

# INTERIM REPORT

April–June 2023





## Overview – company vision

### Financial and operational vision through 2030

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

### April–June 2023, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -51,402 thousand (-28,865)
- Earnings per share before dilution amounted to SEK -2.27(-1.40)
- Cash flow from operating activities amounted to SEK -56,503 thousand (-24,472)
- Cash flow from investing activities amounted to SEK -16,027 thousand (-29,197)

### January–June 2023, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -86,229 thousand (-47,799)
- Earnings per share before dilution amounted to SEK -3.80 (-2.31)
- Cash flow from operating activities amounted to SEK -102,038 thousand (-52,085)
- Cash flow from investing activities amounted to SEK -30,677 thousand (-76,738)

Amounts in parentheses refer to the same period previous year.

### Significant events during the quarter

- The US court has rejected Xspray Pharma's motion to dismiss in the ongoing patent dispute concerning XS004. The lawsuit will thus proceed further with evidence including expert statements, where the counterparty BMS is to demonstrate that XS004 does contain crystalline substances.
- Xspray Pharma announced the outcome of a preferential rights issue of units including two shares and two warrant series. The preferential rights issue was subscribed to 83 percent, thereby raising a total of approximately SEK 251 million in proceeds before transaction expenses for Xspray Pharma. The proceeds were raised after the end of the period. The two warrant series include TO5, which matures on November 30, 2023, and TO6, which matures on May 2, 2024. Together, these could raise approximately a further SEK 251 million upon full subscription.

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

- Xspray Pharma received a complete response letter (CRL) in which the FDA requested that supplementary information be provided to physicians and patients regarding the dosage of Dasynoc, as well as information regarding a third-party manufacturing facility. At the same time, the FDA accepted important aspects of the application by not identifying any deficiencies in stability or the clinical data that has been submitted to date.

Key figures, Group	Q2		Jan-Jun		Full year
	2023	2022	2023	2022	2022
Net sales (SEK thousand)	-	-	-	-	-
Loss before Income tax (SEK thousand)	-51,402	-28,865	-86,229	-47,799	-131,670
Earnings per share before dilution (SEK)	-2.27	-1.40	-3.80	-2.31	-6.25
Earnings per share after dilution (SEK)	-2.27	-1.40	-3.80	-2.31	-6.25
Research and development expenses as % of operating expenses	17.7	5.8	25.2	6.9	16.4
Cash and cash equivalents (SEK thousand)	31,543	142,581	31,543	142,581	120,166
Total assets (SEK thousand)	561,120	566,345	561,120	566,345	585,430
Equity/assets ratio (%)	83.8	96.1	83.8	96.1	95.0
Average number of employees	26	25	26	25	25



## A message from the CEO



Dear shareholders,

Xspray Pharma continues to work towards commercialization of the company's leading product candidate, XS004, with the working name of Dasynoc. Dasynoc is an amorphous version of dasatinib for the treatment of the blood cancer diseases chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL). After the end of the period, we received a Complete Response Letter (CRL) from the FDA requesting more information about our application for market approval of Dasynoc. During the quarter, we also announced the preferential rights issues that successfully raised approximately SEK 251 million after the end of the period. We have now secured the necessary financing for the launch of Dasynoc in the US. We are continuing to make preparations ahead of launch in collaboration with our partner EVERSANA.

### **Complete response letter from FDA**

After the end of the quarter, Xspray Pharma received a CRL from the FDA regarding the company's application for market approval of the six dosage strengths of Dasynoc. The FDA requested more information about Dasynoc, primarily supplementary information for physicians and patients regarding the dosage of Dasynoc and some information about our production partner's facility. Even though supplementing our application requires additional resources, the letter was a positive notification that brings us one step closer to a launch. We note that the FDA did not have any comments on either product stability or the clinical data for Dasynoc.

We are now going to work together with the FDA and our production partner to handle the remaining issues as quickly as possible. We have already begun compiling the requested information and will remain in active dialogue with the FDA in order to ensure that the responses fulfill their requirements. We are convinced that the investigation will result in approval for marketing Dasynoc as an improved version of dasatinib for the treatment of CML and ALL.



### Completion of preferential rights issue

On June 27, 2023, Xspray Pharma presented the outcome of the previously announced preferential rights issue of units including shares and two warrant series. The rights issue was subscribed to 83 percent, thereby raising a total of approximately SEK 251 million in proceeds for Xspray Pharma before transaction expenses. Altogether, the two warrant series could total approximately a further SEK 251 million upon full subscription. The series mature at points in time when we hope to have further news regarding Dasynoc and our other projects.

Our success in carrying out this preferential rights issue in the prevailing market climate is a sign of strength. The preferential rights issue generated sufficient funds for us to be able to launch our innovative initial product, Dasynoc, in the US market and transform Xspray Pharma from a research company into a profitable commercial pharmaceutical company. The purpose of the preferential rights issue was also to finance the continued development of our product candidates XS003 nilotinib and XS008 axitinib as well as future candidates.

### Continued preparations ahead of the launch in the US

In close partnership with EVERSANA, we continued the essential preparations ahead of the impending launch of Dasynoc in the US, including development of training materials and logistics solutions for distribution of Dasynoc. This partnership with EVERSANA grants us exclusive access to a complete and cost-effective countrywide sales organization that is ready to go with years of experience in selling PKIs in the specific segments that we will be targeting.

We also conducted an extensive market survey showing that 80 percent of physicians surveyed are positively inclined toward switching treatment of CML and ALL to a drug that can be used alongside proton-pump inhibitors (PPIs), which Dasynoc can. Naturally, this is positive news since it once again confirms the potential of our product. At present, there are around 11,000 patients treated with Sprycel® as their cancer treatment. Up to 47 percent of these patients need to be treated with PPIs, which is not recommended to be taken during treatment with Sprycel®. We can thus offer clear patient benefits for a significant share of the market.

The legal proceedings for an alleged patent infringement by Dasynoc of the reference drug's secondary patents are still in progress. The patents that the suit pertains to protect the crystalline formulation of the reference drug, but we remain confident that our product candidate, which is based on our own amorphous formulation, does not contain any crystalline substance. Due to the rejection of our Motion to Dismiss the case, it is now up to BMS to demonstrate that Dasynoc contains patent protected crystalline substance, based on expert statements.

We expect a positive outcome of these legal proceedings even though we wish that we could expedite the process in the district of New Jersey. Due to the most recent FDA communication we will have a meeting with the FDA during the third quarter 2023. Subsequently, we will have a better understanding for the timetable for the response to FDA's CRL.

When we receive a positive outcome in the lawsuit and a market approval from the FDA, we will be able to launch Dasynoc, our first product based on our patented HyNap technology. Through systematic and innovative development we have created an efficient formulation technology that can improve medical substances' efficiency and security in a way that established pharmaceutical companies have not been able to do previously.

We look forward to initiating the next stage of Xspray Pharma's journey – becoming a profitable commercial pharmaceutical company and a world leader in improved 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. Since the Group consists of the Parent Company and two dormant subsidiaries, the differences between the Parent Company and consolidated statements consist of the existing differences between RFR2 and IFRS.

## Net sales

Net sales for the company amounted to SEK 0 thousand in the first half-year. The application for market approval of the company's initial product, XS004 dasatinib, was filed in the fourth quarter of 2021 and was supplemented with additional dosage strengths in the second quarter of 2022. Further information on XS004 is available under the Product candidate section on page 18.

## Other operating income

Other operating income totaled SEK 356 thousand (598) in the second quarter and SEK 1,260 thousand (767) for both quarters. This item is attributable to advisory services and development efforts performed by Xspray during the period. Except for the income from advisory services, other operating income consists entirely of exchange rate gains arising in conjunction with payments abroad and translations of the currency account.

## Research and development costs

Total expenditures for research and development for the quarter amounted to SEK -24,280 thousand (-27,623), of which SEK -9,118 thousand (-1,722) was expensed and recognized in profit or loss and SEK -15,162 thousand (-25,901) was capitalized as development expenses and presented in the company's balance sheet. For the two quarters, the figure is SEK -51,153 thousand (-55,330) for total expenditure for research and development, with SEK -22,124 thousand (-3,416) expensed and SEK -29,029 thousand (-51,914) capitalized as development expenditures. A large part of the research and development in the quarter was expensed since XS004 has transitioned into a new phase, including validation efforts, and other consulting that have not been capitalized. Costs are also attributable to the company's two other product candidates, XS003 nilotinib and XS008 axitinib.

## Administration and sales expenses

Administration and sales expenses totaled SEK -41,489 thousand (-27,429) in the second quarter. Of these, personnel costs amounted to SEK -9,423 thousand (-6,762). The corresponding half-year figures are SEK -64,342 thousand (-44,449) for administration and sales expenses, with SEK -18,363 thousand (-13,077) pertaining to personnel costs. The cost increase for the second quarter is attributable primarily to the company's continued market preparation activities as a result of the impending launch in the US. We continue to have legal counsel costs in the US as a result of the lawsuit brought by the reference company in February 2022. Moreover, the company's personnel increased by one full-time position compared with the same period in the previous year, which impacted the cost base.

## Other operating expenses

Other operating expenses totaled SEK -1,011 thousand (-656) for the quarter and SEK -1,445 thousand (-1,393)

for the half-year. The increase is attributable to interest rate expenses linked to the short-term loan received from Flerie Invest AB. Other operating expenses also consist of exchange rate losses arising in conjunction with payments abroad and translations of the currency account.

## Loss for the period

Loss for the period totalled SEK -51,402 thousand (-28,865) for the second quarter and SEK -86,229 thousand (-47,799) for the half-year. This corresponds to earnings per share before dilution of SEK -2.27 (-1.40) and SEK -3.80 (-2.31) respectively. The earnings decrease for the quarter and the half-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, research and development costs were expensed owing to preparatory activities for XS004 dasatinib.

## Cash flow

Cash flow from operating activities amounted to SEK -56,503 thousand (-24,472) in the quarter, of which the effect from working capital comprised SEK -7,740 thousand (2,203). The aggregate figure for the two quarters was SEK -102,038 thousand (-52,085), of which the effect from working capital was SEK -20,430 thousand (-8,753). The negative cash flow 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 XS004 dasatinib.

Cash flow from investing activities amounted to SEK -16,027 thousand (-29,197) and SEK -30,677 thousand (-76,738) for the half-year. The item includes capitalized development expenses of SEK -14,923 thousand (-25,646) and SEK -28,545 thousand (-51,398) for the half-year. The main reason for the decrease is that XS004 dasatinib has now moved from a research and development-intensive project to preparing activities for the launch of XS004, with costs not being capitalized but expensed on an ongoing basis.

No new investments were made in property, plant and equipment during the period, and investments in property, plant and equipment thus totaled SEK 0 thousand (-2,555). During the quarter, the company has continued to make prepayments for the construction of the company's new production unit in Malta. Cash flow from investing activities is in line with our plan.

Cash flow from financing activities amounted to SEK 44,678 thousand (38) for the quarter and SEK 44,092 thousand (-477) for the half-year. The positive effect is attributable to the short-term loan of SEK 45,000 thousand that was raised from Flerie Invest. Total cash flow was SEK -27,852 thousand (-53,631) for



the period and SEK -88,623 thousand (-129,300) for both quarters. The Group had SEK 31,543 thousand (142,581) in cash and cash equivalents on June 30, 2023.

### Intangible assets

Development expenditures for the projects have been capitalized according to plan. Capitalized development expenditures for the quarter totaled SEK 15,162 thousand (26,013). The Group's total capitalized expenditures for development amounted to SEK 414,626 thousand (348,150) on June 30, 2023. The item is associated with the company's product candidates XS004 dasatinib, XS003 nilotinib and XS008 axitinib.

### Financial position

On May 2, the company announced plans for a preferential rights issue of SEK 300 million, which was approved at an extraordinary general meeting on May 25. The preferential rights issue was concluded after the end of the period, and raised proceeds of approximately SEK 251 million for Xspray Pharma before transaction expenses. In addition to the first preferential rights issue, there are two warrant series: TO5, which matures on November 30, 2023, and TO6, which matures on May 2, 2024. Together, these could raise approximately a further SEK 251 million upon full subscription.

The capital raised will be used to finance preparations ahead of the launch of XS004 dasatinib in the US as well as general corporate purposes, ongoing operating costs and the continued development of product candidates XS003 nilotinib and XS008 axitinib.

The equity/assets ratio for the Group was 83.8 percent (96.1) on June 30, 2023.

### Group structure

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

### Parent Company

All activities were pursued in the Parent Company, Xspray Pharma AB (publ). The Parent Company's cash and cash equivalents totaled SEK 31,493 thousand (142,531) and the equity/assets ratio was 83.8 percent (96.6) on June 30, 2023.

### Employees

During the quarter, the organization increased by one full-time position compared with the same period the previous year. The number of employees in the Group on the balance sheet date totaled 26 (25).

### 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 -252 thousand (-252) for the period and SEK -504 thousand (-504) for the half-year.

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 -160 thousand (—) for the period and SEK -264 thousand (—) for the half-year.

During the quarter, the company received a loan of SEK 45,000 thousand from Flerie Invest AB. After the end of the period, the loan was settled against subscription in the share issue. The terms of the loan were on market conditions.

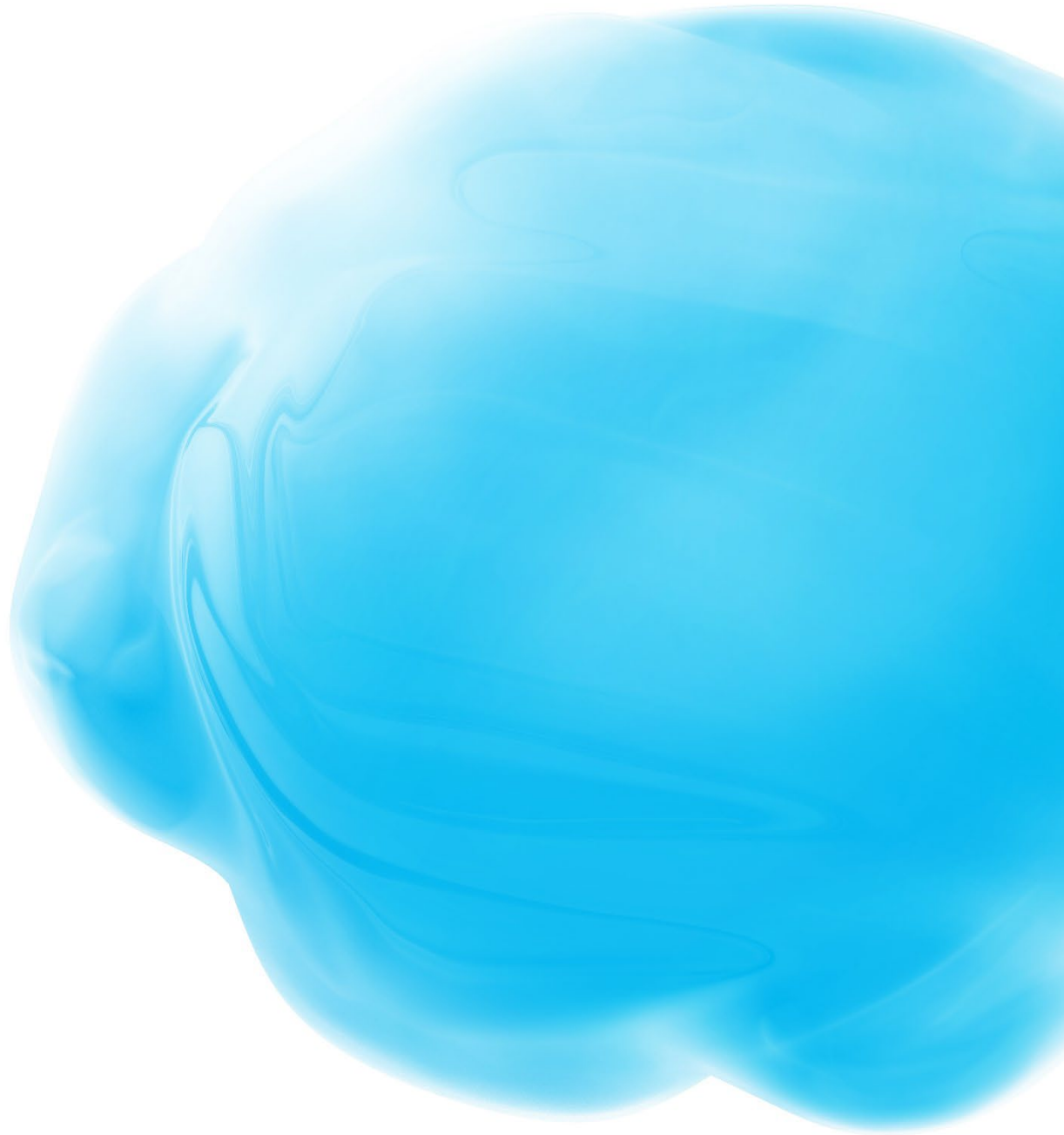
### Corporate governance

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



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# Financial statements





# Consolidated income statement

<i>SEK thousand</i>	Q2		Jan-Jun		Full year
	2023	2022	2023	2022	2022
Net sales	-	-	-	-	-
Other operating income	356	598	1,260	767	2,180
Research and development expenses	-9,118	-1,722	-22,124	-3,416	-22,219
Administration and sales expenses	-41,489	-27,429	-64,342	-44,449	-109,601
Other operating expenses	-1,011	-656	-1,445	-1,393	-3,433
<b>Operating loss</b>	<b>-51,261</b>	<b>-29,210</b>	<b>-86,650</b>	<b>-48,492</b>	<b>-133,073</b>
Finance income	416	348	978	695	1,415
Finance costs	-557	-3	-557	-3	-12
<b>Finance net</b>	<b>-141</b>	<b>345</b>	<b>421</b>	<b>693</b>	<b>1,403</b>
Loss before Income tax	-51,402	-28,865	-86,229	-47,799	-131,670
Tax	-	-	-	-	-
<b>Loss for the period</b>	<b>-51,402</b>	<b>-28,865</b>	<b>-86,229</b>	<b>-47,799</b>	<b>-131,670</b>
Earnings per share for the period before dilution, SEK	-2.27	-1.40	-3.80	-2.31	-6.25
Earnings per share for the period after dilution, SEK	-2.27	-1.40	-3.80	-2.31	-6.25
Average number of shares before dilution	22,680,408	20,680,408	22,680,408	20,680,408	21,070,518
Average number of shares after dilution	22,680,408	20,680,408	22,680,408	20,680,408	21,070,518

# Consolidated statement of comprehensive income

<i>SEK thousand</i>	Q2		Jan-Jun		Full year
	2023	2022	2023	2022	2022
Loss for the period	-51,402	-28,865	-86,229	-47,799	-131,670
Other comprehensive income	-	-	-	-	-
<b>Total comprehensive income for the period</b>	<b>-51,402</b>	<b>-28,865</b>	<b>-86,229</b>	<b>-47,799</b>	<b>-131,670</b>

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





# Consolidated balance sheet

SEK thousand	30 Jun 2023	30 Jun 2022	31 Dec 2022
<b>ASSETS</b>			
<i>Non-current assets</i>			
<i>Intangible assets</i>			
Capitalized development costs	414,626	348,150	385,597
<b>Total intangible assets</b>	<b>414,626</b>	<b>348,150</b>	<b>385,597</b>
<i>Property, plant and equipment</i>			
Machinery and installations	11,622	18,962	15,407
Right-of-use assets	1,359	2,784	2,477
Equipment	95	360	147
Fixed assets under construction and prepayments	49,302	43,359	46,573
<b>Total Property, plant and equipment</b>	<b>62,378</b>	<b>65,465</b>	<b>64,603</b>
<i>Financial assets</i>			
Financial investments	1	1	1
Other long-term receivables	2,999	-	2,999
<b>Total financial assets</b>	<b>3,000</b>	<b>1</b>	<b>3,000</b>
<b>Total non-current assets</b>	<b>480,004</b>	<b>413,616</b>	<b>453,200</b>
<i>Current assets</i>			
Inventories	45,283	6,005	8,552
Current receivables	2,636	2,482	2,362
Accounts receivable	-	270	-
Prepaid expenses and accrued income	1,654	1,392	1,150
Cash and cash equivalents	31,543	142,581	120,166
<b>Total current assets</b>	<b>81,116</b>	<b>152,729</b>	<b>132,229</b>
<b>TOTAL ASSETS</b>	<b>561,120</b>	<b>566,345</b>	<b>585,430</b>



# Consolidated balance sheet cont.

<i>SEK thousand</i>	30 Jun 2023	30 Jun 2022	31 Dec 2022
<b><i>EQUITY AND LIABILITIES</i></b>			
<b><i>Equity</i></b>			
Share capital	22,680	20,680	22,680
Other contributed capital	907,690	814,047	907,420
Reserves	976	976	976
Retained earnings including profit/loss for the period	-461,287	-291,187	-375,057
<b>Total equity attributable to the Parent Company's shareholders</b>	<b>470,059</b>	<b>544,517</b>	<b>556,019</b>
<b><i>Non-current liabilities</i></b>			
Lease liabilities	377	367	560
<b>Total non-current liabilities</b>	<b>377</b>	<b>367</b>	<b>560</b>
<b><i>Current liabilities</i></b>			
Trade accounts payable	20,485	7,782	14,786
Lease liabilities	571	2,105	1,566
Other current liabilities	46,260	1,086	1,043
Accrued expenses and deferred income	23,368	10,488	11,456
<b>Total current liabilities</b>	<b>90,684</b>	<b>21,461</b>	<b>28,851</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>561,120</b>	<b>566,345</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
<b>Opening balance as of January 1, 2022</b>	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>	22,680	907,420	976	-375,057	556,019
<b>Opening balance as of January 1, 2023</b>	22,680	907,420	976	-375,057	556,019
<i>Loss of the period</i>	-	-	-	-86,229	-86,229
Other comprehensive income for the period	-	-	-	-	-
<b>Total comprehensive income for the period</b>	-	-	-	-86,229	-86,229
New share issue	-	-	-	-	-
Transaction costs	-	-252	-	-	-252
Redemption of warrants	-	522	-	-	522
Warrant program	-	-	-	-	-
<b>Closing balance as of June 30, 2023</b>	22,680	907,690	976	-461,287	470,059



# Consolidated cash flow statement

SEK thousand	Q2		Jan-Jun		Full year
	2023	2022	2023	2022	2022
<b>Operating activities</b>					
Operating loss	-51,261	-29,210	-86,650	-48,492	-133,073
<i>Non-cash adjustments</i>					
Depreciation	-	2,387	-	4,708	9,533
Interest received	265	187	551	532	1,611
Interest paid	1	-39	-24	-80	-147
<b>Cash flow from operating activities before changes in working capital</b>	<b>-48,763</b>	<b>-26,675</b>	<b>-81,608</b>	<b>-43,332</b>	<b>-106,604</b>
<i>Changes in working capital</i>					
Change in operating receivables	-27,167	442	-37,681	792	-2,942
Change in operating liabilities	19,427	1,761	17,251	-9,545	-633
<b>Cash flow from operating activities</b>	<b>-56,503</b>	<b>-24,472</b>	<b>-102,038</b>	<b>-52,085</b>	<b>-110,179</b>
<b>Investing activities</b>					
Capitalized development costs	-14,923	-25,646	-28,545	-51,398	-103,820
Acquisition of property, plant and equipment	-	-2,555	-	-23,334	-24,466
Prepayments	-1,104	-996	-2,132	-2,006	-7,059
<b>Cash flow from investing activities</b>	<b>-16,027</b>	<b>-29,197</b>	<b>-30,677</b>	<b>-76,738</b>	<b>-135,345</b>
<b>Financing activities</b>					
New share issue	-	-	-	-	100,000
Loan raised	45,000	-	45,000	-	-
Transaction costs	-252	-300	-252	-300	-4,876
Payment of lease liability	-592	-527	-1,178	-1,042	-2,128
Repurchased warrants	-	-	-	-	-52
Allocated warrants	522	865	522	865	865
<b>Cash flow from financing activities</b>	<b>44,678</b>	<b>38</b>	<b>44,092</b>	<b>-477</b>	<b>93,809</b>
<b>Cash flow for the period</b>	<b>-27,852</b>	<b>-53,631</b>	<b>-88,623</b>	<b>-129,300</b>	<b>-151,715</b>
Cash and cash equivalents at the beginning of the period	59,395	196,212	120,166	271,881	271,881
<b>Cash and cash equivalents at the end of the period</b>	<b>31,543</b>	<b>142,581</b>	<b>31,543</b>	<b>142,581</b>	<b>120,166</b>



# Parent Company income statement

<i>SEK thousand</i>	Q2		Jan-Jun		Full year
	2023	2022	2023	2022	2022
Net sales	-	-	-	-	-
Other operating income	356	598	1,260	767	2,180
Research and development expenses	-9,305	-1,818	-22,392	-3,599	-22,592
Administration and sales expenses	-41,520	-27,456	-64,404	-44,503	-109,710
Other operating expenses	-1,083	-679	-1,535	-1,417	-3,500
<b>Operating loss</b>	<b>-51,551</b>	<b>-29,355</b>	<b>-87,070</b>	<b>-48,751</b>	<b>-133,622</b>
Finance income	153	160	470	329	617
Finance costs	-557	-3	-557	-3	-12
<b>Finance net</b>	<b>-404</b>	<b>157</b>	<b>-87</b>	<b>326</b>	<b>605</b>
Loss before Income tax	-51,955	-29,198	-87,157	-48,425	-133,017
Tax	-	-	-	-	-
<b>Loss for the period</b>	<b>-51,955</b>	<b>-29,198</b>	<b>-87,157</b>	<b>-48,425</b>	<b>-133,017</b>
Average number of shares before dilution	22,680,408	20,680,408	22,680,408	20,680,408	21,070,518
Average number of shares after dilution	22,680,408	20,680,408	22,680,408	20,680,408	21,070,518



# Parent Company balance sheet

<i>SEK thousand</i>	30 Jun 2023	30 Jun 2022	31 Dec 2022
<b>ASSETS</b>			
<b>Non-current assets</b>			
<b>Intangible assets</b>			
Capitalized development costs	413,703	347,703	384,944
<b>Total intangible assets</b>	<b>413,703</b>	<b>347,703</b>	<b>384,944</b>
<b>Property, plant and equipment</b>			
Machinery and installations	11,622	18,962	15,407
Equipment	95	360	147
Fixed assets under construction and prepayments	47,515	42,645	45,383
<b>Total Property, plant and equipment</b>	<b>59,232</b>	<b>61,967</b>	<b>60,936</b>
<b>Financial assets</b>			
Shares in subsidiaries	50	50	50
Financial investments	1	1	1
Other long-term receivables	2,999	-	2,999
<b>Total financial assets</b>	<b>3,050</b>	<b>51</b>	<b>3,050</b>
<b>Total non-current assets</b>	<b>475,985</b>	<b>409,721</b>	<b>448,930</b>
<b>Current assets</b>			
Inventories	45,283	6,005	8,552
<b>Current receivables</b>			
Accounts receivables	-	270	-
Other current receivables	2,636	2,482	2,362
Prepaid expenses and accrued income	2,136	1,874	1,632
<b>Total current receivables</b>	<b>4,772</b>	<b>4,625</b>	<b>3,994</b>
Cash and bank	31,493	142,531	120,116
<b>Total current assets</b>	<b>81,548</b>	<b>153,161</b>	<b>132,661</b>
<b>TOTAL ASSETS</b>	<b>557,533</b>	<b>562,882</b>	<b>581,592</b>



## Parent Company balance sheet cont.

<i>SEK thousand</i>	30 Jun 2023	30 Jun 2022	31 Dec 2022
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital	22,680	20,680	22,680
Statutory reserve	976	976	976
Development expenditure reserve	413,703	347,703	384,944
<b>Total restricted equity</b>	<b>437,360</b>	<b>369,360</b>	<b>408,601</b>
<i>Non-restricted equity</i>			
Other contributed capital	907,690	814,047	907,420
Accumulated earnings	-790,473	-591,456	-628,697
Profit/loss for the period	-87,157	-48,425	-133,017
<b>Total non-restricted equity</b>	<b>30,060</b>	<b>174,166</b>	<b>145,705</b>
<b>Total equity</b>	<b>467,420</b>	<b>543,526</b>	<b>554,306</b>
<i>Current liabilities</i>			
Trade accounts payable	20,485	7,782	14,786
Other current liabilities	46,260	1,086	1,043
Accrued expenses and deferred income	23,368	10,488	11,456
<b>Total current liabilities</b>	<b>90,113</b>	<b>19,356</b>	<b>27,285</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>557,533</b>	<b>562,882</b>	<b>581,592</b>



# Parent Company cash flow statement

<i>SEK thousand</i>	Q2		Jan-Jun		Full year
	2023	2022	2023	2022	2022
<b><i>Operating activities</i></b>					
Operating loss	-51,551	-29,355	-87,070	-48,751	-133,622
<i>Non-cash adjustments</i>					
Depreciation	1,891	2,090	3,836	4,124	8,341
Disposal of intangible fixed assets	-	-	-	-	15,472
Interest received	2	-	43	-	647
Interest paid	-	-3	-	-3	-12
<b>Cash flow from operating activities before changes in working capital</b>	<b>-49,658</b>	<b>-27,268</b>	<b>-83,191</b>	<b>-44,630</b>	<b>-109,174</b>
<b><i>Changes in working capital</i></b>					
Change in operating receivables	-26,830	655	-37,082	1,348	-1,911
Change in operating liabilities	19,447	1,758	17,271	-9,545	-631
<b>Cash flow from operating activities</b>	<b>-57,041</b>	<b>-24,855</b>	<b>-103,002</b>	<b>-52,827</b>	<b>-111,716</b>
<b><i>Investing activities</i></b>					
Purchase of intangible assets	-14,977	-25,790	-28,759	-51,698	-104,411
Acquisition of property, plant and equipment	-	-2,555	-	-23,334	-24,466
Prepayments	-1,104	-996	-2,132	-2,006	-7,059
<b>Cash flow from investing activities</b>	<b>-16,081</b>	<b>-29,341</b>	<b>-30,891</b>	<b>-77,038</b>	<b>-135,936</b>
<b><i>Financing activities</i></b>					
New share issue	-	-	-	-	100,000
Transaction costs	-252	-300	-252	-300	-4,876
Loan raised	45,000	-	45,000	-	-
Redemption of warrants	-	-	-	-	-
Repurchased warrants	-	-	-	-	-52
Allocated warrants	522	865	522	865	865
<b>Cash flow from financing activities</b>	<b>45,270</b>	<b>565</b>	<b>45,270</b>	<b>565</b>	<b>95,937</b>
<b>Cash flow for the period</b>	<b>-27,852</b>	<b>-53,631</b>	<b>-88,623</b>	<b>-129,300</b>	<b>-151,715</b>
Cash and cash equivalents at the beginning of the period	59,345	196,162	120,116	271,831	271,831
<b>Cash and cash equivalents at the end of the period</b>	<b>31,493</b>	<b>142,531</b>	<b>31,493</b>	<b>142,531</b>	<b>120,116</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 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 second quarter of 2023. Comparison figures are presented in parentheses and pertain to the same period in 2022.

### Definitions of key performance indicators

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

## Note 2. Key estimates and assessments

Preparing the financial statements in accordance with IFRS requires management to make assessments and estimates, and to make assumptions that impact the application of the accounting policies and the recognized amounts of assets, liabilities, revenue and expenses. The real outcome may deviate from these estimates and assumptions. The estimates and assumptions are routinely evaluated. Changes to estimates are recognized in the period the changes are made.

The source of uncertainty in estimations that entail a significant risk for the need to significantly adjust the value of assets or liabilities during the coming financial year is the carrying amount of "Capitalized development expenses". Determining whether the requirements for capitalization of development expenditures have been met requires both initial and routine assessments. The capitalized expenditures are regularly tested as to whether they could be exposed to a decrease in value. The company holds capitalized intangible assets that have not yet been completed and are impairment tested either yearly or as soon as there is an indication of a potential decrease in value. Impairment testing involves estimating future cash flows attributable to the asset, or to the cash-generating unit that the asset will be attributed to, once it is complete. These estimates and assumptions encompass expectations pertaining primarily to the selling price of the products, market penetration, and remaining development, sales and marketing costs as well as the probability that the product will successfully pass through the remaining development stages. The assumptions involve industry- and market-specific data produced by corporate management and reviewed by the Board of Directors.

### Material risks and uncertainties

Xsray Pharma's operation is associated with both industry-related and company-specific risks. The company develops product candidates, and there will always be regulatory, market-related and financial risks in the operation. No material changes have occurred in the risks and uncertainties during the period compared with those the company reported in the Annual Report for 2022.

### Financing risk and going concern

On May 2, the company announced plans for a preferential rights issue of SEK 300 million, which was approved at an extraordinary general meeting on May 25. The preferential rights issue was concluded after the end of the period, and raised proceeds of approximately SEK 251 million for Xsray Pharma before transaction expenses. The share issue included two warrant series: TO5, which matures on November 30, 2023, and TO6, which matures on May 2, 2024. Together, these could raise approximately a further SEK 251 million upon full subscription. The reason for including warrants in the offering is to increase visibility for investors since the warrants can be exercised at a later point in time when the company is expected to have achieved key milestones, primarily the launch of Dasynoc. The capital raised will be used to finance preparations ahead of Dasynoc's planned launch in the US as well as general corporate purposes, ongoing operating costs and the continued development of XS003 nilotinib and XS008 axitinib.

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 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.



# 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 in part 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 offer similar substances with improved functionality compared to the original drugs. Xspray Pharma's goal is to be a leader in developing improved PKIs for the treatment of cancer, of which there were just over 80 in the US at the end of 2022.

## Market

Protein kinase inhibitors (PKIs) have quickly become 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: XS004 dasatinib, 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 2022 exceeded USD 3.4 billion in the US market and USD 5.1 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
XS004	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 June 30, 2023 was 22,680,408 and the closing price on that date was SEK 40.80.

Owners as of June 30, 2023	Number of shares	Number of shares & votes
Flerie Invest	3,464,378	15.27%
The Foundation for Baltic And East European Studies Anders Bladh (private & Ribbskottet)	2,742,626	12.09%
Fourth Swedish National Pension Fund	2,644,886	11.66%
Nordnet Pension Insurance	1,995,806	8.80%
Unionen	806,000	3.55%
Third Swedish National Pension Fund	800,000	3.53%
Avanza Pension	733,130	3.23%
Second Swedish National Pension Fund	622,320	2.74%
TIN Funds	608,809	2.68%
TIN Funds	600,000	2.65%
<b>Total, ten largest owners</b>	<b>15,017,955</b>	<b>66.22%</b>
<b>Total, other shareholders</b>	<b>7,662,453</b>	<b>33.78%</b>
<b>Total number of shares</b>	<b>22,680,408</b>	<b>100.00%</b>

## Financial calendar 2023

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

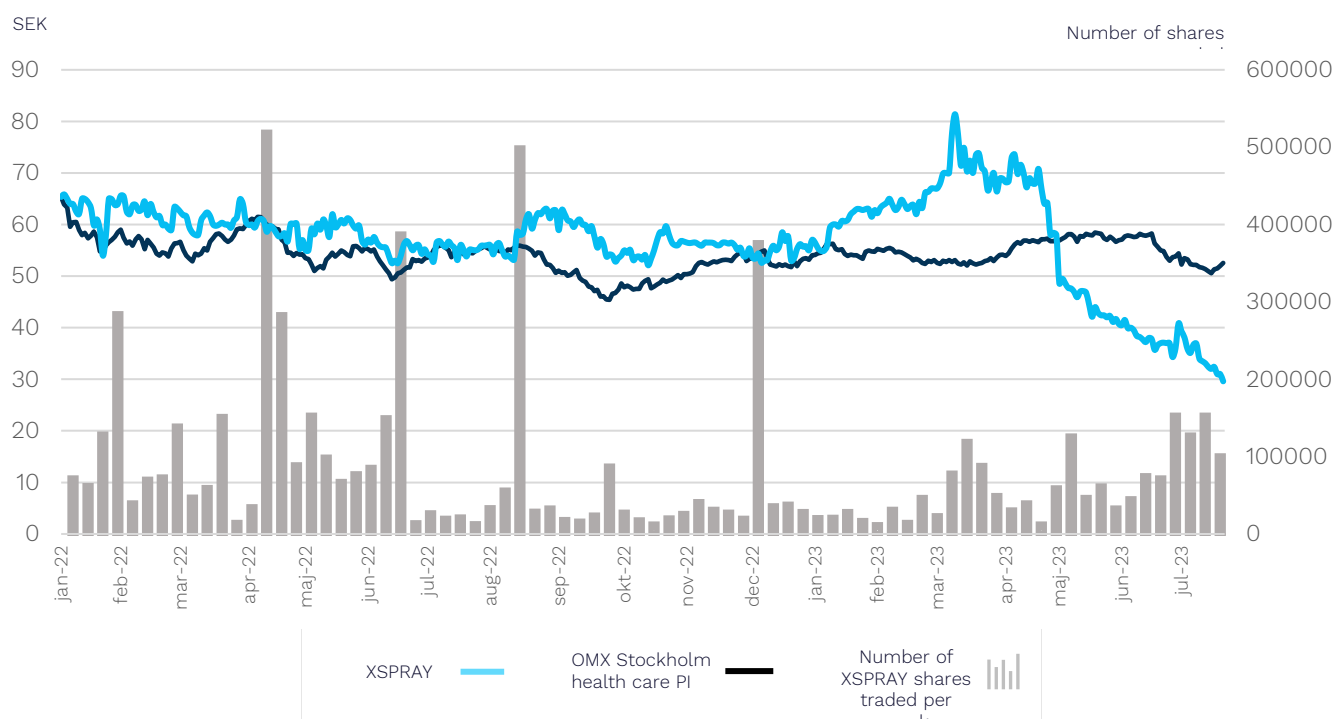
The financial reports are available on the Xspray Pharma website, [www.xspraypharma.com](http://www.xspraypharma.com).

## Analysts monitoring the company

Filip Einarsson, Redeye AB

Dan Aksamutski, 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, August 2, 2023

Anders Ekblom

Chairman of the Board

Anders Bladh  
Board member

Robert Molander  
Board member

Maris Hartmanis  
Board member

Torbjörn Koivisto  
Board member

Christine Lind  
Board member

Carl-Johan Spak  
Board member

Per Andersson  
CEO

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

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# 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>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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