Xspray Pharma Interim report Q4 2020

JANUARY - DECEMBER 2020

"Our business model is different from traditional drug development. Instead of developing a new drug candidate that will have to undergo Phase I, Phase II and Phase III studies, our technology platform produces amorphous PKI versions that need to demonstrate bioequivalence with already marketed drugs. Several of the marketed PKI:s are highly variable and have low solubility, several studies may be required to achieve bioequivalence, which we see with HyNap-Dasa. Our development process is now established, and we will be able to work with several drug candidates in parallel to maximize the number of approved products. Repeated studies are a common procedure in generic drug development."

Per Andersson, CEO
Xspray Pharma AB (publ)

Significant events during the fourth quarter, 2020

October - December 2020

- In October, a directed new issue of shares was made at a subscription price of SEK 142.50 per share. The issue raised approximately SEK 265 million before transaction costs and increased the number of shares by 1,861,291, from 17,031,213 to 18,892,504.
- In October, the composition of the Nomination Committee for the 2021 Annual General Meeting was announced.
- In December, Xspray Pharma received HyNap-Nilo orphan drug status from the FDA for the treatment of chronic myeloid leukemia.
- In December, Xspray Pharma received positive results from a study with HyNap-Dasa during treatment with omeprazole.

Significant events after the end of the reporting period

- As of January 4, 2021, the company's shares were moved from Nasdaq Small Cap to the Mid Cap segment after a significant increase in share price during 2020.
- In January, Xspray Pharma announced results from the extra fasting bioequivalence study conducted with HyNap-Dasa, the results were in line with previous bioequivalence studies.
- In January, it was announced that CEO Per Andersson and other warrant holders subscribed for shares in Xspray Pharma through their respective exercise of the full number of warrants available in the warrant program LTIP 2015/2021.
- In February, the Nomination Committee of Xspray Pharma proposed to elect Anders Ekblom as new Chairman. The Nomination Committee further proposed to re-elect the former Board members and elect Anders Bladh as a new Board member. Resolutions will take place at the Annual General Meeting on May 20, 2021.

October - December 2020, Group

Net sales amounted to SEK 0 thousand (0)

Earnings before tax amounted to SEK -14,972 thousand (-18,738)

Earnings per share before dilution amounted to SEK -0.81 (-1.20)

Cash flow from operating activities amounted to SEK -11,717 thousand (-11,546)

Cash flow from investing activities amounted to SEK -27,926 thousand (-24,147)

January - December 2020, Group

Net sales amounted to SEK 0 thousand (0)

Earnings before tax amounted to SEK -52,410 thousand (-45,771)

Earnings per share before dilution amounted to SEK -3.05 thousand (-3.01)

Cash flow from operating activities amounted to SEK -47,792 thousand (-34,237)

Cash flow from investing activities amounted to SEK -96,828 thousand (-91,994)

Cash and cash equivalents and current investments at the end of the period totalled SEK 325,598 thousand (209,872)

October - December 2020, Parent Company

Net sales amounted to SEK 0 thousand (0)

Earnings before tax amounted to SEK -14,951 thousand (-18,729)

Earnings per share before dilution amounted to SEK -0.81 (-1.20)

Cash flow from operating activities amounted to SEK -11,948 thousand (-11,319)

January - December 2020, Parent Company

Net sales amounted to 0 thousand (0)

Earnings before tax amounted to SEK -52,333 thousand (-45,796)

Earnings per share before dilution amounted to SEK -3.04 (-3.01)

Cash flow from operating activities amounted to SEK -47,614 thousand (-33,338)

Cash and cash equivalents and current investments at the end of the period amounted to SEK 325,548 thousand (209,822)

Amounts in brackets refer to the corresponding period for the previous year.

A message from the CEO

Per Andersson, CEO

Undoubtedly, 2020 was a different year. The start of studies with our generic version of Sprycel® was delayed due to the Covid-19 pandemic. The results of the clinical study in healthy volunteers under fed condition did show formal bioequivalence, but it was of course disappointing that the formal bioequivalence in fasted state as show in previous pilot studies was not achieved. A troubleshooting process followed by an action program was initiated and several adjusted formulations were prepared for studies to be conducted during the first half of 2021. In vitro models were developed to better predict the outcome in humans and the adjusted formulations were tested in these models with good results. Since the study result in a fasted state was very close to the goal, we also decided to repeat the study and were able to start it already after a couple of months. As for our improved version of Sprycel®, the next step will be to initiate a registrational study.

In the repeat study, our tablets again showed an even and consistent absorption on empty stomach. Unfortunately, Sprycel's absorption varies considerably more for which reason formal bioequivalence was not achieved. As a result, we need to reduce bioavailability of our tablets, i.e., the extent of the drug's absorption into the body.
We can conclude that our tablets are stable and of high quality and give an even uptake of the drug to the body. In fed studies where subjects have eaten a meal, HyNap-Dasa is absorbed into the body in the same manner as the original drug Sprycel®, i.e., formal bioequivalence is achieved.

HyNap-Dasa is the first in a series of HyNap product candidates where we aim to achieve bioequivalence. I am very pleased with how the company's acquired experience is being used in the development phase of our pipeline products. Because we have not yet achieved formal bioequivalence the patent window of HyNap-Dasa has been reduced. We are now in the second month of the patent window that totals 45-60 months, where Sprycel® sells for approximately SEK 850 million every month in the USA alone. This very high value of the patent window justifies continued formulation work effort. The first of our new formulations carry little more risk but reaching our goal a little earlier justifies the risk especially since the development costs will be reimbursed after just a few days on the market.

> The process is repeatable and effectively shortens the development time for future products in our pipeline.

Our supply chain is now established on a commercial scale, from the production of amorphous drug substances to the manufacture of the final tablets. The development of new product candidates follows the same path as for HyNap-Dasa. The process is repeatable and effectively shortens the development time for future products in our pipeline. In addition, the technology makes it possible to quickly and in a controlled manner adjust the properties required to take each product candidate to a marketed drug. The studies completed to date confirm that our product candidates can play a key role in improving established cancer drugs during the patent window period during which drug prices are still very high. There is a long list of protein kinase inhibitors compatible with our technology that can be developed as improved products in the future.

Our business model is different from traditional drug development. Instead of developing a new drug candidate that will have to undergo Phase I, Phase II and Phase III studies, our technology platform produces amorphous PKI versions that need to demonstrate bioequivalence with already marketed drugs. Several of the marketed PKI:s are highly variable and have low solubility, several studies may be required to achieve bioequivalence, which we see with HyNap-Dasa. Our development process is now established, and we will be able to work with several drug candidates in parallel to maximize the number of approved products.

Repeated studies are a common procedure in generic drug development. Although negative results are not necessarily expected, since we work with PKI:s, they are a part of our development process. Even if our process entails lower risk than many other biotech business models it has still an unusually high value. For HyNap-Dasa, this has meant that we have been motivated to start new studies as quickly as possible to demonstrate formal bioequivalence before submission for market approval. The studies are fast and relatively inexpensive, and with the high value of the patent window we are willing and motivated to work with this risk-reward profile.

As for our improved version of Sprycel®, the next step will be to initiate a registrational study. The positive results from the bioavailability study with and without omeprazole communicated before Q4 2020 showed that the uptake of HyNap-Dasa is independent of the gastric pH value. It confirms that this product will have clinically relevant advantages compared to Sprycel®.

Our next product candidate HyNap-Nilo is an improved version of Tasigna® (nilotinib) for the treatment of chronic myeloid leukemia (CML). Based on the potential clinical benefit of the product we have obtained orphan drug status for it. Orphan drug classification gives several benefits during the development, including the possibility of market exclusivity for seven years, provided clinical benefit over the original drug has been demonstrated upon approval. Tasigna® has significant food interaction described in a so-called "blackbox warning", designed to draw attention to serious risks associated with food consumption concomitantly with Tasigna® administration. In a previously reported study, the uptake of HyNap-Nilo was practically unaffected by food intake, which would be beneficial to the patients. The next step will be to carry out pilot studies in 2021.

In October, we strengthened our financial position through a directed new share issue that provided the company with approximately SEK 265 million before transaction costs. The shares were subscribed for by several Swedish and international institutional investors, including the Third Swedish National Pension Fund, Handelsbanken Fonder, the Second Swedish National Pension Fund, Swedbank Robur Fonder, the Fourth Swedish National Pension Fund and TIN Ny Teknik. The loss for the year for the Group was SEK -52 million and is in line with our expectations. The loss is attributable to the continued investments in the projects, the production facility in Malta and the increased workforce.

The expansion of our production capacity together with our new CMO partner in Malta will make it possible to work simultaneously and at full speed with several product candidates. The production unit in Malta is now under construction.

Our already strong patent position was further strengthened in 2020 paving the way for a favourable market establishment and strengthening our ability for making attractive deals with our projects. The possibilities are many and the ambitions are high. I look forward to an eventful 2021 and welcome you to share our journey!

Solna, February 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 RightSize technology to develop improved and generic versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. Sales of the PKI drugs constitute around 25 percent of the total oncology market in a segment where drug prices are extremely high.

The innovative RightSize technology allows Xspray Pharma, through licensing to suitable pharmaceutical companies, to gain entry as the first competitor to today's original drugs before secondary patents expire. Xspray Pharma's goal is to become the leader in the development of improved drugs or generic versions of PKIs already marketed for the treatment of cancer.

At the end of 2020, there were 55 approved PKI:s in the U.S. market. The technology has been tested on more than twenty PKI:s with good results. The Company's first product candidates, HyNap-Dasa, HyNap-Nilo and HyNap-Sora, are stable amorphous versions of the three blockbuster cancer drugs Sprycel® (dasatinib), Tasigna® (nilotinib), and Nexavar® (sorafenib). HyNap-Dasa, the leading product candidate, is in the final stages of the development of a generic as well as an improved version of the original drug. The U.S substance patent for the original drug Sprycel® (dasatinib) expired at the end of 2020, and the secondary patents in 2026, which offers HyNap-Dasa a period of several years in a unique position before other competitors gain access to the market. A careful selection process determines which new PKI:s will become future product candidates and be included in the Company's pipeline when manufacturing capacity is possible. The Company has patented the manufacturing technology, the equipment, and the resulting products.

Launching with limited competition

- Unique technology that enables the launch of product candidates after the expiration of the original drug's primary substance patent but before the expiration of secondary product patents
- The original drug secondary patents also give Xspray Pharma protection against the launch of competing products

Low development expenditure

- Development costs are substantially lower than typical development for original drugs
- Total development expenditure is estimated to be USD 8 to 15 million per product candidate

Limited risk

- Proof-of-Concept that production and supply chain on site for commercial production of stable amorphous versions of PKI
- The active substance is already known and tested for safety and efficacy
- Clear regulatory pathway to registration
- Active patent strategy to protect technology and products

Short development time

- Only 3 – 4 years from start of development to market approval
- Bioequivalence studies in healthy volunteers sufficient for registration – long-term studies in patients are not necessary

Financial overview, Group

	Q4		Jan-Dec	
Key figures group	**2020**	**2019**	**2020**	**2019**
Net sales (SEK thousand)	-	-	-	-
Loss before Income tax (SEK thousand)	-14,972	-18,738	-52,410	-45,771
Earnings per share before dilution (SEK)	-0.81	-1.20	-3.05	-3.01
Earnings per share after dilution (SEK)	-0.81	-1.20	-3.05	-3.01
Research and development expenses as % of operating expenses	10.4	6.9	11.9	7.3
Cash and cash equivalents (SEK thousand)	325,598	209,872	325,598	209,872
Total assets (SEK thousand)	605,303	400,672	605,303	400,672
Equity/assets ratio (%)	96.2	93.3	96.2	93.3
Average number of employees	20	17	20	17

Total research and development expenditures for the quarter amounted to SEK -26,094 thousand, of which SEK -1,642 thousand is expensed and SEK -24,452 thousand recorded as capitalized development cost.

Total research and development expenditures for the period January - September amounted to SEK -96,653 thousand of which SEK -6,549 thousand is expensed and SEK -90,104 thousand is recorded as capitalized development cost.

Financial overview, Parent Company

	Q4		Jan-Dec	
Key figures parent company	**2020**	**2019**	**2020**	**2019**
Net sales (SEK thousand)	-	-	-	-
Loss before Income tax (SEK thousand)	-14,951	-18,729	-52,333	-45,796
Earnings per share before dilution (SEK)	-0.81	-1.20	-3.04	-3.01
Earnings per share after dilution (SEK)	-0.81	-1.20	-3.04	-3.01
Research and development expenses as % of operating expenses	10.1	6.7	11.7	7.2
Cash and cash equivalents (SEK thousand)	325,548	209,822	325,548	209,822
Total assets (SEK thousand)	600,472	395,316	600,472	395,316
Equity/assets ratio (%)	97.0	94.5	97.0	94.5
Average number of employees	20	17	20	17

At the end of December 2018, Xspray Pharma AB (publ) acquired a newly incorporated subsidiary company, dormant for the time being. No business activity has taken place in the subsidiary; all business is pursued in the Parent Company Xspray Pharma AB (publ).

Comments on the report

The comments below refer to the Group. As the Group consists of the Parent Company and a dormant subsidiary, the differences between the Parent Company and the consolidated accounts are the difference between RFR2 and IFRS. Net sales for the Company are still SEK 0. The submission for market approval of the first product is planned to take place in 2021.

October - December 2020

The Group´s operating expenses for the period amounted to SEK -15,294 thousand (-18,969). The costs consist mainly of administrative and sales costs which amounted to SEK -13,970 thousand of the total operating costs. Of these, personnel costs classified as administrative and sales costs amount to SEK -2,296 thousand (-5,603).

The Group´s expensed research and development costs for the period were SEK-1,642 (-1,952) thousand and capitalized development expenses were SEK 24,452 thousand (22,802).

January - December 2020

The Group´s operating expenses for the four quarters amounted to SEK -53,457 thousand (-46,564). The costs consist mainly of administrative and sales costs, which amount to SEK -47,101 thousand (-42,327) of the total operating costs. Of these, personnel costs that are classified as administrative and sales costs amount to SEK -17,961 thousand (-12,354).

Revenue and earnings

Net sales for the year and the quarter amounted to SEK 0. Sales are not expected to increase until the Company according to the current business plan obtains market approval of its first product or a business agreement is made.

The Group´s operating losses for the year amounted to SEK -52,410 thousand (-45,771), which is slightly higher than the previous year. The number for fourth quarter amounted to SEK -15,294 thousand (-18,969). The corresponding figure for the Parent Company is SEK -15,273 thousand (-18,960). The operating costs are attributable to the planned increase in costs for the Company's clinical program, strengthened organization, investment in production facility and other related advising costs for the future strategic positioning.

Financial position

The Company's operations are mainly financed by equity. In the beginning of the fourth quarter, a directed new issue of shares was made at a subscription price of SEK 142.50. The issue raised approximately SEK 265 million before transaction costs and increased the number of shares by 1,861,291. The Board assesses that the financial position of the company is thus sufficient for the coming twelve-month period with an acceptable and manageable level of risk in the product portfolio. The Board evaluates the company's financial needs and financial position on an ongoing basis and reviews the best capital structure for the company.

The equity/assets ratio was 96.2 percent (93.3) as of September 30, 2020 in the Group and the corresponding figure for the Parent Company was 97.0 percent (94.5).

Cash flow and investments

Total cash flow for the Group during the year amounted to SEK 115,726 thousand (-11,396). The corresponding figure for the fourth quarter amounted to SEK 208,976 thousand (79,215). The positive outcome is attributable to the new issue of shares that had an effect of SEK 249,132 thousand after transaction costs. Cash flow from operating activities amounted to SEK -47,792 thousand (-34,237) during the year and SEK -11,717 thousand (-11,546) during the fourth quarter. The effect of working capital was SEK -1,315 thousand (8,894)

during the full year and SEK 1,237 thousand (5,987) in the actual quarter.

The total cash flow for the Parent Company during all quarters amounted to SEK 115,726 thousand (-11,394), the number for the fourth quarter amounted to SEK 208,976 thousand (79,216). Cash flow from operating activities amounted to SEK - 47,614 thousand (-33,338) during the year and SEK -11,948 thousand (-11,319) during the quarter. The effect from changes in working capital amounted to SEK -1,463 thousand (8,892) during the full year and SEK 1,229 thousand (5,985) during the fourth quarter.

Cash flow from investing activities in the Group amounted to SEK -97,942 thousand (-93,005) during the year, and SEK -27,926 thousand (-24,147) during the quarter. The costs consists mainly of capitalized development costs of SEK -90,098 thousand (-69,902) respectively SEK -24,172thousand (-20,089) related to the last quarter. The investing activities costs are related to the Company's investments in production lines and the new production facility. The cash flow from investing activities are in line with expectations.

The full year cash flow from financing activities amounted to SEK 260,345 thousand (114,837) SEK, the effect is mainly related e to the new issue of shares that was raised in October and the redemption of warrants. During the fourth quarter the cash flow from financing activities amounted to SEK248,619 thousand (114,908) for the Group, which is a solely effect of the new issue of shares. In total, the number of shares increased by 1,861,291 at a subscription price of SEK 142.50.

The Group had SEK 325,598 thousand (209,872) in cash and cash equivalents as of December 31, 2020 and the corresponding figure for the Parent Company was SEK 325,548 thousand (209,822).

Intangible assets

Development expenses related to the projects have been capitalized according to plan. Capitalized development costs for the fourth quarter in the Group amounted to SEK 24,452 thousand (17,084) and the corresponding figure for the Parent Company amounted to SEK 24,454 thousand (17,017). As of December 31, 2020, the Group's capitalized expenses for development work and similar work amounted to SEK 231,618 thousand (141,515) and the corresponding figure for the Parent Company was SEK 231,512 thousand (141,414).

Group structure

No business activity took place in the subsidiary during the period; all business is pursued in the Parent Company Xspray Pharma AB (publ).

Personnel

During the quarter, the organization has increased with one employee. At the end of the quarter the number of employees in the Group was 20 (17). The subsidiary has still no employees at the period end.

Related Party Transactions

The Company´s Chairman of the Board carries out consultancy assignments in business development and legal advice for the company. The cost for this in the quarter was SEK -19 thousand (-91) and SEK -249 thousand (-234) during the full year.

Corporate governance

The Audit and Remuneration Committees have continued to assist the Board with oversight tasks and remuneration issues.

Share information

Xspray Pharma's shares are listed on Nasdaq Stockholm with the short name XSPRAY since March 27, 2020. Before that, the share was traded on Nasdaq First North Growth Market since September 28, 2017.

During the fourth quarter, the shares and votes increased as a result of the new issue of shares. The number of shares increased by 1,861,291. On December 31, 2020, the number of shares in the Company totalled 18,892,504 and the latest share price for the period was SEK 194.00.

Incentive program

The Company has issued four series of warrant programs to senior executives and employees.

The fourth warrant program (LTI 2020) was resolved at an Extraordinary General Meeting on March 26, 2020 and comprised 79,074 warrants linked to the company´s value growth, to create a stronger link between the employees and shareholder's interest. The fourth program involved 5 persons, including the CFO. The warrants were subscribed on market terms at a price determined on the basis of an estimated market valuation (Black & Scholes) by an independent valuation institution. The value of the warrant was calculated at SEK 4.86 based on a subscription price per share of SEK 89.10. The program provides a maximum dilution effect of 0.47 percent on the current number of shares. The warrant program is conditional upon the holder remaining as an employee.

During the current quarter, no warrant programs have been exercised.

See the 2019 Annual Report for details regarding the three previous warrant programs.

Owners as of December 31, 2020	Number of shares	Number of shares & votes
Östersjöstiftelsen	2,500,826	13.20%
Anders Bladh	2,050,000	10.90%
Swedbank Robour Fonder	1,530,806	8.10%
Fjärde AP-Fonder	1,498,500	7.90%
TiN Fonder	835,590	4.40%
Avanza Pension	762,068	4.00%
Unionen	726,000	3.80%
Handelsbanken Fonder	427,144	2.30%
Futur Pension	402,890	2.10%
Andra AP-fonden	394,738	2.10%
Total, ten largest owners	11,128,562	58.90%
Total, other shareholders	7,763,942	40.10%
Total number of shares	**18,892,504**	**100.00%**

Financial calendar

Annual report, 2020	March 19, 2021
Interim report Q1	May 6, 2021
Annual General Meeting	May 20, 2021
Interim report Q2	August 6, 2021
Interim report Q3	November 4, 2021
Year-end report 2021	February 18, 2022

Financial reports will be available on Xspray Pharma's website on the above reporting date, www.xspraypharma.com.

Analysts covering the Company:

Ludvig Svensson, Redeye

Financial Statements and Notes

At the end of December 2018, Xspray Pharma AB (publ) acquired a newly incorporated subsidiary company, dormant for the time being. No business activity has taken place in the subsidiary; all business is pursued in the Parent Company Xspray Pharma AB (publ).

Consolidated income statement

	Q4		Jan-Dec		Full year
SEK thousand	**2020**	**2019**	**2020**	**2019**	**2019**
Net sales	-	-	-	-	-
Other operating income	502	291	1,364	374	374
Research and development expenses	-1,642	-1,328	-6,549	-3,429	-3,429
Administration and sales expenses	-13,970	-17,725	-47,101	-42,327	-42,327
Other operating expenses	-184	-207	-1,171	-1,182	-1,182
Operating loss	**-15,294**	**-18,969**	**-53,457**	**-46,564**	**-46,564**
Finance income	322	255	1,053	862	862
Finance costs	-0	-24	-6	-69	-69
Finance net	**322**	**231**	**1,047**	**793**	**793**
Loss before Income tax	-14,972	-18,738	-52,410	-45,771	-45,771
Tax	-	-	-	-	-
Loss for the period	**-14,972**	**-18,738**	**-52,410**	**-45,771**	**-45,771**
Earnings per share for the period before dilution, SEK	-0.81	-1.20	-3.05	-3.01	-3.01
Earnings per share for the period after dilution, SEK	-0.81	-1.20	-3.05	-3.01	-3.01
Average number of shares before dilution	18,503,883	15,634,847	17,211,467	15,216,057	15,216,057
Average number of shares after dilution	18,971,879	16,089,438	17,679,463	15,670,648	15,670,648

Consolidated statement of comprehensive income

	Q4		Jan-Dec		Full year
SEK thousand	**2020**	**2019**	**2020**	**2019**	**2019**
Loss for the period	-14,972	-18,738	-52,410	-45,771	-45,771
Other comprehensive income	-	-	-	-	-
Total comprehensive income for the period	**-14,972**	**-18,738**	**-52,410**	**-45,771**	**-45,771**

The profit for the period and the profit of the comprehensive income are entirely attributable to the Parent Company's shareholders.

Consolidated balance sheet

SEK thousand	31 Dec 2020	31 Dec 2019
ASSETS		
Non-current assets		
Intangible assets		
Capitalized development costs	231,618	141,515
Patent	-	-
Total intangible assets	**231,618**	**141,515**
Property, plant and equipment		
Machinery and installations	20,746	26,465
Right-of-use assets	5,207	6,831
Equipment	970	1,266
Fixed assets under construction and prepayments	15,746	8,467
Total Property, plant and equipment	**42,669**	**43,030**
Financial assets		
Financial investments	1	1
Total financial assets	**1**	**1**
Total non-current assets	**274,288**	**184,545**
Current assets		
Current tax asset	546	421
Current receivables	2,121	5,017
Prepaid expenses and accured income	2,750	816
Cash and cash equivalents	325,598	209,872
Total current assets	**331,015**	**216,126**
TOTAL ASSETS	**605,303**	**400,672**

Consolidated balance sheet, cont.

SEK thousand	31 Dec 2020	31 Dec 2019
EQUITY AND LIABILITIES		
Equity		
Share capital	18,893	16,752
Other contributed capital	709,407	450,266
Reserves	976	976
Retained earnings including profit/loss for the period	-146,689	-94,279
Total equity attributable to the Parent Company's shareholders	**582,587**	**373,715**
Non–current liabilities		
Lease liabilities	2,898	4,454
Total non-current liabilities	**2,898**	**4,454**
Current liabilities		
Trade accounts payable	8,438	11,876
Lease liabilities	1,985	876
Other current liabilities	768	743
Accrued expenses and deferred income	8,627	9,007
Total current liabilities	**19,818**	**22,503**
TOTAL EQUITY AND LIABILITIES	**605,303**	**400,672**

Consolidated statement of changes in equity

Amount in SEK thousand	Share capital	Other contributed capital	Reserves	Retained earnings incl profit/loss for the period	Total equity
Opening balance as of Janary 1, 2019	**15,076**	**336,991**	**976**	**-51,327**	**301,716**
Correction of misstatement	-	-	-	2,821	2,821
Adjusted balance as of Janary 1, 2019	**15,076**	**336,991**	**976**	**-48,506**	**304,537**
Loss of the period	-	-	-	-45,771	-45,771
Other comprehensive income for the period	**-**	**-**	**-**	**-**	**-**
Total comprehensive income for the period	**-**	**-**	**-**	**-45,771**	**-45,771**
New share issue	1,675	120,612	-	-	122,287
Transaction costs	-	-7,337	-	-	-7,337
Closing balance as of December 31, 2019	**16,751**	**450,266**	**976**	**-94,279**	**373,715**
Opening balance as of January 1, 2020	**16,752**	**450,266**	**976**	**-94,279**	**373,715**
Loss for 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	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**

Consolidated statement of cash flow

	Q4		Jan-Dec	
SEK thousand	**2020**	**2019**	**2020**	**2019**
Operating activities				
Operating loss	**-15,294**	**-18,969**	**-53,457**	**-46,565**
Non-cash adjustments				
Depreciation	1,927	1,599	7,689	4,803
Capital gains	-	-	-113	-
Dissolved prepaid leasing costs, during the period	-	-473	-1,262	-1,892
Interest received	413	334	674	591
Interest paid	-0	-24	-8	-69
Cash flow from operating activities before changes in working capital	**-12,954**	**-17,533**	**-46,477**	**-43,131**
Changes in working capital		-		-
Change in operating receivables	-2,415	-284	2,479	-1,963
Change in operating liabilities	3,652	6,271	-3,794	10,857
Cash flow from operating activities	**-11,717**	**-11,546**	**-47,792**	**-34,237**
Investing activities		-		-
Capitalized development costs	-24,172	-20,089	-88,983	-68,891
Acquisition of property, plant and equipment	-98	-4,058	-4,572	-23,103
Sales of tangible fixed assets	-	-	383	-
Prepayments	-3,656	-	-3,656	-
Cash flow from investing activities	**-27,926**	**-24,147**	**-96,828**	**-91,994**
Financing activities				
New share issue	249,320	114,949	249,320	114,949
Transaction costs	-188	-	-188	-
Payment of lease liability	-513	-41	-936	-112
Redemption of warrants	-	-	11,840	-
Repurchased warrants	-	-	-74	-
Allocated warrants	-	-	384	-
Cash flow from financing activities	**248,619**	**114,908**	**260,345**	**114,837**
Cash flow for the period	**208,976**	**79,215**	**115,726**	**-11,394**
Cash and cash equivalents at the beginning of the period	116,622	130,657	209,872	221,266
Cash and cash equivalents at the end of the period	**325,598**	**209,872**	**325,598**	**209,872**

Parent Company Income statement

	Q4		Jan-Dec	
SEK thousand	**2020**	**2019**	**2020**	**2019**
Net sales	-	-	-	-
Other operating income	502	291	1,364	374
Research and development expenses	-1,598	-1,296	-6,379	-3,363
Administration and sales expenses	-13,993	-17,748	-47,194	-42,417
Other operating expenses	-184	-207	-1,172	-1,182
Operating loss	**-15,273**	**-18,960**	**-53,381**	**-46,589**
Finance income	322	255	1,053	862
Finance costs	-0	-24	-5	-69
Finance net	**322**	**231**	**1,048**	**793**
Loss before Income tax	-14,951	-18,729	-52,333	-45,796
Tax	-	-	-	-
Loss for the period	**-14,951**	**-18,729**	**-52,333**	**-45,796**

Parent Company balance sheet

SEK thousand	31 Dec 2020	31 Dec 2019
ASSETS		
Non-current assets		
Intangible assets		
Capitalized development costs	231,512	141,414
Patent	-	-
Total intangible assets	**231,512**	**141,414**
Property, plant and equipment		
Machinery and installations	20,747	26,464
Equipment	970	1,266
Fixed assets under construction and prepayments	15,746	8,467
Total Property, plant and equipment	**37,463**	**36,198**
Financial assets		
Shares in subsidiaries	50	50
Financial investments	1	1
Total financial assets	**51**	**51**
Total non-current assets	**269,026**	**177,663**
Current assets		
Current receivables		
Current tax asset	545	421
Other current receivables	2,121	5,017
Prepaid expenses and accured income	3,232	2,393
Total current receivables	**5,898**	**7,831**
Cash and bank	325,548	209,822
Total current assets	**331,446**	**217,653**
TOTAL ASSETS	**600,472**	**395,316**

Parent Company balance sheet, cont.

SEK thousand	31 Dec 2020	31 Dec 2019
EQUITY AND LIABILITIES		
Equity		
Restricted equity		
Share capital	18,893	16,752
Statutory reserve	976	976
Development expenditure reserve	231,512	141,414
Total restricted equity	**251,381**	**159,142**
Non-restricted equity		
Other contributed capital	709,408	450,266
Accumulated earnings	-325,816	-189,922
Profit/loss for the period	-52,333	-45,796
Total non-restricted equity	**331,259**	**214,548**
Total equity	**582,640**	**373,690**
Current liabilities		
Trade accounts payable	8,437	11,876
Other current liabilities	768	743
Accrued expenses and deferred income	8,627	9,007
Total current liabilities	**17,832**	**21,626**
TOTAL EQUITY AND LIABILITIES	**600,472**	**395,316**

Parent Company statement of cash flow

	Q4		Jan-Dec	
SEK thousand	**2020**	**2019**	**2020**	**2019**
Operating activities				
Operating loss	**-15,273**	**-18,960**	**-53,381**	**-46,589**
Non-cash adjustments				
Depreciation	1,683	1,346	6,694	3,837
Captial gains	-	-	-113	-
Interest received	413	334	674	591
Interest paid	-0	-24	-5	-69
Cash flow from operating activities before changes in working capital	**-13,177**	**-17,304**	**-46,131**	**-42,230**
Changes in working capital				
Change in operating receivables	-2,423	-284	2,311	-1,965
Change in operating liabilities	3,652	6,269	-3,794	10,857
Cash flow from operating activities	**-11,948**	**-11,319**	**-47,614**	**-33,338**
Investing activities				
Purchase of intangible assets	-24,454	-20,356	-90,098	-69,902
Acquisition of property, plant and equipment	-98	-4,058	-4,571	-23,103
Sales of tangible fixed assets	-	-	383	-
Prepayments	-3,656	-	-3,656	-
Cash flow from investing activities	**-28,208**	**-24,414**	**-97,942**	**-93,005**
Financing activities				
New share issue	249,320	114,949	249,320	114,949
Transaction costs	-188	-	-188	-
Redemption of warrants	-	-	11,840	-
Repurchased warrants	-	-	-74	-
Allocated warrants	-	-	384	-
Cash flow from financing activities	**249,132**	**114,949**	**261,282**	**114,949**
Cash flow for the period	**208,976**	**79,216**	**115,726**	**-11,394**
Cash and cash equivalents at the beginning of the period	116,572	130,607	209,822	221,216
Cash and cash equivalents at the end of the period	**325,548**	**209,822**	**325,548**	**209,822**

Not 1. Accounting and valuation principles

This interim report was prepared according to the Swedish Annual Accounts Act and IAS 34 Interim Financial Reporting. The same accounting principles and methods as used in the annual report 2019 are valid for this interim report.

The interim financial information for the Group has been prepared in accordance with International Accounting Standard IAS 34 Interim Financial Reporting issued by the International Accounting Standards Board (IASB) and the Swedish Annual Accounts Act. The interim report for the Parent Company has been prepared in accordance with Chapter 9 of the Annual Accounts Act, Interim Report.

The Group and the Parent Company have applied the same accounting principles and calculation bases, in accordance with the 2019 Annual Report.

The amendments to IFRS standards that apply from 1 January 2020 had no impact on the financial statements for the four quarters of 2020.

Amounts in brackets refer to the corresponding period for the previous year.

Xspray Pharma AB (publ) acquired a newly formed subsidiary, which is currently dormant, at the end of December 2018 to prepare the Group structure for possible future structural needs. No operations in the subsidiary have taken place, all operations are conducted in the Parent Company Xspray Pharma AB (publ).

Key ratios, definitions

Earnings per share is calculated as net income divided by the average number of shares during the period. The equity/assets ratio is equity in relation to total assets.

Research and development expenses as a percentage of operating expenses comprised the expensed research and development expenses, divided by operating expenses. Total operating expenses consist of operating profit minus net sales and other operating income.

The carrying amount of receivables, cash and cash equivalents, accounts payable and other liabilities constitute a reasonable approximation of fair value.

Not 2. Significant estimates and assumptions

Preparing the financial statements in accordance with IFRS requires Management to make judgements and estimates, and to make assumptions that affect the application of accounting policies and the carrying amounts of assets, liabilities, revenues, and expenses. Actual outcomes may differ from these estimates. The estimates and assumptions are evaluated regularly. Changes to estimates are recognized in the period that the change is made.

The sources of uncertainty and estimates that involve a significant risk that the value of assets or liabilities may require restatement to a material extent during the forthcoming financial year are impairment testing of intangible assets with indefinite useful lives. Whether the requirements for capitalization of development expenditure is satisfied requires estimates. After capitalization, whether the accounting requirement for development expenses remain satisfied, and whether there are indications that the capitalized expenditure may have been exposed to impairment is assessments both initially and on an ongoing basis. There is an ongoing analysis of whether the capitalized expenses may be subject to a depreciation. The capitalized intangible assets that are not yet complete, which are subject to yearly impairment tests or as soon as there is an indication of impairment. Impairment tests involve estimates of future cash flows attributable to the asset or the cash-generating unit to which the asset relates when it is complete. These estimates and judgements involve expectations primarily regarding the selling price of products, market penetration, remaining development, sales and marketing expenses, and the likelihood that the product passes through the remaining development phases. These assumptions involve sector and market-specific data, are made by Management, then reviewed by the Board of Directors.

Significant risks and uncertainties

Xspray Pharma's operations are associated with both industry-related risks, and company-specific risks. The Company develops drug candidates and there will always be regulatory, market and financial risks in the business. There have been no significant changes in risks and uncertainties during the period compared to those published by the Company in the 2019 Annual Report and in connection with its listing on Nasdaq Stockholm on March 27, 2020

Covid-19

Xspray Pharma has continually adapted the business for the current circumstances as a result of the Covid-19 pandemic. The start of studies with the generic version of Sprycel® was slightly delayed due to the pandemic. Beside the delay, the Company has been able to continue its planned work with its product candidates. Xspray Pharma takes the necessary steps to reduce the impact of the pandemic on the business and continuously follows the recommendations of the Swedish Public Health Authority (Folkhälsomyndigheten).

Certification by the Board

The Board of Directors and the CEO hereby certify that this interim report provides a true and fair view of the Group's and the Parent Company's operations, position and results and describes significant risks and uncertainties facing the Company.

Solna, February 25, 2021

Michael Wolff Jensen
Chairman

Gunnar Gårdemyr
Member

Maris Hartmanis
Member

Torbjörn Koivisto
Member

Christine Lind
Member

Carl-Johan Spak
Member

Per Andersson
Chief Executive Officer

The report has not been reviewed by the Company´s auditors.

Information

Glossary

505(b)(2) • Application for a US drug approval for an improved version of an existing licensed or approved drug.

Amorphous • Amorphous structure is a chemical term that describes substances whose molecules lack an organized structure.

ANDA • An Abbreviated New Drug Application is an application for a U.S. generic drug approval for an existing licensed medication or approved drug.

Bioequivalence • A term used to describe whether two different drugs have similar uptake and elimination from the body and thus can be expected to have a similar equivalent medical effect. If two drugs compared can be found to be bioequivalent, they can be expected to have the same efficacy and safety.

CRO • Contract Research Organization. A service provider that performs assignment research and drug development services.

CMO • Contract Manufacturing Organization

FDA • Food and Drug Administration. The USA's food and drug regulator whose responsibilities cover food, dietary supplements, drugs, cosmetics, medical equipment, radiation emission products and bio products.

Generic • Generic drugs are replacement drugs with the same function, quality, and safety as the original drug.

GMP • Good Manufacturing Practice. Good Manufacturing Practice rules describe how the drug industry must produce medications such that patients can always be sure they are getting the correct and high-quality product. The rules govern the production, including packaging, of drugs, foods – and nutritional supplements. GMP is a system for ensuring that products are always manufactured and controlled for compliance with current quality standards. They are designed to minimize the risks in drug production that cannot be eliminated through testing of the end product.

Protein kinase inhibitors (PKI) • Drugs that block protein kinases. Protein kinase inhibitors act by blocking the activity of enzymes that drive the development and growth of cancer cells.

This interim report for Xspray Pharma AB (publ) has been submitted following approval by the Board of Directors.

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