

Interim Report  
October – December 2023





## Overview – company vision

Financial and operational vision through 2030

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

### October–December 2023, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -54,513 thousand (-55,220)
- Earnings per share before dilution amounted to SEK -1.85 (-2.48)
- Cash flow from operating activities amounted to SEK -32,626 thousand (-35,003)
- Cash flow from investing activities amounted to SEK -20,729 thousand (-29,481)

### January–December 2023, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -179,684 thousand (-131,670)
- Earnings per share before dilution amounted to SEK -6.76 (-6.25)
- Cash flow from operating activities amounted to SEK -203,275 thousand (-110,179)
- Cash flow from investing activities amounted to SEK -65,876 thousand (-135,345)

Amounts in parentheses refer to the year-earlier period.

### Significant events during the quarter

- Xspray Pharma published a registry study in the European Journal of Haematology demonstrating that nearly half of CML patients treated with tyrosine kinase inhibitors (TKIs) take proton pump inhibitors (PPIs) concurrently. The study also indicated a higher risk of patient mortality during treatment in this group compared to a group not receiving concurrent PPI treatment. This can be mitigated with Xspray's enhanced amorphous dasatinib formulation, Dasynoc®, which has demonstrated in a clinical trial that its concentration in the blood was not affected by co-administration of the PPI.
- Xspray Pharma has demonstrated that the uptake of Dasynoc® in the blood is unchanged when omeprazole, a PPI, is taken, whereas the uptake of Sprycel® is significantly lower than previously shown.
- Xspray Pharma published the results of a study with product candidate XS003, Xspray's amorphous non-crystalline version of nilotinib. The results show bioavailability within the 80–125% range in relation to Tassigna® with significantly lower dose.
- Xspray Pharma announced the outcome of the TO5 series of warrants. In total, 2,307,242 warrants of series TO5 were exercised for subscription of an equal number of new shares. Xspray Pharma thereby received issue proceeds of SEK 92.3 million.

### Significant events after the end of the reporting period

- Xspray Pharma appointed Michael af Winklerfelt as acting CFO, started on February 8th.
- Xspray Pharma was assigned a PDUFA date, July 31, 2024, by the FDA, which refers to the FDA's deadline for completing the approval process of Dasynoc®.

Key figures, Group	Q4		Jan-Dec	
	2023	2022	2023	2022
Net sales (SEK thousand)	-	-	-	-
Loss before Income tax (SEK thousand)	-54,513	-55,220	-179,684	-131,670
Earnings per share before dilution (SEK)	-1.85	-2.48	-6.76	-6.25
Earnings per share after dilution (SEK)	-1.85	-2.48	-6.76	-6.25
Research and development expenses as % of operating expenses 1)	22%	30%	19%	16%
Cash and cash equivalents (SEK thousand)	166,303	120,166	166,303	120,166
Total assets (SEK thousand)	765,263	585,430	765,263	585,430
Equity/assets ratio (%)	91%	95%	91%	95%
Average number of employees	26	27	26	25

1) Alternate key performance indicators for assessing the degree of development of the company's product candidates. Refer to the company's annual report for more information on key performance indicators.



## A message from the CEO



Dear shareholders,

We continue to make significant progress on our journey towards the commercialization of our groundbreaking product – Dasynoc®. Dasynoc® may offer potential benefits beyond the currently only available dasatinib-product on the market, Sprycel®. Including increased precision of dosage and allowing cancer patients to simultaneously take medications that elevate stomach pH, such as omeprazol. We have commissioned market research, which reported promising results, together with our commercialization partner EVERSANA, signaling positive prospects for patients, providers, payors, and ultimately, Xspray's shareholders. Sprycel® reported sales of USD 1.45 billion in 2023. If approved, our planned launch is in September 2024. We recently responded to the FDA's Complete Response Letter and received a PDUFA date of July 31, 2024. We look forward with confidence to the regulatory approval of Dasynoc®. Our primary focus is now on continuing the efforts to prepare for a successful US launch on September 1, 2024.

I am also pleased to report progress with our second product candidate, XS003 nilotinib, where study results demonstrate comparable bioavailability to Tassigna®, but achieved with a significantly lower dose using our amorphous formula. We continue to conduct the remaining studies with the goal of submitting a marketing approval application to the FDA for XS003 upon completion of the studies.



## **New time plan confirmed by FDA following response to CRL**

After receiving a Complete Response Letter (CRL) from FDA last year with requests for additional information, we have conducted relatively extensive work to assemble a response. This was primarily related to providing supplementary information for physicians and patients regarding the dosage of Dasynoc® for the six different dosage strengths for Dasynoc® (15 mg, 36 mg, 50 mg, 57 mg, 70 mg and 100 mg). We have developed Dasynoc® to feature 30 percent lower dosage strength than Sprycel®, made possible by the improved bioavailability of Dasynoc® in the body, unaffected by the stomach's pH value. In order to ensure that information to physicians is clear and cannot be misunderstood we needed to perform an extensive and time-consuming physician survey, which delayed our response. The FDA also requested certain information about a third-party manufacturing facility in Italy. At the same time, the FDA had no comments on such critical aspects as stability or clinical data.

We submitted complete answers on all outstanding questions and after the period we registered our complementary application with the FDA, and a new so called PDUFA date was set to July 31, 2024. This date is the agency's own deadline for its approval process and decision. Therefore, we keep our timetable for the launch, on September 1.

We are confident that the FDA's review will result in approval to market Dasynoc® as an improved version of dasatinib for the treatment of CML and ALL. We will now be focusing entirely on ensuring a successful market launch of Dasynoc®.

## **New proof of Dasynoc's product benefits**

During the past quarter, we were able to present additional evidence of Dasynoc's advantages. We published a study in the European Journal of Haematology showing that CML patients are often concurrently treated with tyrosine kinase inhibitors (TKIs) and proton-pump inhibitors (PPI), which can increase the risk of poorer treatment outcomes. This is despite the original medications having warning labels cautioning against concurrent treatment with PPIs. Once again, this study shows that Dasynoc® has a key function to fulfill by facilitating simultaneous treatment for peptic ulcers, among others.

During the quarter, we demonstrated in one study that when Sprycel® is administered together with omeprazole, a common treatment of peptic ulcers, the body's uptake of Sprycel® is significantly reduced. If Sprycel® is administered 10 hours after omeprazole, uptake of the active substance dasatinib was only 12 percent. Previous studies that supported approval of Sprycel® also showed that the uptake of dasatinib decreases with simultaneous treatment of peptic ulcers, but the effect that was demonstrated was more limited than in our study. These earlier studies revealed that only 57% of the intended uptake of dasatinib was absorbed when Sprycel® was administered 22 hours after omeprazole. So, our study highlights that the treatment of peptic ulcers has a greater effect on uptake of dasatinib than was previously known.

Our study with Dasynoc® further demonstrated that uptake of dasatinib was not affected by the administration of Dasynoc® 10 hours after the intake of omeprazole (107 percent of the intended AUC<sub>0-24h</sub>). This collectively enhances our competitiveness as we launch Dasynoc®.

## **Financing**

During the quarter, the subscription period for the TO5 series of warrants ended. These warrants provided existing shareholders in Xspray Pharma with the opportunity to subscribe for new Xspray shares at a subscription price of SEK 40. All together, 74 percent of the warrants were exercised to subscribe for new shares in the company, which thereby raised SEK 92 million before transaction costs for the company. The proceeds received from the warrants will be used for the US launch of Dasynoc® and to continue advances in the development of the company's pipeline. It is pleasing that so many of our both smaller and larger owners invested new capital to fund our commercialization plan despite tough financial market conditions.

Later in the year, it will be possible to also use the warrants of series TO6 to subscribe for new shares in Xspray Pharma on the same terms as TO5. The subscription period for TO6 runs from April 18 to May 2, 2024. If TO6 is fully subscribed, Xspray Pharma will raise an additional SEK 125 million.

## **Positive results in the XS003 study**

During the quarter, we published the results for our product candidate XS003, Xspray's amorphous non-crystalline version of nilotinib. The results show bioavailability within the desired 80–125% range in relation to Tasigna®, thus matching the originator but with a significantly lower dose of XS003. The company continues to complete remaining studies, with the goal of submitting an application to the FDA for market approval of XS003 as soon as the studies are completed.

During the quarter, we moved to our new head office at Campus Solna – one of the world's strongest life science clusters. This provides us with access to state-of-the-art laboratory environments and offices, enabling continued growth of our operations.

We are heading into an exciting year, and I look forward to Xspray Pharma proceeding to the next stage of its journey to become a commercial, profitable pharmaceutical company and a global leader in enhanced versions of established protein kinase inhibitors.

Per Andersson  
CEO, Xspray Pharma



# 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 2022. 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 as of September 1, 2024 when the company launches its initial product, Dasynoc®, in the US market, which is conditional on final FDA approval. Further information on Dasynoc® is available under the Product candidate section on page 18.

## Other operating income

Other operating income was SEK 1,304 thousand (1,081) for the fourth quarter and SEK 31,767 thousand (2,180) for the January–December period. This item is attributable to the legal proceedings in the US as well as advisory services and development efforts performed by Xspray. Other operating income also 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 -25,863 thousand (-41,663), of which SEK -12,488 thousand (-17,099) was recognized as an expense in profit or loss and SEK -13,375 thousand (-24,564) was capitalized as development expenditure and presented in the company's balance sheet. The comparative figures from the preceding year regarding development expenditures recognized as expenses contain a disposal of SEK -15,472 thousand pertaining to the XS005-sorafenib project. For the January–December period, the total expenditure for research and development was SEK -91,442 thousand (-127,052), with SEK -40,259 thousand (-22,219) expensed and SEK -51,183 thousand (-104,834) capitalized as development expenditure. A large part of the expenditure for research and development in the quarter was expensed since Dasynoc® is in a new commercial phase, with validation efforts and other consulting not having been capitalized. Costs are also attributable to the company's two other product candidates, XS003 nilotinib and XS008 axitinib.

## Administration and sales expenses

Administration and sales expenses totaled SEK -43,988 thousand (-38,824) in the fourth quarter. Of these, personnel costs amounted to SEK -9,381 thousand (-9,251). During the quarter, limited operations in the US subsidiary have started. Administration and sales expenses for the January–December period totaled SEK -169,567 thousand (-109,601) with SEK -36,452 thousand (-29,177) pertaining to personnel costs. The cost for the fourth quarter was attributable primarily to the company's continued market preparation activities as a result of the impending launch in the US.

## Other operating expenses

Other operating expenses totaled SEK -676 thousand (-745) for the fourth quarter and SEK -3,675 thousand (-3,433) for the January–December period. This item comprised exchange rate losses arising in conjunction with payments abroad and translations of the currency accounts.

## Loss for the period

Loss for the period totaled SEK -54,496 thousand (-55,220) for the fourth quarter and SEK -179,667 thousand (-131,670) for the January–December period. This corresponds to earnings per share before dilution of SEK -1.85 (-2.48) for the quarter and SEK -6.76 (-6.25) for the full year. The earnings decrease for the full year is attributable primarily to increased administration and sales expenses as a result of the market preparation activities stemming from the forthcoming launch in the US. In addition, expenditure for research and development was expensed owing to preparatory activities for Dasynoc®.

## Cash flow

Cash flow from operating activities amounted to SEK -32,626 thousand (-35,003) in the quarter, of which the effect from working capital was SEK 20,806 thousand (1,901). The aggregate figure for the January–December period was SEK -203,275 thousand (-110,179), in which the effect from working capital was SEK 3,648 thousand (-3,575). The effect from working capital is linked primarily to changes in stock of SEK -37,509 thousand (—) and changes in operating receivables of SEK 64,713 thousand (-3,493). The negative cash flow for operating activities is in accordance with the company's plan, and is primarily attributable to continued project costs, legal advisory services and other preparatory activities prior to the company's forthcoming launch of Dasynoc®.

Cash flow from investing activities amounted to SEK -20,729 thousand (-29,481) in the fourth quarter and SEK -65,876 thousand (-135,345) for the January–December period. The item includes capitalized development expenditure of SEK -12,760 thousand (-24,317) for the fourth quarter and SEK -49,855 thousand (-103,820) for the January–December period. The main reason for the decrease is that Dasynoc® has now moved from a research and development-intensive project to preparatory activities ahead of the launch of Dasynoc®, with costs not being capitalized but expensed on an ongoing basis.

New investments in property, plant and equipment totaled SEK -2,615 thousand (-1,132) in the fourth quarter. During the quarter, the company invested in fixed assets related to the relocation of the head office.



Cash flow from financing activities in the fourth quarter amounted to SEK 87,484 thousand (94,816) and SEK 315,594 thousand (93,809) for the January–December period. The increase for the quarter is due to the issue proceeds from the TO5 series of warrants. The full year also includes the issue proceeds from the preferential rights issue that was concluded in July.

Total cash flow was SEK 34,129 thousand (30,332) for the fourth quarter and SEK 46,443 thousand (-151,715) for the January–December period. The Group had SEK 166,303 thousand (120,166) in cash and cash equivalents at December 31, 2023.

#### Assets

Capitalized development expenditures for the fourth quarter totaled SEK 13,375 thousand (24,564). The Group's total capitalized expenditure for development amounted to SEK 436,780 thousand (385,597) on December 31, 2023. The item is associated with the company's product candidates Dasynoc®, XS003 nilotinib and XS008 axitinib.

During the quarter, the company increased its right-of-use assets as a result of new premises for the company's head office, which also increased the lease liabilities.

#### Financial position

The TO5 series of warrants, which was announced in May, was completed in November. The issue generated proceeds of SEK 92,290 thousand before transaction costs for Xspray.

The TO6 series of warrants, which was announced in conjunction with TO5, will mature in May 2024. This could raise approximately a further SEK 125,318 thousand upon full subscription and would yield a maximum dilution of 10.0 percent for existing shareholders.

Depending on the outcome of the TO6 warrant series, and other types of financing, there is a risk that the Group's cash and cash equivalents for the next twelve months will be insufficient. The company's capital requirement depends on several factors including market uptake of its initial product candidate, Dasynoc®, as well as the earnings from and costs for ongoing and future drug trials. In light of this, the Board of Directors is monitoring the situation and evaluating different financing options including the timing and scope for raising potential capital on the most advantageous terms possible. The Board of Directors believes that the outlook for raising capital is good.

The equity/assets ratio for the Group was 90.6 percent (95.0) on December 31, 2023.

#### Group structure

The Group structure comprises the Parent Company, Xspray Pharma AB (publ), corporate identity number 556649-3671, and its wholly owned subsidiaries Xspray Pharma Futurum AB, corporate identity number 559178-7642, and Xspray Pharma Inc. The two Swedish limited liability companies have their offices in Solna, Sweden, and the US subsidiary has its offices in Delaware. The address of the head office is 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 165,658 thousand (120,116) and the equity/assets ratio was 94.9 percent (95.3) at December 31, 2023.

#### Employees

The organization shrank by three full-time positions in the quarter compared with the preceding quarter, due to the shifting of certain tasks that were previously handled internally are now being performed by our contracted partners in the US. The number of employees in the Group on the balance sheet date totaled 26 (27).

#### Related-party transactions

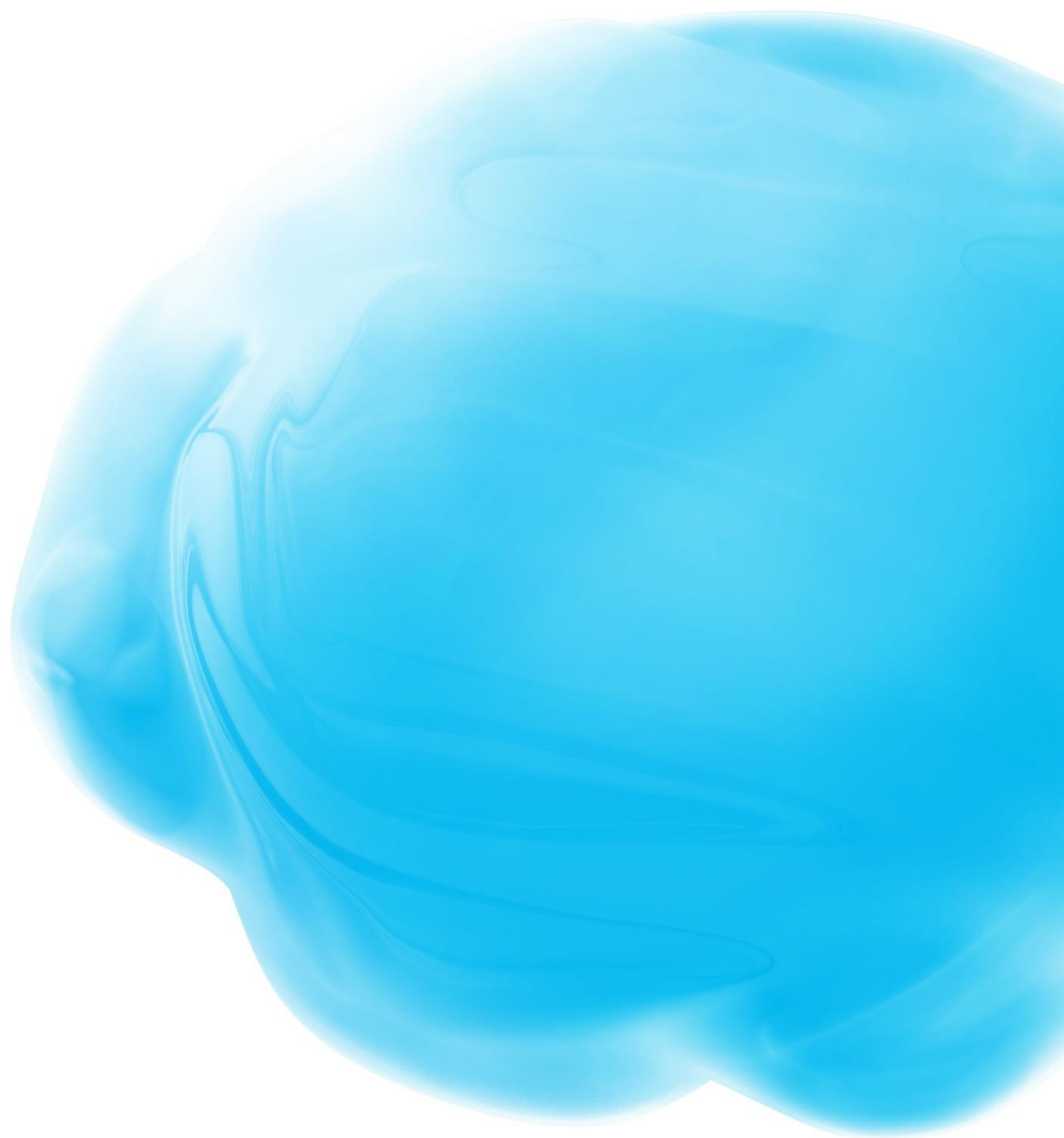
Related parties are defined as the management group in the Parent Company and the Boards of Directors in the Parent Company or subsidiaries. Purchase of services from senior executives pertain to consultant fees from InterCon HB, owned by Andreas Konar, who is part of the company's management group. The total fees amounted to SEK -228 thousand (-252) for the fourth quarter and SEK -984 thousand (-756) for the January–December period.

The company purchased consulting services from Stratfox Healthcare Group LLC, which is owned by the company's Board member Robert Molander. The total fees amounted to SEK -107 thousand (—) for the fourth quarter and SEK -532 thousand (—) for the January–December period.



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# Financial statements





# Consolidated income statement

<i>SEK thousand</i>	Q4		Jan-Dec	
	2023	2022	2023	2022
Net sales	-	-	-	-
Other operating income	1,304	1,081	31,767	2,180
Research and development expenses	-12,488	-17,099	-40,259	-22,219
Administration and sales expenses	-43,988	-38,824	-169,567	-109,601
Other operating expenses	-676	-745	-3,675	-3,433
<b>Operating loss</b>	<b>-55,848</b>	<b>-55,587</b>	<b>-181,734</b>	<b>-133,073</b>
Finance income	1,335	367	2,725	1,415
Finance costs	-	-0	-675	-12
<b>Finance net</b>	<b>1,335</b>	<b>367</b>	<b>2,049</b>	<b>1,403</b>
Loss before Income tax	-54,513	-55,220	-179,684	-131,670
Tax	17	-	17	-
<b>Loss for the period</b>	<b>-54,496</b>	<b>-55,220</b>	<b>-179,667</b>	<b>-131,670</b>
Earnings per share for the period before dilution, SEK	-1.85	-2.48	-6.76	-6.25
Earnings per share for the period after dilution, SEK	-1.85	-2.48	-6.76	-6.25
Average number of shares before dilution	29,523,111	22,223,886	26,593,910	21,070,518
Average number of shares after dilution	29,523,111	22,223,886	26,593,910	21,070,518

# Consolidated statement of comprehensive income

<i>SEK thousand</i>	Q4		Jan-Dec	
	2023	2022	2023	2022
Loss for the period	-54,496	-55,220	-179,667	-131,670
Annual translation differences in the translation of foreign operations	-184	-	-184	-
<b>Total comprehensive income for the period</b>	<b>-54,680</b>	<b>-55,220</b>	<b>-179,851</b>	<b>-131,670</b>

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





# Consolidated balance sheet

<i>SEK thousand</i>	31 Dec 2023	31 Dec 2022
<b>ASSETS</b>		
<i>Non-current assets</i>		
<i>Intangible assets</i>		
Capitalized development costs	436,780	385,597
<b>Total intangible assets</b>	<b>436,780</b>	<b>385,597</b>
<i>Property, plant and equipment</i>		
Machinery and installations	8,581	15,407
Right-of-use assets	37,649	2,477
Equipment	2,056	147
Fixed assets under construction and prepayments	59,365	46,573
<b>Total Property, plant and equipment</b>	<b>107,651</b>	<b>64,603</b>
<i>Financial assets</i>		
Financial investments	1	1
Other long-term receivables	3,016	2,999
<b>Total financial assets</b>	<b>3,017</b>	<b>3,000</b>
<b>Total non-current assets</b>	<b>547,448</b>	<b>453,200</b>
<i>Current assets</i>		
Inventories	43,781	8,552
Current receivables	4,165	2,362
Prepaid expenses and accrued income	3,566	1,150
Cash and cash equivalents	166,303	120,166
<b>Total current assets</b>	<b>217,815</b>	<b>132,229</b>
<b>TOTAL ASSETS</b>	<b>765,263</b>	<b>585,430</b>



# Consolidated balance sheet cont.

<i>SEK thousand</i>	31 Dec 2023	31 Dec 2022
<b><i>EQUITY AND LIABILITIES</i></b>		
<b><i>Equity</i></b>		
Share capital	31,254	22,680
Other contributed capital	1,216,092	907,420
Reserves	792	976
Retained earnings including profit/loss for the period	-554,724	-375,057
<b>Total equity attributable to the Parent Company's shareholders</b>	<b>693,413</b>	<b>556,019</b>
<b><i>Non-current liabilities</i></b>		
Lease liabilities	31,947	560
<b>Total non-current liabilities</b>	<b>31,947</b>	<b>560</b>
<b><i>Current liabilities</i></b>		
Trade accounts payable	12,472	14,786
Lease liabilities	4,861	1,566
Other current liabilities	6,263	1,043
Accrued expenses and deferred income	16,307	11,456
<b>Total current liabilities</b>	<b>39,903</b>	<b>28,851</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>765,263</b>	<b>585,430</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
Opening balance as of January 1, 2022	20,680	813,483	976	-243,387	591,752
<i>Loss of the period</i>	-	-	-	-131,670	-131,670
Other comprehensive income for the period	-	-	-	-	-
<b>Total comprehensive income for the period</b>	-	-	-	-131,670	-131,670
New share issue	2,000	98,000	-	-	100,000
Transaction costs	-	-4 876	-	-	-4,876
Redemption of warrants	-	-52	-	-	-52
Warrant program	-	865	-	-	865
<b>Closing balance as of December 31, 2022</b>	<b>22,680</b>	<b>907,420</b>	<b>976</b>	<b>-375,057</b>	<b>556,019</b>
<b>Opening balance as of January 1, 2023</b>	<b>22,680</b>	<b>907,420</b>	<b>976</b>	<b>-375,057</b>	<b>556,019</b>
<i>Loss of the period</i>	-	-	-	-179,667	-179,667
Other comprehensive income for the period	-	-	-184	-	-184
<b>Total comprehensive income for the period</b>	-	-	-	-179,667	-179,667
New share issue	8,573	334,352	-	-	342,925
Transaction costs	-	-26,201	-	-	-26,201
Warrant program	-	522	-	-	522
<b>Closing balance as of December 31, 2023</b>	<b>31,253</b>	<b>1,216,093</b>	<b>792</b>	<b>-554,725</b>	<b>693,413</b>



# Consolidated cash flow statement

SEK thousand	Q4		Jan-Dec	
	2023	2022	2023	2022
<b>Operating activities</b>				
Operating loss	-55,848	-55,587	-181,734	-133,073
<i>Non-cash adjustments</i>				
Depreciation	2,449	2,426	9,194	9,533
Unrealized currency impact	41	-	41	-
Disposal of intangible fixed assets	-	15,472	-	15,472
Disposal of tangible fixed assets	5	-	5	-
Interest received	1,138	812	1,969	1,611
Interest paid	-439	-27	-1,169	-147
<b>Cash flow from operating activities before changes in working capital</b>	<b>-52,654</b>	<b>-36,904</b>	<b>-171,694</b>	<b>-106,604</b>
<b>Changes in working capital</b>				
Change in inventory	-778	-	-35,229	-
Change in operating receivables	27,982	-3,493	-4,109	-2,942
Change in operating liabilities	-7,176	5,394	7,757	-633
<b>Cash flow from operating activities</b>	<b>-32,626</b>	<b>-35,003</b>	<b>-203,275</b>	<b>-110,179</b>
<b>Investing activities</b>				
Capitalized development costs	-12,760	-24,317	-49,855	-103,820
Acquisition of property, plant and equipment	-2,615	-1,132	-2,692	-24,466
Prepayments of Right-of-Use-Assets	-1,556	-	-1,556	-
Prepayments	-3,798	-4,032	-11,773	-7,059
<b>Cash flow from investing activities</b>	<b>-20,729</b>	<b>-29,481</b>	<b>-65,876</b>	<b>-135,345</b>
<b>Financing activities</b>				
New share issue	92,288	100,000	297,924	100,000
Loan raised*	-	-	45,000	-
Transaction costs	-4,611	-4,576	-26,201	-4,876
Payment of lease liability	-193	-556	-1,651	-2,128
Repurchased warrants	-	-52	-	-52
Allocated warrants	-	-	522	865
<b>Cash flow from financing activities</b>	<b>87,484</b>	<b>94,816</b>	<b>315,594</b>	<b>93,809</b>
<b>Cash flow for the period</b>	<b>34,129</b>	<b>30,332</b>	<b>46,443</b>	<b>-151,715</b>
Cash and cash equivalents at the beginning of the period	132,480	89,834	120,166	271,881
Effect of exchange rate and value changes in cash and cash equivalents	-306	-	-306	-
<b>Cash and cash equivalents at the end of the period</b>	<b>166,303</b>	<b>120,166</b>	<b>166,303</b>	<b>120,166</b>

\*During the third quarter, SEK 45,000 thousand from loan raised was contributed to the set-off issue.



# Parent Company income statement

<i>SEK thousand</i>	Q4		Jan-Dec	
	2023	2022	2023	2022
Net sales	-	-	-	-
Other operating income	1,206	1,081	31,669	2,180
Research and development expenses	-12,909	-17,194	-41,100	-22,592
Administration and sales expenses	-44,292	-38,852	-169,705	-109,710
Other operating expenses	-596	-767	-3,633	-3,500
<b>Operating loss</b>	<b>-56,592</b>	<b>-55,733</b>	<b>-182,769</b>	<b>-133,622</b>
Finance income	1,061	142	1,664	617
Finance costs	-0	-0	-675	-12
<b>Finance net</b>	<b>1,061</b>	<b>142</b>	<b>988</b>	<b>605</b>
Loss before Income tax	-55,530	-55,591	-181,781	-133,017
Tax	-	-	-	-
<b>Loss for the period</b>	<b>-55,530</b>	<b>-55,591</b>	<b>-181,781</b>	<b>-133,017</b>



# Parent Company balance sheet

<i>SEK thousand</i>	31 Dec 2023	31 Dec 2022
<b>ASSETS</b>		
<b>Non-current assets</b>		
<b>Intangible assets</b>		
Capitalized development costs	435,182	384,944
<b>Total intangible assets</b>	<b>435,182</b>	<b>384,944</b>
<b>Property, plant and equipment</b>		
Machinery and installations	8,581	15,407
Equipment	2,056	147
Fixed assets under construction and prepayments	57,156	45,383
<b>Total Property, plant and equipment</b>	<b>67,793</b>	<b>60,936</b>
<b>Financial assets</b>		
Shares in subsidiaries	2,238	50
Financial investments	1	1
Other long-term receivables	2,999	2,999
<b>Total financial assets</b>	<b>5,237</b>	<b>3,050</b>
<b>Total non-current assets</b>	<b>508,213</b>	<b>448,930</b>
<b>Current assets</b>		
<b>Inventories</b>	<b>43,781</b>	<b>8,552</b>
<b>Current receivables</b>		
Other current receivables	4,364	2,362
Prepaid expenses and accrued income	4,491	1,632
<b>Total current receivables</b>	<b>8,855</b>	<b>3,994</b>
Cash and bank	165,658	120,116
<b>Total current assets</b>	<b>218,294</b>	<b>132,661</b>
<b>TOTAL ASSETS</b>	<b>726,507</b>	<b>581,592</b>



## Parent Company balance sheet cont.

<i>SEK thousand</i>	31 Dec 2023	31 Dec 2022
<b>EQUITY AND LIABILITIES</b>		
<b>Equity</b>		
<i>Restricted equity</i>		
Share capital	31,254	22,680
Statutory reserve	976	976
Development expenditure reserve	435,182	384,944
<b>Total restricted equity</b>	<b>467,412</b>	<b>408,601</b>
<i>Non-restricted equity</i>		
Other contributed capital	1,219,092	907,420
Accumulated earnings	-814,952	-628,697
Profit/loss for the period	-181,781	-133,017
<b>Total non-restricted equity</b>	<b>222,358</b>	<b>145,705</b>
<b>Total equity</b>	<b>689,771</b>	<b>554,306</b>
<i>Current liabilities</i>		
Trade accounts payable	14,166	14,786
Other current liabilities	6,263	1,043
Accrued expenses and deferred income	16,307	11,456
<b>Total current liabilities</b>	<b>36,736</b>	<b>27,285</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>726,507</b>	<b>581,592</b>



# Parent Company cash flow statement

SEK thousand	Q4		Jan-Dec	
	2023	2022	2023	2022
<b>Operating activities</b>				
Operating loss	-56,592	-55,733	-182,769	-133,622
Non-cash adjustments				
Depreciation	1,883	2,111	7,604	8,341
Disposal of intangible fixed assets	-	15,472	-	15,472
Disposal of tangible fixed assets	5	-	5	-
Interest received	1,926	586	1,969	647
Interest paid	-	-	-675	-12
<b>Cash flow from operating activities before changes in working capital</b>	<b>-52,778</b>	<b>-37,564</b>	<b>-173,866</b>	<b>-109,174</b>
<b>Changes in working capital</b>				
Changes in inventory	-778	-	-35,229	-
Change in operating receivables	26,302	-3,245	-4,861	-1,911
Change in operating liabilities	-5,449	5,395	9,450	-631
<b>Cash flow from operating activities</b>	<b>-32,703</b>	<b>-35,413</b>	<b>-204,506</b>	<b>-111,716</b>
<b>Investing activities</b>				
Purchase of intangible assets	-12,840	-24,463	-50,238	-104,411
Acquisition of property, plant and equipment	-2,616	-1,132	-2,693	-24,466
Group contributions	-2,188	-	-2,188	-
Prepayments	-3,798	-4,032	-11,773	-7,059
<b>Cash flow from investing activities</b>	<b>-21,442</b>	<b>-29,627</b>	<b>-66,892</b>	<b>-135,936</b>
<b>Financing activities</b>				
New share issue	92,288	100,000	297,924	100,000
Transaction costs	-4,611	-4,576	-26,201	-4,876
Loan raised*	-	-	45,000	-
Repurchased warrants	-	-52	-	-52
Allocated warrants	-	-	522	865
<b>Cash flow from financing activities</b>	<b>87,677</b>	<b>95,372</b>	<b>317,245</b>	<b>95,937</b>
<b>Cash flow for the period</b>	<b>33,532</b>	<b>30,332</b>	<b>45,847</b>	<b>-151,715</b>
Cash and cash equivalents at the beginning of the period	132,430	89,784	120,116	271,831
Effect of exchange rate and value changes in cash and cash equivalents	-305	-	-305	-
<b>Cash and cash equivalents at the end of the period</b>	<b>165,658</b>	<b>120,116</b>	<b>165,658</b>	<b>120,116</b>

\*During the third quarter, SEK 45,000 thousand from loan raised was contributed to the set-off issue.





# Notes

## Note 1. Accounting and measurement policies

The interim report for the Group has been prepared in accordance with IAS 34 Interim Financial Reporting, issued by the International Accounting Standards Board (IASB) and with the applicable provisions in the Swedish Annual Accounts Act. The interim report for the Parent Company has been prepared in accordance with Chapter 9, "Interim Reports", of the Annual Accounts Act. For the Parent Company and the Group, the same accounting policies and bases for calculation as in the Annual Report for 2022 have been applied. The changes in IFRS applied as of January 1, 2023 have not had any impact on the financial statements for the fourth quarter of 2023. Comparison figures are presented in parentheses and pertain to the same period in 2022.

## 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 testing involves estimating future cash flows attributable to the asset, or to the cash-generating unit that the asset will be attributed to, once it is complete. These estimates and assumptions encompass expectations pertaining primarily to the selling price of the products, market penetration, and remaining development, sales and marketing costs as well as the probability that the product will successfully pass through the remaining development stages. The assumptions involve industry- and market-specific data produced by corporate management and reviewed by the Board of Directors.

### Material risks and uncertainties

Xspray Pharma's operation is associated with both industry-related and company-specific risks. The company develops product candidates, and there will always be regulatory, market-related and financial risks in the operation. Otherwise, the risks and uncertainties that the company reported in the Annual Report for 2022 remain.

### Financing risk and going concern

The TO5 warrant series, which was announced in May, was completed in November. The issue generated proceeds of approximately SEK 92.3 million before transaction costs for Xspray. The remaining series of warrants, TO6, matures on May 2, 2024 and has a subscription price of SEK 40 per share. TO6 could raise approximately a further SEK 125.3 million upon full subscription, with a maximum dilution of 10.0 percent on the current number of shares outstanding. The reason for including warrants in the offering was to increase visibility for investors since the warrants could be exercised at a later point in time when the company is expected to have achieved key milestones. The capital raised will be used to finance preparations ahead of the planned launch of Dasynoc® in the US as well as general corporate purposes, ongoing operating costs and the continued development of the company's product candidates.

Depending on the outcome of the TO6 warrant series and other types of financing, the Group's cash and cash equivalents for the next 12 months could be insufficient. The company's capital requirements depend on several factors including market uptake of its initial product candidate, Dasynoc®, and the earnings from and costs for ongoing and future product development. In light of this, the Board of Directors routinely monitors the company's capital situation and evaluates various financing alternatives. If the financing secured is not sufficient, it would suggest material uncertainties that could lead to significant doubt regarding the company's capacity to continue its operations. In accordance with the policy by the Board of Directors, the Group must maintain a strong financial position, which will help the company retain investor and market confidence. This will further facilitate the development of company operations, with continued long-term support for a desirable dividend for the company's owners. Until the company has achieved long-term and sustainable profitability, it is the company's policy to maintain a low level of indebtedness and a high level of equity.

### Definitions of key performance indicators

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



# Xspray Pharma in brief

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

Using the company's innovative technology, Xspray Pharma can step in as the first competitor to the current original drugs before the originator company's secondary patents expire and the market opens up to generics, and in part over time offer substances with improved functionality compared with the original drugs. Xspray Pharma's goal is to be a leader in developing drugs that are improvements to PKIs being sold for the treatment of cancer, of which there were just over 80 in the US at the end of 2023.

## Market

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

## Product candidates

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

The original drugs have secondary patents expiring between 2026 and 2032, and their total annual sales for 2023 exceeded USD 3.0 billion in the US market and USD 4.8 billion globally.<sup>1</sup>

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

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



# Share information

Xspray Pharma's share has been listed on Nasdaq Stockholm in the Small Cap segment under the symbol XSPRAY since March 27, 2020. Prior to that, the share was traded on Nasdaq First North Growth market beginning September 28, 2017. The number of shares in the company at December 31, 2023 was 31,253,542 and the closing price on that date was SEK 40.00.

Owners as of December 31, 2023	Number of shares	Number of shares & votes
Flerie Invest	5,221,566	16.71%
Anders Bladh (private & Ribbskottet)	3,822,205	12.23%
The Foundation for Baltic And East European Studies	3,717,626	11.90%
Fourth Swedish National Pension Fund	3,122,228	9.99%
Unionen	1,237,749	3.96%
Third Swedish National Pension Fund	1,166,666	3.73%
Nordnet Pension Insurance	1,117,619	3.58%
Avanza Pension	1,012,829	3.24%
Second Swedish National Pension Fund	933,480	2.99%
Carl Erik Norman	609,913	1.95%
<b>Total, ten largest owners</b>	<b>21,961,881</b>	<b>70.27%</b>
<b>Total, other shareholders</b>	<b>9,291,661</b>	<b>29.73%</b>
<b>Total number of shares</b>	<b>31,253,542</b>	<b>100.00%</b>

## Financial calendar 2024

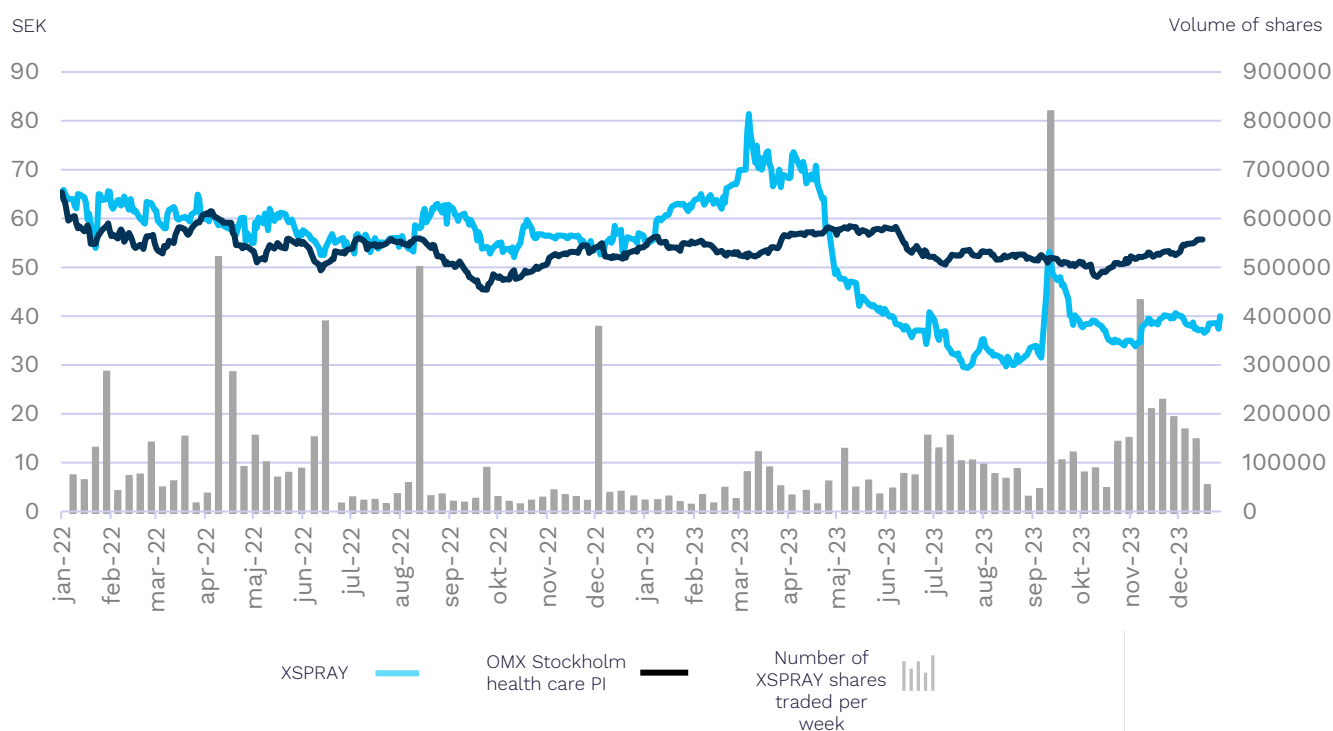
Annual Report 2023	March 27, 2024
Interim Report Q1 2024	May 8, 2024
Interim Report Q2 2024	August 7, 2024
Interim Report Q3 2024	November 6, 2024

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





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# Assurance from the Board

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

Solna, February 14, 2024

Anders Ekblom  
Chairman of the Board

Anders Bladh  
Board member

Robert Molander  
Board member

Maris Hartmanis  
Board member

Torbjörn Koivisto  
Board member

Christine Lind  
Board member

Carl-Johan Spak  
Board member

Per Andersson  
CEO

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



# Glossary

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



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