xspray
PHARMA

Xspray Pharma Annual Review 2017

This is Xspray Pharma

Xspray Pharma AB (publ) is a product development company with several product candidates in clinical development. Xspray utilizes its innovative patented RightSize technology to develop enhanced and generic versions of marketed cancer drugs, primarily protein kinase inhibitors (PKIs) for treating cancer. The segment is the second-largest in the oncology segment, with very high drug prices. The company's innovative technology enables Xspray to enter as the first competitor to extant brand-name drugs, without being obstructed by secondary patents. Xspray's objective is to have three products ready for launch on the US market in 2020-2023, with its first product launch by 2021. The company holds patents on manufacturing technology, equipment and the resulting products. The shares of Xspray Pharma AB (publ) are traded on Nasdaq First North Stockholm, and the company's certified adviser is Redeye.

Financial calendar

Annual General Meeting	14 May 2018
Interim Report Q1, Jan–Mar 2018	14 May 2018
Interim Report Q2, Apr–Jun 2018	24 August 2018
Interim Report Q3, Jul–Sep 2018	28 November 2018

The year in brief

2017 brought many momentous changes to Xspray Pharma. We floated our shares on Nasdaq First North Stockholm, secured a capital injection from strong investors and obtained positive study results. This brought us the potential to develop and commercialize product candidates based on our patented HyNap platform.

Per Andersson, CEO
Xspray Pharma AB (publ)

Business highlights

- Positive study results received in October, demonstrating that the tools Xspray has developed function for creating bioequivalent PKI drugs based on the company's HyNap platform. These results limit the development risk and enable the cost-efficient and rapid development of product candidates.
- Xspray Pharma's shares were approved for listing on First North, with trading commencing on 28 September 2017.
- A new share issue raising some SEK 132 m before issue expenses was executed for the initial public offering. After this transaction, the company had over 2,100 shareholders.
- Xspray Pharma gained approval for two patent filings in Japan. These patents apply firstly to composition and second method for its product candidate HyNap-Dasa.
- Xspray Pharma gained approval for three patent filings in the US. This patent is for composition of the product candidate HyNap-Dasa and composition on the product candidates HyNap-Sora and HyNap-Nilo.
- On two occasions, major shareholders entered agreements on the transfer of shares and lock-up.

Business highlights after the end of the financial year

- Xspray Pharma executed a private placement of 1,350,000 shares, or some SEK 88 m, to expand its product portfolio.
- Xspray Pharma signed a manufacturing and delivery agreement with NerPharMa S.r.l. of Italy that assures production capacity for studies and future production.

Multi-year summary*

SEK 000	2017	2016	2015	2014
Net sales	332	792	3,640	2,742
Profit/loss after financial items	–13,198	–4,097	–12,096	–15,077
Total assets	161,413	51 ,862	14,951	5,245
Cash position	115,512	28,803	11,850	2,478
Equity/assets ratio (%)	96	90	82	34
Earnings per share, SEK	–0.69	–0.64		
Equity per share, SEK	13.04	7.31		
Number of outstanding shares (000)	12,356	6,356		
No. of employees	6	6	6	7

For definitions of key indicators, see accounting and valuation policies.

CEO's statement

2017 brought many momentous changes to Xspray Pharma. We floated our share on Nasdaq First North Stockholm, secured a capital injection from strong investors and obtained positive study results. This brought us the potential to develop and commercialize product candidates based on our patented HyNap platform.

Since Xspray's IPO on Nasdaq First North at the end of September, we have been focusing fully on our work on developing our product candidates so we can bring them to market. The capital injection from the IPO gives us the potential to keep developing our first three product candidates, with the objective of having them ready for launch on the US market in 2020-2023.

The biggest event of the year were the study results we obtained for HyNap-Dasa in October. We secured clinical data that reduces the risk of the generic HyNap-Dasa candidate, and increases understanding of the pharmacokinetics of our products. We achieved the study's primary endpoint of securing data for our product formulations for planned studies in the second and third quarters of 2018.

This demonstrates that the tools we have developed work for creating bioequivalent PKI drug candidates based on our HyNap platform. This limits the development risk and enables us to see the possibilities in developing several more product candidates than planned at the time of our IPO, cost-efficiently and rapidly. Developing more product candidates quickly gives us room to maneuver, and increases the value of the company's product pipeline.

After the end of the financial year, we executed a private placement of 1,350,000 shares at a subscription price of SEK 65 per share, equivalent to a 2% discount on the volume-weighted average share price five trading days prior to publication.

The new share issue raised some SEK 88 m for Xspray Pharma before issue expenses. This capital injection would enable Xspray to expand its portfolio of clinically proven product candidates. We now anticipate being able to finance development of up to four new product candidates based on the company's HyNap platform, in addition to the three originals.

> In a short period, we have clarified and substantially increased the value of our product portfolio.

The new product candidates will be designated from a group of six potential candidates that are currently being screened. They all have a profile resembling the company's current three main candidates. All are new versions of established cancer drugs based on protein kinase inhibitors—PKIs. The main patents of these brand-name drugs expire in 2024-2026. The aggregate yearly sales of these original pharmaceuticals is estimated at over USD 7.3 billion in 2022 on the US market

At the end of the year, we were also able to present a series of news that marked significant steps in our work of bringing products to market. We had a number of patents granted that demonstrate the innovative potential of our platform. The new share issue in early-2018 and new product candidates that we then plan to develop, have quickly created the potential to substantially increase the value of our product portfolio.

After the end of the period, we reached a manufacturing and delivery agreement with NerPharMa S.r.l. of Italy, which enables us to scale up production of studies and future commercial production.

In 2017 and early-2018, we have created good prospects for being able to execute our business plan. We are now continuing our work towards the goal of making Xspray a profitable leader in the development and commercialization of well-documented, currently marketed protein kinase inhibitors for targeted cancer therapy.

Per Andersson
CEO
Xspray Pharma AB (publ)

Solna, Sweden, April 2018

Goals and strategy

The company's goal is to be a profitable leader in the development and commercialization of well-documented, currently marketed PKIs for targeted cancer therapy. Its initial goal is to enable the launch of up to seven product candidates on the US market in 2020-2026, with the first product launch by 2021.

Business concept

Xspray Pharma's business concept is to create value through the development and commercialization of proprietary pharmaceuticals based on a combination of well-documented compounds and self-developed technology. This will enable Xspray to create products that satisfy relevant medical needs, offering substantial commercial potential with attractive pricing based on brand-name product patent status.

Vision

By utilizing its unique technology, Xspray's vision is to secure positioning as a world leader in generic and/or improved versions of established PKIs for targeted cancer therapy, and thus improve patient quality of life and chances of survival. An aggressive pricing and patent strategy will enable the company to win market shares and create sustainable profitability for the company and its owners, while simultaneously reducing the societal cost burden.

Business model

Xspray's technology enables the semi-exclusive sale of its products on selected markets alongside brand-name drugs, and where aggressive pricing enables rapid market penetration and high market shares. Its technology also creates relevant medical benefits for patients. Additionally, the company can out-license its technology to collaborative partners to evaluate and improve drug candidates either in clinical phases or that have already launched.

Xspray's business model is to out-license its product candidates to larger companies that have brand-name drugs on the market or generic companies that can market the company's products. Out-licensing will be timed just before or after product candidates have secured approval as pharmaceuticals. Xspray Pharma expects out-licensing to generate an initial payment for the company and royalties on sales after launch.

Eventually, the company may generate its own sales on selected markets to enable a higher revenue share when products come to market.

Strategy

Xspray's strategy consists of applying the company's technology platform to carefully selected drug candidates offering significant market potential, and where Xspray expects to be able to secure advantageous competitive positioning. Xspray's hybrid nano particles (HyNap) are amorphous, which offers the potential to launch products that are difficult for other parties to develop when a 'patent window' emerges on the market—the time between the expiry date of a primary substance patent for brand-name drugs and the relevant secondary patent. This confers the company with attractive special status contra competitors and the ability to launch immediately after the expiry of

substance patents, compared to competing products, which cannot be launched because of valid secondary patents.

In the clinical development program, based on healthy volunteer subjects, an estimated 36-48 individuals would be required to create a sufficient statistical base in bioequivalence studies, which is required for approval. The FDA has confirmed that Xspray's proposed clinical program maybe based on phase I studies on healthy trial subjects. Such a program takes significantly less time than if it were conducted on patients, primarily in terms of diseases with small patient populations. Based on its own experience, Xspray estimates the cost of clinical studies on healthy volunteer subjects at some one-third of the corresponding cost for cancer patients, which was estimated at some USD 59,500 per patient in 2013.

Business strategy

In the initial phase of its operations, Xspray entered commercial agreements with customers who used Xspray's technology in collaboration with other pharmaceutical companies to evaluate collaborative partners' drug candidates. At present, the company is developing its own drug candidates. The company is endeavoring to build its revenues by having proprietary drug candidates registered as pharmaceuticals, and then enter license agreements with brand-name drug manufacturers, who will be able to improve lifecycle management. As an alternative, the company will enter license agreements with generic producers who will market and sell the company's products. First and foremost, the company wants to address markets where its technology and patent status can provide Xspray's products with a 'patent window'—the period between the expiry date of

the primary substance patent and patent for the original brand-name drug and the expiry date of the relevant secondary patent. During this period, products may be sold with or without limited competition apart from the brand-name drug. Secondarily, Xspray would license its technology to other drug companies with the aim of enabling them to optimize their drug candidates in clinical development and/or currently marketed pharmaceuticals.

The products are expected to secure significant market shares from brand-name drugs as a result of their attractive pricing. The company will focus on the US market, and in the longer term, the European market. Its strategy is intended to reduce Its initial requirement for capital. The risk on the US market is also lower, because the route to product approval as a pharmaceutical is shorter and clearer.

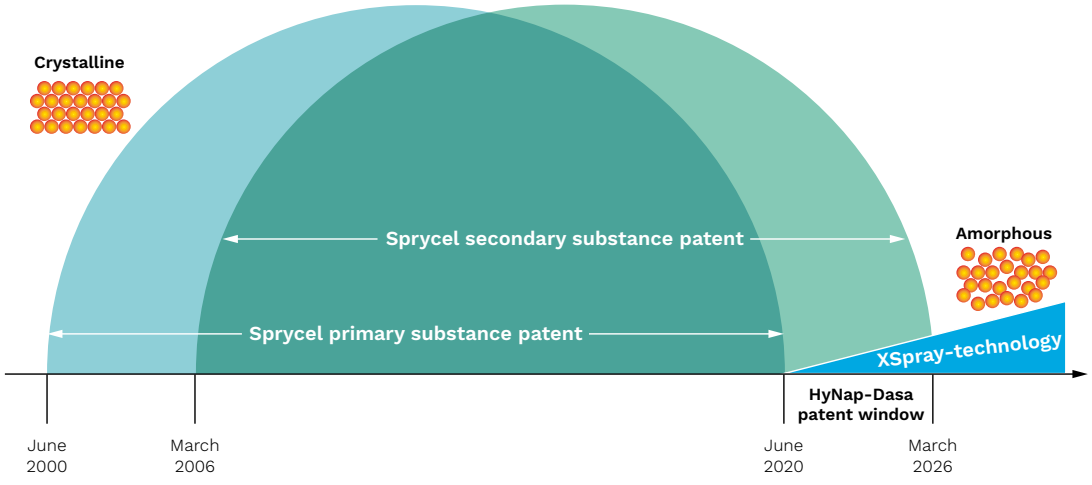
Product strategy

Xspray has two product strategies. The first is to develop generics, i.e. pharmaceutically and therapeutically equivalent versions of previously approved products, where there is a patent window and the product can be sold semi-exclusively in parallel with the brand-name drug. On the US market, such products can be registered through a and abbreviated new drug application (ANDA), section 505 (j) of the Federal Food, Drug and Cosmetic Act.

The second strategy to develop improved versions of previously approved products where there is a patent window and the product can be sold semi-exclusively alongside the brand-name drug. On the US market, such products can be registered pursuant to section 505 (b)(2) of the Federal Food, Drug and Cosmetic Act.

The company is continuing its efforts to focus on pharmaceuticals with orphan drug designation. This is because this type of pharmaceutical often has high pricing, which means that the anticipated effect of attractive pricing would be a major impact on market share secured and brisk market penetration.

Xspray is utilizing the advantage conferred by the company's amorphous product candidates in terms of their significantly lower development expenses and lead-times, with both stated product strategies implying that the company only needs to conduct phase I studies on healthy trial subjects before registering products.



The company's patented technology can create a patent window of opportunities that enable the introduction of a semi-exclusive product on an existing market, as illustrated above for HyNap-Dasa, dasatinib.

Customer strategy

The company's three main product candidates, based on its RightSize technology, are in development and will be offered to pharmaceutical companies that work on managing their product lifecycles, or to companies developing and/or selling generic pharmaceuticals. The company thinks that generally, the pharmaceutical industry faces difficulties in developing new drugs at the rate the patents for many important products are expiring. This is expected to increase the demand for effective lifecycle management of successful products and access to external projects, through more licensing agreements and acquisitions of pharmaceutical companies with product candidates in development.

Marketing and sales strategy

Xspray develops pharmaceuticals by combining well-recognized and well-documented cancer drugs using innovative patented technology.

Patent strategy

Xspray is executing an active patent strategy involving the company protecting its inventions and products on all geographical markets that could be considered relevant. It has established partnerships with internationally recognized patent attorneys for filing, maintaining and defending patents. Xspray's patent strategy is intended to create the greatest possible commercial value for the company and its products. Xspray will continue to expand its product portfolio with new PKIs for drug candidates by utilizing its self-developed and unique technology.

Apart from maintaining an active patent strategy for its proprietary production process, technology platform and product patterns, Xspray is working actively to find a patent window through rigorous screening of the patents in place on compounds that have already been, or will be, launched on the PKI market.

Collaborative partners

After the end of the period, Xspray Pharma entered a manufacturing and delivery agreement with NerPharMa S.r.l. of Italy, which involves the production of HyNap-Dasa for the clinical trial program and for commercial production. NerPharMa has been contracted to produce the pharmaceutical compound and finished product for clinical programs and future commercial sales. NerPharMa's GMP facility has been approved by the Italian drug regulator (AIFA) and the US Food & Drug Administration (FDA). Xspray can also partner with Recipharm Venture Fund AB on the development and future commercial production of its product candidates.

Xspray has established partnerships with internationally recognized patent attorneys in Sweden and the US on filing, maintaining and defending patents. The company's partners are Merchant & Gold P.C. of the US and Awapatent AB of Sweden.

Xspray also collaborates with a UK company Globe Life Sciences Ltd, which it appoints for market research and estimating sales potential.

To conduct clinical trials, the company has appointed Scandinavian CRO AB and CTC Clinical Trial Consultants AB of Uppsala, Sweden and Quotient Clinical of Nottingham, UK.

Products

Xspray's Projects are based on the company's hybrid nano particles (HyNap) produced using its patented RightSize technology, which enables the development of improved and generic versions of protein kinase inhibitors. As of the publication date of this report, Xspray's product portfolio had seven product candidates in development, three of which have been announced.

Protein kinase inhibitors (PKIs) are remarkably effective for treating various types of cancer. Unfortunately, many patients experience side-effects from them, which in certain cases are fatal. PKIs are generally recognized for exhibiting toxicity and varying bioavailability due to suboptimal formulations, for reasons including low solubility and pH-dependent absorption, which represents an important challenge in drug development.

Xspray's patented technology, RightSize, can overcome many of the aforementioned problems in the formulation of PKI products and the company has already successfully developed product candidates with improved pharmacokinetic qualities that have superior therapeutic profiles to extant products.

Because Xspray focuses on already established pharmaceutical compounds, generics or improved versions of brand-name drugs, where phases II and III have already been conducted, the FDA has approved Xspray not needing to test HyNap-Dasa in these phases. If the product candidate is identical to the brand-main drug, the company only needs to demonstrate bioequivalence and food-drug interaction in one clinical study on healthy trial subjects. The product can then go direct to registration and thus secure a faster, simpler and more cost-efficient route to market.

Product candidates

As of the publication date of this report, Xspray's internal development project had up to seven product candidates in development. All are based on the company's RightSize technology. Three of the product candidates have been announced and four are as-yet unannounced. The three announced product candidates are stable amorphous versions of the blockbuster cancer drugs Sprycel (dasatinib), Tasigna (nilotinib) and Nexavar (sorafenib); each of these drugs has annual sales of over USD 1 billion.

For two of Xspray's product candidates, HyNap-Dasa and HyNap-Sora, the company has received formal third-party freedom to operate (FTO) analyses and competition analyses from reputable Swedish and US patent agencies. For both its product candidates HyNap-Dasa and HyNap-Nilo, the company has already demonstrated clinical proof of concept (POC) and both are continuing clinical development. The product candidate HyNap-Sora is in the formulation phase. All three product candidates have a well-defined route to pharmaceutical approval, which for the improved version of HyNap-Dasa, is already confirmed by the FDA.

Xspray is developing HyNap-Dasa as a fully equivalent version of Sprycel that can be registered in the US through a 505 (j) or ANDA, or as an improved product through the 505 (b) (2) procedure.

Announced product candidates

Xspray product candidate	Pharmaceuti-cal compound	Products	Original producer	Indication	Substance patent expiry	Patent window
HyNap-Nilo	Nilotinib	Tasigna	Novartis	Chronic myeloid leukemia (CML)	Jan 2024	Jan 2024 - Jul 2026
HyNap-Dasa	Dasatinib	Sprycel	Bristol-Myers Squibb (BMS)	Chronic myeloid leukemia (CML) and acute lymphoblas-tic leukemia (ALL)	Nov 2020	Nov 2020 - Sep 2026
HyNap-Sora	Sorafenib	Nexavar	Bayer	Liver, kidney and thyroid cancer	Jan 2020	Jan 2020 - Dec 2027

Indications

All currently marketed PKI-based pharmaceuticals are intended to treat patients with different types of cancer. Only one PKI product (Xeljanz, tofacitinib) is indicated for treating patients with rheumatoid arthritis.

The brand-name drugs of two of Xspray's product candidates, HyNap-Dasa (Sprycel) and HyNap-Nilo (Tasigna), are indicated for treating adult patients with newly diagnosed Philadelphia chromosome positive (pH+) chronic myeloid leukemia (CML) in the chronic phase.

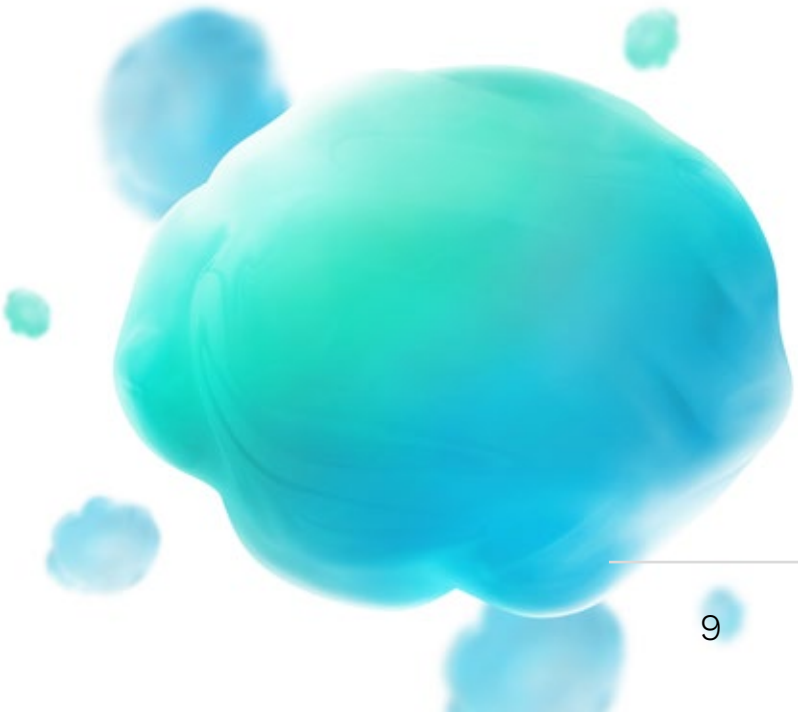
Sprycel is also indicated for treating adult patients with pH+ acute lymphatic leukemia (ALL) and lymphoid blastic CML with resistance to or intolerance of previous therapy. BMS recently filed an application with the FDA for a new formulation of Sprycel (powder for oral suspension) for treating children with Philadelphia-chromosome positive (pH+) chronic myeloid leukemia (CML).

The original product for the brand-name drug for HyNap-Sora, Nexavar, is intended for treating patients with liver cell cancer, kidney cell cancer and differentiated thyroid cancer.

Product benefits

Xspray's technology produces pharmaceuticals that can generate clear clinical advantages by:

- Increasing the pharmaceutical's water solubility, and thus its bioavailability
- Reducing the variability of absorption
- Reducing or eliminating the pharmaceutical's pH-dependent absorption
- Reducing or eliminating food-drug interaction, i.e. the effect on existing food in the stomach during drug absorption
- Minimizing drug interaction, i.e. negative reciprocal action with other pharmaceuticals administered simultaneously



Board of Directors

Michael Wolff Jensen

Board member as well as chairman since 2013
Born 1971
Education: Master of Laws (LL.M.), University of Copenhagen
Other current activities: Chairman of the Board in Ascendis Pharma A/S, Eurocine Vaccines AB, VANX ApS och Chairman of the Board as well as owner of MWJ Partners ApS
Holdings: 35,864 shares and 25,000 warrants through MWJ Partners ApS

Hans Arwidsson

Board member since 2006
Born 1958
Education: Ph.D. in Pharmaceutical Science and Pharmacist's Degree, University of Uppsala as well as Master of Business Administration, Executive MBA, Stockholm School of Economics
Other current activities: Board member of Healthy Bizniz Europe AB, Eurocince Securities AB and Nanexa AB, CEO of Eurocine Vaccines AB
Holdings: None

Maris Hartmanis

Board member since 2015
Born 1953
Education: Dr. of Technology and Associate Professor, Royal Institute of Technology
Other current activities: CEO and Chairman of the Board in Hartmanis & Partners AB as well as board member in Xbrane Biopharma AB, Applied Photophysics Ltd and BioLamina
Holdings: 26,494 shares

Carl-Johan Spak

Board member since 2015
Born 1956
Education: Dr. of Odontology, Degree in Dentistry, Karolinska Institute
Other current activities: Chairman of the Board in Recipharm OT Chemistry AB, Recipharm Pharmaceutical Development AB, board member of Pharmanest AB, Symcel Sverige AB, Cobra Biologics Holding AB, Empros Pharma AB, Inject, Pharma Sweden AB, Atrogi AB, Prokarium Ltd., Synthonics Inc, Kahr Medical Ltd, SwedenBIO Service AB and Bostadsrättsföreningen Smultronhyllan, member of board and CEO of Recipharm Venture Fund AB and RPH Pharmaceuticals AB.
Holdings: None

Torbjörn Koivisto

Board member since 2017
Born 1969
Education: Master of Laws (LL.M.), University of Uppsala
Other current activities: Board member of Moberg Pharma AB (publ), Hemcheck Sweden AB, Cinclus Pharma Holding AB, KIBACQ AB and IARU Institutet för Affärsjuridisk Rådgivning I Uppsala AB, bolagsman in KOL Arts & Craft Handelsbolag as well as deputy (styrelsesuppleant) of RJC Roger Johansson Consulting AB.
Holdings: 4,000 shares via company (IARU)

Auditor

The registered auditing company Grant Thornton Sweden AB (Sveavägen 20, 111 57 Stockholm) has been the company's auditor since 2015 and was re-elected to the company's auditor at the Annual General Meeting held on March 31, 2017 for the period until the end of the Annual General Meeting in 2018. Thomas Lindgren (Authorized Public Accountant and Member of FAR, the Swedish trade association for accounting consultants, auditors and advisors) is the chief accountant auditor since 2015.

Management and Key personnel

CEO

Per Andersson

CEO since 2006
Born 1967
Education: Ph.D. in Analytical Chemistry, Stockholm university
Other current activities: Chariman of the board of Robotic Lawn Care Sweden AB and Deputy of Journeyman Stockholm AB
Holdings: 127,437 shares and 154,857 warrants

BUSINESS DEVELOPMENT

Andreas Konar

Born 1949
Andreas Konar is highly experienced in all management aspects of drug-delivery companies. Previous experiences include positions at Astra, Recordatti and LifeCycle Pharma.

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