

Xspray Pharma Interim report Q3

JANUARY–SEPTEMBER 2019

“It is with a high pace, dedication and broad expertise that Xspray's team continued to drive the development of our furthest progressed product candidate, HyNap-Dasa, towards our first ANDA application. HyNap-Dasa is an amorphous version of Sprycel® (dasatinib). The target of submitting an application to the US FDA during the summer of next year remains firm, as is the planned market launch in the US of HyNap-Dasa in 2021.”

Per Andersson, CEO
Xspray Pharma AB (publ)

Significant events during the third quarter 2019

- Xspray announced that the company aims to up-list to Nasdaq Stockholm in the first half of 2020
- The commercial manufacturing process of amorphous material on a commercial scale with Xspray's patented technology has been validated and tested for robustness by the company's Italian manufacturing partner

Significant events after the interim reporting period

- Xspray announced in October that the US Food and Drug Administration (FDA) has cleared the company's IND application for the product candidate HyNap-Dasa

July – September 2019, Group*

- Net sales amounted to SEK 0 thousand
- Earnings before tax amounted to SEK –10,583 thousand
- Earnings per share before dilution amounted to SEK -0.70
- Cash flow from operating activities totaled SEK –8,747 thousand

* Because no Group existed during the same period in the previous year, there are no comparative figures.

January – September 2019, Group*

- Net sales amounted to SEK 0 thousand
- Earnings before tax amounted to SEK –30,138 thousand
- Earnings per share before dilution amounted to SEK –2.00
- Cash flow from operating activities totaled SEK –22,692 thousand
- Cash and cash equivalents and current investments at the end of the period totaled SEK 130,657 thousand

July – September 2019, Parent Company**

- Net sales amounted to SEK 0 thousand (0)
- Earnings before tax amounted to SEK –10,587 thousand (–4,116)
- Earnings per share before dilution amounted to SEK –0.70 (–0.30)
- Cash flow from operating activities totaled SEK –8,281 thousand (–4,253)

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

January – September 2019, Parent Company**

- Net sales amounted to SEK 0 thousand (71)
- Earnings before tax totaled SEK –30,171 thousand (–12,501)
- Earnings per share before dilution amounted to SEK –2.00 (–0.93)
- Cash flow from operating activities totaled SEK –22,018 thousand (–11,859)
- Cash and cash equivalents and current investments at the end of the period totaled SEK 130,607 thousand (157,922)



A message from the CEO

It is with a high pace, dedication and broad expertise that Xspray's team continued to drive the development of our furthest progressed product candidate, HyNap-Dasa, towards our first ANDA application. HyNap-Dasa is an amorphous version of Sprycel® (dasatinib). The target of submitting an application to the US FDA during the summer of next year remains firm, as is the planned market launch in the US of HyNap-Dasa in 2021.

The regulatory preparation leading to a submission of an ANDA application (Abbreviated New Drug Application, United States Simplified Application Procedure for Generic Drugs) is very extensive. The work during the quarter resulted in a so-called IND (Investigational New Drug) application being submitted to the US FDA. The application relates to permits to produce materials for, and to perform clinical studies with, the product candidate HyNap-Dasa. We received approval from FDA at the end of October and have thus reached yet another important milestone. With the IND approval in place, we look forward to being able to start the registration-based studies with HyNap-Dasa shortly.

At our manufacturing partner in Milan, Italy, the focus is on the commercial production of amorphous material for the upcoming studies with HyNap-Dasa. The production plant in Milan is in full swing since the end of June and we expect an official approval from the Italian pharmaceutical authority AIFA in the coming months. In parallel, our contract manufacturer (CDMO) in the United States has begun to qualify the process for the manufacture of tablets, and a well-established clinical organization is working intensively on all preparations required for the upcoming clinical trials.

Xspray aims to become a long-term profitable company. Our view of our ability to achieve this is based on our HyNap technology being the best we have seen at improving the properties of already marketed protein kinase inhibitors. We base our business concept on the fact that the technology works for most of the 47 protein kinase inhibitors currently approved in the United States. The development and commercialization process that we are now establishing for our first product candidate,

HyNap-Dasa, will also be able to be applied to our future product candidates. The development time for each potential new product is thus judged to be shorter and the development cost lower.

The activities to find a commercial partner for HyNap-Dasa are in full swing. In general, we see that the interest from potential partners grows as a product candidate takes important steps nearing market approval. Such steps may include, for example, a validated manufacturing process, completed registrational studies, or a submitted ANDA application to the FDA. Our partner offering is based on two main scenarios. One of these is that a potential partner, by working with us, can prevent significant loss of revenue for an original drug, while at the same time being able to launch further developed and improved versions of the original drug. The second of these is that a potential partner can market and sell the product with the original drug as the sole competitor, thus building a strong position before the original drug patents expire, and other generic companies enter the market. The time to come will undoubtedly be exciting!

We have chosen to temporarily lay aside other work, such as the ongoing preparations for a list change to Nasdaq Stockholm's main list, in order to have our full force focused on the work in progress for a product registration and commercial work. The list change is now scheduled for the first half of 2020. I look forward to being able to implement the latter part of our business plan, to develop our first product for the market and to show profitability.

Solna, November 14, 2019
Per Andersson, CEO

Business focus and prospects

Xspray Pharma AB (publ) is a product development company with multiple product candidates in clinical development. Xspray uses its innovative, patented RightSize technology to develop improved and generic versions of marketed drugs, primarily protein kinase inhibitors (PKIs) for the treatment of cancer. Sales of the PKI drugs constitute around 25 percent of the total oncology market in a segment where drug prices are extremely high.

The innovative RightSize technology allows Xspray, through licensing to suitable pharmaceutical companies, to gain entry as the first competitor to today's original drugs before secondary patents expire. Xspray's goal is to become the leader in the development of improved drugs or generic versions of PKIs already marketed for the treatment of cancer. There are currently 47 marketed PKI drugs and the Company's leading product candidates, HyNap-Dasa, HyNap-Sora and HyNap-Nilo,

are stable amorphous versions of the three blockbuster cancer drugs Sprycel® (dasatinib), Nexavar® (sorafenib) and Tassigna® (nilotinib).

The launch of HyNap-Dasa, the first product candidate, is planned to take place in 2021. The substance patent for the original drug Sprycel® (dasatinib) expires at the end of 2020, and the secondary patents in 2026, which offers Xspray's HyNap-Dasa a period of several years in a unique position before other competitors gain access to the market. The Company has patented the manufacturing technology, the equipment and the resulting products.

The Company's development has proceeded according to plan and prospects for achieving its business plan targets are good.

Xspray has been listed on Nasdaq First North Growth Market since 2017 with Redeye as its Certified Adviser.

Launching during the current patent window

- Potential to launch product candidates after the expiration of the original drug's primary substance patent but before the expiration of the secondary product patents
- The original drug's secondary patents also give Xspray protection against the launch of competing products

Low development expenditure

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

Limited risk

- Proof-of-Concept demonstrated for the technology program
- The active substance is already known and tested for safety and efficacy
- Clear regulatory pathway to registration
- Unique technology and active patent strategy

Short development time

- Only 2 – 4 years from development to market launch
- Clinical studies in healthy volunteers sufficient for registration of generics – long-term patient studies are not necessary



Financial overview, Group

Key figures Group	Jul–Sep 2019	Jan–Sep 2019
Net sales (SEK thousand)	–	–
Operating loss (SEK thousand)	-10,704	-30,700
Earnings for the period (SEK thousand)	-10,583	-30,138
Earnings per share before dilution, SEK	-0.70	-2.00
Research and development costs as % of operating expenses	18.2%	17.0%
Cash and cash equivalents (SEK thousand)	130,657	130,657
Equity/assets ratio (%)	92.9%	92.9%
Average number of employees	17	13

Total research and development expenditures for the quarter amounted to SEK 24,754 thousand, of which SEK 1,952 thousand is expensed and SEK 22,802 thousand recorded as capitalized development cost.

Total research and development expenditures for the period January – September amounted to SEK 54,841 thousand, of which SEK 5,206 thousand is expensed and SEK 49,635 thousand is recorded as capitalized development cost.

Financial overview, Parent Company

Key figures mother company	Jul–Sep 2019	Jul–Sep 2018	Jan–Sep 2019	Jan–Sep 2018	Full-year 2018
Net sales (SEK thousand)	–	71	–	71	277
Operating loss (SEK thousand)	-10,708	-4,354	-30,733	-12,716	-23,217
Earnings for the period (SEK thousand)	-10,587	-4,116	-30,171	-12,501	-23,098
Earnings per share before dilution, SEK	-0.70	-0.30	-2.00	-0.93	-1.70
Research and development costs as % of operating expenses	18.0%	27.4%	16.8%	17.3%	23.6%
Cash and cash equivalents (SEK thousand)	130,607	157,922	130,607	157,922	221,216
Equity/assets ratio (%)	94.6%	97.8%	94.6%	97.8%	96.6%
Average number of employees	17	11	13	11	11

At the end of December 2018, Xspray Pharma AB (publ) acquired a newly incorporated subsidiary company, dormant for the time being, to prepare the Group for possible future structural needs. No business activity has taken place in the subsidiary; all business is pursued in the Parent Company Xspray Pharma AB (publ). Because the acquisition date was at the end of 2018 and no business activities were pursued in the subsidiary company, no consolidated income statement was presented for 2018, and there exists only a consolidated balance sheet on the closing date December 31, 2018. This as the number of transactions was limited and the 2018 operation as a whole was reported in the Parent Company's statements. The Parent Company's figures are therefore reported separately above to make comparisons between the periods easier.

Comments on the report

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

July – September 2019

The Group's operating expenses for the third quarter amounted to SEK –10,704 thousand. The costs consist mainly of administrative and sales costs which amount to SEK 8,472 thousand of the total operating costs. Of these, costs for lawyers and other advisers prior to the upcoming list change to Nasdaq Stockholm amount to SEK 1,446 thousand. In addition, personnel costs classified as administrative and sales costs amount to SEK 1,590 thousand. Finally, administrative and sales costs are charged with transport costs of SEK 942 thousand linked to the transport of materials to Xspray's contract manufacturers in different parts of the world, a cost that will be recurring as the development work enters a new phase, albeit at a slightly lower level.

The Group's expensed research and development costs for the period were SEK 1,952 thousand and capitalized development expenses were SEK 22,802 thousand.

January – September 2019

The Group's operating expenses for the first three quarters of the year amounted to SEK –30,700 thousand.

The costs consist mainly of administrative and sales costs, which amount to SEK 24,602 thousand of the total operating costs. Of these, costs for lawyers and auditors prior to the upcoming list change to Nasdaq Stockholm amount to SEK 4,209 thousand. Furthermore, the personnel costs that are classified as administrative and sales costs amount to SEK 6,751 thousand. Finally, the administration and sales costs include transport costs of SEK 1,107 thousand linked to the transport of materials to Xspray's contract manufacturers in different parts of the world.

Revenue and earnings

Net sales for the quarter and accumulated for the year continue to amount to SEK 0. Sales are not expected

to increase until 2021 when, according to the current business plan, the company intends to launch the first product onto the market.

The Group's operating losses for the third quarter amounted to SEK –10,704 thousand, which is in line with the operating loss for the second quarter of 2019. The corresponding figure for the Parent Company is SEK –10,708 thousand (–4,354). The increase in costs compared with the previous year is attributable to the planned increase in costs for the company's clinical program, and a strengthened organization.

Financial position

The company's operations are mainly financed by equity. The financial position of the company is sufficient for the coming twelve-month period with an acceptable and manageable level of risk in the product portfolio. The Board evaluates the company's financial needs and financial position on an ongoing basis and reviews the best capital structure for the company. The Board's assessment is that the company is well placed to bring in revenue during the next 12-month period through ongoing and future business development work to find a commercial partner for HyNap-Dasa, or otherwise secure future financing.

The equity/assets ratio was 92.9 percent as of September 30, 2019 in the Group and the corresponding figure for the parent company was 94.6 percent (97.8).

Cash flow and investments

Total cash flow for the Group during the third quarter amounted to SEK –31,681 thousand. Cash flow from operating activities amounted to SEK –8,747 thousand, of which the effect from working capital was SEK –122 thousand.

Total cash flow for the parent company during the first quarter amounted to SEK –31,681 thousand (–13,893). Cash flow from operating activities amounted

to SEK –8,281 thousand (–4,253), of which the effect from changes in working capital amounted to SEK 524 thousand (–840).

Cash flow from investing activities and capitalized development expenses in the Group amounted to SEK –22,523 thousand, which is fully in line with expectations. The investment in tangible fixed assets amounted to SEK –375 thousand for the Group.

Cash flow from financing activities amounted to SEK –36 thousand for the Group, which is a direct effect of IFRS 16.

The Group had SEK 130,657 thousand in cash and cash equivalents and current investments as of September 30, 2019 and the corresponding figure for the parent company was SEK 130,607 thousand (157,922).

Intangible assets

Ongoing development expenses have been capitalized according to plan. Capitalized development costs for the third quarter in the Group amounted to SEK 22,802 thousand and the corresponding figure for the parent company amounted to SEK 22,780 thousand (9,441). As of September 30, 2019, the Group's capitalized expenses for development work and similar work amounted to SEK 121,485 thousand and the corresponding figure for the parent company was SEK 121,396 thousand (63,634).

Parent Company

At the end of 2018, the Parent Company acquired a newly incorporated subsidiary. No business activity took place in the subsidiary during the period; all business is pursued in the Parent Company Xspray Pharma AB (publ).

Related Party Transactions

The company's Chairman of the Board carries out consultancy assignments in business development and legal advice for the company. The cost for this in the quarter was SEK 29 thousand (90).

Corporate governance

After the statutory board meeting, the board appointed an audit committee tasked with assisting the board in oversight responsibilities and a remuneration committee tasked with assisting the board in matters concerning remuneration.

Share information

The share has been traded on Nasdaq First North Growth Market under the name XSPRAY since September 28, 2017. It was introduced at a price of SEK 22.00 per share. On September 30, 2019, the number of shares in the Company totaled 15,076,460. The share forms part of the following index: OMX Stockholm Pharma & Biotech PI

Incentive program

The Company has issued three options programs; see the 2018 Annual Report for details. No new incentive programs were adopted during the quarter.

Financial calendar

Year-end report, 2019

Date

February 20, 2020

Analysts covering the Company:

Jacob Svensson, Redeye

Owners as of September 30, 2019	Number of shares	Number of shares & votes
Östersjöstiftelsen	2,500,826	16.59%
Ribbskottet	1,670,000	11.08%
Swedbank Robur Fonder	1,250,000	8.29%
Fjärde AP-fonden	870,000	5.77%
Catella Fonder	837,024	5.55%
Avanza Pension	625,002	4.15%
Unionen	600,000	3.98%
Familjen Niclas Eriksson	493,000	3.27%
Danica Pension	381,227	2.53%
Länsförsäkringar Fonder	378,585	2.51%
Total, ten largest owners	9,605,664	63.72%
Total, other shareholders	5,470,796	36.28%
Total number of shares	15,076,460	100.00%

Consolidated income statement

SEK thousands	Jul-Sep 2019	Jan-Sep 2019
Net sales	–	–
Research and development expenses	-1,952	-5,206
Administration and sales expenses	-8,472	-24,602
Other operating income	18	83
Other operating expenses	-298	-975
Operating loss	-10,704	-30,700
Finance income	121	607
Finance costs	–	-45
Finance net	121	562
Loss before income tax	-10,583	-30,138
Tax	–	–
Profit for the period	-10,583	-30,138
Earnings per share for the period before dilution, SEK	-0.70	-2.00
Earnings per share for the period after dilution, SEK	-0.70	-2.00
Average number of shares before dilution	15,076,460	15,076,460
Average number of shares after dilution	15,765,556	15,765,556

Consolidated statement of comprehensive income

SEK thousands	Jul-Sep 2019	Jan-Sep 2019
Profit for the period	-10,583	-30,138
Other comprehensive income	–	–
Total comprehensive income for the period	-10,583	-30,138

Consolidated balance sheet

SEK thousands	Sep 30, 2019	Dec 31, 2018
ASSETS		
Non-current assets		
Intangible assets		
Capitalized development costs	121,485	71,850
Patent	11	43
Total intangible assets	121,496	71,893
Property, plant and equipment		
Machinery and installations	25,906	12,447
Right-of-use assets	7,297	–
Equipment	1,305	1,283
Total Property, plant and equipment	34,508	13,730
Financial assets		
Financial investments	1	1
Total financial assets	1	1
Total non-current assets	156,005	85,624
Current assets		
Current receivables	4,282	1,474
Current tax asset	366	201
Prepaid expenses and accrued income	928	3,920
Cash and cash equivalents	130,657	221,266
Total current assets	136,233	226,861
Total assets	292,238	312,485

Consolidated balance sheet *cont.*

SEK thousands	Sep 30, 2019	Dec 31, 2018
EQUITY AND LIABILITIES		
Equity		
Share capital	15,076	15,076
Other contributed capital	336,991	336,991
Reserves	976	976
Retained earnings including profit/loss for the period	-81,465	-51,327
Total equity attributable to the Parent Company's shareholders	271,578	301,716
Non-current liabilities		
Lease liabilities	5,164	–
Total non-current liabilities	5,164	–
Current liabilities		
Trade accounts payable	12,163	7,780
Lease liabilities	139	–
Other current liabilities	887	1,301
Accrued expenses and deferred income	2,307	1,688
Total current liabilities	15,496	10,769
TOTAL EQUITY AND LIABILITIES	292,238	312,485

Consolidated statement of changes in equity

SEK thousands	Share capital	Other contributed capital	Reserves	Retained earnings incl profit/loss for the period	Total equity
Opening balance per January 1, 2019	15,076	336,991	976	-51,327	301,716
Profit/loss for the period				-30,138	-30,138
Other comprehensive income for the period				0	0
Closing balane as of September 30, 2019	15,076	336,991	976	-81,465	271,578

Consolidated statement of cash flow

SEK thousands	Jul–Sep 2019	Jan–Sep 2019
Operating activities		
Operating loss	-10,704	-30,700
Non-cash adjustments		
Depreciation and Amortization	2,142	6,300
Other items that do not affect liquidity	–	166
Interest received	–	257
Interest paid	-63	-108
Cash flow from operating activities before changes in working capital	-8,625	-24,085
Changes in working capital		
Change in operating receivables	-425	-3,195
Change in operating liabilities	303	4,588
Cash flow from operating activities	-8,747	-22,692
Investing activities		
Capitalised development expenditure	-22,523	-48,802
Acquisition of other intangible assets	–	–
Acquisition of property, plant and equipment	-375	-19,044
Cash flow from investing activities	-22,898	-67,846
Financing activities		
Payment of lease liability	-36	-71
Cash flow from financing activities	-36	-71
Cash flow for the period	-31,681	-90,609
Cash and cash equivalents at the beginning of the period	162,338	221,266
Cash and cash equivalents at the end of the period	130,657	130,657

Parent Company Income statement

SEK thousands	Jul-Sep 2019	Jul-Sep 2018	Jan-Sep 2019	Jan-Sep 2018	Full-year 2018
Net sales	-	71	-	71	277
Research and development expenses	-1,932	-1,212	-5,172	-2,210	-5,536
Administration and sales expenses	-8,496	-3,127	-24,669	-9,660	-16,967
Other operating income	18	13	83	44	86
Other operating expenses	-298	-99	-975	-961	-1,077
Operating loss	-10,708	-4,354	-30,733	-12,716	-23,217
Interest income and similar items	121	238	607	215	150
Interest expenses and similar items	-	-	-45	-	-31
Finance net	121	238	562	215	119
Profit/loss before income tax	-10,587	-4,116	-30,171	-12,501	-23,098
Tax	-	-	-	-	-
Profit/loss for the period	-10,587	-4,116	-30,171	-12,501	-23,098
Earnings per share for the period before dilution, SEK	-0.70	-0.30	-2.00	-0.93	-1.70
Earnings per share for the period after dilution, SEK	-0.70	-0.30	-2.00	-0.93	-1.70
Average number of shares before dilution	15,076,460	13,706,460	15,076,460	13,429,537	13,593,172
Average number of shares after dilution	15,765,556	14,161,051	15,765,556	13,884,128	14,055,472

Parent Company balance sheet

SEK thousands	Sep 30, 2019	Sep 30, 2018	Dec 31, 2018
ASSETS			
Non-current			
Intangible assets			
Capitalized development costs	121,396	63,634	71,850
Patent	11	137	43
Total intangible assets	121,407	63,771	71,893
Property, plant and equipment			
Machinery and installations	25,906	6,792	12,447
Equipment	1,305	403	1,283
Total property, plant and equipment	27,211	7,195	13,730
Financial assets			
Shares in subsidiaries	50		50
Financial investments	1	1	1
Total financial assets	51	1	51
Total non-current assets	148,669	70,967	85,674
Current assets			
Current receivables			
Current tax asset	366	540	201
Other current receivables	4,282	886	1,474
Prepaid expenses and accrued income	2,978	707	3,920
Total current receivables	7,626	2,133	5,595
Cash and bank	130,607	157,922	221,216
Total current assets	138,233	160,055	226,811
TOTAL ASSETS	286,902	231,022	312,485

Parent Company balance sheet *cont.*

SEK thousands	Sep 30, 2019	Sep 30, 2018	Dec 31, 2018
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	15,076	13,706	15,076
Development expenditure reserve	121,396	63,634	71,850
Statutory reserve	976	976	976
Total restricted equity	137,448	78,316	87,902
Non-restricted equity			
Accumulated earnings	-172,723	-90,559	-100,079
Other contributed capital	336,991	250,725	336,991
Profit/loss for the period	-30,171	-12,501	-23,098
Total non-restricted equity	134,097	147,665	213,814
Total equity	271,545	225,981	301,716
Current liabilities			
Trade accounts payable	12,163	2,865	7,780
Other current liabilities	887	750	1,301
Accrued expenses and deferred income	2,307	1,426	1,688
Total current liabilities	15,357	5,041	10,769
TOTAL EQUITY AND LIABILITIES	286,902	231,022	312,485

Parent Company statement of cash flow

SEK thousands	Jul–Sep 2019	Jul–Sep 2018	Jan–Sep 2019	Jan–Sep 2018	Full-year 2018
Operating activities					
Operating loss	-10,708	-4,355	-30,733	-12,717	-23,217
Non-cash adjustments					
Depreciation	1,903	703	5,596	1,657	4,101
Interest received	0	239	257	239	150
Interest paid	0	0	-45	-23	-31
Cash flow from operating activities before changes in working capital	-8,805	-3,413	-24,925	-10,844	-18,997
Changes in working capital					
Change in operating receivables	220	-49	-1,681	-303	-3,765
Change in operating liabilities	304	-791	4,588	-712	5,016
Cash flow from operating activities	-8,281	-4,253	-22,018	-11,859	-17,746
Investment activities					
Purchase of intangible assets	-23,024	-8,137	-49,546	-22,444	-31,965
Purchase of property, plant and equipment	-376	-1,503	-19,045	-6,109	-14,993
Other financial assets					-50
Cash flow from investment activities	-23,400	-9,640	-68,591	-28,553	-47,008
Financing activities					
New share issue				82,822	170,458
Cash flow from investment activities	0	0	0	82,822	170,458
Cash flow for the period	-31,681	-13,893	-90,609	42,410	105,704
Cash and cash equivalents at the beginning of the period	162,288	171,815	221,216	115,512	115,512
Cash and cash equivalents at the end of the period	130,607	157,922	130,607	157,922	221,216

Note 1. Accounting and valuation principles

General information, a change in accounting policies and compliance with IAS 34. This interim report was prepared according to the Swedish Annual Accounts Act and IAS 34 Interim Financial Reporting. The same accounting principles and methods as used in the annual report 2018 are valid for this interim report with the exception of the changes specified below.

During the fourth quarter of 2018, the company transitioned to apply the IFRS regulations with the adjustments required under RFR2 Accounting for Legal Entities. The company then switched to a function-based presentation form for the results (income statement).

The effects of the change in presentation are given in more detail in Note 3.

In previous periods, the financial reports have been prepared in accordance with the Swedish Annual Accounts Act and K3.

For further information regarding the changes in accounting principles following the transition to IFRS, see the company's annual report for 2018.

Xspray Pharma AB (publ) acquired a newly formed subsidiary, which is currently dormant, at the end of December 2018 to prepare the Group structure for possible future structural needs. No operations in the subsidiary have taken place, but all operations are conducted in the parent company Xspray Pharma AB (publ). As the acquisition date was at the end of 2018, and no business was conducted in the subsidiary, no consolidated income statement for 2018 is supplied. This provided a more accurate picture of the business as the number of transactions was limited and the entire business in 2018 was therefore reported in the parent company's reports. The consolidated balance sheet was prepared as of the balance sheet date December 31, 2018.

As of January 1, 2019, IAS 17 Leasing is replaced by IFRS 16 Leasing.

According to the new standard, leasing agreements must be recognized in the balance sheet as a right to use an asset and an obligation to pay for this right. Depreciation of the asset is reported in the income statement as is an interest on the lease debt. Leasing fees paid are reported partly as payment of interest and partly as amortization of the lease debt. The standard exempts leases with a lease period of less than 12 months (short-term leases) and leases for assets with a low value. The leasing agreements reported in accordance with IFRS 16 are leases for premises for both R&D and administrative work as well as cars.

The Group applies the simplified transition method, which means, among other things, that a combined effect will not be reported until 1 January 2019, and no recalculation of the comparative figures for 2018 is made. The Group has applied the relief rules that are allowed the first

time IFRS 16 is applied, which includes reporting leases with a remaining lease term of less than 12 months as of January 1, 2019 as short-term leasing agreements. After the transition period, the Group will also apply the relief rules for accounting for leases with a lease period of no more than 12 months and leases of low value as a linear cost in the income statement. The calculations for the transition were that the Group's assets with rights of use as of January 1, 2019, after deduction of prepaid rents, amounted to SEK 8,769 thousand.

The new standard, IFRS 16 Leasing Agreement, had a negative impact on depreciation of SEK 716 thousand during the period January to September 2019 after deduction of depreciation of SEK 646 thousand which has been capitalized in the item balanced development expenses. Furthermore, the application of the standard has had a positive impact on administrative and sales costs, as well as research and development costs, with a total of SEK 749 thousand through the third quarter, which is why a positive net effect on operating profit of SEK 33 thousand has arisen.

Interest expenses related to leasing liabilities amount to SEK 186 thousand through the third quarter, which has been fully capitalized in the item balanced development expenses.

In the parent company, the exception is applied in RFR 2 regarding leasing agreements. In the Parent Company, all leasing agreements are reported in accordance with the rules for operational leasing. This means that the parent company's principles for accounting for leasing contracts will remain unchanged.

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

Key ratios, definitions

Earnings per share is calculated as net income divided by the average number of shares during the period. The equity/assets ratio is equity, and where applicable untaxed reserves (less deferred tax), in relation to total assets.

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

Note 2. Significant estimates and assumptions

When preparing interim reports, the Board and the CEO must, in accordance with the applicable accounting and valuation principles, make certain estimates, assessments and assumptions that affect the recognition and valuation of assets, provisions, liabilities, income and expenses. The outcome may deviate from these estimates and assessments and will very rarely amount to the same sum as the estimated outcome.

Significant risks and uncertainties

Xspray Pharma's operations are associated with both industry-related risks, and company-specific risks. The Company develops drug candidates and there will always be regulatory, market and financial risks in the business. There have been no significant changes in risks and uncertainties during the period compared to those published by the Company in the 2018 Annual Report and in connection with its listing on First North on September 28, 2017.

Note 3. Effects of changes in accounting layout

Xspray Pharma switched to applying IFRS with the adjustments required by RFR 2 Accounting for Legal Entities. Because the Company also switched its accounting to reflect the function of costs instead of their types, a function-based income statement is presented. The interim report has been prepared according to IAS 34 Interim Financial Reporting.

At the end of December, Xspray Pharma AB (publ) acquired a newly incorporated subsidiary, dormant for the time being, and thus reports as a group. In addition to IFRS, the Group also complies with Swedish Financial Reporting Board recommendations, RFR 1. During

previous periods, financial statements were prepared in accordance with the Swedish Annual Accounts Act and K3. The Group uses cost for balance sheet item valuation unless otherwise stated.

The consequences of the transition to the new accounting standard are shown in their entirety in the 2018 annual report. The Company has also switched from a cost-based to a function-based income statement. The effects of the converted income statement for the Parent company on the income statement are shown below.

Income statement

SEK thousands	Restated July – September	Reclassi- fication	Before translation July – September	Restated January – September	Reclassi- fication	Before translation January – September
Operating income						
Net sales	71		71	71	0	71
Capitalized work on own account	0	-8,137	8,137	0	-22,444	22,444
Other operating income	0	-12	12	0	-44	44
Total operating income	71	-8,149	8,220	71	-22,488	22,559
Operating expenses						
Raw materials & necessities	0	6,241	-6,241	0	16,050	-16,050
Other external expenses	0	1,847	-1,847	0	6,926	-6,926
Employee expenses	0	3,686	-3,686	0	10,096	-10,096
Amortization & impairment of tangible & intangible fixed assets	0	703	-703	0	1,657	-1,657
Sales & administration expenses	-3,127	-3,127	0	-9,660	-9,660	0
Research and development expenses	-1,212	-1,212	0	-2,210	-2,209	0
Other operating income	13	13		44	44	0
Other operating expenses	-99	-1	-98	-961	-415	-546
Total operating expenses	-4,425	8,150	-12,575	-12,787	22,489	-35,275
Operating loss	-4,354	1	-4,355	-12,716	1	-12,716
Earnings from financial items	238	-1	239	215	-1	216
Earnings after financial items	-4,116	0	-4,116	-12,501	0	-12,500
Profit/loss for the period	-4,116	0	-4,116	-12,501	0	-12,500

Certification by the Board

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

Solna, November 14, 2019

Michael Wolff Jensen
Chairman

Hans Arwidsson
Member

Gunnar Gårdemyr
Member

Maris Hartmanis
Member

Torbjörn Koivisto
Member

Christine Lind
Member

Carl-Johan Spak
Member

Per Andersson
Chief Executive Officer

This report has been reviewed by the company auditor.

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 2019 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of review

We conducted our review in accordance with International Standard on Review Engagements ISRE 2410 Review of Interim Financial Information Performed by the Independent Auditor of the Entity. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope

than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

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

Stockholm 14 November 2019

KPMG AB

Duane Swanson

Authorized Public Accountant

Information

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This information was made available through the offices of the above contact for publication on November 14, 2019 at 08:00 CET.

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