



## **Interim Report**

April–June 2025

## Key figures, Group

|                                                               | Q2      |         | Jan-Jun |          | Full year |
|---------------------------------------------------------------|---------|---------|---------|----------|-----------|
|                                                               | 2025    | 2024    | 2025    | 2024     | 2024      |
| Net sales (SEK thousand)                                      | -       | -       | -       | -        | -         |
| Loss before Income tax (SEK thousand)                         | -44,885 | -53,620 | -87,206 | -121,401 | -285,674  |
| Earnings per share before dilution (SEK)                      | -2.35   | -1.64   | -2.35   | -3.79    | -8.62     |
| Earnings per share after dilution (SEK)                       | -2.35   | -1.64   | -2.35   | -3.79    | -8.62     |
| Research and development expenses as % of operating expenses* | 9.9     | 27.9    | 10.8    | 27.5     | 27.4      |
| Cash and cash equivalents (SEK thousand)                      | 73,807  | 126,573 | 73,807  | 126,573  | 208,236   |
| Total assets (SEK thousand)                                   | 696,977 | 736,067 | 696,977 | 736,067  | 796,344   |
| Equity/assets ratio (%)                                       | 76.8    | 90.8    | 76.8    | 90.8     | 78.2      |
| Average number of employees                                   | 26      | 26      | 27      | 25       | 26        |

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### April–June 2025, Group

- Net sales amounted to SEK 0 thousand (0)
- Earnings before tax amounted to SEK -44,885 thousand (-53,620)
- Earnings per share before dilution amounted to SEK -2.35 (-1.64)
- Cash flow from operating activities amounted to SEK -44,111 thousand (-64,181)
- Cash flow from investing activities amounted to SEK -6,132 thousand (-8,738)

### January–June 2025, Group

- Net sales amounted to SEK 0 thousand (0)
- Earnings before tax amounted to SEK -87,206 thousand (-121,401)
- Earnings per share before dilution amounted to SEK -2.35 (-3.79)
- Cash flow from operating activities amounted to SEK -110,440 thousand (-119,492)
- Cash flow from investing activities amounted to SEK -20,833 thousand (-13,887)

Amounts in parentheses refer to the year-earlier period.

### Significant events during the quarter

- In April, Xspray Pharma announced that it had re-submitted its application for market approval for Dasynoc® to the US Food and Drug Administration (FDA).
- The Annual General Meeting held on May 13, 2025 resolved to re-elect Anders Ekblom (Chairman), Anders Bladh, Christine Lind, Robert Molander and Carl-Johan Spak as members of the Board of Directors and to elect Markus Haeberlein and Anne Prener as new members of the Board of Directors. The Annual General Meeting also resolved to adopt a long-term incentive program for employees (LTIP 2025).
- The FDA set the PDUFA date of October 7, 2025 for the re-submitted New Drug Application (NDA) for Dasynoc®. The PDUFA date is the FDA's deadline for communicating its decision on the company's application. Xspray Pharma is now continuing to prepare for the US launch of Dasynoc® with the aim that it can begin as soon as possible if market approval is received in October.
- In June, Xspray Pharma announced that the FDA had conducted a successful Pre-Approval Inspection (PAI) of the company's manufacturing lines, located at a contract manufacturing partner. The inspection occurred in connection to the FDA making a general GMP-inspection of the entire production facility.

## Significant events after the reporting period

- In July, Xspray Pharma announced that the company had completed the population pharmacokinetic (PopPK) modeling that confirmed bioequivalence between XS003 and the reference drug Tasigna®. Bioequivalence with XS003 was achieved at less than half the dose compared with Tasigna®. Accordingly, all regulatory documentation has been completed for submitting a 505(b)(2) NDA for the XS003 product candidate.
- In August, Xspray Pharma entered into a license agreement with Handa Therapeutics granting Handa a non-exclusive license to certain Xspray patents. The license covers commercialization of Handa's dasatinib product in the US market and, at a later stage, selected Asian markets. Under the agreement, Xspray will receive up to a double-digit royalty on Handa's net revenue. The agreement also ensures that Xspray's planned launch of Dasynoc® can be done without being affected by regulatory hurdles in the US that can be associated with Handa's market approval.
- After the period, the company announced that the Board had decided to carry out a rights issue of shares of approximately SEK 130 million, with preferential rights for the company's existing owners. The rights issue can be increased by up to SEK 20 million through an over-allotment option. Furthermore, the Board decided to extend and increase an existing loan with an additional SEK 25 million, where the new maturity has been set to March 2027, and the Board also decided to issue warrants to the lenders.

# A message from the CEO

Dear shareholders

Step by step over the past quarter, we continued to work toward the commercialization of our product portfolio. We are now approaching the launch of our first product – Dasynoc®, our improved version of a well-established drug for the treatment of leukemia (CML and ALL). Dasynoc® will provide significant benefits to the treatment outcomes of leukemia patients and their quality of life in the form of lower dosage requirements, lower variability in absorption, and the ability to be co-medicated with all commonly used gastric acid suppressants. After the period, we reached an important milestone when we entered into the company's first out-licensing agreement with Handa Therapeutics. The agreement gives us royalty income on a new dasatinib product that Handa plans to launch, while our own dasatinib product candidate Dasynoc® can be launched without regulatory hurdles that can be associated with Handa's product.



During the quarter, we received two milestone announcements from the FDA – firstly the PDUFA date of October 7, 2025, when we can expect a decision on our application for market approval of Dasynoc®, and secondly the inspection of the company's production line, which had a positive result with no comments. It is also gratifying that we are continuing to make progress on our other product candidates and we will very shortly be submitting a 505(b)(2) NDA to the FDA for market approval of our second product candidate, XS003 – an improved version of the leukemia drug Tasigna®.

## Capital procurement

Today, we announced the next step in our financing plan, a solution that aims to secure our financing needs for the upcoming product launch and commercialization of Dasynoc® as well as continued development of other product candidates in our portfolio. The Board thereby decided to carry out a capital raise, consisting of a rights issue of shares of SEK 130 million with preferential rights for existing shareholders. We also have an oversubscription option entailing that the issue can be expanded by SEK 20 million if oversubscribed.

We are delighted to have received subscription

undertakings and an intention to subscribe for shares amounting to approximately SEK 89 million.

We have also extended and expanded our loan financing. The existing loan of SEK 100 million was increased to SEK 125 million and has a prolonged maturity extending to March 2027. In combination, this means that we have a financing plan and funds in place to enable the successful launch of the company's products. We hope that as we go to market with our products, we can gradually create positive operational cash flows to support the continued development and growth of the operations.

### **Important license agreement with Handa Therapeutics**

After the period, we entered into a licensing agreement with Handa Therapeutics that gives Handa a non-exclusive license to some of Xspray's patents. The license enables Handa to commercialize a dasatinib product in the US market and at a later stage in selected Asian markets. According to the agreement, Xspray will receive a royalty of up to double-digit on Handa's net revenue.

Handa's dasatinib product has the same dose strengths as the original drug Sprycel®, but with some similarities to our own product candidate Dasynoc®. Handa's launch could help increase physicians' knowledge of the pH-related limitations of crystalline dasatinib. Xspray can benefit from this increased knowledge once Dasynoc® is approved. At launch, we believe that Dasynoc® will be "best-in-class" with pH-independent absorption, high precision and lower dose strength, and have compatibility with all proton-pump inhibitors. This means a strong improvement profile with potentially significant clinical benefits for patients.

Our strong patent protection is the basis for us now receiving up to double-digit royalties on Handa's net revenue. The agreement also ensures that the launch of Dasynoc® can be carried out without the impact of existing or any future regulatory exclusivity related to Handa's dasatinib product.

This is the first out-licensing of patents from Xspray's broad patent portfolio and represents a validation of the quality and value of our patent portfolio. We will primarily continue to develop our own, improved PKI drugs based on proven substances, but we will also evaluate potential licensing agreements on a case-by-case basis.

### **Preparations ahead of the launch of Dasynoc®**

The company has enhanced its in-house expertise in a variety of ways ahead of the forthcoming commercialization. The Board was strengthened at the most recent Annual General Meeting through the election of Markus Haeberlein, Ph.D., who has almost three decades of experience in research and development in the life science industry, and Anne Prener, M.D., Ph.D., who has more than 25 years of leadership experience in life science companies. Both directors bring expertise, a valuable network and solid experience of successful drug launches in the US market.

We also continued to pursue market preparation activities during the quarter together with our commercial partner EVERSANA to create a basis for a rapid and successful launch. The partnership with EVERSANA grants us exclusive access to a dedicated US-wide marketing and sales organization. The team consists of skilled experts with years of documented experience in selling PKI drugs to the specific physicians, insurance companies, and other paying customers we are targeting. We will be able to leverage the infrastructure we are now building up when we bring future products to market.

### **Application for market approval of XS003**

We also continue to make progress on other products in our portfolio. We will shortly be submitting a 505(b)(2) NDA to the FDA for the product candidate XS003, an amorphous version of nilotinib for the treatment of chronic myeloid leukemia.

Prior to submitting an 505(b)(2) NDA, we have carried out population pharmacokinetic modeling for XS003. The analysis confirmed the improved properties of XS003 and bioequivalence with the reference drug Tasigna®, at less than half the dose. Clinical data also showed that XS003 has improved food interaction and a more predictable dose response, which can facilitate precise dose adjustments in clinical practice. This is undeniable confirmation of the strength of XS003.

An exciting time lies ahead, and I am looking forward to keeping you updated throughout our journey.

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.

## Vision

Xspray Pharma's goal is to be a leader in developing 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 updated its timetable for the launch of Dasynoc® in the US after the FDA requested supplementary information for market approval in July 2024. The submission was planned for the fourth quarter of 2024, but the timeline was adjusted owing to a deviation in one batch of tablets. The updated application was submitted in early April 2025 and the FDA set the PDUFA date of October 7, 2025, which is the FDA's deadline for communicating its decision on the company's NDA for Dasynoc®. Xspray Pharma has a partnership agreement with EVERSANA that provides access to a cost-effective, ready-to-start sales organization for the entire US. At present, EVERSANA's market preparation activities have been limited pending the FDA's final approval. EVERSANA will provide Xspray Pharma with services in market access, a medical sales organization, and patient support programs. EVERSANA has experts with extensive experience in selling PKI drugs to physicians, insurance companies, and other players that Xspray Pharma will be targeting. This will create good conditions for a rapid launch of Dasynoc®. Xspray Pharma will retain financial and strategic control but grants EVERSANA the 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 field of oncology, with over 3,000 ongoing clinical studies in Phase I, 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), Tasisign® (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, regardless of the pH of the stomach, which could lead to improved uptake and permit lower dosages to be administered to patients with retained efficacy. The total annual sales of the original drugs Sprycel®, Tasisign®, Inlyta® and Cabometyx® for 2024 exceeded USD 4.9 billion in the US market and USD 6.4 billion globally.<sup>1</sup>

<sup>1</sup> The information regarding annual sales has been taken from the reference companies' quarterly reports and IPD analytics.

## 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 under the symbol XSPRAY. The number of shares in the company at June 30, 2025 was 37,138,491 and the closing price on that date was SEK 49.10.

| Owners as of June 30, 2025                          | Number of shares  | Share of capital & votes |
|-----------------------------------------------------|-------------------|--------------------------|
| Flerie Invest AB                                    | 6,669,261         | 17.96%                   |
| Anders Bladh (private & Ribbskottet)                | 4,574,670         | 12.32%                   |
| The Foundation for Baltic and East European Studies | 4,342,626         | 11.69%                   |
| Fourth Swedish National Pension Fund                | 3,710,135         | 9.99%                    |
| Third Swedish National Pension Fund                 | 1,429,998         | 3.85%                    |
| Avanza Pension                                      | 1,230,974         | 3.31%                    |
| Unionen                                             | 1,150,000         | 3.10%                    |
| Second Swedish National Pension Fund                | 1,140,920         | 3.07%                    |
| Carl Erik Norman                                    | 793,878           | 2.14%                    |
| Nordnet Pension Insurance                           | 736,096           | 1.98%                    |
| <b>Total, 10 largest owners</b>                     | <b>25,778,558</b> | <b>69.41%</b>            |
| <b>Other shareholders</b>                           | <b>11,359,933</b> | <b>30.59%</b>            |
| <b>Total</b>                                        | <b>37,138,491</b> | <b>100.0%</b>            |

## Financial calendar

Interim Report Q3 2025 November 5, 2025

Interim Report Q4 2025 February 12, 2026

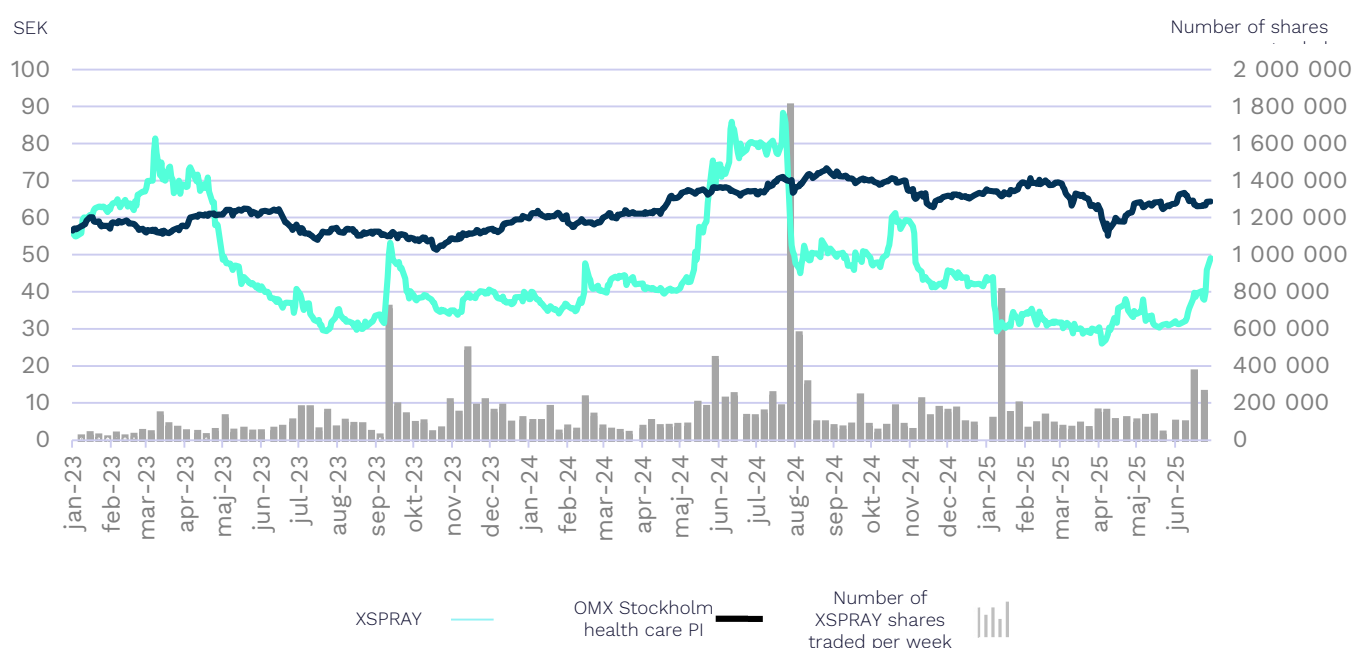
The financial reports are available on the Xspray Pharma website, [www.xspraypharma.com](http://www.xspraypharma.com).

## 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. The Group comprises the Parent Company, a dormant subsidiary and a US subsidiary. 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 2025. Sales are expected to increase when the company launches its initial product, Dasynoc®, in the US market. For further information on Dasynoc®, refer to pages 5–6.

## Other operating income

Other operating income was SEK 1,313 thousand (930) for the second quarter and SEK 3,235 thousand (1,064) for the January–June period. This increase is due primarily to exchange rate gains that arose 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 -11,374 thousand (-20,879), of which SEK -4,214 thousand (-15,373) was recognized as an expense in profit or loss and SEK -7,160 thousand (-5,506) was capitalized as development expenses in the company's balance sheet. For the two quarters, the figure is SEK -32,012 thousand (-45,781) for total expenditure for research and development, with SEK -9,108 thousand (-34,024) expensed and SEK -22,904 thousand (-11,757) capitalized as development expenditures.

The increase in capitalized development expenses is attributable primarily to the clinical studies that were conducted for the product candidate XS003 nilotinib. Research and development costs are 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 -38,106 thousand (-38,436) in the second quarter. Of these, personnel costs amounted to SEK -11,061 thousand (-10,274). The corresponding figures for the January–June period are SEK -74,137 thousand (-87,123) for administration and sales expenses, of which SEK -21,688 thousand (-19,912) pertained to

personnel costs. These costs consist largely of preparatory activities for Dasynoc®.

## Other operating expenses

Other operating expenses totaled SEK -401 thousand (-1,195) in the second quarter and SEK -863 thousand (-2,393) for the January–June period. Other operating expenses consist of exchange rate losses arising in conjunction with payments abroad and translations of the currency account.

## Finance costs

Finance costs amounted to SEK -3,782 thousand (-16) for the second quarter and SEK -7,542 thousand (-16) for the January–June period. The increase year-on-year is the result of interest payments linked to the short-term loan.

## Loss for the period

Loss for the period totaled SEK -44,857 thousand (-53,580) for the second quarter and SEK -87,147 thousand (-121,321) for the January–June period. This corresponds to earnings per share before dilution of SEK -2.35 (-1,64).

## Cash flow

Cash flow from operating activities amounted to SEK -44,111 thousand (-64,181) in the second quarter, of which the effect from working capital comprised SEK -3,727 thousand (-11,836). The corresponding figure for the January–June period was SEK -110,440 thousand (-119,492), of which the effect from working capital was SEK -28,867 thousand (-1,157).

Cash flow from investing activities in the Group amounted to SEK -6,132 thousand (-8,738) for the second quarter and SEK -20,833 thousand (-13,887) for the January–June period. The item consists entirely of capitalized development expenditure of SEK -6,132 thousand (-4,420) in the second quarter. The increase was due primarily to the XS003 nilotinib project being in a period of intensive development, with several clinical trials conducted.

Investment in property, plant and equipment in the January–June period amounted to SEK 0 thousand (-4,318).

Cash flow from financing activities in the second quarter was SEK -1,314 thousand (95,323), which is attributable primarily to amortization of lease liabilities. The corresponding figure for the January–June period was SEK -2,705 thousand (93,499). The decline was due to the fact that no new share issues were carried out. Total cash flow was SEK -51,557 thousand (22,404) for the second quarter and SEK -133,978 thousand (-39,880) for the January–June period. The Group had SEK 73,807 thousand (126,573) in cash and cash equivalents at June 30, 2025.

### **Intangible assets**

Development expenditures for the projects have been capitalized according to plan. Capitalized development expenditures totaled SEK 7,160 thousand (5,506) in the second quarter. The Group's total capitalized development expenditures amounted to SEK 501,830 thousand (448,536) at June 30, 2025. The item is associated with the company's product candidates Dasynoc®, XS003 nilotinib, XS008 axitinib and XS025 cabozantinib.

### **Financial position**

After the end of the period, the company announced that the Board had decided to carry out a new share issue of approximately SEK 130 million, with preferential rights for the company's existing owners. The new share issue can be increased by up to SEK 20 million through an over-allotment option. The Board also decided to extend and increase the existing loan by an additional SEK 25 million, with the new maturity set in March 2027, and to issue warrants to the lenders.

This means that the company may be provided with proceeds totaling SEK 175 million before transaction costs. If Dasynoc® is approved and subsequently launched, the company believes that it will have the capital required to conduct the operations forward. The company's capital requirements depend on several factors including the launch date and market uptake of its initial product candidate, Dasynoc®, as well as the 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 continuously being reviewed.

The equity/assets ratio for the Group was 76.8

percent (90.8) at June 30, 2025.

### **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 71,195 thousand (125,339) and the equity/assets ratio was 80.5 percent (95.3) at June 30, 2025.

### **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 previously pertained 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 Glimberg in the period, since Linda Glimberg transitioned to permanent employment on June 30, 2024.



# Consolidated income statement

| SEK thousand                                           | Q2             |                | Jan-Jun        |                 | Full year       |
|--------------------------------------------------------|----------------|----------------|----------------|-----------------|-----------------|
|                                                        | 2025           | 2024           | 2025           | 2024            | 2024            |
| Net sales                                              | -              | -              | -              | -               | -               |
| Other operating income                                 | 1,313          | 930            | 3,235          | 1,064           | 2,096           |
| Research and development expenses                      | -4,214         | -15,373        | -9,108         | -34,024         | -79,358         |
| Administration and sales expenses                      | -38,106        | -38,436        | -74,137        | -87,123         | -203,878        |
| Other operating expenses                               | -401           | -1,195         | -863           | -2,393          | -5,901          |
| <b>Operating loss</b>                                  | <b>-41,409</b> | <b>-54,074</b> | <b>-80,874</b> | <b>-122,476</b> | <b>-287,041</b> |
| Finance income                                         | 306            | 471            | 1,210          | 1,092           | 3,297           |
| Finance costs                                          | -3,782         | -16            | -7,542         | -16             | -1,929          |
| <b>Finance net</b>                                     | <b>-3,476</b>  | <b>455</b>     | <b>-6,332</b>  | <b>1,076</b>    | <b>1,368</b>    |
| Loss before Income tax                                 | -44,885        | -53,620        | -87,206        | -121,401        | -285,674        |
| Tax                                                    | 27             | 40             | 58             | 80              | 151             |
| <b>Loss for the period</b>                             | <b>-44,857</b> | <b>-53,580</b> | <b>-87,147</b> | <b>-121,321</b> | <b>-285,523</b> |
| Earnings per share for the period before dilution, SEK | -2.35          | -1.64          | -2.35          | -3.79           | -8.62           |
| Earnings per share for the period after dilution, SEK  | -2.35          | -1.64          | -2.35          | -3.79           | -8.62           |
| Average number of shares before dilution               | 37,138,491     | 32,742,235     | 37,138,491     | 32,002,001      | 33,137,306      |
| Average number of shares after dilution                | 37,138,491     | 32,742,235     | 37,138,491     | 32,002,001      | 33,137,306      |

# Consolidated statement of comprehensive income

| SEK thousand                                                            | Q2             |                | Jan-Jun        |                 | Full year       |
|-------------------------------------------------------------------------|----------------|----------------|----------------|-----------------|-----------------|
|                                                                         | 2025           | 2024           | 2025           | 2024            | 2024            |
| Loss for the period                                                     | -44,857        | -53,580        | -87,147        | -121,321        | -285,523        |
| Annual translation differences in the translation of foreign operations | -334           | 35             | -334           | 128             | 205             |
| <b>Total comprehensive income for the period</b>                        | <b>-45,191</b> | <b>-53,544</b> | <b>-87,481</b> | <b>-121,192</b> | <b>-285,318</b> |

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

# Consolidated balance sheet

| SEK thousand                                    | 30 Jun 2025    | 30 Jun 2024    | 31 Dec 2024    |
|-------------------------------------------------|----------------|----------------|----------------|
| <b>ASSETS</b>                                   |                |                |                |
| <b>Non-current assets</b>                       |                |                |                |
| <b>Intangible assets</b>                        |                |                |                |
| Capitalized development costs                   | 501,830        | 448,536        | 478,926        |
| <b>Total intangible assets</b>                  | <b>501,830</b> | <b>448,536</b> | <b>478,926</b> |
| <b>Property, plant and equipment</b>            |                |                |                |
| Machinery and installations                     | 2,488          | 5,335          | 3,565          |
| Right-of-use assets                             | 29,401         | 35,144         | 32,204         |
| Equipment                                       | 1,793          | 2,262          | 2,026          |
| Fixed assets under construction and prepayments | 41,389         | 63,892         | 41,389         |
| <b>Total Property, plant and equipment</b>      | <b>75,072</b>  | <b>106,633</b> | <b>79,185</b>  |
| <b>Financial assets</b>                         |                |                |                |
| Financial investments                           | 1              | 1              | 1              |
| Other long-term receivables                     | 3,225          | 3,096          | 3,167          |
| <b>Total financial assets</b>                   | <b>3,226</b>   | <b>3,097</b>   | <b>3,168</b>   |
| <b>Total non-current assets</b>                 | <b>580,128</b> | <b>558,266</b> | <b>561,279</b> |
| <b>Current assets</b>                           |                |                |                |
| Inventories                                     | 35,119         | 44,507         | 20,335         |
| Current receivables                             | 4,156          | 4,162          | 4,018          |
| Prepaid expenses and accrued income             | 3,768          | 2,559          | 2,476          |
| Cash and cash equivalents                       | 73,807         | 126,573        | 208,236        |
| <b>Total current assets</b>                     | <b>116,849</b> | <b>177,801</b> | <b>235,066</b> |
| <b>TOTAL ASSETS</b>                             | <b>696,977</b> | <b>736,067</b> | <b>796,344</b> |

# Consolidated balance sheet cont.

| SEK thousand                                                          | 30 Jun 2025    | 30 Jun 2024    | 31 Dec 2024    |
|-----------------------------------------------------------------------|----------------|----------------|----------------|
| <b>EQUITY AND LIABILITIES</b>                                         |                |                |                |
| <b>Equity</b>                                                         |                |                |                |
| Share capital                                                         | 37,138         | 33,762         | 37,138         |
| Other contributed capital                                             | 1,425,043      | 1,309,499      | 1,425,208      |
| Reserves                                                              | 663            | 920            | 997            |
| Retained earnings including profit/loss for the period                | -927,394       | -676,045       | -840,247       |
| <b>Total equity attributable to the Parent Company's shareholders</b> | <b>535,451</b> | <b>668,137</b> | <b>623,097</b> |
| <b>Non-current liabilities</b>                                        |                |                |                |
| Lease liabilities                                                     | 24,438         | 29,852         | 27,108         |
| <b>Total non-current liabilities</b>                                  | <b>24,438</b>  | <b>29,852</b>  | <b>27,108</b>  |
| <b>Current liabilities</b>                                            |                |                |                |
| Short-term interest-bearing liabilities                               | 96,000         | -              | 96,000         |
| Trade accounts payable                                                | 9,777          | 6,651          | 17,083         |
| Lease liabilities                                                     | 5,242          | 4,983          | 5,113          |
| Other current liabilities                                             | 9,650          | 11,842         | 9,312          |
| Accrued expenses and deferred income                                  | 16,418         | 14,602         | 18,632         |
| <b>Total current liabilities</b>                                      | <b>137,087</b> | <b>38,078</b>  | <b>146,140</b> |
| <b>TOTAL EQUITY AND LIABILITIES</b>                                   | <b>696,977</b> | <b>736,067</b> | <b>796,344</b> |

# 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    |
|--------------------------------------------------|---------------|---------------------------|-------------|----------------------------------------------------|-----------------|
| <b>Opening balance as of January 1, 2024</b>     | <b>31,253</b> | <b>1,216,093</b>          | <b>792</b>  | <b>-554,724</b>                                    | <b>693,414</b>  |
| <i>Loss of the period</i>                        | <b>0</b>      | <b>0</b>                  | <b>0</b>    | <b>-285,523</b>                                    | <b>-285,523</b> |
| Other comprehensive income for the period        | <b>0</b>      | <b>0</b>                  | <b>205</b>  | <b>0</b>                                           | <b>205</b>      |
| <b>Total comprehensive income for the period</b> | <b>0</b>      | <b>0</b>                  | <b>205</b>  | <b>-285,523</b>                                    | <b>-285,318</b> |
| New share issue                                  | 5,885         | 229,513                   | 0           | 0                                                  | 235,398         |
| Transaction costs                                | <b>0</b>      | -21,519                   | 0           | 0                                                  | <b>-21,519</b>  |
| Warrant program                                  | <b>0</b>      | 1,122                     | 0           | 0                                                  | <b>1,122</b>    |
| <b>Closing balance as of December 31, 2024</b>   | <b>37,138</b> | <b>1,425,208</b>          | <b>997</b>  | <b>-840,247</b>                                    | <b>623,097</b>  |
| <b>Opening balance as of January 1, 2025</b>     | <b>37,138</b> | <b>1,425,208</b>          | <b>997</b>  | <b>-840,247</b>                                    | <b>623,097</b>  |
| <i>Loss of the period</i>                        | -             | -                         | -           | -87,147                                            | <b>-87,147</b>  |
| Other comprehensive income for the period        | -             | -                         | -334        | -                                                  | <b>-334</b>     |
| <b>Total comprehensive income for the period</b> | -             | -                         | <b>-334</b> | <b>-87,147</b>                                     | <b>-87,481</b>  |
| New share issue                                  | -             | -                         | -           | -                                                  | -               |
| Transaction costs                                | -             | -129                      | -           | -                                                  | <b>-129</b>     |
| Warrant program                                  | -             | -36                       | -           | -                                                  | <b>-36</b>      |
| <b>Closing balance as of June 30, 2025</b>       | <b>37,138</b> | <b>1,425,042</b>          | <b>663</b>  | <b>-927,394</b>                                    | <b>535,451</b>  |



# Consolidated statement of cash flow

| SEK thousand                                                                 | Q2             |                | Jan-Jun         |                 | Full year       |
|------------------------------------------------------------------------------|----------------|----------------|-----------------|-----------------|-----------------|
|                                                                              | 2025           | 2024           | 2025            | 2024            | 2024            |
| <b>Operating activities</b>                                                  |                |                |                 |                 |                 |
| Operating loss                                                               | -41,409        | -54,074        | -80,874         | -122,476        | -287,041        |
| <i>Non-cash adjustments</i>                                                  |                |                |                 |                 |                 |
| Depreciation                                                                 | 1,388          | 2,349          | 2,803           | 5,050           | 8,547           |
| Unrealized currency impact                                                   | -              | 41             | -               | -50             | -32             |
| Disposal of inventory                                                        | -              | -              | -               | -               | 29,471          |
| Disposal of tangible fixed assets                                            | -              | 8              | -               | 15              | 22,772          |
| Interest received                                                            | -              | -214           | -               | 2               | 2,240           |
| Interest paid                                                                | -363           | -455           | -3,502          | -876            | -2,913          |
| <b>Cash flow from operating activities before changes in working capital</b> | <b>-40,384</b> | <b>-52,345</b> | <b>-81,573</b>  | <b>-118,335</b> | <b>-226,956</b> |
| <b>Changes in working capital</b>                                            |                |                |                 |                 |                 |
| Change in inventory                                                          | -5,113         | -905           | -14,784         | -726            | -6,025          |
| Change in operating receivables                                              | -389           | 834            | -118            | 1,528           | 1,336           |
| Change in operating liabilities                                              | 1,775          | -11,765        | -13,965         | -1,959          | 9,278           |
| <b>Cash flow from operating activities</b>                                   | <b>-44,111</b> | <b>-64,181</b> | <b>-110,440</b> | <b>-119,492</b> | <b>-222,367</b> |
| <b>Investing activities</b>                                                  |                |                |                 |                 |                 |
| Capitalized development costs                                                | -6,132         | -4,420         | -20,833         | -9,508          | -37,762         |
| Acquisition of property, plant and equipment                                 | -              | -4,318         | -               | -4,379          | -4,380          |
| <b>Cash flow from investing activities</b>                                   | <b>-6,132</b>  | <b>-8,738</b>  | <b>-20,833</b>  | <b>-13,887</b>  | <b>-42,142</b>  |
| <b>Financing activities</b>                                                  |                |                |                 |                 |                 |
| New share issue                                                              | -              | 100,349        | -               | 100,349         | 235,398         |
| Loan raised                                                                  | -              | -              | -               | -               | 96,000          |
| Transaction costs                                                            | -              | -5,017         | -129            | -5,555          | -21,519         |
| Payment of lease liability                                                   | -1,278         | -1,195         | -2,540          | -2,417          | -4,893          |
| Redemption of warrants                                                       | -36            | -              | -36             | -               | -               |
| Repurchased warrants                                                         | -              | -              | -               | -64             | -64             |
| Allocated warrants                                                           | -              | 1,186          | -               | 1,186           | 1,186           |
| <b>Cash flow from financing activities</b>                                   | <b>-1,314</b>  | <b>95,323</b>  | <b>-2,705</b>   | <b>93,499</b>   | <b>306,108</b>  |
| <b>Cash flow for the period</b>                                              | <b>-51,557</b> | <b>22,404</b>  | <b>-133,978</b> | <b>-39,880</b>  | <b>41,599</b>   |
| Cash and cash equivalents at the beginning of the period                     | 125,725        | 104,155        | 208,236         | 166,303         | 166,303         |
| Effect of exchange rate and value changes in cash and cash equivalents       | -361           | 14             | -451            | 150             | 334             |
| <b>Cash and cash equivalents at the end of the period</b>                    | <b>73,807</b>  | <b>126,573</b> | <b>73,807</b>   | <b>126,573</b>  | <b>208,236</b>  |

# Parent Company income statement

|                                                        | Q2             |                | Jan-Jun        |                 | Full year       |
|--------------------------------------------------------|----------------|----------------|----------------|-----------------|-----------------|
| SEK thousand                                           | 2025           | 2024           | 2025           | 2024            | 2024            |
| Net sales                                              | -              | -              | -              | -               | -               |
| Other operating income                                 | 1,313          | 1,849          | 3,235          | 1,983           | 2,096           |
| Research and development expenses                      | -4,694         | -16,056        | -10,141        | -35,500         | -81,982         |
| Administration and sales expenses                      | -38,217        | -38,713        | -74,450        | -86,061         | -201,453        |
| Other operating expenses                               | -401           | -2,052         | -863           | -3,341          | -5,934          |
| <b>Operating loss</b>                                  | <b>-41,999</b> | <b>-54,972</b> | <b>-82,219</b> | <b>-122,919</b> | <b>-287,273</b> |
| Finance income                                         | 306            | 198            | 1,210          | 550             | 2,483           |
| Finance costs                                          | -3,782         | -16            | -7,542         | -16             | -1,929          |
| <b>Finance net</b>                                     | <b>-3,476</b>  | <b>182</b>     | <b>-6,332</b>  | <b>534</b>      | <b>554</b>      |
| Loss before Income tax                                 | -45,475        | -54,790        | -88,551        | -122,385        | -286,719        |
| <b>Loss for the period</b>                             | <b>-45,475</b> | <b>-54,790</b> | <b>-88,551</b> | <b>-122,385</b> | <b>-286,719</b> |
| Earnings per share for the period before dilution, SEK | -2.38          | -1.67          | -2.31          | -3.82           | -8.65           |
| Earnings per share for the period after dilution, SEK  | -2.38          | -1.67          | -2.31          | -3.82           | -8.65           |
| Average number of shares before dilution               | 37,138,491     | 32,742,235     | 37,138,491     | 32,002,001      | 33,137,306      |
| Average number of shares after dilution                | 37,138,491     | 32,742,235     | 37,138,491     | 32,002,001      | 33,137,306      |

# Parent Company balance sheet

| SEK thousand                                    | 30 Jun 2025    | 30 Jun 2024    | 31 Dec 2024    |
|-------------------------------------------------|----------------|----------------|----------------|
| <b>ASSETS</b>                                   |                |                |                |
| <b>Non-current assets</b>                       |                |                |                |
| <b>Intangible assets</b>                        |                |                |                |
| Capitalized development costs                   | 494,821        | 444,835        | 473,481        |
| <b>Total intangible assets</b>                  | <b>494,821</b> | <b>444,835</b> | <b>473,481</b> |
| <b>Property, plant and equipment</b>            |                |                |                |
| Machinery and installations                     | 2,488          | 5,335          | 3,565          |
| Equipment                                       | 1,793          | 2,262          | 2,026          |
| Fixed assets under construction and prepayments | 41,389         | 61,090         | 41,389         |
| <b>Total Property, plant and equipment</b>      | <b>45,671</b>  | <b>68,687</b>  | <b>46,980</b>  |
| <b>Financial assets</b>                         |                |                |                |
| Shares in subsidiaries                          | 2,238          | 2,238          | 2,238          |
| Financial investments                           | 1              | 1              | 1              |
| Other long-term receivables                     | 2,999          | 2,999          | 2,999          |
| <b>Total financial assets</b>                   | <b>5,237</b>   | <b>5,237</b>   | <b>5,237</b>   |
| <b>Total non-current assets</b>                 | <b>545,729</b> | <b>518,759</b> | <b>525,699</b> |
| <b>Current assets</b>                           |                |                |                |
| <b>Inventories</b>                              | <b>35,119</b>  | <b>44,507</b>  | <b>20,335</b>  |
| <b>Current receivables</b>                      |                |                |                |
| Other current receivables                       | 4,398          | 4,372          | 4,299          |
| Prepaid expenses and accrued income             | 4,589          | 3,341          | 3,277          |
| <b>Total current receivables</b>                | <b>8,987</b>   | <b>7,713</b>   | <b>7,576</b>   |
| Cash and bank                                   | 71,195         | 125,339        | 206,682        |
| <b>Total current assets</b>                     | <b>115,301</b> | <b>177,559</b> | <b>234,594</b> |
| <b>TOTAL ASSETS</b>                             | <b>661,030</b> | <b>696,318</b> | <b>760,293</b> |

# Parent Company balance sheet cont.

| SEK thousand                            | 30 Jun 2025    | 30 Jun 2024    | 31 Dec 2024    |
|-----------------------------------------|----------------|----------------|----------------|
| <b>EQUITY AND LIABILITIES</b>           |                |                |                |
| <b>Equity</b>                           |                |                |                |
| <b>Restricted equity</b>                |                |                |                |
| Share capital                           | 37,138         | 33,762         | 37,138         |
| Statutory reserve                       | 976            | 976            | 976            |
| Development expenditure reserve         | 494,821        | 444,835        | 473,481        |
| <b>Total restricted equity</b>          | <b>532,936</b> | <b>479,573</b> | <b>511,596</b> |
| <b>Non-restricted equity</b>            |                |                |                |
| Other contributed capital               | 1,428,043      | 1,312,499      | 1,428,208      |
| Accumulated earnings                    | -1,343,091     | -1,006,386     | -1,035,032     |
| Profit/loss for the period              | -88,551        | -122,385       | -286,719       |
| <b>Total non-restricted equity</b>      | <b>-3,599</b>  | <b>183,728</b> | <b>106,456</b> |
| <b>Total equity</b>                     | <b>529,337</b> | <b>663,302</b> | <b>618,052</b> |
| <b>Current liabilities</b>              |                |                |                |
| Short-term interest-bearing liabilities | 96,000         | -              | 96,000         |
| Trade accounts payable                  | 9,625          | 6,572          | 18,296         |
| Other current liabilities               | 9,650          | 11,842         | 9,312          |
| Accrued expenses and deferred income    | 16,418         | 14,602         | 18,632         |
| <b>Total current liabilities</b>        | <b>131,693</b> | <b>33,016</b>  | <b>142,241</b> |
| <b>TOTAL EQUITY AND LIABILITIES</b>     | <b>661,030</b> | <b>696,318</b> | <b>760,293</b> |

# Parent Company statement of cash flow

| SEK thousand                                                                 | Q2             |                | Jan-Jun         |                 | Full year       |
|------------------------------------------------------------------------------|----------------|----------------|-----------------|-----------------|-----------------|
|                                                                              | 2025           | 2024           | 2025            | 2024            | 2024            |
| <b>Operating activities</b>                                                  |                |                |                 |                 |                 |
| <b>Operating loss</b>                                                        | <b>-41,999</b> | <b>-54,972</b> | <b>-82,219</b>  | <b>-122,919</b> | <b>-287,273</b> |
| <i>Non-cash adjustments</i>                                                  |                |                |                 |                 |                 |
| Depreciation                                                                 | 643            | 1,608          | 1,310           | 3,470           | 5,476           |
| Disposal of inventory                                                        | -              | -              | -               | -               | 29,471          |
| Disposal of tangible fixed assets                                            | -              | -              | -               | 15              | 19,716          |
| Interest received                                                            | -              | -215           | -               | 2               | 2,240           |
| Interest paid                                                                | -1             | -16            | -2,761          | -16             | -1,263          |
| <b>Cash flow from operating activities before changes in working capital</b> | <b>-41,357</b> | <b>-53,595</b> | <b>-83,670</b>  | <b>-119,448</b> | <b>-231,633</b> |
| <b>Changes in working capital</b>                                            |                |                |                 |                 |                 |
| Changes in inventory                                                         | -5,113         | -905           | -14,784         | -726            | -6,025          |
| Change in operating receivables                                              | -488           | 822            | -92             | 1,568           | 1,279           |
| Change in operating liabilities                                              | 143            | -11,763        | -15,329         | -3,718          | 8,837           |
| <b>Cash flow from operating activities</b>                                   | <b>-46,815</b> | <b>-65,441</b> | <b>-113,875</b> | <b>-122,324</b> | <b>-227,542</b> |
| <b>Investing activities</b>                                                  |                |                |                 |                 |                 |
| Purchase of intangible assets                                                | -6,422         | -4,506         | -21,340         | -9,653          | -38,299         |
| Acquisition of property, plant and equipment                                 | -              | -4,318         | -               | -4,379          | -4,379          |
| <b>Cash flow from investing activities</b>                                   | <b>-6,422</b>  | <b>-8,824</b>  | <b>-21,340</b>  | <b>-14,032</b>  | <b>-42,678</b>  |
| <b>Financing activities</b>                                                  |                |                |                 |                 |                 |
| New share issue                                                              | -              | 100,349        | -               | 100,349         | 235,398         |
| Transaction costs                                                            | -              | -5,017         | -129            | -5,555          | -21,519         |
| Loan raised                                                                  | -              | -              | -               | -               | 96,000          |
| Redemption of warrants                                                       | -36            | -              | -36             | -               | -               |
| Repurchased warrants                                                         | -              | -              | -               | -64             | -64             |
| Allocated warrants                                                           | -              | 1,186          | -               | 1,186           | 1,186           |
| <b>Cash flow from financing activities</b>                                   | <b>-36</b>     | <b>96,518</b>  | <b>-165</b>     | <b>95,916</b>   | <b>311,001</b>  |
| <b>Cash flow for the period</b>                                              | <b>-53,273</b> | <b>22,253</b>  | <b>-135,380</b> | <b>-40,440</b>  | <b>40,781</b>   |
| Cash and cash equivalents at the beginning of the period                     | 124,601        | 103,101        | 206,682         | 165,658         | 165,658         |
| Effect of exchange rate and value changes in cash and cash equivalents       | -133           | -15            | -108            | 121             | 243             |
| <b>Cash and cash equivalents at the end of the period</b>                    | <b>71,195</b>  | <b>125,339</b> | <b>71,194</b>   | <b>125,339</b>  | <b>206,682</b>  |

# 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 2024 have been applied.

## 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 2024.

### 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 preferential rights issue and take additional loans during the third quarter of 2025 that could provide net proceeds of a total of SEK 175 million. If Dasynoc® is approved and subsequently launched, the company required to conduct the operations forward.

The company's capital requirements depend on several factors, including the launch date of its first product candidate, Dasynoc®, and the earnings from and costs for ongoing and future drug studies.

In light of this, the Board is monitoring the situation and is evaluating different financing options including timing and scope for raising capital that can be beneficial to the company. The Board believes that the prospects for raising capital are good. However, if financing is insufficient, this indicates material uncertainty, which could lead to significant doubts on the Group's ability 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, August 15, 2025

Anders Ekblom  
*Chairman*

Anders Bladh  
*Board member*

Robert Molander  
*Board member*

Markus Haeberlein  
*Board member*

Anne Prener  
*Board member*

Christine Lind  
*Board member*

Carl-Johan Spak  
*Board member*

Per Andersson  
*CEO*

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



# Glossary

|                                        |                                                                                                                                                                                                                                                                                                                |
|----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>505(b)(2) NDA</b>                   | Application for drug approval in the US for an improved version of an approved drug.                                                                                                                                                                                                                           |
| <b>Amorphous</b>                       | An amorphous structure is a chemical term that describes substances whose molecules lack an ordered structure.                                                                                                                                                                                                 |
| <b>Bioavailability</b>                 | (Biological availability), a concept in pharmacology that shows how large a portion of the drug reaches the blood.                                                                                                                                                                                             |
| <b>Bioequivalence</b>                  | Term used to describe whether two different drugs are processed in a similar manner by the body and are thereby expected to have a similar and equivalent medicinal effect. If it can be confirmed that two drugs being compared are bioequivalent, they can be expected to have the same efficacy and safety. |
| <b>Crystalline</b>                     | A crystalline structure is a chemical term that describes an ordered structure among the molecules of the substance.                                                                                                                                                                                           |
| <b>FDA</b>                             | Food and Drug Administration. The US food and drug authority responsible for foodstuffs, nutritional supplements, drugs, cosmetics, medical equipment, radiation-emitting equipment and blood products.                                                                                                        |
| <b>PDUFA date</b>                      | A target date that the US Food and Drug Administration has set for making a decision on a new drug (Prescription Drug User Fee Act).                                                                                                                                                                           |
| <b>Pilot study</b>                     | An initial study conducted on a smaller scale than a pivotal study. A pilot study can be used both to check whether the arrangement of the study is a functional one, and to collect data that can later be used as control values in the full study.                                                          |
| <b>Pivotal study</b>                   | A study whose results can be used in an application for approval from a medical products authority.                                                                                                                                                                                                            |
| <b>Protein kinase inhibitor (PKI)</b>  | Drugs that block protein kinases. Protein kinase inhibitors work by blocking activity in enzymes that push the development and growth of cancer cells.                                                                                                                                                         |
| <b>Proton-pump inhibitor (PPI)</b>     | 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.                                                                                                                                                                       |
| <b>Tyrosine kinase inhibitor (TKI)</b> | Tyrosine kinase inhibitors are a subgroup of protein kinase inhibitors. This cancer drug group blocks growth-stimulating signals within the cells.                                                                                                                                                             |
| <b>Variability</b>                     | The scope of the distribution in the form of low and high values around the average value as regards the body's uptake of drugs.                                                                                                                                                                               |

For more information,  
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