YEAR-END REPORT JANUARY-DECEMBER 2021

Xspray Pharma is a drug company that focuses on cost-efficient development of improved versions of orphan drugs with high value, primarily protein kinase inhibitors (PKIs). They are formulated as hybrid nanoparticles ("HyNap") and are amorphous, patentable, and stable versions of crystalline original substances.

Significant events during the fourth quarter

October - December 2021

- In October, Xspray Pharma announced that it had chosen to focus solely on its improved product HyNap-Dasa 505(b)(2), or Dasynoc™ ("Dasynoc"), since bio-equivalence had not been achieved for the generic version, HyNap-Dasa ANDA. The earnings effect of the disposal of the capitalized development expenses totaled SEK 31 million.
- In October, the composition of the Nomination Committee for the 2022 Annual General Meeting was announced.
- In October, the company announced that the report for the third quarter had been brought forward from 4 November to 26 October.
- A private placement of new shares was issued to Flerie Invest AB in November, with a subscription price of SEK 62.00 per share. The issue generated SEK 100 million before transaction costs and increased the number of shares by 1,612,904, from 19,067,504 to 20,680,408.
- In November, it was announced that Christina Malmberg Hägerstrand had been appointed Vice President Investor Relations and Communications. Christina joined on January 10, 2022, and is member of the company's management team.
- In November, the company submitted its application to the FDA for US market approval of the company's product candidate Dasynoc (dasatinib) under the 505(b)(2) NDA process.

Significant events after the end of the reporting period

- 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 Anna-Karin Ekberg has been appointed Global Head of Marketing and Sales. Anna-Karin will take office on March 15, 2022, and will become member of the company's management team.

October - December 2021, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -51,944 thousand (-14,972)
- Earnings per share before dilution amounted to SEK -2.62 (-0.81)
- Cash flow from operating activities amounted to SEK -10,280 thousand (-11,717)
- Cash flow from investing activities amounted to SEK -33,691 thousand (-27,926)

January - December 2021, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -96,698 thousand (-52,410)
- Earnings per share before dilution amounted to SEK -5.03 (-3.05)
- Cash flow from operating activities amounted to SEK -51,607 thousand (-47,792)
- Cash flow from investing activities amounted to SEK -105,818 thousand (-96,828)
- Cash and cash equivalents at the end of the period amounted to SEK 271,881 thousand (325,598)

Amounts in parentheses refer to the year-earlier period.

A message from the CEO

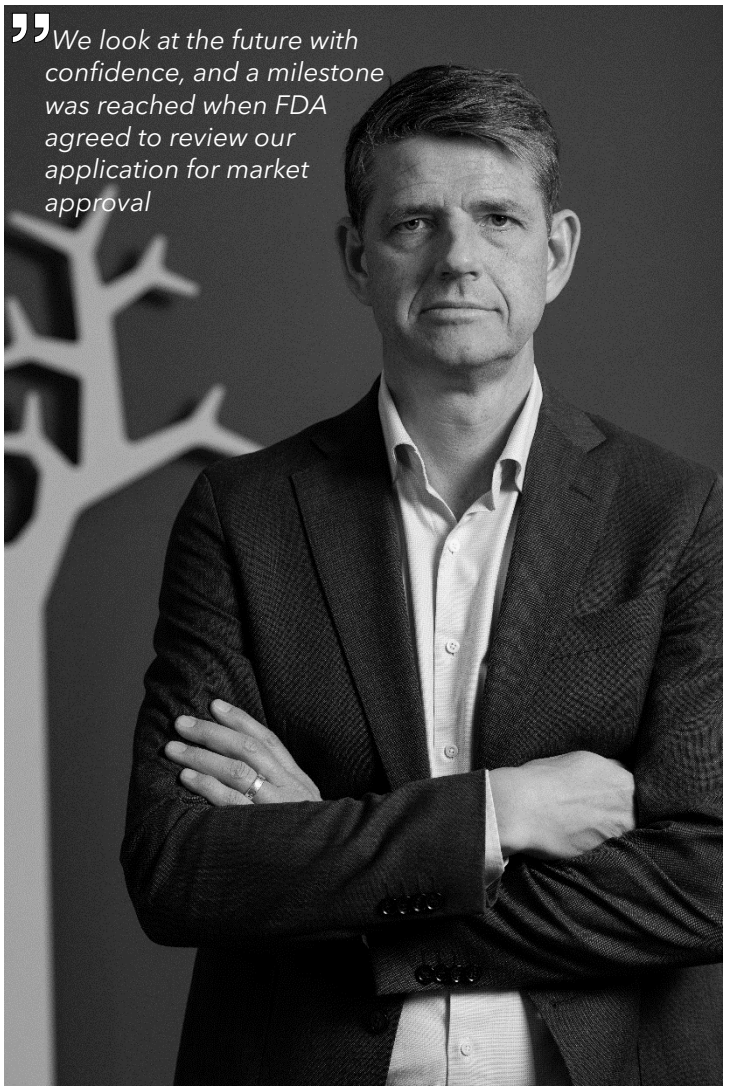
Dasynoc – accepted for full review

When looking back at Xspray Pharma's fourth quarter 2021, I see it marked by hope for the future. After the end of the quarter, we reached a significant milestone when the US Food and Drug Administration (FDA) announced that it had agreed to review Xspray Pharma's first product candidate: Dasynoc, an improved version of dasatinib.

The total time for the FDA's review, which includes the introductory review process, is approximately ten months, but this will likely be adjusted depending on any questions from the FDA. Our application will also be supplemented by lower dose strengths of Dasynoc, and the timing of this supplement will be discussed together with the FDA. We hope to obtain FDA approval for Dasynoc before the end of 2022, but matters now lie primarily in the hands of the FDA.

The commercial preparations for Dasynoc are continuing while the review process is under way. Our studies have confirmed that Dasynoc can offer significant medical benefits: a lower dose of Dasynoc yields the same uptake in the body as the reference product; uptake of the active substance is more even and is not affected by the pH value of the stomach or simultaneous treatment with, for example, drugs for peptic ulcers – which we know that many in this patient group are in need of, it is not recommended to be used together with the reference product.

As is customary, after the FDA has accepted an application for detailed review – and in line with our plans – the company of the original product has been informed that the application has been filed. As previously communicated, we expect a lawsuit, and we are well prepared for such legal proceedings. With an experienced internal team, and in partnership with patent attorneys in the US, we are working to ensure that the proceedings are carried out as efficiently and timely as possible. It is worth emphasizing that a lawsuit will not impact the FDA review process.



Our ambition is that Xspray Pharma's initial product will come to the market during 2023 while the patent protection of the original drug still hinders competition from other generic drugs, which is to our advantage.

The development processes that we have created with Dasynoc can now be used in the development of our other product candidates, and the process with HyNap-Nilo is progressing according to plan. Today, we can take a new product candidate through the development in a much shorter period of time, and the new product line now being constructed in Malta will be extremely valuable for the production of future products.

During the fourth quarter, we were pleased to welcome a new owner, Flerie Invest AB, to the company through a private placement. The share issue was carried out after we decided to focus our unique technology on improved PKIs. Specifically, the increase in losses during the quarter was attributable primarily to expensing of previously capitalized development costs for our product HyNap-Dasa ANDA, which was our generic version.

Despite the advances of the pandemic, I note that neither production nor efficiency for our projects have decreased despite the increase in work from home. I feel proud, and comfortable with the competence we have in the company.

We have expanded our management group with Christina Malmberg Hägerstrand, who took office early in the year as VP Investor Relations and Communications. We have also announced that Anna-Karin Ekberg will take office as Global Head of Marketing and Sales in March. Both are welcome additions and natural steps in Xspray Pharma's continued development. We will continue working intensely on commercialization issues, and we are ready to face various future scenarios.

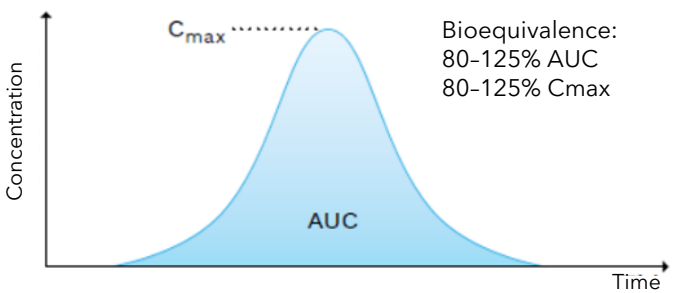
February 18, 2022

Per Andersson
CEO

Business focus and prospects

Xspray Pharma AB (publ) is a drug 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. Since Xspray Pharma's products are amorphous, they can be marketed as soon as the original companies' drug substance patents expire. This is a unique opportunity for favorable market establishment.

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.



Bioequivalence is measured as the area under the curve (AUC) and as maximum blood plasma concentration (C_{max}).

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 2020, Sprycel® sold for USD 2.1 billion, Tasigna® for USD 2.0 billion and Nexavar® for USD 0.7 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 25 percent of the total oncology market, and with sales figures that are increasing annually. In 2020, sales of PKI drugs in the US market totaled approximately USD 24 billion.

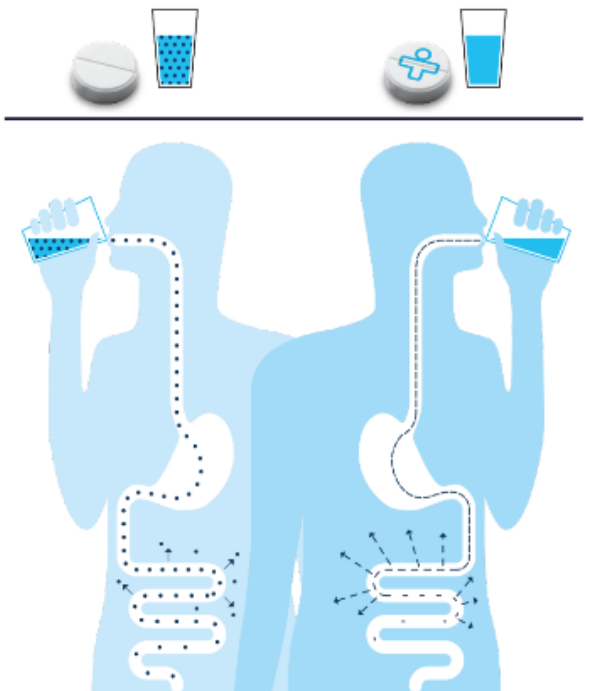
Demand for effective life-cycle products is increasing in pace with the expiration of patents for many crucial reference drugs. Of the over 70 PKIs currently being marketed in the US, 23 drug substance patents are expected to expire by 2030. To date, Xspray Pharma has tested its technology on some twenty of the PKIs established in the US market, with positive results.

PKI drugs with challenges

Protein kinase inhibitors (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 has the solution

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.



Xspray Pharma's amorphous products are easily dissolved and independent of the pH value in the stomach, which yields a more even uptake of the drug into the body in contrast to the crystalline products of the reference drug.

Prospects

The company's new HyNap product candidates are being developed in the same manner as the company's initial product, Dasynoc (HyNap-Dasa). The process is repeatable and 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 products 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 product portfolio

Xspray Pharma's product portfolio is continuously evolving and includes a number of product candidates, of which, three has 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 2020 exceeded USD 2.3 billion in the US market and USD 4.8 billion globally. During the fourth quarter, it was decided to terminate development of the generic version of dasatinib, which was being developed in parallel with Dasynoc.

Dasynoc – HyNap-Dasa 505(b)(2)

Xspray Pharma has developed an improved version of dasatinib, Dasynoc, for the treatment of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL). Dasynoc has achieved bioequivalence with a 30 percent lower dose against the original drug, Sprycel®. The study confirms that Dasynoc:

- is unaffected by the pH value of the stomach and can thus be used together with proton-pump inhibitors without affecting the absorption, which facilitates simultaneous treatment of peptic ulcers with pharmaceuticals such as omeprazole while the patient is being treated for cancer
- yields a more even and consistent uptake in the body without those cases of low uptake that were linked to the original product in previous studies
- can be administered at a lower dosage than the original product, which is expected to yield fewer side effects

The market value for Dasynoc is high both during and after the end of the patent window. The application for market approval of Dasynoc in the US under the 505(b)(2) process was filed with the FDA in the fourth quarter of 2021, and after the end of the quarter the FDA accepted the application for continued detailed review.

The primary patent for the original drug expired in December 2020 and the secondary patent expires in 2026, which could give Dasynoc a favorable market establishment over several years with limited competition. In 2020, the global market for Sprycel® amounted to approximately USD 2.1 billion, of which the US market accounted for approximately USD 1.3 billion.

HyNap-Nilo

Xspray Pharma is developing HyNap-Nilo as an improved version of Tasigna® (nilotinib) for the treatment of chronic myeloid leukemia (CML). Global sales of Tasigna® totaled USD 2.0 billion in 2020, of which the US market accounted for USD 0.9 billion.

Tasigna®'s drug substance patent expires in January 2024, and the secondary patent in February 2029. Xspray Pharma has conducted a clinical trial that investigated the pharmacokinetic properties, and food interaction effects of a HyNap-Nilo prototype have been tested. The study showed that HyNap-Nilo significantly reduces food interaction compared with Tasigna® after a high-fat meal. Studies have also shown significantly higher bioavailability of HyNap-Nilo compared with Tasigna®. Development is progressing, with the target of conducting bioequivalence studies that, in the event of positive findings, will form the basis of the application for market approval under the 505(b)(2) procedure.

The US Food and Drug Administration has granted orphan drug status to HyNap-Nilo for the treatment of chronic myeloid leukemia (CML), in view of the fact that HyNap-Nilo addresses the food interaction that is included in the warning text for Tasigna® in the US. The warning text means that the intake of Tasigna® increases with food intake and thus increases the risk of serious side effects.

The development of the commercial formulation is complete, and manufacturing of clinical trial materials is under way ahead of the program of studies that is planned for 2022.

HyNap-Sora

Xspray Pharma has developed HyNap-Sora as an improved version of Nexavar® (sorafenib) for the treatment of renal cancer and liver cancer as well as several forms of thyroid cancer. Global sales of Nexavar® in 2020 totaled USD 0.7 billion, of which the US market accounted for USD 0.2 billion. Nexavar's primary drug substance patent expired in January 2020, and the secondary patent in the US expires in September 2028.

A pharmacokinetic study in 14 healthy subjects was conducted with HyNap-Sora 100 mg against Nexavar® 200 mg. The study showed that the bioavailability of HyNap-Sora was nearly double that of Nexavar®. The variability in both AUC and C_{max} among subjects was also reduced by approximately half.

Xspray Pharma is holding off on the development of HyNap-Sora in favor of other product candidates in its product portfolio that show a higher market value.

Product			**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
DASYNOC	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-New	Undisclosed										
HyNap-New	Undisclosed										
HyNap-New	Undisclosed										

Financial overview, Group

	Q4		Jan-Dec	
Key figures, Group	**2021**	**2020**	**2021**	**2020**
Net sales (SEK thousand)	-	-	-	-
Loss before Income tax (SEK thousand)	-51,944	-14,972	-96,698	-52,410
Earnings per share before dilution (SEK)	-2.62	-0.81	-5.03	-3.05
Earnings per share after dilution (SEK)	-2.62	-0.81	-5.03	-3.05
Research and development expenses as % of operating expenses	62.7	10.4	39.1	11.9
Cash and cash equivalents (SEK thousand)	271,881	325,598	271,881	325,598
Total assets (SEK thousand)	622,903	605,303	622,903	605,303
Equity/assets ratio (%)	95.0	96.2	95.0	96.2
Number of employees	23	20	23	20

Total expenditure for research and development for the quarter was SEK -28,991 thousand, of which SEK-1,881 thousand has been expensed and SEK -27,112 thousand capitalized as development expenses. During the period, SEK -31,128 thousand was disposal, due to the decision to terminate further development of the generic version in order to focus on the improved product Dasynoc.

Total expenditure for research and development for the period January–December was SEK-72,057 thousand, of which SEK -7,439 thousand has been expensed and SEK -64,618 thousand was capitalized as development expenses. The disposal had an effect of -SEK 31,128 thousand.

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 328 thousand (502). Other operating expenses for the period amounted to SEK -340 thousand (-184). The company's aggregate other operating income and expenses for all four quarters totaled SEK 656 thousand (1,364) respective SEK -1,657 thousand (-1,171). Both categories consist entirely of exchange rate gains and losses arising in conjunction with payments abroad.

Research and development costs

Early in the fourth quarter, the company decided to terminate further development of the generic version in order to focus on its improved product, Dasynoc (HyNap-Dasa). The disposal of the generic version thus had an earning effect of SEK -31,128 thousand for which previously capitalized development costs were expensed. Apart from the item affecting comparability, the total expenditure for research and development was SEK -28,991 thousand (-27,292) during the fourth quarter, of which SEK -1,880 thousand (-1,642) was expensed and recognized in profit or loss and SEK 27,112 (24,452) was capitalized as development expenses and presented in the company's balance sheet. For the full year, the figure is SEK -72,057 thousand (-49,388) for total expenditure for research and development, where SEK -7,439 thousand (-6,549) has been expensed and SEK 64,618 thousand (90,103) has been capitalized as development expenses.
The majority of the cost increase is attributable to the disposal and continuing increases in other activity for the company's two product candidates, Dasynoc and HyNap-Nilo.

Administrative and sales costs

Administrative and sales costs for the final quarter of 2021 amounted to SEK -19,257 thousand (-13,970); of these, personnel costs classified as administrative and sales costs amounted to SEK -4,050 thousand (-2,296). The corresponding figures for the full year are SEK -58,384 thousand (-47,101) for administrative and sales costs, where SEK -19,711 thousand (-17,961) pertained to personnel costs. The cost increase for the four quarters 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 fourth quarter totaled SEK -51,944 thousand (-14,972) and the aggregate figures are SEK -96,698 thousand (-52,410). This corresponds to earnings per share before dilution of SEK -2.62 (-0.81) and SEK -5.03 (-3.05) respectively.
The decline in earnings for the quarter and full year 2021 is primarily attributable to the disposal of the generic version of HyNap-Dasa, an effect of SEK -31,128 thousand that was expensed early in the fourth quarter.

Cash flow, investments, and financial position

Cash flow from operating activities for the quarter amounted to SEK -10,280 thousand (-11,717), of which the effect from operating capital comprised SEK 7,432 thousand (1,237). The aggregate figure for the full year was SEK -51,607 thousand (-47,792), in which the effect from operating capital was SEK4,376 thousand (-1,315). The continued negative cash flow is in accordance with the company's plan, and is primarily attributable to a strengthened organization, increased project costs and other advisory services for the company's future strategic positioning.

Cash flow from investing activities amounted to SEK -33,691 thousand (-27,926) for the quarter and SEK -105,818 thousand (-96,828) for the full year. The item consists primarily of capitalized development expenses of SEK -26,849 thousand (-24,172) and SEK -94,651 thousand (-88,983) for all four quarters. Investment in property, plant and equipment totaled SEK -838 thousand (-98) for the period and SEK -1,313 thousand (-4,572) aggregate. During the period, advances paid increased as a result of the construction of the company's new production unit in Malta. Cash flow from investing activities is in line with expected development, and is forecast to increase as a result of the continued work

on the new production unit.
Cash flow from financing activities during the quarter totaled SEK 99,309 thousand (248,619), which is primarily attributable to the private placement for Flerie Invest in November. The full-year figure for financing activities totaled SEK 103,708 thousand (260,345), the positive effect for the company's four quarters was mainly due to the private placement, but also the redemption and allocation of warrants from the LTIP 2015/2021, LTIP 2021/2024 and Chairman LTIP 2021/2026 programs.

Total cash flow for the last quarter of the year was SEK 55,338 thousand (208,976) and for the full year was SEK -53,717 thousand (115,726). The Group had SEK 271,881 thousand (325,598) in cash and cash equivalents at December 31, 2021.
Company operations are financed primarily by equity. The Board of Directors feels that the company's financial position over the next twelve-month period is good, with an acceptable and manageable level of risk in the product portfolio. The Board routinely evaluates the company's financial requirements and financial position, and reviews the best capital structure for the company. The debt/equity ratio for the Group was 95.0 per cent (96.2) at December 31, 2021.

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 27,112 thousand (24,452). The Group's total capitalized expenditures for development and similar activities totaled SEK 296,236 thousand (231,618) at December 31, 2021. The item is associated with the company's product candidates Dasynoc, HyNap-Nilo and HyNap-Sora.

After the announcement by the Board of Directors on October 13 concerning complete focus on the improved version of dasatinib, Dasynoc, and end development of the generic version, the company disposed of all previously capitalized costs specifically linked to HyNap-Dasa's generic products. The earnings effect of the disposal was SEK -31,128 thousand.

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 271,831 thousand (325,548) and the debt/equity ratio was 95.5 per cent (97.0) at December 31, 2021.

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 23 (20) at December 31, 2021. The subsidiary had no employees as of the balance date.

Related-party transactions

The company's former Chairman of the Board, who left office at the Annual General Meeting on May 20, 2021, performed consultant assignments in business development and legal advisory services for the company. No consultant assignments were performed during the fourth quarter, and fees thereby totaled SEK 0 thousand (-19). The corresponding figure for all four quarters was also SEK 0 thousand (-249).

Corporate governance

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

Dividend

The Board of Directors proposes that no dividend be paid for the financial year 2021. The Board of Directors proposes that the company's retained results be transferred to a new account.

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.

During the fourth quarter, the company's shares and votes increased by 1,608,904 as a result of a private placement of new shares. The subscription price was SEK 62.00 per share and generated SEK 100 million. At December 31, 2021, the number of shares in the company was 20,680,408 and the last price paid in the period was SEK 64.15.

Incentive plans

At December 31, 2021 the company had a total of four series of warrants issued to employees, senior executives and the Chairman of the Board.

The LTIP 2021/2024 and Chairman LTIP 2021/2026 incentive plans were resolved on at the Annual General Meeting on May 20, 2021. The plans encompass 195,725 and 13,214 warrants, respectively, pegged to the company's growth in value for the purpose of creating a stronger link between employee and shareholder interests. Both plans yield a maximum dilution effect of 1.1% on the current number of shares.

LTIP 2021/2024 encompasses 24 persons, including the company's CEO. The plan was subscribed under market terms at a price established by an independent appraisal institute using the Black–Scholes model. The value per option was calculated to be SEK 7.55 and the subscription price per share was calculated to be SEK 148.90. The warrant program runs for three years and is contingent on the holder remaining employed with the company.

The Chairman LTIP 2021/2026 plan included the company's new Chairman of the Board and was signed under similar terms as LTIP 2021/2024. The value per warrant was calculated to be SEK 16.38 and the subscription price per share to be SEK 129.00. The program runs for five years.

Other active warrant programs, LTIP 2018/2022 and LTIP 2020/2023, consist of a total of 292,996 outstanding warrants.
During the second quarter, 6,385 options from LTIP 2021/2024 were returned in connection with termination of employment. All options have been deregistered.

Refer to the Annual Report for 2020 for an account of the previously exercised plans as well as the two remaining incentive plans.

Owners as of December 31, 2021	Number of shares	Number of shares & votes
Östersjöstiftelsen	2,500,826	12.10%
Ribbskottet	2,289,119	11.10%
Flerie Invest	1,612,904	7.80%
Fjärde AP-fonden	1,500,000	7.30%
Swedbank Robur Fonder	1,400,000	6.80%
TIN Fonder	835,590	4.00%
Avanza Pension	779,532	3.80%
Unionen	726,000	3.50%
Nordnet Pensionsförsäkring	599,869	2.90%
Andra AP-fonden	422,320	2.00%
Total, ten largest owners	12,666,160	61.30%
Total, other shareholders	8,014,248	38.70%
Total number of shares	**20,680,408**	**100.00%**

Financial calendar

Annual Report 2021	March 25, 2022
Interim Report Q1 2022	May 6, 2022
Annual General Meeting 2022	May 19, 2022
Interim Report Q2 2022	August 5, 2022
Interim Report Q3 2022	November 9, 2022

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

Analysts monitoring the company

Filip Einarsson, Redeye AB
Naresh Chouhan, Intron Health
Dan Akschuti, Christian Lee and Peter Östling Pareto Securities AB

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

	Q4		Jan-Dec	
SEK thousand	**2021**	**2020**	**2021**	**2020**
Net sales	-	-	-	-
Other operating income	328	502	656	1,364
Research and development expenses	-33,008	-1,642	-38,567	-6,549
Administration and sales expenses	-19,257	-13,970	-58,384	-47,101
Other operating expenses	-340	-184	-1,657	-1,171
Operating loss	**-52,277**	**-15,294**	**-97,953**	**-53,457**
Finance income	334	322	1,259	1,053
Finance costs	-0	-0	-4	-6
Finance net	**333**	**322**	**1,255**	**1,047**
Loss before Income tax	-51,944	-14,972	-96,698	-52,410
Tax	-	-	-	-
Loss for the period	**-51,944**	**-14,972**	**-96,698**	**-52,410**
Earnings per share for the period before dilution, SEK	-2.62	-0.81	-5.03	-3.05
Earnings per share for the period after dilution, SEK	-2.62	-0.81	-5.03	-3.05
Average number of shares before dilution	19,803,830	18,503,883	19,237,743	17,211,467
Average number of shares after dilution	19,803,830	18,971,879	19,237,743	17,679,463

Consolidated statement of comprehensive income

	Q4		Jan-Dec	
SEK thousand	**2021**	**2020**	**2021**	**2020**
Loss for the period	-51,944	-14,972	-96,698	-52,410
Other comprehensive income	-	-	-	-
Total comprehensive income for the period	**-51,944**	**-14,972**	**-96,698**	**-52,410**

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

Consolidated balance sheet

SEK thousand	31 Dec 2021	31 Dec 2020
ASSETS		
Non-current assets		
Intangible assets		
Capitalized development costs	296,236	231,618
Total intangible assets	**296,236**	**231,618**
Property, plant and equipment		
Machinery and installations	20,458	20,746
Right-of-use assets	3,526	5,207
Equipment	574	970
Fixed assets under construction and prepayments	20,043	15,746
Total Property, plant and equipment	**44,601**	**42,669**
Financial assets		
Financial investments	1	1
Total financial assets	**1**	**1**
Total non-current assets	**340,838**	**274,288**
Current assets		
Inventories	6,199	-
Current receivables	2,473	2,667
Prepaid expenses and accured income	1,513	2,750
Cash and cash equivalents	271,881	325,598
Total current assets	**282,065**	**331,015**
TOTAL ASSETS	**622,903**	**605,303**

SEK thousand	31 Dec 2021	31 Dec 2020
EQUITY AND LIABILITIES		
Equity		
Share capital	20,680	18,893
Other contributed capital	813,483	709,407
Reserves	976	976
Retained earnings including profit/loss for the period	-243,387	-146,689
Total equity attributable to the Parent Company's shareholders	**591,752**	**582,587**
Non–current liabilities		
Lease liabilities	1,185	2,898
Total non-current liabilities	**1,185**	**2,898**
Current liabilities		
Trade accounts payable	16,865	8,438
Lease liabilities	2,048	1,985
Other current liabilities	653	768
Accrued expenses and deferred income	10,401	8,627
Total current liabilities	**29,966**	**19,818**
TOTAL EQUITY AND LIABILITIES	**622,903**	**605,303**

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, 2020	**16,752**	**450,266**	**976**	**-94,279**	**373,715**
Loss of the period	-	-	-	-52,410	-52,410
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	**-**	**-**	**-**	**-52,410**	**-52,410**
New share issue	1,861	263,373	-	-	265,234
Transaction costs		-16,102	-	-	-16,102
Redemption of warrants	279	11,560	-	-	11,840
Warrant program	-	310	-	-	310
Closing balance as of December 31, 2020	**18,892**	**709,407**	**976**	**-146,689**	**582,587**
Opening balance as of January 1, 2021	**18,893**	**709,407**	**976**	**-146,689**	**582,587**
Loss for 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**

Consolidated cash flow statement

	Q4		Jan-Dec	
SEK thousand	**2021**	**2020**	**2021**	**2020**
Operating activities				
Operating loss	**-52,277**	**-15,294**	**-97,953**	**-53,457**
Non-cash adjustments				
Depreciation	2,296	1,927	8,870	7,689
Capital gains	-	-	98	-113
Dissolved prepaid leasing costs, during the period	-	-	-	-1,262
Disposal of intangible fixed assets	31,128	-	31,128	-
Interest received	1,141	413	1,878	674
Interest paid	-	-0	-4	-8
Cash flow from operating activities before changes in working capital	**-17,712**	**-12,954**	**-55,983**	**-46,477**
Changes in working capital				
Change in operating receivables	-1,312	-2,415	-5,712	2,479
Change in operating liabilities	8,743	3,652	10,087	-3,794
Cash flow from operating activities	**-10,280**	**-11,717**	**-51,607**	**-47,792**
Investing activities		-		-
Capitalized development costs	-26,849	-24,172	-94,651	-88,983
Acquisition of property, plant and equipment	-838	-98	-1,313	-4,572
Sales of tangible fixed assets	-	-	-	383
Prepayments	-6,004	-3,656	-9,854	-3,656
Cash flow from investing activities	**-33,691**	**-27,926**	**-105,818**	**-96,828**
Financing activities				
New share issue	99,877	249,320	99,877	249,320
Transaction costs	-19	-188	-29	-188
Payment of lease liability	-538	-513	-2,154	-936
Redemption of warrants	-	-	4,375	11,840
Repurchased warrants	-10	-	-54	-74
Allocated warrants	-	-	1,694	384
Cash flow from financing activities	**99,309**	**248,619**	**103,708**	**260,345**
Cash flow for the period	**55,338**	**208,976**	**-53,717**	**115,726**
Cash and cash equivalents at the beginning of the period	216,543	116,622	325,598	209,872
Cash and cash equivalents at the end of the period	**271,881**	**325,598**	**271,881**	**325,598**

Parent Company income statement

	Q4		Jan-Dec	
SEK thousand	**2021**	**2020**	**2021**	**2020**
Net sales	-	-	-	-
Other operating income	328	502	656	1,364
Research and development expenses	-33,065	-1,598	-38,560	-6,379
Administration and sales expenses	-19,281	-13,993	-58,486	-47,194
Other operating expenses	-342	-184	-1,660	-1,172
Operating loss	**-52,361**	**-15,273**	**-98,050**	**-53,381**
Finance income	182	322	938	1,053
Finance costs	-0	-0	-4	-5
Finance net	**181**	**322**	**934**	**1,048**
Loss before Income tax	-52,180	-14,951	-97,116	-52,333
Tax	-	-	-	-
Loss for the period	**-52,180**	**-14,951**	**-97,116**	**-52,333**

Parent Company balance sheet

SEK thousand	31 Dec 2021	31 Dec 2020
ASSETS		
Non-current assets		
Intangible assets		
Capitalized development costs	296,005	231,512
Total intangible assets	**296,005**	**231,512**
Property, plant and equipment		
Machinery and installations	20,458	20,747
Equipment	574	970
Fixed assets under construction and prepayments	19,719	15,746
Total Property, plant and equipment	**40,751**	**37,463**
Financial assets		
Shares in subsidiaries	50	50
Financial investments	1	1
Total financial assets	**51**	**51**
Total non-current assets	**336,808**	**269,026**
Current assets		
Inventories	**6,199**	**-**
Current receivables		
Other current receivables	2,473	2,666
Prepaid expenses and accured income	1,995	3,232
Total current receivables	**4,467**	**5,898**
Cash and bank	271,831	325,548
Total current assets	**282,497**	**331,446**
TOTAL ASSETS	**619,305**	**600,472**

SEK thousand	31 Dec 2021	31 Dec 2020
EQUITY AND LIABILITIES		
Equity		
Restricted equity		
Share capital	20,680	18,893
Statutory reserve	976	976
Development expenditure reserve	296,005	231,512
Total restricted equity	**317,662**	**251,381**
Non-restricted equity		
Other contributed capital	813,483	709,408
Accumulated earnings	-442,642	-325,816
Profit/loss for the period	-97,116	-52,333
Total non-restricted equity	**273,724**	**331,259**
Total equity	**591,386**	**582,640**
Current liabilities		
Trade accounts payable	16,865	8,437
Other current liabilities	653	768
Accrued expenses and deferred income	10,401	8,627
Total current liabilities	**27,919**	**17,832**
TOTAL EQUITY AND LIABILITIES	**619,305**	**600,472**

Parent Company cash flow statement

	Q4		Jan-Dec	
SEK thousand	**2021**	**2020**	**2021**	**2020**
Operating activities				
Operating loss	**-52,361**	**-15,273**	**-98,050**	**-53,381**
Non-cash adjustments				
Depreciation	2,026	1,683	7,781	6,694
Captial gains	-	-	98	-113
Disposal of intangible fixed assets	31,128	-	31,128	-
Interest received	988	413	1,557	674
Interest paid	-	-0	-4	-5
Cash flow from operating activities before changes in working capital	**-18,219**	**-13,177**	**-57,490**	**-46,131**
Changes in working capital				
Change in operating receivables	-1,160	-2,423	-5,389	2,311
Change in operating liabilities	8,743	3,652	10,087	-3,794
Cash flow from operating activities	**-10,637**	**-11,948**	**-52,792**	**-47,614**
Investing activities				
Purchase of intangible assets	-27,031	-24,454	-95,621	-90,098
Acquisition of property, plant and equipment	-838	-98	-1,313	-4,571
Sales of tangible fixed assets	-	-	-	383
Prepayments	-6,004	-3,656	-9,854	-3,656
Cash flow from investing activities	**-33,873**	**-28,208**	**-106,788**	**-97,942**
Financing activities				
New share issue	99,877	249,320	99,877	249,320
Transaction costs	-19	-188	-29	-188
Redemption of warrants	-	-	4,375	11,840
Repurchased warrants	-10	-	-54	-74
Allocated warrants	-	-	1,694	384
Cash flow from financing activities	**99,848**	**249,132**	**105,863**	**261,282**
Cash flow for the period	**55,338**	**208,976**	**-53,717**	**115,726**
Cash and cash equivalents at the beginning of the period	216,493	116,572	325,548	209,822
Cash and cash equivalents at the end of the period	**271,831**	**325,548**	**271,831**	**325,548**

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 2020 have been applied.
The changes in IFRS applied as of January 1, 2021 have not had any impact on the financial statements for the four quarters of 2021.
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 2020.

COVID-19

Xspray Pharma continued to adapt its operations to the prevailing circumstances owing to the COVID-19 pandemic. Xspray Pharma sees continued risks in delays associated with COVID-19 that could thereby have a negative effect on its operating activities and studies. Xspray Pharma is taking the measures necessary to reduce the impact of the pandemic on its operation and continually follows the recommendations of the Swedish Public Health Agency.

Assurance from the Board

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

Solna, February 18, 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
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.

ANDA • (Abbreviated New Drug Application) Application for generic drug approval in the US for an existing licensed drug or approved drug.

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.

Generic • Generic drugs are medically exchangeable drugs with the same function, quality and safety as a reference drug.

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 governs 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.

Pivotal study • A decision-based clinical trial that will provide data on the effectiveness and safety of the drug for market approval.

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.

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