February 20, 2020

InDex Pharmaceuticals Holding AB (publ) year-end report 2019

Cobitolimod's outstanding combination of efficacy and safety confirmed in in-depth analysis

"The robustness and consistency of the CONDUCT results support our strategy to move cobitolimod forward in development and our phase III preparations are continuing according to plan," says Peter Zerhouni, CEO of InDex Pharmaceuticals.

Period October – December 2019
- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –25.6 (–22.3) million
- Result after tax amounted to SEK –25.6 (–22.3) million, corresponding to SEK –0.29 per share (–0.33) before and after dilution
- Cash flow from operating activities amounted to SEK –34.2 (–20.6) million

Period January – December 2019
- Net sales amounted to SEK 0.1 (0.1) million
- Operating result amounted to SEK –87.7 (–82.0) million
- Result after tax amounted to SEK –87.8 (–82.1) million, corresponding to SEK –1.19 per share (–1.29) before and after dilution
- Cash flow from operating activities amounted to SEK –85.1 (–78.6) million
- Cash and cash equivalents at the end of the period amounted to SEK 126.8 (83.0) 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 2018.

Significant events during October – December 2019
- InDex held an extraordinary general meeting, which resolved to approve the Board's resolution on a new issue of shares with deviation from the shareholders' preferential rights.
- InDex updated the list of shareholders on the homepage with information as of October 18, 2019.

Significant events after the reporting period
- InDex in-depth analysis of the CONDUCT study confirmed the successful top line results and supports the strategy going forward.

CEO statement
We have now concluded in-depth analysis of the complete data set from the CONDUCT study with the help of several key opinion leaders in the field of inflammatory bowel diseases. The analysis confirms that the highest dose tested, which met the primary endpoint of the study, demonstrates an outstanding combination of efficacy and safety. Also results in secondary endpoints ranging across clinical, biochemical and quality of life measures provide supportive evidence for the efficacy of this dose in patients with moderate to severe ulcerative colitis. The analysis also confirms cobitolimod's excellent safety profile. Our intention is to present the complete study results in a scientific journal as well as at upcoming international medical conferences.

This patient population is hard to treat, and many do not respond to or cannot tolerate available medical therapies, resulting in a high unmet medical need. This, in combination with the robustness and consistency of the CONDUCT results support our strategy to move cobitolimod forward in development and our phase III preparations are continuing according to plan. Our plan is to be ready to enrol patients in the second half of this year.

The next step in the preparations is to complete the ongoing discussions with the European and American regulatory authorities, EMA and FDA, regarding our proposed design of the phase III program. We should have received all formal feedback from them by the end of the first quarter of this year. In parallel, we are conducting market research as well as consulting with our medical advisors and clinical research organisations (CROs), and this input will also be considered in the study design. We expect to have sufficient information to be able to finalise the design of the phase III program during the second quarter of this year. Then we can also determine the costs and associated capital requirements.

In January, I was in San Francisco during the annual JP Morgan conference that kicks off the biotech year. I presented the positive top line results and the development plans to both pharmaceutical companies and specialist investors who have shown interest in cobitolimod and InDex. That work will intensify now that we have the in-depth conclusions from CONDUCT and soon also the feedback from the regulatory authorities, so that we can provide a complete picture of the continued development towards commercialisation of cobitolimod.

To meet a growing international interest, we have decided to adopt IFRS for our external financial reporting as of this report. I look forward to an eventful spring and hope to see you at the annual general meeting, which this year is held already on April 20.

Conference call for investors, analysts and media
A conference call on the company's year-end report for 2019 and the conclusions from the CONDUCT study will be held with CEO Peter Zerhouni on Thursday, February 20, 2020 at 11:00 (CET). During the conference call, which will be held in Swedish, it will be possible to ask questions to the company.

The conference call can be followed at https://tv.streamfabriken.com/index-pharmaceuticals-q4-2019

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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/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 February 20, 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.