



INTERIM REPORT SECOND QUARTER 2021

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

Significant events during the second quarter

April - June 2021

- In April, Xspray Pharma announced the findings of two bioequivalence studies on fed and fasting healthy volunteers with formulation B of the generic product candidate HyNap-Dasa ANDA. Bioequivalence with Sprycel® was achieved in the study in fed condition. The study in fasting condition demonstrated, as expected, a lowered level of absorption of HyNap-Dasa compared to formulation A, but the effect was not sufficient to achieve bioequivalence.
- In April, Xspray Pharma announced that the company's improved version of dasatinib, HyNap-Dasa 505(b)(2), was expected to have a significantly improved product profile with more efficient absorption, which could lead to clinical advantages for patients. This version is based on the thoroughly tested formulation A, and will be tested in a registrational bioequivalence study in the second quarter.
- In May, the Annual General Meeting resolved, in accordance with the Nomination Committee's proposal, on the re-election of Board members Gunnar Gårde-my, Maris Hartmanis, Torbjörn Koivisto, Christine Lind and Carl-Johan Spak as well as the election of new Board members Anders Ekblom and Anders Bladh. Anders Ekblom replaces Michael Wolff Jensen as Chairman of the Board.
- In June, it was announced that the company's two new long-term incentive programs had been fully subscribed. The first program, LTIP 2021–2024, was offered to all employees including senior executives. The second program, LTIP 2021–2026, was offered to and subscribed by the company's new Chairman of the Board.
- In June, the bioequivalence study announced in April with the improved version of dasatinib, HyNap-Dasa 505(b)(2) commenced, and all participants received a dose. The objective of the study is to demonstrate that a lower dose strength of Xspray Pharma's improved version of dasatinib is bioequivalent to a higher dose strength of the original drug Sprycel®.

Significant events after the end of the reporting period

- In July, Xspray Pharma announced, that the pivotal study with the improved version of dasatinib, HyNap-Dasa 505(b)(2), that started in June, showed that bioequivalence was achieved with healthy margins compared with the reference product.

April - June 2021, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -16,952 thousand (-15,346)
- Earnings per share before dilution amounted to SEK -0.89 (-0.92)
- Cash flow from operating activities amounted to SEK -12,831 thousand (-9,822)
- Cash flow from investing activities amounted to SEK -26,854 thousand (-25,115)

January - June 2021, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -30,863 thousand (-25,878)
- Earnings per share before dilution amounted to SEK -1.62 (-1.54)
- Cash flow from operating activities amounted to SEK -24,802 thousand (-23,311)
- Cash flow from investing activities amounted to SEK -52,042 thousand (-49,033)
- Cash and cash equivalents at the end of the period amounted to SEK 253,737 thousand (137,766)

Amounts in parentheses refer to the year-earlier period.



A message from the CEO

Bioequivalence has been achieved for HyNap-Dasa 505(b)(2)

After the end of the quarter, we reached an important milestone when we received the extremely positive results from the bioequivalence study with our improved product candidate with dasatinib, HyNap-Dasa 505(b)(2), for the treatment of acute lymphoblastic leukemia (ALL) and chronic myeloid leukemia (CML). Bioequivalence was achieved with excellent margins compared with the reference product, Sprycel®, and the results demonstrate that Xspray Pharma can lower the dose strength by 30% but still yield the same uptake in the body as the reference product.

At present, the treatment of ALL and CML consists primarily of protein kinase inhibitors (PKI). Generally, PKI are crystalline, difficult to dissolve and cannot be administered intravenously directly into the blood, it needs to be administrated as a tablet. Tablets that are swallowed can dissolve in the stomach, but if it is a drug that is difficult to dissolve and is also affected by the variable pH of the stomach, there is a risk that the desired amount of the drug will not be absorbed by the body.

To date, Xspray Pharma's amorphous HyNap-Dasa has been scaled up, stability tested, and subsequently used in five clinical trials. We have now demonstrated that we can significantly reduce the dose of dasatinib in a tablet and still achieve the same bioavailability as in the reference product, which is one of the major advantages of our amorphous formulation. Our previous studies have shown that uptake is not affected by the pH value of the stomach, and thus simultaneously allows treatment with, for example, drugs for peptic ulcers – known as proton-pump inhibitors (PPIs) – such as omeprazole, which we know that many in this patient group need. Since this is not possible with the reference product, HyNap-Dasa can offer important medicinal advantages for both patients and care providers. Together with a



“HyNap-Dasa 505(b)(2) can be an important treatment alternative for patients with ALL and CML

favourable patent landscape, these results give us great hopes for this product in the US market.

An application for market approval for the improved version of dasatinib in the US under the 505(b)(2) procedure based on data from this study is expected to be ready for submission in H2 2021. Supplementary data pertaining to dose strength will be sent to the US Food & Drug Administration in H1 2022.

We have seen that our tool for adjusting formulations and our generic product candidate with dasatinib, HyNap-Dasa ANDA C, were developed to further decrease the absorption of dasatinib in the body compared with previous formulations. All preparations for a bioequivalence study with formulation C are complete, but the transportation of the study material has

taken a bit longer than planned due to the Covid-19 pandemic. We believe, however, that the planned study will be able to commence during the summer. We expect the results from this study in the second half of 2021, in the event of a positive outcome and after stability studies are completed, this will form the basis of our application for market approval to the FDA.

Alongside the work on HyNap-Dasa, we are also preparing our next product candidate, HyNap-Nilo. Process development is in full swing at our partner in Italy, Nerpharma, for manufacturing clinical trial material to begin the impending study.

Consolidated cash flow for the second quarter was SEK -38.5 million. This is in line with our expectations, and is attributable to the continued investments in existing and future projects, production facilities in Malta and the increase in staff numbers.

The organization continues to grow, and we have noted substantial interest in our available positions. It is gratifying to welcome even more people to our highly-skilled team. Confidence in the company, commitment and an expectation of what Xspray Pharma can achieve was on display when all of our employees participated fully in our LTIP 2021-2024 warrant program. We regard incentive programs as an excellent way of bringing together the interests of employees and shareholders in the company's stock market value development.

We are also pleased to welcome two new members of the Board of Directors: Anders Ekblom as the new Chairman of the Board and Anders Bladh as a new Board member, thereby expanding the Board to seven members from the earlier six. At the same time, we would like to extend our thanks to Michael Wolff Jensen for his many years of commitment as Chairman of the Board of Xspray Pharma. Anders Ekblom has extensive international experience in the drug industry, including as Global Head of R&D at AstraZeneca and CEO of

AstraZeneca Sweden AB. His other positions include Chairman of the Board of Elypta AB, Vice Chairman of the Board of LEO Pharma A/S, and board member of Alligator Bioscience AB and Mereo Biopharma Group PLC. Anders Bladh is the owner, CEO and a board member of Ribbskottet AB, which is the second largest owner of Xspray Pharma. In addition, he is the owner, CEO and board member of Intervalor AB and Rimtors AB as well as a board member of DistIT AB.

We have now shown that our unique technology platform makes it possible to develop amorphous versions of protein kinase inhibitors, or PKIs. With HyNap-Dasa 505(b)(2) and previous studies, we have demonstrated that we can scale up the process and modify formulations to change the uptake of the drug and achieve bioequivalence. This will be of crucial value for Xspray Pharma over the long term, since our platform was developed to create improved products of many of today's PKI drugs. The team and I are looking forward to an exciting, momentous autumn. Until then, I wish you a continued pleasant summer!

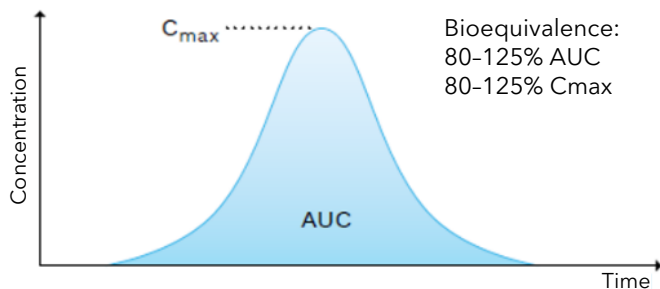
6 August 2021

Per Andersson
CEO

Business focus and prospects

Xspray Pharma AB (publ) is a product development 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 fully amorphous, they can be marketed as soon as the original companies' drug substance patents expire. This is a unique opportunity for market establishment several years ahead of generic products gaining access to the market.

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 must be achieved regardless of whether the company develops improved or generic versions of 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), Tasisigna® (nilotinib) and Nexavar® (sorafenib). In 2020, Sprycel® sold for USD 2.1 billion, Tasisigna® 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 capacity is available.

Market

PKI drugs are the second largest drug 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.

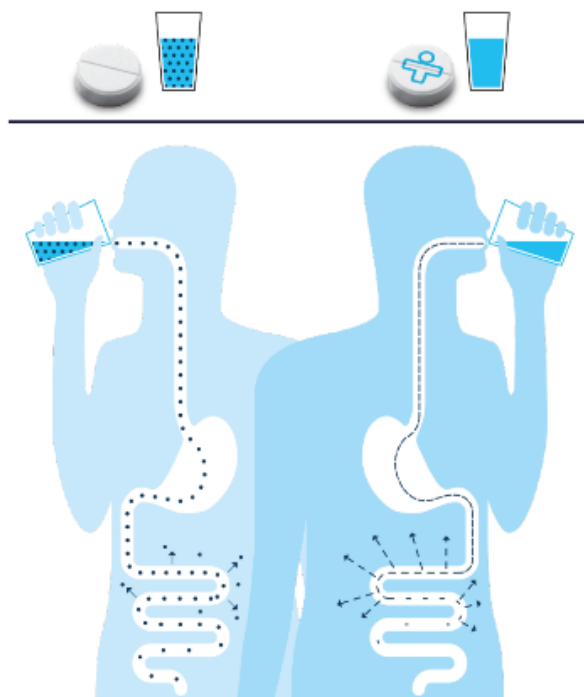
Demand for effective life-cycle products is increasing in pace with the expiration of patents for many crucial original drugs. Of the 68 PKIs currently being marketed in the US, 23 drug substance patents are expected to expire by 2030. To date, Xspray Pharma has tested its technology on some twenty of 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 products is that they are difficult to dissolve and depend on the pH value in the stomach for uptake in the body. This results in a highly uneven uptake of the drug into the body, especially alongside the ingestion of food or pH-increasing drugs such as omeprazole.

Xspray Pharma has the solution

Xspray Pharma's technology is especially suited to overcoming 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, 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 has the conditions for meeting both current market's demand for better-functioning medicines and to offer a wider patient group access to medicines that they cannot use today.






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: HyNap-Dasa, HyNap-Nilo and HyNap-Sora. These are generic or improved 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.

HyNap-Dasa as an improved and generic version

HyNap-Dasa is Xspray Pharma's leading product candidate and is an amorphous version of dasatinib for the treatment of chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL). The primary patent for the original drug Sprycel® expired in December 2020 and the secondary patent expires in 2026, which could give HyNap-Dasa a favorable market establishment over several years with less 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.

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
HyNap-Dasa	dasatinib	Leukemia (CML, ALL)	505(b)(2)	Dec 2020	Sept 2026						Sprycel®/ BMS
HyNap-Nilo	nilotinib	Leukemia (CML)	505(b)(2)	Jan 2024	Feb 2029						Tasigna®/ Novartis
HyNap-Sora	sorafenib	Liver cancer (HCC)	505(b)(2)	Jan 2020	Sept 2028						Nexavar®/ Bayer
HyNap-New	not communicated										

Clinical studies with HyNap-Dasa ANDA, a generic version of dasatinib

In 2020, a registrational study was conducted as part of the requirements for submission of an ANDA application to the FDA for market approval of the generic version in the US, and in the second half of 2020, the results of two studies conducted in fed and fasting volunteers respectively were announced. Both studies were conducted with the primary goal of demonstrating bioequivalence with HyNap-Dasa and the reference product Sprycel®. Formulation A, the first formulation produced on a commercial scale, was used in these studies.

The study in fasting healthy volunteers did not meet the statistical requirements for bioequivalence, primarily because the reference drug Sprycel® showed low or no absorption in a small number of subjects. However, this was not observed for HyNap-Dasa. The second study, in fed conditions, achieved the objective of bioequivalence. The study with formulation A in fasting volunteers was repeated later that same year, but with the same negative results.

A new bioequivalence study with a new formulation B was begun in the first quarter of 2021, and the results from this were announced after the end of the first quarter. The modification of the formula was not sufficient. The results were lower but did not fulfill the criteria for bioequivalence. Bioequivalence was achieved in fed conditions, but not in the group with fasting subjects. The company will conduct bioequivalence studies with a more modified version of HyNap-Dasa, formulation C, with results in the second half of 2021. This formulation will further reduce the absorption levels, which has been demonstrated in laboratory tests.

Clinical studies with HyNap-Dasa 505(b)(2), an improved version of dasatinib

The pivotal study in July with HyNap-Dasa 505(b)(2) showed that bioequivalence was achieved with healthy margins compared with the reference product Sprycel®. Bioequivalence studies conducted in humans confirm that the formulation:

- can be used together with omeprazole without affecting the absorption of dasatinib, which facilitates a treatment of peptic ulcers while the patient is being treated for cancer
- yields a more even and consistent uptake of dasatinib without those cases of low uptake linked to previous studies with Sprycel®
- can be administered at a lower dosage, which is expected to yield fewer side effects

HyNap-Nilo

Xspray Pharma is developing HyNap-Nilo as an improved version of Tasisna® (nilotinib) for the treatment of chronic myeloid leukemia (CML). Global sales of Tasisna® totaled USD 1,958 million in 2020, of which the US market accounted for USD 859 million.

Tasisna'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 of a HyNap-Nilo prototype. The study showed that HyNap-Nilo significantly reduces food interaction compared with Tasisna® after a high-fat meal. Clinical tests have also showed the bioavailability of HyNap-Nilo to be 2.4 times greater than Tasisna®. Like Xspray Pharma's other candidates, HyNap-Nilo also displayed lower variability compared with Tasisna®. The development proceeds with the goal to conducting bioequivalence studies which, in the event of positive results, will form the basis for applying for market approval in accordance with 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).

The development of the commercial formulation and manufacturing of clinical trial materials is progressing, and new clinical studies are planned in 2021.

HyNap-Sora

Xspray Pharma is developing 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. 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 the bioavailability of Nexavar®. The variability in both AUC and C_{max} among subjects was also reduced by approximately half.

Financial overview, Group

Key figures, Group	Q2		Jan-Jun		Full year
	2021	2020	2021	2020	2020
Net sales (SEK thousand)	-	-	-	-	-
Loss before Income tax (SEK thousand)	-16,952	-15,346	-30,863	-25,878	-52,410
Earnings per share before dilution (SEK)	-0.89	-0.92	-1.62	-1.54	-3.05
Earnings per share after dilution (SEK)	-0.89	-0.92	-1.62	-1.54	-3.05
Research and development expenses as % of operating expenses	11.3	10.1	11.4	12.1	11.9
Cash and cash equivalents (SEK thousand)	253,737	137,766	253,737	137,766	325,598
Total assets (SEK thousand)	578,740	371,014	578,740	371,014	605,303
Equity/assets ratio (%)	96.4	95.2	96.4	95.2	96.2
Number of employees	22	20	22	20	20

Total expenditure for research and development for the quarter was SEK -28,634 thousand, of which SEK -1,978 thousand has been expensed and SEK 26,656 thousand capitalized as development expenditure.

Total expenditure for research and development for the period January-June was SEK -55,730 thousand, of which SEK -3,604 thousand has been expensed and SEK 52,126 thousand capitalized as development expenditure.



Comments on the report

Unless otherwise indicated, the comments below pertain to the Group. Comparison figures are presented in parentheses and pertain to the year-earlier period. Since the Group consists of the Parent Company and a dormant subsidiary, the differences between the Parent Company and consolidated statements consist of the 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 in 2021.

Other operating income and expenses

Other operating income for the period amounted to SEK 153 thousand (579). Other operating expenses for the period amounted to SEK -397 thousand (-264). The company's aggregate other operating income and expenses for both quarters totalled SEK 253 thousand (579) and SEK -867 thousand (-805). 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 second quarter was SEK -28,634 thousand (-27,292), of which SEK -1,978 thousand (-1,634) has been expensed and thereby recognized in profit or loss, and SEK 26,656 thousand (25,658) has been capitalized as development expenditures and is presented in the company's balance sheet. For the first two quarters, the figure is SEK -55,730 thousand (-49,388) for total expenditure for research and development, where SEK -3,604 thousand (-3,256) has been expensed and SEK 52,126 thousand (46,133) has been capitalized as development expenditures.

The majority of the cost increase is attributable to higher clinical costs as well as increases in other activity in the company's two product candidates, HyNap-Dasa and HyNap-Nilo.

Administrative and sales costs

Administrative and sales costs for the second quarter of 2021 amounted to SEK -15,067 thousand (-14,319); of these, personnel costs classified as administrative, and sales costs amounted to SEK -6,023 thousand (-8,810). The corresponding half-year figures are SEK

-27,248 thousand (-22,871) for administrative and sales costs, where SEK -9,918 thousand (-12,051) pertained to personnel costs. The increase 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 second quarter totalled SEK -16,952 thousand (-15,346) and for the half-year totalled SEK -30,863 thousand (-25,878). This corresponds to earnings per share before dilution of SEK -0.89 (-0.92) and SEK -1.62 (-1.54) respectively.

Cash flow, investments, and financial position

Cash flow from operating activities for the quarter amounted to SEK -12,831 thousand (-9,822), of which the effect from operating capital comprised SEK 2,150 thousand (4,479). The aggregate figure for the two quarters was SEK -24,802 thousand (-23,311), in which the effect from operating capital was SEK 1,734 thousand (127). 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 -26,854 thousand (-25,115) for the quarter and SEK -52,042 thousand (-49,033) for the half-year. The item consists primarily of capitalized development expenses of SEK -26,379 thousand (-25,377) for the quarter and SEK -51,567 thousand (-45,570) for the half-year. Investment in property, plant and equipment totalled SEK -475 thousand (-121) for the period and SEK -475 thousand (-3,846) for the half-year. 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.

Cash flow from financing activities for the quarter amounted to SEK 1,157 thousand (-37) and SEK 4,983 thousand (238) for the half-year. The positive effect is due to the allocation of warrants from the LTIP 2021/2024 and Chairman LTIP 2021/2026 programs. In total, 195,725 and 13,214 warrants respectively were redeemed at a value of SEK 1,694 thousand. Total cash flow for the second quarter was SEK -38,528 thousand (-34,974)

and for both quarters was SEK -71,861 thousand (-72,106).

The Group had SEK 253,737 thousand (137,766) in cash and cash equivalents at June 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 96.4 per cent (95.2) at June 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 26,656 thousand (25,658). The Group's total capitalized expenditures for development and similar activities totaled SEK 283,744 thousand (187,647) at June 30, 2021. The item is associated primarily with the company's leading product candidate, HyNap-Dasa.

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 253,687 thousand (137,716) in cash and cash equivalents at June 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 on May 20, 2021, performed consultant assignments in business development and legal advisory services for the company. No consultant assignments were performed during the second quarter, and fees thereby totaled SEK 0 thousand (-70). The corresponding figure for the half-year was SEK 0 thousand (-140).

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 second quarter as compared to the preceding quarter. At June 30, 2021, the number of shares in the company was 19,067,504 and the last price paid in the period at June 30, 2021 was SEK 98.00.

Incentive programs

At June 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 programs were resolved on at the Annual General Meeting on May 20, 2021. The programs 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 programs 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 program was subscribed under market terms at a price established by an independent appraisal institute using the Black-Scholes model. The value per warrant 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 program included the company's new Chairman of the Board and was signed under terms similar to the aforementioned program. 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.

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

Owners as of June 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	1,498,500	7.86%
TIN Fonder	835,590	4.38%
Avanza Pension	791,910	4.15%
Unionen	726,000	3.81%
Andra AP-fonden	422,320	2.21%
Futur Pension	402,500	2.11%
C WorldWide Asset Management	320,000	1.68%
Total, ten largest owners	11,197,646	58.73%
Total, other shareholders	7,869,858	41.27%
Total number of shares	19,067,504	100.00%

Financial calendar

Interim report Q3	November 4, 2021
Year-end report 2021	February 18, 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

SEK thousand	Q2		Jan-Jun		Full year
	2021	2020	2021	2020	2020
Net sales	-	-	-	-	-
Other operating income	153	579	253	579	1,364
Research and development expenses	-1,978	-1,634	-3,604	-3,256	-6,549
Administration and sales expenses	-15,067	-14,319	-27,248	-22,871	-47,101
Other operating expenses	-397	-264	-867	-805	-1,171
Operating loss	-17,289	-15,639	-31,466	-26,352	-53,457
Finance income	340	293	606	479	1,053
Finance costs	-3	-0	-3	-5	-6
Finance net	337	292	603	474	1,047
Loss before Income tax	-16,952	-15,346	-30,863	-25,878	-52,410
Tax	-	-	-	-	-
Loss for the period	-16,952	-15,346	-30,863	-25,878	-52,410
Earnings per share for the period before dilution, SEK	-0.89	-0.92	-1.62	-1.54	-3.05
Earnings per share for the period after dilution, SEK	-0.89	-0.92	-1.62	-1.54	-3.05
Average number of shares before dilution	19,067,504	16,751,622	19,035,421	16,751,622	17,211,467
Average number of shares after dilution	19,146,578	17,285,287	19,114,495	17,285,287	17,679,463

Consolidated statement of comprehensive income

SEK thousand	Q2		Jan-Jun		Full year
	2021	2020	2021	2020	2020
Loss for the period	-16,952	-15,346	-30,863	-25,878	-52,410
Other comprehensive income	-	-	-	-	-
Total comprehensive income for the period	-16,952	-15,346	-30,863	-25,878	-52,410

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

Consolidated balance sheet

SEK thousand	30 Jun 2021	30 Jun 2020	31 Dec 2020
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	283,744	187,647	231,618
Patent	-	-	-
Total intangible assets	283,744	187,647	231,618
Property, plant and equipment			
Machinery and installations	24,298	23,801	20,746
Right-of-use assets	4,510	5,900	5,207
Equipment	793	1,183	970
Fixed assets under construction and prepayments	9,118	11,459	15,746
Total Property, plant and equipment	38,719	42,343	42,669
Financial assets			
Financial investments	1	1	1
Total financial assets	1	1	1
Total non-current assets	322,464	229,991	274,288
Current assets			
Current tax asset	630	-	-
Current receivables	874	1,980	2,667
Prepaid expenses and accrued income	1,037	1,277	2,750
Cash and cash equivalents	253,737	137,766	325,598
Total current assets	256,277	141,023	331,015
TOTAL ASSETS	578,740	371,014	605,303

SEK thousand	30 Jun 2021	30 Jun 2020	31 Dec 2020
EQUITY AND LIABILITIES			
Equity			
Share capital	19,068	16,752	18,893
Other contributed capital	715,292	450,576	709,407
Reserves	976	976	976
Retained earnings including profit/loss for the period	-177,552	-120,157	-146,689
Total equity attributable to the Parent Company's shareholders	557,784	348,147	582,587
Non-current liabilities			
Lease liabilities	2,118	3,620	2,898
Total non-current liabilities	2,118	3,620	2,898
Current liabilities			
Trade accounts payable	4,887	6,583	8,438
Lease liabilities	2,095	1,767	1,985
Other current liabilities	1,725	997	768
Accrued expenses and deferred income	10,131	9,900	8,627
Total current liabilities	18,838	19,247	19,818
TOTAL EQUITY AND LIABILITIES	578,740	371,014	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 January 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 / new shares	280	11,560	-	-	11,840
Warrant program	-	310	-	-	310
Closing balance as of December 31, 2020	18,893	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	-	-	-	-30,863	-30,863
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	-	-	-	-30,863	-30,863
Transaction costs	-	4,200	-	-	-
Redemption of warrants / new shares	-	-9	-	-	-9
Closing balance as of June 30, 2021	19,068	715,292	976	-177,552	557,784

Consolidated cash flow statement

SEK thousand	Q2		Jan-Jun		Full year
	2021	2020	2021	2020	2020
Operating activities					
Operating loss	-17,289	-15,639	-31,466	-26,352	-53,457
Non-cash adjustments					
Depreciation	2,312	1,925	4,267	3,832	7,689
Capital gains	-	-113	98	-113	-113
Dissolved prepaid leasing costs, during the period	-	-473	-	-946	-1,262
Interest received	-	-	569	149	674
Interest paid	-4	-1	-4	-8	-8
Cash flow from operating activities before changes in working capital	-14,981	-14,301	-26,536	-23,438	-46,477
Changes in working capital					
Change in operating receivables	1,850	1,207	2,823	4,273	2,479
Change in operating liabilities	300	3,272	-1,089	-4,146	-3,794
Cash flow from operating activities	-12,831	-9,822	-24,802	-23,311	-47,792
Investing activities					
Capitalized development costs	-26,379	-25,377	-51,567	-45,570	-88,983
Acquisition of property, plant and equipment	-475	-121	-475	-3,846	-4,572
Sales of tangible fixed assets	-	383	-	383	383
Prepayments	-	-	-	-	-3,656
Cash flow from investing activities	-26,854	-25,115	-52,042	-49,033	-96,828
Financing activities					
New share issue	-	-	4,375	-	249,320
Lease liability	-0	-	-10	-	-
Transaction costs	-	-	-	-	-188
Payment of lease liability	-537	-37	-1,076	-72	-936
Redemption of warrants	-	-	-	-	11,840
Repurchased warrants	-	-	-	-74	-74
Allocated warrants	1,694	-	1,694	384	384
Cash flow from financing activities	1,157	-37	4,983	238	260,345
Cash flow for the period	-38,528	-34,974	-71,861	-72,106	115,726
Cash and cash equivalents at the beginning of the period	292,265	172,740	325,598	209,872	209,872
Cash and cash equivalents at the end of the period	253,737	137,766	253,737	137,766	325,598

Parent Company income statement

SEK thousand	Q2		Jan-Jun		Full year
	2021	2020	2021	2020	2020
Net sales	-	-	-	-	-
Other operating income	153	579	253	579	1,364
Research and development expenses	-1,951	-1,593	-3,549	-3,172	-6,379
Administration and sales expenses	-15,091	-14,342	-27,298	-22,918	-47,194
Other operating expenses	-397	-264	-867	-805	-1,172
Operating loss	-17,286	-15,620	-31,461	-26,315	-53,381
Finance income	249	293	515	479	1,053
Finance costs	-3	-0	-3	-5	-5
Finance net	246	292	512	474	1,048
Loss before Income tax	-17,040	-15,328	-30,949	-25,841	-52,333
Tax	-	-	-	-	-
Loss for the period	-17,040	-15,328	-30,949	-25,841	-52,333
Earnings per share for the period before dilution, SEK	-0.89	-0.92	-1.63	-1.54	-3.04
Earnings per share for the period after dilution, SEK	-0.89	-0.92	-1.63	-1.54	-3.04
Average number of shares before dilution	19,067,504	16,751,622	19,035,421	16,751,622	17,211,467
Average number of shares after dilution	19,146,578	17,285,287	19,114,495	17,285,287	17,679,463



Parent Company balance sheet

SEK thousand	30 Jun 2021	30 Jun 2020	31 Dec 2020
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	283,616	187,542	231,512
Patent	-	-	-
Total intangible assets	283,616	187,542	231,512
Property, plant and equipment			
Machinery and installations	24,298	23,801	20,747
Equipment	793	1,183	970
Fixed assets under construction and prepayments	9,027	11,459	15,746
Total Property, plant and equipment	34,118	36,442	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	317,785	224,035	269,026
Current assets			
Current receivables			
Current tax asset	630	-	-
Other current receivables	874	1,980	2,666
Prepaid expenses and accrued income	1,519	1,907	3,232
Total current receivables	3,022	3,887	5,898
Cash and bank	253,687	137,716	325,548
Total current assets	256,708	141,604	331,446
TOTAL ASSETS	574,493	365,639	600,472

SEK thousand	30 Jun 2021	30 Jun 2020	31 Dec 2020
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	19,068	16,752	18,893
Statutory reserve	976	976	976
Development expenditure reserve	283,616	187,542	231,512
Total restricted equity	303,660	205,270	251,381
Non-restricted equity			
Other contributed capital	715,292	450,576	709,408
Accumulated earnings	-430,253	-281,846	-325,816
Profit/loss for the period	-30,949	-25,841	-52,333
Total non-restricted equity	254,090	142,889	331,259
Total equity	557,750	348,159	582,640
Current liabilities			
Trade accounts payable	4,887	6,583	8,437
Other current liabilities	1,725	997	768
Accrued expenses and deferred income	10,131	9,900	8,627
Total current liabilities	16,744	17,480	17,832
TOTAL EQUITY AND LIABILITIES	574,493	365,639	600,472

Parent Company cash flow statement

SEK thousand	Q2		Jan-Jun		Full year
	2021	2020	2021	2020	2020
Operating activities					
Operating loss	-17,286	-15,620	-31,461	-26,315	-53,381
Non-cash adjustments					
Depreciation	2,040	1,675	3,723	3,332	6,694
Capital gains	-	-113	98	-113	-113
Interest received	-	-	569	149	674
Interest paid	-4	-1	-4	-5	-5
Cash flow from operating activities before changes in working capital	-15,250	-14,059	-27,075	-22,952	-46,131
Changes in working capital					
Change in operating receivables	1,849	1,207	2,823	4,273	2,311
Change in operating liabilities	301	3,272	-1,089	-4,146	-3,794
Cash flow from operating activities	-13,100	-9,580	-25,341	-22,825	-47,614
Investing activities					
Purchase of intangible assets	-26,647	-25,656	-52,104	-46,128	-90,098
Acquisition of property, plant and equipment	-475	-121	-475	-3,846	-4,571
Sales of tangible fixed assets	-	383	-	383	383
Prepayments	-	-	-	-	-3,656
Cash flow from investing activities	-27,122	-25,394	-52,579	-49,591	-97,942
Financing activities					
New share issue	-	-	4,375	-	249,320
Transaction costs	-	-	-10	-	-188
Redemption of warrants	-	-	-	-	11,840
Repurchased warrants	-	-	-	-74	-74
Allocated warrants	1,694	-	1,694	384	384
Cash flow from financing activities	1,694	-	6,059	310	261,282
Cash flow for the period	-38,528	-34,974	-71,861	-72,106	115,726
Cash and cash equivalents at the beginning of the period	292,215	172,690	325,548	209,822	209,822
Cash and cash equivalents at the end of the period	253,687	137,716	253,687	137,716	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 two quarters of 2021.

Comparison figures are presented in parentheses and pertain to the year-earlier period.

Xspray Pharma AB (publ) acquired a newly-formed subsidiary, dormant for the time being, at the end of December 2018 in order to prepare the Group structure for potential future structural requirements. No activity has taken place in the subsidiary; all activities are pursued in the Parent Company, Xspray Pharma AB (publ).

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 recognised 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. During the preceding fiscal year, there were minor delays to the start of the study with the generic version of Sprycel®. 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, August 6, 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 not been audited.

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 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 • A concept in pharmacology that indicates the proportion of the drug substance in 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 food and drug agency in the US 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.

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