



xspray

P H A R M A

Interim Report

April – June 2024

Key figures, Group

Key figures, Group	Q2		Jan-Jun		Full year
	2024	2023	2024	2023	2023
Net sales (SEK thousand)	-	-	-	-	-
Loss before Income tax (SEK thousand)	-53,620	-51,402	-121,401	-86,229	-179,684
Earnings per share before dilution (SEK)	-1.64	-2.27	-3.79	-3.80	-6.76
Earnings per share after dilution (SEK)	-1.64	-2.27	-3.79	-3.80	-6.76
Research and development expenses as % of operating expenses 1)	27.9	17.7	27.5	25.2	18.9
Cash and cash equivalents (SEK thousand)	126,573	31,543	126,573	31,543	166,303
Total assets (SEK thousand)	736,067	561,120	736,067	561,120	765,263
Equity/assets ratio (%)	90.8	83.8	90.8	83.8	90.6
Average number of employees	26	26	25	26	26

April – June 2024, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -53,620 thousand (-51,402)
- Earnings per share before dilution amounted to SEK -1.64 (-2.27)
- Cash flow from operating activities amounted to SEK -64,181 thousand (-56,503)
- Cash flow from investing activities amounted to SEK -8,738 thousand (-16,027)

Amounts in parentheses refer to the year-earlier period.

January – June 2024, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -121,401 thousand (-86,229)
- Earnings per share before dilution amounted to SEK -3.79 (-3.80)
- Cash flow from operating activities amounted to SEK -119,492 thousand (-102,038)
- Cash flow from investing activities amounted to SEK -13,887 thousand (-30,677)

Amounts in parentheses refer to the year-earlier period.

Significant events during the quarter

- Xspray Pharma received declarations of intent whereby owners of approximately 62 percent of shares in the company stated their interest to subscribe for newly issued shares with their outstanding TO6 warrants.
- Xspray Pharma announced its fourth product candidate, XS025 for clinical study. XS025 will be based on the active substance cabozantinib, which is used in renal cell carcinoma and other cancers. The value in the US market for cabozantinib is projected to reach approximately USD 2.3 billion by 2026.
- Xspray Pharma announced the outcome of the exercised warrants of series TO6. In total, 2,508,723 warrants of series TO6, corresponding to approximately 80 percent, were exercised to subscribe for the same number of new shares. Xspray Pharma thereby received issue proceeds of SEK 100.3 million before transaction costs. Proceeds will be used for the US launch of the company's first product, Dasynoc®, as well as for continued development of other product candidates in the company's portfolio. The number of shares increased by 2,508,723 to 33,762,265 and the share capital increased by SEK 2,508,723 to SEK 33,762,265.

- Xspray Pharma appointed Niklas Adenborg as the company's Chief Financial Officer (CFO) and Linda Glimberg as the company's Chief Operating Officer (COO), a newly established role. Both already work at Xspray Pharma with Niklas Adenborg as Finance Director and Linda Glimberg as consulting Senior Vice President Legal. Both are included in Xspray Pharma's executive management team.
- Xspray presented data at the American Society of Clinical Oncology (ASCO) demonstrating that co-medication with PPIs and TKIs occurs frequently among CML patients. Further, this co-medication has a substantial impact on the bioavailability of crystalline dasatinib, the type of dasatinib currently available in the market. i) 54% of TKI-treated CML-patients received a PPI. ii) 66% of concomitant prescribing was by a different healthcare provider. iii) Crystalline dasatinib Cmax and AUC24 reduced by 96% and 88% respectively. Xspray's dasatinib candidate, Dasynoc®, is not crystalline but amorphous, which drastically reduces the problems with the co-medication of PPIs and results in significantly improved absorption.

Significant events after the end of the reporting period

- Xspray Pharma announced new clinical data from its registration study program for the XS003 product candidate, which is an amorphous, non-crystalline formulation of nilotinib. The data shows matching bioavailability of XS003 to Tasigna® with a 50% reduced dose.
- Xspray Pharma received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding the company's New Drug Application (NDA) for Dasynoc®. The updated NDA was sent to the FDA on January 31, 2024. In the CRL, the FDA requests additional information pertaining to the labeling comprehension and the pre-approval inspection at the third party's manufacturing site, which was conducted 10 to 19 of June, 2024. All issues from the previous CRL were addressed and the responses were accepted by the FDA. The new CRL therefore includes a number of new supplementary requests. Importantly, the CRL does not request any additional clinical studies, nor does it question or remark on any deficiencies in the stability or clinical data.

The company's costs are expected to decrease in the coming quarters due to the postponement of the launch date for Dasynoc® and the delay in commercialization activities. Additionally, we can review the development pace of other product candidates, particularly those that are further away in time, where the time can be recovered later." – Per Andersson, CEO

A message from the CEO



Dear shareholders,
Despite recent challenges, Xspray Pharma is in better shape than ever. Our strong pre-launch shows that both physicians and pharmacists understand the problem with crystalline dasatinib, and that Dasynoc® offers a solution. We have also observed excellent results for nilotinib, and our product platform is truly gaining momentum.

After the period, we received a Complete Response Letter (CRL) from the FDA outlining that we will need to supplement our application for market approval of Dasynoc®. It is unfortunate that we received this notification, which came after a reinspection of our manufacturing site just six weeks before our expected approval date. The site submitted its responses to the first inspection in October 2023, so it is unfortunate that the unexpected reinspection

occurred at such a late date. We have received requests for additional information which we will address as soon as possible and we have requested and anticipate a meeting with the FDA within 30 days.

The launch of Dasynoc® will not be possible in September, but rather we will need to wait for an additional time period. Together with our commercial partner EVERESANA, which provides a dedicated commercial organization, we have decided to temporarily pause our launch preparations for Dasynoc®. This also means that the related costs for the launch will be deferred. However, we will continue to build relationships with both physicians and insurance companies to continue to raise awareness of the clear patient benefits that Dasynoc® offers as well as the health

economic savings that the product enables. These savings are a strong argument for Dasynoc® in discussions with insurance companies, which also greatly contributes to the competitiveness of our offering.

We also presented an important study at the American Society of Clinical Oncology (ASCO) demonstrating that chronic myeloid leukemia (CML) patients often need to be treated for peptic ulcers while they undergo treatment for their leukemia. 54% of CML patients co-medicate dasatinib with a proton-pump inhibitor (PPI), which is problematic because the bioavailability of crystalline dasatinib is significantly reduced when co-medicated with a PPI. The study demonstrated that the effects of a PPI are considerably greater than previously reported, reducing C_{max} and AUC₂₄ by 96% and 88% respectively.

Dasynoc® can offer these patients significant advantages through its amorphous formulation. To successfully treat the disease, consistent absorption and bioavailability of dasatinib are critical. Dasynoc® demonstrates clear clinical benefits through lower dosage requirements, reduced variability in absorption and plasma concentrations, and the ability to be co-medicated with PPIs.

Product portfolio progress

After the end of the reporting period, we presented new data from the registration study program for the XS003 product candidate. The data shows that XS003 can match the bioavailability of XS003 to Tasigna® with a more than 50% reduced dose. Tasigna® is a crystalline formulation of nilotinib and is marketed for the treatment of CML. The results are extremely positive and once again demonstrate the potential of our platform technology. Our target is to complete the clinical program for XS003 before the end of the year and submit an application for approval to the FDA in the first half of 2025.

During the quarter, we also announced that we will initiate a clinical study of our fourth product candidate, XS025 cabozantinib, for the treatment of renal cancer. The value in the market for cabozantinib is expected to total approximately USD 2.3 billion by 2026.

Xspray's product portfolio thus has four publicized product candidates based on the company's HyNap platform: XS004 dasatinib for the treatment of chronic myeloid leukemia (CML) and acute

lymphoblastic leukemia (ALL); XS003 nilotinib for the treatment of CML; and XS008 axitinib and XS025 cabozantinib for the treatment of renal cancer. All of these are improved amorphous versions of established and marketed protein kinase inhibitors and have robust patent protection.

Executive management strengthened

During the quarter, Niklas Adenborg was appointed as the company's Chief Financial Officer (CFO) and Linda Glimberg to the newly established role of Chief Operating Officer (COO). These are important reinforcements for our organization as we continue the transformation of Xspray Pharma into a commercial pharmaceutical company. Both Niklas and Linda already worked at Xspray Pharma and are now part of the company's executive management team.

We also strengthened our cash holdings through the TO6 program, which was approximately 80 percent subscribed, raising approximately SEK 100 million in proceeds before issue expenses for the company. The proceeds will primarily be used for the US launch of Dasynoc® and to continue the development of the company's pipeline. We believe that existing working capital is sufficient to cover the company's capital requirements for the next six to 12 months as we defer costs while awaiting for the delayed FDA approval. However, we are currently unable to forecast exactly how long the delay in the regulatory process will be. As previously expected ahead of planned September launch, which is now delayed, additional external financing will be necessary to ensure a successful launch of Dasynoc® when approval is received from the FDA. However, we believe that this will be possible in the form of non-dilutive financing. Any potential further need for equity will be determined by the pace of development of the rest of our product portfolio, and is therefore a decision that is in the company's hands.

I remain highly optimistic about the company's prospects thanks to the clear product advantages that we are able to demonstrate through our HyNap technology, and I will continue to keep you updated as our journey progresses.

Per Andersson, CEO, Xspray Pharma

About Xspray Pharma

Xspray Pharma AB (publ) is a pharmaceutical company with a number of product candidates under clinical development, and is nearing the launch of its first product, Dasynoc[®]. Xspray Pharma uses its innovative, patented HyNap technology to develop improved versions of protein kinase inhibitors (PKIs) for the treatment of cancer. This segment is the largest in the field of oncology, with just over 80 approved drugs in the US at the end of 2023.

Vision

Xspray Pharma's goal is to be a leader in developing improved drugs from improved PKIs for the treatment of cancer. The company's financial and operational vision through 2030:

- Net sales that exceed USD 400 million
- Profit margin that exceeds 65 percent (profit before tax)
- Five products launched
- Three product candidates under development

Launch of the company's first commercial product – Dasynoc

As a result of the FDA having requested supplementary information for the market approval of Dasynoc in July 2024, the company will provide an updated schedule for the launch of Dasynoc[®] in the US at a future point.

Xspray Pharma has a partnership agreement with EVERSANA that provides Xspray Pharma with access to a complete and cost-effective countrywide sales organization that is ready to go. EVERSANA's market preparation activities are currently on hold pending final approval from the FDA.

EVERSANA will provide Xspray Pharma with services in market access, a medical sales organization, and patient support programs. EVERSANA has several skilled experts with years of experience in selling PKI drugs to the specific physicians, insurance companies, and other paying customers that Xspray Pharma will be targeting. This will create conditions for a rapid launch of Dasynoc[®] on an optimized budget. Xspray Pharma will retain financial and strategic control but grants EVERSANA the exclusive commercial right to provide support in the launch of Dasynoc[®] in the US.

Xspray Pharma has conducted a number of market surveys in the US. These confirmed the company's view of the potential of Dasynoc[®], and that the benefits of the product compared with competing PKI drugs are significant for physicians, nurses, and patients.

Market

Protein kinase inhibitors (PKIs) have become one of the most effective treatments of cancer and for certain types of cancer, PKIs are the only available option. PKIs are the largest segment in the oncology area, with over 1,800 ongoing clinical studies in Phase II or Phase III, and just over 80 PKIs are approved treatments on the US market.

All Xspray Pharma's product candidates in development are currently PKIs. The rise in cancer and autoimmune diseases is an important factor that is expected to increase sales of PKIs.

Product candidates

Xspray Pharma's pipeline contains four announced product candidates. They are all based on the company's HyNap technology: Dasynoc[®], XS003 nilotinib, XS008 axitinib and XS025 cabozantinib. These product candidates are stable amorphous and non-crystalline versions of the four best-selling cancer drugs Sprycel[®] (dasatinib), Tassigna[®] (nilotinib), Inlyta[®] (axitinib) and Cabometyx[®] (cabozantinib). Many protein kinase inhibitors in the market are difficult to dissolve and often have a high degree of variability in uptake. Xspray's amorphous formulation increases solubility, which leads to more stable uptake and permits lower dosages to be administered to patients with retained efficacy. The total annual sales of the original drugs Sprycel[®], Tassigna[®], Inlyta[®] and Cabometyx[®] exceeded USD 5.2 billion in the US market in 2023 and USD 7.1 billion globally.¹

¹ The information regarding annual sales has been taken from the reference companies' quarterly reports.

Overview – product candidates

Product candidate				Patent		Development phase					Original product/Company
Project	Substance	Indication	Regulatory path	Substance patent expiry	Secondary patent expiry	New candidate evaluation	Development of formulation	Pilot studies	Pivotal studies	Regulatory review	
XS004	dasatinib	Leukemia (CML, ALL)	505(b)(2)	Dec 2020	Sep 2026						Sprycel®/BMS
XS003	nilotinib	Leukemia (CML)	505(b)(2)	Jan 2024	Oct 2032						Tasigna®/Novartis
XS008	axitinib	Renal cancer (RCC)	505(b)(2)	Apr 2025	Dec 2030						Inlyta®/Pfizer
XS025	cabozantinib	Renal cancer (RCC)	505(b)(2)	Aug 2026	Jul 2033						Cabometyx®/Exelixis

Share information

Xspray Pharma's share is listed on Nasdaq Stockholm in the Small Cap segment under the symbol XSPRAY. The number of shares in the company at June 30, 2024 was 33,762,265 and the closing price on that date was SEK 80.40.

Owners as of June 30, 2024	Number of shares	Share of capital & votes
Flerie Invest	5,798,962	17.18%
Anders Bladh (private & via Ribbskottet)	4,243,134	12.57%
The Foundation for Baltic And East European Studies	4,030,126	11.94%
Fourth Swedish National Pension Fund	3,372,850	9.99%
Third Swedish National Pension Fund	1,299,999	3.85%
Unionen	1,289,668	3.82%
Avanza Pension	1,103,188	3.27%
Nordnet Pension Insurance	1,056,837	3.13%
Second Swedish National Pension Fund	1,037,200	3.07%
Carl Erik Norman	713,194	2.11%
Total, 10 largest owners	23,945,158	70.9%
Other shareholders	9,817,107	29.1%
Total	33,762,265	100.0%

Financial calendar

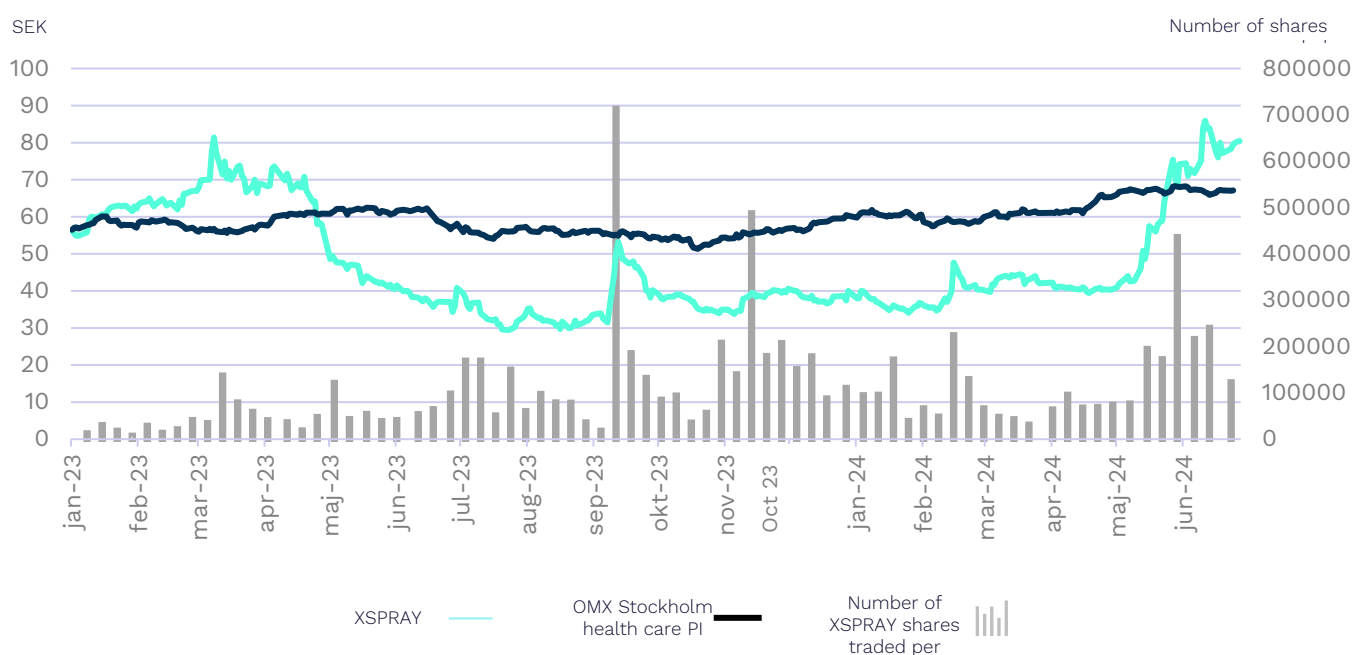
Interim Report Q3 2024	November 6, 2024
Interim Report Q4 2024	February 12, 2025

The financial reports are available on the Xspray Pharma website, www.xspraypharma.com.

Analysts monitoring the company

Filip Einarsson, Redeye AB
Dan Akschuti, Pareto Securities AB

Share price performance



Financial performance

Unless otherwise indicated, the comments below pertain to the Group. Comparison figures are presented in parentheses and pertain to the same period in 2023. The Group comprises the Parent Company, a dormant subsidiary and a US subsidiary with limited operations. The consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) and the Parent Company's statements have been prepared in accordance with RFR2.

Net sales

Net sales for the company amounted to SEK 0 thousand in the first half of 2024. Sales are expected to increase when the company launches its initial product, Dasynoc®, in the US market. Further information on Dasynoc® is available on pages 5–6.

Other operating income

Other operating income totaled SEK 930 thousand (356) in the second quarter and SEK 1,064 thousand (1,260) for both quarters. Other operating income primarily consists of exchange rate gains arising in conjunction with payments abroad and translations of the currency account.

Research and development costs

Total expenditures for research and development for the quarter amounted to SEK -20,879 thousand (-24,280), of which SEK -15,373 thousand (-9,118) was recognized as an expense in profit or loss and SEK -5,506 thousand (-15,162) was capitalized as development expenditure and presented in the company's balance sheet. For the two quarters, the figure is SEK -45,781 thousand (-51,153) for total expenditure for research and development, with SEK -34,024 thousand (-22,124) expensed and SEK -11,757 thousand (-29,029) capitalized as development expenditures. Starting in 2023, a large part of the research and development in the quarter began to be expensed since Dasynoc® has transitioned into a new phase, including validation efforts and other consulting that have not been capitalized. Total research and development costs are also attributable to the company's three other product candidates, XS003 nilotinib, XS008 axitinib and XS025 cabozantinib.

Administration and sales expenses

Administration and sales expenses totaled SEK -38,436 thousand (-41,489) in the second quarter. Of these, personnel costs amounted to SEK

-10,274 thousand (-9,423). The corresponding half-year figures are SEK -87,123 thousand (-64,342) for administration and sales expenses, with SEK -19,912 thousand (-18,363) pertaining to personnel costs. The cost increase for the second quarter is attributable primarily to the company's continued market preparation activities as a result of the expected launch in the US.

Other operating expenses

Other operating expenses totaled SEK -1,195 thousand (-1,011) for the quarter and SEK -2,393 thousand (-1,445) for the half-year. Other operating expenses consist of exchange rate losses arising in conjunction with payments abroad and translations of the currency account. In conjunction with increased expenses for the launch, more expenses have been received in foreign currencies, which explains the increase to some extent.

Loss for the period

Loss for the period totaled SEK -53,580 thousand (-51,402) for the second quarter and SEK -121,321 thousand (-86,229) for the half-year. This corresponds to earnings per share before dilution of SEK -1.64 (-2.27). The earnings decrease for the quarter is attributable primarily to increased administration and sales expenses 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 -64,181 thousand (-56,503) in the quarter, of which the effect from working capital was SEK -11,836 thousand (-7,740). The aggregate figure for the two quarters was SEK -119,492 thousand (-102,038), of which the effect from working capital was SEK -1,157 thousand (-20,430). 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 expected launch of Dasynoc®.

Cash flow from investing activities amounted to SEK -8,738 thousand (-16,027) and SEK -13,877 thousand (-30,677) for the half-year. This includes capitalized development expenditures of SEK -4,420 thousand (-14,923). The main reason for the decrease is that XS004 dasatinib has moved from a research and development-intensive project to preparing for launch.

New investments of SEK -4,318 thousand (0) in property, plant and equipment were made during the period. Cash flow from investing activities is in line with expectations. Cash flow from financing activities totaled SEK 95,323 thousand (44,678) for the quarter, which was primarily attributable to TO6, and SEK 93,499 thousand (-44,092) for the half-year.

Total cash flow was SEK 22,404 thousand (-27,852) for the period. The Group had SEK 126,573 thousand (31,543) in cash and cash equivalents at June 30, 2024.

The company's costs are expected to decrease in the coming quarters due to the postponement of the launch date for Dasynoc® and the deferral in commercialization activities. Additionally, we can review the development pace of other product candidates, particularly those that are further away in time, where the time can be recovered later.

Intangible assets

Development expenditures for the projects have been capitalized according to plan. Capitalized development expenditures for the quarter totaled SEK 5,506 thousand (15,162). The Group's total capitalized development costs amounted to SEK 448,536 thousand (414,626) at June 30, 2024. These costs are associated with the company's product candidates Dasynoc®, XS003 nilotinib, XS008 axitinib and XS025 cabozantinib.

Financial position

Depending on the path and orientation the company chooses to take over the coming year, the Group's cash and cash equivalents may fall below the level needed to pursue operations for the coming 12 months. In light of this, the Board of Directors is still engaged in continually evaluating the company's financial requirements and position, and reviewing various financing alternatives. The equity/assets ratio for the Group was 90.8 percent (83.8) at June 30, 2024.

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 Scheeles väg 2, SE-171 65 Solna, Sweden.

Parent Company

Operations were conducted primarily in the Parent Company, Xspray Pharma AB (publ). The Parent Company's cash and cash equivalents totaled SEK 125,339 thousand (31,493) and the equity/assets ratio was 95.3 percent (83.8) at June 30, 2024.

Employees

The organization has the same number of employees compared with the year-earlier period. The number of employees in the Group on the balance sheet date totaled 26 (26).

Related-party transactions

The management of the Parent Company, the Boards of Directors of the Parent Company and subsidiary are defined as related parties. Purchase of services from senior executives pertain to consultant fees from Glimberg Consulting AB, owned by Linda Glimberg, who is part of the company's executive management team. The total fees amounted to SEK -404 thousand (-427) for the period and SEK -1,015 thousand (-822) for the half-year.

Financial statements

Consolidated income statement

<i>SEK thousand</i>	Q2		Jan-Jun		Full year
	2024	2023	2024	2023	2023
Net sales	-	-	-	-	-
Other operating income	930	356	1,064	1,260	31,767
Research and development expenses	-15,373	-9,118	-34,024	-22,124	-40,259
Administration and sales expenses	-38,436	-41,489	-87,123	-64,342	-169,567
Other operating expenses	-1,195	-1,011	-2,393	-1,445	-3,675
Operating loss	-54,074	-51,261	-122,476	-86,650	-181,734
Finance income	471	416	1,092	978	2,725
Finance costs	-16	-557	-16	-557	-675
Finance net	455	-141	1,076	421	2,049
Loss before Income tax	-53,620	-51,402	-121,401	-86,229	-179,684
Tax	40	-	80	-	17
Loss for the period	-53,580	-51,402	-121,321	-86,229	-179,667
Earnings per share for the period before dilution, SEK	-1.64	-2.27	-3.79	-3.80	-6.76
Earnings per share for the period after dilution, SEK	-1.64	-2.27	-3.79	-3.80	-6.76
Average number of shares before dilution	32,742,235	22,680,408	32,002,001	22,680,408	26,593,910
Average number of shares after dilution	32,742,235	22,680,408	32,002,001	22,680,408	26,593,910

Consolidated statement of comprehensive income

<i>SEK thousand</i>	Q2		Jan-Jun		Full year
	2024	2023	2024	2023	2023
Loss for the period	-53,580	-51,402	-121,321	-86,229	-179,667
Annual translation differences in the translation of foreign operations	35	-	128	-	-184
Total comprehensive income for the period	-53,544	-51,402	-121,192	-86,229	-179,851

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

Consolidated balance sheet

SEK thousand

30 Jun 2024 30 Jun 2023 31 Dec 2023

	30 Jun 2024	30 Jun 2023	31 Dec 2023
ASSETS			
<i>Non-current assets</i>			
<i>Intangible assets</i>			
Capitalized development costs	448,536	414,626	436,780
Total intangible assets	448,536	414,626	436,780
<i>Property, plant and equipment</i>			
Machinery and installations	5,335	11,622	8,581
Right-of-use assets	35,144	1,359	37,649
Equipment	2,262	95	2,056
Fixed assets under construction and prepayments	63,892	49,302	59,365
Total Property, plant and equipment	106,633	62,378	107,651
<i>Financial assets</i>			
Financial investments	1	1	1
Other long-term receivables	3,096	2,999	3,016
Total financial assets	3,097	3,000	3,017
Total non-current assets	558,266	480,004	547,448
<i>Current assets</i>			
Inventories	44,507	45,283	43,781
Current receivables	4,162	2,636	4,165
Prepaid expenses and accrued income	2,559	1,654	3,566
Cash and cash equivalents	126,573	31,543	166,303
Total current assets	177,801	81,116	217,815
TOTAL ASSETS	736,067	561,120	765,263

Consolidated balance sheet cont.

<i>SEK thousand</i>	30 Jun 2024	30 Jun 2023	31 Dec 2023
<i>EQUITY AND LIABILITIES</i>			
<i>Equity</i>			
Share capital	33,762	22,680	31,254
Other contributed capital	1,309,499	907,690	1,216,092
Reserves	920	976	792
Retained earnings including profit/loss for the period	-676,045	-461,287	-554,724
Total equity attributable to the Parent Company's shareholders	668,137	470,059	693,413
<i>Non-current liabilities</i>			
Lease liabilities	29,852	377	31,947
Total non-current liabilities	29,852	377	31,947
<i>Current liabilities</i>			
Trade accounts payable	6,651	20,485	12,472
Lease liabilities	4,983	571	4,861
Other current liabilities	11,842	46,260	6,263
Accrued expenses and deferred income	14,602	23,368	16,307
Total current liabilities	38,078	90,684	39,903
TOTAL EQUITY AND LIABILITIES	736,067	561,120	765,263

Consolidated statement of changes in equity

<i>SEK thousand</i>	Share capital	Other contributed capital	Reserves	Retained earnings incl. profit/loss for the period	Total Equity
Opening balance as of January 1, 2023	22,680	907,420	976	-375,057	556,019
<i>Loss of the period</i>	-	-	-	-179,667	-179,667
Other comprehensive income for the period	-	-	-184	-	-184
Total comprehensive income for the period	-	-	-	-179,667	-179,667
New share issue	8,573	334,352	-	-	342,925
Transaction costs	-	-26,201	-	-	-26,201
Redemption of warrants	-	-	-	-	-
Warrant program	-	522	-	-	522
Closing balance as of December 31, 2023	31,253	1,216,093	792	-554,724	693,413
Opening balance as of January 1, 2024	31,253	1,216,093	792	-554,724	693,413
<i>Loss of the period</i>	-	-	-	-121,321	-121,321
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	-	-	128	-121,321	-121,192
New share issue	2,508	97,841	-	-	100,349
Transaction costs	-	-5,555	-	-	-5,555
Warrant program	-	1,122	-	-	1,122
Closing balance as of June 30, 2024	33,762	1,309,501	920	-676,047	668,137

Consolidated statement of cash flow

SEK thousand	Q2		Jan-Jun		Full year
	2024	2023	2024	2023	2023
Operating activities					
Operating loss	-54,074	-51,261	-122,476	-86,650	-181,734
<i>Non-cash adjustments</i>					
Depreciation	2,349	2,232	5,050	4,515	9,194
Unrealized currency impact	41	-	-50	-	41
Disposal of tangible fixed assets	8	-	15	-	5
Interest received	-214	265	2	551	1,969
Interest paid	-455	1	-876	-24	-1,169
Cash flow from operating activities before changes in working capital	-52,345	-48,763	-118,335	-81,608	-171,694
<i>Changes in working capital</i>					
Change in inventory	-905	-26,692	-726	-36,731	-35,229
Change in operating receivables	834	-475	1,528	-950	-4,109
Change in operating liabilities	-11,765	19,427	-1,959	17,251	7,757
Cash flow from operating activities	-64,181	-56,503	-119,492	-102,038	-203,275
Investing activities					
Capitalized development costs	-4,420	-14,923	-9,508	-28,545	-49,855
Acquisition of property, plant and equipment	-4,318	-	-4,379	-	-2,692
Prepayments of Right-of-Use-Assets	-	-	-	-	-1,556
Prepayments	-	-1,104	-	-2,132	-11,773
Cash flow from investing activities	-8,738	-16,027	-13,887	-30,677	-65,876
Financing activities					
New share issue	100,349	-	100,349	-	297,924
Loan raised	-	45,000	-	45,000	45,000
Transaction costs	-5,017	-252	-5,555	-252	-26,201
Payment of lease liability	-1,195	-592	-2,417	-1,178	-1,651
Allocated warrants	1,186	522	1,186	522	522
Cash flow from financing activities	95,323	44,678	93,499	44,092	315,594
Cash flow for the period	22,404	-27,852	-39,880	-88,623	46,443
Cash and cash equivalents at the beginning of the period	104,155	59,395	166,303	120,166	120,166
Effect of exchange rate and value changes in cash and cash equivalents	14	-	150	-	-306
Cash and cash equivalents at the end of the period	126,573	31,543	126,573	31,543	166,303

Parent Company income statement

<i>SEK thousand</i>	Q2		Jan-Jun		Full year
	2024	2023	2024	2023	2023
Net sales	-	-	-	-	-
Other operating income	1,849	356	1,983	1,260	31,669
Research and development expenses	-16,056	-9,305	-35,500	-22,392	-41,100
Administration and sales expenses	-38,713	-41,520	-86,061	-64,404	-169,705
Other operating expenses	-2,052	-1,083	-3,341	-1,535	-3,633
Operating loss	-54,972	-51,551	-122,919	-87,070	-182,769
Finance income	198	153	550	470	1,664
Finance costs	-16	-557	-16	-557	-675
Finance net	182	-404	534	-87	988
Loss before Income tax	-54,790	-51,955	-122,385	-87,157	-181,781
Loss for the period	-54,790	-51,955	-122,385	-87,157	-181,781
Average number of shares before dilution	32,742,235	22,680,408	32,002,001	22,680,408	26,593,910
Average number of shares after dilution	32,742,235	22,680,408	32,002,001	22,680,408	26,593,910

Parent Company balance sheet

<i>SEK thousand</i>	30 Jun 2024	30 Jun 2023	31 Dec 2023
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	444,835	413,703	435,182
Total intangible assets	444,835	413,703	435,182
Property, plant and equipment			
Machinery and installations	5,335	11,622	8,581
Equipment	2,262	95	2,056
Fixed assets under construction and prepayments	61,090	47,515	57,156
Total Property, plant and equipment	68,687	59,232	67,793
Financial assets			
Shares in subsidiaries	2,238	50	2,238
Financial investments	1	1	1
Other long-term receivables	2,999	2,999	2,999
Total financial assets	5,237	3,050	5,237
Total non-current assets	518,759	475,985	508,213
Current assets			
Inventories	44,507	45,283	43,781
Current receivables			
Other current receivables	4,372	2,636	4,364
Prepaid expenses and accrued income	3,341	2,136	4,491
Total current receivables	7,713	4,772	8,855
Cash and bank	125,339	31,493	165,658
Total current assets	177,559	81,548	218,294
TOTAL ASSETS	696,318	557,533	726,507

Parent Company balance sheet cont.

<i>SEK thousand</i>	30 Jun 2024	30 Jun 2023	31 Dec 2023
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital	33,762	22,680	31,254
Statutory reserve	976	976	976
Development expenditure reserve	444,835	413,703	435,182
Total restricted equity	479,573	437,360	467,412
<i>Non-restricted equity</i>			
Other contributed capital	1,312,499	907,690	1,216,092
Accumulated earnings	-1,006,386	-790,473	-811,952
Profit/loss for the period	-122,385	-87,157	-181,781
Total non-restricted equity	183,728	30,060	222,358
Total equity	663,302	467,420	689,771
<i>Current liabilities</i>			
Trade accounts payable	6,572	20,485	14,166
Other current liabilities	11,842	46,260	6,263
Accrued expenses and deferred income	14,602	23,368	16,307
Total current liabilities	33,016	90,113	36,736
TOTAL EQUITY AND LIABILITIES	696,318	557,533	726,507

Parent Company statement of cash flow

SEK thousand	Q2		Jan-Jun		Full year
	2024	2023	2024	2023	2023
Operating activities					
Operating loss	-54,972	-51,551	-122,919	-87,070	-182,769
<i>Non-cash adjustments</i>					
Depreciation	1,608	1,891	3,470	3,836	7,604
Disposal of tangible fixed assets	-	-	15	-	5
Interest received	-215	2	2	43	1,969
Interest paid	-16	-	-16	-	-675
Cash flow from operating activities before changes in working capital	-53,595	-49,658	-119,448	-83,191	-173,866
<i>Changes in working capital</i>					
Changes in inventory	-905	-26,692	-726	-36,731	-35,229
Change in operating receivables	822	-137	1,568	-351	-4,861
Change in operating liabilities	-11,763	19,447	-3,718	17,271	9,450
Cash flow from operating activities	-65,441	-57,041	-122,324	-103,002	-204,506
<i>Investing activities</i>					
Purchase of intangible assets	-4,506	-14,977	-9,653	-28,759	-50,238
Acquisition of property, plant and equipment	-4,318	-	-4,379	-	-2,693
Group contributions	-	-	-	-	-2,188
Prepayments	-	-1,104	-	-2,132	-11,773
Cash flow from investing activities	-8,824	-16,081	-14,032	-30,891	-66,892
<i>Financing activities</i>					
New share issue	100,349	-	100,349	0	297,924
Transaction costs	-5,017	-252	-5,555	-252	-26,201
Loan raised	-	45,000	-	45,000	45,000
Allocated warrants	1,186	522	1,186	522	522
Cash flow from financing activities	96,518	45,270	95,916	45,270	317,245
Cash flow for the period	22,253	-27,852	-40,440	-88,623	45,847
Cash and cash equivalents at the beginning of the period	103,101	59,345	165,658	120,116	120,116
Effect of exchange rate and value changes in cash and cash equivalents	-15	-	121	-	-305
Cash and cash equivalents at the end of the period	125,339	31,493	125,339	31,493	165,658

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 2023 have been applied. Comparison figures are presented in parentheses and pertain to the same period in 2023.

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 expenditure". Determining whether the requirements for capitalization of development expenditure 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 tests involve estimates of future cash flows attributable to the asset or the cash-generating unit to which the asset relates when it is complete. These estimates and judgments involve expectations primarily regarding the selling price of products, market penetration, remaining development, sales and marketing expenses, and the likelihood that the product passes through the remaining development phases. 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 2023.

Financing risk and going concern

In connection to the preferential rights issue in June 2023, warrants of series TO5 and TO6 were issued. The subscription period for TO5 extended during the period 16–30 November 2023 and the issue raised proceeds of approximately SEK 92.3 million before transaction costs. The subscription period for TO6 extended during the period 16 April–2 May 2024 and the issue raised proceeds of approximately SEK 100.3 million. The proceeds raised will be used to finance the forthcoming launch of Dasynoc® in the US as well as general corporate purposes, ongoing operating costs and the continued development of the company's product candidates.

The company's capital requirements depend on several factors, including market uptake of its initial product candidate, Dasynoc®, 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. It also creates a foundation for further development of company operations, with continued long-term support for its goal of securing returns for the company's owners. Until the company has achieved long-term, sustainable profitability, its policy is to maintain a low level of debt and a high level of equity.

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 expenses 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.

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, August 7, 2024

Anders Ekblom
Chairman

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

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.
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.
Crystalline	A crystalline structure is a chemical term that describes an ordered structure among the molecules of the substance.
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.
Pivotal study	A standard study, the results of which can be used in the registration application for approval from a medical products authority.
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.
Proton-pump inhibitor (PPI)	A proton-pump inhibitor is a group of drugs whose primary effect is a clear and long-lasting decrease in the production of gastric acid.
Tyrosine kinase inhibitor (TKI)	Tyrosine kinase inhibitors are a subgroup of protein kinase inhibitors. This cancer drug group blocks growth-stimulating signals within the 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.

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