November 27, 2019

InDex Pharmaceuticals Holding AB (publ) interim report January – September 2019

Outstanding combination of efficacy and safety in the CONDUCT study

"Something that really differentiates cobitolimod from its competitors is the superior safety profile. Both the approved drugs and those currently being tested in phase III are associated with serious side effects. With an outstanding combination of efficacy and safety, cobitolimod is set to take a leading position within the field," said Peter Zerhouni, CEO of InDex Pharmaceuticals.

Period July – September 2019
- Revenues amounted to SEK 0.0 (0.0) million
- Operating result amounted to SEK –27.2 (–15.1) million
- Result after tax amounted to SEK –27.2 (–15.1) million, corresponding to SEK –0.39 per share (–0.24) before and after dilution
- Cash flow from operating activities amounted to SEK –19.1 (–16.1) million

Period January – September 2019
- Revenues amounted to SEK 0.1 (0.1) million
- Operating result amounted to SEK –62.1 (–59.9) million
- Result after tax amounted to SEK –62.2 (–59.9) million, corresponding to SEK –0.90 per share (–0.96) before and after dilution
- Cash flow from operating activities amounted to SEK –51.6 (–58.6) million
- Cash and cash equivalents at the end of the period amounted to SEK 117.6 (66.4) million
- Number of employees at the end of the period was 7 (7)
- Number of shares at the end of the period was 82,537,530

All comparative amounts in brackets refer to the outcome during the corresponding period 2018.

Significant events during July – September 2019
- The phase IIb study CONDUCT met the primary endpoint.
- InDex updated the list of shareholders on the homepage with information as of August 30, 2019.
- InDex completed a directed share issue of approximately SEK 140 million.
- InDex announced notice of an extraordinary general meeting.

Significant events after the reporting period
- 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.

CEO statement
On August 27, we had the great pleasure of reporting successful top line results in the phase IIb study CONDUCT with cobitolimod. The study met the primary endpoint with a competitive efficacy and superior safety profile. Now it is full speed ahead towards phase III.

The CONDUCT study was an exploratory study to find the best dose to move forward in development, and the study clearly showed that the highest dose was the most effective. As in previous studies, cobitolimod was well tolerated at all dose levels and no differences in the safety profile were observed compared to placebo. The study thus met the objectives that we set up before the start of the study.

The efficacy was within the expected range and is comparable to what has been reported for the drugs that are currently on the market for moderate to severe ulcerative colitis and the new substances that are in phase III right now. Something that really differentiates cobitolimod from its competitors is the superior safety profile. Both the approved drugs and those currently being tested in phase III are associated with serious side effects. With an outstanding combination of efficacy and safety, cobitolimod is set to take a leading position within the field.

An additional advantage of cobitolimod that stands out compared to the competitors is the new and unique mechanism of action. Many patients with moderate to severe ulcerative colitis do not respond to current therapies, and there is more and more talk about combining several drugs to optimise the efficacy for the patients. With its unique mechanism of action and safety profile, cobitolimod is better suited than competing products for such an approach.

DIRECTED SHARE ISSUE TAKES COBITOLIMOD TO PHASE III

With the successful CONDUCT results, we completed a directed share issue on September 19 of SEK 140 million to Swedish and international investors, including reputable, new investors such as the Fourth Swedish National Pension Fund and existing shareholders such as Industrifonden and Bengt Julander (through Linc AB). We received great interest from investors with sector expertise, also internationally, during the roadshow that preceded the transaction, and we did not have to offer any discount, which is otherwise the standard in directed share issues.

The proceeds of the share issue are primarily intended to prepare cobitolimod for phase III, which is the final stage of development before applying for market approval. We had already before the CONDUCT results planned a long list of phase III preparatory activities that we launched as soon as we saw the positive outcome of the study. We are now analysing the full data set with the intention of publishing complete study results in a scientific journal and presenting them at upcoming medical conferences. We have initiated contacts with the European and American regulatory authorities, EMA and the FDA, to discuss phase III design. We are planning market research with physicians and payers. We have started the process of choosing a contract research organisation (CRO). We have ordered study drug and have started the preclinical safety studies required for phase III. With the current timeline, we should have enough information to finalise the design of the phase III program in the second quarter of 2020 and be ready to enrol the first patient in the second half of 2020.

NEW FINANCIALLY STRONG INVESTORS STRENGTHEN THE SHAREHOLDER BASE

The ownership in InDex has changed significantly during the quarter. Former major shareholder NeoMed, which owned 10 percent of the shares in InDex as of June 30, started selling its holdings on the stock exchange in July and continued to sell off large volumes in connection with the results being presented at the end of August. Bengt Julander is now the company's third largest shareholder with 10 percent of the shares and the Fourth Swedish National Pension Fund the fourth largest with 7 percent. SEB Venture Capital and Industrifonden are still the largest shareholders with approximately 15 percent each. We are very pleased that the list of shareholders has been strengthened with additional long-term and financially strong investors.

NEW POSSIBILITIES FOR PHASE III DESIGN CREATES STRATEGIC FLEXIBILITY

Traditionally, phase III programs in moderate to severe ulcerative colitis have included approximately 1,000 patients, which required significant amounts of capital. Over the past six months, we have seen clear signals that the regulatory authorities have opened up for innovative and smaller phase III programs. This shift by the authorities lets us plan for a phase III program that InDex can manage on its own. A key is to carry out the studies sequentially and not in parallel as traditionally done. You can then read out study by study along the way, which lowers the risk as the studies are completed and allows stepwise financing of the program. This without having to take longer time to complete than a traditional design. With the strengthened shareholder base and the positive feedback we received from institutional investors in connection with the directed share issue, we see the opportunity to finance the further development of cobitolimod and thereby create additional value.

From a strategic and negotiation perspective, it is a great strength to be autonomous and be able to control the timing and circumstances for potential future partnerships. As we prepare for phase III on our own, we continue our business development work to present the positive CONDUCT results and development plans to companies that have shown interest in cobitolimod. The possibility of a less

extensive phase III program also widens the universe of potential partners to include regional and speciality pharma companies. Also the large global companies can appreciate the benefits of an innovative phase III program. Even if they do not have capital constraints, there is competition for patients and smaller studies means a faster way to market.

With positive phase IIb results, new capital, a strong shareholder base and strategic flexibility, we look forward to 2020 and the further development of cobitolimod and InDex as a company.

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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 November 27, 2019.

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.