xspray PHARMA

Interim Report January–March 2022

January - March 2022

Q1 2022

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 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.

First Quarter 2022 (January 1–March 31), Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -18,934 thousand (-13,912)
- Earnings per share before dilution amounted to SEK -0.92 (-0.73)
- Cash flow from operating activities amounted to SEK -27,613 thousand (-11,971)
- Cash flow from investing activities amounted to SEK -47,541 thousand (-25,188)
- Cash and cash equivalents at the end of the period amounted to SEK 196,212 thousand (292,265)

Amounts in parentheses refer to the year-earlier period.

Significant events during the quarter

- In January, the FDA announced that the application for market approval of Dasynoc had been accepted for a full review.
- In February, the company announced that it had hired Anna-Karin Ekberg as Global Head of Marketing and Sales. Anna-Karin took office on March 15, 2022 and is now part of the company's management group.
- In February, it was announced that Bristol Myers Squibb had filed a lawsuit against Xspray Pharma in the US claiming patent infringement in relation to the submission of Xspray Pharma's 505(b)(2) New Drug Application to the FDA.

Significant events after the end of the reporting period

- The company has decided to invite investors, analysts, media representatives and other stakeholders to a capital markets day on May 24, 2022.

"Xspray Pharma is in an intense period, with a focus on building up the company, commercialization, the project portfolio and production capacity. It is intensive, rewarding work for all of us."

Per Andersson, CEO
Xspray Pharma AB (publ)

A message from the CEO

An eventful quarter sets the agenda for an intense 2022

The first quarter of the year was an intensive and eventful one, and we are pleased that Xspray Pharma has continually moved forward in its development. You can almost sense Xspray Pharma growing and maturing, and in particular we look forward to launching our first product and expanding our project portfolio. We are working hard to put the company's future commercialization of its operations in place, and on our company-wide communication as well. Our laboratory work is in high gear, and at the plant in Italy we are now able to run two processes in parallel on a commercial scale. During the quarter, we also broke ground on what will be our production unit in Malta, which is particularly favorable for production from a patent perspective.

Loss for the first quarter amounted to SEK -18,934 thousand (-13,912). The result reflects the continued work on strengthening the organization as well as the company's future strategic positioning. The continued negative cash flow is in accordance with the company's plan, and is attributable to the increased investments in Malta.

In January, we reached a significant milestone when the US Food and Drug Administration (FDA) announced that Dasynoc, Xspray Pharma's first product candidate, had been accepted for a comprehensive review. Our application is now being supplemented with lower dose strengths as well, and we hope to obtain FDA approval before the end of 2022, but matters lie primarily in the hands of the FDA. It is important to remember that Xspray Pharma is developing a project portfolio. The lessons we take and have taken from Dasynoc can be advantageous in the development of new products.

Entirely in line with our expectations, the original company for the reference product of the active compound, dasatinib, brought a lawsuit against us in conjunction with our application to the FDA. As a result of the lawsuit, we are limited regarding the information we can disclose around Dasynoc, but we remain convinced of the excellent qualities of the product and that the work on bringing the product to market will progress in accordance with plans. It is positive that the FDA has issued preliminary approval of the product name.

The ambition of having Xspray Pharma's initial product in the market during 2023 remains, while the patent protection of the original drug still hinders competition from other generic drugs, which is to our advantage.

As part of the preparations ahead of the product launch, we are taking measures such as increasing production capacity and scaling up our commercial organization. During the quarter, Anna-Karin Ekberg took office as the Global Head of Marketing and Sales at Xspray Pharma. Anna-Karin has solid expertise in hematology, which in combination with a broad understanding of the industry concerning issues of commercialization – especially in the US – means we are better prepared to sell and market our products there.

In the second quarter, I look forward to working on the favorable results we have seen in the initial clinical studies for HyNap-Nilo and to obtaining the final results for the market research we carried out in order to further understand the US market for Dasynoc.

Xspray Pharma is in an intense period, with a focus on building up the company, commercialization, the project portfolio and production capacity. It is intensive, rewarding work for all of us. Despite this, no one can ignore the fact that there is a war in Europe, and the humanitarian catastrophe that is unfolding is a deeply tragic one. At present, Xspray Pharma's operations have not been directly impacted, but we are closely monitoring the course of events.

May 6, 2022

Per Andersson
CEO

Financial overview, Group

	Q1		Full year
Key figures, Group	**2022**	**2021**	**2021**
Net sales (SEK thousand)	-	-	-
Loss before Income tax (SEK thousand)	-18,934	-13,912	-96,698
Earnings per share before dilution (SEK)	-0.92	-0.73	-5.03
Earnings per share after dilution (SEK)	-0.92	-0.73	-5.03
Research and development expenses as % of operating expenses	8.7	11.4	39.1
Cash and cash equivalents (SEK thousand)	196,212	292,265	271,881
Total assets (SEK thousand)	592,430	594,178	622,903
Equity/assets ratio (%)	96.7	96.4	95.0
Average number of employees	24	21	23

Total expenditure for research and development for the quarter was SEK -27,707 thousand, of which SEK -1,694 thousand has been expensed and SEK -26,013 thousand capitalized as development expenses.

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 differences between RFR2 and IFRS.

Net sales

Net sales for the company remain at SEK 0 thousand. The application for market approval of company's initial product, Dasynoc, was filed in Q4 2021.

Other operating income and expenses

Other operating income for the period amounted to SEK 170 thousand (100). Other operating expenses for the period amounted to SEK -737 thousand (-470). Both categories consist entirely of exchange rate gains and losses arising in conjunction with payments abroad and conversion of foreign currency.

Research and development costs

Total expenditure for research and development amounted to SEK -27,707 thousand (-27,095) during the first quarter, of which SEK -1,694 thousand (-1,626) was expensed and recognized in profit or loss and SEK 26,013 thousand (25,470) was capitalized as development expenses and presented in the company's balance sheet. These costs are in line with the year-earlier period, and are attributable to continued activity for the company's two product candidates, Dasynoc and HyNap-Nilo.

Administrative and sales costs

Administrative and sales costs for the first quarter of 2022 amounted to SEK -17,021 thousand (-12,182); of these, personnel costs classified as administrative, and sales costs amounted to SEK -6,315 thousand (-3,895). The cost increase for the first 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 first quarter amounted to SEK -18,934 thousand (-13,912). This corresponds to earnings per share before dilution of SEK -0.92 (-0.73).

The change in earnings for the quarter is attributable primarily to increased administrative and sales costs resulting from increased consultation costs of SEK -1,933 thousand (-1,077) and shipping costs of SEK -1,145 thousand (-270). Personnel costs classified as administrative, and sales costs increased by SEK -2,420 thousand year-on-year.

Cash flow, investments, financial position and going concern

Cash flow from operating activities for the quarter amounted to SEK -27,613 thousand (-11,971), of which the effect from operating capital comprised SEK -10,955 thousand (-416). The continued negative cash flow is in accordance with the company's plan, and is primarily attributable to a strengthened organization, project costs and other advisory

services for the company's future strategic positioning.
Cash flow from investing activities for the quarter amounted to SEK -47,541 thousand (-25,188). The item includes capitalized development expenses of SEK -25,752 thousand (-25,188). The main explanation for the increase comes from investments in property, plant, and equipment, which amounted to SEK -20,779 thousand (0). During the period, advances paid increased 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 -515 thousand (3,826), which in turn is attributable solely to amortization of lease liabilities.
Total cash flow for the first quarter of the year was SEK -75,669 thousand (-33,333). The Group had SEK 196,212 thousand (292,265) in cash and cash equivalents as of March 31, 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 96.7 per cent (96.4) on March 31, 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 26,013 thousand (25,470). The Group's total capitalized expenditures for development and similar activities totaled SEK 322,249 thousand (257,088) on March 31, 2022. The item is associated with the company's product candidates Dasynoc, HyNap-Nilo and HyNap-Sora.

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 196,162 thousand (292,215) and the debt/equity ratio was 97.2 per cent (96.4) on March 31, 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 24 (21). 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 quarter 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).

Corporate governance

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

Financial statements and notes

Xspray Pharma AB (publ) acquired a newly-formed subsidiary in December 2018, which remains dormant. No activity has taken place in the subsidiary; all activities are pursued in the Parent Company, Xspray Pharma AB (publ).

Consolidated income statement

	Q1		Full year
SEK thousand	**2022**	**2021**	**2021**
Net sales	-	-	-
Other operating income	170	100	656
Research and development expenses	-1,694	-1,626	-38,567
Administration and sales expenses	-17,021	-12,182	-58,384
Other operating expenses	-737	-470	-1,657
Operating loss	**-19,282**	**-14,177**	**-97,953**
Finance income	348	266	1,259
Finance costs	-	-0	-4
Finance net	**348**	**266**	**1,255**
Loss before Income tax	**-18,934**	**-13,912**	**-96,698**
Tax	-	-	-
Loss for the period	**-18,934**	**-13,912**	**-96,698**
Earnings per share for the period before dilution, SEK	-0.92	-0.73	-5.03
Earnings per share for the period after dilution, SEK	-0.92	-0.73	-5.03
Average number of shares before dilution	20,680,408	19,002,616	19,237,743
Average number of shares after dilution	20,680,408	19,081,690	19,237,743

Consolidated statement of comprehensive income

	Q1		Full year
SEK thousand	**2022**	**2021**	**2021**
Loss for the period	**-18,934**	**-13,912**	**-96,698**
Other comprehensive income	-	-	-
Total comprehensive income for the period	**-18,934**	**-13,912**	**-96,698**

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

Consolidated balance sheet

SEK thousand	31 Mar 2022	31 Mar 2021	31 Dec 2021
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	322,249	257,088	296,236
Total intangible assets	**322,249**	**257,088**	**296,236**
Property, plant and equipment			
Machinery and installations	19,270	26,227	20,458
Right-of-use assets	3,299	5,002	3,526
Equipment	467	864	574
Fixed assets under construction and prepayments	41,273	8,590	20,043
Total Property, plant and equipment	**64,310**	**40,683**	**44,601**
Financial assets			
Financial investments	1	1	1
Total financial assets	**1**	**1**	**1**
Total non-current assets	**386,560**	**297,773**	**340,838**
Current assets			
Inventories	6,199	-	6,199
Current receivables	2,138	1,706	2,473
Prepaid expenses and accured income	1,322	2,435	1,513
Cash and cash equivalents	196,212	292,265	271,881
Total current assets	**205,871**	**296,406**	**282,065**
TOTAL ASSETS	**592,430**	**594,178**	**622,903**

SEK thousand	31 Mar 2022	31 Mar 2021	31 Dec 2021
EQUITY AND LIABILITIES			
Equity			
Share capital	20,680	19,068	20,680
Other contributed capital	813,483	713,598	813,483
Reserves	976	976	976
Retained earnings including profit/loss for the period	-262,322	-160,601	-243,387
Total equity attributable to the Parent Company's shareholders	**572,818**	**573,041**	**591,752**
Non–current liabilities			
Lease liabilities	878	2,616	1,185
Total non-current liabilities	**878**	**2,616**	**1,185**
Current liabilities			
Trade accounts payable	8,127	6,657	16,865
Lease liabilities	2,121	2,078	2,048
Other current liabilities	1,052	1,636	653
Accrued expenses and deferred income	7,435	8,150	10,401
Total current liabilities	**18,734**	**18,521**	**29,966**
TOTAL EQUITY AND LIABILITIES	**592,430**	**594,178**	**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	-	-	-	-18,934	-18,934
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	**-**	**-**	**-**	**-18,934**	**-18,934**
Closing balance as of March 31, 2022	**20,680**	**813,483**	**976**	**-262,321**	**572,818**

Consolidated cash flow statement

	Q1		Full year
SEK thousand	**2022**	**2021**	**2021**
Operating activities			
Operating loss	-19,282	-14,177	-97,953
Non-cash adjustments			
Depreciation	2,321	1,955	8,870
Capital gains	-	98	98
Disposal of intangible fixed assets	-	-	31,128
Interest received	345	569	1,878
Interest paid	-41	-	-4
Cash flow from operating activities before changes in working capital	**-16,657**	**-11,555**	**-55,983**
Changes in working capital			
Change in operating receivables	350	973	-5,712
Change in operating liabilities	-11,306	-1,389	10,087
Cash flow from operating activities	**-27,613**	**-11,971**	**-51,607**
Investing activities		-	
Capitalized development costs	-25,752	-25,188	-94,651
Acquisition of property, plant and equipment	-20,779	-	-1,313
Sales of tangible fixed assets	-	-	-
Prepayments	-1,010	-	-9,854
Cash flow from investing activities	**-47,541**	**-25,188**	**-105,818**
Financing activities			
New share issue	-	-	99,877
Transaction costs	-	-10	-29
Payment of lease liability	-515	-539	-2,154
Redemption of warrants	-	4,375	4,375
Repurchased warrants	-	-	-54
Allocated warrants	-	-	1,694
Cash flow from financing activities	**-515**	**3,826**	**103,708**
Cash flow for the period	**-75,669**	**-33,333**	**-53,717**
Cash and cash equivalents at the beginning of the period	271,881	325,598	325,598
Cash and cash equivalents at the end of the period	**196,212**	**292,265**	**271,881**

Parent Company income statement

	Q1		Full year
SEK thousand	**2022**	**2021**	**2021**
Net sales	-	-	-
Other operating income	170	100	656
Research and development expenses	-1,780	-1,598	-38,560
Administration and sales expenses	-17,047	-12,207	-58,486
Other operating expenses	-738	-470	-1,660
Operating loss	**-19,396**	**-14,175**	**-98,050**
Finance income	169	266	938
Finance costs	-	-0	-4
Finance net	**169**	**266**	**934**
Loss before Income tax	**-19,227**	**-13,909**	**-97,116**
Tax	-	-	-
Loss for the period	**-19,227**	**-13,909**	**-97,116**

Parent Company balance sheet

SEK thousand	31 Mar 2022	31 Mar 2021	31 Dec 2021
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	321,913	256,969	296,005
Total intangible assets	**321,913**	**256,969**	**296,005**
Property, plant and equipment			
Machinery and installations	19,270	26,227	20,458
Equipment	467	864	574
Fixed assets under construction and prepayments	40,769	8,590	19,719
Total Property, plant and equipment	**60,506**	**35,681**	**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	**382,470**	**292,701**	**336,808**
Current assets			
Inventories	**6,199**	**-**	**6,199**
Current receivables			
Other current receivables	2,138	1,706	2,473
Prepaid expenses and accured income	1,804	2,917	1,995
Total current receivables	**3,942**	**4,622**	**4,467**
Cash and bank	196,162	292,215	271,831
Total current assets	**206,302**	**296,837**	**282,497**
TOTAL ASSETS	**588,773**	**589,539**	**619,305**

SEK thousand	31 Mar 2022	31 Mar 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	321,913	256,969	296,005
Total restricted equity	**343,570**	**277,013**	**317,662**
Non-restricted equity			
Other contributed capital	813,483	713,598	813,483
Accumulated earnings	-565,666	-403,606	-442,642
Profit/loss for the period	-19,227	-13,909	-97,116
Total non-restricted equity	**228,589**	**296,083**	**273,724**
Total equity	**572,159**	**573,095**	**591,386**
Current liabilities			
Trade accounts payable	8,127	6,657	16,865
Other current liabilities	1,052	1,636	653
Accrued expenses and deferred income	7,435	8,150	10,401
Total current liabilities	**16,614**	**16,444**	**27,919**
TOTAL EQUITY AND LIABILITIES	**588,773**	**589,539**	**619,305**

Parent Company cash flow statement

	Q1		Full year
SEK thousand	**2022**	**2021**	**2021**
Operating activities			
Operating loss	**-19,396**	**-14,175**	**-98,050**
Non-cash adjustments			
Depreciation	2,034	1,683	7,781
Captial gains	-	98	98
Disposal of intangible fixed assets	-	-	31,128
Interest received	-	569	1,557
Interest paid	-	-	-4
Cash flow from operating activities before changes in working capital	**-17,362**	**-11,825**	**-57,490**
Changes in working capital			
Change in operating receivables	693	974	-5,389
Change in operating liabilities	-11,303	-1,390	10,087
Cash flow from operating activities	**-27,972**	**-12,241**	**-52,792**
Investing activities			
Purchase of intangible assets	-25,908	-25,457	-95,621
Acquisition of property, plant and equipment	-20,779	-	-1,313
Prepayments	-1,010	-	-9,854
Cash flow from investing activities	**-47,697**	**-25,457**	**-106,788**
Financing activities			
New share issue	-	-	99,877
Transaction costs	-	-10	-29
Redemption of warrants	-	4,375	4,375
Repurchased warrants	-	-	-54
Allocated warrants	-	-	1,694
Cash flow from financing activities	**-**	**4,365**	**105,863**
Cash flow for the period	**-75,669**	**-33,333**	**-53,717**
Cash and cash equivalents at the beginning of the period	271,831	325,548	325,548
Cash and cash equivalents at the end of the period	**196,162**	**292,215**	**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 quarter 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 costs comprise primarily expensed research and development expenditures divided by operating costs. Total operating costs 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 has followed the events unfolding in Ukraine with no small amount of consternation. The humanitarian catastrophe is a deeply tragic one. 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 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.
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 – Dasynoc (formerly HyNap-Dasa), HyNap-Nilo and HyNap-Sora – 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 candidate, Dasynoc (HyNap-Dasa). The process is repeatable, which reduces the development time for future products 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 project portfolio

Xspray Pharma's project portfolio 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: Dasynoc (HyNap-Dasa), HyNap-Nilo and HyNap-Sora. 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
HyNap-Dasa	dasatinib	Leukemia (CML, ALL)	505(b)(2)	Dec 2020	Sept 2026						Sprycel®/ BMS
HyNap-Nilo	nilotinib	Leukemia (CML)	505(b)(2)	Jan 2024	Feb 2029						Tasigna®/ Novartis
HyNap-Sora	sorafenib	Liver cancer (HCC)	505(b)(2)	Jan 2020	Sept 2028						Nexavar®/ Bayer
HyNap-X	Undisclosed										
HyNap-Y	Undisclosed										
HyNap-Z	Undisclosed										

Source: Evaluate Pharma

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 March 31, 2022, the number of shares in the company was 20,680,408 and the last price paid in the period was SEK 60.50.

Incentive plans

At March 31, 2022 the company had a total of three series of warrants issued to employees, senior executives and the Chairman of the Board. All warrant programs were valued using the Black & Scholes valuation model at the time of allocation. The LTIP 2018–2022 program encompassing 231,922 warrants expired during the quarter. No warrants had been exercised as of the end date on January 17, 2022.

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.

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

Owners as of March 31, 2022	Number of shares	Number of shares & votes
The Foundation for Baltic And East European Studies	2,500,826	12.09%
Ribbskottet	2,439,119	11.79%
Fourth Swedish National Pension Fund	1,620,000	7.83%
Flerie Invest	1,612,904	7.80%
Swedbank Robur Funds	1,385,822	6.70%
Avanza Pension	734,992	3.55%
Unionen	726,000	3.51%
Nordnet Pension Insurance	686,335	3.32%
TIN Funds	685,590	3.32%
Second Swedish National Pension Fund	422,320	2.04%
Total, ten largest owners	12,813,908	61.96%
Total, other shareholders	7,866,500	38.04%
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

Annual General Meeting 2022	May 19, 2022
Interim Report Q2 2022	August 5, 2022
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, May 6, 2022

Anders Ekblom
Chairman of the Board

Anders Bladh
Board member

Gunnar Gårdemyr
Board member

Maris Hartmanis
Board member

Torbjörn Koivisto
Board member

Christine Lind
Board member

Carl-Johan Spak
Board member

Per Andersson
Managing Director

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.
CMO •	Contract Manufacturing Organization.
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

Christina Malmberg Hägerstrand, SVP Communications & Investor Relations
Phone: +46 (0) 72 855 93 29
E-mail: christina.malmberg.hagerstrand@xspray.com
www.xspraypharma.com