Interim Report April–June 2022

Xspray Pharma AB (publ) is a pharmaceutical company with multiple product candidates in the clinical development phase. The Company uses its innovative, patented technology to develop amorphous product candidates that are improved generic versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. They are formulated as hybrid nanoparticles ("HyNap") and are amorphous, patentable, and stable versions of crystalline original substances.

Q2 2022

Second quarter 2022 (April–June), Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -28,865 thousand (-16,952)
- Earnings per share before dilution amounted to SEK -1.40 (-0.89)
- Cash flow from operating activities amounted to SEK -24,472 thousand (-12,831)
- Cash flow from investing activities amounted to SEK -29,197 thousand (-26,854)

First and second quarters (January–June), Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -47,799 thousand (-30,863)
- Earnings per share before dilution amounted to SEK -2.31 (-1.62)
- Cash flow from operating activities amounted to SEK -52,085 thousand (-24,802)
- Cash flow from investing activities amounted to SEK -76,738 thousand (-52,042)
- Cash and cash equivalents at the end of the period amounted to SEK 142,581 thousand (253,737)

Amounts in parentheses refer to the year-earlier period.

Significant events during the quarter

- In May, the Annual General Meeting resolved, in accordance with the Nomination Committee's proposal, on the re-election of Board members Anders Ekblom, Anders Bladh, Maris Hartmanis, Torbjörn Koivisto, Christine Lind and Carl-Johan Spak as well as the election of new Board member Robert Molander for the period up until the end of the next Annual General Meeting. Anders Ekblom was elected Chairman of the Board. Gunnar Gårdemyr declined re-election.
- In June, it was announced that the company's new long-term incentive program had been fully subscribed. The plan, LTIP 2022-2025, which was offered to all employees including senior executives, consists of both warrants and employee stock options.
- In June, the company announced that it had appointed Thomas Walz as Chief Medical Officer. Thomas will take up the new position on September 1, 2022 and will become part of the company's management team.
- In June, it was announced that the US Food and Drug Administration (FDA) had granted XS004 dasatinib* orphan drug designation for the treatment of chronic myeloid leukemia (CML).
- In June, Xspray Pharma supplemented its applications to the FDA for XS004 dasatinib with the lower dosages. As a result of and in line with expectations, the originator supplemented its previous litigation with a new application for the lower dosages.

Significant events after the end of the reporting period

- At the beginning of August, BMS added one additional patent relating to crystalline compounds, to the ongoing XS004 litigation. BMS has previously asserted this patent in similar cases, and it was therefore not unexpected. Xspray Pharma has not applied for FDA approval to market a product that would infringe the patent in question. Accordingly, Xspray Pharma remains confident it will prevail in this litigation, and does not expect the addition of this patent to change the current timeline of the case.

**Xspray Pharma has decided to refer to product candidates according to their development name, as soon as the candidate is on the market, the brand name will be used.*

A message from the CEO

A vision to improve patients' lives

It has now been 20 years since my colleague, Mustafa Demirbuker, stood in his kitchen and had the initial idea for a new method for producing amorphous solid dispersion (ASD), which enables Xspray to produce new improved pharmaceuticals for cancer patients. Since then, we have invested over 200 man-years and over half a billion Swedish kronor in developing our platform to where we are today. There are several good reasons to pursue this, but we are ultimately driven by the desire to improve the lives of patients. Improving lives may be a subjective concept, but for our initial product candidate, XS004 dasatinib, this could mean that patients could ingest ulcer medications alongside their cancer medications, which in turn means that patients are not restricted by stomach problems while the effect of cancer treatment remains.

Simply put, Xspray provides patients with the possibility of living, not just surviving.

There are a number of Swedish companies that have been successful at developing industries further, breaking new ground and being innovative. Even though Xspray's journey is a long one purely in terms of time, we would like to try to provide an idea of what we see ahead of us. That is why we are shaping a vision of what Xspray will look like at the end of this decade. Based on this, we foresee that we will initially be working intensively with two products on the market in the next coming years, evolving to five products on the market by the end of the decade with an additional three in the product candidate portfolio on the way out to the market. Furthermore, we anticipate that the product candidate portfolio has the potential to generate an excess of USD 250 million in annual revenue, as well as operating margin for the company that could exceed 40 percent. It is important to emphasize that this does not constitute a financial target or a forecast – we can potentially do that once we are further along in our journey – but these are reasonable assumptions that helps shed light on the market potential we see as a reality.

We are now approximately 12 to 18 months from commercializing our initial product candidate. We have consolidated several market studies with both physicians and paying partners ("payers") in the US. Based on these positive responses, we are now taking practical steps toward commercialization. Additional capital will be required before we generate a positive cash flow – either through partnerships and/or raising capital and of course tremendous effort before we get there – but we have no doubt that we will get there.

During the quarter, we have submitted the application to the FDA regarding the lower dosages for our initial product candidate, XS004 dasatinib, which leads to two things. We assume that the FDA is now extending the approval process for all dosages instead of one dosage at a time, and the lawsuit pertaining to this same product candidate is being supplemented with a lawsuit for the lower dosages. This means that we now anticipate pursuing one FDA file for all dosages at the same time and one lawsuit handling the entire legal process. This is positive and will streamline the work, while we remain well within the time frame we have called our launch window, which is the foundation of our business model. The work pertaining to the rest of the product candidate portfolio is proceeding in accordance with plans. In order to be fully transparent, I would like to mention that we will continue to refer to product candidates according to their development name, and as soon as the candidate is on the market we will use the brand name of the drug.

We are extremely pleased to share that our efforts at improving the lives of patients have also meant that we continue to recruit highly skilled talent to Xspray. In September, Thomas Walz assumes the position of Chief Medical Officer, which is deeply gratifying. Thomas joins the leadership team most recently from GSK to our office in Solna, where our head office and laboratory are located.

To finish, it is deeply gratifying to convey that Xspray has now repositioned itself from an idea in a kitchen to having large-scale commercial production capacity in Europe. Thank you for your questions, views, and patience during the quarter; it is pleasing to have committed shareholders along on our journey.

August 5, 2022

Per Andersson
CEO

Financial overview, Group

	Q2		Jan-Jun		Full year
Key figures, Group	**2022**	**2021**	**2022**	**2021**	**2021**
Net sales (SEK thousand)	-	-	-	-	-
Loss before Income tax (SEK thousand)	-28,865	-16,952	-47,799	-30,863	-96,698
Earnings per share before dilution (SEK)	-1.40	-0.89	-2.31	-1.62	-5.03
Earnings per share after dilution (SEK)	-1.40	-0.89	-2.31	-1.62	-5.03
Research and development expenses as % of operating expenses	5.8	11.3	6.9	11.4	39.1
Cash and cash equivalents (SEK thousand)	142,581	253,737	142,581	253,737	271,881
Total assets (SEK thousand)	566,345	578,740	566,345	578,740	622,903
Equity/assets ratio (%)	96.1	96.4	96.1	96.4	95.0
Average number of employees	25	22	25	22	23

Total expenditure for research and development for the quarter was SEK -27,623 thousand, of which SEK -1,722 thousand has been expensed and SEK -25,901 thousand capitalized as development expenses.

Total expenditure for research and development for the period January–June was SEK-55,330 thousand, of which SEK -3,416 thousand has been expensed and SEK -51,914 thousand capitalized as development expenditure.

Comments on the report

Unless otherwise indicated, the comments below pertain to the Group. Comparison figures are presented in parentheses and pertain to the year-earlier period. Since the Group consists of the Parent Company and a dormant subsidiary, 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. The application for market approval of company's initial product, XS004 dasatinib, was filed in Q4 2021 and was supplemented with additional dosage strengths in Q2 2022.

Other operating income and expenses

Other operating income for the period amounted to SEK 598 thousand (153). The increase was attributable to advisory services performed by Xspray Pharma during the period. Other operating expenses for the period amounted to SEK -656 thousand (-397). Total other operating income and expenses for the company in both quarters totaled SEK 767 thousand (253) and SEK -1,393 thousand (-867). Except for the income from advisory services, both other operating income and expenses consist entirely of exchange rate gains and losses arising in conjunction with payments abroad and translations of the currency account.

Research and development costs

Total expenditure for research and development in the second quarter amounted to SEK -27,623 thousand (-28,634), of which SEK -1,722 thousand (-1,978) was expensed and recognized in profit or loss and SEK -25,901 thousand (-26,656) was capitalized as development expenses and presented in the company's balance sheet. For the two quarters, the figure is SEK -55,330 thousand (-55,730) for total expenditure for research and development, where SEK -3,416 thousand (-3,604) has been expensed and SEK -51,914 thousand (-52,126) has been capitalized as development expenditures. These costs are in line with the year-earlier period, and are attributable to continued activity for two of the company's product candidates, XS004 dasatinib and HyNap-Nilo.

Administrative and sales costs

Administrative and sales costs for the second quarter of 2022 amounted to SEK -27,429 thousand (-15,067). Of these, personnel costs classified as administrative and sales costs amounted to SEK -6,762 thousand (-6,023). The corresponding half-year figures are SEK -44,449 thousand (-27,248) for administrative and sales costs, where SEK -13,077 thousand (-9,918) pertained to personnel costs. The cost increase for the second quarter reflects continuing activities attributable to the company's routine costs as well as consulting costs linked to company operations. The company's personnel has increased by three full-time positions compared with the year-earlier period, which impacts the cost base.

Loss for the period

Loss for the second quarter totaled SEK -28,865 thousand (-16,952) and for the half-year totaled SEK -47,799 thousand (-30,863). This corresponds to earnings per share before dilution of SEK -1.40 (-0.89) and SEK -2.31 (-1.62) respectively. The change in earnings for the quarter is attributable primarily to increased administrative and sales costs resulting from increased consultation and advisory costs of SEK -5,316 thousand (-2,234) and shipping costs of SEK -1,999 thousand (-902). Personnel costs classified as administrative and sales costs increased by SEK -739 thousand year-on-year.

Cash flow, investments, financial position and going concern

Cash flow from operating activities for the quarter amounted to SEK -24,472 thousand (-12,831), of which the effect from operating capital comprised SEK 2,204 thousand (2,150). The aggregate figure for the two quarters was SEK -52,085 thousand (-24,802), in which the effect from operating capital was SEK -8,752 thousand (1,734). The negative cash flow is in accordance with the company's plan, and is primarily attributable to continued strengthening of the organization, project costs and other advisory services for the company's future strategic positioning.

Cash flow from investing activities amounted to SEK -29,197 thousand (-26,854) for the quarter and SEK -76,738 thousand (-52,042) for the half-year. The item includes capitalized development expenses of SEK -25,646 thousand (-26,379) for the quarter and SEK -51,398 thousand (-51,567) for the half-year. The main explanation for the increase comes from investments in property, plant and equipment, which was high during the first quarter. Investments in property, plant and equipment totaled SEK -2,555 thousand (-475) for the second quarter and SEK -23,334 thousand (-475) for the half-year. During the period, advances paid continued as a result of the construction of the company's new production unit in Malta. This includes modifications to premises as well as machinery. Cash flow from investing activities is in line with expected development.

Cash flow from financing activities for the quarter totaled SEK 38 thousand (1,157) and SEK -477 thousand (4,983) for the half-year, which is attributable solely to allocation of the new warrant program and amortization of lease liabilities.

Total cash flow for the second quarter of the year was SEK -53,631 thousand (-38,528) and for both quarters was SEK -129,300 thousand (-71,861) The Group had SEK 142,581 thousand (253,737) in cash and cash equivalents at June 30, 2022. Depending on the path and orientation the company chooses to take over the coming year, the Group's coverage of cash and cash equivalents may not meet the liquidity needed to pursue accelerated operations for the coming 12 months. In light of this, the Board of Directors is continually evaluating the company's financial requirements and position, and reviewing various financing alternatives. The debt/equity ratio for the Group was 96.1 percent (96.4) at June 30, 2022.

Intangible fixed assets

Development expenditures for the projects have been capitalized according to plan. The Group's capitalized development expenditures for the quarter amounted to SEK -25,901 thousand (-26,656). The Group's total capitalized expenditures for development and similar activities totaled SEK 348,150 thousand (283,744) at June 30, 2022. The item is associated with the company's product candidates XS004 dasatinib, XS003 nilotinib and XS005 sorafenib.

Parent Company

The Parent Company's subsidiary, Xspray Pharma Futurum AB, remained dormant during the period. All activities were pursued in the Parent Company, Xspray Pharma AB (publ). The Parent Company's cash and cash equivalents totaled SEK 142,531 thousand (253,687) and the debt/equity ratio was 96.6 percent (97.1) at June 30, 2022.

Employees

During the quarter, the organization increased by three full-time positions compared with the year-earlier period.
The number of employees in the Group totaled 25 (22). The subsidiary had no employees as of the balance date.

Related-party transactions

Related parties are defined as the management group in the Parent Company and the Boards of Directors in the Parent Company and subsidiary. Purchase of services from senior executives in the first and second quarters of 2022 pertain to consultant fees from InterCon HB, owned by Andreas Konar, who is part of the company's management group. The fees amounted to SEK -252 thousand (-252) for the quarter and SEK -504 thousand (-504) for the half-year.

Corporate governance

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

Financial statements and notes

All activities are pursued in the Parent Company, Xspray Pharma AB (publ).

Consolidated income statement

	Q2		Jan-Jun		Full year
SEK thousand	**2022**	**2021**	**2022**	**2021**	**2021**
Net sales	-	-	-	-	-
Other operating income	598	153	767	253	656
Research and development expenses	-1,722	-1,978	-3,416	-3,604	-38,567
Administration and sales expenses	-27,429	-15,067	-44,449	-27,248	-58,384
Other operating expenses	-656	-397	-1,393	-867	-1,657
Operating loss	**-29,210**	**-17,289**	**-48,492**	**-31,466**	**-97,953**
Finance income	348	340	695	606	1,259
Finance costs	-3	-3	-3	-3	-4
Finance net	**345**	**337**	**693**	**603**	**1,255**
Loss before Income tax	-28,865	-16,952	-47,799	-30,863	-96,698
Tax	-	-	-	-	-
Loss for the period	**-28,865**	**-16,952**	**-47,799**	**-30,863**	**-96,698**
Earnings per share for the period before dilution, SEK	-1.40	-0.89	-2.31	-1.62	-5.03
Earnings per share for the period after dilution, SEK	-1.40	-0.89	-2.31	-1.62	-5.03
Average number of shares before dilution	20,680,408	19,067,504	20,680,408	19,035,421	19,237,743
Average number of shares after dilution	20,680,408	19,146,578	20,680,408	19,114,495	19,237,743

Consolidated statement of comprehensive income

	Q2		Jan-Jun		Full year
SEK thousand	**2022**	**2021**	**2022**	**2021**	**2021**
Loss for the period	-28,865	-16,952	-47,799	-30,863	-96,698
Other comprehensive income	-	-	-	-	-
Total comprehensive income for the period	**-28,865**	**-16,952**	**-47,799**	**-30,863**	**-96,698**

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

Consolidated balance sheet

SEK thousand	30 Jun 2022	30 Jun 2021	31 Dec 2021
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	348,150	283,744	296,236
Total intangible assets	**348,150**	**283,744**	**296,236**
Property, plant and equipment			
Machinery and installations	18,962	24,298	20,458
Right-of-use assets	2,784	4,510	3,526
Equipment	360	793	574
Fixed assets under construction and prepayments	43,359	9,118	20,043
Total Property, plant and equipment	**65,465**	**38,719**	**44,601**
Financial assets			
Financial investments	1	1	1
Total financial assets	**1**	**1**	**1**
Total non-current assets	**413,616**	**322,464**	**340,838**
Current assets			
Inventories	6,005	630	6,199
Current receivables	2,482	874	2,473
Accounts receivable	270	-	-
Prepaid expenses and accured income	1,392	1,037	1,513
Cash and cash equivalents	142,581	253,737	271,881
Total current assets	**152,729**	**256,277**	**282,065**
TOTAL ASSETS	**566,345**	**578,740**	**622,903**

SEK thousand	30 Jun 2022	30 Jun 2021	31 Dec 2021
EQUITY AND LIABILITIES			
Equity			
Share capital	20,680	19,068	20,680
Other contributed capital	814,047	715,292	813,483
Reserves	976	976	976
Retained earnings including profit/loss for the period	-291,187	-177,552	-243,387
Total equity attributable to the Parent Company's shareholders	**544,517**	**557,784**	**591,752**
Non–current liabilities			
Lease liabilities	367	2,118	1,185
Total non-current liabilities	**367**	**2,118**	**1,185**
Current liabilities			
Trade accounts payable	7,782	4,887	16,865
Lease liabilities	2,105	2,095	2,048
Other current liabilities	1,086	1,725	653
Accrued expenses and deferred income	10,488	10,131	10,401
Total current liabilities	**21,461**	**18,838**	**29,966**
TOTAL EQUITY AND LIABILITIES	**566,345**	**578,740**	**622,903**

Consolidated report of changes in equity

SEK thousand	Share capital	Other contributed capital	Reserves	Retained earnings incl. profit/loss for the period	Total Equity
Opening balance as of Janary 1, 2021	**18,893**	**709,407**	**976**	**-146,689**	**582,587**
Loss of the period	-	-	-	-96,698	-96,698
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	**-**	**-**	**-**	**-96,698**	**-96,698**
New share issue	1,612	98,388	-	-	100,000
Transaction costs	-	-134	-	-	-134
Redemption of warrants	175	4,200	-	-	4,375
Warrant program	-	1,621	-	-	1,621
Closing balance as of December 31, 2021	**20,680**	**813,483**	**976**	**-243,387**	**591,752**
Opening balance as of January 1, 2022	**20,680**	**813,483**	**976**	**-243,387**	**591,752**
Loss for the period	-	-	-	-47,799	-47,799
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	**-**	**-**	**-**	**-47,799**	**-47,799**
Transaction costs	-	-300	-	-	-300
Warrant program	-	865	-	-	865
Closing balance as of June 30, 2022	**20,680**	**814,047**	**976**	**-291,187**	**544,517**

Consolidated cash flow statement

	Q2		Jan-Jun		Full year
SEK thousand	**2022**	**2021**	**2022**	**2021**	**2021**
Operating activities					
Operating loss	**-29,210**	**-17,289**	**-48,492**	**-31,466**	**-97,953**
Non-cash adjustments					
Depreciation	2,387	2,312	4,708	4,267	8,870
Capital gains	-	-	-	98	98
Interest received	187	-	532	569	1,878
Interest paid	-39	-4	-80	-4	-4
Cash flow from operating activities before changes in working capital	**-26,675**	**-14,981**	**-43,332**	**-26,536**	**-55,983**
Changes in working capital					
Change in operating receivables	442	1,850	792	2,823	-5,712
Change in operating liabilities	1,761	300	-9,545	-1,089	10,087
Cash flow from operating activities	**-24,472**	**-12,831**	**-52,085**	**-24,802**	**-51,607**
Investing activities		-		-	
Capitalized development costs	-25,646	-26,379	-51,398	-51,567	-94,651
Acquisition of property, plant and equipment	-2,555	-475	-23,334	-475	-1,313
Prepayments	-996	-	-2,006	-	-9,854
Cash flow from investing activities	**-29,197**	**-26,854**	**-76,738**	**-52,042**	**-105,818**
Financing activities					
New share issue	-	-	-	-	99,877
Transaction costs	-300	-	-300	-10	-29
Payment of lease liability	-527	-537	-1,042	-1,076	-2,154
Redemption of warrants	-	-	-	4,375	4,375
Repurchased warrants	-	-	-	-	-54
Allocated warrants	865	1,694	865	1,694	1,694
Cash flow from financing activities	**38**	**1,157**	**-477**	**4,983**	**103,708**
Cash flow for the period	**-53,631**	**-38,528**	**-129,300**	**-71,861**	**-53,717**
Cash and cash equivalents at the beginning of the period	196,212	292,265	271,881	325,598	325,598
Cash and cash equivalents at the end of the period	**142,581**	**253,737**	**142,581**	**253,737**	**271,881**

Parent Company income statement

	Q2		Jan-Jun		Full year
SEK thousand	**2022**	**2021**	**2022**	**2021**	**2021**
Net sales	-	-	-	-	-
Other operating income	598	153	767	253	656
Research and development expenses	-1,818	-1,951	-3,599	-3,549	-38,560
Administration and sales expenses	-27,456	-15,091	-44,503	-27,298	-58,486
Other operating expenses	-679	-397	-1,417	-867	-1,660
Operating loss	**-29,355**	**-17,286**	**-48,751**	**-31,461**	**-98,050**
Finance income	160	249	329	515	938
Finance costs	-3	-3	-3	-3	-4
Finance net	**157**	**246**	**326**	**512**	**934**
Loss before Income tax	-29,198	-17,040	-48,425	-30,949	-97,116
Tax	-	-	-	-	-
Loss for the period	**-29,198**	**-17,040**	**-48,425**	**-30,949**	**-97,116**
Average number of shares before dilution	20,680,408	19,067,504	20,680,408	19,035,421	19,237,743
Average number of shares after dilution	20,680,408	19,146,578	20,680,408	19,114,495	19,237,743

Parent Company balance sheet

SEK thousand	30 Jun 2022	30 Jun 2021	31 Dec 2021
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	347,703	283,616	296,005
Total intangible assets	**347,703**	**283,616**	**296,005**
Property, plant and equipment			
Machinery and installations	18,962	24,298	20,458
Equipment	360	793	574
Fixed assets under construction and prepayments	42,645	9,027	19,719
Total Property, plant and equipment	**61,967**	**34,118**	**40,751**
Financial assets			
Shares in subsidiaries	50	50	50
Financial investments	1	1	1
Total financial assets	**51**	**51**	**51**
Total non-current assets	**409,721**	**317,785**	**336,808**
Current assets			
Inventories	**6,005**	**-**	**6,199**
Current receivables			
Accounts receivables	270	-	-
Other current receivables	2,482	1,504	2,473
Prepaid expenses and accured income	1,874	1,519	1,995
Total current receivables	**4,625**	**3,022**	**4,467**
Cash and bank	142,531	253,687	271,831
Total current assets	**153,161**	**256,708**	**282,497**
TOTAL ASSETS	**562,882**	**574,493**	**619,305**

SEK thousand	30 Jun 2022	30 Jun 2021	31 Dec 2021
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	20,680	19,068	20,680
Statutory reserve	976	976	976
Development expenditure reserve	347,703	283,616	296,005
Total restricted equity	**369,360**	**303,660**	**317,662**
Non-restricted equity			
Other contributed capital	814,047	715,292	813,483
Accumulated earnings	-591,456	-430,253	-442,642
Profit/loss for the period	-48,425	-30,949	-97,116
Total non-restricted equity	**174,166**	**254,090**	**273,724**
Total equity	**543,526**	**557,750**	**591,386**
Current liabilities			
Trade accounts payable	7,782	4,887	16,865
Other current liabilities	1,086	1,725	653
Accrued expenses and deferred income	10,488	10,131	10,401
Total current liabilities	**19,356**	**16,744**	**27,919**
TOTAL EQUITY AND LIABILITIES	**562,882**	**574,493**	**619,305**

Parent Company cash flow statement

	Q2		Jan-Jun		Full year
SEK thousand	**2022**	**2021**	**2022**	**2021**	**2021**
Operating activities					
Operating loss	**-29,355**	**-17,286**	**-48,751**	**-31,461**	**-98,050**
Non-cash adjustments					
Depreciation	2,090	2,040	4,124	3,723	7,781
Captial gains	-	-	-	98	98
Disposal of intangible fixed assets	-	-	-	-	31,128
Interest received	-	-	-	569	1,557
Interest paid	-3	-4	-3	-4	-4
Cash flow from operating activities before changes in working capital	**-27,268**	**-15,250**	**-44,630**	**-27,075**	**-57,490**
Changes in working capital					
Change in operating receivables	655	1,849	1,348	2,823	-5,389
Change in operating liabilities	1,758	301	-9,545	-1,089	10,087
Cash flow from operating activities	**-24,855**	**-13,100**	**-52,827**	**-25,341**	**-52,792**
Investing activities					
Purchase of intangible assets	-25,790	-26,647	-51,698	-52,104	-95,621
Acquisition of property, plant and equipment	-2,555	-475	-23,334	-475	-1,313
Prepayments	-996	-	-2,006	-	-9,854
Cash flow from investing activities	**-29,341**	**-27,122**	**-77,038**	**-52,579**	**-106,788**
Financing activities					
New share issue	-	-	-	-	99,877
Transaction costs	-300	-	-300	-10	-29
Redemption of warrants	-	-	-	4,375	4,375
Repurchased warrants	-	-	-	-	-54
Allocated warrants	865	1,694	865	1,694	1,694
Cash flow from financing activities	**565**	**1,694**	**565**	**6,059**	**105,863**
Cash flow for the period	**-53,631**	**-38,528**	**-129,300**	**-71,861**	**-53,717**
Cash and cash equivalents at the beginning of the period	196,162	292,215	271,831	325,548	325,548
Cash and cash equivalents at the end of the period	**142,531**	**253,687**	**142,531**	**253,687**	**271,831**

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 2021 have been applied. The changes in IFRS applied as of January 1, 2022 have not had any impact on the financial statements for the first and second quarters of 2022. Comparison figures are presented in parentheses and pertain to the year-earlier period.

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 debt/equity ratio is equity as a percentage of the balance sheet total. Research and development costs as a percentage of operating expenses comprise primarily 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 for the asset or 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. No material changes have occurred in the risks and uncertainties during the period compared with those the company reported in the Annual Report for 2021.

Ukraine

Xspray Pharma continues to follow the tragic events unfolding in Ukraine. At present, Xspray Pharma's operations have not been directly impacted, but we are closely monitoring the course of events.

The company and the pipeline

Xspray Pharma AB (publ) is a pharmaceutical company with multiple product candidates in the clinical development phase. Xspray Pharma uses its innovative, patented technology to develop amorphous product candidates that are improved generic versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. Often the original companies have secondary patents that are based on the crystalline forms of the active substance and which thus does not include amorphous versions.

In bioequivalence studies conducted in healthy volunteers, the goal is to achieve bioequivalence comparable to the original drug, meaning that the active drug substance of the product candidate should be processed by the body the same way as the original drug.

The company's initial product candidates – XS004 dasatinib, XS003 nilotinib and XS005 sorafenib – are stable amorphous versions of the three best-selling cancer drugs Sprycel® (dasatinib), Tasigna® (nilotinib) and Nexavar® (sorafenib). In 2021, Sprycel® sold for USD 2.1 billion, Tasigna® for USD 2.1 billion and Nexavar® for USD 0.5 billion worldwide. A careful selection process determines which PKIs will become future product candidates and be included in the company's pipeline.

Market

PKI drugs are a large and important segment for targeted cancer therapies, where sales total approximately 37 percent of the total oncology market, and with sales figures that are increasing annually. In 2021, estimated sales of PKI drugs in the US market totaled approximately USD 33 billion.
Demand for effective life-cycle products is increasing in pace with the expiration of patents for many crucial reference drugs. Of the over 70 PKIs currently being marketed in the US, 23 drug substance patents are expected to expire by 2030. To date, Xspray Pharma has tested its technology on some twenty of the PKIs established in the US market, with positive results.

PKI drugs with challenges

PKIs have been shown to inhibit the growth of cancer, which results in extended survival and the patient most often being treated for several years – in some cases, for life. The majority of the PKIs being marketed contain crystalline forms of the active substances. One generally known problem with these crystalline products is that they are difficult to dissolve, and solubility can vary depending on the pH value in the stomach for uptake in the body, which results in what is known as high variability. This often results in an uneven uptake of the drug into the body, especially alongside the ingestion of food or pH-increasing drugs such as omeprazole. Variability increases the risk of the loss of therapeutic effect, if uptake of the drug is too low the cancer can accelerate again and if uptake is too high severe side effects often increase.

Xspray Pharma's technology is especially suited to overcoming many of the shortcomings that PKI substances generally possess. The company produces stable amorphous PKIs that can be easily dissolved and are pH-independent, which means a more even uptake of the drug even alongside the ingestion of food or pH-increasing drugs. Moreover, this technology makes it possible to adjust how much of the drug is to be taken up into the body.

Prospects

The company's new HyNap product candidates are being developed in the same manner as the company's initial product, XS004 dasatinib. The process is repeatable, which reduces the development time for future product candidates in the company's pipeline. The technology makes it possible to quickly and in a controlled manner change the properties required to make improved amorphous versions of PKI drugs already being marketed and to bring the respective product candidates to market. This means that the company's easily dissolved and pH-independent product candidates have the conditions to both meet current market demand with better functioning drugs and offer a broader patient group access to drugs that they cannot currently use.
Xspray Pharma's goal is to be a leader in developing improved versions of PKIs already being marketed for the treatment of cancer. The company has patented the manufacturing technology, the equipment, and the resulting products.

Xspray Pharma's pipeline

Xspray Pharma's pipeline is continuously evolving and contains a number of product candidates, three of which have been announced and are based on the company's HyNap platform: XS004 dasatinib, XS003 nilotinib and XS005 sorafenib. These are improved amorphous versions of established and marketed protein kinase inhibitors with orphan drug status. The original drugs have secondary patents expiring between 2026 and 2029 and their total annual sales for 2021 exceeded USD 2.4 billion in the US market and USD 4.7 billion globally.

Product candidates				Patent		Developing phase					
Project	Substance	Key indication	Regulatory process	Substance IP expiry-date	Secondary IP expiry date	New product development	Formulation development	Pilot studies	Pivotal studies	Regulatory review	Original-product/ Company
XS004	dasatinib	Leukemia (CML, ALL)	505(b)(2)	Dec 2020	Sept 2026						Sprycel®/ BMS
XS003	nilotinib	Leukemia (CML)	505(b)(2)	Jan 2024	Feb 2029						Tasigna®/ Novartis
XS005	sorafenib	Liver cancer (HCC)	505(b)(2)	Jan 2020	Sept 2028						Nexavar®/ Bayer
HyNap-X	Undisclosed										
HyNap-Y	Undisclosed										

Research and development

Regulatory

In November 2021, an application was submitted to the FDA for market approval of XS004 under the 505(b)(2) New Drug Application procedure for the indications of acute lymphoblastic leukemia (ALL) and chronic myeloid leukemia (CML) in an accelerated phase. In January 2022, the FDA announced that the application for XS004 had been accepted for a comprehensive review. As a result, litigation was also initiated with the original company, which is a process that runs in parallel with the FDA's review of the 505(b)(2) dossier. The application was supplemented in Q2 with additional dosage strengths, which means that the application now simultaneously covers all six dosage strengths corresponding to those of the original company. The supplement also contains updated product information that now includes CML in a chronic phase as well.

After the supplementary submission, Xspray Pharma has held constructive discussions with the FDA and obtained clearer information regarding how the FDA intends to perform the review of all dosage strengths and the updated product information. In accordance with these discussions, the company estimates tentative market approval of XS004 during H1 2023.

The litigation process with the original company is not affected by the ongoing FDA review of the dossier, and the company has continued with its goal of bringing its product to the market in 2023.

In June, the FDA announced that they had granted XS004 orphan drug status for CML. The FDA's decision is based on the plausible hypothesis that XS004 could be clinically superior to other drugs with the same compound that has already been approved for the same indication, since Xspray Pharma's product candidate may provide a major contribution to patient care owing to the gastric pH-resistant qualities of the formulation, since acid-reducing drugs (H2 blockers and proton-pump inhibitors) cannot be taken with the original drug and in the context of the significant concomitant use of acid-reducing agents in the CML population.

Share information

Xspray Pharma's share has been listed on Nasdaq Stockholm in the Mid-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. At June 30, 2022, the number of shares in the company was 20,680,408 and the last price paid in the period was SEK 55.20.

Incentive plans

At June 30, 2022 the company had a total of four series of warrants issued to employees, senior executives and the Chairman of the Board. All warrant programs and employee stock options were valued using the Black & Scholes valuation model at the time of allocation.

LITP 2020–2023

The LTIP 2020–2023 warrant program encompasses 72,485 warrants that can be exercised during the period from April 1, 2023 through May 14, 2023 at a subscription price of SEK 89.10 per share. There is a maximum dilution effect of 0.4% on the current number of shares.

LITP 2021–2024

The LTIP 2021–2024 warrant program encompasses 189,340 warrants that can be exercised during the period from June 3, 2024 through July 15, 2024 at a subscription price of SEK 148.90 per share. There is a maximum dilution effect of 0.9% on the current number of shares.

Chairman LTIP 2021–2026

The Chairman LTIP 2021–2026 warrant program includes the Chairman of the Board and encompasses 13,214 warrants that can be exercised during the period from May 25, 2026 through June 15, 2026 at a subscription price of SEK 129.00 per share. There is a maximum dilution effect of 0.06% on the current number of shares.

LTIP 2022–2025

The program was resolved on at the Annual General Meeting on May 19, 2022. The program encompasses 140,625 warrants and 281,250 that can be exercised during the period from June 15, 2025 through July 15, 2025 at a subscription price of SEK 132.20 per share. The program is pegged to the company's growth in value for the purpose of creating a stronger link between employee and shareholder interests. There is a maximum dilution effect of 2.0% on the current number of shares.

A detailed description of the three earlier warrant programs can be found in the company's 2021 Annual Report.

Owners as of June 30, 2022	Number of shares	Number of shares & votes
Flerie Invest	2,572,096	12.40%
Ribbskottet	2,539,119	12.30%
The Foundation for Baltic And East European Studies	2,500,826	12.10%
Fourth Swedish National Pension Fund	1,795,806	8.70%
Nordnet Pension Insurance	799,442	3.90%
Avanza Pension	755,285	3.70%
Unionen	726,000	3.50%
TIN Funds	600,000	2.90%
Swedbank Robur Funds	469,735	2.30%
Second Swedish National Pension Fund	422,320	2.00%
Total, ten largest owners	13,180,629	63.73%
Total, other shareholders	7,499,779	36.27%
Total number of shares	**20,680,408**	**100.00%**

Analysts monitoring the company

Filip Einarsson, Redeye AB
Naresh Chouhan, Intron Health
Dan Akschuti, Pareto Securities AB

Financial calendar

Interim Report Q3 2022	November 9, 2022
Year-End Report 2022	February 17, 2023

The financial reports will be made available on the Xspray Pharma website on the reporting dates above, www.xspraypharma.com.

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 5, 2022

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 audited.

Information
Glossary

505(b)(2) NDA •	Application for drug approval in the US for an improved version of an existing licensed or approved drug.
Amorphous •	An amorphous structure is a chemical term that describes substances whose molecules lack an ordered structure.
Bioequivalence •	Term used to describe whether two different drugs are processed in a similar manner by the body and are thereby expected to have a similar and equivalent medicinal effect. If it can be confirmed that two drugs being compared are bioequivalent, they can be expected to have the same effect and safety.
Bioavailability •	(Biological availability), a concept in pharmacology that shows how large a portion of the drug reaches the blood.
CRO •	Contract Research Organization. A service company active in contract research and service in the development of drugs.
FDA •	Food and Drug Administration. The US food and drug authority responsible for foodstuffs, nutritional supplements, drugs, cosmetics, medical equipment, radiation-emitting equipment and blood products.
GMP •	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.
Pilot study •	An initial study conducted on a smaller scale than a full study. A pilot study can be used both to check whether the arrangement of the study is a functional one, and to collect data that can later be used as control values in the full study.
Protein kinase inhibitor (PKI) •	Drugs that block protein kinases. Protein kinase inhibitors work by blocking activity in enzymes that push the development and growth of cancer cells.
Variability •	The scope of the distribution in the form of many or few low and high values around the average value as regards the body's uptake of drugs.

This interim report for Xspray Pharma AB (publ) was released after approval by the Board of Directors.

For further information, please contact
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