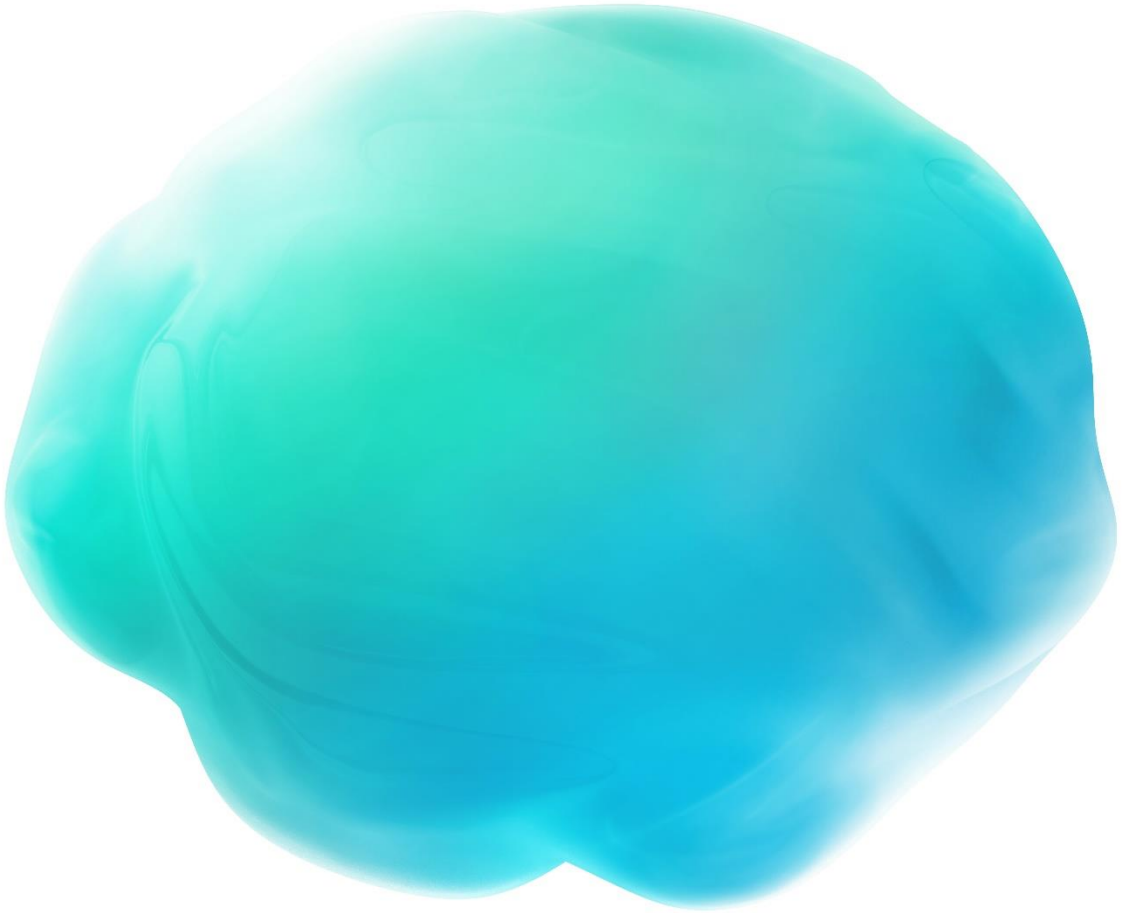


INTERIM REPORT
July–September 2023

xspray
PHARMA

Overview – company vision

Financial and operational vision through 2030

- Net sales that exceed USD 400 million
- Profit margin that exceeds 65 percent
- Five commercialized products
- Three product candidates under development

July–September 2023, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -38,942 thousand (-28,651)
- Earnings per share before dilution amounted to SEK -1.59 (-1.39)
- Cash flow from operating activities amounted to SEK -68,611 thousand (-23,091)
- Cash flow from investing activities amounted to SEK -14,470 thousand (-29,126)

January–September 2023, Group

- Net sales amounted to SEK 0 thousand (0)
- Loss before tax amounted to SEK -125,171 thousand (-76,450)
- Earnings per share before dilution amounted to SEK -5.11 (-3.70)
- Cash flow from operating activities amounted to SEK -170,649 thousand (-75,176)
- Cash flow from investing activities amounted to SEK -45,147 thousand (-105,864)

Amounts in parentheses refer to the year-earlier period.

Significant events during the quarter

- Xspray Pharma received a complete response letter (CRL) in which the FDA requested supplementary information concerning how physicians and users are to dose Dasynoc™, as well as supplementary information regarding a third-party manufacturing facility. At the same time, the FDA accepted critical aspects of the application by not identifying any deficiencies in stability or the clinical data that has been submitted to date.
- Through the preferential rights issue that was completed in July 2023, the number of shares and votes increased 6,265,892, from 22,680,408 to 28,946,300. The share capital increased SEK 6,265,892, from SEK 22,680,408 to SEK 28,946,300. The company received SEK 250,636 thousand before transaction costs.
- Xspray Pharma reached a settlement with Bristol Myers Squibb (BMS) regarding the patent dispute concerning Dasynoc. The settlement removes all claims from BMS regarding patent infringement, including the possibility of an appeal, and makes it possible for Xspray to launch Dasynoc in the US market on September 1, 2024 conditional on final approval from the FDA.
- Xspray Pharma recruited Edward P. Jordan to the position of Chief Commercial Officer. Edward Jordan will lead the launch and commercialization of Dasynoc in the US.

Significant events after the end of the reporting period

- Xspray Pharma published a registry study in the European Journal of Haematology demonstrating that nearly half of CML patients treated with tyrosine kinase inhibitors (TKIs) take proton pump inhibitors (PPIs), concurrently which increases the risk of patient mortality. This can be mitigated with Xspray´s enhanced amorphous dasatinib formulation, Dasynoc.

	Q3		Jan-Sep		Full year
Key figures, Group	2023	2022	2023	2022	2022
Net sales (SEK thousand)	-	-	-	-	-
Loss before Income tax (SEK thousand)	-38,942	-28,651	-125,171	-76,450	-131,670
Earnings per share before dilution (SEK)	-1.59	-1.39	-5.11	-3.70	-6.25
Earnings per share after dilution (SEK)	-1.59	-1.39	-5.11	-3.70	-6.25
Research and development expenses as % of operating expenses 1)	8.3	5.8	17.8	6.5	16.4
Cash and cash equivalents (SEK thousand)	132,480	89,834	132,480	89,834	120,166
Total assets (SEK thousand)	703,305	539,969	703,305	539,969	585,430
Equity/assets ratio (%)	93.9	95.5	93.9	95.5	95.0
Average number of employees	26	26	26	25	25

1) Alternate key performance indicators for assessing the degree of development of the company's product candidates. Refer to the company's annual report for more information on key performance indicators.

A message from the CEO

Dear shareholders,
With a favorable settlement in the patent dispute regarding our lead product candidate, Dasynoc, we took a significant step closer during the quarter to the commercialization of our first product. Dasynoc is an amorphous version of dasatinib that has the potential to enhance the treatment of patients with the blood cancers chronic myeloid leukemia (CML) and acute lymphoblastic leukemia (ALL), who often take dasatinib concurrently with PPIs for the treatment of peptic ulcers. We now have an updated timetable for the ongoing FDA application process for Dasynoc, and continue to progress towards a US launch on September 1 next year. Ahead of the launch, we have recruited the highly experienced and accomplished Edward P. Jordan to the key role as the company's Chief Commercial Officer. The development of our second product candidate, XS003 nilotinib, is making important advances and I hope to present our way forward already in Q4. During the period, we also published a study in the *European Journal of Haematology* that once again demonstrates the need for a product such as Dasynoc to enable co-medication of dasatinib with PPIs.

Settlement with BMS

On September 11, 2023, we announced that Xspray Pharma reached a settlement with Bristol Myers Squibb (BMS) in the patent dispute over Dasynoc. This is a critical milestone for the company, which takes us a major step closer to the launch of our first product, Dasynoc. The settlement removes all claims from BMS regarding patent infringement and makes it possible for Xspray Pharma to launch Dasynoc in the US market on September 1, 2024 conditional on final approval from the FDA.

We can now fully focus on ensuring a rapid market introduction of Dasynoc, and resources previously earmarked for the legal dispute can now be allocated to Dasynoc and the development of Xspray Pharma's future products.

Updated timetable for the FDA process

During the quarter, we received a CRL from the FDA regarding the company's application for market approval

of the six dosage strengths for Dasynoc (15 mg, 36 mg, 50 mg, 57 mg, 70 mg and 100 mg). The FDA has requested additional information, primarily supplementary information for physicians and patients regarding the dosage of Dasynoc as well as certain details about a third-party manufacturing facility in Italy.

During the quarter, we have compiled the requested supplements, and anticipate submitting our response in December 2023. Following that, the timetable for the FDA's processing will be somewhat predictable. Once our response is registered, the FDA has, up to six months to provide a decision on the market approval of Dasynoc, which implies an outcome before the mid-year mark, well in advance of our planned launch in September 2024.

We continue to engage in an active dialogue with the FDA to ensure that our responses fulfill their requirements. We are confident that the FDA's review will result in approval to market Dasynoc as an enhanced version of dasatinib for the treatment of CML and ALL.

Publication of study showing how Dasynoc's advantages can result in higher survival rates for large patient groups

During the period, a registry study was published in the *European Journal of Haematology* in which Xspray Pharma, in partnership with researchers at Uppsala University and Karolinska Institutet, demonstrated a deterioration in survival rates for patients who, despite warnings, co-medicate the original drug Sprycel® with PPIs for peptic ulcers. The study shows that co-medication of this type happens frequently despite the risks. The study also presents data demonstrating that the uptake of Xspray Pharma's product candidate, Dasynoc, is not impacted by this co-medication. The publication serves as crucial evidence of Dasynoc's improved properties and will be vital support in communicating with prescribing physicians during the forthcoming commercialization phase.

Financing

In the previous quarter, we conducted a preferential rights issue of units comprising shares and two warrant series. The rights issue raised a total of approximately SEK 251 million in proceeds for Xspray Pharma before transaction expenses. We are approaching the subscription period for the TO5 warrants, which runs from November 16 to November 30. These warrants provide existing shareholders in Xspray Pharma with the opportunity to subscribe for new Xspray shares at a price of SEK 40. If both TO5 and TO6 warrant series are fully subscribed, Xspray Pharma will raise an additional SEK 251 million.

The proceeds raised from warrants will be used for the US launch of Dasynoc and to continue the development of the company's pipeline.

Preparations ahead of the launch in the US

During the quarter, we announced the appointment of Edward P. Jordan to the key position of Chief Commercial Officer. Edward brings valuable knowledge in commercialization and has successfully launched numerous drug products in the US market – several of which are cancer-related. He is the optimal person to lead the US launch of the company's first commercial product, Dasynoc. In this role, he will collaborate with Xspray Pharma's commercializa-tion partner Eversana.

The preparations ahead for the upcoming launch of Dasynoc in the US are proceeding as planned. Since we now have a specific target launch date for Dasynoc, we have been able to initiate detailed planning of the launch.

We are entering an exciting period, and I look forward to Xspray Pharma proceeding to the next stage of its journey – becoming a commercial-stage, profitable pharma-ceutical company and a global leader in enhanced versions of established protein kinase inhibitors.

Per Andersson
CEO, Xspray Pharma

Financial performance

Unless otherwise indicated, the comments below pertain to the Group. Comparison figures are presented in parentheses and pertain to the same period in 2022. Since the Group consists of the Parent Company and two almost completely dormant subsidiaries, 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. Sales are expected to increase as of September 1, 2024 when the company launches its initial product, Dasynoc, in the US market, which is conditional on final FDA approval. Further information on Dasynoc is available under the Product candidate section on page 18.

Other operating income

Other operating income was SEK 29,203 thousand (333) for the third quarter and SEK 30,463 thousand (1,100) for the January–September period. This is attributable to the legal proceedings in the US as well as advisory services and development efforts performed by Xspray. Other operating income also consists of exchange rate gains arising in conjunction with payments abroad and translations of the currency account.

Research and development costs

Total expenditures for research and development for the quarter amounted to SEK -14,426 thousand (-30,059), of which SEK -5,647 thousand (-1,704) was recognized as an expense in profit or loss and SEK -8,779 thousand (-28,356) was capitalized as development expenditure and presented in the company's balance sheet. For the January–September period, the total expenditure for research and development was SEK -65,580 thousand (-85,390), with SEK-27,771 thousand (-5,120) expensed and SEK -37,808 thousand (-80,270) capitalized as development expenditure. A large part of the research and development in the quarter was expensed since Dasynoc is in a new commercial phase, including validation efforts and other consulting that have not been capitalized. Costs are also attributable to the company's two other product candidates, XS003 nilotinib and XS008 axitinib.

Administration and sales expenses

Administration and sales expenses totaled SEK -61,237 thousand (-26,328) in the third quarter. Of these, personnel costs amounted to SEK -8,708 thousand (-7,687). Administration and sales expenses for the January–September period totaled SEK -125,579 thousand (-70,777) with SEK -27,071 thousand (-20,764) pertaining to personnel costs. The cost increase for the third quarter was attributable primarily to the company's continued market preparation activities as a result of the impending launch in the US. During the quarter, the company had legal counsel costs in the US as a result of the lawsuit brought by the reference company in February 2022. The parties reached a settlement in the legal dispute on September 11, 2023.

Other operating expenses

Other operating expenses totaled SEK -1,554 thousand (-1,295) for the third quarter and SEK -2,999 thousand (-2,688) for the January–September period. This item comprised exchange rate losses arising in conjunction with payments abroad and translations of the currency accounts.

Loss for the period

Loss for the period totaled SEK -38,942 thousand (-28,651) for the third quarter and SEK -125,171 thousand (-76,450) for the January–September period. This corresponds to earnings per share before dilution of SEK -1.59 (-1.39) and SEK -5.11 (-3.70) respectively. The earnings decrease for the quarter is attributable primarily to increased administration and sales expenses as a result of the market preparation activities stemming from the forthcoming launch in the US. In addition, research and development costs were expensed owing to preparatory activities for Dasynoc.

Cash flow

Cash flow from operating activities amounted to SEK -68,611 thousand (-23,091) in the quarter, of which the effect from working capital was SEK -33,459 thousand (3,277). The aggregate figure for the January–September period was SEK -170,649 thousand (-75,176), of which the effect from working capital was SEK -17,158 thousand (-5,476). The effect from working capital is linked primarily to changes in inventory of SEK -34,451 thousand (—) and changes in operating receivables of SEK -32,091 thousand (—). The negative cash flow is in accordance with the company's plan, and is primarily attributable to continued project costs, legal advisory services, and other preparatory activities prior to the company's forthcoming launch of Dasynoc.

Cash flow from investing activities amounted to SEK -14,470 thousand (-29,126) in the third quarter and SEK -45,147 thousand (-105,864) for the January–September period. The item includes capitalized development expenditure of SEK -8,550 thousand (-28,105) for the third quarter and SEK -37,095 thousand (-79,503) for the January–September period. The main reason for the decrease is that Dasynoc has now moved from a research and development-intensive project to preparatory activities ahead of the launch of Dasynoc, with costs not being capitalized but expensed on an ongoing basis.

Investment in property, plant and equipment totaled SEK -77 thousand (0) for the third quarter. During the quarter, advances continued to be paid for the construction of the company's new production unit in Malta.

Cash flow from financing activities amounted to SEK 184,018 thousand (-530) in the third quarter and SEK 228,110 thousand (-1,007) for the January–September period. The increase arose from the preferential rights issue that was carried out in July, with proceeds of SEK 250,636 thousand before transaction costs.

Total cash flow was SEK 100,937 thousand (-52,747) for the third quarter and SEK 12,314 thousand (-182,047) for the January–September period. The Group had SEK 132,480 thousand (89,834) in cash and cash equivalents on September 30, 2023.

Intangible assets

Capitalized development expenditure for the third quarter totaled SEK 8,779 thousand (28,356). The Group's total capitalized development expenditure amounted to SEK 423,405 thousand (376,506) on September 30, 2023. The item is associated with the company's product candidates Dasynoc, XS003 nilotinib and XS008 axitinib.

Financial position

The preferential rights issue that was announced in May was completed in July. The issuance generated proceeds of SEK 250,636 thousand before transaction costs for Xspray.

Apart from the subscription for new shares, the preferential rights issue included two warrant series: TO5, which expires on November 30, 2023, and TO6, which expires on May 2, 2024. Together, these could raise a further approximate SEK 250,636 thousand if fully subscribed and would result in a maximum dilution of 21.6 percent for existing shareholders.

Depending on the outcome of the two warrant series, there is a risk that the Group's cash and cash equivalents for the next 12 months will be insufficient. The company's capital requirement depends on several factors, including market uptake of its initial product candidate, Dasynoc, and the earnings from and costs for ongoing and future drug trials. In light of this, the Board of Directors is monitoring the situation and evaluating different financing options including the timing and scope for raising capital on the most advantageous terms possible for the company. The Board of Directors believes that a capital raise can be carried out.

The equity/assets ratio for the Group was 93.9 per cent (95.5) on September 30, 2023.

Group structure

The Group structure comprises the Parent Company, Pharma AB (publ), corporate identity number 556649-3671, and its wholly owned subsidiaries Xspray Pharma Futurum AB, corporate identity number 559178-7642, and Xspray Pharma Inc. The two Swedish limited liability companies have their offices in Solna, Sweden, and the US subsidiary has its offices in Delaware. The address of the head office is Råsundavägen 12, SE-169 67 Solna, Sweden.

In mid-September, Edward P. Jordan was hired as Chief Commercial Officer in Xspray Pharma Inc.

Parent Company

Operations were conducted primarily in the Parent Company, Xspray Pharma AB (publ). The Parent Company's cash and cash equivalents totaled SEK 132,430 thousand (89,784) and the equity/assets ratio was 94.0 percent (95.9) on September 30, 2023.

Employees

The organization expanded by one full-time position in the quarter compared with the preceding quarter. The new position was added to the subsidiary Xspray Pharma Inc. The number of employees in the Group on the balance sheet date totaled 26 (26).

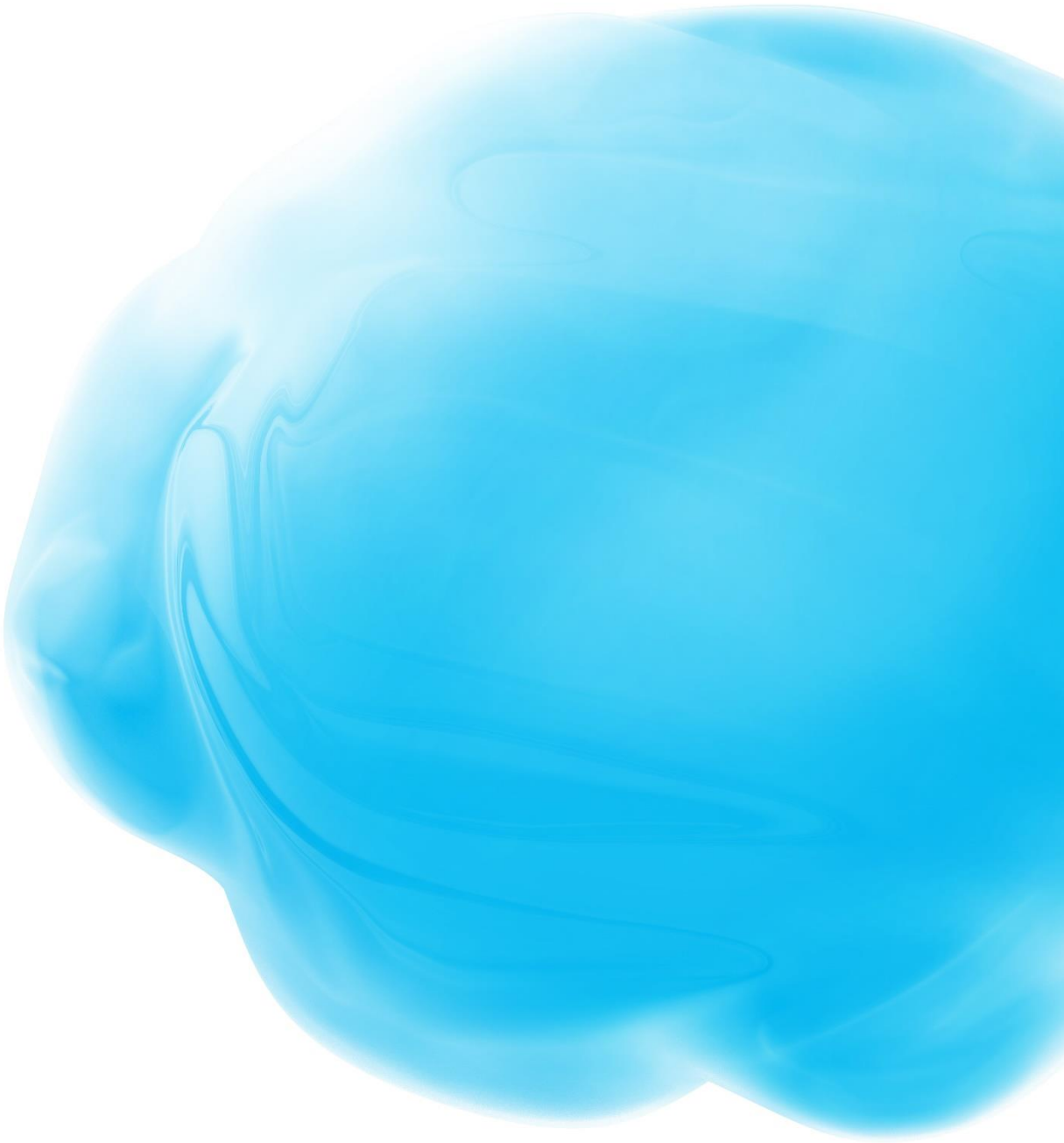
Related-party transactions

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

The company purchased consulting services from Stratfox Healthcare Group LLC, which is owned by the company's Board member Robert Molander. The total fees amounted to SEK -161 thousand (—) for the third quarter and SEK -425 thousand (—) for the January–September period.

During the third quarter, the loan of SEK 45,000 thousand to Flerie Invest AB was settled against subscription for new shares in the preferential rights issue. The terms of the loan were on market conditions.

Financial statements



Consolidated income statement

	Q3		Jan-Sep		Full year
SEK thousand	2023	2022	2023	2022	2022
Net sales	-	-	-	-	-
Other operating income	29,203	333	30,463	1,100	2,180
Research and development expenses	-5,647	-1,704	-27,771	-5,120	-22,219
Administration and sales expenses	-61,237	-26,328	-125,579	-70,777	-109,601
Other operating expenses	-1,554	-1,295	-2,999	-2,688	-3,433
Operating loss	**-39,236**	**-28,994**	**-125,886**	**-77,486**	**-133,073**
					-
Finance income	412	352	1,390	1,048	1,415
Finance costs	-118	-9	-675	-12	-12
Finance net	**294**	**343**	**715**	**1,036**	**1,403**
					-
Loss before Income tax	-38,942	-28,651	-125,171	-76,450	-131,670
Tax	-	-	-	-	-
Loss for the period	**-38,942**	**-28,651**	**-125,171**	**-76,450**	**-131,670**
					-
Earnings per share for the period before dilution, SEK	-1.59	-1.39	-5.11	-3.70	-6.25
Earnings per share for the period after dilution, SEK	-1.59	-1.39	-5.11	-3.70	-6.25
Average number of shares before dilution	24,516,567	20,680,408	24,516,567	20,680,408	21,070,518
Average number of shares after dilution	24,516,567	20,680,408	24,516,567	20,680,408	21,070,518

Consolidated statement of comprehensive income

	Q3		Jan-Sep		Full year
SEK thousand	2023	2022	2023	2022	2022
Loss for the period	-38,942	-28,651	-125,171	-76,450	-131,670
Other comprehensive income	-	-	-	-	-
Total comprehensive income for the period	**-38,942**	**-28,651**	**-125,171**	**-76,450**	**-131,670**

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

Consolidated balance sheet

SEK thousand	30 Sep 2023	30 Sep 2022	31 Dec 2022
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	423,405	376,506	385,597
Total intangible assets	423,405	376,506	385,597
Property, plant and equipment			
Machinery and installations	9,838	16,962	15,407
Right-of-use assets	799	2,540	2,477
Equipment	71	254	147
Fixed assets under construction and prepayments	55,373	44,608	46,573
Total Property, plant and equipment	66,082	64,364	64,603
Financial assets			
Financial investments	1	1	1
Other long-term receivables	2,999	-	2,999
Total financial assets	3,000	1	3,000
Total non-current assets	492,487	440,871	453,200
Current assets			
Inventories	43,003	4,975	8,552
Current receivables	3,839	2,675	2,362
Accounts receivable	860	-	-
Prepaid expenses and accured income	30,637	1,614	1,150
Cash and cash equivalents	132,480	89,834	120,166
Total current assets	210,818	99,098	132,229
TOTAL ASSETS	703,305	539,969	585,430

Consolidated balance sheet cont.

SEK thousand	30 Sep 2023	30 Sep 2022	31 Dec 2022
EQUITY AND LIABILITIES			
Equity			
Share capital	28,946	20,680	22,680
Other contributed capital	1,130,721	814,047	907,420
Reserves	982	976	976
Retained earnings including profit/loss for the period	-500,229	-319,837	-375,057
Total equity attributable to the Parent Company's shareholders	**660,420**	**515,867**	**556,019**
Non–current liabilities			
Lease liabilities	302	323	560
Total non-current liabilities	**302**	**323**	**560**
Current liabilities			
Trade accounts payable	16,092	11,971	14,786
Lease liabilities	366	1,888	1,566
Other current liabilities	5,866	1,322	1,043
Accrued expenses and deferred income	20,258	8,598	11,456
Total current liabilities	**42,583**	**23,779**	**28,851**
TOTAL EQUITY AND LIABILITIES	703,305	539,969	585,430

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, 2022	20,680	813,483	976	-243,387	591,752
Loss of the period	-	-	-	-131,670	-131,670
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	-	-	-	-131,670	-131,670
New share issue	2,000	98,000	-	-	100,000
Transaction costs	-	-4 876	-	-	-4,876
Redemption of warrants	-	-52	-	-	-52
Warrant program	-	865	-	-	865
Closing balance as of December 31, 2022	22,680	907,420	976	-375,057	556,019

Opening balance as of Januar 1, 2023	22,680	907,420	976	-375,057	556,019
Loss of the period	-	-	-	-125,171	-125,171
Other comprehensive income for the period	-	-	-	-	-
Total comprehensive income for the period	-	-	-	-125,171	-125,171
New share issue	6,266	244,370	-	-	250,636
Transaction costs	-	-21,591	-	-	-21,591
Redemption of warrants	-	522	-	-	522
Warrant program	-	-	6	-	6
Closing balance as of September 30, 2023	28,946	1,130,721	982	-500,229	660,420

Consolidated cash flow statement

	Q3		Jan-Sep		Full year
SEK thousand	2023	2022	2023	2022	2022
Operating activities					
Operating loss	**-39,236**	**-28,994**	**-125,886**	**-77,486**	**-133,073**
Non-cash adjustments					
Depreciation	2,230	2,399	6,745	7,107	9,533
Interest received	280	267	831	799	1,611
Interest paid	-706	-40	-730	-120	-147
Cash flow from operating activities before changes in working capital	**-37,432**	**-26,368**	**-119,040**	**-69,700**	**-106,604**
Changes in working capital					
Change in inventory	2,280	-	-34,451	-	-
Change in operating receivables	-31,141	-241	-32,091	551	-2,942
Change in operating liabilities	-2,318	3,518	14,933	-6,027	-633
Cash flow from operating activities	**-68,611**		**-170,649**	**-75,176**	**-110,179**
Investing activities					
Capitalized development costs	-8,550	-28,105	-37,095	-79,503	-103,820
Acquisition of property, plant and equipment	-77	-	-77	-23,334	-24,466
Prepayments	-5,843	-1,021	-7,975	-3,027	-7,059
Cash flow from investing activities	**-14,470**	**-29,126**	**-45,147**	**-105,864**	**-135,345**
Financing activities					
New share issue	205,636	-	205,636	-	100,000
Loan raised*	-	-	45,000	-	-
Transaction costs	-21,338	-	-21,590	-300	-4,876
Payment of lease liability	-280	-530	-1,458	-1,572	-2,128
Repurchased warrants	-	-	-	-	-52
Allocated warrants	-	-	522	865	865
Cash flow from financing activities	**184,018**	**-530**	**228,110**	**-1,007**	**93,809**
Cash flow for the period	**100,937**	**-52,747**	**12,314**	**-182,047**	**-151,715**
Cash and cash equivalents at the beginning of the period	31,543	142,581	120,166	271,881	271,881
Cash and cash equivalents at the end of the period	**132,480**	**89,834**	**132,480**	**89,834**	**120,166**

*In addition to SEK 205,636 thousand, SEK 45,000 thousand from loans raised was contributed in the set-off issue during the period.

Parent Company income statement

	Q3		Jan-Sep		Full year
SEK thousand	2023	2022	2023	2022	2022
Net sales	-	-	-	-	-
Other operating income	29,203	333	30,463	1,100	2,180
Research and development expenses	-5,799	-1,800	-28,191	-5,398	-22,592
Administration and sales expenses	-61,009	-26,355	-125,413	-70,858	-109,710
Other operating expenses	-1,503	-1,317	-3,038	-2,733	-3,500
Operating loss	**-39,108**	**-29,139**	**-126,178**	**-77,890**	**-133,622**
Finance income	132	146	602	475	617
Finance costs	-118	-9	-675	-12	-12
Finance net	**14**	**137**	**-73**	**463**	**605**
Loss before Income tax	-39,094	-29,001	-126,251	-77,426	-133,017
Tax	-	-	-	-	-
Loss for the period	**-39,094**	**-29,001**	**-126,251**	**-77,426**	**-133,017**
Average number of shares before dilution	24,516,567	20,680,408	24,516,567	20,680,408	21,070,518
Average number of shares after dilution	24,516,567	20,680,408	24,516,567	20,680,408	21,070,518

Parent Company balance sheet

SEK thousand	30 Sep 2023	30 Sep 2022	31 Dec 2022
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development costs	422,341	375,953	384,944
Total intangible assets	422,341	375,953	384,944
Property, plant and equipment			
Machinery and installations	9,838	16,962	15,407
Equipment	71	254	147
Fixed assets under construction and prepayments	53,358	43,666	45,383
Total Property, plant and equipment	63,267	60,882	60,936
Financial assets			
Shares in subsidiaries	50	50	50
Financial investments	1	1	1
Other long-term receivables	2,999	-	2,999
Total financial assets	3,050	51	3,050
Total non-current assets	488,658	436,886	448,930
Current assets			
Inventories	43,003	4,975	8,552
Current receivables			
Accounts receivables	860	-	-
Other current receivables	4,060	2,675	2,362
Prepaid expenses and accured income	30,798	2,096	1,632
Total current receivables	35,717	4,771	3,994
Cash and bank	132,430	89,784	120,116
Total current assets	211,150	99,530	132,661
TOTAL ASSETS	699,808	536,416	581,592

Parent Company balance sheet cont.

SEK thousand	30 Sep 2023	30 Sep 2022	31 Dec 2022
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	28,946	20,680	22,680
Statutory reserve	976	976	976
Development expenditure reserve	422,341	375,953	384,944
Total restricted equity	**452,264**	**397,610**	**408,601**
Non-restricted equity			
Other contributed capital	1,130,721	814,047	907,420
Accumulated earnings	-799,111	-619,706	-628,697
Profit/loss for the period	-126,251	-77,426	-133,017
Total non-restricted equity	**205,359**	**116,915**	**145,705**
Total equity	**657,623**	**514,525**	**554,306**
Current liabilities			
Trade accounts payable	16,061	11,971	14,786
Other current liabilities	5,866	1,322	1,043
Accrued expenses and deferred income	20,258	8,598	11,456
Total current liabilities	**42,185**	**21,891**	**27,285**
TOTAL EQUITY AND LIABILITIES	**699,808**	**536,416**	**581,592**

Parent Company cash flow statement

	Q3		Jan-Sep		Full year
SEK thousand	2023	2022	2023	2022	2022
Operating activities					
Operating loss	**-39,108**	**-29,139**	**-126,178**	**-77,890**	**-133,622**
Non-cash adjustments					
Depreciation	1,885	2,106	5,721	6,229	8,341
Disposal of intangible fixed assets	-	-	-	-	15,472
Interest received	-	61	43	61	647
Interest paid	-675	-9	-675	-12	-12
Cash flow from operating activities before changes in working capital	**-37,898**	**-26,981**	**-121,089**	**-71,612**	**-109,174**
Changes in working capital					
Changes in inventory	2,280	-	-34,451	-	-
Change in operating receivables	-30,812	-14	-31,163	1,334	-1,911
Change in operating liabilities	-2,372	3,519	14,899	-6,026	-631
Cash flow from operating activities	**-68,802**	**-23,476**	**-171,804**	**-76,304**	**-111,716**
Investing activities					
Purchase of intangible assets	-8,639	-28,250	-37,398	-79,948	-104,411
Sales of tangible fixed assets	-	-	-	-	-
Prepayments	-5,843	-1,021	-7,975	-3,027	-7,059
Cash flow from investing activities	**-14,559**	**-29,271**	**-45,450**	**-106,309**	**-135,936**
Financing activities					
New share issue	205,636	-	205,636	-	100,000
Transaction costs	-21,338	-	-21,590	-300	-4,876
Loan raised*	-	-	45,000	-	-
Repurchased warrants	-	-	-	-	-52
Allocated warrants	-	-	522	865	865
Cash flow from financing activities	**184,298**	**-**	**229,568**	**565**	**95,937**
Cash flow for the period	**100,937**	**-52,747**	**12,314**	**-182,048**	**-151,715**
Cash and cash equivalents at the beginning of the period	31,493	142,531	120,116	271,831	271,831
Cash and cash equivalents at the end of the period	**132,430**	**89,784**	**132,430**	**89,784**	**120,116**

*In addition to SEK 205,636 thousand, SEK 45,000 thousand from loans raised was contributed in the set-off issue during the period.

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 2022 have been applied. The changes in IFRS applied as of January 1, 2023 have not had any impact on the financial statements for the third quarter of 2023. Comparison figures are presented in parentheses and pertain to the same period in 2022.

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 expenditure". Determining whether the requirements for capitalization of development expenditure 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. During the period, the company resolved the patent dispute with Bristol Myers Squibb (BMS) regarding Dasynoc. The settlement has removed the legal risk and its uncertainties linked to the company's initial product candidate. Otherwise, the risks and uncertainties that the company reported in the Annual Report for 2022 remain.

Financing risk and going concern

The preferential rights issue that was announced in May was completed in July. The issue generated proceeds of approximately SEK 251 million before transaction costs for Xspray. The share issue included two warrant series with a subscription price of SEK 40 per share: TO5, which expires on November 30, 2023, and TO6, which expires on May 2, 2024. Together, these could raise a further approximate SEK 251 million if fully subscribed, with a maximum dilution of 21.6 percent to the current number of shares outstanding. The reason for including warrants in the offer was to increase visibility for investors since the warrants can be exercised at a later point in time when the company is expected to have achieved key milestones. The capital raised will be used to finance preparations ahead of Dasynoc's planned launch in the US as well as general corporate purposes, ongoing operating costs and the continued development of product candidates.

Depending on the outcome of the two warrant series, the Group's cash and cash equivalents for the next 12 months could be insufficient. The company's capital requirements depend on several factors, including market uptake of its initial product candidate, Dasynoc, and the earnings from and costs for ongoing and future product development. In light of this, the Board of Directors routinely monitors the company's capital situation and evaluates 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.

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 equity/assets ratio is equity as a percentage of the balance sheet total. Research and development costs as a percentage of operating expenses equate to 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.

Xspray Pharma in brief

Xspray Pharma AB (publ) is a pharmaceutical company with a number of product candidates under clinical development. Xspray Pharma uses its innovative, patented HyNap technology to develop improved versions of marketed protein kinase inhibitors (PKIs) for the treatment of cancer. The segment is the largest in the field of oncology, and drug prices are extremely high.

Using the company's innovative technology, Xspray Pharma can step in as the first competitor to the current original drugs before the originator company's secondary patents expire and the market opens up to generics, and in part over time offer similar substances with improved functionality compared with the original drugs. Xspray Pharma's goal is to be a leader in developing drugs that are improvements to PKIs being sold for the treatment of cancer, of which there were just over 80 in the US at the end of 2022.

Market

Protein kinase inhibitors (PKIs) have quickly become some of the most efficacious treatments of cancer, and for certain forms PKIs are one of few treatments available. The segment is the largest in the field of oncology with over 600 drug candidates in clinical development, of which around 230 are in the late clinical phase (Phase II or III), and just over 80 of them are approved drugs in the US market. The sale of PKI drugs in the US market in 2021 totaled roughly USD 33 billion. To date, Xspray Pharma has conducted initial testing on some twenty PKIs with the company's patented HyNap technology, with positive results.

Product candidates

Xspray Pharma's pipeline contains three announced product candidates. They are all based on the company's HyNap technology: Dasynoc, XS003 nilotinib and XS008 axitinib. These product candidates are stable amorphous and non-crystalline versions of three best-selling cancer drugs Sprycel® (dasatinib), Tasigna® (nilotinib) and Inlyta® (axitinib). Many protein kinase inhibitors are difficult to dissolve and their uptake in the body is pH-dependent, which often leads to a high degree of variability in uptake and unnecessarily high dose strengths for the patients. An amorphous formulation increases solubility, which leads to lesser variation in uptake and permits lower dosages to be administered to patients with retained efficacy, and thereby also with potentially lower levels of side effects.

The original drugs have secondary patents expiring between 2026 and 2032, and their total annual sales for 2022 exceeded USD 3.4 billion in the US market and USD 5.1 billion globally.[1]

Product candidate				Patent		Development phase					
Project	Substance	Key indication	Regulatory process	Substance IP expiration date	Secondary IP expiration date	New product evaluation	Development formulation	Pilot studies	Pivotal studies	Regulatory review	Original product/ Company
Dasynoc	dasatinib	Leukemia (CML, ALL)	505(b)(2)	Dec 2020	Sep 2026						Sprycel®/ BMS
XS003	nilotinib	Leukemia (CML)	505(b)(2)	Jan 2024	Oct 2032						Tasigna®/ Novartis
XS008	axitinib	Kidney cancer (RCC)	505(b)(2)	Apr 2025	Dec 2030						Inlyta®/ Pfizer
XS00Y	Not communicated										

[1] The information regarding annual sales has been taken from the reference companies' quarterly reports.

Share information

Xspray Pharma's share has been listed on Nasdaq Stockholm in the Small Cap segment under the symbol XSPRAY since March 27, 2020. Prior to that, the share was traded on Nasdaq First North Growth market beginning September 28, 2017. The number of shares in the company at September 30, 2023 was 28,946,300 and the closing price on that date was SEK 40.20.

Owners as of September 30, 2023	Number of shares	Number of shares & votes
Flerie Invest	4,619,170	15.96%
The Foundation for Baltic And East European Studies	3,367,626	11.63%
Anders Bladh (private & Ribbskottet)	3,296,432	11.39%
Fourth Swedish National Pension Fund	2,861,074	9.88%
Unionen	1,127,166	3.89%
Third Swedish National Pension Fund	1,066,666	3.68%
Nordnet Pension Insurance	974,714	3.37%
Avanza Pension	934,334	3.23%
Second Swedish National Pension Fund	829,760	2.87%
TIN Funds	560,000	1.93%
Total, ten largest owners	19,636,942	67.84%
Total, other shareholders	9,309,358	32.16%
Total number of shares	**28,946,300**	**100.00%**

Financial calendar 2023

Year-end Report Q4 2023	February 14, 2024

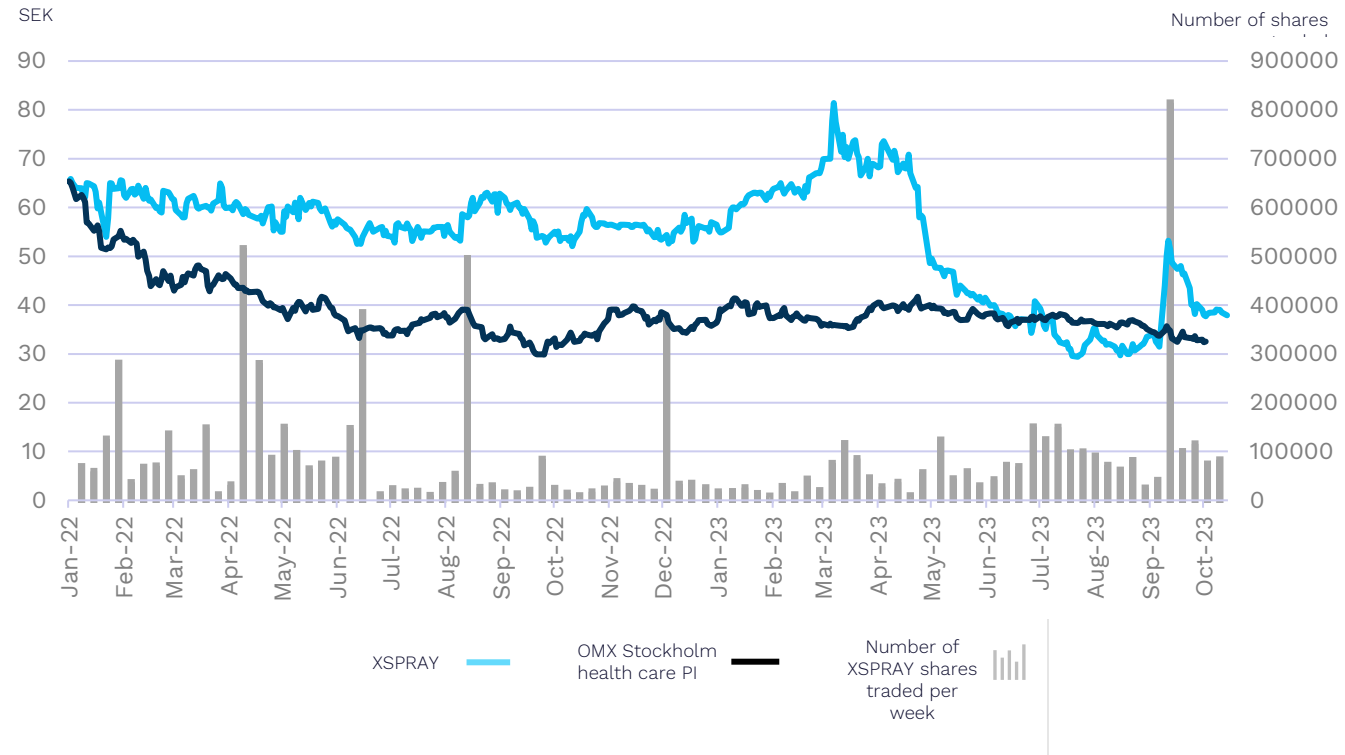
The financial reports are available on the Xspray Pharma website, www.xspraypharma.com.

Analysts monitoring the company

Filip Einarsson, Redeye AB

Dan Akschuti, Pareto Securities AB

Share price performance



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 8, 2023

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 2023 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 6) and in note 2 (page 17) which states that depending on the outcome of the two warrant series, there is a risk that the Group's cash and cash equivalents will be insufficient. It also states that the Board of Directors is monitoring the situation and evaluating different financing options 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 8 November 2023

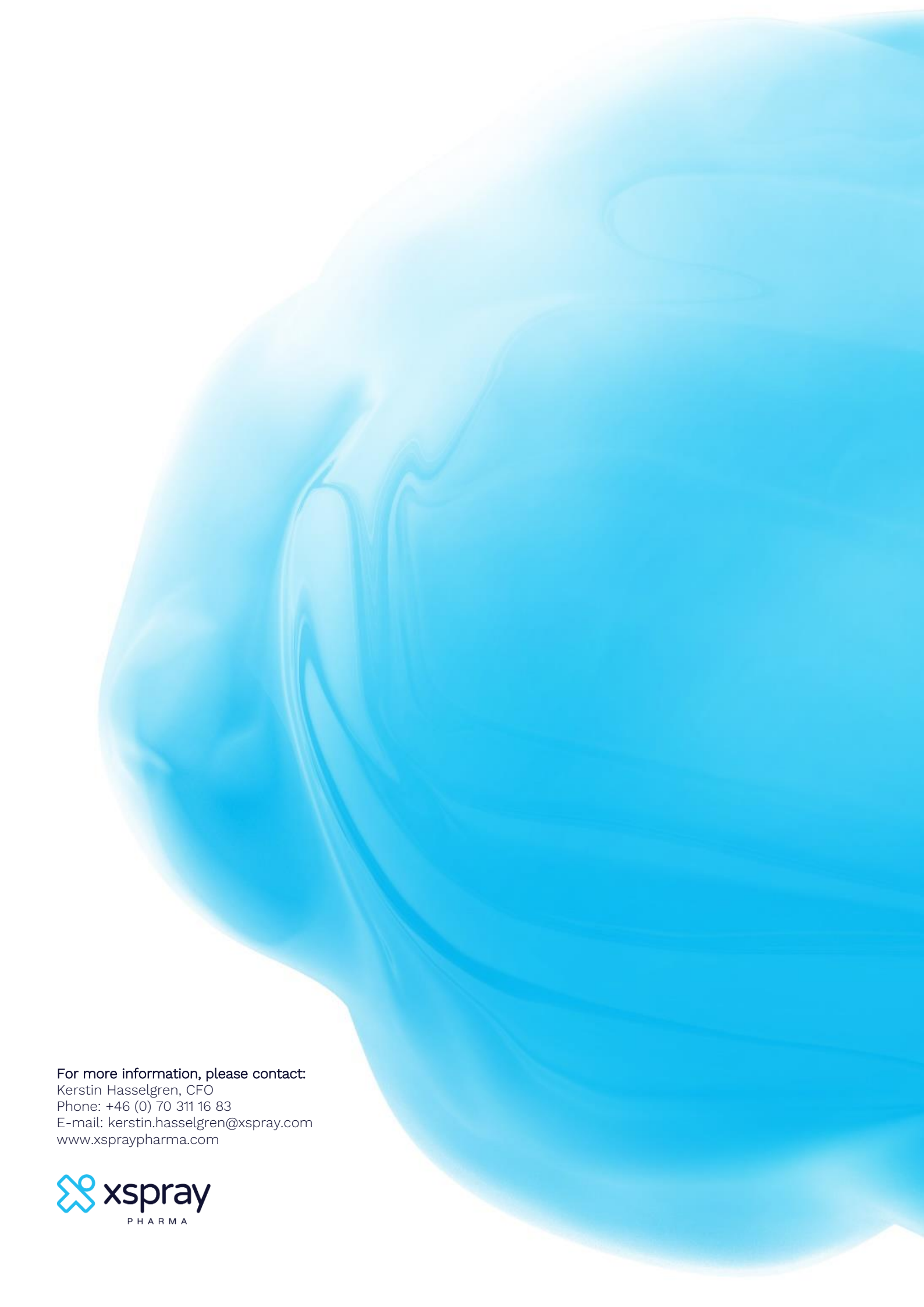
KPMG AB

Duane Swanson

Authorized Public Accountant

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.
Crystalline	A crystalline structure is a chemical term that describes an ordered structure among the molecules of the substance.
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.
Proton-pump inhibitor (PPI)	A proton-pump inhibitor is a group of drugs whose primary effect is a clear and long-lasting decrease in the production of stomach acid.
Tyrosine kinase inhibitors (TKI)	Tyrosine kinase inhibitors are a subgroup of Protein kinase inhibitors. The group of cancer drugs blocks growth-stimulating signals intracellularly.
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.



For more information, please contact:
Kerstin Hasselgren, CFO
Phone: +46 (0) 70 311 16 83
E-mail: kerstin.hasselgren@xspray.com
www.xspraypharma.com

xspray
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