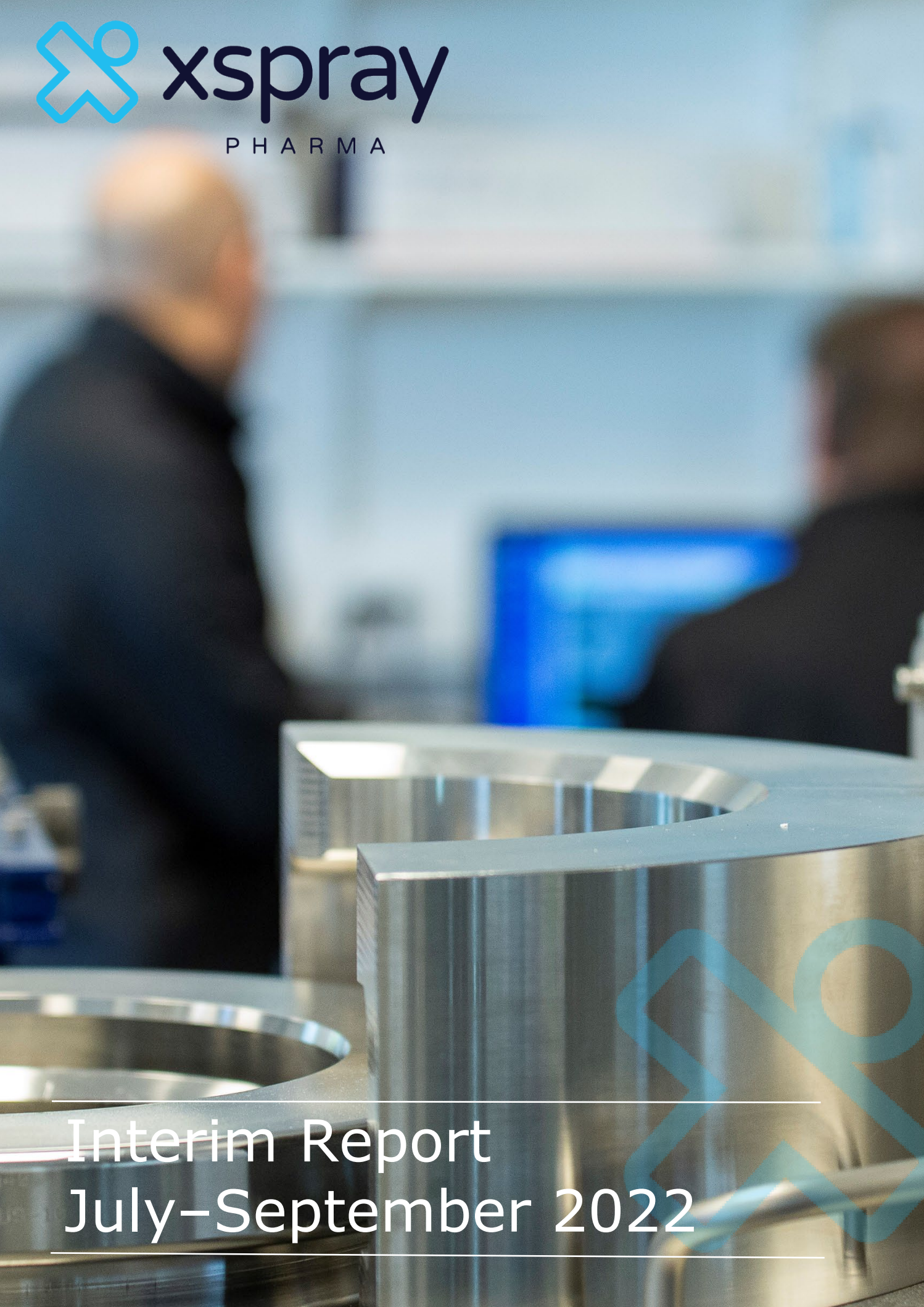

Interim Report July–September 2022

Xspray Pharma AB (publ) is a pharmaceutical company with multiple product candidates in the clinical development phase. Xspray Pharma uses its innovative, patented technology to develop amorphous product candidates that are improved generic versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. They are formulated as hybrid nanoparticles ("HyNap") and are amorphous, patentable, and stable versions of crystalline original substances.

Q3 2022

July–September 2022, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -28,651 thousand (-13,890)
- Earnings per share before dilution amounted to SEK -1.39 (-0.73)
- Cash flow from operating activities amounted to SEK -23,091 thousand (-16,524)
- Cash flow from investing activities amounted to SEK -29,126 thousand (-20,086)

January–September 2022, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -76,450 thousand (-44,754)
- Earnings per share before dilution amounted to SEK -3.70 (-2.35)
- Cash flow from operating activities amounted to SEK -75,176 thousand (-41,327)
- Cash flow from investing activities amounted to SEK -105,864 thousand (-72,127)
- Cash and cash equivalents at the end of the period amounted to SEK 89,834 thousand (216,543)

Amounts in parentheses refer to the year-earlier period.

Significant events during the quarter

- In early August, BMS added a further patent regarding crystalline compounds to the ongoing dispute concerning XS004. BMS has previously asserted this patent against other parties in similar cases, so this was not unexpected. Xspray Pharma has not applied for FDA approval for marketing a product that could infringe on the patent in question. Consequently, Xspray Pharma is still convinced of a positive outcome in the legal dispute, and does not expect that this will result in any delays in the case.

Significant events after the end of the reporting period

- In October, a directed share issue was conducted for a number of Swedish institutional investors including the Third Swedish National Pension Fund, Flerie Invest and the Foundation for Baltic and East European Studies. The subscription price was set at SEK 50.00 per share, and the issue raised proceeds of SEK 100 million before transaction costs. The number of shares increased by 2,000,000, from 20,680,408 to 22,680,408.
- In October, the composition of the Nomination Committee for the 2023 Annual General Meeting was announced.
- In early November, Xspray announced that they will attend with two poster presentations for XS004 at the annual American Society of Hematology (ASH) meeting in December 2022.

A message from the CEO

We have closed another quarter, and once again it has been an eventful period for us at Xspray.

To start, I can conclude that the world looks much different with a tough situation on the financial market during the third quarter compared with how the year started. From this perspective I am particularly pleased that, after the end of the quarter, we completed a directed share issue that was fully subscribed and strengthened our shareholder base with a new owner: the Third Swedish National Pension Fund, AP3. The proceeds will be used for initiatives such as market preparation for the upcoming launch on the US market and for strengthening the company's financials.

For the rest of this year, and the beginning of next, a great deal of effort will be concentrated on preparing for the launch of Xspray's first product on the US market. For us, it is important that the product candidate benefits patients as soon as possible, though we need to consider both the regulatory approval process and the legal dispute we are involved in. We are still convinced of a positive outcome in both of these processes.

We are also continuing the development of the company's product portfolio. Significant advances have been made with the company's second product candidate, XS003 nilotinib. The manufacturing process has been established on a commercial scale, and an initial clinical pilot study has been completed. It demonstrated that XS003 can achieve bioequivalence with a lower dose compared with the reference product, Tasigna®. The pivotal study is in progress. XS003 is an improved amorphous version of nilotinib intended for the treatment of chronic myeloid leukemia. The crystalline version of nilotinib on the market today must be taken on an empty stomach due to the risk of developing potentially fatal cardiotoxicity (arrhythmia) if taken with food. XS003 is designed to reduce the food effect and thereby potentially improving safety with the goal of providing freedom regarding food intake for patients who, at present, fast for 6 hours a day when being treated with the crystalline reference product. In 2020, Xspray obtained orphan drug designation for XS003 from the FDA based on the potential improvements to its safety benefits.

The upcoming few quarters and year could be very defining for Xspray. I see Xspray's potential in reaching its first FDA approval for an improved PKI product based on our world-unique technology. In addition, the legal patent process may be dismissed either through court order or settlement. Furthermore, our second product; XS003 can be fully developed and submitted to the FDA, and product number three, XS008, which is now being scaled up, receives positive clinical results. In short, I see that Xspray can then be a validated company with a unique and proven business model where the risk is relatively low, and upside potentially very high. There will always be some built-in uncertainty due to the fact that the business model, as it stands today, is based on time windows that may influence the value of the products. When we see the patient benefit of our improved products after the initial launch, the importance of the time window may change. It is extremely rewarding to meet shareholders and be able to show what the development cycle for our products looks like. We benefit from the fact that our business model let us repeat the same steps in our efforts to produce amorphous versions of existing drugs. This applies to everything from the selection process itself to developing an amorphous version for clinical studies and the approval process using our HyNap technology. At present, we have five products across the development process; XS004 and XS003 have come the furthest and we still expect approval of XS004 from the FDA in the first half of 2023.

November 9, 2022

Per Andersson
CEO

Financial overview, Group

	Q3		Jan-Sep		Full year
Key figures, Group	**2022**	**2021**	**2022**	**2021**	**2021**
Net sales (SEK thousand)	-	-	-	-	-
Loss before Income tax (SEK thousand)	-28,651	-13,890	-76,450	-44,754	-96,698
Earnings per share before dilution (SEK)	-1.39	-0.73	-3.70	-2.35	-5.03
Earnings per share after dilution (SEK)	-1.39	-0.73	-3.70	-2.35	-5.03
Research and development expenses as % of operating expenses	5.8	13.7	6.5	12.1	39.1
Cash and cash equivalents (SEK thousand)	89,834	216,543	89,834	216,543	271,881
Total assets (SEK thousand)	539,969	566,749	539,969	566,749	622,903
Equity/assets ratio (%)	95.5	96.0	95.5	96.0	95.0
Average number of employees	26	22	25	22	23

Total expenditure for research and development for the quarter was SEK -30,059 thousand, of which SEK -1,704 thousand has been expensed and SEK -28,356 thousand capitalized as development expenses.

Total expenditure for research and development for the period January–September was SEK -85,390 thousand, of which SEK -5,120 thousand has been expensed and SEK -80,270 thousand was capitalized as development expenditure.

Comments on the report

Unless otherwise indicated, the comments below pertain to the Group. Comparison figures are presented in parentheses and pertain to the year-earlier period. Since the Group consists of the Parent Company and a dormant subsidiary, the differences between the Parent Company and consolidated statements consist of the existing differences between RFR2 and IFRS.

Net sales

Net sales for the company amounted to SEK 0 thousand. The application for market approval of company's initial product, XS004 dasatinib, was filed in Q4 2021 and was supplemented with additional dosage strengths in Q2 2022, see further information under Research and Development on page 15.

Other operating income and expenses

Other operating income for the period amounted to SEK 333 thousand (75). The increase was attributable to advisory services performed by Xspray Pharma during the period. Other operating expenses for the period amounted to SEK -1,295 thousand (-450). Total other operating income and expenses for the company in all three quarters totalled SEK 1,100 thousand (328) and SEK -2,688 thousand (-1,317) Except for the income from advisory services, both other operating income and expenses consist entirely of exchange rate gains and losses arising in conjunction with international payments and translations of the currency account.

Research and development costs

Total expenditures for research and development in the third quarter amounted to SEK -30,059 thousand (-18,463), of which SEK-1,704 thousand (-1,955) was expensed and recognized in profit or loss and SEK -28,356 thousand (-16,508) was capitalized as development expenses and presented in the company's balance sheet. For the first three quarters, the figure is SEK -85,390 thousand (-74,193) for total expenditure for research and development, where SEK -5,120 thousand (-5,559) has been expensed and SEK -80,270 thousand (-68,634) capitalized as development expenditures. Expenditure for research and development in the third quarter increased by SEK -11,596 thousand compared with the previous year. This is due primarily to a continued high level of activity for two of the company's product candidates, XS004 dasatinib and XS003 nilotinib.

Administrative and sales costs

Administrative and sales costs for the third quarter totaled SEK -26,328 thousand (-11,878). Of these, personnel costs classified as administrative and sales costs amounted to SEK -7,687 thousand (-5,743). The corresponding aggregate figures are SEK -70,777 thousand (-39,127) for administrative and sales costs, where SEK -20,764 thousand (-15,661) pertained to personnel costs. The cost increase for the third quarter is attributable primarily to the company's continued market preparation activities as a result of the impending launch in the US. The cost of legal counsel in the US has increased as a result of the suit by the company behind the original drug in February. Moreover, the company's personnel increased by four full-time employees compared with the previous year, which impacts the cost base. Administrative and sales costs for the third quarter are in line with the preceding quarter.

Loss for the period

Loss for the third quarter totaled SEK -28,651 (-13,890) and for all three quarters totaled SEK -76,450 thousand (-44,754). This corresponds to earnings per share before dilution of SEK -1.39 (-0.73) and SEK -3.70 (-2.35) respectively. The change in earnings for the quarter is attributable primarily to increased administrative and sales costs resulting from increased consultation and advisory costs of SEK -8,569 thousand (-2,938).
Personnel costs classified as administrative, and sales costs increased by SEK -1,944 thousand year-on-year.

Cash flow, investments, financial position and going concern

Cash flow from operating activities for the quarter amounted to SEK -23,091 thousand (-16,524), of which the effect from operating capital comprised SEK 3,277 thousand (-4,790). The aggregate figure for the three quarters was SEK -75,176 thousand (-41,327), in which the effect from operating capital was SEK -5,476 thousand (-3,056). The negative cash flow is in accordance with the company's plan, and is primarily attributable to continued strengthening of the organization with several key individuals, project costs, legal counsel and other advisory services for the company's future strategic positioning.
Cash flow from investing activities amounted to SEK -29,126 thousand (-20,086) for the quarter and SEK -105,864 thousand (-72,127) for the three quarters. The item includes capitalized development expenses of SEK -28,105 thousand (-16,236) for the quarter and SEK -79,503 thousand (-67,802) for the three quarters. The main explanation for the increase comes from investments in property, plant and equipment, which were high during the first quarter. In the third quarter, investments in property, plant and equipment totaled SEK 0 thousand (0), but for all three quarters the total figure was SEK -23,334 thousand (-475). During the period, advances paid continued as a result of the construction of the company's new production unit in Malta. Cash flow from investing activities is in line with expected development. Cash flow from financing activities for the quarter totaled SEK -530 thousand (-584) and SEK -1,007 thousand (4,399) for the three quarters, which is attributable to allocation of warrant programs in the second quarter and repayment of lease liabilities.
Total cash flow for the third quarter of the year was SEK -52,747 thousand (-37,194) and for all three quarters was SEK -182,047 thousand (-109,055). The Group had SEK 89,834 thousand (216,543) in cash and cash equivalents at September 30, 2022. After the end of the period, a direct share issue was carried out that raised SEK 100 million before transaction costs for the company.
Depending on the path and orientation the company chooses to take over the coming year, the Group's coverage of cash and cash equivalents may fall below the liquidity needed to pursue accelerated operations for the coming 12 months. In light of this, the Board of Directors is continually evaluating the company's financial requirements and position, and reviewing various financing alternatives. The debt/equity ratio for the Group was 95.5 per cent (96.0) at September 30, 2022.

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 28,356 thousand (16,508). The Group's total capitalized expenditures for development and similar activities totaled SEK 376,506 thousand (300,252) at September 30, 2022. The item is associated with the company's product candidates XS004 dasatinib, XS003 nilotinib and XS005 sorafenib.

Parent Company

The Parent Company's subsidiary, Xspray Pharma Futurum AB, remained dormant during the period. All activities were pursued in the Parent Company, Xspray Pharma AB (publ). The Parent Company's cash and cash equivalents totaled SEK 89,784 thousand (216,493) and the debt/equity ratio was 95.9 percent (96.6) at September 30, 2022.

Employees

During the quarter, the organization increased by four full-time positions compared with the year-earlier period.
The number of employees in the Group totaled 26 (22). The subsidiary had no employees as of the balance date.

Related-party transactions

Related parties are defined as the management group in the Parent Company and the Boards of Directors in the Parent Company and subsidiary. Purchase of services from senior executives in the third quarter pertain to consultant fees from InterCon HB, owned by Andreas Konar, who is part of the company's management group. The fees amounted to SEK -252 thousand (-252) for the quarter and SEK -756 thousand (-756) for all three quarters.

Corporate governance

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

Financial statements and notes

All activities are pursued in the Parent Company, Xspray Pharma AB (publ).

Consolidated income statement

	Q3		Jan-Sep		Full year
SEK thousand	**2022**	**2021**	**2022**	**2021**	**2021**
Net sales	-	-	-	-	-
Other operating income	333	75	1,100	328	656
Research and development expenses	-1,704	-1,955	-5,120	-5,559	-38,567
Administration and sales expenses	-26,328	-11,878	-70,777	-39,127	-58,384
Other operating expenses	-1,295	-450	-2,688	-1,317	-1,657
Operating loss	**-28,994**	**-14,209**	**-77,486**	**-45,676**	**-97,953**
Finance income	352	319	1,048	925	1,259
Finance costs	-9	-1	-12	-4	-4
Finance net	**343**	**319**	**1,036**	**922**	**1,255**
Loss before Income tax	-28,651	-13,890	-76,450	-44,754	-96,698
Tax	-	-	-	-	-
Loss for the period	**-28,651**	**-13,890**	**-76,450**	**-44,754**	**-96,698**
Earnings per share for the period before dilution, SEK	-1.39	-0.73	-3.70	-2.35	-5.03
Earnings per share for the period after dilution, SEK	-1.39	-0.73	-3.70	-2.35	-5.03
Average number of shares before dilution	20,680,408	19,067,504	20,680,408	19,046,272	19,237,743
Average number of shares after dilution	20,680,408	19,367,125	20,680,408	19,345,893	19,237,743

Consolidated statement of comprehensive income

	Q3		Jan-Sep		Full year
SEK thousand	**2022**	**2021**	**2022**	**2021**	**2021**
Loss for the period	-28,651	-13,890	-76,450	-44,754	-96,698
Other comprehensive income	-	-	-	-	-
Total comprehensive income for the period	**-28,651**	**-13,890**	**-76,450**	**-44,754**	**-96,698**

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

Consolidated balance sheet

SEK thousand	30 Sep 2022	30 Sep 2021	31 Dec 2021
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	376,506	300,252	296,236
Total intangible assets	**376,506**	**300,252**	**296,236**
Property, plant and equipment			
Machinery and installations	16,962	22,373	20,458
Right-of-use assets	2,540	4,018	3,526
Equipment	254	684	574
Fixed assets under construction and prepayments	44,608	13,047	20,043
Total Property, plant and equipment	**64,364**	**40,121**	**44,601**
Financial assets			
Financial investments	1	1	1
Total financial assets	**1**	**1**	**1**
Total non-current assets	**440,871**	**340,374**	**340,838**
Current assets			
Inventories	4,975	-	6,199
Current receivables	2,675	3,996	2,473
Prepaid expenses and accured income	1,614	5,837	1,513
Cash and cash equivalents	89,834	216,543	271,881
Total current assets	**99,098**	**226,375**	**282,065**
TOTAL ASSETS	**539,969**	**566,749**	**622,903**

SEK thousand	30 Sep 2022	30 Sep 2021	31 Dec 2021
EQUITY AND LIABILITIES			
Equity			
Share capital	20,680	19,068	20,680
Other contributed capital	814,047	715,248	813,483
Reserves	976	976	976
Retained earnings including profit/loss for the period	-319,837	-191,443	-243,387
Total equity attributable to the Parent Company's shareholders	**515,867**	**543,849**	**591,752**
Non–current liabilities			
Lease liabilities	323	1,661	1,185
Total non-current liabilities	**323**	**1,661**	**1,185**
Current liabilities			
Trade accounts payable	11,971	8,483	16,865
Lease liabilities	1,888	2,064	2,048
Other current liabilities	1,322	979	653
Accrued expenses and deferred income	8,598	9,713	10,401
Total current liabilities	**23,779**	**21,239**	**29,966**
TOTAL EQUITY AND LIABILITIES	**539,969**	**566,749**	**622,903**

Consolidated report of changes in equity

SEK thousand	Share capital	Other contributed capital	Reserves	Retained earnings incl. profit/loss for the period	Total Equity
Opening balance as of Janary 1, 2021	**18,893**	**709,407**	**976**	**-146,689**	**582,587**
Loss of the period	-	-	-	-96,698	-96,698
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	**-**	**-**	**-**	**-96,698**	**-96,698**
New share issue	1,612	98,388	-	-	100,000
Transaction costs	-	-134	-	-	-134
Redemption of warrants	175	4,200	-	-	4,375
Warrant program	-	1,621	-	-	1,621
Closing balance as of December 31, 2021	**20,680**	**813,483**	**976**	**-243,387**	**591,752**
Opening balance as of January 1, 2022	**20,680**	**813,483**	**976**	**-243,387**	**591,752**
Loss for the period	-	-	-	-76,450	-76,450
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	**-**	**-**	**-**	**-76,450**	**-76,450**
Transaction costs	-	-300	-	-	-300
Warrant program	-	865	-	-	865
Closing balance as of September 30, 2022	**20,680**	**814,047**	**976**	**-319,837**	**515,867**

Consolidated cash flow statement

	Q3		Jan-Sep		Full year
SEK thousand	**2022**	**2021**	**2022**	**2021**	**2021**
Operating activities					
Operating loss	**-28,994**	**-14,209**	**-77,486**	**-45,676**	**-97,953**
Non-cash adjustments					
Depreciation	2,399	2,307	7,107	6,574	8,870
Capital gains	-	-	-	98	98
Interest received	267	168	799	737	1,878
Interest paid	-40	-	-120	-4	-4
Cash flow from operating activities before changes in working capital	**-26,368**	**-11,734**	**-69,700**	**-38,271**	**-55,983**
Changes in working capital					
Change in operating receivables	-241	-4,875	551	-2,052	-5,712
Change in operating liabilities	3,518	85	-6,027	-1,004	10,087
Cash flow from operating activities	**-23,091**	**-16,524**	**-75,176**	**-41,327**	**-51,607**
Investing activities					
Capitalized development costs	-28,105	-16,236	-79,503	-67,802	-94,651
Acquisition of property, plant and equipment	-	-	-23,334	-475	-1,313
Prepayments	-1,021	-3,850	-3,027	-3,850	-9,854
Cash flow from investing activities	**-29,126**	**-20,086**	**-105,864**	**-72,127**	**-105,818**
Financing activities					
New share issue	-	-	-	-	99,877
Transaction costs	-	-	-300	-10	-29
Payment of lease liability	-530	-540	-1,572	-1,616	-2,154
Redemption of warrants	-	-	-	4,375	4,375
Repurchased warrants	-	-44	-	-44	-54
Allocated warrants	-	-	865	1,694	1,694
Cash flow from financing activities	**-530**	**-584**	**-1,007**	**4,399**	**103,708**
Cash flow for the period	**-52,747**	**-37,194**	**-182,047**	**-109,055**	**-53,717**
Cash and cash equivalents at the beginning of the period	142,581	253,737	271,881	325,598	325,598
Cash and cash equivalents at the end of the period	**89,834**	**216,543**	**89,834**	**216,543**	**271,881**

Parent Company income statement

	Q3		Jan-Sep		Full year
SEK thousand	**2022**	**2021**	**2022**	**2021**	**2021**
Net sales	-	-	-	-	-
Other operating income	333	75	1,100	328	656
Research and development expenses	-1,800	-1,946	-5,398	-5,495	-38,560
Administration and sales expenses	-26,355	-11,905	-70,858	-39,204	-58,486
Other operating expenses	-1,317	-450	-2,733	-1,317	-1,660
Operating loss	**-29,139**	**-14,227**	**-77,890**	**-45,689**	**-98,050**
Finance income	146	241	475	756	938
Finance costs	-9	-1	-12	-4	-4
Finance net	**137**	**240**	**463**	**752**	**934**
Loss before Income tax	-29,001	-13,986	-77,426	-44,936	-97,116
Tax	-	-	-	-	-
Loss for the period	**-29,001**	**-13,986**	**-77,426**	**-44,936**	**-97,116**
Average number of shares before dilution	20,680,408	19,067,504	20,680,408	19,046,272	19,237,743
Average number of shares after dilution	20,680,408	19,367,125	20,680,408	19,345,893	19,237,743

Parent Company balance sheet

SEK thousand	30 Sep 2022	30 Sep 2021	31 Dec 2021
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	375,953	300,102	296,005
Total intangible assets	**375,953**	**300,102**	**296,005**
Property, plant and equipment			
Machinery and installations	16,962	22,373	20,458
Equipment	254	684	574
Fixed assets under construction and prepayments	43,666	12,876	19,719
Total Property, plant and equipment	**60,882**	**35,933**	**40,751**
Financial assets			
Shares in subsidiaries	50	50	50
Financial investments	1	1	1
Total financial assets	**51**	**51**	**51**
Total non-current assets	**436,886**	**336,087**	**336,808**
Current assets			
Inventories	**4,975**	**-**	**6,199**
Current receivables			
Other current receivables	2,675	3,996	2,473
Prepaid expenses and accured income	2,096	6,319	1,995
Total current receivables	**4,771**	**10,314**	**4,467**
Cash and bank	89,784	216,493	271,831
Total current assets	**99,530**	**226,807**	**282,497**
TOTAL ASSETS	**536,416**	**562,894**	**619,305**

SEK thousand	30 Sep 2022	30 Sep 2021	31 Dec 2021
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	20,680	19,068	20,680
Statutory reserve	976	976	976
Development expenditure reserve	375,953	300,102	296,005
Total restricted equity	**397,610**	**320,146**	**317,662**
Non-restricted equity			
Other contributed capital	814,047	715,248	813,483
Accumulated earnings	-619,706	-446,739	-442,642
Profit/loss for the period	-77,426	-44,936	-97,116
Total non-restricted equity	**116,915**	**223,572**	**273,724**
Total equity	**514,525**	**543,718**	**591,386**
Current liabilities			
Trade accounts payable	11,971	8,483	16,865
Other current liabilities	1,322	979	653
Accrued expenses and deferred income	8,598	9,713	10,401
Total current liabilities	**21,891**	**19,175**	**27,919**
TOTAL EQUITY AND LIABILITIES	**536,416**	**562,894**	**619,305**

Parent Company cash flow statement

	Q3		Jan-Sep		Full year
SEK thousand	**2022**	**2021**	**2022**	**2021**	**2021**
Operating activities					
Operating loss	**-29,139**	**-14,227**	**-77,890**	**-45,689**	**-98,050**
Non-cash adjustments					
Depreciation	2,106	2,033	6,229	5,755	7,781
Captial gains	-	-	-	98	98
Disposal of intangible fixed assets	-	-	-	-	31,128
Interest received	61	-	61	569	1,557
Interest paid	-9	-	-12	-4	-4
Cash flow from operating activities before changes in working capital	**-26,981**	**-12,194**	**-71,612**	**-39,270**	**-57,490**
Changes in working capital					
Change in operating receivables	-14	-4,705	1,334	-1,882	-5,389
Change in operating liabilities	3,519	85	-6,026	-1,004	10,087
Cash flow from operating activities	**-23,476**	**-16,814**	**-76,304**	**-42,156**	**-52,792**
Investing activities					
Purchase of intangible assets	-28,250	-16,487	-79,948	-68,589	-95,621
Acquisition of property, plant and equipment	-	-	-23,334	-475	-1,313
Prepayments	-1,021	-3,850	-3,027	-3,850	-9,854
Cash flow from investing activities	**-29,271**	**-20,337**	**-106,309**	**-72,914**	**-106,788**
Financing activities					
New share issue	-	-	-	-	99,877
Transaction costs	-	-	-300	-10	-29
Redemption of warrants	-	-	-	4,375	4,375
Repurchased warrants	-	-44	-	-44	-54
Allocated warrants	-	-	865	1,694	1,694
Cash flow from financing activities	**-**	**-44**	**565**	**6,015**	**105,863**
Cash flow for the period	**-52,747**	**-37,194**	**-182,048**	**-109,055**	**-53,717**
Cash and cash equivalents at the beginning of the period	142,531	253,687	271,831	325,548	325,548
Cash and cash equivalents at the end of the period	**89,784**	**216,493**	**89,784**	**216,493**	**271,831**

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 2021 have been applied. The changes in IFRS applied as of January 1, 2022 have not had any impact on the financial statements for the first, second, and third quarters of 2022. Comparison figures are presented in parentheses and pertain to the year-earlier period.

Definitions of key performance indicators

Earnings per share are calculated as earnings for the period divided by the average number of shares during the period. The debt/equity ratio is equity as a percentage of the balance sheet total. Research and development costs as a percentage of operating expenses comprise primarily expensed research and development expenditures divided by operating expenses. Total operating expenses consist of operating profit less net sales and other operating income. The carrying amount of receivables, cash and cash equivalents, trade payables and other liabilities constitute a reasonable approximation of fair value.

Note 2. Key estimates and assessments

Preparing the financial statements in accordance with IFRS requires management to make assessments and estimates, and to make assumptions that impact the application of the accounting policies and the recognized amounts of assets, liabilities, revenue and expenses. The real outcome may deviate from these estimates and assumptions. The estimates and assumptions are routinely evaluated. Changes to estimates are recognized in the period the changes are made.

The source of uncertainty in estimations that entail a significant risk for the need to significantly adjust the value of assets or liabilities during the coming financial year is the carrying amount of "Capitalized development expenses". Determining whether the requirements for capitalization of development expenditures have been met requires both initial and routine assessments. The capitalized expenditures are regularly tested as to whether they could be exposed to a decrease in value. The company holds capitalized intangible assets that have not yet been completed and are impairment tested either yearly or as soon as there is an indication of a potential decrease in value. Impairment testing involves estimating future cash flows attributable to the asset, or to the cash-generating unit that the asset will be attributed to, once it is complete. These estimates and assumptions encompass expectations pertaining primarily to the selling price of the products, market penetration, and remaining development, sales and marketing costs as well as the probability that the product will successfully pass through the remaining development stages. The assumptions involve industry- and market-specific data produced by corporate management and reviewed by the Board of Directors.

Material risks and uncertainties

Xspray Pharma's operation is associated with both industry-related and company-specific risks. The company develops product candidates, and there will always be regulatory, market-related and financial risks in the operation. No material changes have occurred in the risks and uncertainties during the period compared with those the company reported in the Annual Report for 2021.

Financing risk and going concern

Depending on the path and orientation the company chooses to take over the coming year, the Group's coverage of cash and cash equivalents may not meet the liquidity needed to pursue accelerated operations for the coming 12 months. In light of this, the Board of Directors is continually evaluating the company's financial requirements and position, and reviewing various financing alternatives. If the financing secured is not sufficient, it would suggest material uncertainties that could lead to significant doubt regarding the company's capacity to continue its operations. In accordance with the policy by the Board of Directors, the Group must maintain a strong financial position, which will help the company retain investor and market confidence. This will further facilitate the development of company operations, with continued long-term support for a desirable dividend for the company's owners. Until the company has achieved long-term and sustainable profitability, it is the company's policy to maintain a low level of indebtedness and a high level of equity.

Ukraine

Xspray Pharma continues to follow the tragic events unfolding in Ukraine. At present, Xspray Pharma's operations have not been directly impacted, but we are closely monitoring the course of events.

The company and the pipeline

Xspray Pharma AB (publ) is a pharmaceutical company with multiple product candidates in the clinical development phase. Xspray Pharma uses its innovative, patented technology to develop amorphous product candidates that are improved generic versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. Often the original companies have secondary patents that are based on the crystalline forms of the active substance and thus do not encompass amorphous versions. This means that Xspray will be able to launch its product candidates earlier than would be possible with generic products.

In bioequivalence studies conducted in healthy volunteers, the goal is to achieve bioequivalence comparable to the original drug, meaning that the active drug substance of the product candidate should be processed by the body the same way as the original drug. Since Xspray's products are amorphous and have better uptake in the body compared with the original drug, bioequivalence can often be achieved at a lower dosage.

The company's initial product candidates – XS004 dasatinib, XS003 nilotinib and XS005 sorafenib – are stable amorphous versions of the three best-selling cancer drugs Sprycel® (dasatinib), Tasigna® (nilotinib) and Nexavar® (sorafenib). In 2021, Sprycel® sold for USD 2.1 billion, Tasigna® for USD 2.1 billion and Nexavar® for USD 0.5 billion worldwide. A careful selection process determines which PKIs will become future product candidates and included in the company's pipeline.

Market

PKI drugs are a large and important segment for targeted cancer therapies, where sales total approximately 37 percent of the total oncology market, and with sales figures that are increasing annually. In 2021, estimated sales of PKI drugs in the US market totaled approximately USD 33 billion.

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

PKI drugs with challenges

PKIs have been shown to inhibit the growth of cancer, which results in extended survival and the patient most often being treated for several years – in some cases, for life. The majority of the PKIs being marketed contain crystalline forms of the active substances. One generally known problem with these crystalline products is that they are difficult to dissolve, and solubility can vary depending on the pH value in the stomach for uptake in the body, which results in what is known as high variability. This often results in an uneven uptake of the drug into the body, especially alongside intake of food or pH-increasing drugs such as omeprazole. Variability increases the risk of the loss of therapeutic effect, if uptake of the drug is too low the cancer can accelerate again and if uptake is too high severe side effects often increase.

Xspray Pharma's technology is especially suited to overcoming many of the shortcomings that PKI substances generally possess. The company produces stable amorphous PKIs that can be easily dissolved, have greater bioavailability, and have pH-independent uptake, which means a more even uptake of the drug even alongside the intake 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.

Prospects

The company's new HyNap product candidates are being developed in the same manner as the company's initial product, XS004 dasatinib. The process is repeatable, which reduces the development time for future product candidates in the company's pipeline. The technology makes it possible to quickly and in a controlled manner change the properties required to make improved amorphous versions of PKI drugs already being marketed and to bring the respective product candidates to market faster. This means that the company's easily dissolved and pH-independent product candidates have the conditions to both meet current market demand with better functioning drugs and also offer a broader patient group access to drugs that they cannot currently use.

Xspray Pharma's goal is to be a leader in developing improved versions of PKIs already being marketed for the treatment of cancer. The company has patented the manufacturing technology, the equipment, and the resulting products. The manufacturing has been established on a commercial scale, and the company has the capacity to provide the market with drugs made from its first product candidates.

Xspray Pharma's pipeline

Xspray Pharma's pipeline is continuously evolving and contains a number of product candidates, three of which have been announced and are based on the company's HyNap platform: XS004 dasatinib, XS003 nilotinib and XS005 sorafenib. These are improved amorphous versions of established and marketed protein kinase inhibitors with orphan drug status. The original drugs have secondary patents expiring between 2026 and 2029 and their total annual sales for 2021 exceeded USD 2.4 billion in the US market and USD 4.7 billion globally.

Product candidates				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
XS004	dasatinib	Leukemia (CML, ALL)	505(b)(2)	Dec 2020	Sept 2026						Sprycel®/ BMS
XS003	nilotinib	Leukemia (CML)	505(b)(2)	Jan 2024	Feb 2029						Tasigna®/ Novartis
XS005	sorafenib	Liver cancer (HCC)	505(b)(2)	Jan 2020	Sept 2028						Nexavar®/ Bayer
XS008	Undisclosed										
XS00Y	Undisclosed										

Research and development

Regulatory

In November 2021, an application was submitted to the FDA for market approval of XS004 under the 505(b)(2) New Drug Application procedure for the indications of acute lymphoblastic leukemia (ALL) and chronic myeloid leukemia (CML) in an accelerated phase. In January 2022, the FDA announced that the application for XS004 had been accepted for a comprehensive review. As a result, litigation was also initiated by the original company, which is a process that runs in parallel with the FDA's review of the 505(b)(2) dossier. The application was supplemented in Q2 with additional dosage strengths, which means that the application now simultaneously covers all six dosage strengths corresponding to those of the original company. The supplement also contains updated product information that now includes CML in a chronic phase as well.

After the supplementary submission, Xspray Pharma has held constructive discussions with the FDA and obtained clearer information regarding how the FDA intends to perform the review of all dosage strengths and the updated product information. In accordance with these discussions, the company estimates tentative market approval of XS004 during H1 2023.

The litigation process with the original company is not affected by the ongoing FDA review of the dossier, and the company´s goal remains to bring the product to the market in 2023.

In June, the FDA announced that they had granted XS004 orphan drug status for CML. The FDA's decision is based on the plausible hypothesis that XS004 could be clinically superior to other drugs with the same compound that has already been approved for the same indication. This is since Xspray Pharma's product candidate may provide a major contribution to patient care owing to the gastric pH-resistant qualities of the formulation, since acid-reducing drugs (H2 blockers and proton-pump inhibitors) cannot be taken with the original drug and in the context of the significant concomitant use of acid-reducing agents in the CML population.

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. At September 30, 2022, the number of shares in the company was 20,680,408 and the last price paid in the period was SEK 54.00.

Incentive plans

At September 30, 2022 the company had a total of four series of warrants issued to employees, senior executives and the Chairman of the Board. All warrant programs and employee stock options were valued using the Black & Scholes valuation model at the time of allocation.

LTIP 2020–2023

The LTIP 2020–2023 warrant program encompasses 72,485 warrants that can be exercised during the period from April 1, 2023 through May 14, 2023 at a subscription price of SEK 89.10 per share. There is a maximum dilution effect of 0.4% on the current number of shares.

LTIP 2021–2024

The LTIP 2021–2024 warrant program encompasses 189,340 warrants that can be exercised during the period from June 3, 2024 through July 15, 2024 at a subscription price of SEK 148.90 per share. There is a maximum dilution effect of 0.9% on the current number of shares.

Chairman LTIP 2021–2026

The Chairman LTIP 2021–2026 warrant program includes the Chairman of the Board and encompasses 13,214 warrants that can be exercised during the period from May 25, 2026 through June 15, 2026 at a subscription price of SEK 129.00 per share. There is a maximum dilution effect of 0.06% on the current number of shares.

LTIP 2022–2025

The program was resolved on at the Annual General Meeting on May 19, 2022. The program encompasses 140,625 warrants and 281,250 employee stock options that can be exercised during the period from June 15, 2025 through July 15, 2025 at a subscription price of SEK 132.20 per share. The program is pegged to the company's growth in value for the purpose of creating a stronger link between employee and shareholder interests. There is a maximum dilution effect of 2.0% on the current number of shares.

A detailed description of the three earlier warrant programs can be found in the company's 2021 Annual Report.

Owners as of September 30, 2022	Number of shares	Number of shares & votes
Flerie Invest	3,022,378	14.61%
Ribbskottet	2,540,719	12.29%
The Foundation for Baltic And East European Studies	2,500,826	12.09%
Fourth Swedish National Pension Fund	1,795,806	8.68%
Nordnet Pension Insurance	846,234	4.09%
Avanza Pension	756,271	3.66%
Unionen	726,000	3.51%
TIN Funds	600,000	2.90%
Swedbank Robur Funds	422,320	2.04%
Second Swedish National Pension Fund	404,241	1.95%
Total, ten largest owners	13,614,795	65.83%
Total, other shareholders	7,065,613	34.17%
Total number of shares	**20,680,408**	**100.00%**

Analysts monitoring the company

Filip Einarsson, Redeye AB

Dan Akschuti, Pareto Securities AB

Financial calendar

Year-End Report 2022	February 15, 2023
Annual Report 2022	March 29, 2023
Interim Report Q1 2023	May 4, 2023
Interim Report Q2 2023	August 2, 2023
Interim Report Q3 2023	November 8, 2023

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

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, November 9, 2022

Anders Ekblom
Chairman of the Board

Anders Bladh
Board member

Robert Molander
Board member

Maris Hartmanis
Board member

Torbjörn Koivisto
Board member

Christine Lind
Board member

Carl-Johan Spak
Board member

Per Andersson
CEO

This report has been reviewed by the company's auditors.

Review report

To the Board of Directors of Xspray Pharma AB (publ)

Corp. id. 556649-3671

Introduction

We have reviewed the condensed interim financial information (interim report) of Xspray Pharma AB (publ) as of 30 September 2022 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.

Material uncertainty as to going concern

We bring to your attention the information in the interim report (page 5) and in note 2 (page 13) which states that the cash and cash equivalents may not be sufficient to cover planned operations for the coming 12 months It also states that the Board of Directors is continually evaluating the company's financial requirements and position and reviewing various financing alternatives but also there is a risk that the basis of going concern cannot be used if sufficient financing is not secured. These circumstances indicate that there are material uncertainties that may cast significant doubt on the Group's ability to continue as a going concern. We have not modified our conclusion in regards to this.

Stockholm 9 November 2022

KPMG AB

Duane Swanson

Authorized Public Accountant

Information
Glossary

505(b)(2) NDA •	Application for drug approval in the US for an improved version of an existing licensed or approved drug.
Amorphous •	An amorphous structure is a chemical term that describes substances whose molecules lack an ordered structure.
Bioequivalence •	Term used to describe whether two different drugs are processed in a similar manner by the body and are thereby expected to have a similar and equivalent medicinal effect. If it can be confirmed that two drugs being compared are bioequivalent, they can be expected to have the same effect and safety.
Bioavailability •	(Biological availability), a concept in pharmacology that shows how large a portion of the drug reaches the blood.
CRO •	Contract Research Organization. A service company active in contract research and service in the development of drugs.
FDA •	Food and Drug Administration. The US food and drug authority responsible for foodstuffs, nutritional supplements, drugs, cosmetics, medical equipment, radiation-emitting equipment and blood products.
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.
Protein kinase inhibitor (PKI) •	Drugs that block protein kinases. Protein kinase inhibitors work by blocking activity in enzymes that push the development and growth of cancer cells.
Variability •	The scope of the distribution in the form of many or few low and high values around the average value as regards the body's uptake of drugs.

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

For further information, please contact

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