Xspray Pharma Interim Report Q2 2018

JANUARY–JUNE 2018

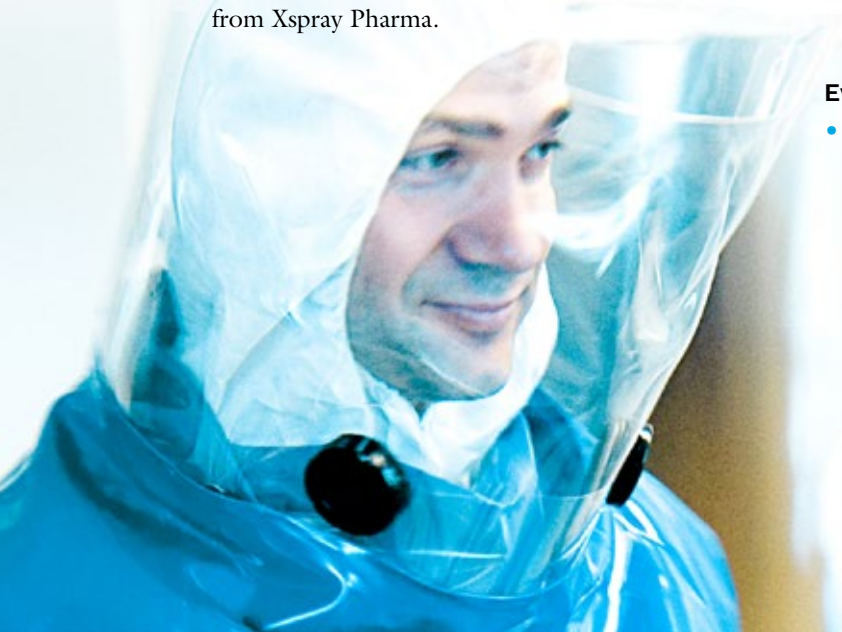
The second quarter involved continued intensive work for Xspray, primarily in-house. We executed the planned additions to our organization through successful recruitment work. I'm really satisfied with the competences the company has succeeded in bringing in. We improved all core competences necessary for late-stage drug development including regulatory affairs, quality and process validation.

Per Andersson, CEO
Xspray Pharma AB (publ)

Second quarter, April-June 2018

Figures in brackets are for the corresponding period of the previous year.

- Profit/loss before tax was SEK –6,789,000 (681,000).
- Net sales were SEK 0 (143,000)
- Earnings per share were SEK –0.50 (0.11).
- Cash flow from operating activities was SEK –4,343,000 (817,000).
- The Swedish Medical Products Agency granted Xspray Pharma a permit to execute a previously announced study on the formulation of the company's product candidate HyNap-Dasa, which will be conducted as planned in the third quarter.
- The Chairman of Xspray Pharma's Board, Michael Wolff Jensen, sold 4,000 shares in the period to cover Danish capital gains tax on unrealized gains from Xspray Pharma.



First half-year, January-June 2018

Figures in brackets are for the corresponding period of the previous year.

- Profit/loss before tax was SEK –8,384,000 (–5,652,000).
- Net sales were SEK 0 (212,000).
- Earnings per share were SEK –0.61 (–0.89).
- Cash flow from operating activities was SEK –7,606,000 (–6,651,000).
- Cash and cash equivalents were SEK 171,815,000 (12,024,000) at the end of the period.
- Total equity amounted to SEK 230,098,000 (40,822,000).
- Xspray Pharma executed a private placement of 1,350,000 shares, raising some SEK 88 m before issue expenses, to expand its product portfolio.
- The company hired Charlotta Liljebris as its new VP of Research & Development.

Events after 30 June 2018

- Xspray Pharma and NerPharMa delivered study materials to the clinical HyNap-Dasa trial, which then initiated. The preliminary results are expected during the third quarter of 2018.

CEO's statement

The second quarter involved continued intensive work for Xspray, primarily in-house. We executed the planned additions to our organization through successful recruitment work. I'm really satisfied with the competences the company has succeeded in bringing in. We improved all core competences necessary for late-stage drug development including regulatory affairs, quality and process validation.

Even after our hirings, Xspray has a lean and efficient organization with strong creativity, short decision-paths and high levels of personal commitment. Our new organization harbors specialist competences through our proprietary technology, and extensive drug development experience. Several of our new colleagues have participated in new product launches on the US and global markets, experience that will be crucial to our own upcoming product launches.

With our new organization in place, I'm looking forward to our work on next year's pivotal studies on the HyNap-Dasa project and our regulatory ANDA (Abbreviated New Drug Application). In June, the Swedish Medical Products Agency granted us a permit to conduct a study on the formulation of HyNap-Dasa, which is designed to confirm bio-equivalence of the optimized formulation that we have developed. We anticipate the results in the third quarter, which will be the foundation for forthcoming registration studies.

Our strategic pharmaceutical manufacturing partner in Milan, NerPharMa, delivered the first clinical trial material for the current pilot study in the quarter, exactly to plan. This collaboration commenced with a complex technology transfer that was executed rapidly. This partnership is going really well, and we are now working on scaling up the production process to commercial levels. NerPharMa has long-term experience of product manufacture in the cancer segment, and is a good complement to Xspray's in-house team.

Much of our work is focused on HyNap-Dasa, the generic version of dasatinib, marketed as Sprycel in the US. We have also made advances developing the formulation of HyNap-Sora. The amorphous solid dispersion process was optimized in the quarter, and technical and clinical trial material of the granulate has been produced for the clinical trial, which is scheduled for the fourth quarter 2018.

In parallel with the HyNap-Dasa and HyNap-Sora projects, we're conducting reviews and planning for upcoming projects, with HyNap-Nilo, an enhanced version of nilotinib/Tasigna, first up. We are continuing business intelligence and market research, and adapting our plans accordingly. Once the current scale-up and production of HyNap-Dasa are in place, this will pave the way for new products with the developed process for amorphous solid dispersion, which is unique to our technology.

Per Andersson, CEO
Solna, Sweden, 24 August 2018

Xspray Pharma Q2 2018

Business highlights in the quarter
In the period, the Swedish Medical Products Agency granted Xspray Pharma a permit to conduct a previously announced study on the formulation of the company's product candidate, HyNap-Dasa. This study is part of Xspray's clinical program, and will be executed in the third quarter as planned. Its purpose is to confirm bio-equivalence of the optimized formulation that Xspray has developed, based on its patented RightSize technology.

The Chairman of Xspray Pharma's Board, Michael Wolff Jensen, sold 4,000 shares in the period to cover Danish capital gains tax on unrealized gains from Xspray Pharma.

Business highlights after the end of the reporting period
Xspray Pharma and NerPharMa, Xspray's strategic contract manufacturing partner in Milan, delivered clinical study material to the HyNap-Dasa trial, which then initiated. The study's preliminary results are expected in the third quarter of 2018. HyNap-Dasa is one of three product candidates Xspray currently has in development. The company's target is to launch HyNap-Dasa on the US market in 2021.

Revenues
Net sales in the second quarter were SEK 0 (143,000). Net sales for the first half-year 2018 amounted to SEK 0 (212,000).

Expenses
Total expenses for the second quarter were SEK –14,764,000 (–8,829,000). Total expenses for the first half-year amounted to SEK –22,699,000 (–15,233,000).

Profit/loss
The company reported an operating loss of SEK –6,766,000 (682,000) in the second quarter. The net loss for the second quarter was SEK –6,789,000 (681,000). Earnings per share amounted to SEK –0.50 (0.11) for the second quarter 2018.

The company reported an operating loss of SEK –8,361,000 (–5,651,000) for the first half-year 2018. The net loss for the first half-year was SEK –8,384,000 (–5,652,000). Earnings per share amounted to SEK –0.61 (–0.89) for the first half-year 2018.

Intangible assets
Current development expenses have been capitalized according to plan. Work by the company for its own use and capitalized amounted to SEK 7,990,000 (9,366,000) in the quarter. Capitalized expenditure for development and similar work amounted to SEK 55,497,000 (28,690,000) as of 30 June 2018.

Work performed by the company for its own use and capitalized for the first half-year 2018 was SEK 14,307,000 (9,366,000).

Equity
Total equity amounted to SEK 230,098,000 (40,822,000) as of 30 June 2018. The total number of shares as of 30 June 2018 was 13,706,460.

Cash flow
Total cash flow for the second quarter was SEK –17,074,000 (–9,011,000). Cash flow from operating activities amounted to SEK –4,343,000 (817,000). The effect from working capital amounted to SEK 1,759,000 (–76,000).

Total cash flow for the first half-year 2018 was an inflow of SEK 56,303,000 (–16,779,000). Cash flow from operating activities amounted to SEK –7,606,000 (–6,651,000). The effect from working capital amounted to SEK –176,000 (–1,377,000).

Cash flow from investing activities amounted to SEK –18,913,000 (–10,128,000). Cash flow from financing activities amounted to SEK 82,822,000 (0).

At the end of the quarter, Xspray held cash and cash equivalents of SEK 171,815,000 (12,024,000).

Risks and uncertainties

Xspray Pharma's operations are associated with sector-related risks and company-specific risks. These risks are reviewed in detail in the prospectus the company published for its initial public offering on First North on 28 September 2017.

Share information

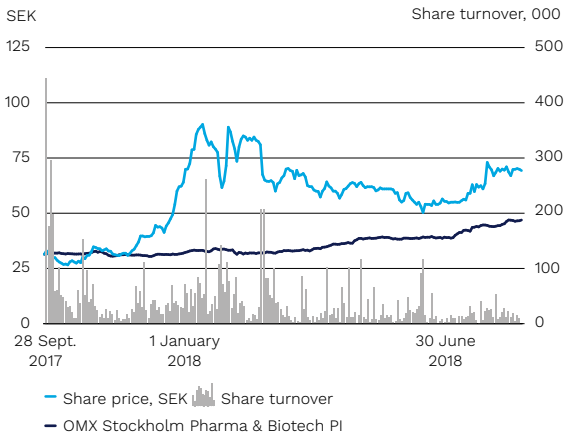
Xspray's share has traded on NASDAQ First North with the ticker XSPRAY since 28 September 2017. The share was floated at a price of SEK 22.00 per share. The number of shares of the company as of 30 June 2018 was 13,706,460.

In the period, the company executed a private placement of 1,350,000 new shares at a subscription price of SEK 65 per share, implying share capital increasing by SEK 1,350,000. This issue was addressed to a limited number of strategic and institutional investors, and raised the company some SEK 88 m before transaction expenses. The reason for waiving shareholders' preferential rights was to expand the company's institutional ownership base, whilst enabling prompt funding for the development of more product candidates. The dilution effect is some 9.8% of the number of shares and votes. The company has issued two classes of share warrants to senior managers.

The first warrant program consists of 255,000 share warrants with an exercise price of SEK 25.00 per share. These warrants can be exercised until 21 January 2021. Upon full exercise, these warrants imply maximum dilution of 1.99% based on the current number of shares. The second warrant program consists of 199,591 share warrants that can be exercised until August 2020, with a subscription price of SEK 49.30. This program implies a maximum dilution effect of 1.56% based on the current number of shares. The second program is conditional on the holder remaining an employee of the company.

The company's certified adviser is Redeye AB.

Share price and share turnover



Shareholders as of 30 June 2018	No. of shares	Proportion of shares & votes
Östersjö Foundation	2,500,826	18.2%
Vasastaden Holding AB	1,342,082	9.8%
Anders Bladh	1,141,200	8.3%
Swedbank Robur Fonder	1,140,000	8.3%
Catella Fonder	1,130,977	8.3%
Avanza Pension	720,163	5.2%
Kåre Gilstring	485,472	3.6%
Recipharm Venture Fund AB	474,838	3.5%
Danica Pension	319,162	2.3%
BNP Paribas Investment Partners	247,500	1.8%
Holdings, 10 largest shareholders	9,502,220	69.3%
Other shareholders	4,204,240	30.7%
Total no. of shares	**13,706,460**	**100%**

Financial calendar	Date
Interim Report Q3, Jul-Sep 2018	28 November 2018
Year-end Report 2018	14 February 2019

For more information, please contact

For more information, please contact
Per Andersson, CEO
Tel: +46 (0)8 730 3700
email: per.andersson@xspray.com

This information is mandatory for Xspray Pharma AB To publish pursuant to the EU's Market Abuse Regulation (MAR) and the Swedish Securities Markets Act. This information was submitted for publication on 24 August at 8:00 a.m. CET through the agency of the above contact.

Condensed Income Statement

SEK 000	Apr–Jun 2018	Apr–Jun 2017	Jan–Jun 2018	Jan–Jun 2017	Full year 2017
Operating income, etc.					
Net sales	-	143	-	212	332
Work performed by the company for its own use and capitalized	7,990	9,366	14,307	9,366	21,865
Other operating income	8	2	31	4	824
	7,998	**9,511**	**14,338**	**9,582**	**23,021**
Operating expenses					
Raw materials and consumables	–6,412	–4,336	–9,808	–7,468	–17,730
Other external expenses	–3,268	–2,454	–5,079	–3,853	–8,618
Personnel expenses	–4,015	–1,819	–6,410	–3,525	–8,785
Depreciation, amortization and impairment of property, plant and equipment and intangible assets	–687	–212	–954	–378	–1,166
Other operating expenses	–382	–8	–448	–9	-
	–14,764	**–8,829**	**–22,699**	**–15,233**	**–36,299**
Operating profit/loss	**–6,766**	**682**	**–8,361**	**–5,651**	**–13,278**
Profit/loss from financial items					
Other interest income, etc.	-	-	-	-	80
Interest expenses, etc.	–23	–1	–23	–1	–1
	–23	**–1**	**–23**	**–1**	**79**
Profit/loss after financial items	**–6,789**	**681**	**–8,384**	**–5,652**	**–13,199**
Profit/loss before tax	**–6,789**	**681**	**–8,384**	**–5,652**	**–13,199**
Tax	-	-	-	-	-
Net profit/loss	**–6,789**	**681**	**–8,384**	**–5,652**	**–13,199**

Condensed Balance Sheet

SEK 000	30 Jun 2018	30 Jun 2017	31 Dec 2017
ASSETS			
Non-current assets			
Intangible assets			
Capitalized development expenditure etc.	55,497	28,690	41,190
Concessions, patents, licenses, trademarks & brands and similar rights	231	608	419
	55,728	**29,298**	**41,609**
Property, plant and equipment			
Machinery and other technical plant	5,951	972	2,180
Equipment, tools, fixtures and fittings	350	81	281
	6,301	**1,053**	**2,461**
Financial assets			
Other securities held as non-current assets	1	1	1
	1	**1**	**1**
Total non-current assets	**62,030**	**30,352**	**44,071**
Current assets			
Current receivables			
Accounts receivable	-	-	23
Current tax asset	311	311	201
Other receivables	1,138	981	824
Prepaid expenses and accrued income	635	5	782
	2,084	**1,297**	**1,830**
Cash and bank balances			
Cash and bank balances	171,815	12,024	115,512
Total cash and bank balances	**171,815**	**12,024**	**115,512**
Total current assets	**173,899**	**13,321**	**117,342**
Total assets	**235,929**	**43,673**	**161,413**

Condensed Balance Sheet, *cont.*

SEK 000	30 Jun 2018	30 Jun 2017	31 Dec 2017
EQUITY AND LIABILITIES			
Equity			
Restricted equity			
Share capital	13,706	6,356	12,356
Development expenditure fund	55,497	28,690	41,190
Statutory reserve	976	976	976
	70,179	**36,022**	**54,522**
Non-restricted equity			
Accumulated profit or loss	168,303	10,452	114,336
Net profit/loss	–8,384	–5,652	–13,198
	159,919	**4,800**	**101,138**
Total equity	**230,098**	**40,822**	**155,660**
Current liabilities			
Accounts payable	3,531	1,396	2,890
Other liabilities	525	239	252
Accrued expenses and deferred income	1,775	1,216	2,611
Total current liabilities	**5,831**	**2,851**	**5,753**
Total equity and liabilities	**235,929**	**43,673**	**161,413**

Cash Flow Statement

SEK 000	Apr–Jun 2018	Apr–Jun 2017	Jan–Jun 2018	Jan–Jun 2017	Full year 2017
Operating activities					
Operating profit/loss	–6,766	682	–8,361	–5,651	–13,278
Adjustment for non-cash items	687	212	954	378	1,166
Interest received	-	-	-	-	80
Interest paid	–23	–1	–23	–1	–1
Cash flow from operating activities before changes in working capital	**–6,102**	**893**	**–7,430**	**–5,274**	**–12,033**
Cash flow from changes in working capital					
Decrease (+)/increase (-) in accounts receivable	-	5	23	18	–4
Decrease (+)/increase (-) in receivables	–2	–189	–277	1,142	632
Decrease (+)/increase (-) in accounts payable	525	–222	641	–2,947	–1,453
Decrease (+)/increase (-) in current liabilities	1,236	330	–563	410	1,818
Cash flow from operating activities	**–4,343**	**817**	**–7,606**	**–6,651**	**–11,040**
Investing activities					
Acquisition of capitalized development expenditure, etc.	–7,990	–9,366	–14,307	–9,366	–21,865
Acquisition of machinery and other technical plant	–4,201	–462	–4,606	–762	–2,770
Cash flow from investing activities	**–12,191**	**–9,828**	**–18,913**	**–10,128**	**–24,635**
Financing activities					
New share issue	–540	-	82,822	-	122,384
Cash flow from financing activities	**–540**	**0**	**82,822**	**0**	**122,384**
Cash flow for the period	**–17,074**	**–9,011**	**56,303**	**–16,779**	**86,709**
Cash and cash equivalents at beginning of period	188,889	21,035	115,512	28,803	28,803
Cash and cash equivalents at end of period	**171,815**	**12,024**	**171,815**	**12,024**	**115,512**

Statement of Changes in Equity

SEK 000	Share capital	Other restricted equity	Other non-restricted equity	Net profit/loss	Total non-restricted equity
Opening balance, 1 January 2017	**6,356**	**20,301**	**23,914**	**–4,097**	**19,817**
New share issue	6,000		116,384		116,384
Profit/loss pursuant to AGM resolution			–4,097	4,097	0
Development expenditure fund		21,865	–21,865		–21,865
Net profit/loss				–13,198	–13,198
Closing balance, 31 December 2017	**12,356**	**42,166**	**114,336**	**–13,198**	**101,138**

SEK 000	Share capital	Other restricted equity	Other non-restricted equity	Net profit/loss	Total non-restricted equity
Opening balance, 1 January 2018	**12,356**	**42,166**	**114,336**	**–13,198**	**101,138**
New share issue	1,350		81,472		81,472
Profit/loss pursuant to AGM resolution			–13,198	13,198	0
Development expenditure fund		14,307	–14,307		–14,307
Net profit/loss				–8,384	–8,384
Closing balance, 30 June 2018	**13,706**	**56,473**	**168,303**	**–8,384**	**159,919**

Board of Directors' certification

The Board of Directors and Chief Executive Officer hereby certify that this Interim Report gives a true and fair view of the company's operations, financial position and results of operations, and states the material risks and uncertainties facing the company.

Michael Wolff Jensen
Chairman of the Board

Hans Arwidsson
Board member

Maris Hartmanis
Board member

Carl-Johan Spak
Board member

Torbjörn Koivisto
Board member

Per Andersson, VD
Xspray Pharma AB (publ)

Stockholm, Sweden, 24 August 2018

Summary key figures

SEK 000	Jan–Jun 2018	Jan–Jun 2017	Full year 2017
Cash and cash equivalents, SEK 000	171,815	12,024	115,512
Equity/assets ratio (%)	97.5	93.5	96.4
Earnings per share, SEK	–0.61	–0.89	–1.07
Equity per share, SEK	16.8	6.4	12.60
Number of employees at the end of the period	11	6	6
Number of outstanding shares (000)	13,706	6,356	12,356

Equity/assets ratio is defined as equity as a percentage of total assets. The equity/assets ratio is reported because the company considers that this measure of the company's financial position is used customarily by certain investors, securities analysts and other stakeholders. The company considers that the equity/assets ratio aids investor understanding of the company's financial position at the end of the period. Earnings per share are defined as net profit/loss divided by the number of outstanding shares at the end of the period. Equity per share is defined as equity divided by the number of outstanding shares at the end of the period.

Accounting policies and review

This Interim Report has been prepared in accordance with the Swedish Annual Accounts Act and BFN's (the Swedish Accounting Standards Board) K3 standard. The accounting policies for preparing this Interim Report are the same as those applied in the company's annual accounts for 2017, where the accounting policies are reviewed in detail.

This Report has not been reviewed by the company's auditor.

Addresses

Xspray Pharma AB
Gunnar Asplunds Allé 32
171 63 Solna
Sweden
info@Xspray.com
www.Xspraypharma.com

Certified Adviser
Redeye AB
+46 (0)8 545 01330
www.redeye.se