

INTERIM REPORT  
January–March 2023





## Overview – company vision

### Financial and operational vision through 2030:

- Net sales that exceed USD 400 million
- Profit margin that exceeds 65 percent
- Five commercialized products
- Three product candidates under development

### Product candidates (XS004, XS003 and XS008):

- Launch of XS004 in the US is expected in H2 2023, conditional upon regulatory approval and a positive outcome in the ongoing legal dispute.

## January–March 2023, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -34,827 thousand (-18,934)
- Earnings per share before dilution amounted to SEK -1.54 (-0.92)
- Cash flow from operating activities amounted to SEK -45,535 thousand (-27,613)
- Cash flow from investing activities amounted to SEK -14,650 thousand (-47,541)

Amounts in parentheses refer to the same period in the previous year.

## Significant events during the quarter

- Xspray Pharma has entered into a partnership agreement with EVERSANA for the launch and commercialization of the company's product candidate XS004 in the US. Xspray Pharma retains financial and strategic control while granting EVERSANA exclusive rights to commercialize XS004. The goal is to be prepared to launch the product in the second half of 2023.
- Xspray Pharma announced a new product candidate: XS008, which is based on the original substance axitinib, used in the treatment of kidney cancer.
- Xspray's production partner NerPharMa obtained approval from AIFA, the Italian Medicines Agency, for commercial production of amorphous material for XS004.

## Significant events after the end of the reporting period

- The US court has rejected Xspray Pharma's motion to dismiss in the ongoing patent dispute involving XS004. The lawsuit will thus continue with a review of the technical details of the case, which provides Xspray Pharma the opportunity to demonstrate that XS004 does not contain any patented crystalline substances.
- The Board of Xspray Pharma announced a planned rights issue of units of approximately SEK 300 million, with two warrant series totaling an additional approximately SEK 300 million upon full exercise. An extraordinary general meeting is proposed to authorize the Board of Directors to resolve on the rights issue. Approximately 83 percent of the rights issue is secured by subscription commitments and intentions, as well as guarantee commitments.
- The shareholders of Xspray Pharma were summoned to an extraordinary general meeting on Thursday, 25 May 2023 at 13.00 CEST at Advokatfirman Vinge's office on Smålandsgatan 20 in Stockholm.

## Key performance indicators, Group

	Q1 2023	Q1 2022	Full year 2022
Net sales (SEK thousand)	—	—	—
Loss before tax (SEK thousand)	-34,827	-18,934	-131,670
Earnings per share before dilution (SEK)	-1.54	-0.92	-6.25
Earnings per share after dilution (SEK)	-1.54	-0.92	-6.25
Research and development expenses as % of operating costs	35.8	8.7	16.4
Cash and cash equivalents (SEK thousand)	59,395	196,212	120,166
Total assets (SEK thousand)	547,840	592,430	585,430
Equity/assets ratio (%)	95.1	96.7	95.0
Average number of employees	26	24	25



## A message from the CEO



Dear shareholders,

We have started the year with important preparations for the launch of Xspray Pharma's first commercial product: XS004, with the working name Dasynoc. Dasynoc, which is intended to treat the blood cancer diseases chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL), may provide clinical benefits by reducing the variability in uptake and enabling co-medication with proton-pump inhibitors. During the quarter, we entered into a partnership agreement with EVERSANA and continued to make preparations for launch of Dasynoc in the US, which is expected by July 2024, but with potential for launch as early as the second half of 2023. In addition, we have obtained approval from AIFA, the Italian Medicines Agency, for the production of commercial volumes of amorphous material for Dasynoc at NerPharMa's manufacturing facility in Italy.

### **Collaboration with commercial partner**

As we announced previously, we have signed a partnership agreement with EVERSANA to market and sell our product candidate, Dasynoc, throughout the US. This partnership grants us exclusive access to a complete and cost-effective countrywide marketing and sales organization that is ready to go. EVERSANA has several skilled experts with years of experience in selling PKI drugs to the specific physicians, research companies, and other paying customers we are targeting. We pay for the

service for the product launch, while the agreement enables us to retain financial and strategic control over Dasynoc.

In addition to the partnership with EVERSANA, we carried out a number of market surveys in the US that confirm our view of Dasynoc's potential, and that the benefits of the product compared with competing PKI drugs are relevant for physicians, nurses, and patients. To give an early indication of the financial potential in our product,



there are currently 11,000 patients receiving Sprycel® as their cancer treatment. Up to 47 percent<sup>1</sup> of these patients need to be treated with proton pump inhibitors (PPIs), which is recommended not to be taken during treatment with Sprycel®. We can thus offer clear benefits for the several thousand patients in this group.

### **Continued efforts toward launch in the US in the second half of 2023**

Xspray Pharma's partner NerPharMa is preparing the production of commercial volumes of amorphous material for Dasynoc after approval from the Italian Medicines Agency AIFA. The amorphous material is produced by NerPharMa and is then shipped to the US for production of finished tablets.

The lawsuit concerning patent infringement of the drug Sprycel® and its secondary patents is in progress. The patent protects Sprycel's crystalline form. Our product candidate Dasynoc has an amorphous form with no traces of crystalline properties. We therefore feel certain that Dasynoc does not infringe any patent. In the early stages of the lawsuit, Xspray Pharma submitted a motion to dismiss based on legal grounds. On April 25, the court denied our motion, indicating that the lawsuit will proceed and the case will be litigated based on technical details. The company stands firm on its assessment that the case can be resolved within the current year but at the latest by July 2024, when according to court practices the dispute will have to be resolved.

The FDA review of Xspray Pharma's application for approval for Dasynoc is expected to conclude in the summer of 2023. Our communication with the FDA has proceeded in accordance with plans, and they have inspected the plant in Italy. We believe that the application will lead to a market approval for Dasynoc, which will make it easier for patients to receive a relevant and improved treatment compared to crystalline dasatinib in the fight against CML and ALL.

### **Capital raise**

On May 2<sup>nd</sup>, we announced plans for a rights issue of units of approximately SEK 300 million, consisting of ordinary shares and two warrant series that total an additional SEK 300 million upon full exercise. The rights issue is intended to be decided based on authorization from the Extraordinary General Meeting which will be held on May 25, 2023. The reason for including warrants in the offering is to increase visibility for investors since the warrants can be exercised at a later point in time when the company is expected to have achieved key milestones, primarily the launch of Dasynoc. Approximately 83 percent of the rights issue is secured by subscription commitments and intentions, as well as guarantee commitments.

The proceeds will be used to finance the pre-launch activities for Dasynoc in the US as well as general corporate purposes, ongoing operating costs and the continued development of product candidates XS003 and XS008.

### **Continued development of other product candidates**

The development of XS003 is proceeding according to plan, and clinical trials are in progress. The current market preparations being carried out for Dasynoc are creating meaningful synergistic benefits for XS003. Introducing Dasynoc first, with its benefits for physicians and paying parties, will make the introduction of XS003 easier and less expensive since both product candidates are built on our patented HyNap technology.

During the quarter, we announced a new product candidate: XS008, which is based on the original substance axitinib, used in the treatment of kidney cancer. The PKI market for kidney cancer in the US had roughly USD 3 billion in sales in 2022. We thus now have three product candidates with announced substances in different phases of development.

Our HyNap technology has great potential to improve PKIs in the treatment of cancer. We are continuing to evaluate new product candidates, where key parameters include clinical need and market potential. We have exciting times before us, and I look forward to Xspray now being able to initiate the next stage of its journey toward becoming a commercial pharmaceutical company and a world leader in improved versions of established protein kinase inhibitors.

Per Andersson  
*CEO, Xspray Pharma*

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<sup>1</sup> Gunnar Larfors Et Al 3013 ASH 2022





# Financial performance

Unless otherwise indicated, the comments below pertain to the Group. Comparison figures are presented in parentheses and pertain to the same period for the previous year. Since the Group consists of the Parent Company and two dormant subsidiaries, 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 in the first quarter. The application for market approval of company's first product, XS004 dasatinib, was filed in the fourth quarter of 2021 and was supplemented with additional dosage strengths in the second quarter of 2022. Further information on XS004 is available under the Product candidate section on page 18.

## Other operating income

Other operating income amounted to SEK 904 thousand (170) in the first quarter, and the increase was attributable to advisory services and development efforts performed by Xspray during the period. Except for the income from advisory services, other operating income consists entirely of exchange rate gains arising in conjunction with payments abroad and translations of the currency account.

## Research and development costs

During the quarter, total expenditure for research and development amounted to SEK -26,873 thousand (-27,707), of which SEK -13,006 thousand (-1,694) was expensed and recognized in profit or loss, and SEK -13,867 thousand (-26,013) was capitalized as development expenses and is presented in the company's balance sheet. A large part of the research and development in the quarter was expensed since XS004 has transitioned into a new phase, including validation efforts and other consulting, that have not been capitalized. Costs are also attributable to the company's two other product candidates, XS003 nilotinib and XS008 axitinib.

## Administration and sales expenses

Administrative and sales costs totaled SEK -22,853 thousand (-17,021) in the first quarter. Of these, personnel costs amounted to SEK -8,940 thousand (-6,315). The cost increase for the first quarter is attributable primarily to the company's continued market preparation activities as a result of the impending launch in the US. Legal counsel costs in the US have also increased as a result of the lawsuit brought by the reference company in February 2022. Moreover, the company's personnel increased by two full-time positions compared with the same period last year, which impacts the cost base.

## Other operating expenses

Other operating expenses for the quarter amounted to SEK -434 thousand (-737). Other operating expenses consist of exchange rate losses arising in conjunction with payments abroad and translations of the currency account.

## Loss for the period

Loss for the period totaled SEK -34,827 thousand (-18,934) for the first quarter. This corresponds to earnings per share before dilution of SEK -1.54 (-0.92). The earnings decrease for the quarter is attributable primarily to increased administration and sales costs as a result of the market preparation activities stemming from the forthcoming launch in the US.

## Cash flow

Cash flow from operating activities amounted to SEK -45,535 thousand (-27,613) in the quarter, of which the effect from working capital comprised SEK -12,690 thousand (-10,956). The negative cash flow is in accordance with the company's plan, and is primarily attributable to continued strengthening of the organization, project costs, and legal and other advisory services prior to the company's forthcoming launch of XS004 dasatinib.

Cash flow from investing activities amounted to SEK -14,650 thousand (-47,541). The item includes capitalized development expenses of SEK -13,622 thousand (-25,752). The main reason for the decrease is that XS004 dasatinib has transitioned from a research and development-intensive project to making preparations for the launch of XS004.

No new investments were made in property, plant and equipment during the period, and investments in property, plant and equipment thus totaled SEK 0 thousand (-20,779). During the quarter, advances continued to be paid as a result of the construction of the company's new production unit in Malta. Cash flow from investing activities is in line with expectations. Cash flow from financing activities amounted to SEK -586 thousand (-515), attributable in its entirety to amortization of lease liability.

Total cash flow was SEK -60,771 thousand (-75,669) for the period. The Group had SEK 59,395 thousand (196,212) in cash and cash equivalents at March 31, 2023.

## Intangible assets

Development expenditures for the projects have been capitalized according to plan. Capitalized development expenditures totaled SEK 13,867 thousand (26,013) for the quarter. The Group's total capitalized development costs amounted to SEK 399,464 thousand (322,249) as of March 31, 2023. The item is associated with the company's product candidates XS004 dasatinib, XS003 nilotinib and XS008 axitinib.

## Financial position

On May 2<sup>nd</sup>, the company announced plans for a rights issue of units of approximately SEK 300 million, with two warrant series, which total an additional SEK 300 million



upon full exercise. The reason for including warrants in the offering is to increase visibility for investors since the warrants can be exercised at a later point in time when the company is expected to have achieved key milestones, primarily the launch of Dasynoc. In total, approximately 83 percent of the rights issue is secured by subscription commitments and intentions, as well as guarantee commitments.

The raised capital will be used to finance the pre-launch activities for Dasynoc in the US as well as general corporate purposes, ongoing operating costs and the continued development of product candidates XS003 nilotinib and XS008 axitinib.

The equity/assets ratio for the Group was 95.0 per cent (96.7) at March 31, 2023.

### **Group structure**

The Group structure comprises the Parent Company, Xspray Pharma AB (publ), corporate identity number 556649-3671, and its wholly owned subsidiaries Xspray Pharma Futurum AB, corporate identity number 559178-7642, and Xspray Pharma Inc. The two Swedish limited liability companies have their offices in Solna, Sweden, and the US subsidiary has its offices in Delaware. The address of the head office is Råsundavägen 12, SE-169 67 Solna, Sweden.

### **Parent Company**

All activities were conducted in the Parent Company, Xspray Pharma AB (publ). The Parent Company's cash and cash equivalents totaled SEK 59,345 thousand (196,162) and the equity/assets ratio was 95.4 percent (97.2) at March 31, 2023.

### **Employees**

During the quarter, the organization increased by two full-time positions compared with the same period last year. The number of employees in the Group on the balance sheet date totaled 26 (24).

### **Related-party transactions**

Related parties are those associated with the management group in the Parent Company or the Boards of Directors in the Parent Company or subsidiaries. Purchase of services from senior executives pertain to consultant fees from InterCon HB, owned by Andreas Konar, who is part of the company's management group. The total fees amounted to SEK -252 thousand (-252).

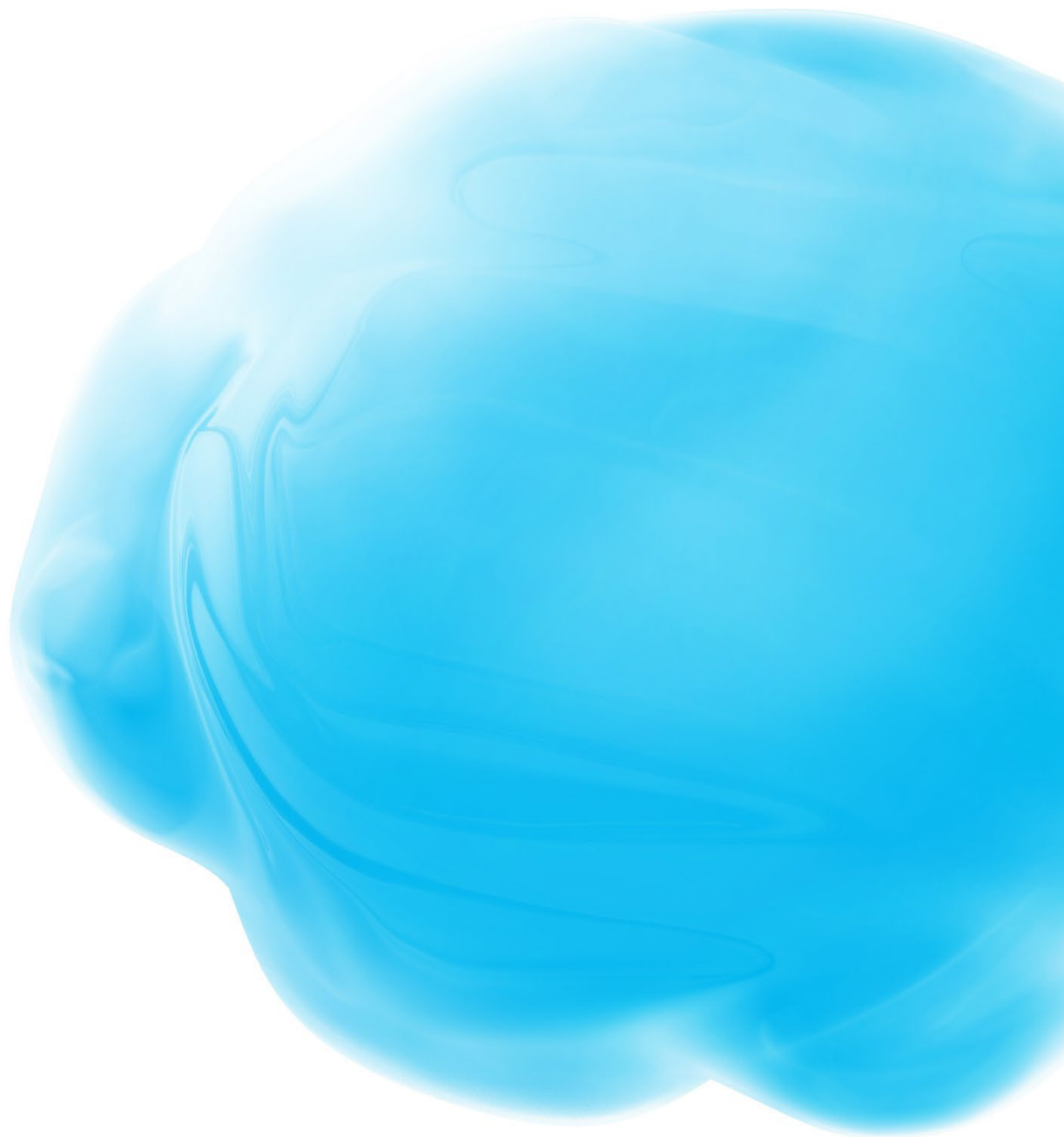
### **Corporate governance**

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



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# Financial statements





# Consolidated income statement

<i>Amounts in SEK thousand</i>	Q1 2023	Q1 2022	Full year 2022
Net sales	—	—	—
Other operating income	904	170	2,180
Research and development costs	-13,006	-1,694	-22,219
Administration and sales expenses	-22,853	-17,021	-109,601
Other operating expenses	-434	-737	-3,433
Operating loss	<b>-35,389</b>	<b>-19,282</b>	<b>-133,073</b>
Finance income	562	348	1,415
Finance costs	—	—	-12
Net financial items	<b>562</b>	<b>348</b>	<b>1,403</b>
Loss before tax	-34,827	-18,934	-131,670
Tax	—	—	—
Loss for the period	<b>-34,827</b>	<b>-18,934</b>	<b>-131,670</b>
Earnings per share before dilution, SEK	-1.54	-0.92	-6.25
Earnings per share after dilution, SEK	-1.54	-0.92	-6.25
Average number of shares before dilution	22,680,408	20,680,408	21,070,518
Average number of shares after dilution	22,680,408	20,680,408	21,070,518

# Consolidated statement of comprehensive income

<i>Amounts in SEK thousand</i>	Q1 2023	Q1 2022	Full year 2022
Loss for the period	<b>-34,827</b>	<b>-18,934</b>	<b>-131,670</b>
Other comprehensive income	—	—	—
Total comprehensive income for the period	<b>-34,827</b>	<b>-18,934</b>	<b>-131,670</b>

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





# Consolidated balance sheet

<i>Amounts in SEK thousand</i>	31 Mar 2023	31 Mar 2022	31 Dec 2022
<b>ASSETS</b>			
<i>Non-current assets</i>			
<i>Intangible assets</i>			
Capitalized development costs	399,464	322,249	385,597
<b>Total intangible assets</b>	<b>399,464</b>	<b>322,249</b>	<b>385,597</b>
<i>Property, plant and equipment</i>			
Machinery and installations	13,488	19,270	15,407
Right-of-use assets	1,918	3,299	2,477
Equipment	120	467	147
Fixed assets under construction and prepayments	47,862	41,273	46,573
<b>Total property, plant and equipment</b>	<b>63,389</b>	<b>64,310</b>	<b>64,603</b>
<i>Financial assets</i>			
Financial investments	1	1	1
Other long-term receivables	2,999	—	2,999
<b>Total financial assets</b>	<b>3,000</b>	<b>1</b>	<b>3,000</b>
<b>Total non-current assets</b>	<b>465,852</b>	<b>386,560</b>	<b>453,200</b>
<i>Current assets</i>			
Inventories	18,591	6,199	8,552
Current receivables	2,422	2,138	2,362
Accounts receivable	355	—	—
Prepaid expenses and accrued income	1,224	1,322	1,150
Cash and cash equivalents	59,395	196,212	120,166
<b>Total current assets</b>	<b>81,988</b>	<b>205,871</b>	<b>132,229</b>
<b>TOTAL ASSETS</b>	<b>547,840</b>	<b>592,430</b>	<b>585,430</b>



## Consolidated balance sheet cont.

<i>Amounts in SEK thousand</i>	31 Mar 2023	31 Mar 2022	31 Dec 2022
<b><i>EQUITY AND LIABILITIES</i></b>			
<i>Equity</i>			
Share capital	22,680	20,680	22,680
Other contributed capital	907,420	813,483	907,420
Reserves	976	976	976
Retained earnings including profit/loss for the period	-409,885	-262,322	-375,057
Total equity attributable to the Parent Company's shareholders	<b>521,191</b>	<b>572,818</b>	<b>556,019</b>
<i>Non-current liabilities</i>			
Lease liabilities	475	878	560
Total non-current liabilities	<b>475</b>	<b>878</b>	<b>560</b>
<i>Current liabilities</i>			
Trade payables	12,941	8,127	14,786
Lease liabilities	1,065	2,121	1,566
Other current liabilities	3,346	1,052	1,043
Accrued expenses and deferred income	8,822	7,435	11,456
Total current liabilities	<b>26,174</b>	<b>18,734</b>	<b>28,851</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>547,840</b>	<b>592,430</b>	<b>585,430</b>



# Consolidated statement of changes in equity

<i>Amounts in SEK thousand</i>	Share capital	Other contributed capital	Reserves	Retained earnings	Total equity
Opening balance as of January 1, 2022	20,680	813,483	976	-243,387	591,752
<i>Loss for the period</i>	—	—	—	-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

Opening balance as of January 1, 2023	22,680	907,420	976	-375,057	556,019
<i>Loss for the period</i>	—	—	—	-34,827	-34,827
Other comprehensive income for the period	—	—	—	—	—
Total comprehensive income for the period	—	—	—	-34,827	-34,827
New share issue	—	—	—	—	—
Transaction costs	—	—	—	—	—
Redemption of warrants	—	—	—	—	—
Warrant program	—	—	—	—	—
Closing balance as of March 31, 2023	22,680	907,420	976	-409,885	-521,191



# Consolidated cash flow statement

<i>Amounts in SEK thousand</i>	Q1 2023	Q1 2022	Full year 2022
<i>OPERATING ACTIVITIES</i>			
Operating loss	-35,389	-19,282	-133,073
<i>Non-cash adjustments</i>			
Depreciation	—	2,321	9,533
Disposable of intangible fixed assets	—	—	15,472
Interest received	286	345	1,611
Interest paid	-25	-41	-147
Cash flow from operating activities before changes in working capital	<b>-32,845</b>	<b>-16,657</b>	<b>-106,604</b>
<i>Changes in working capital</i>			
Change in operating receivables	-10,514	350	-2,942
Change in operating liabilities	-2,176	-11,306	-633
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>	<b>-45,535</b>	<b>-27,613</b>	<b>-110,179</b>
<i>INVESTING ACTIVITIES</i>			
Capitalized development costs	-13,622	-25,752	-103,820
Investment in property, plant and equipment	—	-20,779	-24,466
Prepayments	-1,028	-1,010	-7,059
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>	<b>-14,650</b>	<b>-47,541</b>	<b>-135,345</b>
<i>FINANCING ACTIVITIES</i>			
New share issue	—	—	100,000
Transaction costs	—	—	-4,876
Payment of lease liability	-586	-515	-2,128
Repurchased warrants	—	—	-52
Allocated warrants	—	—	865
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>	<b>-586</b>	<b>-515</b>	<b>93,809</b>
<b>CASH FLOW FOR THE PERIOD</b>	<b>-60,771</b>	<b>-75,669</b>	<b>-151,715</b>
Cash and cash equivalents at the beginning of the period	120,166	271,881	271,881
Cash and cash equivalents at the end of the period	<b>59,395</b>	<b>196,212</b>	<b>120,166</b>



# Parent Company income statement

<i>Amounts in SEK thousand</i>	Q1 2023	Q1 2022	Full year 2022
Net sales	—	—	—
Other operating income	904	170	2,180
Research and development costs	-13,087	-1,780	-22,592
Administration and sales expenses	-22,884	-17,047	-109,710
Other operating expenses	-452	-738	-3,500
Operating loss	<b>-35,518</b>	<b>-19,396</b>	<b>-133,622</b>
Finance income	317	169	617
Finance costs	—	—	-12
Net financial items	<b>317</b>	<b>169</b>	<b>605</b>
Loss before tax	-35,201	-19,227	-133,017
Tax	—	—	—
Loss for the period	<b>-35,201</b>	<b>-19,227</b>	<b>-133,017</b>





# Parent Company balance sheet

<i>Amounts in SEK thousand</i>	31 Mar 2023	31 Mar 2022	31 Dec 2022
<b>ASSETS</b>			
<i>Non-current assets</i>			
<i>Intangible assets</i>			
Capitalized development costs	398,726	321,913	384,944
<b>Total intangible assets</b>	<b>398,726</b>	<b>321,913</b>	<b>384,944</b>
<i>Property, plant and equipment</i>			
Machinery and installations	13,488	19,270	15,407
Equipment	120	467	147
Fixed assets under construction and prepayments	46,411	40,769	45,383
<b>Total property, plant and equipment</b>	<b>60,019</b>	<b>60,506</b>	<b>60,936</b>
<i>Financial assets</i>			
Shares in subsidiaries	50	50	50
Financial investments	1	1	1
Other long-term receivables	2,999	—	2,999
<b>Total financial assets</b>	<b>3,050</b>	<b>51</b>	<b>3,050</b>
<b>Total non-current assets</b>	<b>461,795</b>	<b>382,470</b>	<b>448,930</b>
Inventories	18,591	6,199	8,552
<i>Current receivables</i>			
Current receivables	2,422	2,138	2,362
Other current receivables	1,706	1,804	1,632
<b>Total non-current receivables</b>	<b>4,484</b>	<b>3,942</b>	<b>3,994</b>
Cash and bank balances	59,345	196,162	120,116
<b>Total current assets</b>	<b>82,420</b>	<b>206,302</b>	<b>132,661</b>
<b>TOTAL ASSETS</b>	<b>544,215</b>	<b>588,773</b>	<b>581,592</b>



# Parent Company balance sheet cont.

<i>Amounts in SEK thousand</i>	31 Mar 2023	31 Mar 2022	31 Dec 2022
<b><i>EQUITY AND LIABILITIES</i></b>			
<i>Equity</i>			
<i>Restricted equity</i>			
Share capital	22,680	20,680	22,680
Statutory reserve	976	976	976
Development expenditure reserve	398,726	321,913	384,944
<b>Total restricted equity</b>	<b>422,383</b>	<b>343,570</b>	<b>408,601</b>
<i>Non-restricted equity</i>			
Share premium reserve	907,420	813,483	907,420
Retained earnings	-775,496	-565,666	-628,697
Loss for the period	-35,201	-19,227	-133,017
<b>Total restricted equity</b>	<b>96,723</b>	<b>228,589</b>	<b>145,705</b>
<b>Total equity</b>	<b>519,106</b>	<b>572,159</b>	<b>554,306</b>
<i>Current liabilities</i>			
Trade payables	12,941	8,127	14,786
Other current liabilities	3,346	1,052	1,043
Accrued expenses and deferred income	8,822	7,435	11,456
<b>Total current liabilities</b>	<b>25,109</b>	<b>16,614</b>	<b>27,285</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>544,215</b>	<b>588,773</b>	<b>581,592</b>



# Parent Company cash flow statement

<i>Amounts in SEK thousand</i>	Q1 2023	Q1 2022	Full year 2022
<b>OPERATING ACTIVITIES</b>			
Operating loss	-35,518	-19,396	-133,622
<i>Non-cash adjustments</i>			
Depreciation	1,945	2,034	8,341
Disposable of intangible fixed assets	—	—	15,472
Interest received	41	—	647
Interest paid	—	—	-12
Cash flow from operating activities before changes in working capital	-33,532	-17,362	-109,174
<i>Changes in working capital</i>			
Change in operating receivables	-10,253	693	-1,911
Change in operating liabilities	-2,176	-11,303	-631
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>	<b>-45,961</b>	<b>-27,972</b>	<b>-111,716</b>
<b>INVESTING ACTIVITIES</b>			
Capitalized development costs	-13,782	-25,908	-104,411
Investment in property, plant and equipment	—	-20,779	-24,466
Prepayments	-1,028	-1,010	-7,059
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>	<b>-14,810</b>	<b>-47,697</b>	<b>-135,936</b>
<b>FINANCING ACTIVITIES</b>			
New share issue	—	—	100,000
Transaction costs	—	—	-4,876
Repurchased warrants	—	—	-52
Allocated warrants	—	—	865
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>	<b>—</b>	<b>—</b>	<b>95,937</b>
<b>CASH FLOW FOR THE PERIOD</b>	<b>-60,771</b>	<b>-75,669</b>	<b>-151,715</b>
Cash and cash equivalents at the beginning of the period	120,116	271,831	271,831
Cash and cash equivalents at the end of the period	59,345	196,162	120,116



# 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 2022 have been applied. The changes in IFRS applied as of January 1, 2023 have not had any impact on the financial statements for the first quarter of 2023. Comparison figures are presented in parentheses and pertain to the same period in the previous year.

### 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 equity/assets ratio is equity as a percentage of the balance sheet total. Research and development costs as a percentage of operating expenses equate to 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

Xsray 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 2022.

### Financing risk and going concern

On May 2<sup>nd</sup>, the company announced plans for a rights issue of units of approximately SEK 300 million, with two warrant series, which total an additional SEK 300 million upon full exercise. The decision is conditional upon approval from an Extraordinary General Meeting to be held on May 25, 2023. The reason for including warrants in the offering is to increase visibility for investors since the warrants can be exercised at a later point in time when the company is expected to have achieved key milestones, primarily the launch of Dasynoc. The raised capital will be used to finance preparations ahead of Dasynoc's planned launch in the US as well as general corporate purposes, ongoing operating costs and the continued development of product candidates XS003 nilotinib and XS008 axitinib. In total, approximately 83 percent of the rights issue is secured by subscription commitments and intentions, as well as guarantee commitments, corresponding to approximately SEK 251 million.

The company's capital requirements depend on several factors, including the launch date of its first product candidate, XS004, and the earnings from and costs for ongoing and future product development. In light of this, the Board of Directors routinely monitors the company's capital situation and evaluates 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 return 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.



# Xspray Pharma in brief

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

Using the company's innovative technology, Xspray Pharma can step in as the first competitor to the current original drugs before the originator company's secondary patents expire and the market opens up to generics. Xspray Pharma's goal is to be a leader in developing drugs that are improvements to PKIs being sold for the treatment of cancer, of which there were just over 80 in the US at the end of 2022.

## Market

Protein kinase inhibitors (PKIs) have quickly become some of the most efficacious treatments of cancer, and for certain forms PKIs are one of few treatments to be had. The segment is the largest in the field of oncology with over 600 drug candidates in clinical development, of which around 230 are in the late clinical phase (Phase II or III), and just over 80 of them are approved drugs in the US market. The sale of PKI drugs in the US market in 2021 totaled roughly USD 33 billion. To date, Xspray Pharma has conducted initial testing on some twenty PKIs with the company's patented HyNap technology, with positive results.

## Product candidates

Xspray Pharma's pipeline contains three product candidates where the substance has been announced. These are based on the company's HyNap technology: XS004 dasatinib, XS003 nilotinib and XS008 axitinib. These product candidates are stable amorphous and non-crystalline versions of the three highly-sold cancer drugs Sprycel® (dasatinib), Tasisign® (nilotinib) and Inlyta® (axitinib). Many protein kinase inhibitors in the market are difficult to dissolve and their uptake in the body is pH-dependent, which often leads to a high degree of variability in uptake and unnecessarily high dose strengths for the patients. An amorphous formulation increases solubility, which leads to lesser variation in uptake and permits lower dosages to be administered to patients with retained efficacy but with potentially lower levels of side effects.

The original drugs have secondary patents expiring between 2026 and 2032, and their total annual sales for 2022 exceeded USD 3.4 billion in the US market and USD 5.1 billion globally.<sup>2</sup>

Product candidate				Patent		Development phase					
Project	Substance	Key indication	Regulatory process	Substance IP expiration date	Secondary IP expiration date	New product evaluation	Development formulation	Pilot studies	Pivotal studies	Regulatory review	Original product/ Company
XS004	dasatinib	Leukemia (CML, ALL)	505(b)(2)	Dec 2020	Sep 2026	[Progress bar: ~80% complete]					Sprycel®/ BMS
XS003	nilotinib	Leukemia (CML)	505(b)(2)	Jan 2024	Oct 2032	[Progress bar: ~60% complete]					Tasisign®/ Novartis
XS008	axitinib	Kidney cancer (RCC)	505(b)(2)	Apr 2025	Dec 2030	[Progress bar: ~30% complete]					Inlyta®/ Pfizer
XS00Y	Not communicated					[Progress bar: ~10% complete]					

<sup>2</sup> The information regarding annual sales has been taken from the reference companies' quarterly reports.





# Share information

Xspray Pharma's share has been listed on Nasdaq Stockholm in the Mid-Cap segment 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 at March 31, 2023 was 22,680,408 and the closing price on that date was SEK 68.9.

Owners as of March 31, 2023	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)	2,644,886	11.66%
Fourth Swedish National Pension Fund	1,995,806	8.80%
Nordnet Pension Insurance	838,730	3.70%
Unionen	806,000	3.55%
Third Swedish National Pension Fund	800,000	3.53%
Avanza Pension	754,842	3.33%
Second Swedish National Pension Fund	622,320	2.74%
TIN Funds	600,000	2.65%
<b>Total, 10 largest owners</b>	<b>15,244,588</b>	<b>67.21%</b>
<b>Other shareholders</b>	<b>7,435,820</b>	<b>32.79%</b>
<b>Total</b>	<b>22,680,408</b>	<b>100.00%</b>

## Financial calendar

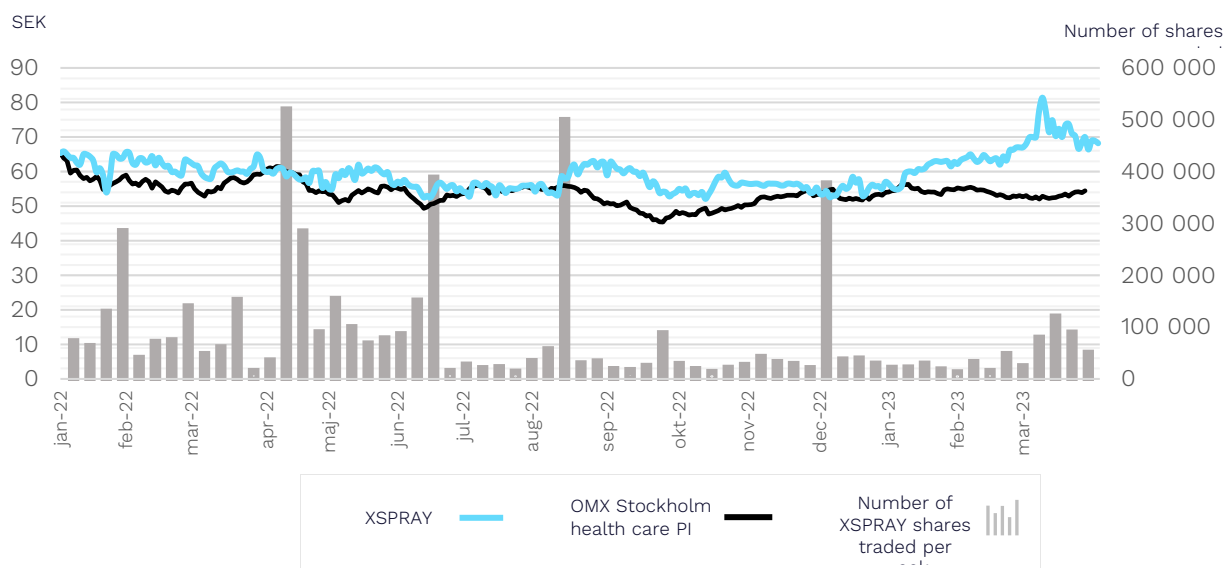
Interim Report Q2 2023	August 2, 2023
Interim Report Q3 2023	November 8, 2023
Year-end Report Q4 2023	February 14, 2024

The financial reports are available on the Xspray Pharma website, [www.xspraypharma.com](http://www.xspraypharma.com).

## Analysts covering the company

- Filip Einarsson, Redeye AB
- Dan Akschuti, Pareto Securities AB

## Share price performance





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# 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, May 4, 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.



# Glossary

<b>505(b)(2) NDA •</b>	Application for drug approval in the US for an improved version of an existing licensed or approved drug.
<b>Amorphous •</b>	An amorphous structure is a chemical term that describes substances whose molecules lack an ordered structure.
<b>Bioequivalence •</b>	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.
<b>Bioavailability •</b>	(Biological availability), a concept in pharmacology that shows how large a portion of the drug reaches the blood.
<b>CRO •</b>	Contract Research Organization. A service company active in contract research and service in the development of drugs.
<b>FDA •</b>	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.
<b>GMP •</b>	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.
<b>Pilot study •</b>	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.
<b>Protein kinase inhibitor (PKI)</b>	Drugs that block protein kinases. Protein kinase inhibitors work by blocking activity in enzymes that push the development and growth of cancer cells.
<b>Variability •</b>	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.

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