November 23, 2022

InDex Pharmaceuticals Holding AB (publ) interim report January – September 2022

The Board has appointed Jenny Sundqvist as new CEO

"It has been an eventful quarter, and we are very pleased to welcome Jenny Sundqvist as the new CEO of InDex. Patient recruitment for the phase III study CONCLUDE with cobitolimod is underway and although the study has had a slower start-up than expected, a number of clinics have been very active in enrolling patients. We look forward to an exciting winter where we continue to take measures that we believe will have a positive effect on the recruitment rate going forward", says Johan Giléus, acting CEO of InDex Pharmaceuticals.

Period July – September 2022
- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –4.5 (–28.2) million
- Result after tax amounted to SEK –3.5 (–28.2) million, corresponding to SEK –0.01 per share (–0.05) before and after dilution
- Cash flow from operating activities amounted to SEK –23.8 (–26.5) million

Period January – September 2022
- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –45.0 (–80.2) million
- Result after tax amounted to SEK –44.0 (–80.2) million, corresponding to SEK –0.08 per share (–0.16) before and after dilution
- Cash flow from operating activities amounted to SEK –95.2 (–80.1) million
- Cash and cash equivalents at the end of the period amounted to SEK 398.3 (463.1) million
- Number of employees at the end of the period was 7 (8)
- Number of shares at the end of the period was 532,687,650

All comparative amounts in brackets refer to the outcome during the corresponding period 2021.

Significant events during the quarter
- InDex got a new patent for cobitolimod granted in Europe

Significant events after the reporting period
- InDex's Board of Directors named Jenny Sundqvist as new CEO

Other events
- InDex received positive feedback from the Japanese regulatory authority, the PMDA, regarding the clinical development plan for cobitolimod

CEO statement
It has been an eventful quarter, the Board has appointed a new CEO and InDex has received great interest in cobitolimod at Europe's largest scientific meeting for gastroenterologists, UEGW. In addition, EMA's safety committee has recently recommended new measures to limit the use of JAK inhibitors, which again highlights the need for new drugs for ulcerative colitis without severe side effects.

Patient recruitment for the phase III study CONCLUDE with cobitolimod is underway and a number of clinics have been very active in enrolling patients. However, the study has had a slower start-up than expected with several underlying reasons. Many clinics are still handling the effects of the covid pandemic, which has

and continues to result in longer administrative processes. Russia's invasion of Ukraine has had a clear impact, as the planned clinics in Russia have had to be replaced with clinics in other countries. The work continues at full speed to activate the remaining clinics in, among other places, Ukraine and not least to ensure that the initiated clinics include patients. We continue to take measures that we believe will have positive effect on the recruitment rate going forward. In our dialogue with the clinics, it is clear that there is a strong interest in participating in the CONCLUDE study with its new mechanism of action and a great medical need for new treatment options for patients with moderate to severe ulcerative colitis.

Based on the previously communicated successful interactions with the Japanese regulatory authority, the Pharmaceuticals and Medical Devices Agency (PMDA), we continue to plan to include Japanese patients in our second induction study in the phase III program for cobitolimod and are simultaneously evaluating the possibility of entering strategic collaborations in Japan. We have received encouraging feedback on the unique and positive decision from PMDA in our contacts with potential partners, and the decision also indicates great potential for cobitolimod.

In the beginning of October, InDex participated as an exhibitor at the United European Gastroenterology Week (UEGW) in Vienna, the largest scientific meeting for gastroenterologists in Europe. Informing healthcare professionals and other stakeholders about cobitolimod and the phase III study CONCLUDE is part of our planned activities. There was a great interest in cobitolimod and CONCLUDE, with many visitors to our booth, both from clinics already participating in our study and from new clinics expressing interest to join.

Our ongoing clinical pharmacokinetic study (PK study) with cobitolimod is progressing according to plan and the results are expected to be presented during the first quarter of 2023. The study will include at least 6 patients with moderate to severe ulcerative colitis treated with doses of 500 mg cobitolimod administered rectally. The aim of the study is to confirm that the systemic uptake of cobitolimod is limited, which has been shown in previous preclinical and clinical studies. A limited systemic uptake is a significant advantage compared to competing drugs for ulcerative colitis that act on the whole body and can cause severe side effects outside the inflamed colon.

On October 28, EMA's safety committee recommended new measures for the use of JAK inhibitors due to their risk of severe side effects. The new measures imply that several patient groups should only use JAK inhibitors if there are no other treatment options available. The recommendations are another reminder that the safety profile of a drug is very important, which is good news for cobitolimod which has so far shown an excellent safety profile. FDA updated its safety warnings and restricted the use of JAK inhibitors already back in September 2021.

On October 10, InDex announced that the Board has appointed Jenny Sundqvist as the new CEO, effective from January 1, 2023. Jenny brings a broad experience from pharmaceutical development and business management, and we all look forward to working together with Jenny.

During the quarter, we have continued with our appreciated investor presentations. For those of you who did not have the opportunity to watch the presentations live, the recordings are available on our website. We will present InDex tomorrow on November 24, at Redeye Life Science Day and I hope to see you then!

Johan Giléus, acting CEO

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The full report is attached as a PDF and is available on the company's website https://www.indexpharma.com/en/financial-reports/

Publication
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InDex Pharmaceuticals in brief
InDex is a pharmaceutical development company focusing on immunological diseases where there is a high unmet medical need for new treatment options. The company's lead asset is the drug candidate cobitolimod, which is being evaluated in the phase III study CONCLUDE as a novel treatment of moderate to severe ulcerative colitis – a debilitating, chronic inflammation of the large intestine. InDex has also developed a platform of patent protected discovery stage substances, so called DNA based ImmunoModulatory Sequences (DIMS), with the potential to be used in the treatment of various immunological diseases.

InDex is based in Stockholm, Sweden. The company's shares (ticker INDEX) are traded on Nasdaq First North Growth Market Stockholm. Redeye AB is the company's Certified Adviser. For more information, please visit www.indexpharma.com.