INTERIM REPORT
THIRD QUARTER 2021

Xspray Pharma is a pharmaceutical company that focuses on cost-efficient development of improved and generic 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 third quarter

July - September 2021

- In July, Xspray Pharma announced that bioequivalence had been achieved compared with the reference product in the bioequivalence study with the company's improved version of dasatinib, HyNap-Dasa 505(b)(2), which now goes under the name Dasynoc™.
- In August, bioequivalence studies were conducted with the company's generic version of dasatinib, HyNap-Dasa ANDA C. The studies were conducted in two groups of healthy volunteers under fed and fasting conditions.

Significant events after the end of the reporting period

- In October, it was announced that bioequivalence had not been achieved for HyNap-Dasa ANDA, and that the company chooses that further development of the generic version will be terminated and instead focusing on the improved product HyNap-Dasa 505(b)(2), Dasynoc™, which demonstrated bioequivalence in previous studies. The disposals of the capitalized development expenses attributable to the generic version will impact earnings in the fourth quarter. The estimated total of the effect is 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 November 4, 2021, to October 26, 2021.

July - September 2021, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -13,890 thousand (-11,560)
- Earnings per share before dilution amounted to SEK -0.73 (-0.69)
- Cash flow from operating activities amounted to SEK -16,524 thousand (-12,764)
- Cash flow from investing activities amounted to SEK -20,086 thousand (-19,868)

January - September 2021, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -44,754 thousand (-37,438)
- Earnings per share before dilution amounted to SEK -2.35 (-2.23)
- Cash flow from operating activities amounted to SEK -41,327 thousand (-36,076)
- Cash flow from investing activities amounted to SEK -72,127 thousand (-68,901)
- Cash and cash equivalents at the end of the period amounted to SEK 216,543 thousand (116,622)

Amounts in parentheses refer to the year-earlier period.

A message from the CEO

Dasynoc™ – an improved product

The third quarter of the year was a very important period for Xspray. Since the Company's start, the business's focus and communication has been on generic and improved versions of PKIs. Going forward we have now decided to focus entirely on improved PKIs. In recent years, the value of generics in our models has gradually decreased, while the value of improved drugs has instead increased. This is a very important decision that will significantly simplify and streamline the development of new product candidates and lead to increased focus for the entire organization. The decision was made in October at which time we have also informed the market.

Our first drug candidate, HyNap-Dasa, is the only product candidate that was developed in parallel as both a generic and improved version, other product candidates are only improved versions where we make optimal use of our technology. We continue to focus exclusively on the improved version that we previously named HyNap-Dasa 505(b)(2), and which now goes by the name Dasynoc™. It contains the same active substance and is bioequivalent to the original drug Sprycel® but has improved properties. Dasynoc™ can therefore be prescribed knowing that it treats the disease in the same way as the original medicine, while at the same time offers the patient an increased quality of life thanks to the associated improvements.

It was very gratifying that Dasynoc™ achieved bioequivalence as reported in July. We have now shown that we can reduce the dose of dasatinib significantly but still achieve the same uptake into the body as the reference product, which is one of the great benefits of our amorphous formulation. Our studies have also shown that dasatinib uptake is not affected by the stomach pH which allows for concomitant treatment with, for example, drugs for gastric ulcers, so-called proton pump inhibitors (PPIs) such as omeprazole. Such concomitant use of PPIs is not recommended for the reference product although many patients in this group greatly need it. We have also shown that Dasynoc™ has an even uptake of dasatinib, in contrast to the reference product, where low and very low uptake occurs. All in all, this shows that Dasynoc™ will be able to offer important medical benefits for patients as well as doctors and payers. The study results together with a favorable patent situation means that we have high hopes for this product, primarily in the US market.

Dasynoc™ has in recent years gained increased value in our business model. This is largely due to a market development change in the US for biosimilars that, as in our case, are also equivalent but not generic products and have shown a much faster market uptake than when we started the development of the generic HyNap-Dasa. In addition, the value of an improved product, such as Dasynoc™, is higher than for a generic product after the end of the patent window. In general, we believe that there is great value for amorphous PKIs in the market. The current market for Dasynoc™ consists of a single original product with 2020 sales of $ 1.3 billion in the US alone. A launch of Dasynoc™ before the end of the patent window will thus be on a market with very limited competition and great opportunities to compete with both medical advantage and, if necessary, price. Since generic products are

copies of the originator drug they will suffer from the same problems as the originator when launched giving the enhancer Dasynoc™ continued competitive advantages.
Since we presented positive study results from the bioequivalence study with Dasynoc™ in July, we have been working on completing our first application for market approval in the United States under the 505(b)(2) procedure, which is the registration route for improved drugs. The application is scheduled according to plan in the fourth quarter of this year and supplementary data for other dose strengths will be sent to the FDA in 2022. The FDA conducts a comprehensive review of the application for up to 60 days and then decides on whether the application is accepted for further detailed review. The FDA review time of the application is then 12 months.

In parallel with the FDA's review, we expect the original company to initiate a lawsuit against Xspray Pharma, for which we are well prepared. Court proceedings concerning improved and generic drug candidates are common in the United States where about 400 cases are initiated annually, and the processes follow an established and agreed schedule. We therefore believe that the cost of the legal process will be limited. Fundamental to our case is the amorphous structure of Xspray Pharma's product candidates, which means that the products are technically and patent-wise completely different from the original company's crystalline products. We analyze all our produced batches to ensure that they are completely amorphous. With an experienced internal team and some of the leading patent attorneys in the US, we work intensively to shorten a possible court process and thus be able to enter the market as early as possible in 2023. The original drug's patent protection then prevents competition from other generic products, which is to our advantage.

After the end of the Q3 period, we obtained results from the bioequivalence study with the generic version of dasatinib, HyNap-Dasa ANDA. It achieved bioequivalence to the reference product Sprycel® in the fed but not in the fasting state. It has been a challenge beyond the ordinary to try to imitate such a highly variable formulation as that of the reference product. As previously mentioned, we have now decided to leave the track of generic development. Our intention has never been to market both a generic and an improved product at the same time, but we have pursued the parallel tracks for risk minimization reasons. We are very pleased to be able to move forward with only Dasynoc™, an important product in our portfolio. This will soon be joined by HyNap-Nilo, an improved formulation of nilotinib intended for launch in the US market during 2024.

In parallel with the development of Dasynoc™ and HyNap-Nilo, we continue the exciting work of expanding our pipeline. Our unique technology is applicable to a majority of the currently 72 marketed PKIs. For the majority of those we can offer clinically significant improvements to patients. It is a privilege to have a systematic process for selection of new valuable projects. Our new projects will focus on the same indications as Dasynoc™ and HyNap-Nilo as well as on other cancer indications. The development processes we have created with Dasynoc™ and HyNap-Nilo will be applicable to our new projects allowing us to significantly reduce development timelines.

Consolidated cash flow for the third quarter was SEK -37.2 million. This is according to plan, and is attributable to project-related costs as well as other operational costs for the company.

We have certainly learned a lot during the past year and the last quarter, certainly at a cost, but it leads us to great values in the future.

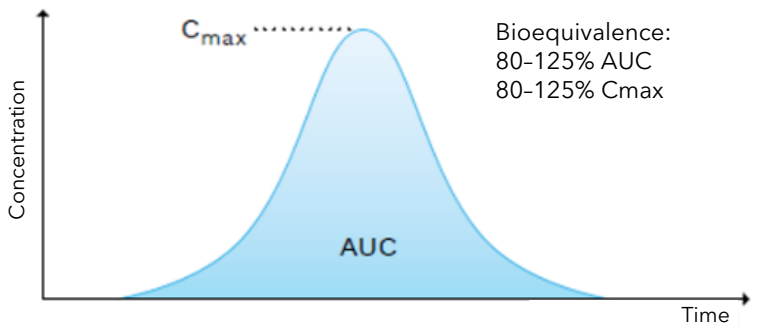
October 26, 2021

Per Andersson
CEO

Business focus and prospects

Xspray Pharma AB (publ) is a pharmaceutical company with multiple product candidates in clinical development phase. Xspray Pharma uses its innovative, patented technology to develop amorphous product candidates that are improved and/or 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 reference drug, meaning that the active drug substance of the product candidate should be processed by the body the same way as the reference 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 – 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 1.96 billion and Nexavar® for USD 729 million globally. A careful selection process determines which PKIs will become future product candidates and be included in the company's pipeline once the capacity exists.

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.

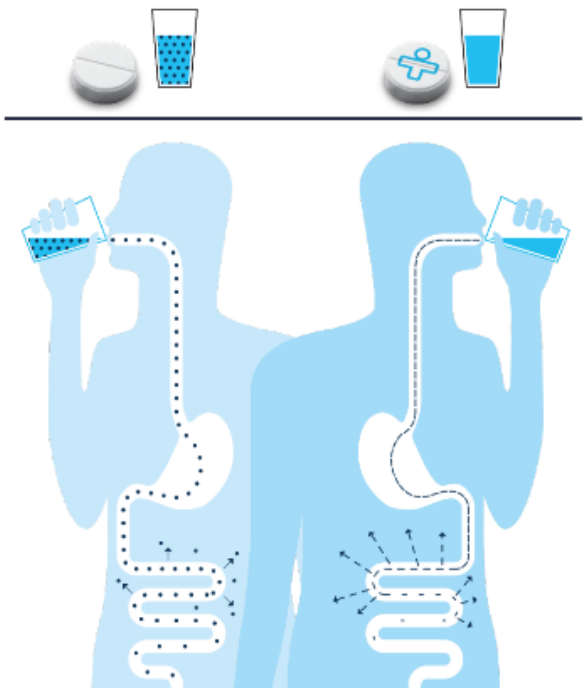
Demand for effective life-cycle products is increasing in pace with the expiration of patents for many crucial original drugs. Of the 72 PKIs currently being marketed in the US, 23 drug substance patents are expected to expire by 2030. To date, Xspray Pharma has tested its technology on some twenty of 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.

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 effective development time for future products in the company's pipeline. Moreover, the technology makes it possible to quickly and in a controlled manner change the properties required to make either generic or improved versions of PKI drugs already being marketed and to bring the respective product candidates to market. This means that the company's easily soluble 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 and generic 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, to date, has three announced product candidates 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. After the end of the reporting period the company has decided to terminate further development of the generic version of dasatinib, that has been 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 omeprazole without affecting the absorption of dasatinib, which facilitates treatment of peptic ulcers while the patient is being treated for cancer
- yields a more even and consistent uptake of dasatinib in the body without those cases of low uptake that were linked to the reference product in previous studies
- can be administered at a lower dosage than the reference 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. It is expected that the application for market approval of Dasynoc™ in the US will be made in accordance with plans during the fourth quarter of 2021 under the 505(b)(2) procedure.

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-Dasa ANDA

In parallel with the development of Dasynoc™, a generic version of dasatinib has also been developed. Bioequivalence studies on healthy volunteers were conducted in 2020 and 2021. Bioequivalence to the reference product Sprycel® has been shown in non-fasting conditions but not in the fasting conditions due to the high variability of the reference product. Since the company does not intend to bring both an improved and a generic version to market at the same time, it chooses to terminate the generic version, and focus entirely on Dasynoc™, which has already shown bioequivalence and is thus closer to an application process. After the end of the reporting period, the company has decided to terminate the development of the generic version with dasatinib, HyNap-Dasa ANDA.

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 1,958 million in 2020, of which the US market accounted for USD 859 million.

Tasignas 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 development of the commercial formulation is complete, and manufacturing of clinical trial materials is under way ahead of clinical studies that are 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 729 million, of which the US market accounted for USD 194 million. Nexavars 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
*	HyNap-Dasa	dasatinib	Leukemia (CML, ALL)	ANDA	Dec 2020	Sept 2026						Sprycel®/ BMS
	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										

* After the end of the reporting period, the company has decided to terminate the development of the generic version with dasatinib, HyNap-Dasa ANDA.

Financial overview, Group

	Q3		Jan-Sep		Full year
Key figures, Group	**2021**	**2020**	**2021**	**2020**	**2020**
Net sales (SEK thousand)	-	-	-	-	-
Loss before Income tax (SEK thousand)	-13,890	-11,560	-44,754	-37,438	-52,410
Earnings per share before dilution (SEK)	-0.73	-0.69	-2.35	-2.23	-3.05
Earnings per share after dilution (SEK)	-0.73	-0.69	-2.35	-2.23	-3.05
Research and development expenses as % of operating expenses	13.7	13.7	12.1	12.6	11.9
Cash and cash equivalents (SEK thousand)	216,543	116,622	216,543	116,622	325,598
Total assets (SEK thousand)	566,749	367,708	566,749	367,708	605,303
Equity/assets ratio (%)	96.0	94.8	96.0	94.8	96.2
Number of employees	22	20	22	20	20

Total expenditure for research and development for the quarter was SEK -18,463 thousand, of which -1,955 thousand has been expensed and SEK 16,508 thousand capitalized as development expenditure.

Total expenditure for research and development for the period January–September was SEK-74,193 thousand, of which SEK -5,559 thousand has been expensed and SEK 68,634 thousand was 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 differences between RFR2 and IFRS.

Net sales

Net sales for the company remain at SEK 0. Submission of the application for market approval of the initial product is planned for Q4 2021.

Other operating income and expenses

Other operating income for the period amounted to SEK 75 thousand (283). Other operating expenses for the period amounted to SEK -450 thousand (-183). The company's aggregate other operating income and expenses for all three quarters totalled SEK 328 thousand (862) and SEK -1,317 thousand (-987). Both categories consist entirely of exchange rate gains and losses arising in conjunction with payments abroad.

Research and development costs

Total expenditure for research and development for the third quarter was SEK -18,463 thousand (-27,292), of which SEK -1,955 thousand (-1,651) has been expensed and thereby recognized in profit or loss, and SEK 16,508 thousand (25,658) has been capitalized as development expenditures and is presented in the company's balance sheet. For the first three quarters, the figure is SEK -74,193 thousand (-49,388) for total expenditure for research and development, where SEK -5,559 thousand (-4,907) has been expensed and SEK 68,634 thousand (65,644) has been capitalized as development expenditures. The majority of the cost increase is attributable to higher activity in the company's two product candidates, HyNap-Dasa (ANDA & 505(b)(2)) and HyNap-Nilo.

Administrative and sales costs

Administrative and sales costs for the third quarter of 2021 amounted to SEK -11,878 thousand (-10,260); of these, personnel costs classified as administrative and sales costs amounted to SEK -5,743 thousand (-3,692). The corresponding figures for all three quarters are SEK -39,127 thousand (-33,131) for administrative and sales costs, where SEK -15,661 thousand (-15,665) pertained to personnel costs. The cost increase for the three quarters reflects continuing activities attributable to the company's routine costs as well as consulting costs linked to the company's operating activities. The company's personnel has increased by two full-time positions compared with the year-earlier period, which impacts the cost base.

Loss for the period

Loss for the third quarter totalled SEK -13,890 thousand (-11,560) and for all three quarters totalled SEK -44,754 thousand (-37,438). This corresponds to earnings per share before dilution of SEK -0.73 (-0.69) and SEK -2.35 (-2.23) respectively.

Cash flow, investments and financial position

Cash flow from operating activities for the quarter amounted to SEK -16,524 thousand (-12,764), of which the effect from operating capital comprised SEK -4,790 thousand (-2,679). The aggregate figure for the three quarters was SEK -41,327 thousand (-36,076), in which the effect from operating capital was SEK -3,056 thousand (-2,553). 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 -20,086 thousand (-19,868) for the quarter and SEK -72,127 thousand (-68,901) for the three quarters. The item consists primarily of capitalized development expenses of SEK -16,236 thousand (-19,240) for the quarter and SEK -67,802 thousand (-64,810) for the three quarters. Investment in property, plant and equipment totalled SEK 0 thousand (-628) for the period and SEK -475 thousand (-4,474) aggregate for the three quarters. 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 company's new production unit on Malta.

Cash flow from financing activities for the quarter totaled SEK -584 thousand (11,488), which in turn consists entirely of repurchase of warrants and amortization of lease liabilities. The aggregate figure totaled SEK 4,399 (11,727), the positive effect for the company's three quarters is due to 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 third quarter was SEK -37,194 thousand (-21,144) and for all three quarters was SEK

-109,055 thousand (-93,250). The Group had SEK 216,543 thousand (116,622) in cash and cash equivalents at September 30, 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 96.0 per cent (94.8) at September 30, 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 16,508 thousand (25,658). The Group's total capitalized expenditures for development and similar activities totaled SEK 300,252 thousand (207,167) at September 30, 2021. The item is associated with the company's product candidates HyNap-Dasa, 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 termination of development of the generic version, the company will dispose of all previously capitalized costs specifically linked to HyNap-Dasa's generic products. The estimated effect of the disposal on earnings is approximately SEK -31 million, and will occur in the fourth quarter of 2021.

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 had SEK 216,493 thousand (116,572) in cash and cash equivalents and the debt/equity ratio was 96.6 per cent (96.1) at September 30, 2021.

Employees

The organization expanded by two full-time positions in the quarter. The number of employees in the Group totaled 22 (20). 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 third quarter, and fees thereby totaled SEK 0 thousand (28). The corresponding figure for all three quarters was also SEK 0 thousand (240).

Corporate governance

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

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.

The company's shares and votes were unchanged during the third quarter as compared to the preceding quarter. At September 30, 2021, the number of shares in the company was 19,067,504 and the last price paid in the period was SEK 129.80.

Incentive plans

At September 30, 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 quarter, 6,589 options from LTIP 2020/2023 and 4,385 warrants 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 September 30, 2021	Number of shares	Number of shares & votes
Östersjöstiftelsen	2,500,826	13.12%
Ribbskottet AB	2,150,000	11.28%
Swedbank Robur Fonder	1,550,000	8.13%
Fjärde AP-fonden	1,500,000	7.87%
TIN Fonder	835,590	4.38%
Avanza Pension	800,892	4.20%
Unionen	726,000	3.81%
Andra AP-fonden	422,320	2.21%
Futur Pension	403,450	2.12%
C WorldWide Asset Management	320,000	1.68%
Total, ten largest owners	11,209,078	58.79%
Total, other shareholders	7,858,426	41.21%
Total number of shares	**19,067,504**	**100.00%**

Financial calendar

Year-end report 2021	February 18, 2022
Annual Report 2021	March 25, 2022
Interim Report Q1 2022	May 6, 2022
Interim Report Q2 2022	August 5, 2022
Interim Report Q3 2022	November 4, 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
Naresh Chouhan, Intron Health

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

	Q3		Jan-Sep		Full year
SEK thousand	**2021**	**2020**	**2021**	**2020**	**2020**
Net sales	-	-	-	-	-
Other operating income	75	283	328	862	1,364
Research and development expenses	-1,955	-1,651	-5,559	-4,907	-6,549
Administration and sales expenses	-11,878	-10,260	-39,127	-33,131	-47,101
Other operating expenses	-450	-183	-1,317	-987	-1,171
Operating loss	**-14,209**	**-11,811**	**-45,676**	**-38,163**	**-53,457**
Finance income	319	251	925	730	1,053
Finance costs	-1	-0	-4	-5	-6
Finance net	**319**	**251**	**922**	**725**	**1,047**
Loss before Income tax	-13,890	-11,560	-44,754	-37,438	-52,410
Tax	-	-	-	-	-
Loss for the period	**-13,890**	**-11,560**	**-44,754**	**-37,438**	**-52,410**
Earnings per share for the period before dilution, SEK	-0.73	-0.69	-2.35	-2.23	-3.05
Earnings per share for the period after dilution, SEK	-0.73	-0.69	-2.35	-2.23	-3.05
Average number of shares before dilution	19,067,504	16,844,819	19,046,272	16,782,688	17,211,467
Average number of shares after dilution	19,367,125	17,312,815	19,345,893	17,250,684	17,679,463

Consolidated statement of comprehensive income

	Q3		Jan-Sep		Full year
SEK thousand	**2021**	**2020**	**2021**	**2020**	**2020**
Loss for the period	-13,890	-11,560	-44,754	-37,438	-52,410
Other comprehensive income	-	-	-	-	-
Total comprehensive income for the period	**-13,890**	**-11,560**	**-44,754**	**-37,438**	**-52,410**

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

Consolidated balance sheet

SEK thousand	30 Sep 2021	30 Sep 2020	31 Dec 2020
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	300,252	207,167	231,618
Total intangible assets	**300,252**	**207,167**	**231,618**
Property, plant and equipment			
Machinery and installations	22,373	22,323	20,746
Right-of-use assets	4,018	5,435	5,207
Equipment	684	1,076	970
Fixed assets under construction and prepayments	13,047	11,992	15,746
Total Property, plant and equipment	**40,121**	**40,826**	**42,669**
Financial assets			
Financial investments	1	1	1
Total financial assets	**1**	**1**	**1**
Total non-current assets	**340,374**	**247,994**	**274,288**
Current assets			
Current receivables	3,996	1,889	2,667
Prepaid expenses and accured income	5,837	1,203	2,750
Cash and cash equivalents	216,543	116,622	325,598
Total current assets	**226,375**	**119,714**	**331,015**
TOTAL ASSETS	**566,749**	**367,708**	**605,303**

SEK thousand	30 Sep 2021	30 Sep 2020	31 Dec 2020
EQUITY AND LIABILITIES			
Equity			
Share capital	19,068	17,031	18,893
Other contributed capital	715,248	462,136	709,407
Reserves	976	976	976
Retained earnings including profit/loss for the period	-191,443	-131,717	-146,689
Total equity attributable to the Parent Company's shareholders	**543,849**	**348,427**	**582,587**
Non–current liabilities			
Lease liabilities	1,661	3,195	2,898
Total non-current liabilities	**1,661**	**3,195**	**2,898**
Current liabilities			
Trade accounts payable	8,483	3,170	8,438
Lease liabilities	2,064	1,906	1,985
Other current liabilities	979	1,916	768
Accrued expenses and deferred income	9,713	9,094	8,627
Total current liabilities	**21,239**	**16,086**	**19,818**
TOTAL EQUITY AND LIABILITIES	**566,749**	**367,708**	**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	-	-	-	-37,438	-37,438
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	**-**	**-**	**-**	**-37,438**	**-37,438**
Redemption of warrants / new shares	279	11,560	-	-	11,840
Warrant program	-	310	-	-	310
Closing balance as of September 30, 2020	**17,031**	**462,136**	**976**	**-131,717**	**348,427**
Opening balance as of January 1, 2021	**18,893**	**709,407**	**976**	**-146,689**	**582,587**
Loss for the period	-	-	-	-44,754	-44,754
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	-	-	-	**-44,754**	**-44,754**
Transaction costs		-9			-9
Redemption of warrants / new shares	175	4,200	-	-	4,375
Warrant program	-	1,650	-	-	1,650
Closing balance as of September 30, 2021	**19,068**	**715,248**	**976**	**-191,443**	**543,849**

Consolidated cash flow statement

	Q3		Jan-Sep		Full year
SEK thousand	**2021**	**2020**	**2021**	**2020**	**2020**
Operating activities					
Operating loss	**-14,209**	**-11,811**	**-45,676**	**-38,163**	**-53,457**
Non-cash adjustments					
Depreciation	2,307	1,930	6,574	5,762	7,689
Capital gains	-	-	98	-113	-113
Dissolved prepaid leasing costs, during the period	-	-316	-	-1,262	-1,262
Interest received	168	112	737	261	674
Interest paid	-	-	-4	-8	-8
Cash flow from operating activities before changes in working capital	**-11,734**	**-10,085**	**-38,271**	**-33,523**	**-46,477**
Changes in working capital					
Change in operating receivables	-4,875	621	-2,052	4,893	2,479
Change in operating liabilities	85	-3,300	-1,004	-7,446	-3,794
Cash flow from operating activities	**-16,524**	**-12,764**	**-41,327**	**-36,076**	**-47,792**
Investing activities		-		-	
Capitalized development costs	-16,236	-19,240	-67,802	-64,810	-88,983
Acquisition of property, plant and equipment	-	-628	-475	-4,474	-4,572
Sales of tangible fixed assets	-	-	-	383	383
Prepayments	-3,850	-	-3,850	-	-3,656
Cash flow from investing activities	**-20,086**	**-19,868**	**-72,127**	**-68,901**	**-96,828**
Financing activities					
New share issue	-	-	-	-	249,320
Transaction costs	-	-	-10	-	-188
Payment of lease liability	-540	-352	-1,616	-423	-936
Redemption of warrants	-	11,840	4,375	11,840	11,840
Repurchased warrants	-44	-	-44	-74	-74
Allocated warrants	-	-	1,694	384	384
Cash flow from financing activities	**-584**	**11,488**	**4,399**	**11,727**	**260,345**
Cash flow for the period	**-37,194**	**-21,144**	**-109,055**	**-93,250**	**115,726**
Cash and cash equivalents at the beginning of the period	253,737	137,766	325,598	209,872	209,872
Cash and cash equivalents at the end of the period	**216,543**	**116,622**	**216,543**	**116,622**	**325,598**

Parent Company income statement

	Q3		Jan-Sep		Full year
SEK thousand	**2021**	**2020**	**2021**	**2020**	**2020**
Net sales	-	-	-	-	-
Other operating income	75	283	328	862	1,364
Research and development expenses	-1,946	-1,609	-5,495	-4,781	-6,379
Administration and sales expenses	-11,905	-10,283	-39,204	-33,201	-47,194
Other operating expenses	-450	-183	-1,317	-987	-1,172
Operating loss	**-14,227**	**-11,792**	**-45,689**	**-38,108**	**-53,381**
Finance income	241	251	756	730	1,053
Finance costs	-1	-0	-4	-5	-5
Finance net	**240**	**251**	**752**	**725**	**1,048**
Loss before Income tax	-13,986	-11,541	-44,936	-37,382	-52,333
Tax	-	-	-	-	-
Loss for the period	**-13,986**	**-11,541**	**-44,936**	**-37,382**	**-52,333**
Average number of shares before dilution	19,067,504	16,844,819	19,046,272	16,782,688	17,211,467
Average number of shares after dilution	19,367,125	17,312,815	19,345,893	17,250,684	17,679,463

Parent Company balance sheet

SEK thousand	30 Sep 2021	30 Sep 2020	31 Dec 2020
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	300,102	207,058	231,512
Total intangible assets	**300,102**	**207,058**	**231,512**
Property, plant and equipment			
Machinery and installations	22,373	22,323	20,747
Equipment	684	1,076	970
Fixed assets under construction and prepayments	12,876	11,992	15,746
Total Property, plant and equipment	**35,933**	**35,391**	**37,463**
Financial assets			
Shares in subsidiaries	50	50	50
Financial investments	1	1	1
Total financial assets	**51**	**51**	**51**
Total non-current assets	**336,087**	**242,501**	**269,026**
Current assets			
Current receivables			
Other current receivables	3,996	1,889	2,666
Prepaid expenses and accured income	6,319	1,676	3,232
Total current receivables	**10,314**	**3,565**	**5,898**
Cash and bank	216,493	116,572	325,548
Total current assets	**226,807**	**120,137**	**331,446**
TOTAL ASSETS	**562,894**	**362,638**	**600,472**

SEK thousand	30 Sep 2021	30 Sep 2020	31 Dec 2020
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	19,068	17,031	18,893
Statutory reserve	976	976	976
Development expenditure reserve	300,102	207,058	231,512
Total restricted equity	**320,146**	**225,066**	**251,381**
Non-restricted equity			
Other contributed capital	715,248	462,136	709,408
Accumulated earnings	-446,739	-301,362	-325,816
Profit/loss for the period	-44,936	-37,382	-52,333
Total non-restricted equity	**223,572**	**123,392**	**331,259**
Total equity	**543,718**	**348,458**	**582,640**
Current liabilities			
Trade accounts payable	8,483	3,170	8,437
Other current liabilities	979	1,916	768
Accrued expenses and deferred income	9,713	9,094	8,627
Total current liabilities	**19,175**	**14,180**	**17,832**
TOTAL EQUITY AND LIABILITIES	**562,894**	**362,638**	**600,472**

Parent Company cash flow statement

	Q3		Jan-Sep		Full year
SEK thousand	**2021**	**2020**	**2021**	**2020**	**2020**
Operating activities					
Operating loss	**-14,227**	**-11,792**	**-45,689**	**-38,108**	**-53,381**
Non-cash adjustments					
Depreciation	2,033	1,679	5,755	5,011	6,694
Captial gains	-	-	98	-113	-113
Interest received	-	112	569	261	674
Interest paid	-	-	-4	-5	-5
Cash flow from operating activities before changes in working capital	**-12,194**	**-10,001**	**-39,270**	**-32,954**	**-46,131**
Changes in working capital					
Change in operating receivables	-4,705	462	-1,882	4,735	2,311
Change in operating liabilities	85	-3,300	-1,004	-7,446	-3,794
Cash flow from operating activities	**-16,814**	**-12,839**	**-42,156**	**-35,665**	**-47,614**
Investing activities					
Purchase of intangible assets	-16,487	-19,516	-68,589	-65,644	-90,098
Acquisition of property, plant and equipment	-	-628	-475	-4,474	-4,571
Sales of tangible fixed assets	-	-	-	383	383
Prepayments	-3,850	-	-3,850	-	-3,656
Cash flow from investing activities	**-20,337**	**-20,144**	**-72,914**	**-69,735**	**-97,942**
Financing activities					
New share issue	-	-	-	-	249,320
Transaction costs	-	-	-10	-	-188
Redemption of warrants	-	11,840	4,375	11,840	11,840
Repurchased warrants	-44	-	-44	-74	-74
Allocated warrants	-	-	1,694	384	384
Cash flow from financing activities	**-44**	**11,840**	**6,015**	**12,150**	**261,282**
Cash flow for the period	**-37,194**	**-21,143**	**-109,055**	**-93,250**	**115,726**
Cash and cash equivalents at the beginning of the period	253,687	137,716	325,548	209,822	209,822
Cash and cash equivalents at the end of the period	**216,493**	**116,572**	**216,493**	**116,572**	**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 first three 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 expenditures". 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 drug 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, 26 October 2021

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 been reviewed by the company's auditors.

Translation from the Swedish original

Review report

To the Board of Directors of Xspray Pharma (publ)
Corp. id. 556649-3671

Introduction

We have reviewed the condensed interim financial information (interim report) of Xspray Pharma (publ) as of 30 September 2021 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements ISRE 2410 Review of Interim Financial Information Performed by the Independent Auditor of the Entity. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Stockholm 26 October 2021

KPMG AB

Duane Swanson
Authorized Public Accountant

Information

Glossary

505(b)(2) • 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 an original 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 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.

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.

For further information, please contact
Per Andersson, CEO
Tel: +46 (0)8 730 37 00
E-mail: per.andersson@xspray.com
www.xspraypharma.com