Xspray Pharma
Interim report Q3 2020

JANUARY - SEPTEMBER 2020

"Xspray is in an eventful phase with several crucial milestones within reach. After completing bioequivalence studies, intensive work is being done on the preparations for the Company's first ANDA application and finding the right partner for HyNap-Dasa."

Per Andersson
CEO, *Xspray Pharma AB (publ)*

Significant events during the third quarter, 2020

July - September 2020

- In August, a term sheet for a new manufacturing facility in Malta, with Pharmacare Premium Ltd, was signed.
- In August, the preliminary results of the first study for HyNap-Dasa were announced. The study did not fulfil statistical bioequivalence requirements due to high variability in pharmacokinetic parameters for the reference product Sprycel®. A few subjects had very low absorption from Sprycel® which was not observed for HyNap-Dasa.
- In August, the company strengthened its IP rights by receiving a Notice of Allowance from the US Patent Office regarding its patent application for tablets containing dasatinib propylene glycol solvate (dasatinib PG).
- In August, it was announced that the CEO Per Andersson and other warrant holders have chosen to make full use of the opportunity to subscribe for shares in Xspray by fully exercising their respective number of warrants in the warrant program LTIP 2017/2020.
- In August, six months data from the company's stability study with commercially manufactured HyNap-Dasa tablets were published. Data from the study demonstrates that the tablets comply with the specifications and that they can be used in an upcoming ANDA filing.
- In September, the Chairman of the Board, Michael Wolff Jensen, announced that he will not be available for re-election at the 2021 Annual General Meeting.
- In September, the preliminary results from the second out of two bioequivalence studies in healthy volunteers with HyNap-Dasa, were announced. The study fulfilled statistical and formal bioequivalence requirements for HyNap-Dasa compared to the reference product Sprycel®. The study was conducted in healthy volunteers under fed conditions.

Significant events after the end of the reporting period

- 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.

July - September 2020, Group

- Net sales amounted to SEK 0 thousand (0)
- Earnings before tax amounted to SEK -11,560 thousand (-9,921)
- Earnings per share before dilution amounted to SEK -0.69 (-0.62)
- Cash flow from operating activities amounted to SEK -12,764 thousand (-8,747)
- Cash flow from investing activities amounted to SEK -19,868 thousand (-22,898)

January - September 2020, Group

- Net sales amounted to SEK 0 thousand (0)
- Earnings before tax amounted to SEK -37,438 thousand (-27,033)
- Earnings per share before dilution amounted to SEK -2.23 thousand (-1.79)
- Cash flow from operating activities amounted to SEK -36,076 thousand (-22,692)
- Cash flow from investing activities amounted to SEK -68,901 thousand (-67,846)
- Cash and cash equivalents and current investments at the end of the period totalled SEK 116,622 thousand (130,657)

July - September 2020, Parent Company

- Net sales amounted to SEK 0 thousand (0)
- Earnings before tax amounted to SEK -11,541 thousand (-9,925)
- Earnings per share before dilution amounted to SEK -0.69 (-0.66)
- Cash flow from operating activities amounted to SEK -12,839 thousand (-8,281)

January - September 2020, Parent Company

- Net sales amounted to 0 thousand (0)
- Earnings before tax amounted to SEK -37,382 thousand (-27,066)
- Earnings per share before dilution amounted to SEK -2.23 (-1.80)
- Cash flow from operating activities amounted to SEK -35,665 thousand (-22,018)
- Cash and cash equivalents and current investments at the end of the period amounted to SEK 116,572 thousand (130,607)

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

A message from the CEO

Xspray is in an eventful phase with several crucial milestones within reach. After completing bioequivalence studies, intensive work is being done on the preparations for the Company's first ANDA application and finding the right partner for HyNap-Dasa.

The results from the HyNap-Dasa studies were long-awaited. As expected, our tablets complied with specifications for stability. The results of the clinical study in healthy volunteers under fed condition showed formal bioequivalence. As we previously showed bioequivalence also in fasting subjects, it was unexpected not to show bioequivalence also this time, which was a consequence of the original drug Sprycel® showing low or no absorption at all in a few test subjects.

The completed bioequivalence and stability studies of HyNap-Dasa confirm the high quality and stability of our tablets. We have a commercial scale manufacturing process in place that is ready to support a market launch. Short development processes in combination with relatively low costs for conducting clinical studies make it possible for Xspray to develop several different product versions in parallel, which for HyNap-Dasa means parallel development of both a generic and an improved version of the original drug. As a consequence, we have been able to quickly prepare a back-up HyNap-Dasa study in fasting healthy volunteers to show formal bioequivalence. We expect to start the first study already during the fourth quarter of this year.

We are working intensively to be able to submit the ANDA application, i.e. the application for market approval, for the generic version before the year end. With positive results from the back-up studies, we will be able to supplement the application, otherwise we will submit a new application during the first quarter of 2021. This type of procedure is not entirely uncommon for companies that develop generic drugs and has been carried out in the past for Sprycel® (dasatinib).

We are collaborating with an international investment bank to find the best commercial partner for HyNap-Dasa, work that is being conducted in parallel with the preparation of the ANDA application. These two important milestones are not interdependent, the ANDA application can be submitted either before or after a partnership deal. Our most important priority is to enter a partnership on the right terms with the right partner and that our ANDA application is complete for a quick FDA review and potential approval.

In October, we carried out a directed offering to Swedish and international investors. The placement attracted very high interest from the investors and was oversubscribed more than twice. Moreover, the participants did not receive any discount to the actual share price on the transaction date. We note that we have strong, long-term investor base and welcome our new international investors. Xspray is currently and for a foreseeable future, in an expansive phase. With the added capital of SEK 265 million before issue costs, we now have the financial strength required to run our various processes in a strategically advantageous manner. It is of great importance that we are in a financially strong position in the forthcoming partner discussions to increase our opportunities to finalize an agreement faster and on better terms. It also improves our negotiating position in case the other parties delay the process.

As we continue negotiations with potential partners for our leading product candidate HyNap-Dasa, we are also accelerating the development of our next product candidates, HyNap-Nilo, and an improved version of HyNap-Dasa. The study program for HyNap-Nilo can start as early as in the first quarter of 2021. The recently announced expansion of our production capacity together with our CMO partner, Pharmacare Premium Ltd., in Malta enables us to work at full speed with several products simultaneously. Securing production of stable HyNap material and being able to control the formulation properties required to make either generic copies or improved versions of various PKI drugs, significantly reduces the development time of our pipeline product candidates. Our current estimate of the development process from the choice of a product candidate to submission for market approval is approximately three years. We continue the exciting development work of the not yet communicated product candidates, and I look forward to presenting one of them in 2021.

Our way of working - carefully, methodically and with continuous follow-up - together with the gained expertise and know-how of the various development processes for our HyNap products, creates confidence from both the team and me. We look forward to submitting our first registration application to the US FDA shortly and presenting our first product to potential future partners.

I would like to take this opportunity to thank all owners, new and old, for the trust you have in Xspray. I am glad to have you all on our journey.

Per Andersson, CEO
Solna, November 2020

Business focus and prospects

Xspray Pharma AB (publ) is a product development company with multiple product candidates in clinical development phase. Xspray 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, through licensing to suitable pharmaceutical companies, to gain entry as the first competitor to today's original drugs before secondary patents expire. Xspray'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 2019, there were 54 approved PKIs in the U.S market. The Company's leading product candidates, HyNap-Dasa, HyNap-Sora and HyNap-Nilo, are stable amorphous versions of the three blockbuster cancer drugs Sprycel® (dasatinib), Nexavar® (sorafenib) and Tasigna® (nilotinib). The launch of HyNap-Dasa, the first product candidate, is planned to take place in 2021. The U.S substance patent for the original drug Sprycel® (dasatinib) expires at the end of 2020, and the secondary patents in 2026, which offers Xspray's HyNap-Dasa a period of several years in a unique position before other competitors gain access to the market. The Company has patented the manufacturing technology, the equipment and the resulting products. The Company's development has proceeded according to plan and prospects for achieving its business plan targets are good.

Xspray has been listed on Nasdaq Stockholm since March 27, 2020 and was previously listed on Nasdaq First North Growth Market since 2017

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

Low development expenditure

- Development costs are substantially lower than typical development costs for original drugs
- Total development expenditure is estimated to be USD 7 to 15 million per product candidate

Limited risk

- Proof-of-Concept demonstrated for the technology program
- 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 launch
- Bioeqvivalence studies in healthy volunteers sufficient for registration – long-term studies in patients are not necessary

Financial overview, Group

	Q3		Jan-Sep		Full year
Key figures group	**2020**	**2019**	**2020**	**2019**	**2019**
Net sales (SEK thousand)	-	-	-	-	-
Loss before Income tax (SEK thousand)	-11,560	-9,921	-37,438	-27,033	-45,771
Earnings per share before dilution (SEK)	-0.69	-0.62	-2.23	-1.79	-3.01
Earnings per share after dilution (SEK)	-0.69	-0.62	-2.23	-1.79	-3.01
Research and development expenses as % of operating expenses	13.7	18.2	12.6	17.0	7.3
Cash and cash equivalents (SEK thousand)	116,622	130,657	116,622	130,657	209,872
Total assets (SEK thousand)	367,708	298,164	367,708	298,164	400,672
Equity/assets ratio (%)	94.8	92.9	94.8	92.9	93.3
Average number of employees	20	17	20	13	17

Total research and development expenditures for the quarter amounted to SEK -21,162 thousand, of which SEK -1,651 thousand is expensed and SEK -19,511 thousand recorded as capitalized development cost.

Total research and development expenditures for the period January - September amounted to SEK -70,551 thousand of which SEK -4,907 thousand is expensed and SEK -65,644 thousand is recorded as capitalized development cost.

Financial overview, Parent Company

	Q3		Jan-Sep		Full year
Key figures parent company	**2020**	**2019**	**2020**	**2019**	**2019**
Net sales (SEK thousand)	-	-	-	-	-
Loss before Income tax (SEK thousand)	-11,541	-9,925	-37,382	-27,066	-45,796
Earnings per share before dilution (SEK)	-0.69	-0.66	-2.23	-1.80	-3.01
Earnings per share after dilution (SEK)	-0.69	-0.66	-2.23	-1.80	-3.01
Research and development expenses as % of operating expenses	13.3	18.0	12.3	16.8	7.2
Cash and cash equivalents (SEK thousand)	116,572	130,607	116,572	130,607	209,822
Total assets (SEK thousand)	362,638	292,828	362,638	292,828	395,316
Equity/assets ratio (%)	96.1	94.6	96.1	94.6	94.5
Average number of employees	20	17	20	13	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 is the difference between RFR2 and IFRS. Net sales for the company are still SEK 0. The Market approval of the first product is planned to take place in 2021.

July - September 2020

The Group´s operating expenses for the period amounted to SEK -11,811 thousand (-10,042). The costs consist mainly of administrative and sales costs which amounted to SEK -10,260 thousand of the total operating costs. Of these, personnel costs classified as administrative and sales costs amount to SEK -3,692 thousand (-590).

The Group´s expensed research and development costs for the period were SEK-1,651 (-1,952) thousand and capitalized development expenses were SEK 19,511 thousand (22,802).

January - September 2020

The Group´s operating expenses for the three quarters amounted to SEK -38,163 kSEK (-27,595). The costs consist mainly of administrative and sales costs, which amount to SEK -33,131 thousand (-24,602) of the total operating costs. Of these, personnel costs that are classified as administrative and sales costs amount to SEK -15,665 thousand (-6,751).

Revenue and earnings

Net sales for the quarter amounted to SEK 0. Sales are not expected to increase until 2021 as the company according to the current business plan intends to obtain market approval of its first product and a business agreement is made.

The Group´s operating losses for the third quarter amounted to SEK -11,811 thousand (-10,042), which is slightly higher than the third quarter of 2019. The corresponding figure for the Parent Company is SEK -11,792 thousand (-10,046). The operating costs are attributable to the planned increase in costs for the company's clinical program, strengthened organization and other related advising costs for the future strategic positioning.

Financial position

The company's operations are mainly financed by equity. In October, 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 94.8 percent (92.9) as of September 30, 2020 in the Group and the corresponding figure for the parent company was 96.1 percent (94.6).

Cash flow and investments

Total cash flow for the Group during the period amounted to SEK -21,144 thousand (-31,681). The decrease is attributable to the redemption of warrants from the two warrants programs, 2015/2021 and 2017/2020, which had a positive effect of SEK 11,840 thousand. Cash flow from operating activities amounted to SEK -12,764 thousand (-8,747), of which the effect of working capital was SEK -2,679 thousand (523).

The total cash flow for the parent company during the third quarter amounted to SEK -21,143 thousand (-31,681). Cash flow from operating activities amounted to SEK -12,839 thousand (-8,281), of which the effect from changes in working capital amounted to SEK -2,838 thousand (524).

Cash flow from investing activities in the Group amounted to SEK -19,868 thousand (-22,898), it consists of capitalized development costs of SEK

-19,240 thousand (-22,523). The investment in tangible fixed assets amounted to SEK -628 thousand (-376). The cash flow from investing activities are in line with expectations.

Cash flow from financing activities amounted to SEK 11,488 thousand (-36) for the Group, which is an effect of the redemption of warrants from programs LTIP 2015/2021 and LTIP 2017/2020. A total of 279,591 warrants were redeemed to a value of SEK 11,840 thousand.

The Group had SEK 116,622 thousand (130,657) in cash and cash equivalents as of September 30, 2020 and the corresponding figure for the Parent Company was SEK 116,572 thousand (130,607).

Intangible assets

Development expenses related to the projects have been capitalized according to plan. Capitalized development costs for the third quarter in the Group amounted to SEK 19,511 thousand (17,084) and the corresponding figure for the Parent Company amounted to SEK 19,516 thousand (17,017). As of September 30, 2020, the Group's capitalized expenses for development work and similar work amounted to SEK 207,167 thousand (121,485) and the corresponding figure for the Parent Company was SEK 207,058 thousand (121,396).

Parent Company

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 been unchanged compared to the previous quarter. 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 -28 thousand (-28).

Corporate governance

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

Share information

Xspray's shares are listed on Nasdaq Stockholm in the Small Cap-index 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 third quarter, the shares and votes increased as a result of the exercise of warrants. The number of shares increased by 279,591. On September 30, 2020, the number of shares in the Company totalled 17,031,213 and the latest share price for the period was SEK 163.50.

Incentive program

The company has issued four series of share options to senior executives and employees.

The fourth share option 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 shareholders interest. The fourth program involved 5 persons, including the CFO. The share options 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 option 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 share option is conditional upon the holder remaining as an employee.

During the current quarter, the warrant program 2017/2020 was exercised by all warrant holders, of which the CEO, Per Andersson, invested a total of SEK 3.4 million and thereby increased his number of shares to 185,260.

Furthermore, the Chairman of the Board, Michael Wolff Jensen, through his private owned company, MWJ Partners ApS, has exercised his full number of warrants in the LTIP 2015/2021 program with a useful period 1 - 21 August 2020, and 1 - 21 January 2021, respectively. See the 2019 Annual Report for details regarding the three previous programs.

Owners as of September 30, 2020	Number of shares	Number of shares & votes
Östersjöstiftelsen	2,500,826	14.68%
Ribbskottet AB	1,910,000	11.21%
Swedbank Robur Fonder	1,380,000	8.10%
Fjärde AP-fonden	1,368,500	8.04%
Avanza Pension	713,927	4.19%
TIN Fonder	680,590	4.00%
Unionen	666,000	3.91%
Futur Pension	379,207	2.23%
Kåre Gilstring	308,000	1.81%
C WorldWide Asset Management	285,000	1.67%
Total, ten largest owners	10,192,050	59.84%
Total, other shareholders	6,839,163	40.16%
Total number of shares	**17,031,213**	**100.00%**

Financial calendar

Year-end report, 2020	February 25, 2021
Annual report, 2020	March 19, 2021
Interim report Q1	May 6, 2021
Annual General Meeting	May 20, 2021
Interim report Q2	August 5, 2021
Interim report Q3	November 4, 2021
Year-end report 2021	February 17, 2022

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).

Retroactive adjustment of depreciation and reclassification was made during the fourth quarter, 2019, the comparative figures that were affected by the correction are described in Appendix 1 of the Year-end report, 2019.

Consolidated income statement

	Q3		Jan-Sep		Full year
SEK thousand	**2020**	**2019**	**2020**	**2019**	**2019**
Net sales	-	-	-	-	-
Other operating income	283	18	862	83	374
Research and development expenses	-1,651	-1,290	-4,907	-2,101	-3,429
Administration and sales expenses	-10,260	-8,472	-33,131	-24,602	-42,327
Other operating expenses	-183	-298	-987	-975	-1,182
Operating loss	**-11,811**	**-10,042**	**-38,163**	**-27,595**	**-46,564**
Finance income	251	121	730	607	862
Finance costs	-0	-	-5	-45	-69
Finance net	**251**	**121**	**725**	**562**	**793**
Loss before Income tax	-11,560	-9,921	-37,438	-27,033	-45,771
Tax	-	-	-	-	-
Loss for the period	**-11,560**	**-9,921**	**-37,438**	**-27,033**	**-45,771**
Earnings per share for the period before dilution, SEK	-0.69	-0.62	-2.23	-1.79	-3.01
Earnings per share for the period after dilution, SEK	-0.69	-0.62	-2.23	-1.79	-3.01
Average number of shares before dilution	16,844,819	15,076,460	16,782,688	15,076,460	15,216,057
Average number of shares after dilution	17,312,815	15,531,051	17,250,684	15,531,051	15,670,648

Consolidated statement of comprehensive income

	Q3		Jan-Sep		Full year
SEK thousand	**2020**	**2019**	**2020**	**2019**	**2019**
Loss for the period	-11,560	-9,921	-37,438	-27,033	-45,771
Other comprehensive income	-	-	-	-	-
Total comprehensive income for the period	**-11,560**	**-9,921**	**-37,438**	**-27,033**	**-45,771**

Consolidated balance sheet

SEK thousand	30 Sep 2020	30 Sep 2019	31 Dec 2019
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	207,167	121,485	141,515
Patent	-	11	-
Total intangible assets	**207,167**	**121,496**	**141,515**
Property, plant and equipment			
Machinery and installations	22,323	19,154	26,465
Right-of-use assets	5,435	7,297	6,831
Equipment	1,076	1,305	1,266
Fixed assets under construction	11,992	12,678	8,467
Total Property, plant and equipment	**40,826**	**40,434**	**43,030**
Financial assets			
Financial investments	1	1	1
Total financial assets	**1**	**1**	**1**
Total non-current assets	**247,994**	**161,931**	**184,545**
Current assets			
Current tax asset	456	366	421
Current receivables	1,433	4,282	5,017
Prepaid expenses and accured income	1,203	928	816
Cash and cash equivalents	116,622	130,657	209,872
Total current assets	**119,714**	**136,233**	**216,126**
TOTAL ASSETS	**367,708**	**298,164**	**400,672**

Consolidated balance sheet, cont.

SEK thousand	30 Sep 2020	30 Sep 2019	31 Dec 2019
EQUITY AND LIABILITIES			
Equity			
Share capital	17,031	15,076	16,752
Other contributed capital	462,136	336,991	450,266
Reserves	976	976	976
Retained earnings including profit/loss for the period	-131,717	-75,539	-94,279
Total equity attributable to the Parent Company's shareholders	**348,427**	**277,504**	**373,715**
Non–current liabilities			
Lease liabilities	3,195	5,164	4,454
Total non-current liabilities	**3,195**	**5,164**	**4,454**
Current liabilities			
Trade accounts payable	3,170	12,163	11,876
Lease liabilities	1,906	139	876
Other current liabilities	1,916	887	743
Accrued expenses and deferred income	9,094	2,307	9,007
Total current liabilities	**16,086**	**15,496**	**22,503**
TOTAL EQUITY AND LIABILITIES	**367,708**	**298,164**	**400,672**

Consolidated statement 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 for the period	-	-	-	-37,438	-37,438
Other comprehensive income for the period	**-**	**-**	**-**	**-**	**-**
Total comprehensive income for the period	**-**	**-**	**-**	**-37,438**	**-37,438**
Redemption of warrants	279	11,560	-	-	11,840
Warrant program	-	310	-	-	310
Closing balance as of 30 September 2020	**17,031**	**462,136**	**976**	**-131,717**	**348,427**

Consolidated statement of cash flow

	Q3		Jan-Sep		Full year
SEK thousand	**2020**	**2019**	**2020**	**2019**	**2019**
Operating activities					
Operating loss	**-11,811**	**-10,042**	**-38,163**	**-27,595**	**-46,565**
Non-cash adjustments					
Depreciation	1,930	1,245	5,762	3,204	4,803
Capital gains	-	-	-113	-	-
Dissolved prepaid leasing costs, during the period	-316	-473	-1,262	-1,419	-1,892
Interest received	112	-	261	257	591
Interest paid	-	-	-8	-45	-69
Cash flow from operating activities before changes in working capital	**-10,085**	**-9,270**	**-33,523**	**-25,598**	**-43,131**
Changes in working capital					
Change in operating receivables	621	220	4,893	-1,682	-1,963
Change in operating liabilities	-3,300	303	-7,446	4,588	10,857
Cash flow from operating activities	**-12,764**	**-8,747**	**-36,076**	**-22,692**	**-34,237**
Investing activities					
Capitalized development costs	-19,240	-22,523	-64,810	-48,802	-68,891
Acquisition of property, plant and equipment	-628	-375	-4,474	-19,044	-23,103
Sales of tangible fixed assets	-	-	383	-	-
Cash flow from investing activities	**-19,868**	**-22,898**	**-68,901**	**-67,846**	**-91,994**
Financing activities					
New share issue	-	-	-	-	114,949
Lease liability	-	-	-	-	-
Payment of lease liability	-352	-36	-423	-71	-112
Redemption of warrants	11,840	-	11,840	-	-
Repurchased warrants	-	-	-74	-	-
Allocated warrants	-	-	384	-	-
Cash flow from financing activities	**11,488**	**-36**	**11,727**	**-71**	**114,837**
Cash flow for the period	**-21,144**	**-31,681**	**-93,250**	**-90,609**	**-11,394**
Cash and cash equivalents at the beginning of the period	137,766	162,338	209,872	221,266	221,266
Cash and cash equivalents at the end of the period	**116,622**	**130,657**	**116,622**	**130,657**	**209,872**

Parent Company Income statement

	Q3		Jan-Sep		Full year
SEK thousand	**2020**	**2019**	**2020**	**2019**	**2019**
Net sales	-	-	-	-	-
Other operating income	283	18	862	83	374
Research and development expenses	-1,609	-1,270	-4,781	-2,067	-3,363
Administration and sales expenses	-10,283	-8,496	-33,201	-24,669	-42,417
Other operating expenses	-183	-298	-987	-975	-1,182
Operating loss	**-11,792**	**-10,046**	**-38,108**	**-27,628**	**-46,589**
Finance income	251	121	730	607	862
Finance costs	-0	-	-5	-45	-69
Finance net	**251**	**121**	**725**	**562**	**793**
Loss before Income tax	-11,541	-9,925	-37,382	-27,066	-45,796
Tax	-	-	-	-	-
Loss for the period	**-11,541**	**-9,925**	**-37,382**	**-27,066**	**-45,796**
Earnings per share for the period before dilution, SEK	-0.69	-0.66	-2.23	-1.80	-3.01
Earnings per share for the period after dilution, SEK	-0.69	-0.66	-2.23	-1.80	-3.01
Average number of shares before dilution	16,844,819	15,076,460	16,782,688	15,076,460	15,216,057
Average number of shares after dilution	17,312,815	15,765,556	17,250,684	13,884,128	15,670,648

Parent Company balance sheet

SEK thousand	30 Sep 2020	30 Sep 2019	31 Dec 2019
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	207,058	121,396	141,414
Patent	-	11	-
Total intangible assets	**207,058**	**121,407**	**141,414**
Property, plant and equipment			
Machinery and installations	22,323	19,154	26,464
Equipment	1,076	1,305	1,266
Fixed assets under construction	11,992	12,678	8,467
Total Property, plant and equipment	**35,391**	**33,137**	**36,198**
Financial assets			
Shares in subsidiaries	50	50	50
Financial investments	1	1	1
Total financial assets	**51**	**51**	**51**
Total non-current assets	**242,501**	**154,595**	**177,663**
Current assets			
Current receivables			
Current tax asset	456	366	421
Other current receivables	1,433	4,282	5,017
Prepaid expenses and accured income	1,676	2,978	2,393
Total current receivables	**3,565**	**7,626**	**7,831**
Cash and bank	116,572	130,607	209,822
Total current assets	**120,137**	**138,233**	**217,653**
TOTAL ASSETS	**362,638**	**292,828**	**395,316**

Parent Company balance sheet, cont.

SEK thousand	30 Sep 2020	30 Sep 2019	31 Dec 2019
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	17,031	15,076	16,752
Statutory reserve	976	976	976
Development expenditure reserve	207,058	121,396	141,414
Total restricted equity	**225,066**	**137,448**	**159,142**
Non-restricted equity			
Other contributed capital	462,136	336,991	450,266
Accumulated earnings	-301,362	-169,902	-189,922
Profit/loss for the period	-37,382	-27,066	-45,796
Total non-restricted equity	**123,392**	**140,023**	**214,548**
Total equity	**348,458**	**277,471**	**373,690**
Current liabilities			
Trade accounts payable	3,170	12,163	11,876
Other current liabilities	1,916	887	743
Accrued expenses and deferred income	9,094	2,307	9,007
Total current liabilities	**14,180**	**15,357**	**21,626**
TOTAL EQUITY AND LIABILITIES	**362,638**	**292,828**	**395,316**

Parent Company statement of cash flow

	Q3		Jan-Sep		Full year
SEK thousand	**2020**	**2019**	**2020**	**2019**	**2019**
Operating activities					
Operating loss	**-11,792**	**-10,046**	**-38,108**	**-27,628**	**-46,589**
Non-cash adjustments					
Depreciation	1,679	1,241	5,011	2,491	3,837
Captial gains	-	-	-113	-	-
Interest received	112	-	261	257	591
Interest paid	-	-	-5	-45	-69
Cash flow from operating activities before changes in working capital	**-10,001**	**-8,805**	**-32,954**	**-24,925**	**-42,230**
Changes in working capital					
Change in operating receivables	462	220	4,735	-1,681	-1,965
Change in operating liabilities	-3,300	304	-7,446	4,588	10,857
Cash flow from operating activities	**-12,839**	**-8,281**	**-35,665**	**-22,018**	**-33,338**
Investing activities					
Purchase of intangible assets	-19,516	-23,024	-65,644	-49,546	-69,902
Acquisition of property, plant and equipment	-628	-376	-4,474	-19,045	-23,103
Other financial assets	-	-	383	-	-
Cash flow from investing activities	**-20,144**	**-23,400**	**-69,735**	**-68,591**	**-93,005**
Financing activities					
New share issue	-	-	-	-	114,949
Redemption of warrants	11,840	-	11,840	-	-
Repurchased warrants	-	-	-74	-	-
Allocated warrants	-	-	384	-	-
Cash flow from financing activities	**11,840**	**-**	**12,150**	**-**	**114,949**
Cash flow for the period	**-21,143**	**-31,681**	**-93,250**	**-90,609**	**-11,394**
Cash and cash equivalents at the beginning of the period	137,716	162,288	209,822	221,216	221,216
Cash and cash equivalents at the end of the period	**116,572**	**130,607**	**116,572**	**130,607**	**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 for the period has been prepared in accordance with International Accounting Standard (IAS) 34 Interim Financial Reporting as issued by the International Accounting Standards Board (IASB) and the Swedish Annual Accounts Act, and for the parent company in accordance with the Swedish Annual Accounts Act and RFR 2 Reporting for legal entities and other statements issued by the Swedish Financial Reporting Board.

In all respects other than those described below, Xspray has presented the financial statements for the period, in accordance with the accounting policies and principles applied in the 2019 Annual Report. The description of these principles and definitions is found on page 44-49 (Note 1) in the Annual Report 2019.

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

The figures given in this interim report refer to outcomes during July 1 - September 30, 2020 unless otherwise stated. Comparative figures have been presented in brackets and refer to the corresponding period 2019.

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, and where applicable untaxed reserves (less deferred tax), in relation to total assets.

Research and development expenses as a percentage of operating expenses comprise the former divided by the latter, which include selling and administrative expenses and other operating expenses.

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 monitored on a continuous basis. The Group has 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 has continually adapted the business for the current circumstances as a result of the Covid-19 pandemic. Despite these circumstances, the company has been able to continue its planned work with its product candidates. Xspray 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, November 20, 2020

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 been reviewed by the company´s auditors.

Review report

To the Board of Directors of Xspray Pharma (publ)

Corp. id. *556649-3671*

Introduction

We have reviewed the condensed interim financial information (interim report) of Xspray Pharma (publ) as of 30 September 2020 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

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

Conclusion

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

Stockholm 20 November 2020

KPMG AB

Duane Swanson

Authorized Public Accountant

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.

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