| **Current receivables** | | |
| Other current receivables | 2,362 | 2,473 |
| Prepaid expenses and accured income | 1,632 | 1,995 |
| **Total current receivables** | **3,994** | **4,467** |
| Cash and bank | 120,116 | 271,831 |
| **Total current assets** | **132,661** | **282,497** |
| **TOTAL ASSETS** | **581,592** | **619,305** |

| SEK thousand | 31 Dec 2022 | 31 Dec 2021 |
|---|---|---|
| **EQUITY AND LIABILITIES** | | |
| **Equity** | | |
| **Restricted equity** | | |
| Share capital | 22,680 | 20,680 |
| Statutory reserve | 976 | 976 |
| Development expenditure reserve | 384,944 | 296,005 |
| **Total restricted equity** | **408,601** | **317,662** |
| | | |
| **Non-restricted equity** | | |
| Other contributed capital | 907,420 | 813,483 |
| Accumulated earnings | -628,697 | -442,642 |
| Profit/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 | 14,786 | 16,865 |
| Other current liabilities | 1,043 | 653 |
| Accrued expenses and deferred income | 11,456 | 10,401 |
| **Total current liabilities** | **27,285** | **27,919** |
| **TOTAL EQUITY AND LIABILITIES** | **581,592** | **619,305** |

## Parent Company cash flow statement

| | Q4 | | Jan-Dec | |
|---|---|---|---|---|
| **SEK thousand** | **2022** | **2021** | **2022** | **2021** |
| **Operating activities** | | | | |
| **Operating loss** | **-55,733** | **-52,361** | **-133,622** | **-98,050** |
| Non-cash adjustments | | | | |
| Depreciation | 2,111 | 2,026 | 8,341 | 7,781 |
| Captial gains | - | - | - | 98 |
| Disposal of intangible fixed assets | 15,472 | 31,128 | 15,472 | 31,128 |
| Interest received | 586 | 988 | 647 | 1,557 |
| Interest paid | - | - | -12 | -4 |
| **Cash flow from operating activities before changes in working capital** | **-37,564** | **-18,219** | **-109,174** | **-57,490** |
| **Changes in working capital** | | | | |
| Change in operating receivables | -3,245 | -1,160 | -1,911 | -5,389 |
| Change in operating liabilities | 5,395 | 8,743 | -631 | 10,087 |
| **Cash flow from operating activities** | **-35,413** | **-10,637** | **-111,716** | **-52,792** |
| **Investing activities** | | | | |
| Purchase of intangible assets | -24,463 | -27,031 | -104,411 | -95,621 |
| Acquisition of property, plant and equipment | -1,132 | -838 | -24,466 | -1,313 |
| Prepayments | -4,032 | -6,004 | -7,059 | -9,854 |
| **Cash flow from investing activities** | **-29,627** | **-33,873** | **-135,936** | **-106,788** |
| **Financing activities** | | | | |
| New share issue | 100,000 | 99,877 | 100,000 | 99,877 |
| Transaction costs | -4,576 | -19 | -4,876 | -29 |
| Redemption of warrants | - | - | - | 4,375 |
| Repurchased warrants | -52 | -10 | -52 | -54 |
| Allocated warrants | - | - | 865 | 1,694 |
| **Cash flow from financing activities** | **95,372** | **99,848** | **95,937** | **105,863** |
| **Cash flow for the period** | **30,332** | **55,338** | **-151,715** | **-53,717** |
| Cash and cash equivalents at the beginning of the period | 89,784 | 216,493 | 271,831 | 325,548 |
| **Cash and cash equivalents at the end of the period** | **120,116** | **271,831** | **120,116** | **271,831** |

# Notes

## Note 1. Accounting and measurement policies

The interim report for the Group has been prepared in accordance with IAS 34 Interim Financial Reporting, issued by the International Accounting Standards Board (IASB) and with the applicable provisions in the Swedish Annual Accounts Act. The interim report for the Parent Company has been prepared in accordance with Chapter 9, "Interim Reports", of the Annual Accounts Act. For the Parent Company and the Group, the same accounting policies and bases for calculation as in the Annual Report for 2021 have been applied. The changes in IFRS applied as of January 1, 2022 have not had any impact on the financial statements for the four quarters of 2022. Comparison figures are presented in parentheses and pertain to the year-earlier period.

**Definitions of key performance indicators**

Earnings per share are calculated as earnings for the period divided by the average number of shares during the period. The debt/equity ratio is equity as a percentage of the balance sheet total. Research and development costs as a percentage of operating expenses comprise primarily expensed research and development expenditures divided by operating expenses. Total operating expenses consist of operating profit less net sales and other operating income. The carrying amount of receivables, cash and cash equivalents, trade payables and other liabilities constitute a reasonable approximation of fair value.

## Note 2. Key estimates and assessments

Preparing the financial statements in accordance with IFRS requires management to make assessments and estimates, and to make assumptions that impact the application of the accounting policies and the recognized amounts of assets, liabilities, revenue and expenses. The real outcome may deviate from these estimates and assumptions. The estimates and assumptions are routinely evaluated. Changes to estimates are recognized in the period the changes are made.

The source of uncertainty in estimations that entail a significant risk for the need to significantly adjust the value of assets or liabilities during the coming financial year is the carrying amount of "Capitalized development expenses". Determining whether the requirements for capitalization of development expenditures have been met requires both initial and routine assessments. The capitalized expenditures are regularly tested as to whether they could be exposed to a decrease in value. The company holds capitalized intangible assets that have not yet been completed and are impairment tested either yearly or as soon as there is an indication of a potential decrease in value. Impairment testing involves estimating future cash flows attributable to the asset, or to the cash-generating unit that the asset will be attributed to, once it is complete. These estimates and assumptions encompass expectations pertaining primarily to the selling price of the products, market penetration, and remaining development, sales and marketing costs as well as the probability that the product will successfully pass through the remaining development stages. The assumptions involve industry- and market-specific data produced by corporate management and reviewed by the Board of Directors.

**Material risks and uncertainties**

Xspray Pharma's operation is associated with both industry-related and company-specific risks. The company develops product candidates, and there will always be regulatory, market-related and financial risks in the operation. No material changes have occurred in the risks and uncertainties during the period compared with those the company reported in the Annual Report for 2021.

**Financing risk and going concern**

Depending on the path and orientation the company chooses to take over the coming year, the Group's coverage of cash and cash equivalents may not meet the liquidity needed to pursue accelerated operations for the coming 12 months. In light of this, the Board of Directors is continually evaluating the company's financial requirements and position, and reviewing various financing alternatives. If the financing secured is not sufficient, it would suggest material uncertainties that could lead to significant doubt regarding the company's capacity to continue its operations. In accordance with the policy by the Board of Directors, the Group must maintain a strong financial position, which will help the company retain investor and market confidence. This will further facilitate the development of company operations, with continued long-term support for a desirable dividend for the company's owners. Until the company has achieved long-term and sustainable profitability, it is the company's policy to maintain a low level of indebtedness and a high level of equity.

**Ukraine**

Xspray Pharma continues to follow the tragic events unfolding in Ukraine. At present, Xspray Pharma's operations have not been directly impacted, but we are closely monitoring the course of events.

# The company and the pipeline

**Xspray Pharma AB (publ)** is a pharmaceutical company with multiple product candidates in the clinical development phase. Xspray Pharma uses its innovative, patented technology to develop amorphous product candidates that are improved versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. Often the original companies have secondary patents that are based on the crystalline forms of the active substance and thus do not encompass amorphous versions. This means that Xspray will be able to launch its product candidates earlier than would be possible with generic products.

In bioequivalence studies conducted in healthy volunteers, the goal is to achieve bioequivalence comparable to the original drug, meaning that the active drug substance of the product candidate should be processed by the body the same way as the original drug. Since Xspray's products are amorphous and have better uptake in the body compared with the original drug, bioequivalence can often be achieved at a lower dosage.

The company's communicated product candidates – XS004 dasatinib, XS003 nilotinib and XS008 axitinib – are stable amorphous versions of the three best-selling cancer drugs Sprycel® (dasatinib), Tasigna® (nilotinib) and Inlyta® (axitinib). In 2022, Sprycel® sold for USD 2.2 billion, Tasigna® for USD 1.9 billion and Inlyta® for USD 1.0 billion worldwide. A careful selection process determines which PKIs will become future product candidates and included in the company's pipeline.

### Market

PKI drugs are a large and important segment for targeted cancer therapies, where sales total approximately 37 percent of the total oncology market, and with sales figures that are increasing annually. In 2021, estimated sales of PKI drugs in the US market totaled approximately USD 33 billion.
Demand for effective life-cycle products is increasing as the expiration of patents occurs for many crucial reference drugs. Of the over 70 PKIs currently being marketed in the US, 23 drug substance patents are expected to expire by 2030. To date, Xspray Pharma has tested its technology on some twenty of the PKIs established in the US market, with positive results.

### PKI drugs with challenges

PKIs have been shown to inhibit the growth of cancer, which results in extended survival and the patient most often being treated for several years – in some cases, for life. The majority of the PKIs being marketed contain crystalline forms of the active substances. One generally known problem with these crystalline products is that they are difficult to dissolve, and solubility can vary depending on the pH value in the stomach for uptake in the body, which results in what is known as high variability. This often results in an uneven uptake of the drug into the body, especially alongside intake of food or pH-increasing drugs such as omeprazole. Variability increases the risk of the loss of therapeutic effect, if uptake of the drug is too low the cancer can accelerate again and if uptake is too high severe side effects often increase.
Xspray Pharma's technology is especially suited to overcoming many of the shortcomings that PKI substances generally possess. The company produces stable amorphous PKIs that can be easily dissolved, have greater bioavailability, and have pH independent uptake, which means a more even uptake of the drug even alongside the intake of food or pH-increasing drugs. Moreover, this technology makes it possible to adjust how much of the drug is to be taken up into the body.

### Prospects

The company's new HyNap product candidates are being developed in the same manner as the company's initial product, XS004 dasatinib. The process is repeatable, which reduces the development time for future product candidates in the company's pipeline. The technology makes it possible to quickly and in a controlled manner change the properties required to make improved amorphous versions of PKI drugs already being marketed and to bring the respective product candidates to market faster. This means that the company's easily dissolved and pH-independent product candidates have the conditions to both meet current market demand with better functioning drugs and also offer a broader patient group access to drugs that they cannot currently use.

Xspray Pharma's goal is to be a leader in developing improved versions of PKIs already being marketed for the treatment of cancer. The company has patented the manufacturing technology, the equipment, and the resulting products. The manufacturing has been established on a commercial scale, and the company has the capacity to provide the market with drugs made from its first product candidates.

### Xspray Pharma's pipeline

Xspray Pharma's pipeline is continuously evolving and contains a number of product candidates, three of which have been announced and are based on the company's HyNap platform: XS004 dasatinib, XS003 nilotinib and XS008 axitinib. These are improved amorphous versions of established and marketed protein kinase inhibitors with orphan drug status. The original drugs have secondary patents expiring between 2026 and 2023 and their total annual sales for exceeded USD 3.4 billion on the US market in 2022 and USD 5.1 billion globally.[1]

| Product candidates | | | Patent | | | Developing phase | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Project | Substance | Key indication | Regulatory process | Substance IP expiry-date | Secondary IP expiry date | Early product development | Formulation development | Pilot studies | Pivotal studies | Regulatory review | Original-product/ Company |
| XS004 | dasatinib | Leukemia (CML, ALL) | 505(b)(2) | Dec 2020 | Sept 2026 | | | | | | Sprycel®/ BMS |
| XS003 | nilotinib | Leukemia (CML) | 505(b)(2) | Jan 2024 | Feb 2029 | | | | | | Tasigna®/ Novartis |
| XS008 | axitinib | Kidney cancer (RCC) | 505(b)(2) | Apr 2025 | Dec 2030 | | | | | | Inlyta®/ Pfizer |
| XS00Y | Undisclosed | | | | | | | | | | |

In December 2022, management decided to discontinue development of XS005, following a re-evaluation of the clinical needs and the products commercial potential. The project is thereby no longer part of the company's product portfolio.

## Research and development

### Regulatory

In November 2021, an application was submitted to the FDA for market approval of XS004 under the 505(b)(2) New Drug Application procedure for the indications of acute lymphoblastic leukemia (ALL) and chronic myeloid leukemia (CML) in an accelerated phase. In January 2022, the FDA announced that the application for XS004 had been accepted for a comprehensive review. As a result, litigation was also initiated by the original company, which is a process that runs in parallel with the FDA's review of the 505(b)(2) dossier. The application was supplemented in Q2 with additional dosage strengths, which means that the application now simultaneously covers all six dosage strengths corresponding to those of the original company. The supplement also contains updated product information that now includes CML in a chronic phase as well. After the supplementary submission, Xspray Pharma has held constructive discussions with the FDA and obtained clearer information regarding how the FDA intends to perform the review of all dosage strengths and the updated product information. In accordance with these discussions, the company estimates tentative market approval of XS004 during H1 2023 and the company expects to launch the product in the US in H2 2023.

In June 2022, the FDA announced that they had granted XS004 orphan drug status for CML. The FDA's decision is based on the plausible hypothesis that XS004 could be clinically superior to other drugs with the same compound that has already been approved for the same indication. This is since Xspray Pharma's product candidate may provide a major contribution to patient care owing to the gastric pH-resistant qualities of the formulation which means that XS004 can be comedicated with acid-reducing agents (H2 blockers and proton-pump inhibitors), and this is not possible with the original drug. The company estimates that 20-45 percent of patients that are treated for CML also take acid-reducing agents.

[1] Data on annual sales has been collected from the individual companies' interim reports.

# Share information

Xspray Pharma's share has been listed on Nasdaq Stockholm under the symbol XSPRAY since March 27, 2020. Prior to that, the share was traded on Nasdaq First North Growth market beginning September 28, 2017. The number of shares in the company was 22,680,408 on December 31, 2022 and the closing price on this day was SEK 57.00.

## Incentive plans

On December 31, 2022 the company had a total of four series of warrants issued to employees, senior executives and the Chairman of the Board. All warrant programs and employee stock options were valued using the Black & Scholes valuation model at the time of allocation.

LTIP 2020–2023

The LTIP 2020–2023 warrant program encompasses 72,485 warrants that can be exercised during the period from April 1, 2023 through May 14, 2023 at a subscription price of SEK 89.10 per share. There is a maximum dilution effect of 0.3% on the current number of shares.

LTIP 2021–2024

The LTIP 2021–2024 warrant program encompasses 189,340 warrants that can be exercised during the period from June 3, 2024 through July 15, 2024 at a subscription price of SEK 148.90 per share. There is a maximum dilution effect of 0.8% on the current number of shares.

Chairman LTIP 2021–2026

The Chairman LTIP 2021–2026 warrant program includes the Chairman of the Board and encompasses 13,214 warrants that can be exercised during the period from May 25, 2026 through June 15, 2026 at a subscription price of SEK 129.00 per share. There is a maximum dilution effect of 0.06% on the current number of shares.

LTIP 2022–2025

The program was resolved on at the Annual General Meeting on May 19, 2022. The program encompasses 140,625 warrants and 281,250 employee stock options that can be exercised during the period from June 15, 2025 through July 15, 2025 at a subscription price of SEK 132.20 per share. The program is pegged to the company's growth in value for the purpose of creating a stronger link between employee and shareholder interests. During the quarter, 8,438 warrants and 16,876 employee stock options were returned and deregistered as a result of a terminated employment. There is a maximum dilution effect of 1.7% on the current number of shares.
A detailed description of the three earlier warrant programs can be found in the company's 2021 Annual Report.

| Owners as of December 31, 2022 | Number of shares | Number of shares & votes |
|---|---|---|
| Flerie Invest | 3,439,378 | 15.16% |
| The Foundation for Baltic And East European Studies | 2,742,626 | 12.09% |
| Anders Bladh (private & Ribbskottet) | 2,591,800 | 11.43% |
| Fourth Swedish National Pension Fund | 1,995,806 | 8.80% |
| Nordnet Pension Insurance | 852,858 | 3.76% |
| Unionen | 806,000 | 3.55% |
| Third Swedish National Pension Fund | 800,000 | 3.53% |
| Avanza Pension | 762,009 | 3.36% |
| Second Swedish National Pension Fund | 622,320 | 2.74% |
| TIN Funds | 404,241 | 1.78% |
| Total, ten largest owners | 15,017,038 | 66.21% |
| Total, other shareholders | 7,663,370 | 33.79% |
| **Total number of shares** | **22,680,408** | **100.00%** |

## Analysts monitoring the company

Filip Einarsson, Redeye AB

Dan Akschuti, Pareto Securities AB

## Financial calendar

| | |
|---|---|
| Annual Report 2022 | March 29, 2023 |
| Interim Report Q1 2023 | May 4, 2023 |
| Interim Report Q2 2023 | August 2, 2023 |
| Interim Report Q3 2023 | November 8, 2023 |

The financial reports will be made available on the Xspray Pharma website on the reporting dates above, www.xspraypharma.com.

## Assurance from the Board

The Board of Directors and the CEO declare that this quarterly report provides a true and fair overview of the Group's and Parent Company's business operations, financial position and performance and describes principal risks and uncertainties faced by the company.

Solna February 15, 2023

Anders Ekblom
Chairman of the Board

Anders Bladh
Board member

Robert Molander
Board member

Maris Hartmanis
Board member

Torbjörn Koivisto
Board member

Christine Lind
Board member

Carl-Johan Spak
Board member

Per Andersson
CEO

This report has not been reviewed by the company's auditors.

## Information
Glossary

| | |
|---|---|
| **505(b)(2) NDA •** | Application for drug approval in the US for an improved version of an existing licensed or approved drug. |
| **Amorphous •** | An amorphous structure is a chemical term that describes substances whose molecules lack an ordered structure. |
| **Bioequivalence •** | Term used to describe whether two different drugs are processed in a similar manner by the body and are thereby expected to have a similar and equivalent medicinal effect. If it can be confirmed that two drugs being compared are bioequivalent, they can be expected to have the same effect and safety. |
| **Bioavailability •** | (Biological availability), a concept in pharmacology that shows how large a portion of the drug reaches the blood. |
| **CRO •** | Contract Research Organization. A service company active in contract research and service in the development of drugs. |
| **FDA •** | Food and Drug Administration. The US food and drug authority responsible for foodstuffs, nutritional supplements, drugs, cosmetics, medical equipment, radiation-emitting equipment and blood products |
| **GMP •** | Good Manufacturing Practice. Rules that describe how the drug industry is to manufacture medicines so that patients can always be sure that they are taking the right product with a high level of quality. The rules govern manufacturing and packaging of drugs, foodstuffs and nutritional supplements. GMP is a system for ensuring that the products are always produced and checked in accordance with quality norms. The system has been designed to minimize the risks in drug production that cannot be eliminated by testing the final product. |
| **Pilot study •** | An initial study conducted on a smaller scale than a full study. A pilot study can be used both to check whether the arrangement of the study is a functional one, and to collect data that can later be used as control values in the full study. |
| **Protein kinase inhibitor (PKI) •** | Drugs that block protein kinases. Protein kinase inhibitors work by blocking activity in enzymes that push the development and growth of cancer cells. |
| **Variability •** | The scope of the distribution in the form of many or few low and high values around the average value as regards the body's uptake of drugs. |

This interim report for Xspray Pharma AB (publ) was released after approval by the Board of Directors.

For more information, please contact

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