xspray PHARMA

Interim Report

July – September 2024

Key figures, Group

	Q3		Jan-Sep		Full year
	2024	2023	2024	2023	2023
Net sales (SEK thousand)	-	-	-	-	-
Loss before Income tax (SEK thousand)	-82,272	-38,942	-203,672	-125,171	-179,684
Earnings per share before dilution (SEK)	-2.44	-1.59	-6.24	-5.11	-6.76
Earnings per share after dilution (SEK)	-2.44	-1.59	-6.24	-5.11	-6.76
Research and development expenses as % of operating expenses*	42.4	8.3	33.5	17.8	18.9
Cash and cash equivalents (SEK thousand)	74,759	132,480	74,759	132,480	166,303
Total assets (SEK thousand)	667,696	703,305	667,696	703,305	765,263
Equity/assets ratio (%)	87.7	93.9	87.7	93.9	90.6
Average number of employees	24	26	24	26	26

Definitions of key figures, p. 21

July – September 2024, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -82,272 thousand (-38,942)
- Earnings per share before dilution amounted to SEK -2.44 (-1.59)
- Cash flow from operating activities amounted to SEK -41,275 thousand (-68,611)
- Cash flow from investing activities amounted to SEK -9,053 thousand (-14,470)

January – September 2024, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -203,672 thousand (-125,171)
- Earnings per share before dilution amounted to SEK -6.24 (-5.11)
- Cash flow from operating activities amounted to SEK -160,767 thousand (-170,649)
- Cash flow from investing activities amounted to SEK -22,940 thousand (-45,147)

Amounts in parentheses refer to the year-earlier period.

Significant events during the quarter

- In early July, Xspray Pharma announced new clinical data from its registration study program for its product candidate XS003, which is an amorphous, non-crystalline formulation of nilotinib. The data shows matching bioavailability of XS003 to Tasigna® with a 50% reduced dose.
- In late July, 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®. All of the questions in the previous CRL were answered on January 31, 2024, but the FDA was now requesting additional information as a result of the pre-approval inspection at the third party's manufacturing site, which was conducted on June 10-19, 2024, as well as information pertaining to labeling comprehension. Importantly, the FDA did not request any additional clinical studies, nor did it question or remark on any deficiencies in the stability or clinical data.
- In late August, Xspray Pharma released an update concerning Dasynoc® after a meeting with the FDA. The company plans to resubmit its New Drug Application (NDA) in Q4 2024. A decision on whether the company's application will be approved by the FDA is anticipated within two or six months of the resubmission.

Significant events after the end of the reporting period

- In mid-October, Xspray Pharma announced the composition of its Nomination Committee for the Annual General Meeting on May 13, 2025. The Nomination Committee, which has been appointed in accordance with the principles adopted by the Annual General Meeting on May 21, 2024, consists of: Thomas Eldered, appointed by Flerie AB, Chairman of the Nomination Committee; Johan Gyllenswärd, appointed by Ribbskottet AB; Mattias Klintemar, appointed by the Foundation for Baltic and East European Studies; Johan Wadell, appointed by AP2; and Anders Ekblom, Chairman of the Board of Directors, Xspray Pharma AB.
- The Board resolved, with authorization from the annual general meeting on May 21, 2024, to carry out a new share issue of approximately SEK 135 million, with preferential rights for the company's existing shareholders. Furthermore, the Board decided to issue a loan of a total of SEK 100 million and issue warrants to the lenders. The financing is carried out with the primary purpose of financing preparatory activities for the planned launch of Dasynoc® on the American market, as well as the implementation of registration-based studies for XS003 nilotinib and continued development of the company’s other product portfolio. The rights issue is covered by subscription commitments, declarations of intent regarding the subscription of shares and guarantee commitments of 100% of the rights issue, corresponding to SEK 135 million.

A message from the CEO

Dear shareholders,
During the quarter, Xspray focused on completing the work to bring our first product, Dasynoc®, to market approval and launch in the US. In July, we received a complete response letter (CRL) from the FDA, and we plan to resubmit our New Drug Application (NDA) in the fourth quarter of 2024.

Preparations for launch

As part of this resubmission, we had a positive meeting with the FDA, which provided increased clarity regarding the information that is being requested in order to get Dasynoc® approved. If the FDA designates our resubmission as a "class 1", we can expect a review period of two months, which means that Dasynoc® could be launched as early as the first quarter of 2025. If the resubmission is instead deemed to be a "class 2", the process could take six months, with a potential launch at the end of the second quarter of 2025.

There are a number of reasons for why we believe that FDA will be satisfied with our resubmission. The reason for the CRL is related to the inspection, concerning the third-party manufacturing facility in Italy. Even though the previous production results were good, we have implemented improvements that have raised the quality further.

- The previous solvent levels in Dasynoc® were low, but we have now managed to lower them further and thereby achieve results that are 30 times lower than the FDA's safety limit, which we expect will satisfy their requirements.
- The FDA has accepted the responses related to the inspection concerning the manufacturing facility in Italy, and is now only requesting a follow-up to verify that these improvements function as intended. We have results that lead us to believe this follow-up will confirm that these measures are sufficient for approval.
- At a positive and constructive meeting with the FDA during the period, we agreed on minor adjustments to three out of six of the dosage strengths in order to reduce the risk of medication errors, compared with other dasatinib products that require higher dosage strengths to achieve the same uptake. According to the agreement with FDA we will manufacture new product batches for the adjusted dosage strengths, and this process is progressing according to plan. Along with further labeling discussions we believe this will resolve any remaining questions pertaining to prescribing and product safely.

As we prepare for commercialization along with EVERSANA, our flexible model has demonstrated value allowing us to temporarily pause costly launch activities related to Dasynoc®. Nevertheless, we have continued to build relationships with both physicians and insurance companies to raise awareness of the clear patient benefits that Dasynoc® offers as well as its potential health economic savings. To date, we have received very positive feedback regarding the medical benefits of Dasynoc® that other dasatinib products lack.

Benefits of technology platform gain attention

We are continuing to receive crucial scientific support for our patented HyNap™ technology. A

scientific article that was published in a US journal, Clinical Pharmacology in Drug Development[1], demonstrates how Xspray Pharma's HyNap™ technology improves bioavailability and reduces variability for drugs such as Dasynoc®. The article shows that Dasynoc® achieves bioequivalence at a 30% lower dose, with up to 4.8 times less variation in plasma exposure compared with the reference product. Once again, I would like to emphasize the importance of the attention our research has garnered in leading US scientific journals. This scientific article strengthens our position as a leader in amorphous PKI products.

Positive results for XS003 nilotinib

During the quarter, we also presented positive results for our product candidate, XS003. The data shows that XS003 can match the bioavailability of Tasigna® with a more than a 50% reduced dose. Tasigna® is a crystalline formulation of nilotinib and is marketed for the treatment of chronic myeloid leukemia (CML). The results are extremely positive and once again demonstrate the potential of our platform technology. We are now concluding the clinical program for XS003, and we expect to be able to report interim results by year-end. We expect to submit the application for approval in the first half of 2025.

We continue to maintain a rapid pace of development of the company's product portfolio, which besides Dasynoc® and XS003 comprises XS008 axitinib and XS025 cabozantinib for the treatment of renal cancer. All of these are improved amorphous versions, with robust patent protection, of established and marketed protein kinase inhibitors.

Earnings for the period and cash flow

During the period, the company reduced its negative cash flow from operating activities compared with the year-earlier period. This is due primarily to reduced costs for commercialization activities pertaining to Dasynoc®. Looking at earnings for the quarter, they are significantly lower than in the year-earlier period. The main reasons for this are two non-cash items that affected comparability.

(i) Earnings from the year-earlier period were affected by SEK 28 million in other operating income attributable to the legal proceedings in the US.

(ii) In the current period, the company has carried out a disposal of inventory by SEK -29 million, which is the result of the FDA's recommendation that the company adjust some of its tablet strengths for Dasynoc® to reduce the risk of medication errors. It is important to note that the majority of the disposal cost is attributable to one time efforts to validate upscaling, which will not have to be repeated for the adjusted dosage strengths.

After the period, we have decided not to proceed with the planned expansion of production capacity in Malta due to new timelines and changed patent implications. The decision does not affect the company's future cash flow, but parts of previous investments will be written off in the next quarter.

After the quarter, the Board resolved on a capital raise, consisting of a new share issue with preferential rights for existing shareholders of SEK 135 million, a loan of SEK 100 million and an issue of warrants to the lenders. The share issue is covered to 100% corresponding to SEK 135 million by various forms of commitments. With this funding, we expect to be able to continue with undiminished energy the work of preparing, and in case of a market approval by the FDA, launching Dasynoc® as planned. Likewise, the funding enables us to carry out the registration-based studies required to be able to complete and submit an application for market approval of our next product candidate XS003 nilotinib to the FDA in the first half of 2025. I would like to once again express my gratitude to our major shareholders who, through the financial commitments they make in connection with the rights issue, show continued confidence in our commercialization plan.

Although the CRL in July was a disappointment, we are continuing to improve manufacturing and are working intensively with scientifically based marketing. Our communications with physicians and key opinion leaders have been successful and have been met with positive reactions from both the medical profession and payors, which bolster confidence ahead of the launch of Dasynoc®.

Our business model is a new one that was developed to generate high levels of earnings in a short period of time since the product is easily comprehensible for physicians in an already established market where they are accustomed to the high costs of drugs and there is a need to eliminate side effects.
There are exciting times ahead, and I look forward to Xspray Pharma completing the next stage of its journey toward becoming a commercial-stage, profitable pharmaceutical company and a global leader in enhanced versions of established protein kinase inhibitors.

Per Andersson, CEO, Xspray Pharma

[1] *Lennernäs, Hans, et al. Clinical Pharmacology in Drug Development 2024;13(9) 985-999. doi 10.1002/cpdd.1416*

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% (profit before tax)
- Five products launched
- Three product candidates under development

Launch of the company's first commercial product – Dasynoc

In September, the company returned with an updated timetable regarding the launch of Dasynoc® in the US. The updated timetable was created following the FDA request in July 2024 for supplementary information for market approval of Dasynoc®. The company plans to resubmit in the fourth quarter of 2024. After the resubmission, Xspray expects that the FDA will assign a new Prescription Drug User Free Act (PDUFA) date with a decision within two or six months after the resubmit is made, depending on the timetable for the review.

Since February 2023, Xspray Pharma has a partnership agreement with EVERSANA that provides Xspray Pharma with access to a complete and cost-effective countrywide sales organization in the US that is ready to go. At present, EVERSANA's market preparation activities have been limited 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 documented experience in selling PKI drugs to the specific physicians, insurance companies, and other paying customers 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), Tasigna® (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®, Tasigna® Inlyta® and Cabometyx® for 2023 exceeded USD 5.2 billion in the US market and USD 7.1 billion globally.[2]

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

Overview – product candidates

Product candidate				Patent		Development phase					
Project	Substance	Indication	Regulatory path	Substance patent expiry	Secondary patent expiry	New candidate evaluation	Development of formulation	Pilot studies	Pivotal studies	Regulatory review	Original product/ Company
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 September 30, 2024 was 33,762,265 and the closing price on that date was SEK 49.60.

Owners as of September 30, 2024	Number of shares	Share of capital & votes
Flerie Invest	5,910,238	17.51%
Anders Bladh (private & Ribbskottet)	4,349,700	12.88%
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	1,126,881	3.34%
Second Swedish National Pension Fund	1,037,200	3.07%
Carl Erik Norman	721,708	2.14%
Nordnet Pension Insurance	665,765	1.97%
Total, 10 largest owners	**23,804,135**	**70.51%**
Other shareholders	**9,958,130**	**29.49%**
Total	**33,762,265**	**100.0%**

Financial calendar

Interim Report Q4 2024	February 12, 2025
Annual Report 2024	March 27, 2025
Interim Report Q1 2025	May 7, 2025
Interim Report Q2 2025	August 6, 2025

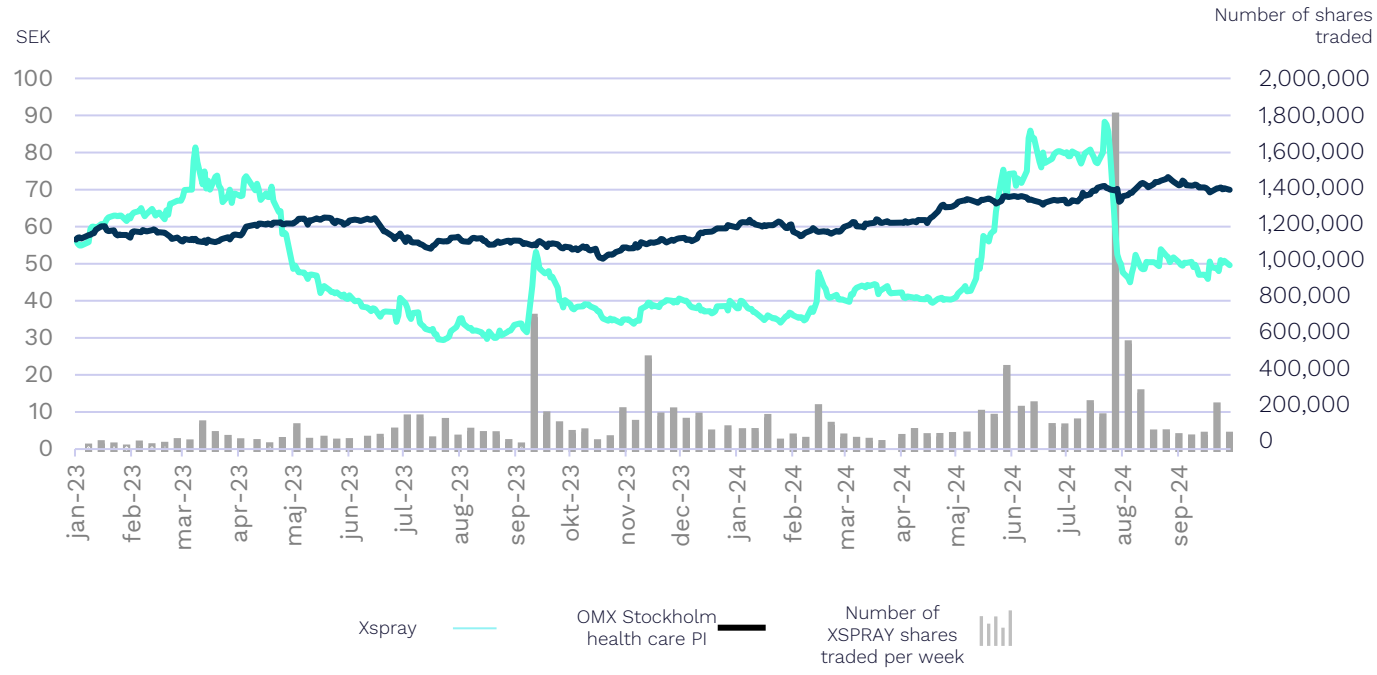
The financial reports are available on the Xspray Pharma website, www.xspraypharma.com.

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. 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 6–7.

Other operating income

Other operating income was SEK 865 thousand (29,203) for the third quarter and SEK 1,929 thousand (30,463) for the January–September period. The change compared with the preceding period related to a positive effect of SEK 28,223 thousand that was attributable to the legal proceedings in the US that concluded in September 2023. 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 -45,551 thousand (-14,426), of which SEK -35,420 thousand (-5,647) was recognized as an expense in profit or loss and SEK -10,131 thousand (-8,779) was capitalized as development expenditure and presented in the company's balance sheet. For the first three quarters, the figure is SEK -91,331 thousand (-65,580) for total expenditure for research and development, with SEK -69,444 thousand (-27,771) being expensed and SEK -21,887 thousand (-37,809) capitalized as development expenditures. The increase in expenses recognized during the quarter primarily consists of a disposal of inventory totaling SEK -29,471 thousand. The disposal followed discussions with FDA, who recommended that the company adjust certain tablet strengths to further differentiate Dasynoc® from Sprycel® and thus reduce the risk of dosing errors. The disposal also includes validation work for scaling up, which will not need to be repeated for the newly adjusted dose strengths.

In addition to the disposal, 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 -47,203 thousand (-61,237) in the third quarter. Of these, personnel costs amounted to SEK -9,140 thousand (-8,708). The decrease in cost comprised largely a reduction in market preparation activities for Dasynoc® due to the CRL that was received. Administration and sales expenses for the January–September period totaled SEK -134,326 thousand (-125,579) with SEK -29,052 thousand (-27,071) pertaining to personnel costs.

Other operating expenses

Other operating expenses totaled SEK -931 thousand (-1,554) for the third quarter and SEK -3,324 thousand (-2,999) for the January–September period. 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 -82,235 thousand (-38,942) for the third quarter and SEK -203,672 thousand (-125,171) for the January–September period. This corresponds to earnings per share before dilution of SEK -2.44 (-1.59) and SEK -6.24 (-5.11) respectively. The deterioration in earnings for the quarter is attributable primarily to two items:

(i) In the year-earlier period, SEK 28,223 thousand in other operating income was received, attributable to the legal proceedings in the US.

(ii) In the current period, the company has carried out a disposal of inventory by SEK -29,471 thousand. The disposal was the result of a recommendation from the FDA that the company adjust the strength of some of its tablets to further distinguish Dasynoc® from Sprycel®, thereby reducing the risk of medication errors. It is important to note that most of the disposal is attributable to efforts to validate upscaling, which will now not need to be repeated for the adjusted dosage strengths.

Cash flow

Cash flow from operating activities amounted to SEK -41,275 thousand (-68,611) in the quarter, of which

the effect from working capital was SEK 10,520 thousand (-31,179). The aggregate figure for the three quarters was SEK -160,767 thousand (-170,649), in which the effect from working capital was SEK 9,363 thousand (-51,609). The negative cash flow thus decreased as a result of the launch date being for Dasynoc® being pushed back and commercialization activities being postponed.

Cash flow from investing activities amounted to SEK -9,053 thousand (-14,470) in the third quarter and SEK -22,940 thousand (-45,147) for the January–September period. The item includes capitalized development expenditure of SEK -9,053 thousand (-8,550) for the third quarter and SEK -18,561 thousand (-37,095) for the January–September period. 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 0 thousand (-77) in property, plant and equipment were made during the third quarter.
Cash flow from financing activities amounted to SEK -1,413 thousand (184,018) in the third quarter and SEK 92,086 thousand (228,110) for the January–September period. The decrease arose from the preferential rights issue that was carried out in July 2023, which raised SEK 250,636 thousand before transaction costs.
Total cash flow was SEK -51,741 thousand (100,937) for the third quarter and SEK -91,621 thousand (12,314) for the January–September period. The Group had SEK 74,759 thousand (132,480) in cash and cash equivalents on September 30, 2024.

Intangible assets

Development expenditures for the projects have been capitalized according to plan. Capitalized development expenditures for the quarter totaled SEK 10,131 thousand (8,779). The Group's total capitalized expenditure for development amounted to SEK 458,667 thousand (423,405) on September 30, 2024. The item is associated with the company's product candidates Dasynoc®, XS003 nilotinib, XS008 axitinib and XS025 cabozantinib.

Financial position

After the period, the company announced that the Board had decided to carry out a new share issue of approximately SEK 135 million, with preferential rights for the company's existing shareholders. Furthermore, the Board resolved to issue loans of SEK 100 million and issue warrants to the lenders. This means that the company will receive proceeds of SEK 235 million upon full subscription of the rights issue. Upon approval of Dasynoc® with a subsequent launch, the company's need for working capital will increase in the short term due to build up of inventory, higher accounts receivable and increased costs for marketing and sales activities linked to the company's partner Eversana. In such a scenario, the company intends to raise non-dilutive debt financing of SEK 200 million, which is estimated to be repaid through cash flows from operating activities.

The equity/assets ratio for the Group was 87.7% (93.9) at September 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 73,384 thousand (132,430) and the equity/assets ratio was 92.1% (94.0) at September 30, 2024.

Employees

The number of employees in the organization decreased by two compared with the year-earlier period. The average number of employees in the Group totaled 24 (26).

Related-party transactions

The management of the Parent Company, the Boards of Directors of the Parent Company and subsidiaries 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 company did not purchase any services from Lind Glimberg in the third quarter, since she transitioned to permanent employment on June 1, 2024. The fees thus totaled SEK 0 thousand (-427) for the quarter and SEK -1,015 thousand (-1,249) for the January–September period.

The company did not purchase any consulting services during the year from Stratfox Healthcare Group LLC, which is owned by the company's Board member Robert Molander. The fees thus totaled SEK 0 thousand (-161) for the third quarter and SEK 0 thousand (-425) for the January–September period.

Financial statements

Consolidated income statement

	Q3		Jan-Sep		Full year
SEK thousand	2024	2023	2024	2023	2023
Net sales	-	-	-	-	-
Other operating income	865	29,203	1,929	30,463	31,767
Research and development expenses	-35,420	-5,647	-69,444	-27,771	-40,259
Administration and sales expenses	-47,203	-61,237	-134,326	-125,579	-169,567
Other operating expenses	-931	-1,554	-3,324	-2,999	-3,675
Operating loss	**-82,690**	**-39,236**	**-205,166**	**-125,886**	**-181,734**
Finance income	426	412	1,518	1,390	2,725
Finance costs	-8	-118	-24	-675	-675
Finance net	**418**	**294**	**1,494**	**715**	**2,049**
Loss before Income tax	-82,272	-38,942	-203,672	-125,171	-179,684
Tax	37	-	117	-	17
Loss for the period	**-82,235**	**-38,942**	**-203,555**	**-125,171**	**-179,667**
Earnings per share for the period before dilution, SEK	-2.44	-1.59	-6.24	-5.11	-6.76
Earnings per share for the period after dilution, SEK	-2.44	-1.59	-6.24	-5.11	-6.76
Average number of shares before dilution	33,762,265	24,516,567	32,595,203	24,516,567	26,593,910
Average number of shares after dilution	33,762,265	24,516,567	32,595,203	24,516,567	26,593,910

Consolidated statement of comprehensive income

	Q3		Jan-Sep		Full year
SEK thousand	2024	2023	2024	2023	2023
Loss for the period	-82,235	-38,942	-203,555	-125,171	-179,667
Annual translation differences in the translation of foreign operations	-130	-	-2	-	-184
Total comprehensive income for the period	**-82,365**	**-38,942**	**-203,557**	**-125,171**	**-179,851**

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

Consolidated balance sheet

SEK thousand	30 Sep 2024	30 Sep 2023	31 Dec 2023
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	458,667	423,405	436,780
Total intangible assets	**458,667**	**423,405**	**436,780**
Property, plant and equipment			
Machinery and installations	4,360	9,838	8,581
Right-of-use assets	33,745	799	37,649
Equipment	2,144	71	2,056
Fixed assets under construction and prepayments	64,146	55,373	59,365
Total Property, plant and equipment	**104,395**	**66,082**	**107,651**
Financial assets			
Financial investments	1	1	1
Other long-term receivables	3,133	2,999	3,016
Total financial assets	**3,134**	**3,000**	**3,017**
Total non-current assets	**566,196**	**492,487**	**547,448**
Current assets			
Inventories	20,711	43,003	43,781
Current receivables	3,500	3,839	4,165
Accounts receivable	-	860	-
Prepaid expenses and accured income	2,530	30,637	3,566
Cash and cash equivalents	74,759	132,480	166,303
Total current assets	**101,500**	**210,818**	**217,815**
TOTAL ASSETS	**667,696**	**703,305**	**765,263**

Consolidated balance sheet cont.

SEK thousand	30 Sep 2024	30 Sep 2023	31 Dec 2023
EQUITY AND LIABILITIES			
Equity			
Share capital	33,762	28,946	31,254
Other contributed capital	1,309,318	1,130,721	1,216,092
Reserves	790	982	792
Retained earnings including profit/loss for the period	-758,279	-500,229	-554,724
Total equity attributable to the Parent Company's shareholders	**585,592**	**660,420**	**693,413**
Non–current liabilities			
Lease liabilities	28,561	302	31,947
Total non-current liabilities	**28,561**	**302**	**31,947**
Current liabilities			
Trade accounts payable	19,229	16,092	12,472
Lease liabilities	5,045	366	4,861
Other current liabilities	12,675	5,866	6,263
Accrued expenses and deferred income	16,594	20,258	16,307
Total current liabilities	**53,543**	**42,583**	**39,903**
TOTAL EQUITY AND LIABILITIES	**667,696**	**703,305**	**765,263**

Consolidated statement 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 January 1, 2023	22,680	907,420	976	-375,057	556,019
Loss of the period	-	-	-	-179,667	-179,667
Other comprehensive income for the period	-	-	-184	-	-184
Total comprehensive income for the period	-	-	-	-179,667	-179,851
New share issue	8,573	334,352	-	-	342,925
Transaction costs	-	-26201	-	-	-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
Loss of the period	-	-	-	-203,555	-203,555
Other comprehensive income for the period	-	-	-2	-	-2
Total comprehensive income for the period	-	-	-2	-203,555	-203,557
New share issue	2,509	97,840	-	-	100,349
Transaction costs	-	-5,736	-	-	-5,736
Warrant program	-	1,122	-	-	1,122
Closing balance as of September 30, 2024	33,762	1,309,318	788	-758,279	585,592

Consolidated statement of cash flow

	Q3		Jan-Sep		Full year
SEK thousand	2024	2023	2024	2023	2023
Operating activities					
Operating loss	**-82,690**	**-39,236**	**-205,166**	**-125,886**	**-181,734**
Non-cash adjustments					
Depreciation	1,836	2,230	6,886	6,745	9,194
Unrealized currency impact	18	-	-32	-	41
Disposal of inventory	29,471	-	29,471	-	-
Disposal of tangible fixed assets	-	-	15	-	5
Interest received	-	280	2	831	1,969
Interest paid	-430	-706	-1,306	-730	-1,169
Cash flow from operating activities before changes in working capital	**-51,795**	**-37,432**	**-170,130**	**-119,040**	**-171,694**
Changes in working capital					
Change in inventory	-5,675	2,280	-6,401	-34,451	-35,229
Change in operating receivables	780	-31,141	2,308	-32,091	-4,109
Change in operating liabilities	15,415	-2,318	13,456	14,933	7,757
Cash flow from operating activities	**-41,275**	**-68,611**	**-160,767**	**-170,649**	**-203,275**
Investing activities					
Capitalized development costs	-9,053	-8,550	-18,561	-37,095	-49,855
Acquisition of property, plant and equipment	-	-77	-4,379	-77	-2,692
Prepayments of Right-of-Use-Assets	-	-	-	-	-1,556
Prepayments	-	-5,843	-	-7,975	-11,773
Cash flow from investing activities	**-9,053**	**-14,470**	**-22,940**	**-45,147**	**-65,876**
Financing activities					
New share issue	-	205,636	100,349	205,636	297,924
Loan raised *	-	-	-	45,000	45,000
Transaction costs	-181	-21,338	-5,736	-21,590	-26,201
Payment of lease liability	-1,232	-280	-3,649	-1,458	-1,651
Repurchased warrants	-	-	-64	-	-
Allocated warrants	-	-	1,186	522	522
Cash flow from financing activities	**-1,413**	**184,018**	**92,086**	**228,110**	**315,594**
Cash flow for the period	**-51,741**	**100,937**	**-91,621**	**12,314**	**46,443**
Cash and cash equivalents at the beginning of the period	126,573	31,543	166,303	120,166	120,166
Effect of exchange rate and value changes in cash and cash equivalents	-73	-	77	-	-306
Cash and cash equivalents at the end of the period	**74,759**	**132,480**	**74,759**	**132,480**	**166,303**

**In addition to SEK 205,636 thousand, SEK 45,000 thousand from loans raised was contributed in the set-off issue during the period.*

Parent Company income statement

	Q3		Jan-Sep		Full year
SEK thousand	2024	2023	2024	2023	2023
Net sales	-	-	-	-	-
Other operating income	1,073	29,203	3,056	30,463	31,669
Research and development expenses	-36,012	-5,799	-71,512	-28,191	-41,100
Administration and sales expenses	-49,039	-61,009	-135,100	-125,413	-169,705
Other operating expenses	-1,143	-1,503	-4,484	-3,038	-3,633
Operating loss	**-85,121**	**-39,108**	**-208,040**	**-126,178**	**-182,769**
Finance income	154	132	704	602	1,664
Finance costs	-8	-118	-24	-675	-675
Finance net	**146**	**14**	**680**	**-73**	**988**
Loss before Income tax	-84,975	-39,094	-207,360	-126,251	-181,781
Loss for the period	**-84,975**	**-39,094**	**-207,360**	**-126,251**	**-181,781**
Average number of shares before dilution	33,762,265	24,516,567	32,595,203	24,516,567	26,593,910
Average number of shares after dilution	33,762,265	24,516,567	32,595,203	24,516,567	26,593,910

Parent Company balance sheet

SEK thousand	30 Sep 2024	30 Sep 2023	31 Dec 2023
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	454,067	422,341	435,182
Total intangible assets	454,067	422,341	435,182
Property, plant and equipment			
Machinery and installations	4,360	9,838	8,581
Equipment	2,144	71	2,056
Fixed assets under construction and prepayments	61,090	53,358	57,156
Total Property, plant and equipment	67,594	63,267	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	526,898	488,658	508,213
Current assets			
Inventories	20,711	43,003	43,781
Current receivables			
Accounts receivables	-	860	-
Other current receivables	3,711	4,060	4,364
Prepaid expenses and accured income	3,321	30,798	4,491
Total current receivables	7,032	35,717	8,855
Cash and bank	73,384	132,430	165,658
Total current assets	101,127	211,150	218,294
TOTAL ASSETS	628,025	699,808	726,507

Parent Company balance sheet cont.

SEK thousand	30 Sep 2024	30 Sep 2023	31 Dec 2023
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	33,762	28,946	31,254
Statutory reserve	976	976	976
Development expenditure reserve	454,067	422,341	435,182
Total restricted equity	**488,805**	**452,264**	**467,412**
Non-restricted equity			
Other contributed capital	1,312,318	1,130,721	1,216,092
Accumulated earnings	-1,015,617	-799,111	-811,952
Profit/loss for the period	-207,360	-126,251	-181,781
Total non-restricted equity	**89,340**	**205,359**	**222,358**
Total equity	**578,145**	**657,623**	**689,771**
Current liabilities			
Trade accounts payable	19,196	16,061	14,166
Other current liabilities	12,675	5,866	6,263
Accrued expenses and deferred income	18,009	20,258	16,307
Total current liabilities	**49,880**	**42,185**	**36,736**
TOTAL EQUITY AND LIABILITIES	**628,025**	**699,808**	**726,507**

Parent Company statement of cash flow

	Q3		Jan-Sep		Full year
SEK thousand	2024	2023	2024	2023	2023
Operating activities					
Operating loss	**-85,121**	**-39,108**	**-208,040**	**-126,178**	**-182,769**
Non-cash adjustments					
Depreciation	1,093	1,885	4,563	5,721	7,604
Disposal of inventory	29,471	-	29,471	-	-
Disposal of tangible fixed assets	-	-	15	-	5
Interest received	-	-	2	43	1,969
Interest paid	-8	-675	-24	-675	-675
Cash flow from operating activities before changes in working capital	**-54,565**	**-37,898**	**-174,013**	**-121,089**	**-173,866**
Changes in working capital					
Changes in inventory	-5,675	2,280	-6,401	-34,451	-35,229
Change in operating receivables	880	-30,812	2,448	-31,163	-4,861
Change in operating liabilities	16,862	-2,372	13,144	14,899	9,450
Cash flow from operating activities	**-42,498**	**-68,802**	**-164,822**	**-171,804**	**-204,506**
Investing activities					
Purchase of intangible assets	-9,232	-8,639	-18,885	-37,398	-50,238
Acquisition of property, plant and equipment	-	-77	-4,379	-77	-2,693
Group contributions	-	-	-	-	-2,188
Prepayments	-	-5,843	-	-7,975	-11,773
Cash flow from investing activities	**-9,232**	**-14,559**	**-23,264**	**-45,450**	**-66,892**
Financing activities					
New share issue	-	205,636	100,349	205,636	297,924
Transaction costs	-181	-21,338	-5,736	-21,590	-26,201
Loan raised	-	-	-	45,000	45,000
Repurchased warrants	-	-	-64	-	-
Allocated warrants	-	-	1,186	522	522
Cash flow from financing activities	**-181**	**184,298**	**95,735**	**229,568**	**317,245**
Cash flow for the period	**-51,911**	**100,937**	**-92,351**	**12,314**	**45,847**
Cash and cash equivalents at the beginning of the	125,339	31,493	165,658	120,116	120,116
Effect of exchange rate and value changes in cash and cash equivalents	-44	-	77	-	-305
Cash and cash equivalents at the end of the period	**73,384**	**132,430**	**73,384**	**132,430**	**165,658**

**In addition to SEK 205,636 thousand, SEK 45,000 thousand from loans raised was contributed in the set-off issue during the period.*

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

To meet the company's strategic goals, including the launch of Dasynoc® and further development of the business, the company plans to carry out a rights issue and take out a loan during the fourth quarter of 2024 that will provide net proceeds of SEK 235 million.

Upon approval of Dasynoc® with a subsequent launch, the company's need for working capital will increase in the short term due to build up of inventory, higher accounts receivable and increased costs for marketing and sales activities linked to the company's partner Eversana. In such a scenario, the company intends to raise non-dilutive debt financing of SEK 200 million, which is estimated to be repaid through cash flows from operating activities.

The company's capital needs depend on a number of factors, including the launch timing and market uptake of the company's first product candidate, Dasynoc®, as well as results from, and costs for, ongoing and future drug studies. In light of this, the Board is actively engaged in evaluating the company's financial requirements and position, with various financing alternatives being reviewed. 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, 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, November 6, 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 been reviewed by the company's auditor.

Review report

To the Board of Directors of Xspray Pharma AB (publ)

Corp. id. 556649-3671

Introduction

We have reviewed the condensed interim financial information (interim report) of Xspray Pharma AB (publ) as of September 30, 2024 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements ISRE 2410 *Review of Interim Financial Information Performed by the Independent Auditor of the Entity*. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Material uncertainty as to going concern

We bring to your attention the information in the interim report (page 9) and in note 2 (page 20) which states that dependent on the result of the preferential rights issue and other financing, there is a risk that the Group's cash and cash equivalents will be insufficient. It also states that the Board of Directors is actively engaged in evaluating the company's financial requirements and position with various financial alternatives being reviewed. It also states that there is a risk that the basis of going concern cannot be used if sufficient financing is not secured. These circumstances indicate that there are material uncertainties that may cast significant doubt on the Group's ability to continue as a going concern. We have not modified our conclusion in regards to this.

Solna, November 6, 2024

KPMG AB

Duane Swanson

Authorized Public Accountant

Glossary

505(b)(2) NDA	Application for drug approval in the US for an improved version of an existing approved drug.
Amorphous	An amorphous structure is a chemical term that describes substances whose molecules lack an ordered structure.
Bioavailability	(Biological availability), a concept in pharmacology that shows how large a portion of the drug reaches the blood.
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.
Crystalline	A crystalline structure is a chemical term that describes an ordered structure among the molecules of the substance.
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.
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.
PDUFA date	A target date that the US Food and Drug Administration has set for making a decision on approving a new drug.
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.
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.

For more information, please contact:
Kerstin Hasselgren, Investor Relations
Tel: +46 (0) 70 311 16 83
E-mail: kerstin.hasselgren@xspray.com
www.xspraypharma.com