May 7, 2020

InDex Pharmaceuticals Holding AB (publ) interim report January – March 2020

FDA and EMA endorse the advancement of cobitolimod into phase III studies

"The positive responses from the regulators is an important external validation of our study results and cobitolimod's potential," says Peter Zerhouni, CEO of InDex Pharmaceuticals.

Period January – March 2020
- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –24.0 (–17.2) million
- Result after tax amounted to SEK –24.0 (–17.2) million, corresponding to SEK –0.27 per share (–0.25) before and after dilution
- Cash flow from operating activities amounted to SEK –21.9 (–18.4) million
- Cash and cash equivalents at the end of the period amounted to SEK 104.6 (64.4) million
- Number of employees at the end of the period was 7 (7)
- Number of shares at the end of the period was 88,781,275

All comparative amounts in brackets refer to the outcome during the corresponding period 2019.

Significant events during January – March 2020
- InDex in-depth analysis of the CONDUCT study confirmed the successful top line results and supports the strategy going forward
- InDex published mechanism of action data for cobitolimod in scientific journal
- InDex received grant from Vinnova for pre-clinical development of DIMS compounds in inflammation

Significant events after the reporting period
- InDex received positive responses from FDA and EMA regarding phase III development of cobitolimod for the treatment of moderate to severe ulcerative colitis
- The annual general meeting in InDex Pharmaceuticals Holding AB was held on April 20, 2020

CEO statement
Following the phase IIb study CONDUCT meeting its primary endpoint in August 2019, dialogues were initiated with FDA and EMA respectively, for the further development of cobitolimod. These processes have now been completed and both authorities endorse the advancement of cobitolimod into phase III studies in patients with moderate to severe left-sided ulcerative colitis. The positive responses from the regulators is an important external validation of our study results and cobitolimod's potential.

This regulatory feedback gives flexibility for different designs of the phase III program, for example, to conduct studies sequentially and potentially to include a higher dose in addition to the highest dose regimen tested in the phase IIb study (2x250 mg). We continue to evaluate the most advantageous study design based on, among other things, development risk, commercial potential, time to market and cost.

The covid-19 pandemic affects the healthcare systems and the investor sentiment globally, which must be taken into account in our strategic planning. Before we can start phase III, the healthcare situation must have normalised, and the necessary funding be secured. In addition to assessing the conditions for InDex conducting the phase III program, we continue to engage with potential partners, presenting the now complete business development package.

An important component is the qualitative market research conducted by an independent market research company with senior gastroenterologists active in ulcerative colitis and payers, such as experts from pricing authorities and insurance companies, in France, the UK, Germany and the USA during the

first quarter of 2020. Both target groups recognise the unmet need for new safe and effective treatments for moderate to severe ulcerative colitis.

Cobitolimod's Target Product Profile, based on the phase IIb data, tested well as a novel treatment and the efficacy/safety ratio is considered unsurpassable. Gastroenterologists in the study are likely to prescribe cobitolimod to a significant proportion of their patients with moderate to severe ulcerative colitis in a future commercialization, and the study supports pricing in line with modern treatment options. All in all, the results from this market research support our assessment that the annual sales of cobitolimod at a successful commercialization could reach more than USD 1 billion.

Regarding the development of additional drug candidates from the DIMS platform, we have received a new grant of SEK 2 million from Vinnova to evaluate selected substances in inflammatory disease models outside the area of inflammatory bowel disease.

After an extended period with minimal sales of the diagnostic test DiBiCol, and due to upcoming changes in regulations, we have decided to discontinue that business.

On April 20, a covid-19 adapted annual general meeting was held. Instead of a CEO presentation at the annual general meeting, I gave a webcasted company update the same day on InDex's phase III preparations. The webcast is available on InDex's homepage.

During the first quarter of 2020 we have been able to complete several important steps on the path towards phase III and I look forward to the continued work in which the mutually dependent activities: decision on study design and securing funding, will be the highest priority in the coming months.

For more information:
Peter Zerhouni, CEO
Phone: +46 8 508 847 35
E-mail: peter.zerhouni@indexpharma.com

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

Publication
This information is information that InDex Pharmaceuticals Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation (MAR). The information was submitted for publication through the agency of the contact person set out above at 8:00 CET on May 7, 2020.

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 foremost asset is the drug candidate cobitolimod, which is in late stage clinical development for the 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 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 with email address certifiedadviser@redeye.se och phone number +46 8 121 576 90 is the company's Certified Adviser. For more information, please visit www.indexpharma.com.