

CEO speech Xsprays AGM 2020

Xspray develops improved and generic versions of already market approved drugs where is a large medical need. Due to the favorable patent situation Xspray can launch its product alongside a high priced and commercially successful original drug. Our leading product candidate, HyNap-Dasa, is an amorphous version of dasatinib where the crystalline original drug, Sprycel[®], sells for approximately SEK 12 billion per year on the US market.

Xspray made significant progress during 2019 and the year became the important springboard for the first in our series of product candidates, HyNap-Dasa. Our production facility in Italy opened in 2019, the first of its kind in the world and it is the result of three years of development. It turned out so well that we could start the full-scale production very soon after the opening. This shows competence, organizational ability, and goal awareness in our new organization, which I am very pleased with. It was very important to start production according to plan as we are working towards an important patent window for HyNap-Dasa. The original drug's substance patent expires in December 2020 and the secondary patent expires in 2026.

We have further strengthened Xspray's intellectual property. In the US, our most important market, we note that Xspray are completely dominant in patents for amorphous protein kinase inhibitors, including the amorphous version of dasatinib. The 54 approved substances of the protein kinase inhibitor class are estimated to sell for more than SEK 200 billion in the United States in 2020.

We have prepared the documentation required to apply for market approval for HyNap-Dasa in the US. Once we have obtained the results of both the upcoming clinical bioequivalence studies and the ongoing stability studies, we can complete the dossier and apply for FDA approval during the fall of 2020.

At the time of writing, during the ongoing pandemic, we can see the result of the extensive work performed in 2019 to minimize risks of slowdowns or stops in our development and production, and create a secure supply chain by having several alternatives of suppliers of goods and services. I also want to highlight our successful directed share issue that was carried out in December, which enabled us to start the process of establishing a secondary production facility for our important HyNap production. This has made our business relatively unaffected by the pandemic and we are working to make it stay that way.

We entered the year 2019 with very high ambitions and we succeeded in meeting all our goals. This has created a solid foundation for many of the strategically important decisions and businesses that we intend to carry out in 2020 and onwards. It is with great confidence that I and our dedicated team work resolutely, we see the potential for 2020 to be an international breakthrough year for Xspray.

Per Andersson
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