InDex Pharmaceuticals

Annual Report 2020

Interview with Felicia on living with ulcerative colitis

CAN YOU TELL US ABOUT YOUR DISEASE?
I was 16 years old when I was diagnosed with ulcerative colitis. My symptoms came very suddenly one day in the autumn of 2013. I noticed that something was wrong when I went to the toilet and it was only blood coming. With each day, it only got worse with the toilet visits and the pain in my stomach. After 2 weeks at home with these problems, we went to the ER in Gävle, and I stayed there for almost a month. I lost a lot of blood due to the problems I was having, so I got 2 blood transfusions and was connected to a nutrient drip all the time, as I could not keep anything I ate. This led to that my body did not receive enough nutrients to live on. After 3 weeks, they started to talk about investigating different intestinal diseases. I was then transported down to Uppsala to undergo gastroscopy and colonoscopy, where they check what the intestine looks like with a camera. I was put to sleep and after about 2 hours I woke up, and shortly afterwards I got my diagnosis. I was then told that I have total ulcerative colitis, which means that it is in the entire colon and rectum.

After I got my disease, it has affected my daily life very much. More than I probably first thought it would. People may think everything lies in the disease itself, but there is so much more that people do not know and that people do not see. At first when I was discharged, I could not eat properly, which led to me having to live with a probe back and forth for 8 months, and that caused a lot of distress. Then, my disease was not good for the first five years. It was like living on thin ice until the next flare came. There were a lot of visits to the hospital and a lot of experimenting with different medications back and forth, which led to a lot of side effects. Today, my stomach is more in balance, I would say. I take much stronger drugs now, Humira and Salazopyrin to get my bowel under control, but this has led to me having a lot of side effects in the joints. One day it can be fine while other days I have to lie in bed all day because my whole body hurts.

DID YOU EVER EXPERIENCE DIFFICULTIES IN SCHOOL DUE TO YOUR DISEASE?
Yes, because my disease was very aggressive and I got a flare at least 2 times a year, it affected my schooling a lot. The year I became ill, I had just started the first year of high school, and this led to that I had not much choice but to repeat the first year. My whole time in school was very difficult. When my friends were on leave and could do fun things, I either went to the hospital or tried to catch up on everything I had missed.

WHAT IS THE WORST THING ABOUT HAVING ULCERATIVE COLITIS?
The worst thing about having ulcerative colitis is probably not knowing. The flares, i.e. the periods when you are ill, can come at any time. I can feel great today and my stomach is behaving normally, but tomorrow I can wake up and have a lot of pain in my stomach and have to go to the toilet several times per hour. That's probably what consumes me the most. Not knowing when the next setback will come. To not being able to manage your disease the way you want, but learning to adapt to it, and having to eat these strong medications

Name: Felicia Oskarsson, 23 years old
Occupation: Salesperson in a store
Interests: Being outdoors, spending time with my family
Diagnosis: Ulcerative colitis

that make my body not function as a "normal" 23-year-old does. Instead, I alternate between feeling good or being completely bedridden because of the side effects and that the associated problems in the joints are so severe.

WHAT DIFFERENT TYPES OF MEDICATIONS HAVE YOU BEEN TREATED WITH FOR YOUR DISEASE?
I have been treated with a lot of different medications in different variants. When I got sick for the first time, there were a lot of tablets. I do not remember today what all of it was. It was up to almost 30 tablets per day. I have eaten cortisone a lot back and forth during these years, which has led to side effects such as nausea and vomiting, fatigue and general malaise. I have previously taken Imuran and Dipentum as maintenance medications, but these did not work properly. I have in short tried a lot of different things. Today, I am unfortunately on a stronger biological drug to get the disease under control. Today I take Humira injections and Salazopyrin in tablet form.

HOW DO YOU LOOK AT THE FUTURE?
I used to think a lot about the future. What it would look like. How everything would turn out. Questions I asked myself that I did not get answers to, such as: will I get cancer later in life? Will I be able to have biological children without any complications? Will I have this pain all my life? Will I be able to live normally again? Today I have put these questions aside, I am trying anyway, because I know there are no answers to them. Of course, these questions and thoughts can come up sometimes, but not as before when I almost sat and waited for answers. I do not think so much about my future today. I take one day at a time. It feels easier that way, but on the whole I'm not very worried.

2020 in brief

- InDex announced on February 19, 2020 the conclusions from in-depth analysis of the complete data set from the phase IIb dose optimisation study CONDUCT. The analysis confirmed that the highest dose tested, which met the primary endpoint of the study, demonstrates an outstanding combination of efficacy and safety.
- InDex announced on April 16, 2020 that the company had received positive responses from FDA and EMA regarding phase III development of cobitolimod, for the treatment of moderate to severe ulcerative colitis. Both authorities endorse the advancement of cobitolimod into phase III studies. The 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 (250 mg x 2). InDex continued to evaluate the most advantageous study design based on, among other things, development risk, commercial potential, time to market and cost.
- InDex announced on October 6, 2020 that the high-impact medical journal The Lancet Gastroenterology & Hepatology had published the results of InDex's phase IIb study CONDUCT with cobitolimod. CONDUCT was a phase IIb dose optimisation study, evaluating the first-in-class TLR9 agonist cobitolimod for the treatment of moderate to severe ulcerative colitis. The study met the primary endpoint and cobitolimod demonstrated an outstanding combination of efficacy and safety. The medicinal journal also published an independent expert commentary that provides strong support for cobitolimod's potential.
- InDex announced on November 25, 2020 the intention to carry out a fully guaranteed rights issue of approximately SEK 500 million with preferential rights for the company's existing shareholders. The Board proposed that an extraordinary general meeting to be held in January 2021 would authorize the Board to resolve on the rights issue and the terms thereof. The net proceeds from the contemplated rights issue are mainly intended to be used to fund the important initial induction study in a sequential phase III program in moderate to severe left-sided ulcerative colitis for the company's lead drug candidate, cobitolimod.

CONSOLIDATED FINANCIAL SUMMARY

SEK million	2020	2019	2018	2017	2016[1]
Net sales	0.0	0.1	0.1	0.1	0.4
Operating loss	–57.3	–87.7	–82.0	–73.2	–39.5
Result after tax	–57.4	–87.8	–82.1	–72.7	–41.3
Earnings per share before and after dilution, SEK[2]	–0.24	–0.45	–0.48	–0.44	–0.41
Cash flow from operating activities	–70.6	–85.1	–78.6	–67.3	–31.9
Cash and cash equivalents at year-end	53.8	126.8	83.0	125.1	193.2
Number of employees at year-end	7	7	7	7	7

[1] According to historical accounting principles (K3).
[2] Adjusted for the completed rights issue in February 2021.

FINANCIAL CALENDER

Interim report Q I 2021	May 5, 2021
Annual general meeting	June 3, 2021
Interim report Q II 2021	August 25, 2021
Interim report Q III 2021	November 24, 2021

InDex 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 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 Immuno-Modulatory 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 (+46 8 121 576 90 or certifiedadviser@redeye.se).

Contents

The following definitions have been used in this annual report – "the company", "the group" or "InDex" for the operations conducted in InDex Pharmaceuticals Holding AB together with the subsidiaries InDex Pharmaceuticals AB and InDex Diagnostics AB.

This is InDex Pharmaceuticals

Improve the lives of patients with immunological diseases through the development of innovative drugs

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 in late stage clinical development for the treatment of moderate to severe ulcerative colitis – a debilitating, chronic inflammation of the large intestine.

In addition, InDex has a broad portfolio of other DNA based ImmunoModulatory Sequences (DIMS) in discovery stage, with the potential to be used in the treatment of various immunological diseases.

Ulcerative colitis is a chronic disease caused by inflammation of the large intestine. The symptoms are characterised by blood- and mucus-mixed diarrhea, frequent stools, pain, fever, weight loss and anemia. Despite the currently available drugs on the market, many patients with ulcerative colitis still suffer from severe symptoms, and current therapies can cause serious side effects. For those patients that do not respond to medical treatment, the last resort is to surgically remove the colon.

InDex's clinical studies have shown that cobitolimod has a competitive efficacy and a more favorable safety profile than what has been reported for the currently approved biological drugs. Sales of biologics for treatment of ulcerative colitis amount to more than USD 5 billion a year.

Cobitolimod has a new type of mechanism of action. It is a so-called Toll-like receptor 9 (TLR9) agonist that can provide an anti-inflammatory effect locally in the large intestine, which may induce mucosal healing and relief of the clinical symptoms in ulcerative colitis.

In 2019 InDex reported positive top line results from the phase IIb study CONDUCT with cobitolimod. CONDUCT was a dose optimisation study with the objective to identify the most efficacious dose to move forward in development. The study met the primary endpoint clinical remission with a superior efficacy of 15 percent (delta) for patients treated with the highest dose of cobitolimod compared to placebo. Cobitolimod was well tolerated at all dose levels and no differences in the safety profile were observed compared to placebo. CONDUCT was a randomised, double blind, placebo-controlled study including 213 patients with left-sided moderate to severe active ulcerative colitis at 91 sites in 12 countries. The patients were divided into four treatment arms who received different doses of cobitolimod and one arm who received a placebo.

InDex has already in previous clinical trials shown that cobitolimod has an excellent safety profile and has statistically significant effects on those endpoints that are most relevant in this disease, both from a regulatory and clinical perspective. These endpoints include the key clinical symptoms such as blood in stool, number of stools, and mucosal healing, respectively.

Vision

InDex's vision is to be an innovation driven company focused on bringing drugs from the DIMS platform for immune mediated conditions to market approval, alone or in collaboration with partners, starting with the lead drug candidate cobitolimod.

Mission

InDex's mission is to significantly improve the lives of patients suffering from immunological disorders by providing effective and safe drugs for diseases with high unmet medical needs.

Given the outstanding combination of efficacy and safety, InDex is now advancing cobitolimod into phase III, which is the final stage of development before application for market approval.

Based on regulatory guidance, the company is planning a sequential phase III program with two induction studies and a maintenance study with patients that have responded to cobitolimod as induction therapy. The important initial induction study is planned to include approximately 400 patients. The primary endpoint of clinical remission is to be measured at week 6. In addition to the 250 mg dose, which was the highest dose and the one that showed the best efficacy in the phase IIb study CONDUCT, the study is also planned to evaluate a higher dose, 500 mg, in an adaptive study design. This higher dose has the potential to provide an even better efficacy than what was observed in the phase IIb study CONDUCT.

CEO statement

InDex's lead asset is the drug candidate cobitolimod, which we are developing as a novel therapy for moderate to severe ulcerative colitis. This is a hard-to-treat patient group and many do not respond to or experience side effects from current therapies, resulting in a high unmet medical need. Given the outstanding combination of efficacy and safety, InDex is now advancing cobitolimod into phase III, which is the final stage of development before application for market approval. For InDex, 2020 was marked by the preparations for phase III, where the crucial pieces of the puzzle now have fallen into place.

To finance phase III development of cobitolimod we conducted a successful rights issue in the beginning of 2021 of approximately SEK 533 million. The subscription ratio amounted to as much as 153 percent and more than 99 percent was subscribed for by exercise of subscription rights. HBM Healthcare Investments and Handelsbanken Funds came in as new large owners in the rights issue. These are two internationally recognized and successful life sciences specialists that chose to invest significant amounts, which not only strengthens the ownership base, but also constitutes a strong validation of the potential of InDex.

The rights issue will primarily fund the important initial induction study in a sequential phase III program with cobitolimod for left-sided moderate to severe ulcerative colitis. The results of this induction study will constitute a significant value inflection point and the remaining program can be optimised according to the outcome of the study. We estimate that the study will take 18 to 24 months to complete from initiation.

The study, which has been named CONCLUDE, will be a global study with approximately 400 patients at a few hundred clinics. The primary endpoint, clinical remission, is to be measured at week 6. Apart from the dosing 250 mg x 2, which was the highest dose and the one that showed the best efficacy in the phase IIb study CONDUCT, cobitolimod's excellent safety profile allows to also evaluate a higher dose, 500 mg x 2, in an adaptive study design. This higher dose has the potential to provide an even better efficacy than what was observed in the CONDUCT study.

After the successful collaboration in CONDUCT, we are very pleased to once again have Parexel Biotech as our clinical development partner. They are a leading global CRO with considerable experience managing phase III studies in inflammatory bowel disease, which will ensure an efficient execution of CONCLUDE. The clinical study must now be approved by the authorities of each participating country. The goal is to start the study in the second quarter of 2021, but it is subject to the development of the Covid-19 pandemic if authorities and healthcare providers will be able to prioritize the start of new clinical studies in the near future.

It has been an intensive process since we in early 2020 received positive responses from the regulatory authorities FDA and EMA, that endorse the advancement of cobitolimod into phase III based on our previous positive study results and the high unmet medical need for new treatment options for patients with ulcerative colitis. During the year, in collaboration with our well-developed network of key opinion leaders within the field, we then developed a phase III design that in an efficient manner will provide the basis to be able to draw firm conclusions regarding cobitolimod's efficacy and safety as well as solid ground for a successful future commercialisation.

In the beginning of 2020, we also received the results of 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 Europe and the US. Cobitolimod's Target Product Profile with its novel mechanism of action tested well 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 have the potential to reach more than USD 1 billion.

The successful results from the phase IIb study CONDUCT were published in October 2020 in The Lancet Gastroenterology & Hepatology, which is one of the highest ranked international medical journals within the field of gastroenterology. The journal also chose to publish an independent expert commentary that provides strong support for the potential of cobitolimod to become an essential part of the future treatment of ulcerative colitis, as many patients do not respond to or suffer severe side effects from current treatments. During the autumn, the principal investigator of the study, Professor Atreya at the University of Erlangen-Nürnberg, also presented the results at the two leading gastroenterology conferences, UEGW and ACG. Furthermore, Professor Atreya won the award for best international abstract at ACG.

For those who want to know more about the phase III design, cobitolimod and ulcerative colitis, I highly recommend the webcast from the virtual R&D day we hosted in December 2020, which can be found on our website.

Strong stories like our patient interview with Felicia confirm the need for new effective and safe treatment options for ulcerative colitis. With the financing secured until the next pivotal read-out of clinical data, it feels very inspiring to move into phase III and bring cobitolimod another step closer to market to be able to help patients suffering from this severe disease.

Peter Zerhouni, CEO

Ulcerative colitis

A chronic disease with high unmet medical need for new treatment options

WHAT IS ULCERATIVE COLITIS?
Inflammatory bowel disease ("IBD") refers to chronic inflammation of all or parts of the gastrointestinal tract. The term IBD is commonly used to describe two conditions, ulcerative colitis and Crohn's disease. Ulcerative colitis is limited to the colon and rectum. Crohn's disease can affect any part of the gastrointestinal tract, most commonly the most distal part of the small bowel. Ulcerative colitis causes long-lasting inflammation that gives ulceration in the innermost lining of the colon and rectum, and for many patients it is very debilitating to live with. Ulcerative colitis is characterised by blood- and mucus-mixed diarrhea, frequent stools, pain, fever, weight loss, and anemia. The disease can, despite lifelong medication, complicate all parts of life and make it impossible to work, as severely affected patients always need to be close to a toilet. Studies show that patients suffering from ulcerative colitis have a significantly lower quality of life than the general population.[1] In addition, patients suffering from ulcerative colitis have a significantly elevated risk of developing colon cancer.[2] Most commonly, ulcerative colitis debuts between 15 and 30 years of age. Typically, the course of ulcerative colitis is intermittent; periods of disease aggravation (relapses) are followed by periods of remission (absence of symptoms). Almost half of the patients are estimated to have active disease at a given time.[3]

HOW COMMON IS ULCERATIVE COLITIS?
Today, about 0.2 percent of the population in developed countries has ulcerative colitis, which corresponds to more than 800,000 ulcerative colitis patients in Europe's five largest countries and more than 1,100,000 in the US.[4] Market research studies predict that the prevalence of ulcerative colitis will increase at an annual rate of 0.8 percent.[5] The increasing global burden of ulcerative colitis is already posing societal challenges due to high costs of the disease. Annually, the economic burden, i.e. the overall costs for society, of ulcerative colitis has been estimated to between EUR 12.5 billion and EUR 29.1 billion in Europe and between USD 8.1 billion and USD 14.9 billion in the US.[6] In addition to this, a 2019 systematic literature review estimated the indirect costs of ulcerative colitis per patient and year to be between EUR 1,362 and EUR 2,470, including absence from work, early retirement, and loss of productivity.[7]

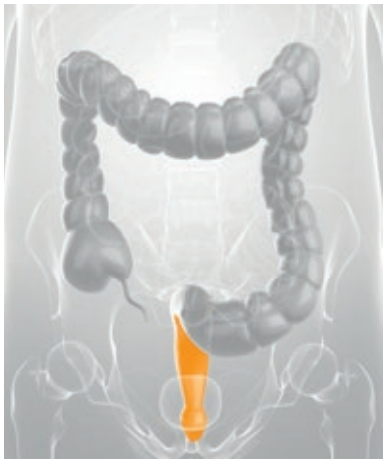
HOW DOES THE SEVERITY OF ULCERATIVE COLITIS VARY?
Ulcerative colitis varies in severity based on the intensity of the symptoms, and is categorised as mild, moderate or severe disease.[8] The extent of the inflammation may also differ and is usually divided into proctitis (only the rectum), left-sided colitis (from the rectum up to the splenic flexure, i.e. the first curve of the colon on the left side of the abdomen) and total colitis, so-called pancolitis (the whole colon). The severity and extent of the inflammation is assessed by the physician looking inside the rectum and colon using an endoscope (endoscopy).

HOW IS ULCERATIVE COLITIS TREATED TODAY?
There is no cure for ulcerative colitis and most patients will require lifelong treatment. The aim of treatment in ulcerative

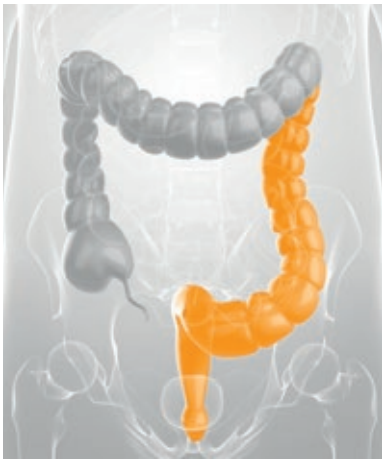
ULCERATIVE COLITIS SYMPTOMS

Illustrations: Freepik

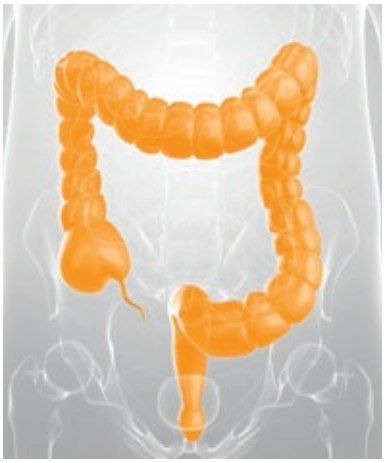
EXTENT OF INFLAMMATION



Proctitis



Left-sided colitis

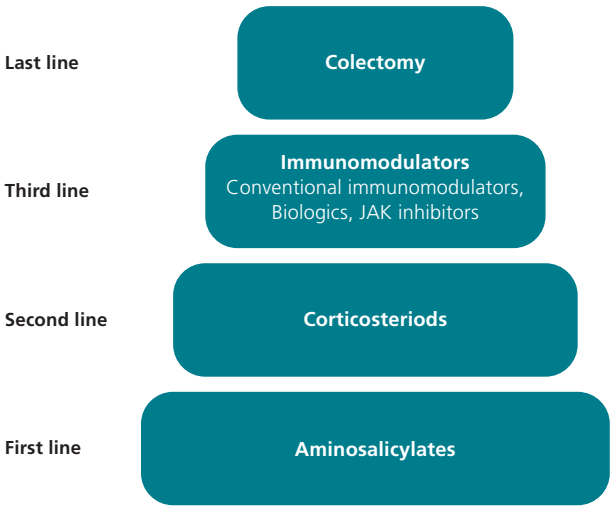


Pancolitis

colitis is to induce remission by induction therapy, followed by maintenance therapy to reduce the risk of future relapses. The standard treatment for ulcerative colitis depends on the extent of the disease and how severe the symptoms are. The current first and second line treatment options are aminosalicylates and corticosteroids, respectively. Corticosteroids are generally used to treat active disease in the relapse setting and are not recommended for maintenance treatment due to the risks associated with long-term use. In the significant portion of patients who fail to respond to these first and second line treatments, the addition of immunomodulatory drugs is the next option in order to induce remission. These third line options include conventional immunomodulators such as azathioprine and 6-mercaptopurine, biological therapies such as TNF-alpha inhibitors, integrin inhibitors and IL12/IL23 inhibitors, or JAK inhibitors. However, these third-line treatment options have several limitations in that the effect is often delayed and they are associated with serious side effects. A substantial percentage of patients with moderate to severe ulcerative colitis will not respond to available therapies or will eventually develop tolerance to the treatment. Often, these patients require periods of medium- to long-term hospitalisation.

Colectomy, i.e. surgical removal of the colon, is the last option for patients with severe ulcerative colitis who do not respond to medical treatment. It is estimated that approximately 10 percent of patients will eventually require surgery.[9] During colectomy, the small intestine is surgically connected to an opening in the abdominal wall (stoma) through which faecal waste is collected in stoma bags. It can also be achieved by using a part of the small intestine to surgically create an internal pouch that is connected to the anus. Colectomy entails risks such as infections, abdominal pain, infertility and even death. Patients also experience a low quality of life post-surgery, which is associated with physiological and psychological co-morbidities, high unemployment rates and high rates of sick leave.

CURRENT TREATMENT PARADIGM FOR ULCERATIVE COLITIS



1 Knowles et al. Quality of Life in Inflammatory Bowel Disease: A Systematic Review and Meta-analyses-Part I. Inflamm Bowel Dis. 2018 Mar 19;24(4):742-751
2 Kobayashi et al, Nat Rev Dis Primers. 2020 Sep 10;6(1):74.
3 The facts about Inflammatory Bowel Diseases, The Crohn's & Colitis Foundation of America (CCFA).
4 Global data Ulcerative colitis prevalence
5 Ulcerative Colitis Disease Coverage, Datamonitor Healthcare 2016
6 Cohen RD et al. (2010), Systematic review: the costs of ulcerative colitis in Western countries, Aliment Pharmacol Ther. 31(7):693-707.
7 Constantin, J., Atanasov, P., Wirth, D., & Borsi, A. (2019), Indirect costs associated with ulcerative colitis: a systematic literature review of real-world data. BMC gastroenterology, 19(1), 179.
8 Kobayashi et al, Nat Rev Dis Primers. 2020 Sep 10;6(1):74.
9 Fumery et al. Clinical Gastroenterology and Hepatology 2018;16:343–356.

Interview with gastroenterologist Jonas Halfvarson about ulcerative colitis

WHAT IS ULCERATIVE COLITIS?
Ulcerative colitis is a chronic disease characterised by an inflammation of the mucosa of the colon and rectum. The disease usually has flares with periods of low or no disease activity in between. Together with Crohn's disease, it is the main form of inflammatory bowel disease (IBD).

WHO GETS ULCERATIVE COLITIS AND WHY?
Ulcerative colitis often debuts at the age of 20-40, but can manifest at any age. The cause of the disease is not fully known, but both genetic and environmental factors are important. According to a current explanatory model, inflammation develops because the body's immune system reacts to the intestinal flora in individuals who have a hereditary tendency to develop the disease. Deficiencies in the intestinal "barrier function" and various external factors are also considered to be important for the onset of the disease.

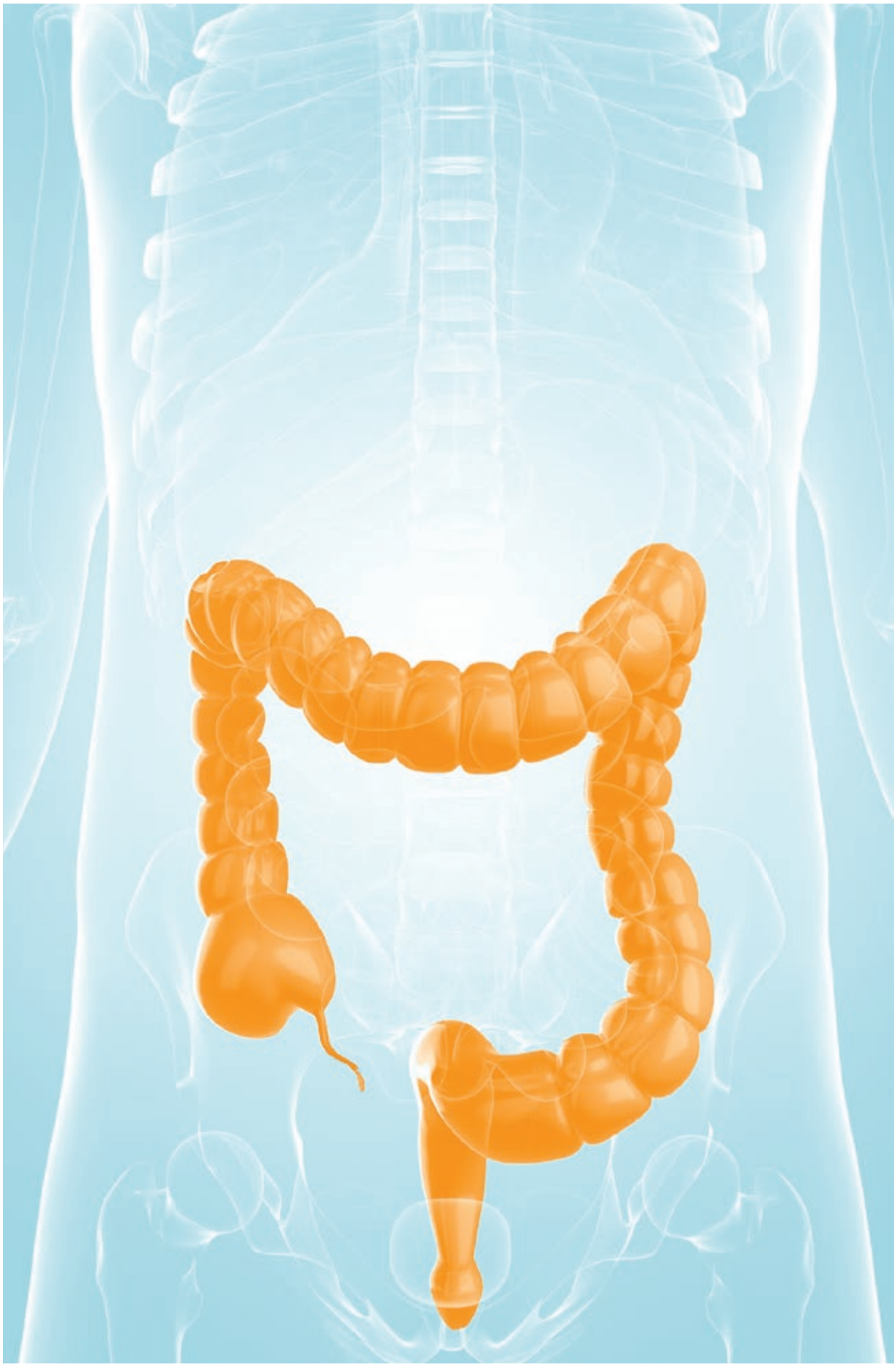
IN WHAT WAY ARE PATIENTS AFFECTED BY THEIR DISEASE?
Blood- and mucus-mixed loose stools or diarrhea are typical symptoms of ulcerative colitis. Many patients have frequent urges to urgently need to empty their bowel. The worry of not reaching a toilet in time, means that many patients with ulcerative colitis must constantly be aware of the nearest toilet. Some even have difficulty leaving their homes. Fatigue and tenesmus, i.e. painful cramps in the abdomen that relieve with bowel movements, make it difficult to cope with everyday life and the expectations of those around you. In more severe cases, weight loss, fever and constitutional symptoms occur, after which the patient needs to be hospitalized. Not all patients respond to medical treatment and ten years after diagnosis, almost one in ten patients have had surgery to remove the colon.

WHAT IS THE LARGEST MEDICAL NEED IN ULCERATIVE COLITIS TODAY?
The fact that the disease often begins at a young age and that it can have a major impact on the quality of life of the patient makes it important to identify an effective treatment at an early stage. Unfortunately, most of the treatments available are associated with various forms of risks. As a doctor, I currently lack tools that can guide me regarding which treatment is best for the individual patient.

WHAT DO YOU THINK ARE THE MOST IMPORTANT PROPERTIES OF A GOOD TREATMENT FOR ULCERATIVE COLITIS?
A good treatment for ulcerative colitis should give a quick and lasting effect over time without being associated with any risks of serious side effects. It is also an advantage if the medicine can be taken at home by the patients themselves without having to go to a care facility, and that the medicine can be combined with other therapies if needed.

Name: Jonas Halfvarson
Title: Professor and chief physician in gastroenterology at Örebro University och Örebro University Hospital, member of InDex's European Advisory Board

Photo: Kicki Nilsson/Icon Photography



Cobitolimod

InDex's lead drug candidate

Cobitolimod is a potential new medication for patients with moderate to severe ulcerative colitis. Many of the current treatment options have problems with side effects[1]. In addition, a substantial percentage of the patients with moderate to severe ulcerative colitis does not respond to available therapies or will eventually develop tolerance to the treatment and stop responding. For this patient group there is a high unmet medical need. Cobitolimod is planned to be positioned as an efficacious and safer alternative to the therapies used today for moderate to severe ulcerative colitis.

HOW DOES COBITOLIMOD WORK?

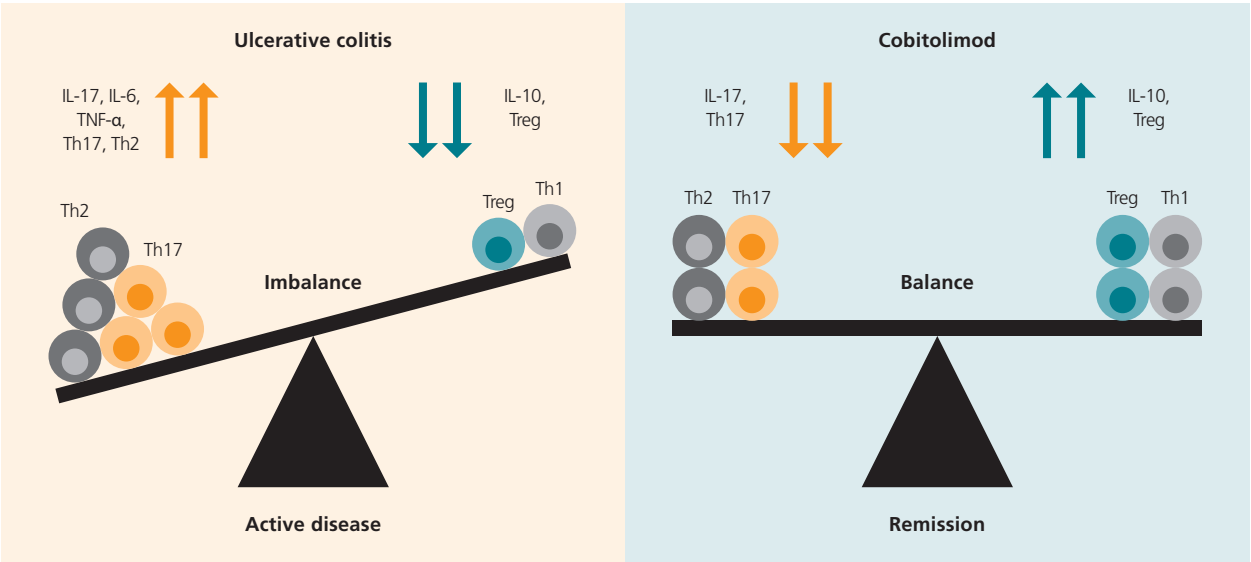
The intestinal mucosa acts as a barrier to the outside world and constitutes an important part of the body's immune system. It is rich in immune cells that protect the body from disease organisms and harmful substances in the intestinal tract. A healthy intestinal mucosa responds to potential threats with a balanced immune response. However, an imbalance in the immune system of the intestinal mucosa can cause a vicious circle where the immune response is amplified and leads to chronic inflammation. In ulcerative colitis, an increased production of the cytokine interleukin (IL)-23 is seen, which stimulates the production of pro-inflammatory cytokines such as IL-1, TNF-alpha and IL-6, as well as IL-17, where IL-17 stimulates additional production of inflammatory mediators. Research has also demonstrated an increased proportion of inflammatory T helper 17 cells (Th17 cells) and Th2 cells, but a reduced number of regulatory T cells (Treg cells), creating an immunological imbalance in the intestinal mucosa.

Cobitolimod has a novel and unique mechanism of action. It is a so-called Toll-like receptor 9 (TLR9) agonist. TLR9 is a receptor that is expressed by certain immune cells and is the immune system's receptor for recognising DNA from bacteria and viruses. Cobitolimod is a synthetically manufactured oligonucleotide which by mimicking microbial DNA binds to TLR9 and can thereby modulate the immune system. Cobitolimod has in both experimental models of ulcerative colitis as well as in patients with ulcerative colitis been able to stimulate immune cells to produce beneficial anti-inflammatory cytokines like IL-10 and increase the number of Treg cells. At the same time cobitolimod decreases the production of inflammatory cytokines such as IL-17 (refer to the figure below). By increasing the number of Treg cells and reducing the number of Th17 cells, cobitolimod helps to restore the balance of the immune system. In this way, cobitolimod can provide a local anti-inflammatory effect, which may lead to healing of the mucosa in the large intestine and relief of the clinical symptoms in ulcerative colitis. A comprehensive scientific paper with these mechanistic data was published in the medical journal Journal of Chrohn's and Colitis (JCC) in 2019.[2]

1 Agrawal et al. JAK Inhibitors Safety in Ulcerative Colitis: Practical Implications. Journal of Crohn's and Colitis, 2020, S755–S760 and Holmer et al. Overall and comparative safety of biologic and immunosuppressive therapy in inflammatory bowel diseases, Expert Rev Clin Immunol. 2019 Sep;15(9):969-979.

2 Schmitt H. et al. The TLR9 agonist cobitolimod induces IL10 producing wound healing macrophages and regulatory T cells in ulcerative colitis. Journal of Crohn's and Colitis, 2019 Oct 20:508-24.

MECHANISM OF ACTION



In ulcerative colitis, there is an imbalance in the immune system leading to a chronic inflammation of the colon. Cobitolimod helps to restore the balance in the immune system by reducing the number of inflammatory Th17 cells and increasing the number of regulatory T cells, which reduces the inflammation in the colon.

What are the key benefits of cobitolimod?

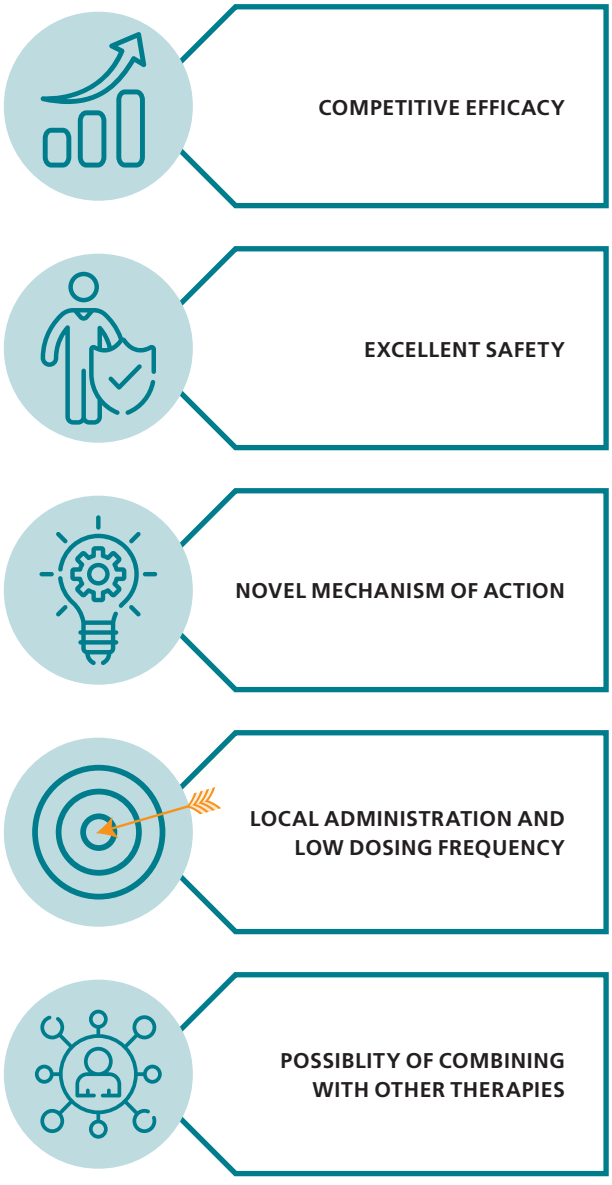
1. EFFICACY
Cobitolimod has demonstrated a statistically significant, clinically relevant and competitive efficacy in the phase IIb study CONDUCT. The observed effect size is comparable to what marketed products and other compounds in phase III development have reported in their clinical studies.

2. SAFETY PROFILE
Cobitolimod has demonstrated an excellent safety profile to date, with virtually no serious adverse effects of the treatment reported in the phase IIb and earlier studies where in total 416 IBD patients were treated with cobitolimod. This is an important benefit as the existing modern drugs are associated with increased risks of serious side effects like infections, malignancies, and skin disorders, perforation in the stomach and intestines, and pulmonary embolisms. In market research conducted in 2016 and 2020 surveying in total more than 200 physicians and patients, the safety profile was one of the most attractive features of cobitolimod in combination with a clinically relevant efficacy.

3. MECHANISM OF ACTION
The novel and unique approach behind cobitolimod relies on the mechanism of modulating the body's own immune system via TLR9, to regulate the immunological imbalance caused by the disease. There is no other therapeutic option on the market or in active development for ulcerative colitis based on targeting TLR9. Advantages with a novel and unique mechanism of action include no competition for the specific mechanism of action and the opportunity to address patients that have failed treatments with other mechanisms of action.

4. ADMINISTRATION AND LOW DOSING FREQUENCY
Cobitolimod is administered via the rectum as a 50 ml solution using an enema. After administration, the patient is asked to lie down on the side for at least 30 minutes for the solution to cover the left side of the colon, i.e. up to the splenic flexure. This mode of administration allows cobitolimod to come in contact directly with the target cells in the inflamed mucosa, allowing a rapid onset of action without systemic exposure and off-target effects. Patients surveyed viewed the site-specific effect of cobitolimod as a significant advantage. Cobitolimod is designed to be self-administered by the patient at home. To induce remission, cobitolimod is given as two applications over a three-week period and is intended to be given every three weeks as maintenance therapy, in order to reduce the risk of future relapses. Rectal administration is not uncommon in ulcerative colitis treatment in general, but the dosing of cobitolimod (every three weeks) is infrequent compared to other enemas used in ulcerative colitis such as corticosteroids and aminosalicylates which are usually administered daily or several times per week.

5. THERAPY USED IN COMBINATION WITH OTHERS
As other third line medications for moderate to severe ulcerative colitis are systemically administered and are associated with severe side effects, there is a risk of adverse reactions from combining them. Cobitolimod's unique and site-specific mechanism of action and excellent safety profile means cobitolimod can potentially be used in combination with other third line medications to offer treatment to an even broader range of patients with ulcerative colitis. This is viewed as a significant advantage by physicians in market research.



Illustrations: Freepik

The CONDUCT study

Outstanding combination of efficacy and safety

STUDY DESIGN AND OBJECTIVE

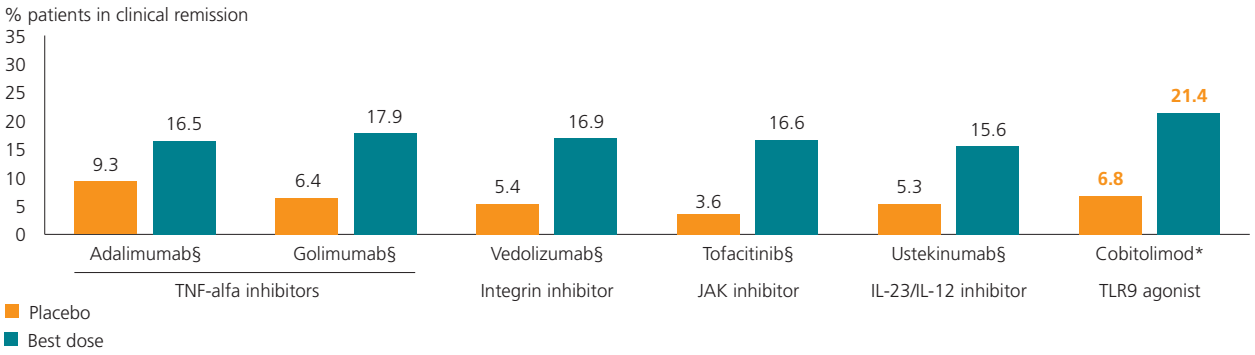
The CONDUCT study was a randomised, double-blind, placebo-controlled, exploratory phase IIb study where different doses of cobitolimod were evaluated in patients with left-sided moderate to severe active ulcerative colitis not responding to conventional treatment. The study objective was to identify the most efficacious dose and dose regimen for further development. The study included 213 patients divided into four treatment arms that received different doses of cobitolimod and an arm receiving placebo. In addition to cobitolimod or placebo, all patients continued with their standard of care treatment. The study was conducted at 91 sites in 12 different European countries from June 2017 to August 2019. The primary endpoint of the study was induction of clinical remission at week 6.

SUCCESSFUL RESULTS PUBLISHED IN HIGH-IMPACT MEDICAL JOURNAL

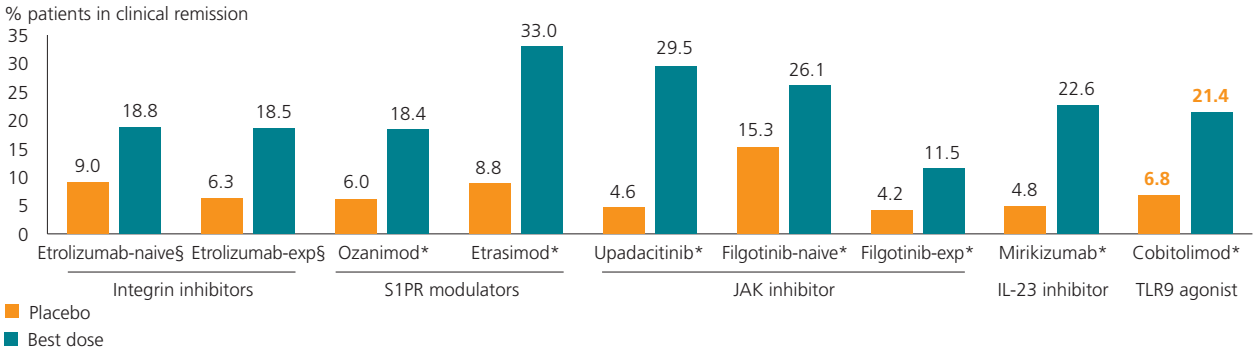
The study met the primary endpoint and clearly demonstrated that it was the highest dose of cobitolimod, 250 mg x 2, that was the most effective. Clinical remission at week 6 was achieved in 21.4 percent of patients treated with two doses of 250 mg cobitolimod, which was statistically significantly better (p-value = 0.0247) than patients treated with placebo where only 6.8 percent of the patients achieved clinical remission, i.e. a difference (delta) of 14.6 percent. No statistically significant difference was noted between the other doses of cobitolimod and placebo. The results in secondary endpoints also confirm the efficacy of the highest dose. Thus, the CONDUCT study fulfilled its objectives in both the primary and a number of clinically relevant secondary endpoints. Cobitolimod was well tolerated in all dose groups and no differences in safety profile were noted compared to placebo. In October 2020, the CONDUCT results were published in the reputable medical journal, The Lancet Gastroenterology & Hepatology which also included a positive independent expert commentary.[1]

1 Atreya et al, Cobitolimod for moderate-to-severe, left-sided ulcerative colitis (CONDUCT): a phase 2b randomised, double-blind, placebo-controlled, dose-ranging induction trial, Lancet Gastroenterol Hepatol, 2020 Dec;5(12):1063-1075.

VS. MARKETED PRODUCTS



VS. PIPELINE PRODUCTS



*§ Full Mayo Score ≤2; * 3-component Mayo Score ≤2. Caution advised when comparing data across clinical studies. The patient population in the studies included a mix of both biological naïve and biological experienced patients, except for etrolizumab and filgotinib where separate studies were performed. Infliximab excluded from comparison as not comparable phase III patient population. The results presented in the rightmost column in the above figure is taken from the CONDUCT study.*

InDex has in previous clinical trials shown that cobitolimod has an excellent safety profile and has statistically significant effects on those endpoints that are most relevant in ulcerative colitis. These endpoints include the key clinical symptoms such as blood in stool, stool frequency, and mucosal healing respectively.

COMPETITIVE EFFICACY AND EXCELLENT SAFETY PROFILE COMPARED TO THE COMPETITORS

Comparisons to drugs tested in other clinical studies (so-called indirect comparisons) should always be made with caution, as both the patient population, time point, endpoints etc. may differ between the studies. If, however, the results in the CONDUCT study are put into perspective with the results in the phase III studies for the drugs that are currently on the market for moderate to severe ulcerative colitis, cobitolimod has a competitive profile. The approved drugs reported around 17 percent of the patients in clinical remission in their respective phase III studies. The proportion of patients in the placebo group that went into remission differs between the studies and leads to a delta ranging from 7.2 to 13.0 percent between the studies and substances (refer to the top figure above). Cobitolimod also has a competitive profile when compared to the clinical results for other drugs that are currently in phase III development for moderate to severe ulcerative colitis (refer to the bottom figure above). The exact effect size of cobitolimod remains to be determined in a larger patient sample in phase III. Something that really differentiates cobitolimod from its competitors is the safety profile. The biological drugs are associated with serious side effects such as infections and cancer. One of the substances that recently came to the market for ulcerative colitis, the JAK inhibitor, tofacitinib, has an increased risk of infections and cancer as well as an increased risk of perforation in the stomach and intestines and an increased risk of blood clots in the lung. All the TNF-alfa inhibitors and the JAK inhibitor tofacitinib have black box warnings, which alerts the public and healthcare providers to serious side effects, such as injury or death. Several of the classes of substances now being tested in phase III are also associated with serious side effects. In contrast, cobitolimod has demonstrated an excellent safety profile in five clinical studies across a total of 416 IBD patients.

The phase III study CONCLUDE

ADVANCING COBITOLIMOD INTO PHASE III

InDex is now advancing cobitolimod into phase III, which is the final stage of development before application for market approval. Following the results of the phase IIb study CONDUCT, InDex received positive response from both FDA and EMA regarding phase III development, and both authorities endorse the advancement of cobitolimod into phase III in patients with moderate to severe left-sided ulcerative colitis.

A wide range of phase III preparatory activities have already been completed. InDex has for example already manufactured study drug for the first part of the phase III program. Furthermore, all preclinical studies required prior to phase III have been completed and an agreement has been signed with a leading global contract research organisation (CRO) that InDex have selected to conduct the phase III study. The clinical study must finally be formally approved by the authorities in each participating country.

InDex's key focus is to start phase III as soon as possible on the back of the positive results in the phase IIb study CONDUCT, the positive regulatory response and the supportive findings in market research commissioned by InDex underpinning the company's belief in the market potential of cobitolimod.

PHASE III DESIGN

Based on guidance from FDA and EMA, InDex is planning a sequential phase III program with two induction studies and a one-year maintenance study with patients that have responded to cobitolimod as induction therapy. The phase III program will form the basis for market approval by confirming the overall efficacy and safety of cobitolimod in a sufficiently large sample of patients with moderate to severe, left-sided ulcerative colitis with an inadequate response or failure to tolerate conventional therapy, biological therapy or JAK inhibitors.

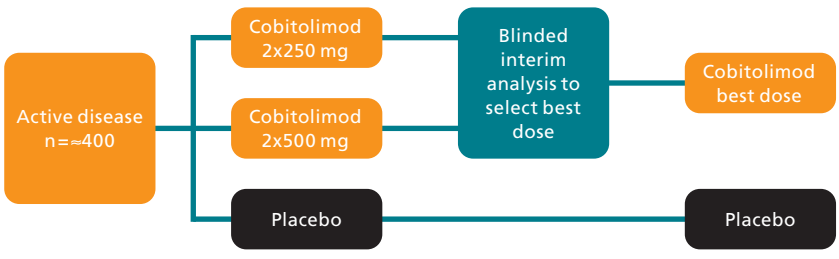
The important initial phase III induction study will be a global study including a few hundred clinics. The company estimates this first induction study will take 18 to 24 months to complete from initiation. The study will include approximately 400 patients and the effect is measured at week 6. Apart from the dosing 250 mg x 2, which was the highest dose and the one that showed the best efficacy in the phase IIb study CONDUCT, cobitolimod's excellent safety profile allows to also evaluate a higher dose, 500 mg x 2. This higher dose has the potential to provide an even better efficacy than what was observed in the CONDUCT study.

When a sufficient number of the participants in the study have been randomised and have eligible data for the primary endpoint (i.e. induction of clinical remission at week 6), an interim analysis will be performed in a blinded fashion to select the best dose of cobitolimod and the other dose will be dropped. Following the blinded interim analysis, the additional patients to be randomised into the study will receive only the best dose of cobitolimod or placebo. This is referred to as an adaptive study design.

The participants in the study will receive treatment with cobitolimod or placebo in a double-blinded fashion. This means that neither the participant, nor doctor giving the treatment or study personnel, the CRO personnel or InDex know which treatment is administered. All study drugs will be identical in appearance, packaging and labelling. The study will remain blinded until all data have been confirmed and "clean file" has been prepared. Only then will the results be compiled by treatment group.

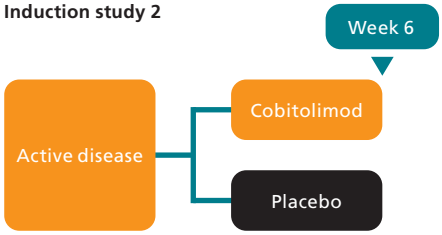
Upon a positive read-out of the first induction study, InDex plans to initiate the second induction study with the best dose. Reading out the outcome of the first induction study before the next study is started, will reduce the development risk of the program. The results of the first induction study will constitute a significant value inflection point and the remaining program can be optimised accordingly.

PHASE III DESIGN
Induction study 1 – adaptive design

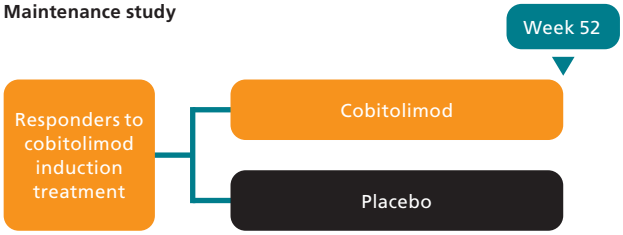


- Moderate to severe, left-sided ulcerative colitis
- Patients failed conventional treatment and/or biologics/ JAK inhibitor
- Dosing at week 0 and 3
- Primary endpoint clinical remission at week 6

Induction study 2



Maintenance study



Margareth Jorvid, Head of Regulatory Affairs

Interview about the regulatory work at InDex

Margareth Jorvid is working as Head of Regulatory Affairs at InDex since 2013. Margareth has over 30 years of experience in Regulatory Affairs and has worked at both the Medical Products Agency and at large and small pharmaceutical companies. Since 2006, she has worked as a consultant in Regulatory Affairs and quality assurance for pharmaceuticals, advanced therapies and medical devices. She is a member and honorary member of TOPRA (The Organization for Professionals in Regulatory Affairs), and has previously been a board member and 2005-2006 TOPRA president.

We took the opportunity to ask Margareth some questions about her work and why Regulatory Affairs is important.

WHAT DOES THE TERM REGULATORY AFFAIRS MEAN?
During the development of a drug, it is important to do the right things and to document this in a good way. This applies to how the drug is manufactured and controlled so that it meets the requirements and regulations that apply to medicinal products. This also applies to the preclinical trials and studies performed in laboratories as well as the clinical studies on patients which are the basis for a drug to be approved by the authorities to treat and help patients. The work with Regulatory Affairs means being up to date on the regulations and requirements that apply, and that during the development of a drug, already from an early stage in the development, have a dialogue and meetings with the regulatory authorities, and to ensure that everyone in the company knows the requirements and how we best meet them. This applies both before a drug is approved and also when it is used by patients after approval.

HOW DOES CONTACT WITH THE REGULATORY AUTHORITIES WORK IN PRACTICE?
A company can apply for and get so-called scientific advice meetings with the authorities. This applies, for example, to the Swedish Medical Products Agency, the European Medicines Agency (EMA), the US agency (FDA) and the national authorities of other countries. These meetings have previously usually taken place via physical meetings at the authority, but during the past year with the pandemic they have been replaced by telephone meetings and / or written questions and answers. Prior to such a meeting or dialogue, the company compiles a document with the questions they want to ask the agency's representatives, but also information on how far the company has come in the development of the drug, how it is manufactured and controlled, and what studies have been conducted or planned. The questions may, for example, be regarding manufacturing, whether further preclinical studies should be performed or how the company intends to carry out the next clinical study on patients.

WHY IS REGULATORY AFFAIRS IMPORTANT?
Research and development of new drugs is a challenging journey over time. To get a drug approved, its quality, efficacy and safety need to be determined. Regulations and guidelines change and new requirements are added as research develops, and they need to be interpreted and understood. The dialogue with the regulatory authorities is important to succeed with getting a drug approved so that it can benefit patients, who often have a great medical need. Here, the work and role within Regulatory Affairs is important.

HOW DO YOU WORK WITH REGULATORY AFFAIRS AT INDEX?
This is based on a collaboration between different functions in the company. My role in Regulatory Affairs is to clarify what needs to be done to achieve approval, and then virtually all employees contribute in different ways, from manufacturing, quality, patents, preclinical, medical knowledge, clinical studies, financing, market analysis and health economics, for us to succeed. It's a team effort.

INDEX IS PREPARING THE START OF A PHASE III PROGRAM FOR COBITOLIMOD, WHAT IS THE MOST IMPORTANT THING TO THINK ABOUT WHEN IT COMES TO REGULATORY AFFAIRS WHEN SETTING UP A PHASE III PROGRAM?
The phase III program is the last step before a drug can be approved by the authorities. It is important to have had a dialogue with the regulatory as well as the health economic authorities, so that the right things are followed and documented in the studies. These dialogues and meetings are something we have put great emphasis on at InDex before the start of the phase III program for cobitolimod, so that it includes what is expected of the authorities. In this way, the possibility for an approval of cobitolimod for the treatment of patients with ulcerative colitis who need new treatment options increases.

Market overview

Large and growing market for the treatment of ulcerative colitis

The total annual sales of pharmaceuticals for ulcerative colitis was estimated in 2016 to be approximately USD 6.3 billion and is expected to grow to about USD 8 billion by 2023.[1] Biologic drugs, approved for third line treatment, represent the largest market segment in terms of value with annual sales in 2016 estimated to be more than USD 5 billion.[2] A substantial percentage of patients with moderate to severe ulcerative colitis will not respond to or cannot tolerate available therapies. Often, these patients require periods of medium- to long-term hospitalisation, and there is an enduring high unmet medical need for new treatment options. Cobitolimod, InDex's lead drug candidate for treatment of ulcerative colitis, is under development as an efficacious and safer alternative to the current drugs in third line. The initial intended application is for moderate to severe left-sided ulcerative colitis.

CHALLENGES WITH CURRENT THIRD-LINE THERAPIES

The third-line options for treatment of moderate to severe ulcerative colitis have several limitations. Some of the challenges with current third-line therapies are set out below.

Limited efficacy and the development of tolerance – Although the medical management of ulcerative colitis has changed significantly since the introduction of biological therapies 20 years ago, a significant proportion of patients do not respond to these therapies or will eventually develop tolerance and thus stop responding. For example, TNF-alpha inhibitors have long-term therapeutic effects in only about 30 percent of patients.[3] The only approved JAK-inhibitor, tofacitinib, did not show a better effect in its phase III program than the marketed biological drugs.[4]

The systemic administration of the current third-line therapies also gives a delayed onset of action and can cause off-target effects compared to locally administered therapies given directly to the inflamed colon avoiding systemic exposure.

Serious side effects – Conventional immunomodulators such as 6-mercaptopurine, azathioprine, methotrexate or ciclosporine have been used extensively in the past but are used less frequently nowadays in view of their side-effect profile and toxicity issues in prolonged treatment regimens and at high doses.[5] TNF-alpha inhibitors affect the patient's immune system and patients face increased risk of developing severe side-effects such as infections, cancer and skin diseases.[6] The integrin inhibitor vedolizumab and the IL12/IL23 inhibitor ustekinumab are also associated with an increased risk of severe side effects such as infections, hypersensitivity reactions and joint pain for vedozilumab, and infections, hypersensitivity reactions and malignancies for ustekinumab.[7] Finally, the JAK-inhibitor tofacitinib is associated with severe side effects such as serious infections, cancer, immune system problems and perforation in the stomach or intestine, as well as pulmonary embolism.[8]

SAFETY CONCERNS WITH CURRENT DRUG CLASSES

Drug class	Safety profile
TNF-alfa inhibitors	Infections, cancer, skin diseases
Integrin inhibitors	Infections, hypersensitivity reactions, joint pain
JAK inhibitors	Infections, cancer, immune system problems, perforation in the stomach or intestines, pulmonary embolism
IL23 inhibitors	Infections, hypersensitivity reactions, malignancies

NEW THERAPIES IN LATE STAGE CLINICAL DEVELOPMENT

There are several other companies conducting drug development in IBD. Many of the substances in late stage development for moderate to severe ulcerative colitis are new variants of anti-integrins (i.e. the same mechanism of action as vedolizumab), JAK inhibitors (i.e. the same mechanism of action as tofacitinib) or IL-23 inhibitors (i.e. similar mechanism of action as ustekinumab). Substances with a new mechanism of action for moderate to severe ulcerative colitis that are in phase III are ozanimod and etrasimod (S1P receptor modulators). The patient population which all these compounds seek to target is similar to what InDex is addressing with cobitolimod, but their reported mechanisms of action are significantly different and they are systemic based approaches, while cobitolimod has a local effect. Several of the compounds in development for moderate to severe ulcerative colitis can cause serious side effects.

ADDRESSABLE MARKET FOR COBITOLIMOD

Approximately 2,200,000 patients suffer from ulcerative colitis in the US, the five largest European countries and Japan, with 1,100,000 in the US, 800,000 in EU-5 and 260,000 in Japan.[9] Of these, approximately 1,320,000

1 Ulcerative Colitis Disease Coverage, Datamonitor Healthcare 2016.
2 Ulcerative Colitis Disease Coverage, Datamonitor Healthcare 2016.
3 Altwegg R et al. TNF Blocking Therapies and Immunomonitoring in Patients with Inflammatory Bowel Disease. Hindawi Publishing Corporation, Mediators of Inflammatory Bowel Disease. Hindawi Publishing Corporation, Mediators of Inflammation, Vol. 2014, Artikel-ID 172821.
4 Sandborn WJ et al, Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med. 2017 Aug 3;377(5):496-7.
5 Mowat C, et al (2011) Gut 60:571-607.
6 Macaluso FS, Renna S, Orlando A, Cottone M. Expert Opin Biol Ther. 2017 Feb;17(2):175-184.
7 https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/761044s003lbl.pdf och https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/125476s000lbl.pdf
8 Agrawal et al. JAK Inhibitors Safety in Ulcerative Colitis: Practical Implications. Journal of Crohn's and Colitis, 2020, S755–S760.
9 Global Data Ulcerative Colitis prevalence.

patients (60 percent) suffer from moderate to severe ulcerative colitis.[10] Furthermore, approximately 726,000 patients suffer from moderate to severe left-sided ulcerative colitis, which is roughly 55 percent of the population with moderate to severe ulcerative colitis.[11] Of these 726,000 patients, approximately 400,000 patients, equivalent to roughly 55 percent, is failing conventional therapy.[12] Assuming an annual price per patient in line with the most recently approved products for moderate to severe ulcerative colitis of USD 35,000[13] in US and USD 11,000[14] in EU-5 and Japan, cobitolimod has an estimated addressable market of USD 9.1 billion market with 400,000 patients. However, this should be interpreted as a theoretical addressable market. For a number of reasons not all eligible patients will access cobitolimod.

COBITOLIMOD'S MARKET POTENTIAL

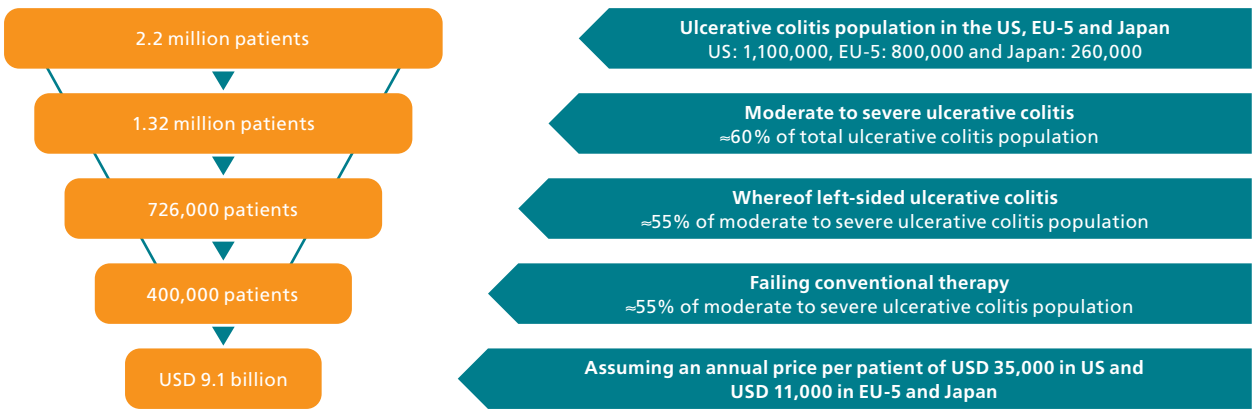
With cobitolimod's unique mechanism of action, competitive efficacy and excellent safety profile, InDex believes there is significant market potential for the product. Based on the sales of recently launched products, as well as the company's proprietary market research and analyses, including the addressable market described above, the annual global peak sales at a successful commercialisation of cobitolimod are estimated by the company to have the potential to reach more than USD 1 billion.

InDex conducted in 2016 a first market research study for cobitolimod among doctors and patients in the US and the five largest European markets, so called EU-5 (France, Germany, Italy, Spain and the UK). A total of 65 physicians specialised in IBD and 148 patients with ulcerative colitis participated in the study. The overall perception of cobitolimod's product profile was positive from both physicians and patients, and characteristics such as quick onset of action, efficacy and safety were highly valued.

These findings were further confirmed in physician and payer market research performed in early 2020. The research was conducted in three European countries (UK, France and Germany) and the US by in-depth telephone interviews. A total of 40 senior level gastroenterologists were interviewed and 13 payer interviews were conducted with individuals who had been involved in the evaluation of recent ulcerative colitis market entrants. Both physicians and payers recognised the medical need for new safe and effective treatments. Cobitolimod's combination of efficacy and safety was considered unsurpassable by the gastroenterologists and they said that they were likely to prescribe cobitolimod to a significant proportion of their patients. In addition, many of the gastroenterologists would want to use cobitolimod before TNF-alpha inhibitors, and in preference to late stage clinical pipeline therapies. Payers confirmed that cobitolimod can be priced in line with recently launched third line ulcerative colitis therapies.

The results of this primary market research support a future market acceptance and commercial potential for cobitolimod in both the US and Europe, provided that future clinical studies confirm the target product profile.

10 Apex Healthcare Consulting. Evaluation of cobitolimod for the treatment of ulcerative colitis. HCP Research Report March 2020.
11 Rutgeerts et al. N Engl J Med 2005;353:2462-76, Sandborn et al. Gastroenterology 2012;142:257–265, Sandborn et al. Gastroenterology 2014;146:85–95, Feagan et al. N Engl J Med 2013;369:699-710, Sandborn et al. N Engl J Med 2017;376:1723-36, Sandborn et al N Engl J Med 2019;381:1201-14 and Atreya et al. JCC 2016 Nov;10(11):1294-1302.
12 Apex Healthcare Consulting. Evaluation of cobitolimod for the treatment of ulcerative colitis. HCP Research Report March 2020.
13 Apex Healthcare Consulting. Evaluation of cobitolimod for the treatment of ulcerative colitis. Payer Research Report March 2020.
14 Apex Healthcare Consulting. Evaluation of cobitolimod for the treatment of ulcerative colitis. Payer Research Report March 2020.



Addressable market for cobitolimod.

Patents

InDex's policy is to protect its own proprietary position by seeking patent protection related to the company's proprietary technology. The company's patent portfolio covers use of cobitolimod in the treatment of various inflammatory diseases, as well as composition of matter patents for other DIMS compounds and their methods of use.

The use of cobitolimod in treatment of patients afflicted with an inflammatory condition, such as ulcerative colitis, and that have a history of steroid use is covered by two granted patent families. This portfolio provides a broad method of use patent protection in the US, Europe, Japan, Canada, Hong Kong and Australia until at least 2026, with the possibility of up to five years term extension after marketing approval. Furthermore, the use of cobitolimod for treatment of active ulcerative colitis in a patient that is refractory or responds insufficiently or is intolerant to anti-inflammatory therapy, with or without history of steroid use, is covered by a third patent family. This patent family has been granted in the US, Europe and Japan and is being prosecuted in Canada, Hong Kong and as a so called divisional patent in Europe. It will protect cobitolimod until 2032 with the possibility of up to five years term extension after marketing approval.

In addition, further patent applications have been filed or are contemplated in the light of advances in the formulation and clinical development of cobitolimod, to provide exclusivity beyond the term of InDex's already granted patents. The further patent applications filed would potentially provide protection until 2041 if granted.

Cobitolimod will also be subject to data protection as a new chemical entity for ten years from marketing approval in Europe, eight years in Japan and five years in the US.

GRANTED COBITOLIMOD PATENTS IN IBD

Patent family	Geographic area	Granted	Expire*
Modulating responsiveness to steroids WO2007004979	US/EP/JP	EP1904077	2026-06-30
		EP2179737	2026-06-30
		US8148341	2027-05-31
		US8569257	2026-06-30
		JP5208734	2026-06-30
		JP5886699	2026-06-30
Immunostimulatory method WO2007004977	US/EP/JP/ AUS/CA	EP1901759	2026-06-29
		EP2269622	2026-06-29
		EP2380584	2026-06-29
		US8258107	2027-05-31
		US8592390	2026-06-29
		JP5074392	2026-06-29
		JP5945176	2026-06-29
		AU2006266503	2026-06-29
		AUS2012200661	2026-06-29
		CA 2612162	2026-06-29
Method for prevention of colectomy WO2013076262	US/EP/ JP/CA/HK	EP2782602	2032-11-23
		US9492516	2032-11-23
		US9795627	2032-11-23
		JP6193248	2032-11-23
		JP6318221	2032-11-23

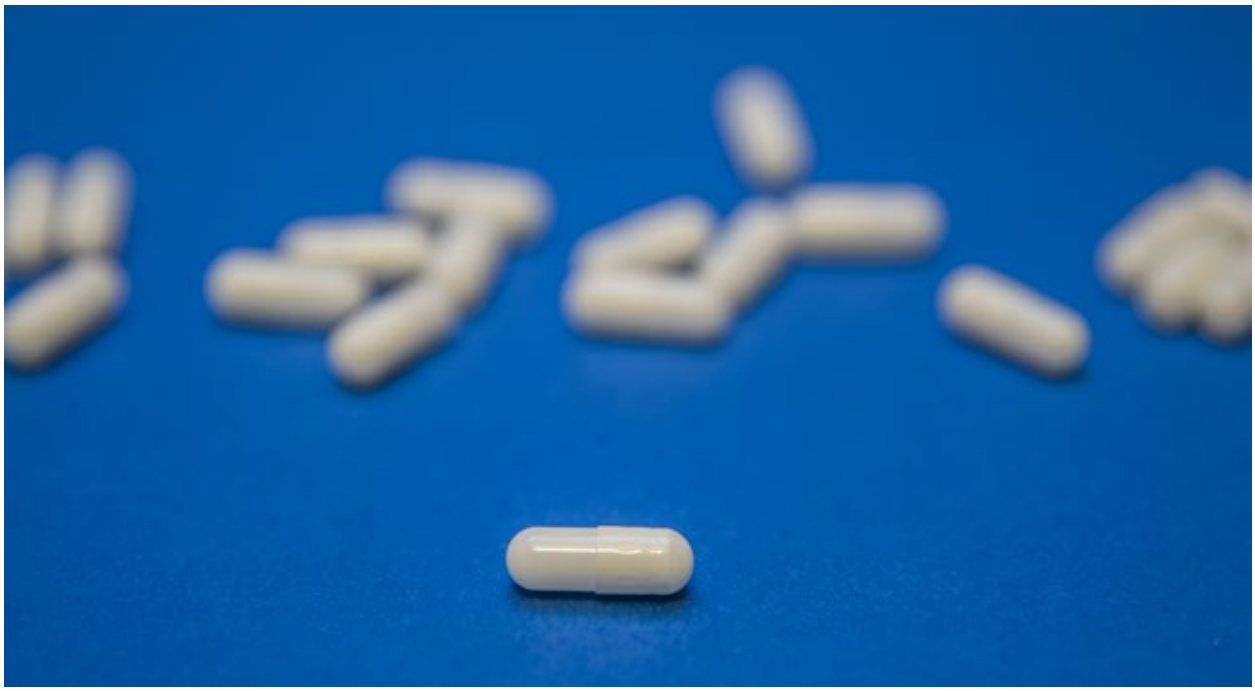
** Supplementary Protection Certificate (SPC) or Patent Term Extension (PTE) is not included and may give up to five years extension in Europe and the US.*

Oral formulation of cobitolimod

InDex has developed a prototype of a novel formulation of its lead drug candidate cobitolimod for oral administration, with targeted drug substance release or delivery to the lower part of the gastrointestinal tract, and thus again avoiding systemic exposure. The capsule is a potential follow-on product to the current topical formulation. An oral therapy makes it possible to deliver cobitolimod to parts of the gastrointestinal tract which are inaccessible to an enema and could be more convenient for patients.

This opens the possibility to broaden the therapeutic use of cobitolimod to also include pancolitis and Crohn's disease, where the inflammation can be located higher up in the gastrointestinal tract. The oral formulation development also provides the opportunity to secure additional patent protection for cobitolimod.

The prototype oral formulation consists of a core matrix in a capsule with a pH sensitive coating. Different parts of the gastrointestinal tract have different pH, and by using a coating that dissolves at a specific pH, one can direct the release of a substance to a specific part of the intestine. The capsule with cobitolimod is designed to initiate release of cobitolimod in the end of the small intestine for controlled delivery to the colon. Additionally, the release profile can be adjusted to target other parts of the gastrointestinal tract, both by modifying the composition of the core matrix and the coating of the capsule.



DIMS compounds under development

InDex has, besides cobitolimod, a preclinical portfolio of more than 150 DNA-based ImmunoModulatory Sequences (DIMS). The DIMS candidates are oligonucleotides that differ in sequence and length but are all TLR9 agonists. DIMS mimic bacterial DNA, without being harmful, and stimulate immune cells to produce beneficial anti-inflammatory cytokines that will help to dampen inflammation. This opens opportunities for the treatment of different inflammatory conditions, in which the immune responses are imbalanced. To capitalise on the substantial historical investments in the DIMS portfolio and to take advantage of the expertise and experience built up during the development of cobitolimod in ulcerative colitis, InDex is testing a selected number of DIMS candidates in models of other inflammatory diseases. Positive signals have been observed, and InDex is now confirming these early results with alternative and complementary methods in order to be able to select a DIMS substance for further development.

Advisory boards

InDex has a long-standing and well-developed network of key opinion leaders and has more recently established both a North American and a European advisory board. These advisory boards bolster the strong InDex team, ensure the clinical relevance of InDex's studies, support increased awareness of cobitolimod and allow outreach for wide patient recruitment. Several key opinion leaders are also involved in the development of the design of InDex's clinical studies, and will be involved in the conduct of the phase III program.

Advisory board Europe

Laurent Peyrin-Biroulet, Prof., MD (chairman)
Nancy University Hospital, France

Raja Atreya, Prof., MD
University of i Erlangen-Nürnberg, Germany

Geert D'Haens, Prof., MD
Amsterdam University Medical Center, the Netherlands

Jonas Halfvarson Prof., MD
Örebro University, Sweden

Walter Reinisch, Prof., MD
Medical University of Vienna, Austria

Franco Scaldaferri, Prof., MD
Catholic University of Rome, Italy

Advisory board North America

William Sandborn, Prof., MD (chairman)
IBD Center, UC San Diego Health, USA

Brian Feagan, Prof., MD
Robarts Clinical Trials, Western University, Canada

Christina Ha, Ass. Prof., MD
Cedars-Sinai Medical Center, USA

Florian Rieder, Ass. Prof., MD
Cleveland Clinic, USA

David Rubin, Prof., MD
UChicago Medicine, USA

Bruce Sands, Prof., MD
Icahn School of Medicine at Mount Sinai, USA

"I am very pleased that the CONDUCT study met the primary endpoint and could demonstrate a significant and clinically important effect in inducing clinical remission in this difficult to treat patient population of moderate to severe left-sided ulcerative colitis."

Prof. Raja Atreya, University of Erlangen-Nürnberg and Principal Investigator in the CONDUCT study

"A significant number of patients with moderate to severe ulcerative colitis do not respond to or cannot tolerate available medical therapies, resulting in a high unmet medical need. With the convincing results seen in patients with left-sided ulcerative colitis in the CONDUCT study, together with the novel and unique mechanism of action, I believe that cobitolimod has great potential as a future treatment alternative"

Prof. Walter Reinisch, Medical University of Vienna and Medical Advisor in the CONDUCT study

"Ulcerative colitis is a chronic and lifelong disease with an enduring unmet medical need for safe and effective treatments, where I believe topical therapies have been long ignored. Cobitolimod has a novel mechanism of action and is progressing into global phase III studies. Based on the available data, it appears to have a compelling safety profile, while delivering clinically relevant efficacy. Given also the infrequent dosage regimen, cobitolimod looks a promising candidate for moderate to severe left-sided ulcerative colitis."

Prof. William Sandborn, UC San Diego

Organisation

InDex has a small number of employees with core competences and cooperates with experienced consultants within different areas of the development process. The plans are developed in close cooperation with key opinion leaders such as clinicians and scientists together with other experts such as Clinical Research Organisations (CROs) and Contract Manufacturing Organisations (CMOs), as well as through scientific advice from regulatory authorities and pricing authorities. InDex is using a so-called outsourcing model for its preclinical, clinical and pharmaceutical development work. Such a model provides a high degree of flexibility and utilises employees and other resources in a cost efficient way. InDex is selecting the most suitable CROs and CMOs to conduct trials and manufacturing of study drugs under the supervision of InDex.

As of December 31, 2020 InDex had seven full time employees. Three of the employees have Ph.D. degrees in immunology and inflammation. InDex has established cooperation with ten qualified consultants each specialised in different areas, such as clinical trials, regulatory affairs, statistics, medicine, preclinical, manufacturing, business development, finance, economy and quality assurance in order to ensure that the necessary competences and experiences are covered. The management has a strategy to involve all members of the team, regardless of employment status, to create a well-functioning team to meet the company's objectives.

InDex's management and the Board have together large and documented highly qualified international experience in the pharmaceutical industry. This covers the vast majority of the functions involved in the process to develop and commercialise new and innovative drugs.

Part of the InDex team




The share

InDex Pharmaceuticals Holding AB's share is listed on Nasdaq First North Growth Market Stockholm since October 11, 2016 under the ticker symbol INDEX and with the ISIN code SE0008966295. The share is included in the Health Care segment.

SHARE PRICE DEVELOPMENT AND TURNOVER OF SHARES

The share price as of December 30, 2020 was SEK 4.62, which corresponded to a market cap of SEK 410 million. The highest share price paid on Nasdaq First North Growth Market Stockholm during 2020 was SEK 9.38 and the lowest share price paid was SEK 3.91. During 2020, 55,518,931 shares were traded on Nasdaq First North Growth Market Stockholm corresponding to a value of SEK 363 million.

RIGHTS ISSUE IN 2021

The Swedish Companies Registration Office recorded the completed rights issue of 443,906,375 new shares on February 11, 2021.

The subscription price was set to SEK 1.20. InDex received after the end of the reporting period approximately SEK 488 million after deduction of the transaction related costs for financial and legal services and for costs for registration and practical management.

The information on pages 24-27 has not been recalculated due to the completed rights issue. Updated information is available on InDex webpage.

SHAREHOLDERS

InDex had as of December 30, 2020 4,312 shareholders according to Euroclear. The 15 largest shareholders in InDex held approximately 65.9 percent of the capital and the votes.

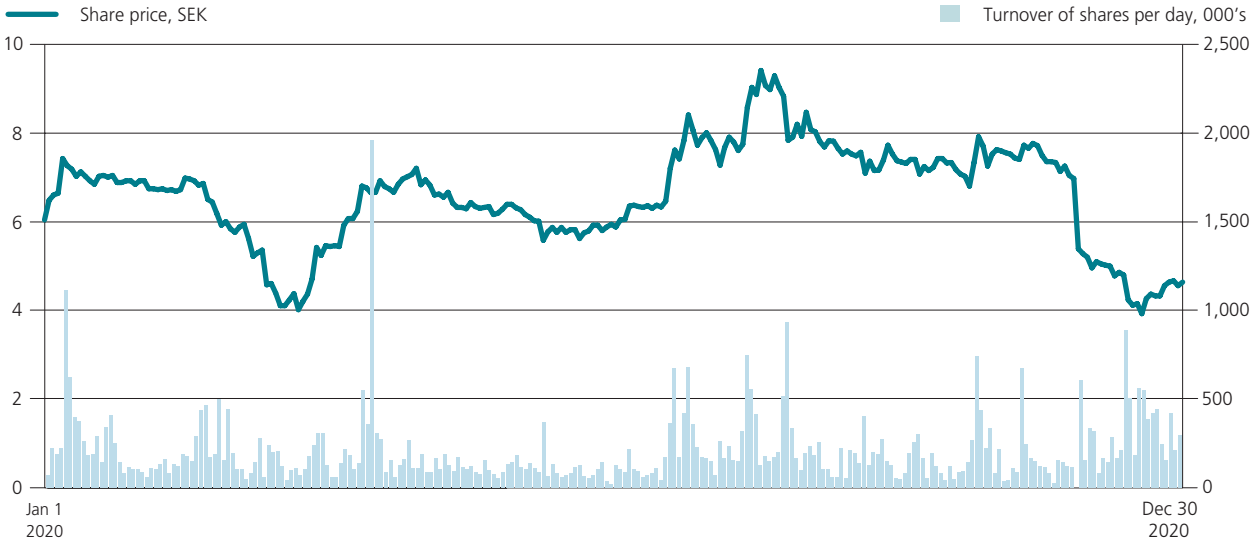
CERTIFIED ADVISER

According to the rules of Nasdaq First North Growth Market Stockholm a listed company needs to appoint a Certified Adviser to conduct certain surveillance tasks. Redeye AB is the company's Certified Adviser.

LARGEST SHAREHOLDERS AS OF DECEMBER 30, 2020

	Number of shares	Percentage of capital and votes
SEB Venture Capital	12,994,367	14.6
Stiftelsen Industrifonden	12,865,296	14.5
Linc AB	8,875,650	10.0
Fjärde AP-fonden	6,635,679	7.5
Avanza Pension	3,240,008	3.7
Staffan Rasjö	3,124,718	3.5
SEB Life International	2,321,225	2.6
SEB Stiftelsen	1,785,714	2.0
Nordnet Pensionsförsäkring AB	1,490,317	1.7
Originat AB	1,200,000	1.4
Rune Pettersson, dödsbo	980,081	1.1
Ponderus Invest AB	950,000	1.1
Tomas Timander	741,457	0.8
Ålandsbanken	604,915	0.7
Hans Haraldsson	596,558	0.7
Other	30,357,290	34,1
Total	**88,781,275**	**100.0**

SHARE PRICE AND TURNOVER OF SHARES



The traded volume was extremely high during one day. This is therefore provided separately and thus not included in the graph. November 25, 2020 – 3,283,591 shares.

OWNERSHIP STRUCTURE BY SIZE OF HOLDINGS AS OF DECEMBER 30, 2020

Holding	Number of shareholders	Number of shares	Percentage of capital and votes
1-500	1,083	190,680	0.2
501-1,000	894	716,656	0.8
1,001-5,000	1,439	3,684,618	4.2
5,001-10,000	388	3,050,159	3.4
10,001-15,000	137	1,774,403	2.0
15,001-20,000	98	1,788,872	2.0
20,001-	273	77,575,887	87.4
Total	**4,312**	**88,781,275**	**100.0**

DEVELOPMENT OF SHARE CAPITAL

Date	Transaction	Change in share capital	Total share capital	Number of new shares	Total number of shares	Paid in amount
Jun 27, 2016	Inception of the company	500,000	500,000	500,000	500,000	500,000
Sep 7, 2016	Split of shares	–	500,000	45,500,000	50,000,000	–
Sep 7, 2016	Share issue in-kind	601,345	1,101,345	60,134,466	110,134,466	–
Sep 7, 2016	Reduction of number of shares	–500,000	601,345	–50,000,000	60,134,466	–
Sep 7, 2016	Share issue	–	601,345	2	60,134,468	–
Sep 8, 2016	Reversed split of shares	–	601,345	–30,067,234	30,067,234	–
Oct 6, 2016	Share issue for pref. shares	52,685	654,030	2,634,279	32,701,513	52,685
Oct 6, 2016	Share issue	560,479	1,214,509	28,023,969	60,725,482	235,401,340
Oct 12, 2016	Share issue	14,305	1,228,814	715,250	61,440,732	6,008,100
Oct 25, 2016	Share issue	17,969	1,246,783	898,421	62,339,153	7,546,736
Nov 14, 2016	Share issue	1,895	1,248,678	94,725	62,433,878	795,690
Dec 29, 2016	Share issue in-kind	1,300	1,249,978	65,015	62,498,893	–
Jan 13, 2017	Share issue	591	1,250,569	29,540	62,528,433	248,136
Oct 23, 2018	Share issue	125,057	1,375,626	6,252,842	68,781,275	37,642,109
Sep 23, 2019	Share issue	275,125	1,650,751	13,756,255	82,537,530	96,018,660
Oct 10, 2019	Share issue	124,874	1,775,625	6,243,745	88,781,275	43,581,340
Feb 11, 2021	*Share issue*	*8,878,127*	*10,653,753*	*443,906,375*	*532,687,650*	*532,687,650*

Board of directors, senior management and auditors

PROF. WENCHE ROLFSEN
Chairman since 2011.
Born: 1952.
Current assignments: Chairman of BioArctic. Board member of Swedish Match and Cinclus Pharma. In addition, partner in Serendipity Partners.
Experience: Managerial positions at Pharmacia and Quintiles. Board member of several listed companies. Former associate Professor in Pharmacology at Uppsala University.
Holdings: Direct holdings of 18,900 shares, indirect holdings of 81,224 shares.

MARLENE FORSELL
Board member since 2020.
Born: 1976.
Current assignments: Board member of Nobia, STG Group, Kambi Group and Lime Technologies.
Experience: CFO for Swedish Match, 2013-2018 and from 2004 in several leading financial positions at the same company. Advisor within M&A at EY. MSc in Economics at Stockholm School of Economics.
Holdings: –.

PROF. ULI HACKSELL
Board member since 2016.
Born: 1950.
Current assignments: Board member of Medivir, Active Biotech, Beactica and Synact Pharma.
Experience: CEO and chairman of Cerecor, CEO of ACADIA Pharmaceuticals and managerial positions at Astra. Professor in organic chemistry at Uppsala University.
Holdings: Direct holdings of 68,000 shares.

DR. LENNART HANSSON
Board member since 2011.
Born: 1956.
Current assignments: Chairman of Ignitus, Cinclus Pharma and Sixera Pharma. Board member of Medivir and Calliditas Therapeutics.
Experience: Former head of Life Science investments at Industrifonden, CEO of Arexis and managerial positions at AstraZeneca and Karolinska Development.
Holdings: Indirect holdings of 72,000 shares.

DR. YILMAZ MAHSHID
Board member since 2020.
Born: 1979.
Current assignments: CEO of Medivir and board member of Mahshid Advisors and Venaticus Capital.
Experience: Investment Manager and Controller at Industrifonden as member of Life Science team. Health Care analyst at Pareto Securities and Öhman Fondkommission. Researcher at Karolinska Institute, Biolipox and Orexo. PhD in Medical Biochemistry and Biophysics at Karolinska Institute.
Holdings: –.

STIG LÖKKE PEDERSEN
Board member since 2012.
Born: 1961.
Current assignments: Chairman of moksha8, SSI-Diagnostics, Union Therapeutics and Stemform. Board member of Skybrands, Hasle Refractories, TAP and BroenLab.
Experience: Managerial positions at Lundbeck and Ciba-Geigy.
Holdings: Indirect holdings of 63,962 shares.

All board members are independent in relation to InDex, InDex's management and InDex's major shareholders.

PETER ZERHOUNI
Chief Executive Officer (CEO) since 2015. Board member of InDex Pharmaceuticals and InDex Diagnostics.
Born: 1972.
Current assignments: –.
Experience: CEO of Diamyd Medical and different positions at ING Bank in Amsterdam and Brussels.
Holdings: Direct holdings of 110,000 shares and 333,333 warrants.

JOHAN GILÉUS
Chief Financial Officer (CFO) since 2017. Board member of InDex Pharmaceuticals and InDex Diagnostics.
Born: 1965.
Current assignments: Board member of Gileus Consulting and Gileus Invest, as well as board member and chairman of the audit committee of BHG Group.
Experience: Former Partner at Deloitte focusing on M&A, financial reporting and stock market issues.
Holdings: Direct holdings of 40,000 shares and 133,333 warrants.

DR. THOMAS KNITTEL
Chief Medical Officer (CMO) since 2012.
Born: 1962.
Current assignments: Board member of Heparegenix.
Experience: More than 15 years of experience from clinical work within gastroenterology and managerial positions at Novo Nordisk, Harlan Laboratories and Develogen.
Holdings: Direct holdings of 10,000 shares and 66,667 warrants.

PERNILLA SANDWALL
Chief Operating Officer (COO) since 2012.
Born: 1963.
Current assignments: Board member of Alzinova, Innovativa Mindre Life Science företag (part of Läkemedelsindustriföreningen), InDex Pharmaceuticals and InDex Diagnostics.
Experience: Managerial positions within clinical operations at Merck (MSD).
Holdings: Direct holdings of 27,500 shares and 133,333 warrants.

AUDITORS
PricewaterhouseCoopers AB with the authorised auditor Magnus Lagerberg as public accountant in charge since 2017.

Note: The years refer to InDex Pharmaceuticals AB as applicable.

Holdings per December 30, 2020.

Directors' report

InDex Pharmaceuticals Holding AB (publ) Corp. Reg. No. 559067-6820

The Board and the CEO of InDex Pharmaceuticals Holding AB hereby issue the annual report and the consolidated financial statements for 2020.

INTRODUCTION

This annual report includes the group ("the group", "the company" or "InDex"), i.e. InDex Pharmaceuticals Holding AB, Corp. Reg. No 559067-6820, the subsidiaries InDex Pharmaceuticals AB, Corp. Reg. No. 556704-5140 and InDex Diagnostics AB, Corp. Reg. No. 556602-2751. The employees are employed, and the consultants are engaged, in the parent company or the subsidiary InDex Pharmaceuticals AB depending on the type of work performed. Invoicing of services between the group companies is based on utilisation. Revenues and direct costs for the diagnostic services (the diagnostic test DiBiCol) have been accounted for in InDex Diagnostics AB until September 30, 2020 when the diagnostic services were terminated. The company's share is traded on Nasdaq First North Growth Market Stockholm since October 11, 2016. Redeye AB is the company's Certified Adviser. The operations are conducted at Karolinska Institutet, with postal address Berzelius väg 13, 171 65 Solna.

BUSINESS OVERVIEW

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 in late stage clinical development for the treatment of moderate to severe ulcerative colitis – a debilitating, chronic inflammation of the large intestine.

In addition, InDex has a broad portfolio of other DNA based ImmunoModulatory Sequences (DIMS) in discovery stage, with the potential to be used in the treatment of various immunological diseases.

Ulcerative colitis is a chronic disease caused by inflammation of the large intestine. The symptoms are characterized by blood- and mucus-mixed diarrhea, frequent stools, pain, fever, weight loss and anemia. Despite the currently available drugs on the market, many patients with ulcerative colitis still suffer from severe symptoms, and current therapies can cause serious side effects. For those patients that do not respond to medical treatment, the last resort is to surgically remove the colon.

InDex's clinical studies have shown that cobitolimod has a competitive efficacy and a more favorable safety profile than what has been reported for the currently approved biological drugs. Sales of biologics for treatment of ulcerative colitis amount to more than USD 5 billion a year.

Cobitolimod has a new type of mechanism of action. It is a so-called Toll-like receptor 9 (TLR9) agonist that can provide an anti-inflammatory effect locally in the large intestine, which may induce mucosal healing and relief of the clinical symptoms in ulcerative colitis.

In 2019 InDex reported positive top line results from the phase IIb study CONDUCT with cobitolimod. CONDUCT was a dose optimisation study with the objective to identify the most efficacious dose to move forward in development. The study met the primary endpoint clinical remission with a superior efficacy of 15 percent (delta) for patients treated with the highest dose of cobitolimod compared to placebo. Cobitolimod was well tolerated at all dose levels and no differences in the safety profile were observed compared to placebo. CONDUCT was a randomised, double blind, placebo-controlled study including 213 patients with left-sided moderate to severe active ulcerative colitis at 91 sites in 12 countries. The patients were divided into four treatment arms who received different doses of cobitolimod and one arm who received a placebo.

InDex has already in previous clinical trials shown that cobitolimod has a very favorable safety profile and has statistically significant effects on those endpoints that are most relevant in this disease, both from a regulatory and clinical perspective. These endpoints include the key clinical symptoms such as blood in stool, number of stools, and mucosal healing, respectively.

Given the outstanding combination of efficacy and safety, InDex is now advancing cobitolimod into phase III, which is the final stage of development before application for market approval.

Based on regulatory guidance, the company is planning a sequential phase III program with two induction studies and a maintenance study with patients that have responded to cobitolimod as induction therapy. The important initial induction study is planned to include approximately 400 patients. The primary endpoint of clinical remission is to be measured at week 6. In addition to the 250 mg dose, the study is also planned to evaluate a higher dose, 500 mg, in an adaptive study design. This higher dose has the potential to provide an even better efficacy than what was observed in the phase IIb study CONDUCT.

SIGNIFICANT EVENTS DURING THE REPORTING PERIOD

- InDex announced on February 19, 2020 the conclusions from in-depth analysis of the complete data set from the phase IIb dose optimisation study CONDUCT. The analysis confirmed that the highest dose tested, which met the primary endpoint of the study, demonstrates an outstanding combination of efficacy and safety. The company also announced that the phase III preparations were continuing according to plan.
- InDex announced on April 16, 2020 that the company had received positive responses from FDA and EMA regarding phase III development of cobitolimod, for the treatment of moderate to severe ulcerative colitis. Both authorities endorse the advancement of cobitolimod into phase III studies. The 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 (250 mg x 2). InDex continued to evaluate the most advantageous study design based on, among other things, development risk, commercial potential, time to market and cost.
- The annual general meeting in InDex Pharmaceuticals Holding AB was held on Monday April 20, 2020. Board members Wenche Rolfsen (also chairman), Uli Hacksell, Lennart Hansson and Stig Lökke Pedersen were re-elected, and Marlene Forsell and Yilmaz Mahshid were elected as new ordinary board members.
- InDex announced on November 25, 2020 the intention to carry out a fully guaranteed rights issue of approximately SEK 500 million with preferential rights for the company's existing shareholders. The Board proposed that an extraordinary general meeting to be held in January 2021 would authorize the Board to resolve on the rights issue and the terms thereof. The net proceeds from the contemplated rights issue are mainly intended to be used to fund the important initial induction study in a sequential phase III program in moderate to severe left-sided ulcerative colitis for the company's lead drug candidate, cobitolimod.

SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

- On January 12, 2021 an extraordinary general meeting was held in InDex Pharmaceuticals Holding AB. The general meeting resolved, in accordance with the Board's proposal, to amend the company's articles of association with respect to, inter alia, prerequisites for participation at general meetings, the limits for the share capital and number of shares. The general meeting also resolved, in accordance with the Board's proposal, to authorise the Board, for the period up to the next annual general meeting, to increase the company's share capital through issuing new shares with preferential rights for the company's shareholders. Payment shall be made by cash or through payment in kind, by set-off or subject to other conditions. Issuance by virtue of the authorization can include no more than as many shares that can be issued without changing the, at the time of the issue, adopted articles of association. The purpose of the authorization was to enable a capital raise in the company as efficiently as possible to enable further development of the company's business.
- On January 14, 2021 the Board of InDex announced that they had, with the support of the authorisation from the extraordinary general meeting held on January 12, 2021, resolved on a rights issue of approximately 444 million shares at a subscription price of SEK 1.20 per share. The rights issue was fully covered by subscription undertakings and guarantee commitments from existing shareholders and new investors, including amongst others HBM Healthcare Investments, Handelsbanken Funds, Linc and The Fourth Swedish National Pension Fund. At full subscription in the rights issue the company will receive approximately SEK 533 million before deduction of costs related to the transaction. The intention of the rights issue is to fund the important initial induction study in a sequential phase III program for the company's lead drug candidate, cobitolimod, including drug manufacturing and in addition, to finance general corporate purposes as well as create financial flexibility. For each existing share held on the record date, five subscription rights were received. The subscription rights entitled the holder to subscribe for new shares with preferential rights, whereby one subscription right gave the right to subscribe for one new share, i.e. a subscription ratio of 5:1.
- On January 21, 2021 InDex published a prospectus in connection with the fully guaranteed rights issue of approximately SEK 533 million. The prospectus has been approved and registered by the Swedish Financial Supervisory Authority and is available on the company's website. In connection with the rights issue the Board and executive management has entered into customary lock-up agreements, restricting disposals of shares or warrants for a period of 180 days from the settlement date of the rights issue.

- InDex announced on February 9, 2021 that the subscription ratio in the rights issue amounted to 152.6 percent. Guarantee commitments made in connection with the rights issue will thus not be utilized. InDex receives, through the rights issue, approximately SEK 533 million before deduction of costs related to the transaction. 99.1 percent of the rights issue was subscribed for by exercise of subscription rights and 0.9 percent of the rights issue was subscribed for without subscription rights.

OTHER EVENTS

- InDex announced on February 25, 2020 the publication of scientific data on the mechanism of action of cobitolimod. The paper, published in the peer-reviewed Journal of Crohns and Colitis, shows that cobitolimod can modulate the immune system in ulcerative colitis by balancing the mucosal Th17/Treg cell response. The publication has also been highlighted in the journal's podcast.
- InDex announced on March 31, 2020 that SEK 2.0 million has been granted from Sweden's innovation agency Vinnova to develop new, more effective and safer treatments for inflammatory diseases. The grant from Vinnova will be used for a preclinical project to evaluate selected compounds from InDex's DIMS platform in inflammatory disease models outside the field of inflammatory bowel disease. This is a continuation of the project that InDex received a grant from Vinnova for in 2016. Positive signals were observed in the previous project, which will now be confirmed with alternative and complementary methods for selecting a DIMS compound for further development.
- InDex announced on August 24, 2020 that the successful results of the CONDUCT study will during the fall of 2020 be presented orally at two leading gastroenterology conferences; the United European Gastroenterology Week (UEGW) and the American College of Gastroenterology (ACG) Annual Scientific Meeting. UEGW is the largest scientific meeting for gastroenterologists in Europe and ACG Annual Scientific Meeting is the premier clinical conference for gastroenterologists in the US.
- InDex announced on October 6, 2020 that the high-impact medical journal The Lancet Gastroenterology & Hepatology had published the results of InDex's phase IIb study CONDUCT with cobitolimod. CONDUCT was a phase IIb dose optimisation study, evaluating the first-in-class TLR9 agonist cobitolimod for the treatment of moderate to severe ulcerative colitis. The study met the primary endpoint and cobitolimod demonstrated an outstanding combination of efficacy and safety. The medicinal journal also published an independent expert commentary that provides strong support for cobitolimod's potential.
- On December 8, 2020 InDex hosted a virtual R&D day for investors, analysts and media. The purpose of the R&D day was to provide an overview of ulcerative colitis and the drug candidate cobitolimod from a scientific and market perspective.

CORPORATE STRUCTURE

InDex Pharmaceuticals Holding AB was incepted on December 14, 2015 and was registered with the Swedish Companies Registration Office on June 27, 2016. At an Extraordinary General Meeting held on August 25, 2016 it was resolved, and on September 7, 2016 an issue for non-cash consideration was registered at the Swedish Companies Registration Office, whereby the shareholders of InDex Pharmaceuticals AB transferred 99.76 percent (on December 31, 2020 99.99 percent have been transferred) of the shares in the company in exchange for new shares in the new parent company, InDex Pharmaceuticals Holding AB. The intention is that also the remaining shares in InDex Pharmaceuticals AB will be exchanged for shares in the parent company. With the support of valuations provided by two independent external parties, the Board attributed the shares in InDex Pharmaceuticals AB a total value of SEK 247.0 million, out of which the shares held by the parent company were reported in the balance sheet at the same value, as the remaining shares will be transferred alternatively compulsory acquired. A debt of SEK 0.0 million to the minority shareholders has therefore been reported as of December 31, 2020.

The Board has concluded that the restructuring described above has not in itself changed the business or the shareholder structure, why the consolidated financial statements have been prepared in accordance with the guidelines for acquisition under common control. In short this means that the consolidated financial statements are prepared as if InDex Pharmaceuticals AB is the acquiring company in the consolidated financial statements and, therefore, the assets and liabilities are reported at historical values. This further means that the comparative periods for InDex can be presented in the financial report for InDex where InDex Pharmaceuticals AB was the legal parent.

FINANCIAL DEVELOPMENT

CONSOLIDATED FINANCIAL SUMMARY

SEK million	2020	2019	2018	2017	2016[1]
Net sales	0.0	0.1	0.1	0.1	0.4
Operating loss	–57.3	–87.7	–82.0	–73.2	–39.5
Result after tax	–57.4	–87.8	–82.1	–72.7	–41.3
Earnings per share before and after dilution, SEK[2]	–0.24	–0.45	–0.48	–0.44	–0.41
Cash flow from operating activities	–70.6	–85.1	–78.6	–67.3	–31.9
Cash and cash equivalents at the year-end	53,8	126.8	83.0	125.1	193.2
Weighted average number of shares (thousands)[2]	236,750	197,001	169,846	166,697	101,604
Number of shares at the year-end (thousands)[2]	236,750	236,750	183,417	166,700	166,622

[1] According to historical accounting principles (K3)
[2] Adjusted for the completed rights issue in February 2021.

Because of the nature of the business operations, there may be large fluctuations between different periods.

Group

Net sales for the period January to December 2020 amounted to SEK 0.0 (0.1) million. The net sales are related to the sale of DiBiCol test kits up to September 30, 2020. Sale of DiBiCol test kits was then terminated. Other operating income SEK 0.4 (0.0) million refers to grant received from Vinnova.

Operating expenses for the period amounted to SEK 57.8 (87.8) million. The decrease is attributable to lower costs for phase III preparations compared to the costs for the phase IIb study CONDUCT during the corresponding period previous year.

The operating expenses during the period refer to costs for phase III preparations and general operating expenses.

Costs for the personnel during the reporting period amounted to SEK 9.6 (12.8) million.

Cash and cash equivalents as of December 31, 2020 amounted to SEK 53.8 million, which is SEK 73.0 million lower than as of December 31, 2019.

Parent company

Net sales amounted to SEK 11.3 (11.0) million during the period January to December 2020 and consisted of invoicing of group wide expenses to the other companies within the group.

The expenses amounted to SEK 17.3 (17.0) million and consisted of personnel expenses and other operating expenses relating to the administration of InDex.

To reset the equity in the subsidiary InDex Pharmaceuticals AB, InDex Pharmaceuticals Holding AB provided during 2020 a shareholder contribution of in total SEK 50 (90) million. A write-down of shares in subsidiaries were made simultaneously.

FINANCIAL SUMMARY AFTER THE REPORTING PERIOD

The Covid-19 pandemic affects the healthcare systems and the investor sentiment globally and must be taken into account in the company's strategic planning. The Board of Directors, however, assess that there is no impact on the company's financial position as of December 31, 2020 due to events after the reporting period.

The Swedish Companies Registration Office recorded the completed rights issue of 443,906,375 new shares on February 11, 2021. The subscription price was set to SEK 1.20 per share. InDex received after the end of the reporting period approximately SEK 488 million after deduction of the transaction related costs for financial and legal services and for costs for registration and practical management.

THE BOARD OF DIRECTORS AND CEO

The Board in InDex Pharmaceuticals Holding AB was elected at the Annual General Meeting on April 20, 2020 and consists of the chairman Wenche Rolfsen, Marlene Forsell, Uli Hacksell, Lennart Hansson, Yilmaz Mahshid and Stig Lökke Pedersen.

Peter Zerhouni is CEO since April 1, 2015.

RISKS AND UNCERTAINTIES

The business of the company can be affected by a number of risk factors. The ambition of the group is to establish a group wide risk management program that focuses on minimising potential negative effects on InDex's profit. The Board is ultimately responsible for identifying, managing and monitoring InDex's risks. The policy for identifying, management and monitoring of financial risks is decided by the Board and is subject to annual revisions. The Board has delegated the daily work regarding risk management to the CEO, who has delegated to the CFO. The Board may decide on temporary exemptions from the policy. There is no guarantee that InDex's research and development will result in commercial success. There is no guarantee that InDex will develop products that can be patented, that granted patents can be retained, that future inventions will lead to patents, or that granted patents will provide sufficient protection for InDex's products. There is no guarantee that InDex obtains necessary approvals to conduct the clinical trials that InDex would like to implement, or that the clinical trials conducted by InDex, independently or in collaboration with partners, will demonstrate sufficient safety and efficacy to obtain necessary regulatory approvals or that the trials will lead to drugs that can be sold on the market. It cannot be excluded that the regulatory approval process will require increased documentation and thereby increased costs and delays in projects or lead to projects being shut down. Increased development costs and longer development time may mean that the risks of a project increase and that the compound's potential to successfully reach the commercial stage decreases or that the time for patent protected sales is reduced. For more information see page 70-73.

EXPECTED FUTURE DEVELOPMENT

The Board is reviewing the forecasted cash flow on an ongoing basis to determine InDex's capital requirements and resources required to conduct the business activities in accordance with the strategic direction decided by the Board.

It is the assessment of the Board that InDex has enough capital to finance all financial commitments InDex has for the coming 12-month period.

InDex provides no financial forecast or similar forward-looking statement.

NON-FINANCIAL INFORMATION

Employees

The number of employees at the end of the year was 7 (7) and the number of people closely associated with InDex through consultancy arrangements amount to 9 (10).

Environment

InDex is a small company and is therefore procuring services such as production of substance, drug production and preclinical and clinical trials services. InDex is cooperating with well-known partners and have rigorous oversight of permits, quality assurance and environmental obligations.

Annual General Meeting in the parent company

In light of the ongoing Covid-19 pandemic the annual general meeting of InDex Pharmaceuticals Holding AB to be held on June 3, 2021 will be conducted through advance voting pursuant to temporary regulations. Therefore, it will not be possible to attend the meeting in person or by proxy.

In order to be entitled to participate in the meeting, shareholders must be entered in the register of shareholders maintained by Euroclear by May 26, 2021 and must announce their intention to attend the meeting no later than June 2, 2021 by casting their advance vote no later than on that date and in accordance with the instructions to be found in the notice to the annual general meeting.

PROPOSED DISTRIBUTION OF EARNINGS

THE FOLLOWING RETAINED EARNINGS ARE AT THE DISPOSAL OF THE ANNUAL GENERAL MEETING

SEK	
Retained earnings	317,284,031
Net result	–56,025,317
	261,258,714
The Board's suggestion to be carried forward	261,258,714

THE BOARD'S OPINION REGARDING THE SUGGESTED DISTRIBUTION AND DIVIDEND POLICY

The Board does not propose a dividend for 2020. The Board has no intention to propose a dividend until InDex can forecast long term profit and sustainable positive cash flow.

Regarding the parent company's and the group's result and financial position the reader is referred to the pages overleaf presenting the statement of total comprehensive income, balance sheet, statement of changes in equity, cash flow and associated notes. All amounts are presented in thousands of SEK unless stated otherwise.

Consolidated statement of total comprehensive income

SEKk	Note	2020	2019	2018
Revenues				
Net sales	5	35	88	128
Other income	8	380	–	612
Total revenues		**415**	**88**	**740**
Operating expenses				
Raw material and consumables		–16,021	–3,903	–560
Other external expenses	6, 7	–30,990	–70,189	–71,685
Personnel costs	7	–9,561	–12,769	–9,553
Depreciations/amortisations of fixed assets and right-of-use assets	14, 15	–1,192	–939	–940
Total expenses		**–57,764**	**–87,800**	**–82,738**
Operating loss		**–57,349**	**–87,712**	**–81,998**
Result from financial investments				
Financial income	9	46	–	–
Financial expenses	9	–115	–61	–86
Other		–	–	–64
Financial items – net		**–69**	**–61**	**–150**
Earnings before tax		**–57,418**	**–87,773**	**–82,148**
Taxes for the period	10	–	–	–
LOSS FOR THE PERIOD		**–57,418**	**–87,773**	**–82,148**
Earnings per share, attributable to the shareholders of the parent company:				
Earnings per share, before and after dilution, SEK[1]		–0.24	–0.45	–0.48

[1] Adjusted for the completed rights issue in February 2021.

In the group there are no items reported in other comprehensive income. So total comprehensive income is consistent with profit/loss for the period. The profit/loss for the period and total comprehensive income are entirely attributable to the shareholders of the parent company.

The notes on pages 38 to 54 are an integrated part of these consolidated financial statements.

Consolidated balance sheet

SEKk	Note	December 31, 2020	December 31, 2019	December 31, 2018
ASSETS				
Fixed assets				
Tangible fixed assets				
Equipment, tools and installations	14	818	11	21
Total tangible fixed assets		**818**	**11**	**21**
Right-of-use assets	15	**2,593**	**464**	**1,393**
Financial assets				
Other financial assets	16	1	1	1
Total financial assets		**1**	**1**	**1**
Total fixed assets		**3,412**	**476**	**1,415**
Current assets				
Current receivables				
Accounts receivable	17	–	4	10
Other current receivables	18	907	1,343	1,480
Prepaid expenses and accrued income	19	3,031	474	482
Cash and cash equivalents	20	53,834	126,790	83,034
Total current receivables		**57,772**	**128,611**	**85,006**
Total current assets		**57,772**	**128,611**	**85,006**
TOTAL ASSETS		**61,184**	**129,087**	**86,421**
EQUITY AND LIABILITIES				
Equity	21			
Share capital		1,776	1,776	1,376
Additional paid in capital		384,557	384,314	254,930
Retained earnings (including profit/loss for the year)		–337,005	–279,587	–191,814
Total equity attributable to the shareholders of the parent company		**49,328**	**106,503**	**64,492**
Liabilities				
Non-current liabilities				
Non-current lease liabilities	15	1,578	–	484
Total non-current liabilities		**1,578**	**–**	**484**
Current liabilities				
Current lease liabilities	15	763	484	947
Account payables		3,023	3,153	3,550
Other current liabilities	23	852	1,138	1,311
Accrued expenses and prepaid income	24	5,640	17,809	15,637
Total current liabilities		**10,278**	**22,584**	**21,445**
Total liabilities		**11,856**	**22,584**	**21,929**
TOTAL EQUITY AND LIABILITIES		**61,184**	**129,087**	**86,421**

The notes on pages 38 to 54 are an integrated part of these consolidated financial statements.

Consolidated statement of changes in equity

	Equity attributable to the shareholders of the parent company			
SEKk	Share capital	Additional paid in capital	Retained earnings, including loss for the year	Total equity
Opening balance January 1, 2018	**1,251**	**217,581**	**–109,666**	**109,166**
Profit/loss for the period equal to total comprehensive income	–	–	–82,148	–82,148
Total comprehensive income for the year	**–**	**–**	**–82,148**	**–82,148**
Transactions with shareholders of the parent company:				
Issue of shares	125	37,517	–	37,642
Transaction costs	–	–168	–	–168
Total transactions with shareholders of the parent company	**125**	**37,349**	**–**	**37,474**
Closing balance December 31, 2018	**1,376**	**254,930**	**–191,814**	**64,492**
Opening balance January 1, 2019	**1,376**	**254,930**	**–191,814**	**64,492**
Profit/loss for the period equal to total comprehensive income	–	–	–87,773	–87,773
Total comprehensive income for the year	**–**	**–**	**–87,773**	**–87,773**
Transactions with shareholders of the parent company:				
Issue of shares	400	139,260	–	139,660
Transaction costs	–	–9,876	–	–9,876
Total transactions with shareholders of the parent company	**400**	**129,384**	**–**	**129,784**
Closing balance December 31, 2019	**1,776**	**384,314**	**–279,587**	**106,503**
Opening balance January 1, 2020	**1,776**	**384,314**	**–279,587**	**106,503**
Profit/loss for the period equal to total comprehensive income	–	–	–57,418	–57,418
Total comprehensive income for the year	**–**	**–**	**–57,418**	**–57,418**
Transactions with shareholders of the parent company:				
Issue of warrants	–	243	–	243
Total transactions with shareholders of the parent company	**–**	**243**	**–**	**243**
Closing balance December 31, 2020	**1,776**	**384,557**	**–337,005**	**49,328**

Consolidated cash flow

SEKk	Note	2020	2019	2018
Operating activities				
Operating result		–57,349	–87,712	–81,998
Adjustment for non-cash items:				
Depreciations/amortisations		1,192	939	940
Interest paid and received		–70	–61	–155
Income tax paid		–	–	–
Cash flow from operating activities before changes in working capital		**–56,227**	**–86,834**	**–81,213**
Cash flow in working capital				
Decrease/increase of current receivables		–2,117	151	–187
Decrease/increase of current liabilities		–12,306	1,602	2,833
Cash flow from changes in working capital		**–14,423**	**1,753**	**2,646**
Cash flow from operating activities		**–70,650**	**–85,081**	**–78,567**
Investing activities				
Investments in tangible assets		–909	–	–
Cash flow from investment activities		**–909**	**–**	**–**
Financing activities				
Amortisation of lease liabilities	15	–1,639	–947	–932
Issue of shares, net after transaction costs	21	–	129,784	37,478
Issue of warrants	7	242	–	–
Cash flow from financing activities		**–1,397**	**128,837**	**36,546**
Cash flow for the period		**–72,956**	**43,756**	**–42,021**
Decrease/increase of cash and cash equivalents				
Cash and cash equivalents at the beginning of the year		126,790	83,034	125,055
Currency translation difference in cash and cash equivalents		–	–	–
Cash and cash equivalents at the end of the year		**53,834**	**126,790**	**83,034**

The notes on pages 38 to 54 are an integrated part of these consolidated financial statements.

Notes to the consolidated statements

NOTE 1 GENERAL INFORMATION

InDex Pharmaceuticals Holding AB (publ) Corp. Reg. No. 559067-6820 is a registered limited liability corporation in Sweden with its registered office in Stockholm. The address to the head office is Berzelius väg 13, Solna. InDex Pharmaceuticals Holding AB, and its subsidiaries InDex Pharmaceuticals AB and InDex Diagnostics AB ("InDex", "the company" or "the group"), operations constitute research, clinical trials, development of technology and commercialisation of scientific discoveries within in the field of biomedicine.

The Board approved the annual report on April 22, 2021.

All amounts are presented in thousands of SEK (SEKk) unless stated otherwise.

NOTE 2 SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below. These accounting policies have been applied consistently for all periods presented. The consolidated financial statements present InDex Pharmaceuticals Holding AB (publ) and its subsidiaries.

i) Basis of preparation for the reports

The consolidated financial statements for InDex Pharmaceuticals Holding AB were prepared in accordance with the *Swedish Annual Accounts Act*, RFR 1 *Supplementary Accounting Rules for Groups*, *International Financial Reporting Standards* (IFRS) and interpretations from *IFRS Interpretations Committee* (IFRS IC) as adopted by the EU.

The consolidated financial statements have been prepared using the cost method.

The preparation of financial statements compliant in accordance with IFRS requires the use of certain critical accounting estimates. In addition, the management must make certain assessments when applying the group's accounting policies. Those areas that involve a high degree of assessment, that are complex or such areas where assumptions and estimates are of material importance for the consolidated financial statements are presented in note 4.

ii) New and revised standards not yet adopted by the group

A few amendments of the current standards and interpretations came into effect for financial periods beginning on January 1, 2020 or later. Non of these have had a material impact on the financial statements of the group during the current year nor are these expected to have a material impact on any future financial periods or transactions.

A number of new standards and interpretations that came into effect for financial periods beginning on or after January 1, 2021 have not been applied in the preparation of this financial report. No standards that are in issue but not yet effective are assessed to have a significant impact when adopted.

2.1 CONSOLIDATED FINANCIAL STATEMENTS

Subsidiaries

Subsidiaries are all companies in which the group has a controlling interest. The group controls a company when it is exposed to, or entitled to, variable returns from its holding in the company and has the ability to affect those returns through its control over the company. Subsidiaries are included in the consolidated financial statements from the date on which the controlling interest is transferred to the group. They are excluded from the consolidated financial statements from the date on which the controlling interest ceases.

Intercompany transactions, balance-sheet items and unrealised gains and losses on transactions between group companies are eliminated. The accounting policies of subsidiaries have been changed where necessary to ensure consistent application of the group's policies.

2.2 SEGMENT REPORTING

InDex's chief operating decision maker is the CEO, since the CEO is primarily responsible for allocating resources and evaluating results. The assessment of the group's operating segments is based on the financial information reported to the CEO. The financial information reported to the CEO, to support the allocation of resources and assessment of the group's results, pertains to the group as a whole. The group conducts pharmaceutical development and the operations currently consist entirely of research and development of pharmaceuticals for immunological diseases. Against this background, the assessment is that InDex conducts joint development activities within the group and therefore has one business segment, which is the group as a whole.

2.3 TRANSLATION OF FOREIGN CURRENCY

(i) Functional and presentation currency

The functional currency of the various entities in the group is the local currency, as this has been defined as the currency that is used in the primary economic environment in which each entity mainly operates. The Swedish krona (SEK) is used in the consolidated financial statements, and is the functional currency of the parent company and the presentation currency of the group.

(ii) Transactions and balance sheet items

Transactions in foreign currency are translated into the functional currency at the exchange rates prevailing on the date of the transaction. Exchange rate gains and losses arising from the payment of such transactions and from the translation of monetary assets and liabilities in foreign currency at the closing-day rate are recognised through profit or loss in the statement of comprehensive income.

Exchange rate gains and losses attributable to cash and cash equivalents are recognised as financial income or expenses in the statement of comprehensive income.

2.4 REVENUE RECOGNITION
The group sells services in the form of research or analysis assignments on an ongoing basis. The contracts are normally classified as a distinct performance obligation. Revenue from the services provided is recognised in the accounting period in which they are rendered.

A receivable is recognised when the services are completed as this is the point in time when the consideration is unconditional (meaning only the passage of time is required before payment of that consideration is due).

2.5 GOVERNMENT GRANTS
Grants from the government are recognised at their fair value where there is a reasonable assurance that the grant will be received and the group will comply with all attached conditions. Grants received before the conditions for recognition as income have been met are recognised as a liability.

The group's grants consist in their entirety of grants to cover costs. Grants to cover costs are accrued and recognised in profit or loss over the period necessary to match them with the costs that they are intended to compensate.

2.6 INTEREST INCOME
Interest income is recognised using the effective interest method.

2.7 CURRENT AND DEFERRED TAX
Tax expense for the period comprises current and deferred tax. Tax is recognised in the consolidated statement of comprehensive income, except when the tax pertains to items that are recognised in other comprehensive income or directly in equity. In such cases, the tax is also recognised in other comprehensive income or directly in equity, respectively.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted on the balance sheet date in the countries where the company and its subsidiaries and associates operate and generate taxable income. Management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation. It establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Deferred tax is recognised for all temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred tax is not recognised to the extent it arises from the initial recognition of an asset or liability in a transaction that is not a business combination and at the time of the transaction, affects neither accounting profit nor taxable profit. Deferred tax is calculated using tax rates (and laws) enacted or substantially enacted on the balance sheet date and that are expected to apply when the related deferred tax asset is realised or the deferred tax liability is settled.

Deferred tax assets are recognised only if it is probable that future taxable amounts will be available to offset those temporary differences and losses.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets and liabilities and when the deferred tax balances relate to the same taxation authority and pertain to either the same or different tax entities, where there is an intention to realise the asset and settle the liability on a net basis.

2.8 LEASES
The group's leases essentially pertain to an office space.

The leases are recognised as right-of-use assets and a corresponding lease liability at the date at which the leased asset is available for use by the group. Each lease payment is allocated between amortisation of the liability and finance cost. The finance cost is allocated over the lease term so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

The right-of-use asset is subsequently amortised over the shorter of the useful life of the asset and the lease term on a straight-line basis. The lease has a fixed initial term of three years with an option to extend or terminate the contract.

Assets and liabilities arising from leases are initially recognised at present value. Lease liabilities include the present value of the following lease payments:

- fixed payments and
- variable lease payments dependent on an index.

The lease payments are discounted using the incremental borrowing rate.

Right-of-use assets are measured at cost comprising the following:

- the initial measurement of the lease liability and
- payments made on or before the point in time when the leased asset is made available to the lessee.

Lease payments attributable to short-term leases and low-value leases are recognised over the lease term on a straight-line basis. Short-term leases are leases with a lease term of 12 months or less. Low-value leases essentially pertain to office equipment.

Options to extend or terminate leases
Options to extend or terminate leases are included in the group's lease contracts for offices. These terms are used to maximise operational flexibility in terms of managing contracts. Options to extend or terminate leases are included in the asset and the liability where it is reasonably certain they will be exercised.

2.9 TANGIBLE FIXED ASSETS
Tangible fixed assets include equipment, tools, fixtures and fittings. Tangible fixed assets are recognised at cost less depreciation. Cost includes expenses directly attributable to the acquisition of the asset.

Subsequent costs are added to the carrying amount of the asset or recognised as a separate asset, whichever is the most appropriate, only when it is probable that the future economic benefits embodied in the asset will flow to the group and the cost of the asset can be measured reliably. The

carrying amount of the part that is replaced is derecognised. All other repairs and maintenance are recognised as costs in the statement of comprehensive income in the period in which they occur.

In order to allocate their cost down to the residual value over the estimated useful life, assets are depreciated on a straight-line basis as follows.

- Equipment, tools, fixtures and fittings 5 years

The residual values and useful lives of the assets are reviewed at the end of every reporting period and adjusted if appropriate.

An asset's carrying amount is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount. Gains and losses on disposals are determined by comparing the proceeds with the carrying amount, and recognised net in other operating income/other operating expenses in the statement of comprehensive income.

2.10 INTANGIBLE ASSETS

Research and development

InDex is a pharmaceutical development company focused on immunological diseases. All expenses directly attributable to the development and testing of identifiable and unique products controlled by InDex are recognised as intangible assets when the following criteria are met:

- it is technically feasible to complete the product or process so that it will be available for use,
- InDex's intention is to complete the product and to use or sell it,
- there is an ability to use or sell the product,
- it can be demonstrated how the product will generate probable future economic benefits,
- adequate technical, financial and other resources to complete the development and to use or sell the product are available, and
- the expenditure attributable to the product during its development can be reliably measured.

The overall risk in ongoing development projects is high. Risk includes safety and efficacy-related risks that can arise in clinical trials, regulatory risks related to applications for the approval of clinical trials and marketing authorisation, and IP risks related to the approval of patent applications and maintaining patents. All development is therefore considered research, since development processes do not meet the criteria listed above. At December 31, 2020 and in the comparative periods, no development costs had been recognised as intangible assets in the balance sheet since none of the above criteria for capitalisation were considered met for any of the pharmaceutical development projects conducted by the group. Research costs are expensed as incurred. Development costs expensed in prior periods are not recognised as assets in subsequent periods.

2.11 IMPAIRMENT OF NON-FINANCIAL ASSETS

Assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of the asset's fair value less costs of disposal and value in use.

2.12 FINANCIAL INSTRUMENTS

The group's financial assets and liabilities consist of other long-term receivables, accounts receivable, other receivables, accrued income, cash and cash equivalents, accounts payable, other liabilities and accrued costs.

(i) Initial recognition

Financial assets and liabilities are recognised when the group becomes a party to the financial instrument's contractual conditions. The purchase or sale of financial assets and liabilities is recognised on the trade date, i.e. the date on which the group commits to buy or sell the asset.

At initial recognition, a financial asset or a liability is measured at its fair value plus or minus, in the case of a financial asset or a liability not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition or issue of the financial asset or liability, such as fees and commissions. Transaction costs for financial assets and liabilities measured at fair value through profit or loss are expensed in the statement of comprehensive income.

(ii) Financial assets – Classification and measurement

The group classifies and measures its financial assets in the categories amortised cost and fair value through profit or loss. The classification of investments in debt instruments depends on the group's business model for managing financial assets and the contractual terms for the cash flows of the assets.

Financial assets measured at amortised cost

Assets that are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest are measured at amortised cost. The carrying amount of these assets is adjusted for any expected credit losses recognised (see Impairment of financial assets below). The group's financial assets that are measured at amortised cost consist of accounts receivable, other receivables, accrued income and cash and cash equivalents.

Financial assets measured at fair value through profit or loss

Financial assets measured at fair value through profit or loss are financial assets held for sale. These are also measured at fair value in subsequent periods and the change in fair value is recognised in the statement of comprehensive income. Financial assets measured at fair value are treated as other non-current receivables.

(iii) Financial liabilities – Classification and measurement

Financial liabilities measured at amortised cost

After initial recognition, the group's financial liabilities are measured at amortised cost using the effective interest method. Financial liabilities consist of account payables, other current liabilities and accrued expenses.

(iv) Derecognition of financial assets and financial liabilities
Financial assets are derecognised when the rights to the cash flows from the instrument have expired or been transferred and the group has transferred substantially all of the risks and rewards of ownership. Financial liabilities are derecognised when the contractual obligations have been fulfilled or otherwise extinguished. Since the terms of a financial liability are renegotiated and not derecognised, a gain or loss is recognised in the statement of comprehensive income and the gain or loss is calculated as the difference between the original contractual cash flows and the modified cash flows discounted at the original effective interest rate.

(v) Offsetting of financial instruments
Financial assets and liabilities are offset and the net amount recognised in the balance sheet only when there is a legally enforceable right to offset the carrying amounts and an intention to settle on a net basis or to realise the asset and settle the liability simultaneously. The right of set-off must not be contingent on a future event and must be legally enforceable in the normal course of business, in the event of default, and the event of insolvency or bankruptcy of the group and all of its counterparties.

(vi) Impairment of financial assets
Assets measured at amortised cost
The group determines the future expected credit losses attributable to assets measured at amortised cost. The group recognises a loss allowance for such expected credit losses at the end of each reporting period. For accounts receivable, the group applies the simplified approach to loss allowances, meaning that the allowance will correspond to the expected loss over the life of a receivable. To measure the expected credit losses, accounts receivable are grouped on the basis of shared credit risk characteristics and days past due.
The group uses forward-looking variables to determine expected credit losses. Expected credit losses are treated as other operating expenses in the consolidated statement of comprehensive income.

2.13 ACCOUNTS RECEIVABLE
Accounts receivable are amounts due from customers for services sold and performed in the ordinary course of business. Accounts receivable are classified as current assets. Accounts receivable are initially recognised at the transaction price. The group holds the accounts receivable with the objective to collect the contractual cash flows. Accounts receivable are therefore measured at amortised cost in subsequent accounting periods using the effective interest method.

2.14 CASH AND CASH EQUIVALENTS
Cash and cash equivalents include bank balances in both the balance sheet and the cash flow statement.

2.15 SHARE CAPITAL
Ordinary shares are classified as equity. Transaction costs directly attributable to the issue of new shares or options are recognised in equity, net of tax, as a deduction from the issue proceeds.

2.16 ACCOUNT PAYABLES
Account payables are financial instruments and pertain to obligations to pay for goods and services acquired from suppliers in the ordinary course of business. Account payables are classified as current liabilities if payment is due within 12 months. If not, they are recognised as long-term liabilities.

Account payables are initially measured at fair value and thereafter at amortised cost using the effective interest method.

2.17 EMPLOYEE BENEFITS
(i) Short-term employee benefits
Liabilities for salaries and benefits, including non-monetary benefits and paid absence, that are expected to be settled within 12 months after the end of the financial year, are recognised as current liabilities at the undiscounted amount expected to be paid when the liabilities are settled. The cost is recognised in the statement of comprehensive income as the services are provided by the employees. The liability is recognised as an obligation to provide employee benefits in the consolidated balance sheet.

(ii) Pension obligations
The group has only defined contribution pension plans. A defined contribution pension plan is a pension plan for which the company pays fixed contribution to a separate legal entity. The group has no legal or constructive obligations to pay further contributions if the legal entity does not have sufficient assets to pay all employee benefits relating to employee service in the current or previous periods. The contributions are recognised as personnel costs in the statement of comprehensive income when they fall due for payment.

2.18 DIVIDENDS
Dividends to the parent company's shareholders are reported as a liability in the group's financial reports when the dividend is approved by the parent company's shareholders.

2.19 EARNINGS PER SHARE
(i) Earnings per share before dilution
Earnings per share before dilution is calculated by dividing:
- the result attributable to shareholders of the parent company, excluding dividends attributable to preference shares
- by a weighted average number of ordinary shares outstanding during the period, adjusted for bonus elements in ordinary shares issued and excluding treasury shares.

(ii) Earnings per share after dilution
To calculate the earnings per share after dilution, the amounts used to calculate the earnings per share before dilution are adjusted by taking into account:
- The after-tax effect of dividends and interest expenses associated with potential ordinary shares, and

- the weighted average number of additional ordinary shares that would have been outstanding assuming the conversion of all potential ordinary shares.

NOTE 3 FINANCIAL RISK MANAGEMENT

3.1 FINANCIAL RISK FACTORS

The group's activities expose it to a variety of financial risks: different market risks, credit risk, liquidity risk and refinancing risk. The group focuses on the unpredictability of financial markets and seeks to minimise potential adverse effects on the group's financial performance. The objective of the group's financial operations is to:

- ensure that the group is able to fulfill its payment obligations,
- manage financial risks,
- ensure access to the required financing, and
- optimize the group's net financial income/expense.

It is the Board who is ultimately responsible for exposure, management and monitoring of InDex risks. The framework applicable to exposure, management and follow-up of financial risks is established by the Board and audited annually. The Board has delegated the responsibility for the daily risk management to the CEO, who in turn has delegated to the CFO. The Board can decide on temporary departures from the established framework.

(i) Market risk

Foreign exchange risk

The group operates in Sweden as well as internationally and is exposed to foreign exchange risks arising from various currency exposures, primarily in relation to the euro (EUR) and US dollars (USD). Foreign exchange risks arise from future transactions, primarily payment outflows, and recognised assets and liabilities in a currency that is not the company's functional currency, known as transaction exposure. The group's exposure to foreign exchange risk is medium-high as a number of transactions in foreign currency occur. Therefore, the group does not currently use derivative instruments, such as currency swaps, to manage currency risk.

In InDex, foreign exchange risk mainly arises from cross-border transactions, where pricing and invoicing is done in EUR and USD. Sensitivity in earnings regarding changes in exchange rates arises mainly in EUR and USD. Significant balance sheet items in foreign currency are found in accounts payable. Accounts payable in foreign currency amounts to SEK 1,293k (December 31, 2019: SEK 2,194k, December 31, 2018: SEK 3,074k). According to its financial policy, the group can reduce its transaction exposure by using derivative instruments in the form of forward contracts, swaps and currency options. As of December 31, 2020, and for all comparative periods, there were no outstanding derivative instruments.

Sensitivity analysis – transaction exposure

The group is primarily exposed to changes in the exchange rate for EUR and from 2020 USD. Sensitivity in earnings relating to changes in exchange rates arises mainly through accounts payable in EUR within the group. If the Swedish krona had weakened/strengthened by 1 percent in relation to the EUR and USD as applicable, with all other variables constant, the recalculated profit after tax for the financial year 2020 would have been SEK 400k (2019: SEK 600k, 2018: SEK 600k) lower/higher mostly as a result of gains/losses on translation of accounts payable.

(ii) Credit risk

Credit risk is managed at group level. Credit risk arises from bank balances and credit exposures to customers. For banks and financial institutions, only independently rated parties with a minimum rating of 'A' are accepted. The group's accounts receivable are low during all periods, as drug development has not yet been commercialised, which is why credit risk linked to accounts receivable is considered low. In order to limit credit risk, an analysis is made of each central counterparty. The counterparty's financial situation is also continuously monitored to identify warning signals at an early stage.

(iii) Liquidity risk

Through careful liquidity management, the group ensures that sufficient liquid funds are available to meet the needs of the ongoing operations. At the same time, the group ensures that there is sufficient cash and cash equivalents so that debt payments can be made when they fall due. Management monitors rolling forecasts of the group's liquidity requirements based on expected cash flows.

(iv) Refinancing risk

Refinancing risk is defined as the risk that difficulties arise in refinancing the company, that financing cannot be obtained, or that it can only be obtained at increased costs. Both the size and the timing of the group's potential future capital requirements depend on a number of factors, including the possibility of entering into cooperation or licensing agreements and the progress made in research and development projects. There is a risk that the required financing of the business is not available at the right time and at a reasonable cost.

New share issues have been carried out to secure the financing of research and development projects. The risk is limited by the group continuously evaluating various financing solutions. The table below analyses the group's financial liabilities broken down by the time remaining on the balance sheet date until the contractual maturity date. The amounts stated in the table are the contractual, undiscounted cash flows. Future cash flows in foreign currency have been calculated on the basis of the exchange rate prevailing at the balance sheet date.

THE GROUP'S FINANCIAL LIABILITIES ON DECEMBER 31, 2018

On December 31, 2018	Less than 3 months	Between 3 months and 1 year	Between 1 and 2 years	Between 2 and 5 years	Over 5 years	Total contractual cash flows	Carrying amount
Financial liabilities							
Lease liabilities	255	733	486	–	–	1,474	1,431
Accounts payable	3,550	–	–	–	–	3,550	3,550
Other liabilities	1,311	–	–	–	–	1,311	1,311
Accrued expenses	15,637	–	–	–	–	15,637	15,637
Total	**20,573**	**733**	**486**	**–**	**–**	**21,972**	**21,929**

THE GROUP'S FINANCIAL LIABILITIES ON DECEMBER 31, 2019

On December 31, 2019	Less than 3 months	Between 3 months and 1 year	Between 1 and 2 years	Between 2 and 5 years	Over 5 years	Total contractual cash flows	Carrying amount
Financial liabilities							
Lease liabilities	243	243	–	–	–	486	484
Accounts payable	3,153	–	–	–	–	3,153	3,153
Other liabilities	1,138	–	–	–	–	1,138	1,138
Accrued expenses	17,809	–	–	–	–	17,809	17,809
Total	**22,343**	**243**	**–**	**–**	**–**	**22,586**	**22,584**

THE GROUP'S FINANCIAL LIABILITIES ON DECEMBER 31, 2020

On December 31, 2020	Less than 3 months	Between 3 months and 1 year	Between 1 and 2 years	Between 2 and 5 years	Over 5 years	Total contractual cash flows	Carrying amount
Financial liabilities							
Lease liabilities	268	805	1,073	447	–	2,593	2,341
Accounts payable	3,023	–	–	–	–	3,023	3,023
Other liabilities	852	–	–	–	–	852	852
Accrued expenses	5,640	–	–	–	–	5,640	5,640
Total	**9,783**	**805**	**1,073**	**447**	**–**	**12,108**	**11,856**

3.2 FAIR VALUE ESTIMATION AND DISCLOSURE

The carrying amounts of the group's financial assets and liabilities are deemed to be a reasonable estimate of the fair value as they relate to current receivables and liabilities, thus the discounting effect is immaterial.

3.3 CAPITAL MANAGEMENT

The group's goal regarding capital structure is to ensure the group's ability to continue its operations, so that it can continue to generate a reasonable return to the shareholders and benefit other stakeholders and to maintain an optimal capital structure to keep the cost of capital down. For InDex, the ability to forecast future cash outflows is of utmost importance paired with the ability to ensure that new capital is procured well in advance of additional capital requirements. At this stage, the group is currently not following a specific measure to assess the return to shareholders. InDex's return capacity is dependent on the quality and value of research results generated. The value and quality of the research and development business is evaluated on an ongoing basis by management and the Board.

NOTE 4 IMPORTANT ESTIMATIONS AND ASSUMPTIONS

The group makes estimates and assumptions about the future. The resulting accounting estimates will, by definition, rarely correspond to the actual results. The assumptions and other sources of estimation uncertainty where there is a significant risk of material adjustment to the carrying amounts of assets or liabilities within the next financial year are outlined below.

(i) Accrued costs for clinical trials
At each balance sheet date, management estimates the proportion of the coming milestone payments that have been accrued. The accrual for accrued costs is based on external parameters coupled with management's estimate of percentage of completion.

(ii) Tax loss carry-forwards
Deferred tax assets related to loss carry-forwards or other future tax deductions are recognised to the extent it is probable that the deduction can be offset against future taxable profits. Since the group does not report positive results no deferred tax asset related to loss carry-forwards has yet been recognised.

(iii) Estimates and assessments linked to development costs.
An important assessment in financial reporting refers to the point in time for capitalising pharmaceutical development costs. Based on the accounting policies set out under note 2, no pharmaceutical development costs meet the criteria for capitalisation and have therefore been expensed. Pharmaceutical development costs will be, at the earliest, capitalised after positive results have been achieved in phase III clinical trials or until registration studies have commenced. The reasons being that before that time, it is too uncertain whether the costs will generate future economic benefits and that financing of the asset's completion has not been secured.

NOTE 5 NET SALES

REVENUE
Revenue from external parties that is reported to the CEO is valued in the same way as in the group's statement of comprehensive income. The main revenue stream for the group is sales of research and analysis services on an ongoing basis and is reported as revenue during the period the work was performed.

REVENUE FROM EXTERNAL CLIENTS

	2020	2019	2018
Research and analysis services	35	88	128
Total	**35**	**88**	**128**

REVENUE FROM EXTERNAL CLIENTS ALLOCATED PER COUNTRY BASED ON WHERE THEY ARE LOCATED

	2020	2019	2018
Sweden	35	88	128
Total	**35**	**88**	**128**

All non-current assets, other than financial instruments and deferred tax assets (there are no assets in connection with post-employment benefits or rights under insurance contracts) are located in Sweden.

NOTE 6 FEES AND REMUNERATION TO AUDITORS

	2020	2019	2018
PwC			
– Audit engagement	265	194	210
– Other services	663	254	75
Total	**928**	**448**	**285**

NOTE 7 PERSONNEL COSTS

EMPLOYEE BENEFITS

	2020	2019	2018
Salaries and other benefits	5,858	8,307	5,869
Social security charges	1,703	2,596	2,016
Pension expenses – defined contribution plans	1,572	1,510	1,445
Fees	7,596	6,934	5,704
Total remuneration	**16,729**	**19,347**	**15,034**

REMUNERATION, OTHER BENEFITS AND SOCIAL SECURITY CONTRIBUTIONS

	2020		2019		2018	
	Salary and other benefits	Social security contributions (whereof pension expenses)	Salary and other benefits	Social security contributions (whereof pension expenses)	Salary and other benefits	Social security contributions (whereof pension expenses)
Board of Directors, CEO and other senior executives	4,241	2,175 (998)	6,093	2,721 (992)	4,175	2,162 (1,068)
Other employees	2,523	1,245 (574)	3,214	1,529 (518)	2,727	1,299 (377)
Total group	**6,764**	**3,420 (1,572)**	**9,307**	**4,250 (1,510)**	**6,902**	**3,461 (1,445)**

AVERAGE NUMBER OF EMPLOYEES SPLIT BY COUNTRY

	2020		2019		2018	
	At year-end	Whereof men	At year-end	Whereof men	At year-end	Whereof men
Sweden	7	1	7	1	7	1
Total group	**7**	**1**	**7**	**1**	**7**	**1**

SPLIT BY GENDER IN THE GROUP FOR BOARD OF DIRECTORS AND SENIOR EXECUTIVES

	2020		2019		2018	
	At year-end	Whereof men	At year-end	Whereof men	At year-end	Whereof men
Board of Directors	6	4	4	3	5	4
CEO and other senior executives	4	3	4	3	4	3
Total group	**10**	**7**	**8**	**6**	**9**	**7**

REMUNERATION AND OTHER BENEFITS 2020

	Basic salary/ Board remuneration	Variable remuneration	Other benefits	Pension expenses	Fees	**Total**
Chairman of the Board – Wenche Rolfsen	400	–	–	–	–	**400**
Member of the Board – Marlene Forsell	134	–	–	–	–	**134**
Member of the Board – Uli Hacksell	200	–	–	–	–	**200**
Member of the Board – Lennart Hansson	200	–	–	–	–	**200**
Member of the Board – Yilmaz Mahshid	134	–	–	–	–	**134**
Member of the Board – Stig Lökke Pedersen	200	–	–	–	–	**200**
CEO – Peter Zerhouni	1,853	–	–	602	–	**2,455**
Other senior executives (3 people)	1,130	–	–	396	3,279	**4,795**
Total group	**4,241**	**–**	**–**	**998**	**3,279**	**8,518**

The group of senior executives includes COO, CFO and CMO, of which CFO and CMO are engaged as consultants.

REMUNERATION AND OTHER BENEFITS 2019

	Basic salary/ Board remuneration	Variable remuneration	Other benefits	Pension expenses	Fees	**Total**
Chairman of the Board – Wenche Rolfsen	400	–	–	–	–	**400**
Member of the Board – Uli Hacksell	200	–	–	–	–	**200**
Member of the Board – Lennart Hansson	200	–	–	–	–	**200**
Member of the Board – Stig Lökke Pedersen	200	–	–	–	–	**200**
CEO – Peter Zerhouni	1,759	1,872	–	593	–	**4,224**
Other senior executives (3 people)	1,120	341	–	399	1,674	**3,534**
Total group	**3,879**	**2,213**	**–**	**992**	**1,674**	**8,758**

REMUNERATION AND OTHER BENEFITS 2018

	Basic salary/ Board remuneration	Variable remuneration	Other benefits	Pension expenses	Fees	**Total**
Chairman of the Board – Wenche Rolfsen	400	–	–	–	–	**400**
Member of the Board – Uli Hacksell	200	–	–	–	–	**200**
Member of the Board – Lennart Hansson	200	–	–	–	–	**200**
Member of the Board – Stig Lökke Pedersen	200	–	–	–	–	**200**
Member of the Board – Andreas Pennervall	–	–	–	–	–	**–**
CEO – Peter Zerhouni	1,706	302	–	575	–	**2,583**
Other senior executives (3 people)	1,054	113	–	493	2,144	**3,804**
Total group	**3,760**	**415**	**–**	**1,068**	**2,144**	**7,387**

No fees for other engagements have been paid to any of the members of the Board during the period.

GUIDELINES

Fees are paid to the Chairman and members of the Board in accordance with the decision of the Annual General Meeting. Remuneration to the CEO and other senior executives consists of basic salary, variable remuneration, other benefits, pensions, etc. Where applicable, consulting fees are paid in accordance with agreements. Other senior executives refer to the three persons who together with the CEO constitute the management.

The distribution between basic salary and variable remuneration must be in proportion to the manager's responsibility and authority. For the CEO, the variable remuneration is maximized to 30% of the basic salary. For other senior executives, variable remuneration is maximised to two monthly salaries. The variable remuneration is based on the outcome in relation to individually set goals. Pension benefits and other benefits to the CEO and other senior executives are paid as part of the total remuneration.

DEFINED CONTRIBUTION PENSION PLANS

The group only has defined contribution pension plans. Pension cost refers to the cost that has been expensed during the year. The retirement age for the CEO is 65 years. The pension premium shall amount to 32% of the pensionable salary. Pensionable salary means basic salary. For other senior executives, the retirement age is 65 years. The pension agreement states that the pension premium shall be in accordance with ITP. No pension commitments have been made for board members.

SEVERANCE AGREEMENTS

A mutual notice period of 6 months applies between the company and the CEO. There are no severance pay agreements.

There are a mutual notice periods of 3 months between InDex and other senior executives. There are no severance pay agreements.

EMPLOYEE SHARE-OPTION PLANS

The following is a summary of employee share-option plans found in the group during any of the periods covered by the annual report 2020.

TO 2016/2019

At the Extraordinary General Meeting held on September 12, 2016 it was resolved to issue 3,250,000 warrants, TO 2016/2019. The price was SEK 0.20 per warrant according to a valuation based on Black&Scholes. All warrants were acquired by employees and other key persons in InDex at market value. Each warrant TO 2016/2019 had an exercise price of SEK 19 and could be exercised in September 2019. No warrants were exercised.

TO 2020/2023

At the Annual General Meeting held on April 20, 2020 it was resolved to issue 3,965,000 warrants, TO 2020/2023. The Board allocated in July 2020 958,388 warrants to employees and other key persons. The price was SEK 0.2522 per warrant according to a valution based on Black&Scholes. The warrants gave the holder the right to subscribe for one new share in InDex Pharmaceuticals Holding AB at an exercise price of SEK 20 during May-October 2023. All participants acquired the warrants at market value.

After the completed rights issue the exercise price and the number of shares each warrants entitles to have been recalculated in accordance with the agreed terms. Recalculated exercise price amounts to SEK 7.804 and for each warrant 2.5627 shares can be subscribed. Remaining warrants have been terminated after the completed rights issue.

For the comparative periods senior executives held the following number of warrants:

- December 31, 2020 666,667
- December 31, 2019 0
- December 31, 2018 1,500,000

	2020		2019[1]		2018[1]	
	Average exercised price per warrant	Warrants	Average exercised price per warrant	Warrants	Average exercised price per warrant	Warrants
Per January 1	–	–	19.00	3,237,500	19.00	3,237,500
Granted	7.804	958,388	–	–	–	–
Forfeited	–	–	–	–	–	–
Exercised	–	–	–	–	–	–
Expired	–	–	19.00	–3,237,500	–	–
Per December 31	**7.804**	**958,388**	**–**	**–**	**19.00**	**3,237,500**

[1] Not recalculated due to the completed rights issue in February 2021.

NOTE 8 OTHER INCOME

	2020	2019	2018
Government grants	380	–	612
Total	**380**	**–**	**612**

NOTE 9 FINANCIAL ITEMS

	2020	2019	2018
Interest income	46	–	–
Other financial income	0	0	0
Total financial income	**46**	**0**	**0**
Interest expense	–113	–61	–86
Exchange differences lost	–	–	–
Other financial expenses	–2	–	–64
Total financial expenses	**–115**	**–61**	**–150**
Financial items – net	**–69**	**–61**	**–150**

NOTE 10 TAXES

	2020	2019	2018
Current tax expense:			
Current tax expense	–	–	–
Adjustments of prior year income tax	–	–	–
Total current tax expense	**–**	**–**	**–**
Deferred tax (note 22)			
Deferred tax on temporary differences	–	–	–
Total deferred tax	**–**	**–**	**–**
Total taxes	**–**	**–**	**–**

The income tax on the group's profit before tax differs from the theoretical amount that would have been obtained when using the Swedish tax rate for the results of the consolidated companies as follows:

	2020	2019	2018
Earnings before tax	**–57,418**	**–87,773**	**–82,315**
Tax as per applicable tax rate for parent company in Sweden (2020 and 2019: 21.4%, 2018: 22%)	12,287	18,783	18,109
Tax effects due to:			
Non-taxable income	–	–	–
Non-deductible expenses	–7	–79	–30
Tax effect related to unrecognised tax losses carried forward	–12,280	–18,704	–18,079
Taxes	**–**	**–**	**–**

The weighted average tax rate for the group was 0% (2019: 0%, 2018: 0%).

In 2019, it was decided that the corporate tax rate in Sweden would be reduced in two steps. The corporate tax rate is lowered from 22.0% to 21.4% for fiscal years beginning January 1, 2019 or later. In the next step, the corporate tax rate will be reduced to 20.6% from the fiscal year beginning January 1, 2021.

NOTE 11 EXCHANGE RATE DIFFERENCES - NET

Exchange rate differences have been reported in the statement of comprehensive income as follows:

	2020	2019	2018
Other income (note 8)	–	–	–
Other external expenses	–	–	–
Financial items - net (note 9)	–69	–61	–150
Total	**–69**	**–61**	**–150**

NOTE 12 EARNINGS PER SHARE

Earnings per share is calculated by dividing the result after tax with the average number of ordinary share for the period.

InDex has pending ordinary shares through warrants. The warrants have no dilution effect during 2018, 2019 and 2020 as a conversion to ordinary shares would lead to a lower negative earnings per share.

	2020	2019	2018
Result after tax attributable to the shareholders of the parent company	–57,418	–87,773	–82,148
Total	**–57,418**	**–87,773**	**–82,148**
Weighted average number of shares (thousands)[1]	**236,750**	**197,001**	**169,846**
Earnings per share, SEK	**–0.24**	**–0.45**	**–0.48**

[1] Adjusted for the completed rights issue in February 2021.

NOTE 13 PARTICIPATIONS IN GROUP COMPANIES

The group had the following subsidiaries as of December 31, 2020:

Company	Registered office	Operations	Participations owned by the parent company (%)	Participations owned by the group (%)
InDex Pharmaceuticals AB	Sweden	Drug development	100	100
InDex Diagnostics AB	Sweden	Drug development	–	100

NOTE 14 TANGIBLE FIXED ASSETS

EQUIPMENT, TOOLS AND INSTALLATIONS

Fiscal year 2018	
Opening net book amount	31
Investments	–
Divestments/scrapping	–
Depreciations	–11
Closing net book amount	**20**
Per December 31, 2018	
Acquisition cost	1,129
Accumulated depreciations	–1,109
Net book amount	**20**
Fiscal year 2019	
Opening net book amount	20
Investments	–
Divestments/scrapping	–
Depreciations	–9
Closing net book amount	**11**
Per December 31, 2019	
Acquisition cost	1,129
Accumulated depreciations	–1,118
Net book amount	**11**

Fiscal year 2020	
Opening net book amount	11
Investments	909
Divestments/scrapping	–
Depreciations	–102
Closing net book amount	**818**
Per December 31, 2020	
Acquisition cost	2,038
Accumulated depreciations	–1,220
Net book amount	**818**

NOTE 15 LEASING AGREEMENTS

The balance sheets include the following amounts related to lease agreements:

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Right-of-use assets			
Office space	2,593	464	1,393
Total	**2,593**	**464**	**1,393**
Leasing liabilities			
Non-current	1,578	–	484
Current	763	484	947
Total	**2,341**	**484**	**1,431**

In June 2020 a new lease contract for office rent was signed and at the same the old lease contract was ended.

The following amounts related to leasing agreements are reported in the income statement:

	2020	2019	2018
Amortisation of right-of-use assets			
Office space	–1,090	–929	–929
Total	**–1,090**	**–929**	**–929**
Interest expense (included in financial expenses)	–82	–41	–87
Expenses attributable to variable lease payments that are not included in lease liabilities	–	–	–
Expenses attributable to short-term leasing agreements	–	–	–
Expenses attributable to leases for which the underlying asset is of low value that is not short-term leasing	–23	–12	–12

No significant variable lease payments that are not included in the lease liability have been identified.

The total cash flow in respect of leases was SEK 1,198k (2019: SEK 1,000k, 2018: SEK 1,030k). For information on the maturity of the lease liability, see Note 3.

NOTE 16 FINANCIAL INSTRUMENTS PER CATEGORY

December 31, 2018	Financial assets measured at fair value through profit and loss	Financial assets measured at amortised cost	Total
Assets on the balance sheet			
Other non-current receivables	1	–	1
Accounts receivable	–	10	10
Other current receivables	–	1,480	1,480
Prepaid expenses and accrued income	–	482	482
Cash and cash equivalents	–	83,034	83,034
Total	**1**	**85,006**	**85,007**

December 31, 2018		Financial liabilities measured at amortised cost	Total
Liabilities on the balance sheet			
Accounts payable	–	3,550	3,550
Other current liabilities	–	1,311	1,311
Accrued expenses and deferred income	–	15,637	15,637
Total	**–**	**20,498**	**20,498**

December 31, 2019	Financial assets measured at fair value through profit and loss	Financial assets measured at amortised cost	Total
Assets on the balance sheet			
Other non-current receivables	1	–	1
Accounts receivable	–	4	4
Other current receivables	–	1,343	1,343
Prepaid expenses and accrued income	–	474	474
Cash and cash equivalents	–	126,790	126,790
Total	**1**	**128,611**	**128,612**

December 31, 2019		Financial liabilities measured at amortised cost	Total
Liabilities on the balance sheet			
Accounts payable	–	3,153	3,153
Other current liabilities	–	1,138	1,138
Accrued expenses and deferred income	–	17,809	17,809
Total	**–**	**22,100**	**22,100**

December 31, 2020	Financial assets measured at fair value through profit and loss	Financial assets measured at amortised cost	Total
Assets on the balance sheet			
Other non-current receivables	1	–	1
Accounts receivable	–	–	–
Other current receivables	–	907	907
Prepaid expenses and accrued income	–	3,031	3,031
Cash and cash equivalents	–	53,834	53,834
Total	**1**	**57,772**	**57,773**

December 31, 2020		Financial liabilities measured at amortised cost	Total
Liabilities on the balance sheet			
Accounts payable	–	3,023	3,023
Other current liabilities	–	852	852
Accrued expenses and deferred income	–	5,640	5,640
Total	**–**	**9,515**	**9,515**

NOTE 17 ACCOUNTS RECEIVABLE

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Accounts receivable	–	4	10
Less: Provision for loss allowance	–	–	–
Accounts receivable - net	**–**	**4**	**10**

The group has no provision for expected credit losses for any of the periods since accounts receivable at this stage is limited.

The fair value of accounts receivable corresponds to its carrying amount, since the discount effect is not material.

No receivables have been pledged as collateral for any debt.

NOTE 18 OTHER RECEIVABLES

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Tax receivable	–	–	–
Other	907	1,343	1,480
Total	**907**	**1,343**	**1,480**

NOTE 19 PREPAID EXPENSES AND ACCRUED INCOME

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Prepaid insurance premiums	72	89	145
Other	2,959	385	337
Total	**3,031**	**474**	**482**

NOTE 20 CASH AND CASH EQUIVALENTS

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Bank accounts	**53,834**	**126,790**	**83,034**
Total	**53,834**	**126,790**	**83,034**

NOTE 21 SHARE CAPITAL AND ADDITIONAL PAID IN CAPITAL

	No of shares (thousands)	Share capital	Additional paid in capital
Per January 1, 2018	**62,528**	**1,251**	**217,581**
Issue of shares	6,253	125	37,349
Per December 31, 2018	**68,781**	**1,376**	**254,930**
Issue of shares	20,000	400	129,384
Per December 31, 2019	**88,781**	**1,776**	**384,314**
Issue of warrants	–	–	243
Per December 31, 2020	**88,781**	**1,776**	**384,557**

The share capital as of December 31, 2020 consisted of 88,781,275 ordinary shares with a quotient value of SEK 0.02.

All ordinary shares have been paid in full.

NOTE 22 DEFERRED TAXES

Deferred taxes were divided into the following:

DEFERRED TAX ASSETS	Tax losses carried forward	Total
Per January 1, 2018		
Net results and total comprehensive income for the year	–	–
Per December 31, 2018		
Net results and total comprehensive income for the year	–	–
Per December 31, 2019		
Net results and total comprehensive income for the year	–	–
Per December 31, 2020	**–**	**–**

Unutilised loss carryforwards for which no deferred tax assets have been reported amount to SEK 631,158k as of December 31, 2020 (December 31, 2019: SEK 586,788k, December 31, 2018: SEK 503,737k). The loss carryforwards can be carried forward indefinitely.

Deferred tax assets are recognised for tax loss carryforwards or other deductions to the extent that they are likely to be credited through future taxable profits. No deferred tax assets are reported as the group has not assessed that the criteria for reporting deferred tax in accordance with IAS 12 are met. Deferred tax assets are only valued at an amount corresponding to deferred tax liabilities and no deferred tax assets or tax liabilities are recognised in the balance sheet when deferred tax liabilities are offset against deferred tax assets.

NOTE 23 OTHER LIABILITIES

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Tax liabilities	–	90	209
Other	852	1,038	1,102
Total	**852**	**1,138**	**1,311**

NOTE 24 ACCURED COSTS AND DEFERRED INCOME

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Accrued vacation salaries	1,405	1,318	1,258
Accrued social security charges	442	414	456
Accured costs, clinical trials	–	8,987	12,628
Other items	3,793	7,090	1,295
Total	**5,640**	**17,809**	**15,637**

NOTE 25 PLEDGED ASSETS

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Bank guarantee, Euroclear	50	50	50
Bank guarantee, Akademiska Hus	537	–	–
Total	**587**	**50**	**50**

NOTE 26 RELATED PARTY TRANSACTIONS

The group is controlled by InDex Pharmaceuticals Holding AB. Related parties are all subsidiaries within the group as well as senior executives in the group and their affiliates. No transactions with related parties have occurred during the periods covered by the annual report, except remuneration and consulting fees to senior executives and the acquisition of warrants at market value in 2020. Remuneration to senior executives is disclosed in Note 7.

NOTE 27 CHANGES IN LIABILITIES FROM FINANCING ACTIVITIES

	January 1, 2018	Cash inflow	Cash outflow	Non-cash items	December 31, 2018
Lease liability	2,322	–	–929	–	1,393
Total	**2,322**	**–**	**–929**	**–**	**1,393**

	January 1, 2019	Cash inflow	Cash outflow	Non-cash items	December 31, 2019
Lease liability	1,393	–	–929	–	464
Total	**1,393**	**–**	**–929**	**–**	**464**

	January 1, 2020	Cash inflow	Cash outflow	Non-cash items	December 31, 2020
Lease liability	464	–	–1,054	3,219	2,629
Total	**464**	**–**	**–1,054**	**3,219**	**2,629**

Statement of comprehensive income for the parent company

SEKk	Note	2020	2019	2018
Revenues				
Net sales	2	11,265	10,997	9,112
Total revenues		**11,265**	**10,997**	**9,112**
Operating expenses				
Other external expenses	3	–11,485	–9,108	–9,194
Personnel costs	4	–5,754	–7,852	–5,252
Depreciation	7	–91	–	–
Total operating expenses		**–17,330**	**–16,960**	**–14,446**
Operating loss		**–6,065**	**–5,963**	**–5,334**
Net financial items				
Write-down of financial assets	5	–50,000	–90,000	–40,000
Financial income	5	46	–	–
Financial costs	5	–6	–21	–36
Total net financial items		**–49,960**	**–90,021**	**–40,036**
Profit or loss before tax		**–56,025**	**–95,984**	**–45,370**
Taxes for the period	6	–	–	–
PROFT OR LOSS FOR THE YEAR		**–56,025**	**–95,984**	**–45,370**

In the parent company there are no items reported in other comprehensive income. So total comprehensive income is consistent with profit or loss for the period.

The notes on pages 60 to 64 are an integrated part of these financial statements.

Balance sheet for the parent company

SEKk	Note	December 31, 2020	December 31, 2019	December 31, 2018
ASSETS				
Fixed assets				
Tangible fixed assets				
Equipment, tools and installations	7	818	–	–
Total tangible fixed assets		**818**	**–**	**–**
Financial assets				
Shares in subsidiaries	8	247,030	247,030	247,030
Total financial assets		**247,030**	**247,030**	**247,030**
Total fixed assets		**247,848**	**247,030**	**247,030**
Current assets				
Current receivables				
Intercompany receivables		779	563	351
Other receivables	9	219	58	15
Prepaid expenses and accrued income	10	1,247	366	353
Total current receivables		**2,245**	**987**	**719**
Cash and cash equivalents	11	**45,491**	**124,965**	**82,388**
Total current assets		**47,736**	**125,952**	**83,107**
TOTAL ASSETS		**295,584**	**372,982**	**330,137**
EQUITY AND LIABILITIES				
Equity				
Restricted equity				
Share capital	12	1,776	1,776	1,376
Total restricted equity		**1,776**	**1,776**	**1,376**
Non-restricted equity				
Share premium reserve		630,274	630,031	500,647
Retained earnings		–312,989	–217,005	–171,635
Profit or loss for the year		–56,025	–95,984	–45,370
Total non-restricted equity		**261,260**	**317,042**	**283,642**
Total equity		**263,036**	**318,818**	**285,018**
Current liabilities				
Account payables		1,114	243	168
Intercompany liabilities		28,800	47,262	42,266
Other current liabilities	13	323	1,222	1,066
Accrued expenses and deferred income	14	2,311	5,437	1,619
Total current liabilities		**32,548**	**54,164**	**45,119**
TOTAL EQUITY AND LIABILITES		**295,584**	**372,982**	**330,137**

The notes on pages 60 to 64 are an integrated part of these financial statements.

Statement of change in equity for the parent company

	Restricted equity	Non-restricted equity			
SEKk	Share capital	Share premium	Retained earnings	Result after tax	Total equity
Opening balance January 1, 2018	**1,251**	**463,294**	**–46,972**	**–124,663**	**292,910**
Disposition of last year's result	–	–	–124,663	124,663	–
Net results and total comprehensive income for the year	–	–	–	–45,370	–45,370
Total comprehensive income	**–**	**–**	**–**	**–45,370**	**–45,370**
Transactions with shareholders in their capacity as owners					
Issue of shares	125	37,517	–	–	37,642
Transaction costs	–	–164	–	–	–164
Transactions with shareholders of the parent company	**125**	**37,353**	**–**	**–**	**37,478**
Closing balance December 31, 2018	**1,376**	**500,647**	**–171,635**	**–45,370**	**285,018**
Opening balance January 1, 2019	**1,376**	**500,647**	**–171,635**	**–45,370**	**285,018**
Disposition of last year's result	–	–	–45,370	45,370	–
Net results and total comprehensive income for the year	–	–	–	–95,984	–95,984
Total comprehensive income	**–**	**–**	**–**	**–95,984**	**–95,984**
Transactions with shareholders in their capacity as owners					
Issue of shares	400	139,620	–	–	139,660
Transaction costs	–	–9,876	–	–	–9,876
Transactions with shareholders of the parent company	**400**	**129,384**	**–**	**–**	**129,784**
Closing balance December 31, 2019	**1,776**	**630,031**	**–217,005**	**–95,984**	**318,818**
Opening balance January 1, 2020	**1,776**	**630,031**	**–217,005**	**–95,984**	**318,818**
Disposition of last year's result	–	–	–95,984	95,984	–
Net results and total comprehensive income for the year	–	–	–	–56,025	–56,025
Total comprehensive income	**–**	**–**	**–**	**–56,025**	**–56,025**
Transactions with shareholders in their capacity as owners					
Issue of warrants	–	243	–	–	243
Transactions with shareholders of the parent company	**–**	**243**	**–**	**–**	**243**
Closing balance December 31, 2020	**1,776**	**630,274**	**–312,989**	**–56,025**	**263,034**

The notes on pages 60 to 64 are an integrated part of these financial statements.

Statement of cash flows for the parent company

SEKk	2020	2019	2018
Operating activities			
Earnings before tax	–56,025	–95,984	–45,370
Adjustment for non-cash items:			
Write-down	50,000	90,000	40,000
Income tax paid	–	–	–
Depreciations	91	–	–
Cash flow from operating activities before changes in working capital	**–5,934**	**–5,984**	**–5,370**
Cash flow in working capital			
Changes in current receivables	–1,258	–268	–88
Changes in current liabilities	–21,616	9,045	–21,314
Cash flow from changes in working capital	**–22,874**	**8,777**	**–21,402**
Cash flow from operating activities	**–28,808**	**2,793**	**–26,772**
Cash flow from investment activities			
Shareholders contribution	–50,000	–90,000	–40,000
Investment in tangible fixed assets	–909	–	–
Cash flow from investment activities	**–50,909**	**–90,000**	**–40,000**
Financing activities			
Issue of shares, net after transaction costs	–	129,784	37,478
Issue of warrants	243	–	–
Cash flow from financing activities	**243**	**129,784**	**37,478**
Cash flow for the year	**–79,474**	**42,577**	**–29,294**
Decrease/increase in cash and cash equivalents			
Cash and cash equivalents at the beginning of the year	124,965	82,388	111,682
Cash and cash equivalents at the end of the year	**45,941**	**124,965**	**82,388**

The notes on pages 60 to 64 are an integrated part of these financial statements.

Notes to the parent company

NOTE 1 PARENT COMPANY ACCOUNTING PRINCIPLES

The most important accounting principles applied when this annual report has been prepared are set out below. Unless otherwise stated, these principles have been applied consistently for all presented years. The annual report for the parent company has been prepared in accordance with RFR 2 *Accounting for Legal Entities* and the *Swedish Annual Accounts Act*. Where the parent company applies accounting principles other than the group's accounting principles, which are described in Note 2 to the consolidated financial statements, these are set out below. In connection with the transition to accounting in accordance with IFRS in the consolidated financial statements, the parent company has transitioned to applying RFR 2 *Accounting for Legal Entities*. The transition has not caused any change in previously reported income statements and balance sheets. The annual report has been prepared on a historical cost basis.

The preparation of reports in accordance with RFR 2 requires the use of some important estimates for accounting purposes. Furthermore, the management is required to make certain judgments in the application of the parent company's accounting principles. The areas that comprise a high degree of assessment, which are complex or such areas where assumptions and estimates are of significant importance for the annual report, are stated in Note 4 of the consolidated accounts.

Through its operations, the parent company is exposed to a variety of financial risks: market risk (currency risk and interest rate risk), credit risk and liquidity risk. The parent company's overall risk management policy focuses on the unpredictability of the financial markets and strives to minimise potential adverse effects on the group's financial results. For more information on financial risks, see Note 3 to the consolidated financial statements. The parent company applies accounting principles other than the group in the cases stated below:

PRESENTATION

The income statement and balance sheet follow the format set out in the *Annual Accounts Act*. The report on changes in equity follows the group's presentation format but must contain the columns specified in the *Annual Accounts Act*. Furthermore, this means a difference in terms, compared to the consolidated accounts, mainly regarding financial income and expenses and equity.

CONTRIBUTIONS

Group contributions made from parent companies to subsidiaries and group contributions received to parent companies from subsidiaries are reported as appropriations. Paid shareholders' contribution is reported in the parent company as an increase in the carrying amount of the shares in the subsidiary and in the receiving company as an increase in equity.

FINANCIAL INSTRUMENTS

IFRS 9 Financial instruments is not applied in the parent company. Instead, the parent company applies the items specified in RFR 2 (IFRS 9 *Financial Instruments*, p. 3-10).

Financial instruments are valued at cost. In subsequent periods, financial assets that are acquired with the intention of being held in the short term will be reported at lower of cost and market. Derivative instruments with a negative fair value are recognised at this value. When calculating the net realisable value of receivables that are recognised as current assets, the principles for impairment testing and loss provisioning in IFRS 9 shall be applied. For a receivable that is recognised at amortised cost at group level, this means that the loss reserve recognised in the group in accordance with IFRS 9 must also be entered in the parent company.

LEASED ASSETS

The parent company has chosen not to apply IFRS 16 *Leases* but has instead chosen to apply RFR 2 IFRS 16 *Leases* p. 2-12. This policy choice means that no right-of-use assets or lease liabilities are recognised in the balance sheet. Instead, leasing fees are expensed on a straight-line basis over the lease period.

NOTE 2 NET SALES

The parent company has reported the following amounts in the income statement attributable to revenue:

NET SALES

	2020	2019	2018
Net sales, see note 16	11,265	10,997	9,112
Total	**11,265**	**10,997**	**9,112**

NET SALES PER COUNTRY

	2020	2019	2018
Sweden	11,265	10,997	9,112
Total	**11,265**	**10,997**	**9,112**

NOTE 3 FEES AND REMUNERATION TO AUDITORS

	2020	2019	2018
PwC			
– Audit engagement	265	194	210
– Other services	663	254	75
Total	**928**	**448**	**285**

NOTE 4 PERSONNEL COSTS

EMPLOYEE BENEFITS

	2020	2019	2018
Salaries and other benefits	3,335	5,093	3,142
Social security charges	1,177	1,586	1,143
Pension expenses – defined contribution plan	998	992	945
Fees	4,381	3,750	3,219
Total	**9,891**	**11,421**	**8,449**

REMUNERATION, OTHER BENEFITS AND SOCIAL SECURITY CONTRIBUTIONS

	2020		2019		2018	
	Salary and other benefits	Social security contributions (whereof pension expenses)	Salary and other benefits	Social security contributions (whereof pension expenses)	Salary and other benefits	Social security contributions (whereof pension expenses)
Board of directors, CEO and other senior executives	4,241	2,175 (998)	6,093	2,721 (992)	4,175	2,162 (1,068)
Other employees	–	–	–	–	–	–
Total parent company	**4,241**	**2,175 (998)**	**6,093**	**2,721 (992)**	**4,175**	**2,162 (1,068)**

AVERAGE NUMBER OF EMPLOYEES SPLIT BY COUNTRY

	2020		2019		2018	
	At year-end	Whereof men	At year-end	Whereof men	At year-end	Whereof men
Sweden	2	1	2	1	2	1
Total parent company	**2**	**1**	**2**	**1**	**2**	**1**

SPLIT BY GENDER IN THE PARENT COMPANY FOR THE BOARD OF DIRECTORS AND SENIOR EXECUTIVES

	2020		2019		2018	
	At year-end	Whereof men	At year-end	Whereof men	At year-end	Whereof men
Board of directors	6	4	4	3	5	4
CEO and other senior executives	4	3	4	3	4	3
Total parent company	**10**	**7**	**8**	**6**	**9**	**7**

For information on remuneration to senior executives, see Note 9 in the consolidated financial statements.

NOTE 5 INTEREST INCOME, INTEREST EXPENSE AND SIMILAR ITEMS

	2020	2019	2018
Write-down of financial assets	–50,000	–90,000	–40,000
Interest costs	–6	–21	–36
Total interest expense and similar items	**–50,006**	**–90,021**	**–40,036**
Interest incomes	46	–	–
Total interest income	**46**	**–**	**–**
Financial items, net	**–49,960**	**–90,021**	**–40,036**

NOTE 6 TAXES

REPORTED TAX IN STATEMENT OF COMPREHENSIVE INCOME

	2020	2019	2018
Current tax:			
Current tax expense	–	–	–
Adjustment of prior year tax income	–	–	–
Total current tax	**–**	**–**	**–**
Total taxes	**–**	**–**	**–**

The income tax on profit before tax differs from the theoretical amount that would have been obtained from the use of the tax rate for the parent company as follows:

	2020	2019	2018
Pre-tax loss	**–56,025**	**–95,984**	**–45,370**
Income tax calculated according to the tax rate in Sweden (2020 and 2019: 21.4%, 2018: 22%)	11,989	20,541	9,981
Tax effects from:			
Non-taxable income	–	–	–
Non-deductible expenses	–10,697	–19,262	–8,802
Unused tax credits for which no deferred tax is recognised	1,292	–1,279	–1,179
Total reported tax	**–**	**–**	**–**

NOTE 7 EQUIPMENT, TOOLS AND INSTALLATIONS

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Opening acquisition cost	–	–	–
Investments	909	–	–
Closing acquisition cost	**909**	**–**	**–**
Opening depreciations	–	–	–
Depreciations	–91	–	–
Closing depreciations	**–91**	**–**	**–**
Net book amount	**818**	**–**	**–**

NOTE 8 SHARES IN SUBSIDIARIES

The parent company holds shares in the following subsidiaries:

Company	Corp. Reg. No	Registrered office	No of shares	Carrying value Dec 31, 2020	Carrying value Dec 31, 2019	Carrying value Dec 31, 2018
InDex Pharmaceuticals AB	556704-5140	Stockholm, Sweden	60,281,586	247,030	247,030	247,030

InDex Pharmaceuticals AB	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Opening acquisition value	544,030	454,030	414,030
Shareholders contribution	50,000	90,000	40,000
Closing acquisition value	**594,030**	**544,030**	**454,030**
Opening accumulated depreciations/write-downs	–297,000	–207,000	–167,000
Depreciations/write-downs	–50,000	–90,000	–40,000
Closing accumulated depreciations/write-downs	**–347,000**	**–297,000**	**–207,000**
Carrying value	**247,030**	**247,030**	**247,030**

NOTE 9 OTHER RECEIVABLES

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Tax account	160	58	1
Tax receivable preliminary tax	–	–	14
Other	59	–	–
Total	**219**	**58**	**15**

NOTE 10 PREPAID EXPENSES AND ACCRUED INCOME

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Prepaid rent	289	243	255
Prepaid insurance premiums	33	6	33
Other	925	117	65
Total	**1,247**	**366**	**353**

NOTE 11 CASH AND CASH EQUIVALENTS

Cash and cash equivalents in the cash flow statement include the following:

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Bank accounts	45,491	124 965	82 388
Total	**45,491**	**124 965**	**82 388**

NOTE 12 SHARE CAPITAL

See Note 21 to the consolidated financial statements for information on the parent company's share capital.

NOTE 13 OTHER LIABILITIES

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Calculated employee contribution on pensions	69	293	429
Liability to the Tax Authority (VAT, employee withholding tax and social contributions)	254	929	485
Current liabilities to employees	–	–	89
Other	–	–	63
Total	**323**	**1,222**	**1,066**

NOTE 14 ACCRUED COSTS AND DEFERRED INCOME

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Accrued vacation salaries	929	851	773
Accrued social security charges	292	267	304
Other	1,090	4,319	542
Total	**2,311**	**5,437**	**1,619**

NOTE 15 PLEDGED ASSETS

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Bank guarantee, Euroclear	50	50	50
Bank guarantee, Akademiska Hus	537	–	–
Total	**587**	**50**	**50**

NOTE 16 OPERATIONAL LEASING

The parent company rents premises according to non-terminable operating lease agreements. The lease period is three years, and the agreement can be extended at the end of the lease period for a fee that corresponds to a market fee. Lease expenses amounting to SEK 1,048k (2019: SEK 988k and 2018: SEK 1,284k) for office leases are included in the statement of comprehensive income.

Future total minimum lease fees for non-cancellable operating leases are as follows:

	2020	2019	2018
Within 1 year	1,048	988	1,284
Between 1 and 5 years	1,624	–	–
Beyond 5 years	–	–	–
Total	**2,672**	**988**	**1,284**

NOTE 17 RELATED PARTY TRANSACTIONS

InDex Pharmaceuticals Holding AB controls the group. Related parties are all subsidiaries within the group as well as senior executives in the group and their affiliates. Transactions take place on market terms.

RELATED PARTY TRANSACTIONS

	2020	2019	2018
Revenue from services			
Sales to group companies	11,265	10,997	9,112
Total	**11,265**	**10,997**	**9,112**
Procurement of services			
Purchases	0.0	0.0	0.0
Total	**0.0**	**0.0**	**0.0**

All costs for overall group functions, such as the Board, management and premises, etc. are reported in the parent company, InDex Pharmaceuticals Holding AB. Detailed calculations of the cost distribution between the group companies have been made, calculations that are regularly reviewed and form the basis for the cost distribution between the units. Based on these, internal charges are made and are then reported as internal sales as shown in the tables above.

RECEIVABLES AND LIABILITIES AT THE END OF THE YEAR AS A RESULT OF SALES AND PURCHASES OF GOODS AND SERVICES

	Dec 31, 2020	Dec 31, 2019	Dec 31, 2018
Receivables from related parties:			
Receivables from group companies	779	563	351
Liabilities to related parties			
Liabilities to group companies	28,800	47,261	42,266
Total	**29,579**	**47,824**	**42,617**

The parent company has no provisions for bad debts attributable to related parties. The parent company has also not reported any costs relating to bad debts on related parties during the period. No collateral is provided for the debts. The debts to related parties are largely derived from purchase transactions and fall due 1 month after the date of purchase.

Remunerations to senior executives is shown in Note 7.

NOTE 18 PROPOSED DISTRIBUTION OF EARNINGS

THE FOLLOWING RETAINED EARNINGS ARE AT THE DISPOSAL OF THE ANNUAL GENERAL MEETING

SEK	
Retained earnings	317,284,031
Net result	–56,025,317
	261,258,714
The Board's suggestion to be brought forward	261,258,714

Signatures

The consolidated income statement and balance sheets will be submitted to the Annual General Meeting on June 3, 2021 for adoption.

The Board and the CEO ensure that the consolidated accounts have been prepared in accordance with international accounting standards IFRS as adopted by the EU and give a true and fair view of the group's position and earnings.

The annual report has been prepared in accordance with generally accepted accounting principles and gives a true and fair view of the parent company's position and earnings.

The Directors' Report for the group and the parent company provides a true and fair view of the development of the group's and the parent company's operations, position and results and describes the significant risks and uncertainties that the parent company and the companies that are part of the group face.

Stockholm April 22, 2021

Wenche Rolfsen
Chairman of the Board

Marlene Forsell

Uli Hacksell

Lennart Hansson

Yilmaz Mahshid

Stig Lökke Pedersen

Peter Zerhouni
CEO

Our audit report was submitted on April 22, 2021

PricewaterhouseCoopers AB

Magnus Lagerberg
Authorised Public Accountant

This is an English translation of the Swedish annual report. In case of discrepancies between the English translation and the Swedish annual report, the Swedish annual report shall prevail.

Auditor's report

To the general meeting of the shareholders of InDex Pharmaceuticals Holding AB, corporate identity number 559067-6820

REPORT ON THE ANNUAL ACCOUNTS AND CONSOLIDATED ACCOUNTS

Opinions

We have audited the annual accounts and consolidated accounts of InDex Pharmaceuticals Holding AB (publ) for the year 2020. The annual accounts and consolidated accounts of the company are included on pages 28-65 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of parent company and the group as of 31 December 2020 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2020 and their financial performance and cash flow for the year then ended in accordance with International Financial Reporting Standards (IFRS), as adopted by the EU, and the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

We therefore recommend that the general meeting of shareholders adopts the statement of comprehensive income and balance sheet for the group and the income statement and balance sheet for the parent company.

Basis for Opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Other Information than the annual accounts and consolidated accounts

This document also contains other information than the annual accounts and consolidated accounts and is found on pages 1-27 and 68-75. The Board of Directors and the Managing Director are responsible for this other information.

Our opinion on the annual accounts and consolidated accounts does not cover this other information and we do not express any form of assurance conclusion regarding this other information.

In connection with our audit of the annual accounts and consolidated accounts, our responsibility is to read the information identified above and consider whether the information is materially inconsistent with the annual accounts and consolidated accounts. In this procedure we also take into account our knowledge otherwise obtained in the audit and assess whether the information otherwise appears to be materially misstated.

If we, based on the work performed concerning this information, conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Board of Director's and the Managing Director

The Board of Directors and the Managing Director are responsible for the preparation of the annual accounts and consolidated accounts and that they give a fair presentation in accordance with the Annual Accounts Act and, concerning the consolidated accounts, in accordance with IFRS as adopted by the EU. The Board of Directors and the Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts and consolidated accounts, The Board of Directors and the Managing Director are responsible for the assessment of the company's and the group's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Managing Director intend to liquidate the company, to cease operations, or has no realistic alternative but to do so.

Auditor's responsibility

Our objectives are to obtain reasonable assurance about whether the annual accounts and consolidated accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts and consolidated accounts.

A further description of our responsibility for the audit of the annual accounts and consolidated accounts is available on Revisorsinspektionen's website: www.revisorsinspektionen.se/revisornsansvar. This description is part of the auditor´s report.

REPORT ON OTHER LEGAL AND REGULATORY REQUIREMENTS

Opinions

In addition to our audit of the annual accounts and consolidated accounts, we have also audited the administration of the Board of Director's and the Managing Director of InDex

Pharmaceuticals Holding AB (publ) for the year 2020 and the proposed appropriations of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Director's and the Managing Director be discharged from liability for the financial year.

Basis for Opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of the parent company and the group in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

Responsibilities of the Board of Director's and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's and the group's type of operations, size and risks place on the size of the parent company's and the group' equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes among other things continuous assessment of the company's and the group's financial situation and ensuring that the company´s organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

Auditor's responsibility

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Managing Director in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

A further description of our responsibility for the audit of the administration is available on Revisorsinspektionen's website: www.revisorsinspektionen.se/revisornsansvar. This description is part of the auditor's report.

Stockholm 22 April 2021
PricewaterhouseCoopers AB

Magnus Lagerberg
Authorized Public Accountant

Corporate governance report

LEGISLATION AND ARTICLES OF ASSOCIATION

InDex is a Swedish public limited liability company and is governed by Swedish legislation, mainly the Swedish Companies Act (*Sw. Aktiebolagslagen (2005:551)*) and the Swedish Annual Accounts Act (*Sw. Årsredovisningslagen (1995:1554)*). The company is listed on Nasdaq First North Growth Market Stockholm ("First North") and apply the First North Rulebook. In addition to legislation and the First North Rulebook, the company's articles of association and its internal guidelines for corporate governance form the basis for the company's corporate governance. The articles of association, to be found on the company's website, contain e.g. the seat of the board of directors, the focus of the business activities, the limits for the share capital and number of shares and the conditions for participation at general meetings. The most recently adopted and registered articles of association were adopted at the extraordinary general meeting held on January 12, 2021.

THE SWEDISH CODE OF CORPORATE GOVERNANCE

The Swedish Code of Corporate Governance (the "Code") defines a norm for good corporate governance at a higher level of ambition than the Swedish Companies Act's minimum requirements and applies to companies whose shares are being traded on a regulated market in Sweden. Currently, the Code is not binding to companies whose shares are listed on First North; thus, the Code is not binding to the company. However, the Code is an important part of the company's internal guidelines for corporate governance.

GENERAL MEETINGS

The shareholders' influence in the company is exercised at general meetings, which, in accordance with the Swedish Companies Act, is the company's highest decision-making body. As the company's highest decision-making body, the general meeting may resolve upon every issue for the company, not specifically reserved for another corporate body's exclusive competence. Thus, the general meeting has a sovereign role over the board of directors and the CEO. Notices, minutes and bulletines from general meetings are made available on the company's website.

At annual general meetings, which according to the Swedish Companies Act shall be held within six months from the end of each financial year, resolutions must be passed on adoption of the profit and loss account and balance sheet for the parent company and the group, allocation of the parent company's profit or loss, discharge from liability for the board of directors and the CEO, elections of members of the board of directors and auditor and on remuneration for the board of directors and the auditor. At general meetings, the shareholders also resolve on other key matters in the company, such as amending of the articles of association, any issue of new shares etc. If the board of directors considers there is reason to hold a general meeting before the next annual general meeting, or if an auditor of the company or owners of at least one-tenth of all shares in the company so demand in writing, the board of directors must issue a notice to convene an extraordinary general meeting.

Notice to attend a general meeting shall, in accordance with the company's articles of association, be made by announcement in the Swedish Official Gazette (Sw. *Post och Inrikes Tidningar*) and by making the notice available on the company's website. At the same time as notice is made, it shall be announced in *Dagens Industri* that a notice has been made. Notice of a general meeting must be issued no earlier than six weeks and no later than two weeks before the meeting.

All shareholders who are registered directly in the company's share register, kept by Euroclear, five (5) weekdays prior to the general meeting (i.e. on the record date) and who notify the company of their intention to attend the general meeting no later than the date specified in the notice of the meeting shall be entitled to attend and vote at the general meeting, either in person or through a proxy. A shareholder may be accompanied by assistants at general meetings upon notification. Each shareholder of the company submitting a matter with sufficient foresight has the right to have the matter addressed at the general meeting.

To be able to determine who is entitled to participate and vote at general meetings, Euroclear shall, upon the request of the company, supply the company with a list of all holders of shares on the record date in connection with each general meeting. Shareholders who have their shares nominee-registered need to instruct the nominee to register the shares temporarily in the name of the shareholder in order to be entitled to attend and vote for their shares at general meetings (voting rights registration). Such registration must be completed no later than on the applicable record date and ceases to be in force once the record date has passed. Shareholders who have their shares directly registered on an account in the Euroclear system will automatically be included in the list of shareholders.

At the extraordinary general meeting held on September 12, 2016, it was resolved to establish a nomination committee and to adopt rules of procedure for the nomination committee. The main duties and responsibilities of the nomination committee are to propose candidates for the post of chairman and other members of the board of directors. The nomination committee also proposes fees and other remuneration to the members of the board of directors as well as makes proposals on the election and remuneration of the auditor.

According to the rules of procedure for the nomination committee, the nomination committee shall, as a main rule, consist of the chairman of the board of directors and four members appointed by each of the four, in terms of voting rights, largest shareholders. Should any of these shareholders waive their right to appoint a member, the right to appoint a member goes to the, in terms of voting rights, fifth largest shareholder etc. The nomination committee appoints a chairman. The chairman of the board of directors shall not be the chairman of the nomination committee. The members of the nomination committee and the shareholders who have appointed the members shall be announced no later than six months before the next annual general meeting. Should a member resign from the nomination committee before its work is completed, and the nomination committee considers it necessary to replace him or her, a substitute shall be appointed by the same shareholder who appointed the member who resigned or, if this shareholder

is no longer one of the four largest shareholders in terms of voting rights, by the largest shareholder in turn. If a shareholder that has appointed a member has substantially reduced its shareholding in the company, and the nomination committee does not consider it inappropriate taking into account any need for continuity for an upcoming general meeting, the member shall resign from the nomination committee and the nomination committee shall offer the largest shareholder not having appointed a member of the nomination committee to appoint a new member. The nomination committee's mandate period extends until the next annual general meeting or if necessary until a new nomination committee is appointed. The members of the nomination committee shall perform their duties and responsibilities in accordance with the Code.

The nomination committee before the annual general meeting 2021, appointed on March 15, 2021, has consisted of Bengt Julander, chairman, and appointed by Linc, Ivo Staijen appointed by HBM Healthcare Investments, Sussi Kvart appointed by Handelsbanken Funds, Björn Wasing appointed by SEB-Stiftelsen and Wenche Rolfsen, chairman of the board of directors.

BOARD OF DIRECTORS

Subsequent to the general meeting, the board of directors is the company's highest decision-making body. The board of directors is also the company's highest executive body and the company's representative. Further, the board of directors is, according to the Swedish Companies Act, responsible for the organisation of the company and management of the company's affairs and must regularly assess the company's and the group's financial position and ensure that the company's organisation is arranged so that the company's accounts, asset management, and finances in general are satisfactorily monitored. The chairman of the board of directors has a particular responsibility to preside over the work of the board of directors and to ensure that the board of directors fulfils its statutory duties.

According to the company's articles of association, the board of directors shall consist of a minimum of three (3) and a maximum of ten (10) ordinary members, without deputy members. Members of the board are elected annually at an annual general meeting for the period until the next annual general meeting. There is no limit in time for how long a member may be on the board of directors.

The company's board of directors is currently composed of Wenche Rolfsen (chairman), Marlene Forsell, Uli Hacksell, Lennart Hansson, Yilmaz Mahshid and Stig Lökke Pedersen. Further information about the members of the board, can be found under the "Board of directors, senior management and auditors" section above.

The responsibilities of the board of directors include e.g. to set the company's overall goals and strategies, oversee major investments, ensure that there is a satisfactory process for monitoring the company's compliance with laws and other regulations relevant to the company's operations, as well as the compliance with internal guidelines. The responsibilities of the board of directors also include ensuring that the company's disclosure to the market and investors is transparent, correct, relevant and reliable and to appoint, evaluate and, if necessary, dismiss the company's CEO.

The board of directors has, in accordance with the Swedish Companies Act, adopted written rules of procedure for its work, which will be evaluated, updated and re-adopted annually. The board of directors meets regularly in accordance with a program set out in the rules of procedure containing certain permanent items and certain items when necessary.

Provisions on the establishment of audit committees are found in the Swedish Companies Act. Provisions on the establishment of remuneration committees are found in the Code. In this respect, the provisions of the Swedish Companies Act only apply to companies whose shares are being traded on a regulated market, which does not include First North, and, as noted above in this section, the Code is not binding to the company. In light of the scope of the operations and the group's current size, it is the opinion of the company's board of directors that it is presently not justified to establish specific audit or remuneration committees. Instead, the board of directors believes that the responsibilities of the committees are best addressed within the board of directors. It is the company's board of directors' responsibility to ensure transparency and control of the company's operations through reports and contacts with the company's auditor.

CEO AND OTHER SENIOR EXECUTIVES

The company's CEO is, in accordance with the provisions of the Swedish Companies Act, responsible for the day-to-day management of the company in line with guidelines and instructions from the board of directors. Measures of an unusual nature or of great significance in view of the scope and nature of the company's operations are not considered as "day-to-day management" and should therefore, as a main rule, be prepared and presented to the board of directors for its decision. The CEO must also take any measures necessary to ensure that the company's accounts are maintained in accordance with applicable law and that its asset management is conducted satisfactorily. The CEO is subordinated to the board of directors, and the board of directors itself may also decide on matters that are a part of the day-to-day management. The work and role of the CEO as well as the allocation of duties between, on the one hand, the board of directors and, on the other, the CEO is established by written instructions (a so called "Instruction for the CEO") by the board of directors and the board of directors continuously evaluates the work of the CEO.

INTERNAL CONTROL AND AUDIT

The company's board of directors is, according to the Swedish Companies Act, responsible for the organisation of the company and management of the company's affairs, must regularly assess the company's and the group's financial position and ensure that the company's organisation is arranged so that the company's accounts, asset management, and finances in general are satisfactorily monitored. The rules of procedure adopted by the board of directors for its work contains instructions for internal financial reporting, and all interim reports and press releases are published on the company's website upon publication.

Being a public company, the company must have at least one auditor for the review of the company's and the group's annual report and accounts as well as the management by its board of directors and CEO. The review must be as detailed and extensive as required by generally accepted auditing standards. The company's auditor is, according to the Swedish Companies Act, appointed by the general meeting. Thus, auditors of Swedish limited liability companies are given their assignment by, and are obliged to report to, the general meeting, and must not allow their work to be governed or influenced by the board of directors or the senior management.

Risk factors

An investment in securities is associated with risk. When assessing the future development of InDex, it is important to consider the risk factors associated with the company and its share. These include risks related to the company's business and industry, legal risks and financial risks. The risk factors that are deemed to be of material importance for the Company's future development are described below. The company has assessed the risks based on the probability of their occurrence and the potential negative impact if a risk were to materialize. The risk factors are presented in a limited number of categories, in which the most significant risks according to the company's assessment as described above are stated first.

BUSINESS AND INDUSTRY RELATED RISKS

Risks related to the phase III program for cobitolimod

Drug development is a complicated and capital intense process involving a substantial degree of risk. The research and development required for a drug is subject to risks such as delays in product development and/or costs becoming higher than expected or that the products do not have the anticipated effect or that they turn out to have unexpected and/or unwanted side effects. Prior to launching a drug on the market, its safety and efficacy for treatment of patients with a certain disease must be ascertained by performing an extensive number of preclinical studies (evaluation of the drug candidate in laboratory and animal studies) and clinical studies (patient studies). In August 2019 InDex announced results from the phase IIb dose optimisation study CONDUCT, which evaluated cobitolimod for the treatment of moderate to severe left-sided ulcerative colitis. The study met the primary endpoint of clinical remission. Phase III trials are the basis for marketing approval applications and are conducted in patients to document statistically significant treatment efficacy and safety.

Results in previous clinical studies are not necessarily predictive of the results in future studies. The company cannot predict when planned clinical studies can start or be completed since several different factors that are crucial, such as approvals from authorities including ethics committees, the entering into agreements with e.g. CROs and clinics as well as access to patients are partly outside the company's control. Patient access refers to the participating clinics' ability to identify and include patients in the company's studies (for further information please refer to headings "Risks related to the Covid-19 pandemic" and "InDex operates in a highly competitive market"). Patient access is vital to how long a study will take and there is a risk that the Covid-19 pandemic may adversely affect participating clinics' ability to identify and include patients which can lead to a delay of the phase III program (see in more detail under the heading "Risks related to Covid-19"). Accordingly, delays in completing the company's phase III program for cobitolimod could incur increased product development costs as well as delays in introducing the product on the market.

Risks related to the Covid-19 pandemic

The Covid-19 pandemic affects healthcare systems and investor sentiment globally and must be taken into account in the company's strategic planning. If the spread of Covid-19 does not subside, InDex may experience difficulties in conducting its planned phase III program for cobitolimod since it may affect patient access. This impact may both be a result of governments or authorities imposing restrictions in order to limit the spread of the Covid-19 pandemic limiting patients' access to hospitals as well as hospitals being congested by Covid-19 related patients. If the patients in InDex's upcoming phase III program are prohibited access to hospitals this may result in these patients not receiving their doses of cobitolimod according to the dose-schedule, which may prevent these patients from participating or continuing their participation in the program. Any such limitations in patient access may result in delays in the planned phase III program for cobitolimod. Furthermore, if InDex's staff or persons engaged by InDex, such as scientists, are infected by Covid-19 this may limit their possibilities to work with the planned phase III program, which in turn could delay the program.

Furthermore, the demand for oligonucleotide raw materials from the Covid-19 mRNA vaccine manufacturers may affect InDex's access to oligonucleotide raw material needed to produce cobitolimod, which may delay or increase the cost of the production of study drug for the phase III program.

Risks related to commercialisation, market acceptance and reimbursement systems

In the event that the phase III program for cobitolimod is successful (see in more detail under the heading "Risks related to the phase III program for cobitolimod") and cobitolimod – or any other product – later is approved by FDA in the United States and/or by EMA in the EU/EEA and other applicable authorities, there is a risk that sales do not meet expectations and that the product is not commercially successful. The level of market acceptance and sales of a drug depend on a number of factors, including product properties, clinical documentation and results, competing products, distribution channels, physician accessibility, availability, price, subsidization/reimbursement and sales and marketing efforts.

Sales of prescription drugs are affected by the price set and obtained from the responsible authorities (such as the Dental and Pharmaceutical Benefits Agency in Sweden), from reimbursement payers and by healthcare payers, including insurance companies, hospitals and nationally responsible authorities. There is a risk that the prices achieved are lower than expected. The reimbursement rate that from time to time applies for a drug often depends on the value that the product is deemed to add for the patient and the healthcare system. There is a risk that the products do not qualify for subsidies from privately and publicly financed healthcare programs or that reimbursement is lower than expected, which e.g. may affect the market acceptance of the product or the operating margin.

Reimbursement systems may also change from time to time, making it more difficult to predict the benefit and reimbursement that a prescription product may obtain. Such changes could result in fewer reimbursement possibilities and lower reimbursement levels in some markets.

InDex operates in a highly competitive market
The pharmaceutical industry is a highly competitive industry characterised by global competition, rapid technological development and extensive investments. The company is facing competition from e.g. large pharmaceutical companies, including multinational companies, other companies active in the healthcare sector and universities. Some of the competitors have great financial resources and there is a risk that the company's competitors develop similar drugs or alternative medicinal products which prove more successful. The company faces competition for cobitolimod from competing therapies approved for the treatment of moderate to severe ulcerative colitis. Further, other companies are currently developing drugs that compete with or may compete with cobitolimod, InDex may also have to compete with these companies over patients to conduct necessary studies.

Furthermore, the highly competitive market may lead to that InDex is forced to take measures due to high competition, such as lowering its prices, or if the company is unable to compete successfully this may lead to a negative impact on the company's profitability and a future market share, or a loss of the company's ability to establish relationships with potential new customers.

Risks related to manufacturers and suppliers
The company engages external manufacturers (Contract Manufacturing Organisations "**CMO**") for all of its required active pharmaceutical ingredients, such as cobitolimod substance, and finished products for preclinical and clinical studies. The company has collaborated with some of its external manufacturers for a long time. The company has entered into two framework agreements but these agreements does not guarantee the delivery of products. The company has not entered into any other agreements that runs over a longer period of time with a manufacturer in addition to the aforementioned two agreements.

The company also engages external suppliers (e.g. CROs) for conducting preclinical and clinical studies. The suppliers, in turn, contracts clinics specialised in the therapeutic area and/or clinical trials that can provide access to patients.

There is a risk that current and future manufacturers and suppliers, who in turn might have contractual obligations towards third parties (e.g. sub-suppliers) which are out of the company's control, fail to deliver according to agreement, which could lead to delays and increased costs affecting an entire development project. None of the company's current manufacturers or suppliers are considered material in the sense that they cannot be replaced, but the company is dependent on such manufacturers and suppliers as changing manufacturers and suppliers might be both costly and time consuming. There is a risk that the company will not be able to find suitable manufacturers and suppliers offering the same quality and quantities on similar terms and conditions. In addition, InDex's manufacturer's and supplier's operations are subject to laws and regulations. Should the manufacturers and suppliers fail to comply with applicable laws and regulations in this regard, InDex could be negatively affected. Further, the company does not have any current agreements for the manufacture of commercial supplies of any active pharmaceutical ingredients or drug candidates if they are approved. There is a risk that the company will not find suitable manufacturers offering the required quality and quantities on terms and conditions satisfactory to the company.

Risks related to key employees and key consultants
InDex has a small number of employees with core competences and cooperates with experienced consultants within different areas of the development process. The company has seven full time employees and has established cooperation with ten qualified consultants each specialised in different areas, such as clinical trials, regulatory affairs, statistics, medicine, preclinical, manufacturing, business development, quality assurance, finance and accounting in order to ensure that the necessary competences and experiences are covered. InDex's management and the Board have together large and documented highly qualified international experience from the pharmaceutical industry and publicly listed companies. This covers the vast majority of the functions involved in the process to develop and commercialise new and innovative drugs. The company is dependent on its employees and consultants, especially on its executive management and other key individuals, and on its ability to recruit and retain highly qualified personnel. In the event a key employee or a key consultant would leave the company, this could have an adverse effect on the company's ongoing projects. The company's ability to recruit and retain qualified personnel is thereby crucial for its future success and growth.

Risks related to development of other DIMS
Prior to launching a drug on the market, its safety and efficacy for treatment of patients with a certain disease must be ascertained by performing an extensive number of preclinical studies (evaluation of the drug candidate in laboratory and animal studies) and clinical studies (patient studies). InDex has a preclinical portfolio of more than 150 DNA-based ImmunoModulatory Sequences (DIMS). To capitalise on the historical investments in the DIMS portfolio and to take advantage of the expertise and experience built up during the development of cobitolimod in ulcerative colitis, InDex is testing a selected number of DIMS candidates in models of other inflammatory diseases. The preclinical studies evaluate the chemistry, toxicity and effects through appropriate laboratory trials and animal models. Once the preclinical requirements of the substance are fulfilled the substance may proceed to clinical development. The research and development required for the DIMS candidates is subject to risks such as delays in product development and/or costs

becoming higher than expected or that the products do not have the anticipated effect or that they turn out to have unexpected and/or unwanted side effects. There is a risk that the preclinical studies for the DIMS candidates will not be successful and that the candidates will not reach clinical studies.

If successful studies were to be conducted for a DIMS candidate it is likely that other risk factors, such as those stated under headings "Risks related to manufacturers and suppliers", "InDex operates in a highly competitive market" and "Risks related to commercialisation, market acceptance and dependence on reimbursement systems", would become relevant for the applicable DIMS candidate as well.

LEGAL RISKS

Risks related to regulatory approvals, licenses and registrations with authorities

In order to develop, manufacture, market and sell drugs, regulatory approvals or licenses must be obtained from, and registrations must be made with, relevant authorities e.g. the FDA and EMA and/or national authorities, which can be both time consuming and expensive. Prior to starting the first phase III induction study, the company will apply for clinical trial approvals with national authorities, such as FDA, in the countries that will participate in the study. If the company do not receive clinical trial approvals in time (which can be a result due to both rejection from the applicable authority as well as an inquiry from the applicable authority for changes or additions to InDex's submission), delays in the company's phase III program for cobitolimod could arise.

Further, the authorities might make different assessments as regards e.g. the need for additional studies, and interpretation of data from performed studies. The requirements for approvals may differ between authorities in different countries and the actual registration procedures may require extensive work. Further, current rules and interpretations for drug approval may change in the future, which could adversely affect the company's ability to obtain the necessary regulatory approvals, which, in turn, could have a material adverse effect on the company's business and profits in the future. Subsequent to the approval of a drug, the company will still be obliged to meet certain regulatory requirements, such as requirements for safety reporting and supervision of marketing of drugs. In the event the company fails to meet post-approval regulatory requirements, previously obtained regulatory approvals may be withdrawn. The company could also be subject to other sanctions, such as fines, operational restrictions or criminal sanctions.

InDex rely on intellectual property rights and know-how

The future success of InDex is dependent on the company being able to protect its current and future intellectual property rights. The company's intellectual property rights are mainly protected through granted patents and patent applications and the company's patent portfolio covers use of cobitolimod in the treatment of various inflammatory diseases, as well as composition of matter patents for other DIMS compounds and their methods of use. InDex only has method of use patents, but no composition of matter patent for cobitolimod. Generally, a method of use patent is deemed to give a more narrow protection compared to the protection given by a composition of matter patent.

There is a risk that the company's patents are challenged by third parties, which could result in the patents being declared null and void by a patent court, adversely affecting the company. Further, there is a risk that the company's patents, trademarks and other intellectual property rights are intentionally or unintentionally infringed by third parties. In addition to being time consuming and thus disrupting the company's operations, patent infringements or challenges of intellectual property rights could entail considerable legal costs for defending the company's intellectual property rights. There is also a risk of the company unintentionally infringing intellectual property rights held by third parties, or wrongfully being alleged to do so, which also could entail considerable legal costs. Patents are only granted for a limited period of time. After a patent has expired, there is a risk that the company's products are copied by third parties, adversely affecting the sale of the company's own products. The company is also dependent on the protection of know-how, including information related to inventions for which patent applications have not yet been filed. Unlike patents and other intellectual property rights, know-how is not protected by exclusive rights by registration or similar. There is a risk that unauthorised disclosure or use of the company's know-how would render it impossible to obtain a patent or depriving the company of competitive advantages.

Risks related to product liability and insurance

In the event that any of the company's drug candidates or products – such as cobitolimod – turn out (during phase III program for cobitolimod or subsequent to obtaining approval and launching the product on the market) to cause illness, injury, disability or death, this could lead to compensation claims against the company from patients participating in clinical studies and/or patients using the products. If product liability claims are made against the company, the company may also be required to stop further sales of and prevent the use of its products. There is a risk that the applicable insurance policies will not provide sufficient coverage in the event of a product liability claim (e.g. in connection with phase III program for cobitolimod) or any other claim against the company. There is also a risk that the company could fail to obtain or maintain adequate insurance coverage at acceptable terms in the future.

InDex is subject to safety regulations and ethical standards

InDex's operations are subject to reporting requirements on safety and will upon potential future market approval be subject to additional requirements. The company need to comply with current Good Clinical Practice ("GCP"), which is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. The aim

of the standard is to provide a unified standard for the ICH41[1] regions to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions. If the company would not comply with the relevant GCP, this could mean that the company would face problems with national and regional authorities that uses the GCP standard when it comes to approval to commence clinical trials.

Further, should the company fail to comply with applicable laws and regulations in this regard, InDex could be subject to criminal sanctions and extensive damages or become obliged to cease or alter its activities. In addition, some of the company's employees could prove guilty of unethical or criminal conduct or conduct that would otherwise be in conflict with applicable laws and regulations, as well as internal guidelines. Such conduct would also damage the company's reputation. The corresponding conduct of partners could also have a material adverse effect.

FINANCIAL RISKS

Risks related to funding

Pharmaceutical development is generally very costly and InDex has incurred losses each year since the company was formed. The drug development programs are expected to generate significant costs and to lead to net losses until the company generates revenues in the form of sales of drugs on the market, potential upfront and milestone payments and/or royalties from license and collaboration agreements.

There is a risk that InDex will not have sufficient revenue or positive cash flows in the future to finance its operations. There is a risk that new capital cannot be raised when needed or on satisfying terms or that capital raised would not be sufficient to finance operations in accordance with established development plans and objectives. This could result in the company being forced to delay or change the design of the company's development program for cobitolimod.

Should the company manage to secure additional funding when required, there is a risk that the company's future capital requirements may differ from the management's estimates. The future capital requirements depend on several factors, including the costs of development and commercialisation of drug candidates, sales of products on the market, when payments are received and the size of upfront, milestone and royalty payments from license and collaboration agreements.

Risks related to global economic factors and currency fluctuations

Foreign exchange risks arise from future transactions, primarily payment outflows, and recognised assets and liabilities in a currency that is not the company's functional currency, known as transaction exposure. The company's financial accounting and functional currency is SEK but a larger part of the company's operating costs in the next few years will be denominated in e.g. EUR and USD. As a result, the company could be subject to risks relating to currency exchange rates in respect of cash flows inside and outside Sweden such as fluctuations where the exchange rate changes from when entering into an agreement until payment pursuant to the agreement. Currency fluctuations could cause currency transaction losses which the company cannot predict.

In addition, the company's operations can be adversely affected by world economic factors and the company is exposed to market factors such as supply and demand, inflation and interest rate fluctuations, upswings and downturns and the will to invest etc. The last financial crisis caused extreme volatility and disruptions in the capital and credit markets, and the markets are now facing another form of crisis because of the continued development of the Covid-19 pandemic (see in more detail under the heading "Risks related to the Covid-19 pandemic"). As the pandemic continues, it is uncertain to what extent the economic downturn will continue, and to have an adverse effect on the pharmaceuticals market and consequently have a negative effect on the company's operations in the future. A weak or declining economy could also strain the company's suppliers, possibly resulting in supply disruptions. Any of the foregoing could harm the company's operations and the company cannot anticipate all of the ways in which the future economic climate and financial market conditions could adversely affect the company's operations.

1 The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

Glossary

BIOLOGICAL DRUG
A biological drug is a drug whose active substance has been produced in or purified from materials of biological origin.

CLINICAL STUDY/TRIAL
Is a study on healthy or ill people to investigate the effect and safety of a drug or treatment method.

COLECTOMY
A surgical procedure performed to remove the large intestine.

COLONOSCOPY
Examination of the large intestine using an endoscope.

CRO (CONTRACT RESEARCH ORGANISATION)
Contract research organisation.

CROHN'S DISEASE
Inflammatory disease that may occur throughout the whole gastrointestinal tract.

CYTOKINES
Cytokines are a group of proteins and peptides whose function is to carry chemical signals. They attach to specific receptors on the target cells and are produced only when needed. They have many different kinds of target cells. Some cytokines contribute to the immune system.

DIMS
DNA-based ImmunoModulatory Sequence. Synthetically manufactured oligonucleotide that is immunomodulatory through binding to Toll-like receptor 9.

ENDOSCOPY
Endoscopy is a term for examinations in which a so-called endoscope is used. The doctor can see the inside of the body using the instrument.

ENDPOINT
How to measure the effect of a particular treatment.

ENEMA
Enema is a medical device with which a fluid is inserted into the large intestine through a tip by way of the rectum.

FLARE
A significant deterioration of a chronic but cyclical disease condition.

GASTROENTEROLOGY
Gastroenterology is the study of the digestive system and its disorders.

INFLAMMATORY BOWEL DISEASE (IBD)
Inflammatory bowel disease includes a number of conditions with inflammation of the digestive system, especially the intestine.

INVESTIGATOR
Physician participating in a clinical study.

MECHANISM OF ACTION
The way in which a treatment achieves the desired effect.

ORAL FORMULATION
A formulation of a drug taken by mouth.

PLACEBO
Inactive substance.

PRECLINICAL DEVELOPMENT
Laboratory tests and documentation of a drug candidate's characteristics in model systems.

PROOF-OF-CONCEPT
Concept validation in order to verify whether a particular method or idea works in practice.

RECTAL ADMINISTRATION
Administration through rectum.

REMISSION
Remission is a medical diagnostic term for when the symptoms have partially subsided or temporarily disappeared completely in chronic diseases.

SAFETY PROFILE
The side effects that a drug may cause.

STOMA
Stoma is a medical term for a surgical procedure in which an opening is placed on the front of the abdomen for the purpose of emptying the body's waste, such as stools.

TOLL-LIKE RECEPTOR (TLR9)
TLR9 is a member of the Toll-like receptor family and recognises DNA from bacteria and viruses.

ULCERATIVE COLITIS (UC)
Ulcerative colitis is an inflammation of the mucosa in the colon or rectum, which causes the bowel function to deteriorate.

Pharmaceutical development in brief

PRECLINICAL DEVELOPMENT
Preclinical studies evaluate the chemistry, toxicity and effects through appropriate laboratory trials and animal models. Once the preclinical requirements of the substance are fulfilled the substance may proceed to clinical development.

CLINICAL DEVELOPMENT
Clinical development is typically conducted in four sequential phases where the prior phase needs to show promising results including safety in order to move into the next phase:

Phase I: Phase I trials are most often conducted in healthy volunteers, but may also be performed in patients with the targeted disease. The goal is to determine the safety of the medicinal product and how it is absorbed, distributed, metabolised in and excreted from the body.

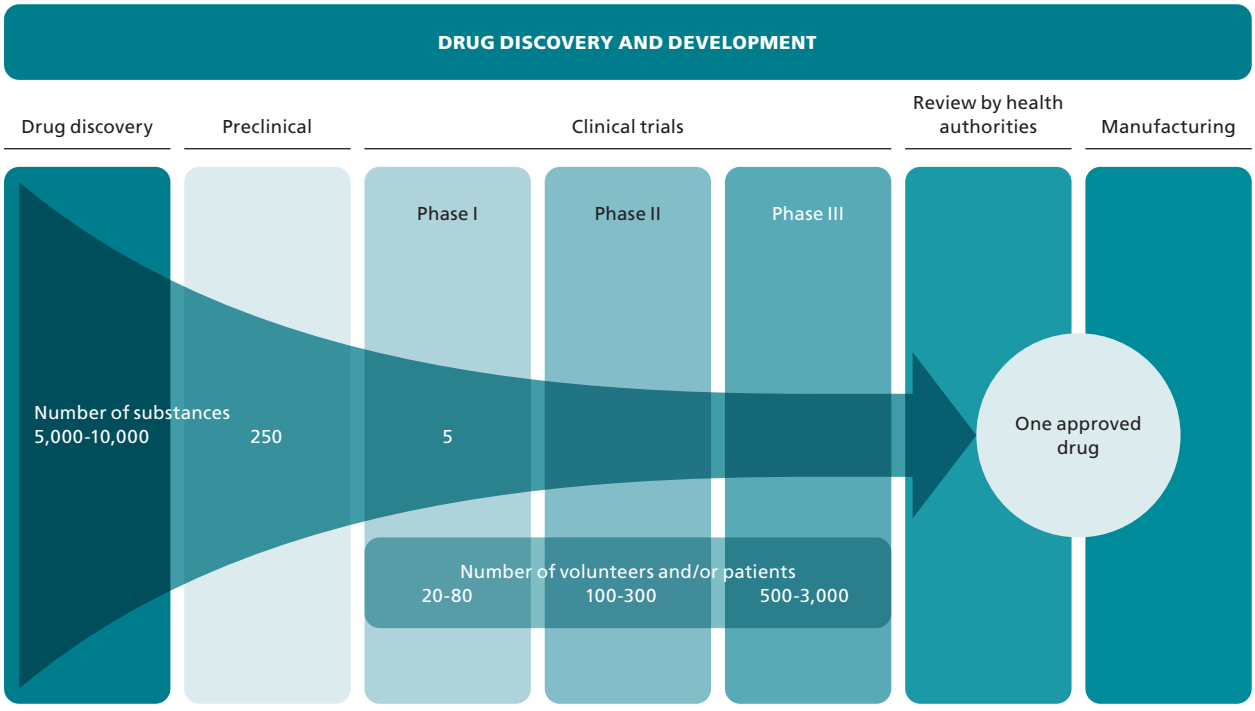
Phase II: Phase II trials are conducted in patients with the disease concerned, with the aim to establish an appropriate dosage for the phase III programme. The phase II studies also aim to obtain preliminary data on the efficacy of the substance. Safety is also carefully monitored. Phase II is usually divided into early phase (phase IIa) and late phase (phase IIb).

Phase III: Phase III trials, the basis for the marketing approval application, are conducted in patients to document statistically significant treatment efficacy, safety and tolerance. Sometimes different populations and different dosages are studied.

Phase IV: After the approval of a new medicinal product the development usually continues through so-called phase IV studies. More information from large groups of patients being treated for a long time is collected, whereby rare side effects may be discovered and further treatment effects can be evaluated. Sometimes efficacy and tolerance are compared between different medicinal products for a particular disease.

Development of medicinal products is thus a strictly regulated process, with many control steps along the way. During and after each phase the results are evaluated to decide if the development project will continue into the next stage. Approximately 10-20 percent of the substances that reach clinical development and begin a phase I study become an approved medicinal product[1]. The likelihood that the substance reaches the market generally increases the further into the development process the substance has come.

[1] Hay M, et al. vol 32,Nr 1, 2014, *Nature biotechnology. Clinical development success rates for investigational drugs* and David Taylor, *The Pharmaceutical Industry and the Future of Drug Development, in Pharmaceuticals in the Environment*, 2015, pp. 1-33.



The figure shows the drug development from the early substance to an approved drug.

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