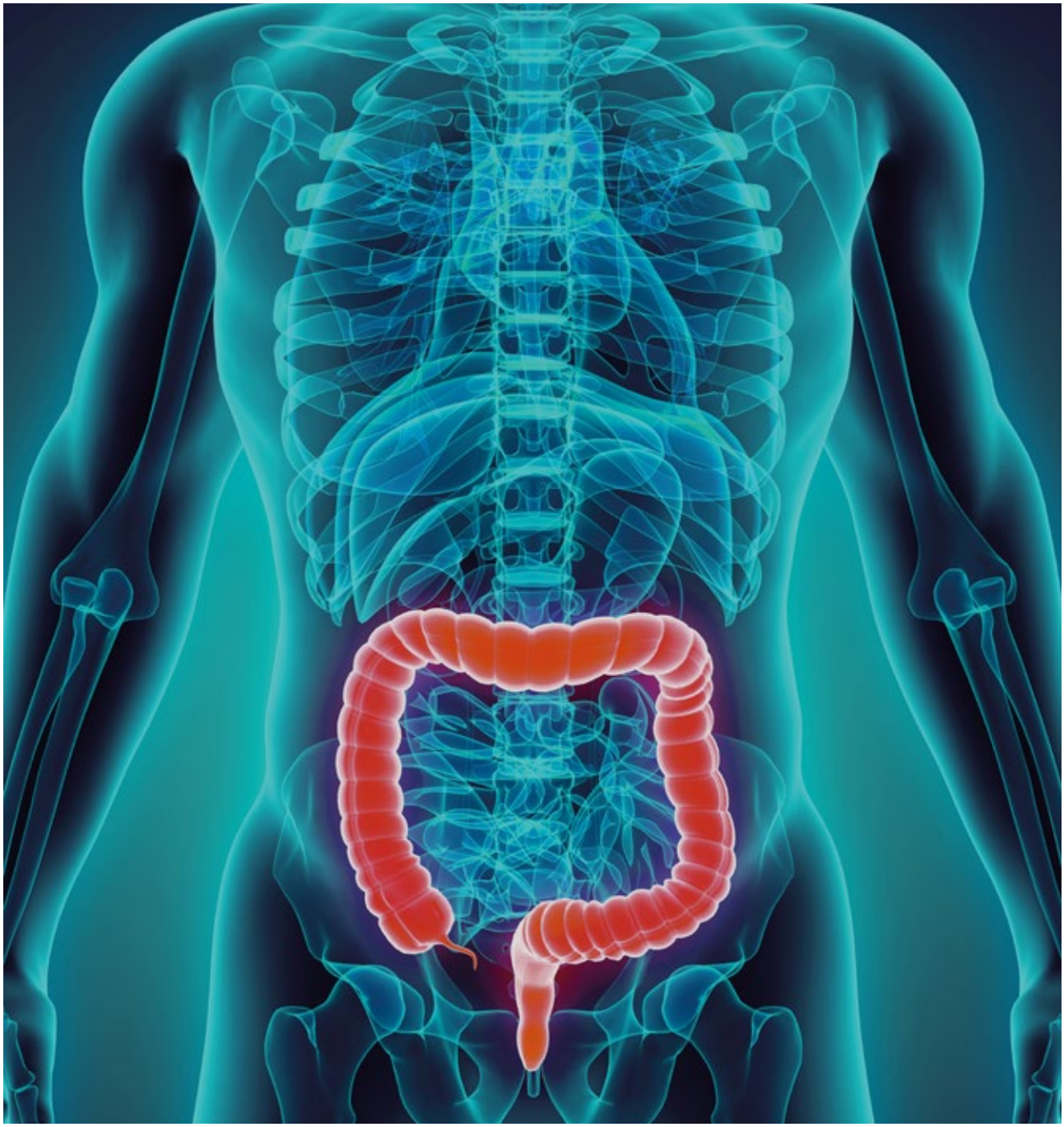
InDex Pharmaceuticals

Annual Report 2021



conclude

CObitolimod **N**ovel **C**oncept for
Left-sided **U**lcerative Colitis
Disease **E**valuation Study

Interview with Sofie on living with ulcerative colitis

CAN YOU TELL US ABOUT YOUR DISEASE JOURNEY?
When I had my first child, he had colic for the first 10 weeks of his life and when he wasn't hanging in a bag on my stomach, he was screaming more or less the whole time, poor thing. When the colic then one day in May suddenly disappeared, my ulcerative colitis started with my first flare a month later. My stomach became bloated, I had loose stools, blockage in the colon and finally also blood in the stools. I was really scared! My son will soon be 19 years old, and I count the ulcerative colitis as a partner who has been around for 18 of those years. I still think that I have been lucky, as I have managed for long periods on maintenance medicine, which I in certain phases have had to increase to prevent relapses. When that has not worked, cortisone has been a must and what has helped me.

The last 6 months has been difficult, my doctor who I have had since 2004 retired and after that the flares have been replacing each other. During this time, I have undergone three 6-8 week cortisone treatments with all that it entails. Examinations that hurt so much that they had to stop without being able to see the entire colon. Doctors who did not want me to start cortisone treatment without a physical examination, for which there were no appointments, so the inflammation spread and became larger than it has ever been. Now they think that my body has become dependent on cortisone and want me to start medication with biological drugs. However, I feel hesitant. I worry about all the side effects that are listed when reading about these drugs.

HOW DOES THE DISEASE AFFECT YOUR DAILY LIFE?
As long as the flares stay away, there is no major impact on my everyday life other than that I always must remember to have the medicines with me. However, when the flares come everything changes. Stomach pain and bloating start, the anxiety in the body increases and you never know when the blood will appear or if the stomach will be blocked as the stool does not get past the inflammation. Eating high doses of cortisone does not allow exercising with a heart rate increase, so in those weeks I really get affected mentally because movement in life is important to me.

HAVE YOU EXPERIENCED LIMITATIONS IN YOUR FAMILY LIFE DUE TO YOUR DISEASE?
I do not think that my children have thought about my disease while growing up, it has just always been there. I do not have a hard time showing my feelings whether I am ill or not, but it could be that those times that I have become afraid of my illness, I have also scared them with my fear. However, during my last flare when the inflammation was the largest ever, I had to have my own toilet to spare the children.

HAVE YOU EXPERIENCED DIFFICULTIES IN TALKING TO PEOPLE ABOUT YOUR DISEASE?
Talking about my disease has never been a problem for me, but it may have been for some recipients. Ulcerative colitis is not visible on the outside, and that can sometimes be difficult. You have to remind your managers and colleagues about your illness, and that you cannot perform at your best if you have a flare.

Name: Sofie "Fiffi" Skåhl, 54 years old
Occupation: Childcare worker, runs an after-school club
Interests: Horses, exercise, spending time on Öland
Diagnosis: Ulcerative colitis

DO YOU WORRY A LOT ABOUT YOUR DISEASE?
My biggest fear is getting a bag on my stomach, which IF it would happen might then feel like a gift! My worry about the disease goes up and down, sometimes when I bleed, I get the feeling that I have cancer in the colon. My dad passed away far too early and then it was the blood in the stool that was the start of his cancer journey away from us.

WHAT DIFFERENT TYPES OF MEDICATIONS HAVE YOU BEEN TREATED WITH FOR YOUR DISEASE?
I use mesalazine, 2-4 tablets morning and evening as maintenance treatment. Cortisone in tablet form as 6-8 weeks courses in case of relapses. Enemas with cortisone when I am in a flare. Inolaxol twice a day so that my stomach does not get blocked.

The medicine that gives me the worst side effects is the cortisone in tablet form, my heart races and beats a lot. I have recently also started with a special anti-inflammatory diet and have started with eating windows where I let my gut rest for 16 hours a day, when I do not eat anything. It remains to be seen if it works for me.

WHAT DO YOU THINK ARE THE MAIN CHARACTERISTICS OF A GOOD ULCERATIVE COLITIS TREATMENT?
What has been most important to me during all my years with ulcerative colitis, I don't think I have understood until this year. To have ONE doctor to turn to, who knows MY disease course and who can help ME with the right medications, who listens and tries to understand and explain. Then, it is of course very important that further research is done and that you find new medications with as few side effects as possible. So that we who are ill can live our lives almost as if we were healthy, that would be the dream!

2021 in brief

- On January 14, 2021 the Board 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 Fjärde AP-fonden.
- 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 were thus not utilized. InDex received, through the rights issue approximately SEK 488 million after 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.
- InDex announced on November 9, 2021 that a new method of use patent for the drug candidate cobitolimod has been granted by the United States Patent and Trademark Office (USPTO). The patent provides protection for the use of certain dosage regimens of cobitolimod for treating inflammatory bowel disease, including the 250 mg dose which was successful in the phase IIb study CONDUCT.
- InDex announced on November 24, 2021 that the first patient has been enrolled in the pivotal phase III study CONCLUDE. The study will evaluate the efficacy and safety of the first-in-class TLR9 agonist cobitolimod as a novel treatment for patients with moderate to severe left-sided ulcerative colitis.
- InDex announced on December 8, 2021 that the first patient has been enrolled in the clinical pharmacokinetic study (PK study) with cobitolimod. The purpose of the study is to evaluate the systemic uptake of cobitolimod in local treatment of colonic inflammation.

CONSOLIDATED FINANCIAL SUMMARY

SEK million	2021	2020	2019	2018	2017
Net sales	0.0	0.0	0.1	0.1	0.1
Operating loss	–102.9	–57.3	–87.7	–82.0	–73.2
Result after tax	–103.0	–57.4	–87.8	–82.1	–72.7
Earnings per share before and after dilution, SEK[1]	–0.21	–0.24	–0.45	–0.48	–0.44
Cash flow from operating activities	–124.1	–70.6	–85.1	–78.6	–67.3
Cash and cash equivalents at year-end	428.4	53.8	126.8	83.0	125.1
Number of employees at year-end	9	7	7	7	7

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

FINANCIAL CALENDER

Interim report Q I 2022	May 16, 2022
Annual general meeting	June 1, 2022
Interim report Q II 2022	August 26, 2022
Interim report Q III 2022	November 23, 2022

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 being evaluated in the phase III study CONCLUDE as a novel treatment of moderate to severe ulcerative colitis – a debilitating, chronic inflammation of the large intestine. InDex has also developed a platform of patent protected discovery stage substances, so called DNA based ImmunoModulatory Sequences (DIMS), with the potential to be used in the treatment of various immunological diseases. InDex is based in Stockholm, Sweden. The company's shares (ticker INDEX) are traded on Nasdaq First North Growth Market Stockholm. Redeye AB is the company's Certified Adviser (+46 8 121 576 90 or certifiedadviser@redeye.se).

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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 being evaluated in the phase III study CONCLUDE as a novel treatment of moderate to severe ulcerative colitis – a debilitating, chronic inflammation of the large intestine. 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. InDex is based in Stockholm, Sweden. The company's shares are traded on Nasdaq First North Growth Market Stockholm.

Ulcerative colitis is a chronic disease caused by inflammation of the large intestine. Today, about two million people in Europe and the United States suffer from ulcerative colitis, a disease that has a major impact on the patient's quality of life. The symptoms are characterized by blood- and mucus mixed diarrhea, frequent stools, pain, fever, weight loss and anemia. Patients also have a significantly elevated risk of developing colon cancer. Most commonly, ulcerative colitis debuts between 15 and 30 years of age and most patients require lifelong medication. 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.

Cobitolimod is a local treatment with a novel 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. Cobitolimod is administered rectally directly to the inflammed colon using an enema allowing a rapid onset of action without systemic exposure and off-target effects.

Cobitolimod met the primary endpoint in the phase IIb study CONDUCT and demonstrated an outstanding combination of efficacy and safety. Data from four previous completed placebo-controlled clinical trials support the efficacy and safety demonstrated in the CONDUCT study. Given the outstanding combination of efficacy and safety, cobitolimod is now being evaluated in the pivotal phase III study CONCLUDE. Phase III is the final stage of development before application for market approval can be submitted to regulatory authorities.

Based on the sales of recently launched products, as well as the company's proprietary market research and analyses, the global peak annual sales at a successful commercialisation of cobitolimod is estimated by the company to have the potential to reach more than USD 1 billion.

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.

CEO statement

At the end of 2021, the first patient was enrolled in the phase III study CONCLUDE and I am proud that we have achieved this important milestone on the way towards marketing approval. The study evaluates the drug candidate cobitolimod as a novel treatment for patients with moderate to severe left-sided ulcerative colitis. With cobitolimod, we want to give new hope to the patients suffering from this severe disease. Now that the phase III program is up and running we have also started to prepare for commercialisation of cobitolimod.

InDex is planning for self-commercialisation of cobitolimod in the US with strategic collaborations in other regions. Launch is expected in 2027, with the potential for peak annual sales to reach more than USD 1 billion, in moderate to severe left-sided ulcerative colitis.

Approximately 400,000 patients suffer from moderate to severe left-sided ulcerative colitis despite treatment with conventional therapies. Provided that CONCLUDE confirms the results of previous positive clinical trials with cobitolimod, patients can get access to a treatment with as good, or higher, efficacy than today's advanced therapies but without the serious side effects that these may cause. In addition, cobitolimod is easy to self-administer and has an infrequent dosing regimen – in contrast to current market leading products, which require injections at the clinic or at home.

The market for ulcerative colitis is expected to grow with a CAGR of approximately 6% and reach USD 11-12 billion by 2026. We estimate that the market segment of moderate to severe left-sided ulcerative colitis will amount to more than USD 5 billion by the time of launch and that cobitolimod can reach a market share of 20-30%.

We have together with external experts analysed the commercialisation options for cobitolimod in the US and Europe, where the US accounts for approximately 65% of the global market. The conclusion is that the market potential, the required commercial footprint, and the profitability profile in the US respectively are well suited for self-commercialisation by a focused commercial organisation to be built closer to launch. The fragmented European market, as well as other regions, offer attractive opportunities to enter strategic collaborations as cobitolimod advances towards launch.

As a basis for marketing approval in both the US and Europe, we are now conducting a phase III program. Results from the ongoing first phase III study CONCLUDE are expected to be available during the second half of 2023.

CONCLUDE will include approximately 440 patients and be conducted at several hundred clinics in around 30 countries. In the start-up phase our focus is on obtaining approval to start the study in each country and activating the clinics there. The study is currently approved in more than half of the planned countries. The pandemic has continued to affect the start-up of new clinical studies, but we now see that it is easing up and that many clinics are eager to get started. As a result of Russia's invasion of Ukraine, we have decided not to start patient recruitment in these countries and are working together with our experienced CRO, Parexel Biotech, on how to replace the planned patients from these countries.

The first patient has also been enrolled in a smaller PK study with cobitolimod, that is conducted in parallel with the phase III study CONCLUDE. With the PK study, we aim to confirm the limited systemic uptake of cobitolimod shown in previous studies. This is a significant advantage compared to competing drugs for ulcerative colitis that act on the whole body and can cause serious side effects outside the inflamed colon.

There continues to be a lot of news coming out of the field of ulcerative colitis and the competitive landscape has evolved in cobitolimod's favour over the last 2 years. For example, in 2021 the FDA updated its safety warnings for JAK inhibitors and limited their use. They added serious heart-related events, cancer, blood clots, and death to the already boxed warnings. It is a reminder that a product's safety profile is very important, and good news for cobitolimod that has demonstrated an excellent safety profile to date.

Our current focus is on the development of the rectal formulation of cobitolimod for moderate to severe left-sided ulcerative colitis. However, we also see significant potential for cobitolimod in related indications. For that reason, the development of an oral formulation, as a potential follow-on product, is ongoing in parallel. An oral formulation that enables delivery of cobitolimod to other parts of the gastrointestinal tract would open the possibility to broaden the therapeutic use of cobitolimod and thereby increase the commercial potential severalfold.

To secure financing until the pivotal clinical study results in CONCLUDE, we conducted a successful rights issue in the beginning of 2021 of approximately SEK 533 million and we have today a strong cash position. At the same time the ownership base in the company was strengthened as several recognized and successful life sciences specialists chose to invest significant amounts, which also constitutes a strong validation of InDex's potential.

After the Swedish pandemic restrictions were lifted, we were finally able to hold a physical Capital Markets Day in March 2022. My InDex colleagues and I, together with external experts on US commercialisation, gave an in-depth presentation of CONCLUDE, cobitolimod's market potential and the plans for commercialisation. Those of you who were unable to participate can watch the recording on our website. I hope we get many more opportunities to meet each other during the year!

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. There is no cure for ulcerative colitis and most patients will require lifelong treatment. 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]

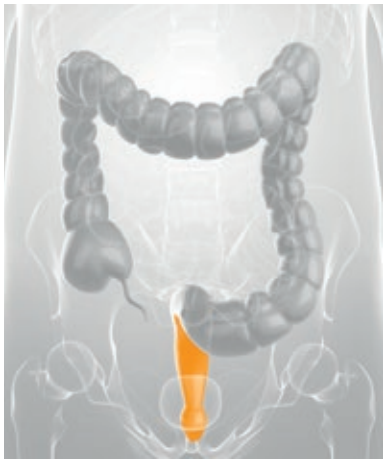
HOW COMMON IS ULCERATIVE COLITIS?
Today, about 0.2 percent of the population in developed countries has ulcerative colitis, which corresponds to more than 1 000,000 ulcerative colitis patients in Europe's five largest countries and more than 1,100,000 in the US.[4] Market research studies predict that 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 1,392 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).

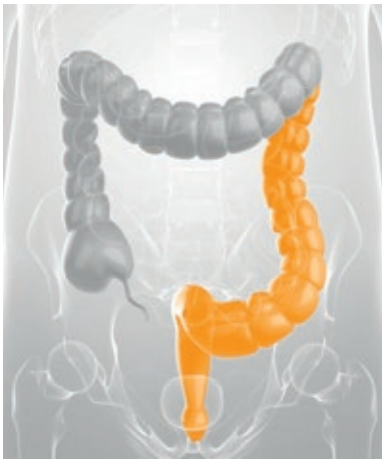
ULCERATIVE COLITIS SYMPTOMS

Illustrations: Freepik

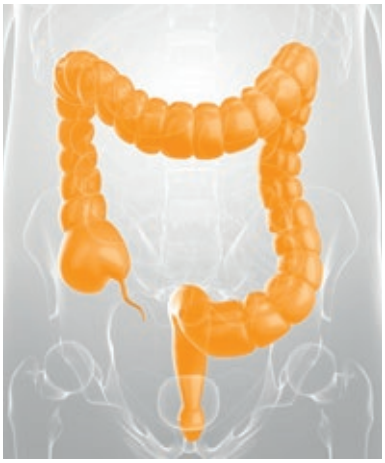
EXTENT OF INFLAMMATION



Proctitis



Left-sided colitis

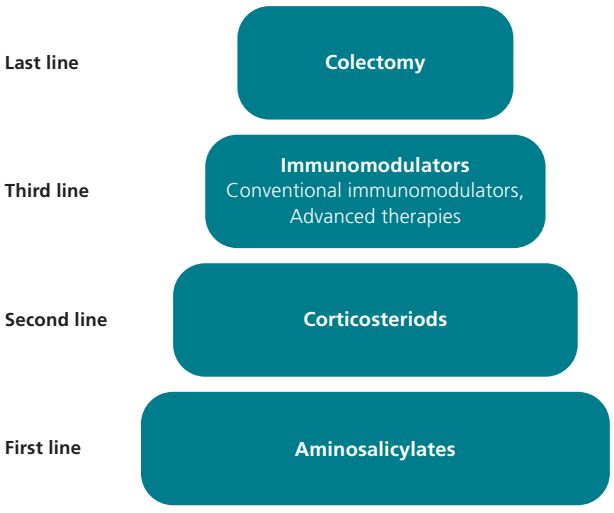


Pancolitis

HOW IS ULCERATIVE COLITIS TREATED TODAY?

The aim of treatment in ulcerative 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, advanced therapies including biological therapies such as TNF-alpha inhibitors, integrin inhibitors and IL12/IL23 inhibitors, JAK inhibitors or S1P receptor modulators. However, these advanced therapies 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 lower 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 "Market research Alira Health 2021" and "Market Research 2021 Effimed Research LLC".
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.

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 serious 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?

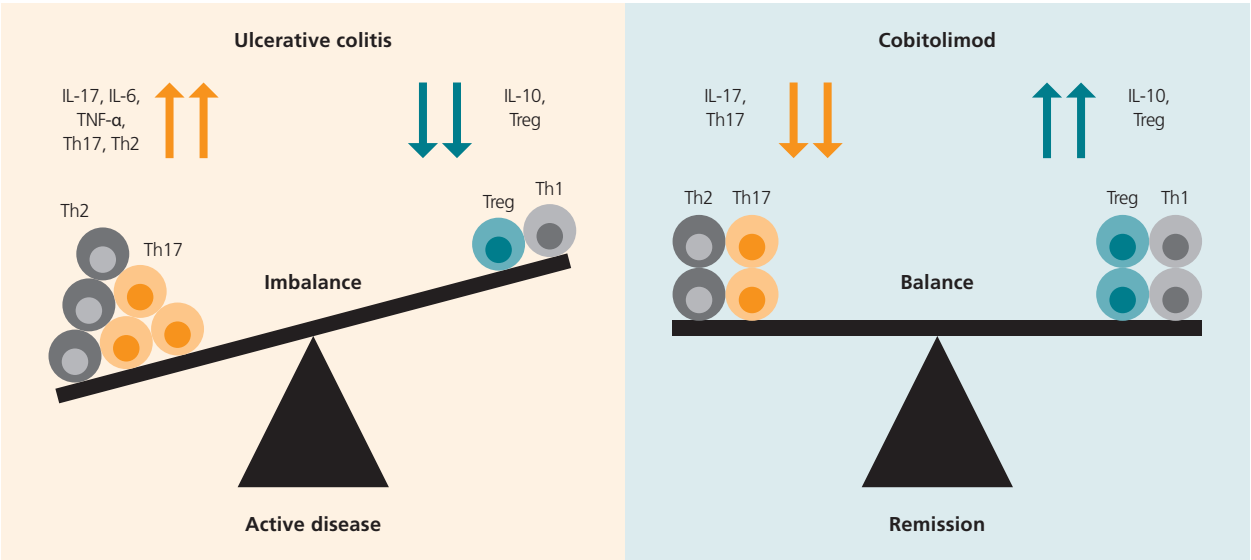
The intestinal mucosa acts as a barrier to the outside world and constitutes an important part of the body's immune system. It is rich in immune cells that protect the body from disease organisms and harmful substances in the intestinal tract. A healthy intestinal mucosa responds to potential threats 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 has been published in the medical journal Journal of Chrohn's and Colitis (JCC).[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.

COBITOLIMOD HAS SHOWN A COMPETITIVE EFFICACY AND AN EXCELLENT SAFETY PROFILE

In previous clinical studies, InDex has shown that cobitolimod, with an excellent safety profile, provides a statistically significant improvement in those endpoints that are most relevant in ulcerative colitis. These endpoints include the most important clinical symptoms such as blood in stool, number of stools and mucosal healing, respectively. A total of 5 placebo-controlled clinical trials with cobitolimod have been performed in which a total of 416 patients have been treated with cobitolimod.

The most recent completed clinical study CONDUCT was a randomised, double-blind, placebo-controlled, exploratory phase IIb study where different doses of cobitolimod were evaluated in patients with moderate to severe left-sided 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. 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. 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. The CONDUCT results have been published in the reputable medical journal, The Lancet Gastroenterology & Hepatology which also included a positive independent expert commentary.[3]

3 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.

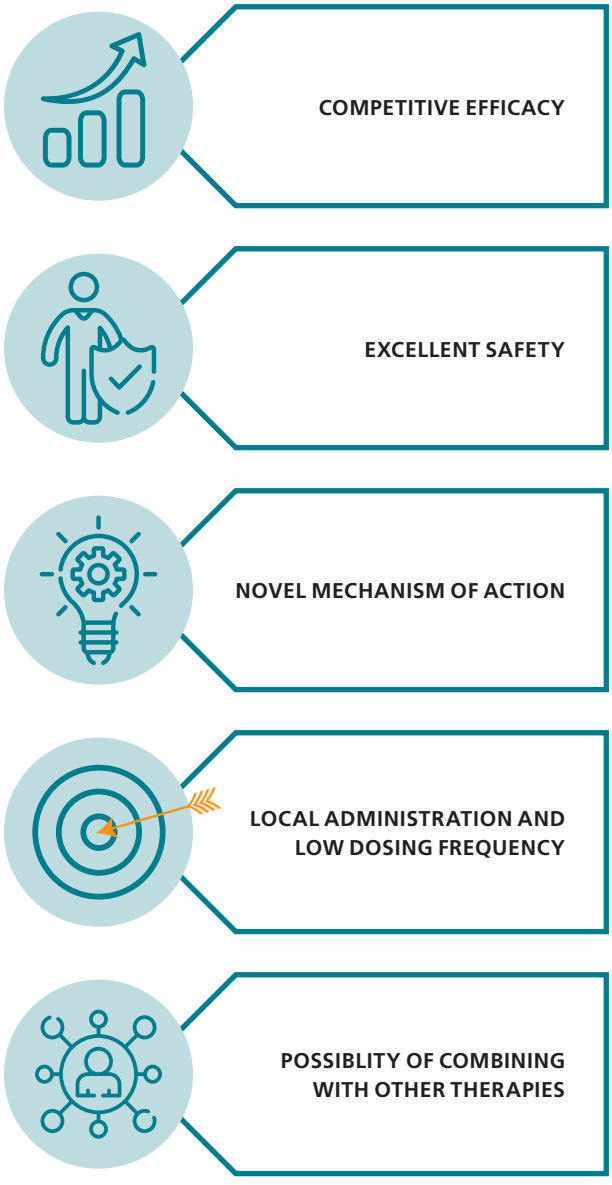
What are the key benefits of cobitolimod?

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

2. EXCELLENT 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 advanced therapies are associated with increased risks of serious side effects like infections, malignancies, and skin disorders, perforation in the stomach and intestines, and pulmonary embolisms and even death. 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. NOVEL 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. LOCAL 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.



Illustrations: Freepik

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 local 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.

Anders Bröijersén, Senior Medical Director Clinical Operations

Interview on the importance of drug safety

In recent years, the safety aspects when introducing new drugs have received increasing attention. Anders Bröijersen works as Senior Medical Director Clinical Operations at InDex and has extensive experience in drug safety from several leading pharmaceutical companies. We took the opportunity to ask Anders a few questions about his work and why drug safety is so important.

WHAT DOES DRUG SAFETY MEAN?
All drugs that are approved must have a positive risk-benefit ratio. Evaluation of this ratio runs as a common thread through all phases of drug development and is later regularly monitored when the drug has reached the market. The science that studies drug safety is called pharmacovigilance and aims to detect, assess and prevent drug-related side effects.

WHY IS THE SAFETY PROFILE OF A DRUG IMPORTANT?
The safety profile of a drug is absolutely crucial to how useful it is. A drug that the patient does not tolerate or that causes potentially serious side effects will be used to a small extent even if the efficacy is very good. For a life-threatening disease without treatment alternatives, however, a poorer safety profile can be accepted if the effect is otherwise good. For a non-life-threatening disease with more treatment options, however, the safety profile will be a component that is as important as the drug's effect on the disease activity.

HOW DOES THE SAFETY PROFILE AFFECT THE POSSIBILITY FOR A DRUG TO OBTAIN MARKET APPROVAL?
As I mentioned above, the risk-benefit ratio must be positive for a drug to be approved by the authorities. A drug with many or serious side effects can be difficult to get approved even if the effect on the disease is good.

WHAT IS THE SAFETY PROFILE OF CURRENT DRUGS FOR ULCERATIVE COLITIS AND HOW DOES THE SAFETY PROFILE OF COBITOLIMOD DIFFER FROM THESE?
More than 400 patients have been treated with cobitolimod since the start of the clinical drug development. The safety profile has so far been excellent with very few and non-serious side effects. This is completely in line with what one can expect, as cobitolimod is administered locally in the inflamed colon at the site of inflammation. Uptake of cobitolimod into the blood and further into the body is minimal, so the risk of systemic side effects is low. This distinguishes cobitolimod compared to other advanced ulcerative colitis drugs that are administered for the purpose of transporting the substance to the intestinal wall via the bloodstream. The safety profile of these drugs is much worse where two drug classes, TNF-alfa inhibitors and JAK inhibitors, even have so-called Black Box warnings in the US, as the FDA flagged that these drugs could cause e.g. severe infections and cancer. Other classes of drugs are also associated with serious side effects such as severe infections (IL-12/IL-23 inhibitors, integrin inhibitors and S1PR modulators), cancer (IL-12/IL-23 inhibitors) and hypersensitivity reactions (IL-12/IL-23 inhibitors and integrin inhibitors).

Name: Anders Bröijersén
Title: Senior Medical Director Clinical Operations

The phase III study CONCLUDE

COBITOLIMOD IN PHASE III

Given the outstanding combination of efficacy and safety that cobitolimod has demonstrated in previous clinical studies, cobitolimod is now evaluated in the ongoing phase III study CONCLUDE as a novel treatment for patients with moderate to severe left-sided ulcerative colitis. Phase III is the final stage of development before application for market approval by the regulatory authorities. InDex has entered into an agreement for services with the leading global clinical research organisation (CRO) Parexel Biotech for the phase III study CONCLUDE. Parexel Biotech has considerable experience managing phase III studies in inflammatory bowel disease and was the CRO that InDex successfully collaborated with in the phase IIb study CONDUCT. The first patient was enrolled end of 2021, and the results are expected to be presented during H2 2023.

PHASE III DESIGN

Based on guidance from FDA and EMA, InDex is conducting 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, or advanced treatments such as biological therapy or JAK inhibitors.

The first phase III study CONCLUDE is a randomised, double-blind, placebo-controlled induction study that will include approximately 440 patients at several hundred clinics and be conducted in over 30 countries including Europe, the Americas and the Asia-Pacific region. The study has been designed in consultation with both the US and European regulatory authorities, the FDA and EMA respectively. The primary endpoint will be clinical remission at week 6, which is the same primary endpoint as used in the successful phase IIb study CONDUCT.

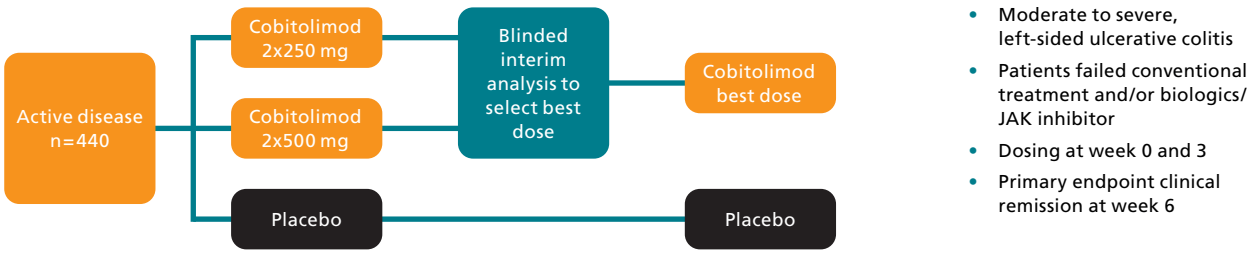
Apart from the dosing 250 mg x 2, which was the highest dose and the one that showed the best efficacy in the phase IIb study CONDUCT, the phase III study will also evaluate a higher dose, 500 mg x 2, in an adaptive design. This higher dose has the potential to provide an even better efficacy than what was observed in the CONDUCT study. When approximately 30% of the participants in the study have been randomised and have eligible data for the primary endpoint, 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. Patients responding to cobitolimod in the induction study will be eligible to continue in the one-year maintenance study, in which they will be treated with either cobitolimod or placebo once every three weeks.

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.

Professor Raja Atreya of the University of Erlangen-Nürnberg in Germany are the principal investigator of the study, and Professor William Sandborn at the University of California San Diego and Professor Walter Reinisch at the Medical University of Vienna are the Medical Advisors in the study.

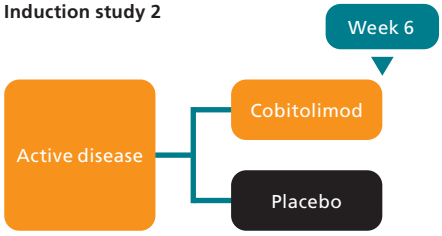
Upon a positive read-out of the first induction study, InDex plans to initiate the second induction study with the

PHASE III DESIGN
Induction study 1 – adaptive design

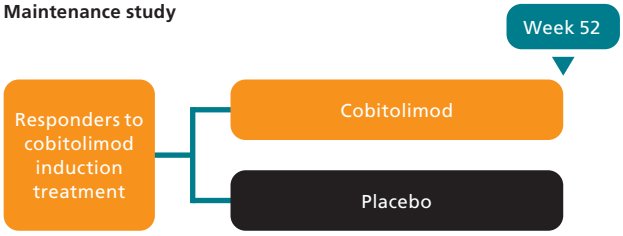


- Moderate to severe, left-sided ulcerative colitis
- Patients failed conventional treatment and/or biologics/ JAK inhibitor
- Dosing at week 0 and 3
- Primary endpoint clinical remission at week 6

Induction study 2

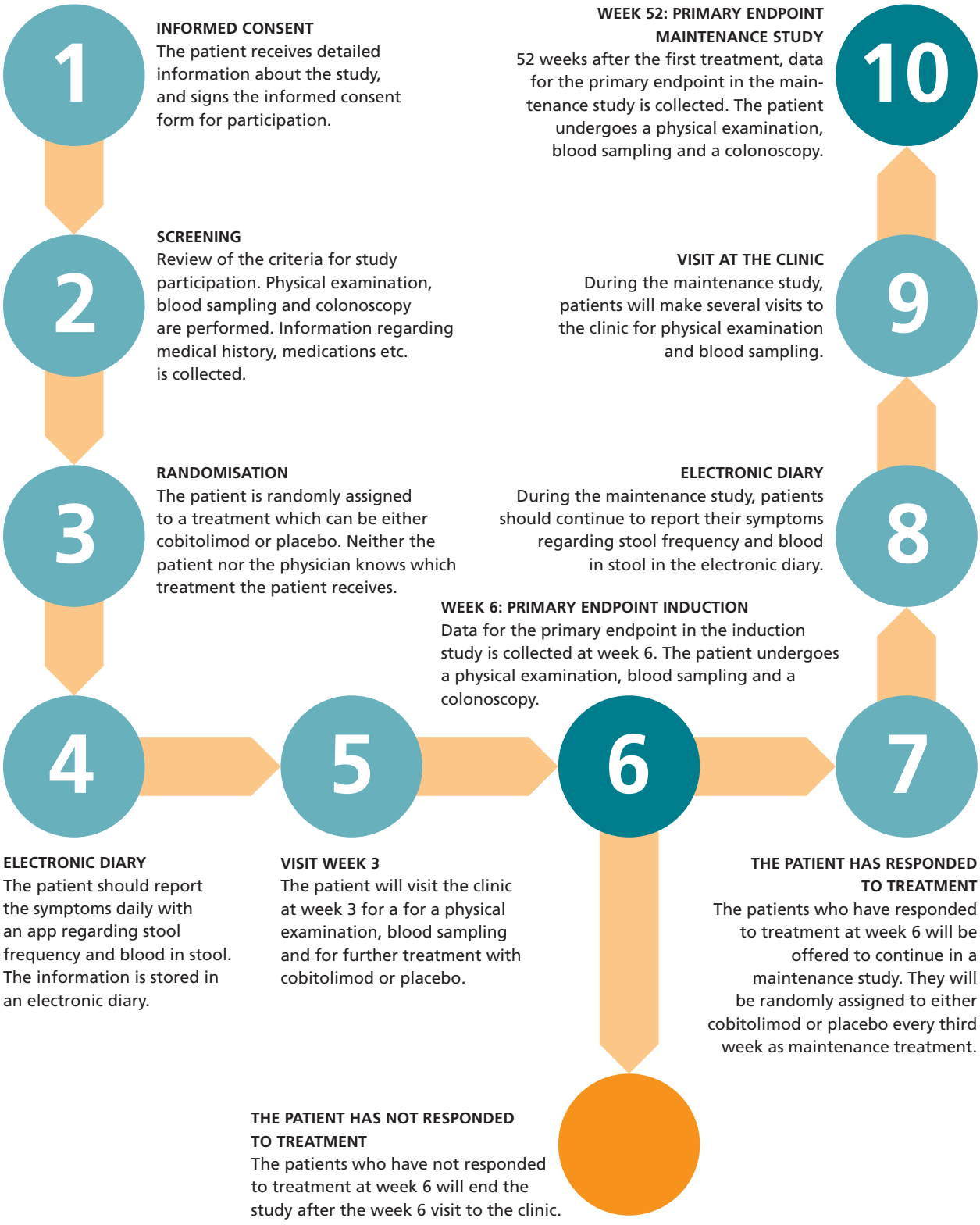


Maintenance study



best dose. The sequential design enables reading out the outcome of the first induction study before the next study is started, which 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.

THE PATIENT JOURNEY IN THE CONCLUDE STUDY



InDex's organization for clinical trials – a growing team

As InDex has taken cobitolimod to phase III, the company's team for clinical studies has expanded. The team consists of Karin Arnesson, Clinical Trial Manager; Johan Levin, Project Manager and Anders Bröijersén, Senior Medical Director. They are responsible for the daily activities of the phase III study CONCLUDE with support from several other functions at InDex. The team works closely with the leading global CRO that InDex has contracted for the study. We asked the team a few questions about their work with CONCLUDE.

INDEX IS COLLABORATING WITH A LEADING GLOBAL CRO FOR THE IMPLEMENTATION OF CONCLUDE, WHAT IS YOUR ROLE IN THE DAY-TO-DAY WORK WITH THE STUDY?
"According to the existing regulations regarding clinical studies, InDex as a sponsor have the overall responsibility for the study. We at InDex are very active in large and small details in the study. We focus a lot on how we can facilitate the implementation of the study for the clinics, while maintaining the highest quality. However, it would be impossible for a small company like InDex to conduct a study of this size without a CRO", Karin answers.

Karin continues: "InDex makes all decisions regarding the implementation of the study. The CRO can have several options, such as which countries should be included, and then it is InDex, in consultation with the CRO, who decides what should apply to the study. We also have the knowledge of the substance and the study, in a way that the CRO does not have. This makes it easier for us to formulate certain documents, for example for applications to the authorities or materials for patient information."

Anders adds: "The CRO does many tasks that we at InDex do not have the possibility and time for, while we at InDex spend more time on the qualitative aspects of the study."

Johan continues: "We can really make our mark on the CONCLUDE study, even though we have hired a large CRO. It is also extremely important that we can be involved at an early stage and influence the work with the study by creating clear and efficient processes."

BEFORE CONCLUDE, INDEX RAN THE PHASE IIB STUDY CONDUCT, WHAT ARE THE MAIN DIFFERENCES OPERATIONALLY BETWEEN CONDUCTING A PHASE II AND A PHASE III STUDY?
"The biggest difference is that CONCLUDE is a much larger study. In CONDUCT, 12 countries were involved, while we in CONCLUDE plan to conduct the study in more than 30 countries. However, the way we work is the same. It should be delivered with the same quality regardless of phase. Then there are countries in CONCLUDE that we have never worked with before, and there may be certain cultural differences that we need to consider and differences in the countries' regulations," Karin answers.

Anders adds: "CONDUCT was carried out before the covid-19 pandemic, while CONCLUDE was initiated in the middle of the pandemic, which of course led to some adjustments. A further difference is that prior to a phase III study, an "end of phase II" meeting is held with the regulatory authorities, in order to obtain a go ahead from them for a specific study design, which should be sufficient for applying for market approval."

Johan continues: "Another difference between the studies is that we in CONCLUDE have maintenance treatment, so the patients will participate in the study for a longer period of time."

WHAT LEARNINGS FROM PREVIOUS STUDIES DO YOU TAKE WITH YOU FOR THE WORK WITH CONCLUDE?
"The major thing I take with me from previous studies is that clinical development is a team effort, that InDex, the CRO and the clinics have the same goals for the study," Anders answers.

Karin continues: "We collaborate with the same CRO in CONCLUDE as in the previous study, which is an advantage as we know how the CRO works, what parts we at InDex need to pay more attention to, what pitfalls there are and how to avoid them. We have the same project manager as in the previous study, which also makes it much easier as she is well acquainted with the development program. We received the feedback in the previous study that the clinics appreciated that we at InDex were a committed sponsor who was present at the clinics. The clinics are aware of who the sponsor is, and they can come directly to us with questions. We take that with us also for CONCLUDE. The clinics valued the fact that a small Swedish company offers a substance with a new mechanism of action and a good safety profile. We are proud that we had the same patient recruitment rate in the previous study as the large pharmaceutical companies."

Johan continues: "My learning and my focus has been to train our clinics, so that they can cope with all the challenges that arise during a clinical study. It is important to be responsive and identify areas where we can assist and facilitate the clinics' work. Committed staff and close collaboration with the clinics is a winning concept for a clinical study. It is very important that the clinics feel involved and important. Together, we will fulfill our common goals of recruiting participants within set time frames and deliver a high-quality study."

Interview with Professor Raja Atreya, principal investigator of the phase III study CONCLUDE

THE PHASE III STUDY CONCLUDE WITH COBITOLIMOD IS NOW UP AND RUNNING, HOW IS IT TO BE PRINCIPAL INVESTIGATOR OF THE STUDY?
It is very exciting to be part of this important study where we are a few hundred IBD centers in over 30 countries collaborating. I, together with all the colleagues around the world, are working together to make this the best possible study and to enrol the patients as quickly as possible.

The CONCLUDE study comes at a very timely point, because we have to be aware that ulcerative colitis is indeed a progressive and debilitating disease, and there is still an unmet medical need in daily clinical practice for patients with moderate to severe disease. We have various treatment options nowadays, but there is still a substantial proportion of the patients that do not benefit from available treatments, because they either do not respond to them or they cannot tolerate them. There is therefore an urgent need for safe and efficacious new therapeutics with a novel mechanism of action, to be able to offer a beneficial treatment approach for these patients. Cobitolimod has shown a competitive efficacy and an excellent safety profile in previous clinical studies. This together with a novel mechanism of action sets cobitolimod apart from the available treatments. If the previous results can be confirmed also in the phase III study CONCLUDE, I believe cobitolimod holds great potential as an attractive treatment alternative for these patients.

HOW DO YOU SEE THE POSSIBILITY TO RECRUIT PATIENTS TO THE STUDY?
There are competing clinical studies, but what sets cobitolimod apart from the competitors is the novel mechanism of action of being a TLR9 agonist. One should keep in mind that the patients that are recruited in the study are patients that have failed previous conventional or advanced therapy, and to really be efficacious in this patient group you need to offer a novel mechanism of action. This we do with cobitolimod, as we are targeting a signalling pathway that is not primarily blocked by other available treatments. From my point of view, cobitolimod fulfils the three major requirements to be successful in a clinical trial; a convincing clinical efficacy, an excellent safety profile, and a novel mechanism of action. We have previously shown, in the phase IIb clinical study CONDUCT, that we can be successful with a very competitive patient recruitment rate, so I believe that the phase III study CONCLUDE will be as successful as the previous study.

WHAT DO YOU EXPECT TO SEE IN TERMS OF RESULTS FROM THE PHASE III STUDY?
I am very excited and looking forward to the results from the phase III study. I really hope that the study will confirm the previous results regarding an excellent efficacy and safety for cobitolimod. If we can repeat the convincing results seen in the previous studies with cobitolimod also in phase III, I am sure that cobitolimod will become an attractive novel treatment alternative that can give new hope to patients suffering from this debilitating disease.

Challanges with existing treatments for moderate to severe ulcerative colitis

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. Some of the challenges with current third-line therapies are set out below.

Limited efficacy – 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.[1] The approved JAK-inhibitors, tofacitinib and filgotinib (only approved in Europe) and the only approved S1PR-modulator, ozanimod, did not show a better efficacy in their phase III programs than the marketed biological drugs.[2] The by FDA recently approved JAK inhibitor upadacitinib has shown a slightly better effect in its phase III studies, but is associated with an increased risk of serious side effects, see section below.[3]

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.[4] TNF-alpha inhibitors affect the patient's immune system and patients face increased risk of developing serious side-effects such as infections, cancer and skin diseases.[5] The integrin inhibitor vedolizumab, the IL12/IL23 inhibitor ustekinumab, and the S1PR modulator ozanimod are also associated with an increased risk of serious side effects such as infections, hypersensitivity reactions and joint pain for vedolizumab, infections, hypersensitivity reactions and malignancies for ustekinumab and infections, cardiac effects and elevated liver enzymes for ozanimod.[6] Finally, JAK-inhibitors are associated with serious side effects such as serious infections, cancer, immune system problems and perforation in the stomach or intestine, pulmonary embolism, serious cardiovascular effects and even death.[7] FDA updated its safety warnings for JAK inhibitors in September 2021, restricting all use to patients who do not respond to or cannot tolerate TNF-alpha inhibitors.[8]

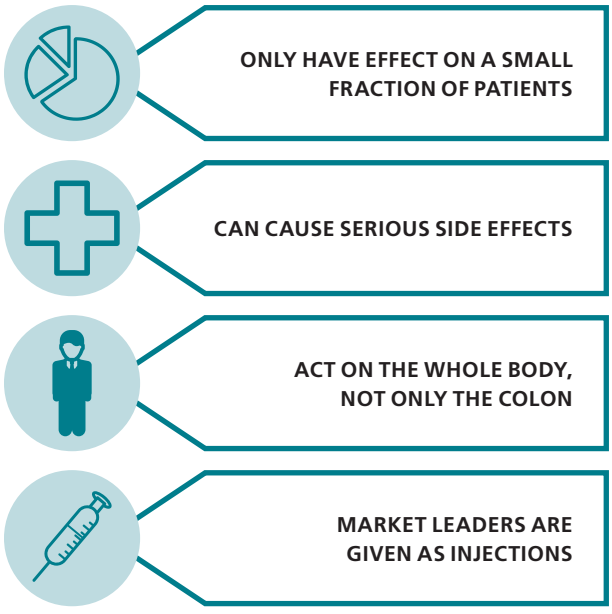
SAFETY CONCERNS WITH CURRENT DRUG CLASSES

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, death
IL23 inhibitors	Infections, hypersensitivity reactions, malignancies

Act on the whole body – The systemic administration of the current advanced therapies for moderate to severe ulcerative colitis can cause off-target effects, compared to locally administered therapies given directly to the inflamed colon avoiding systemic exposure. In addition, current market-leading products require injections at home or at the clinic.

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 JAK inhibitors (i.e. the same mechanism of action as tofacitinib), IL-23 inhibitors (i.e. similar mechanism of action as ustekinumab) or S1PR-modulators (same mechanism of action as ozanimod). Cobitolimod is in phase III for moderate to severe ulcerative colitis with a completely new and unique mechanism of action. Several of the compounds in development for moderate to severe ulcerative colitis are acting systemically and can cause serious side effects, in contrast to cobitolimod which has a local effect and an excellent safety profile.



Addressable market for cobitolimod.

Icons: Freepik

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2 Sandborn WJ et al, Tofacitinib as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med. 2017 Aug 3;377(5):496-7. + Feagan BG et al. Filgotinib as induction and maintenance therapy for ulcerative colitis (SELECTION): a phase 2b/3 double-blind, randomised, placebo-controlled trial. Lancet 2021; 397: 2372–84 + Sandborn WJ et al, Ozanimod as Induction and Maintenance Therapy for Ulcerative Colitis. N Engl J Med 2021;385:1280-91.

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4 Mowat C, et al (2011) Gut 60:571-607.

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7 Agrawal et al. JAK Inhibitors Safety in Ulcerative Colitis: Practical Implications. Journal of Crohn's and Colitis, 2020, S755–S760.

8 https://www.fda.gov/drugs/drug-safety-and-availability/fda-requireswarnings-about-increased-risk-serious-heart-related-events-cancerblood-clots-and-death

Market potential and commercialisation strategy for cobitolimod

LARGE AND GROWING MARKET FOR THE TREATMENT OF ULCERATIVE COLITIS

The total global annual sales of pharmaceuticals for ulcerative colitis were estimated in 2020 to be approximately USD 7.5 billion with an annual average growth of 10% the last four years.[1] The market for ulcerative colitis is expected to grow by about 6% annually to reach 11-12 billion USD by 2026.[1] Advanced therapies for moderate to severe ulcerative colitis represent the largest market segment in terms of value, and is estimated to account for at least 85% of the total market.[2]

COBITOLIMOD'S MARKET POTENTIAL

Cobitolimod's target product profile has been evaluated in several primary market research studies, demonstrating that cobitolimod has strong potential to be positioned as the first treatment option for patients with moderate to severe left-sided ulcerative colitis, that do not respond to conventional treatments. InDex estimates, based on external sources, that the current market segment for moderate to severe left-sided ulcerative colitis amount to approximately USD 3.5 billion and is expected to grow to more than USD 5 billion by 2026. InDex estimates that cobitolimod can reach a market share of 20-30%, corresponding to global peak annual sales of more than USD 1 billion.

COMMERCIALISATION STRATEGY FOR COBITOLIMOD

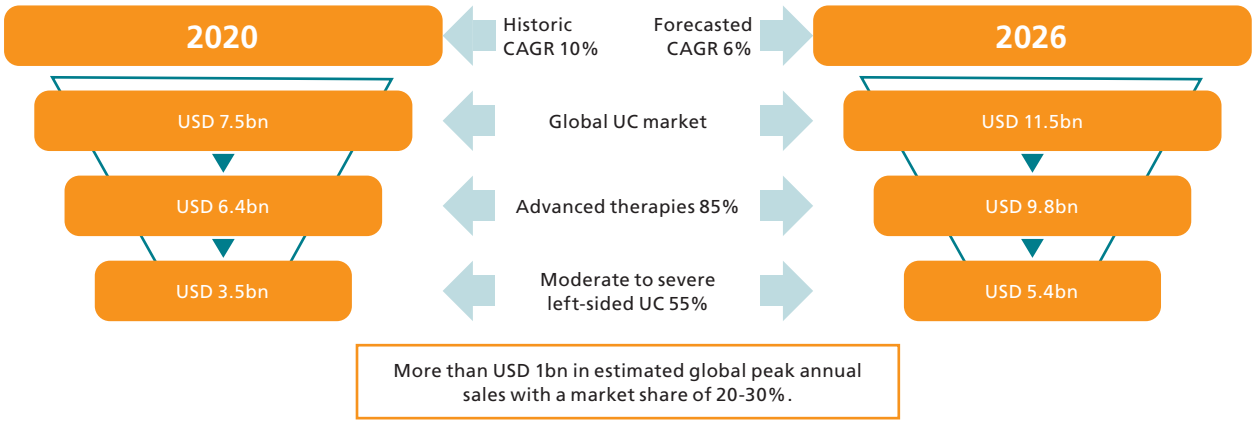
InDex has together with external experts analysed the commercialisation options for cobitolimod in the US and Europe. The US market accounts for approximately 65% of the total market for ulcerative colitis.[1] The conclusion is that the market potential, the required commercial footprint, and the profitability profile in the US respectively are well suited for self-commercialisation by a focused commercial organisation to be built closer to launch.

The fragmented European market, as well as other regions, offer attractive opportunities to enter strategic collaborations as cobitolimod advances towards launch

TIMETABLE TO LAUNCH

Results from the ongoing first phase III study with cobitolimod are expected to be available during H2 2023. An interim analysis to select the best dose is planned when approximately 30% of the participants have completed the study. The complete phase III program, including a second induction study and a one-year maintenance study, is expected to be completed during 2026. Applications for marketing approval will then be submitted to the regulatory authorities, with an expected launch of cobitolimod in 2027.

1 Rami Al-Horani et al Nat Rev Drug Discov. 2022 Jan;21(1):15-16
2 Market Research 2021 Effimed Research LLC.



Estimated market potential for cobitolimod in moderate to severe left-sided ulcerative colitis.

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, 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, Japan and Canada and is being prosecuted in 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.

A new patent family which protects the use of certain dosage regimens of cobitolimod for treating inflammatory bowel disease has been filed in the US, Europe, Japan, Canada, Australia, China, Korea, Brazil, Russia, and Hong Kong. The dosage includes the 250 mg dose which was successful in the phase IIb study CONDUCT. This new patent family constitutes a valuable complement to our robust intellectual property portfolio for cobitolimod and has already been granted in e.g. the US. The patent will provide an exclusivity period until 2038, with the possibility of up to 5 years term extension after market 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 2042 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
		AUS2006266503	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
		CA2892203	2032-11-23
New Therapy WO2018206711	US/EP/JP/ CA/AUS/ CN/KR/HK/ BR/RU	US11166975	2038-05-20
		RU201935630	2038-05-09

** 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.*

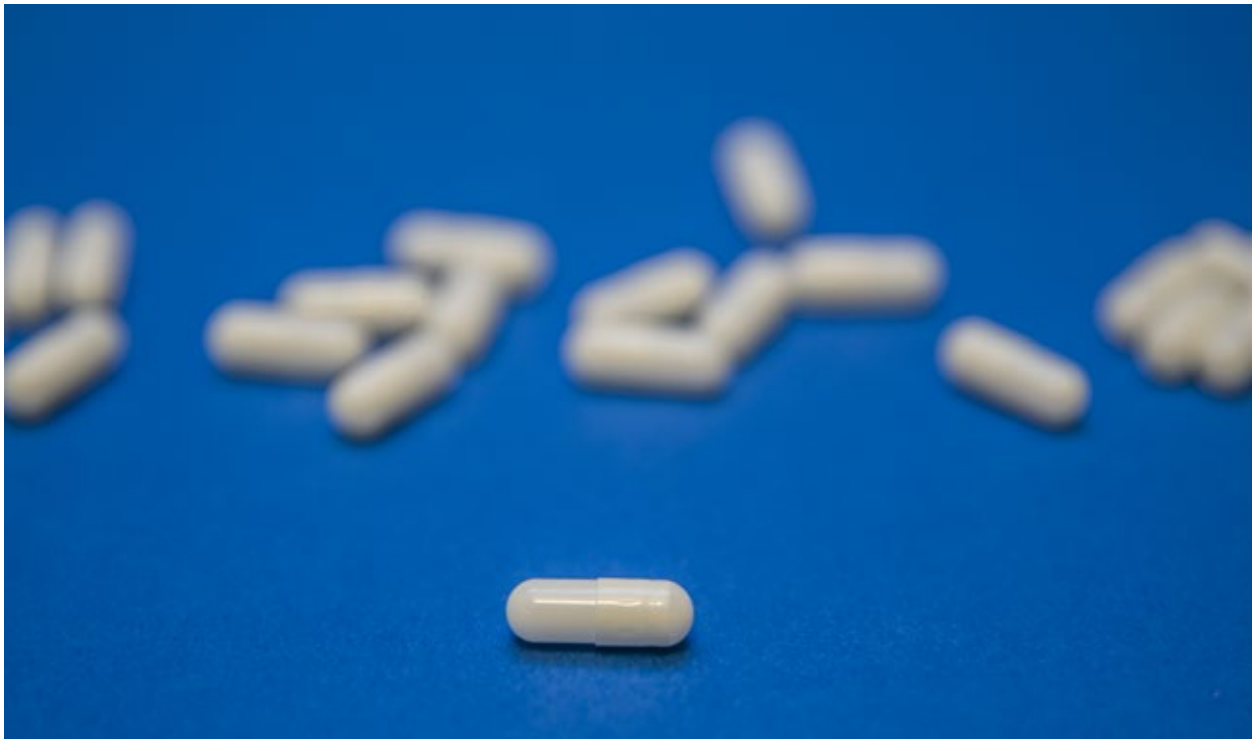
PK study with cobitolimod

In parallel with the global clinical phase III study CONCLUDE, InDex is conducting a clinical pharmacokinetic study (PK study) with cobitolimod in Sweden. The aim of the study is to confirm that the systemic uptake of cobitolimod in local treatment of colonic inflammation is limited, which has been shown in previous preclinical and clinical studies. The study will include at least 6 patients with moderate to severe ulcerative colitis treated with doses of 500 mg of cobitolimod administered rectally. First the uptake of cobitolimod will be measured in patients with active disease, and then a second time in those of the patients that respond to the treatment. The data from the PK study with cobitolimod will support future regulatory applications for market approval.

Oral formulation of cobitolimod

InDex is also developing an oral formulation of its lead drug candidate cobitolimod, with targeted drug delivery to the lower part of the gastrointestinal tract. This allows for a local release of cobitolimod in the colon with low systemic exposure, similar to the enema formulation. However, the oral formulation would enable delivery of cobitolimod to parts of the gastrointestinal tract which are inaccessible to an enema. This opens the possibility to broaden the therapeutic use of cobitolimod to also include pancolitis and Crohn's disease, thereby increasing the commercial potential for the substance severalfold. The oral formulation of cobitolimod is a potential follow-on product to the enema formulation, which is currently being investigated in the phase III study CONCLUDE in moderate to severe left-sided ulcerative colitis.

InDex has entered an agreement for services with one of the world's leading contract development and manufacturing companies (CDMO) for the continued pharmaceutical development. The aim is to optimize the oral formulation to align with the dosing under evaluation in the phase III study CONCLUDE with the enema formulation. The continued development could also provide opportunities for securing additional intellectual property for cobitolimod.



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.


conclude

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, 2021 InDex had nine full time employees. Four of the employees have Ph.D. degrees in immunology, inflammation and clinical pharmacology. InDex has established cooperation with about ten qualified consultants each specialised in different areas, such as regulatory affairs, statistics, medicine, preclinical, manufacturing, business development, finance, accounting, HR 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.

ADVISORY BOARDS

InDex has a long-standing and well-developed network of key opinion leaders and has 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 are involved in the conduct of the phase III program.

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, 2021, was SEK 1.74, which corresponded to a market cap of SEK 927 million. The highest share price paid on Nasdaq First North Growth Market Stockholm during 2021 was SEK 2.45 and the lowest share price paid was SEK 1.084. During 2021, 188,345,742 shares were traded on Nasdaq First North Growth Market Stockholm corresponding to a value of SEK 310 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 approximately SEK 488 million after deduction of the transaction related costs for financial and legal services and for costs for registration and practical management.

SHAREHOLDERS

InDex had as of December 30, 2021, 5,280 shareholders according to Euroclear. The 15 largest shareholders in InDex held approximately 63 percent of the capital and the votes.

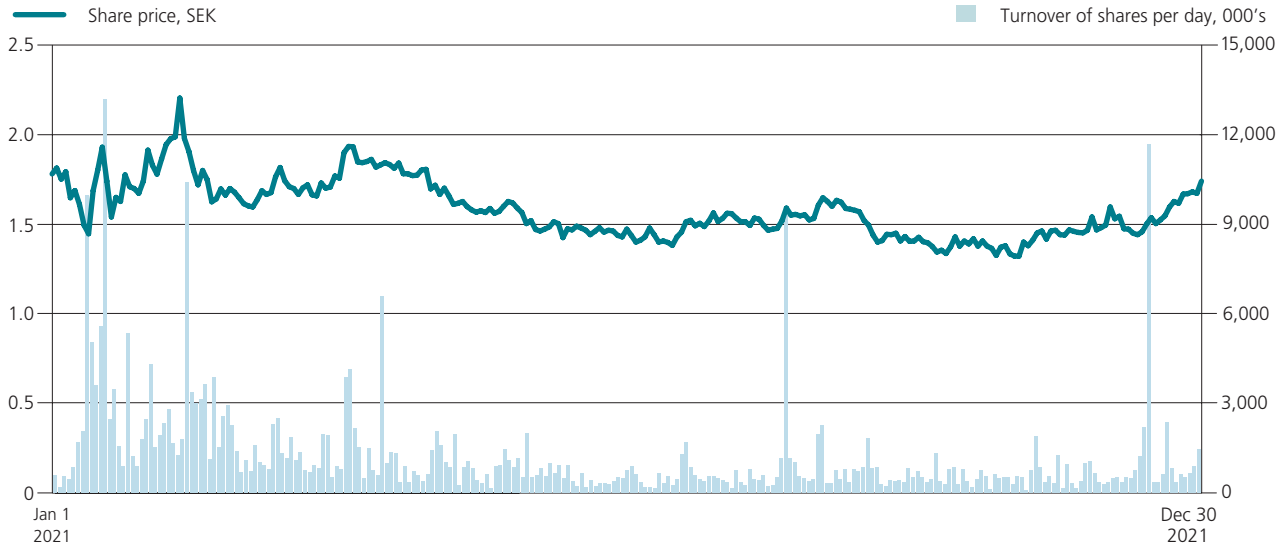
CERTIFIED ADVISER

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, 2021

	Number of shares	Percentage of capital and votes
Linc AB	69,920,567	13.1
HBM Healthcare Investments	52,916,667	9.9
Fjärde AP-fonden	52,314,074	9.8
Handelsbanken Funds	24,938,537	4.7
Avanza Pension	20,944,160	3.9
SEB-Stiftelsen	19,047,617	3.6
SEB Life International	13,927,350	2.6
Bengt Thornberg, dödsbo	13,417,394	2.5
SEB Venture Capital	12,994,367	2.4
Stiftelsen Industrifonden	12,865,296	2.4
Nordnet Pensionsförsäkring	10,814,151	2.0
Staffan Rasjö	10,318,953	1.9
S-E-Bankens Utvecklingsstiftelse	10,000,000	1.9
Swedbank försäkring AB	7,238,531	1.4
Ulti AB	7,000,000	1.3
Other	194,029,986	36.6
Total	**532,687,650**	**100.0**

SHARE PRICE AND TURNOVER OF SHARES



OWNERSHIP STRUCTURE BY SIZE OF HOLDINGS AS OF DECEMBER 30, 2021

Holding	Number of shareholders	Number of shares	Percentage of capital and votes
1-500	844	147,697	0.0
501-1,000	562	444,123	0.1
1,001-5,000	1,281	3,644,628	0.7
5,001-10,000	786	5,866,047	1.1
10,001-15,000	377	4,779,859	0.9
15,001-20,000	266	4,837,633	0.9
20,001-	1,164	512,967,663	96.3
Total	**5,280**	**532,687,650**	**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 Holding. 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 113,400 shares, indirect holdings of 487,344 shares.

MARLENE FORSELL
Board member since 2020.
Born: 1976.
Current assignments: Board member of Nobia, STG Group, Kambi Group, Lime Technologies and Addsecure.
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: Chairman of Medivir and Annexin Pharmaceuticals. Board member of Active Biotech 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 408,000 shares.

DR. LENNART HANSSON
Board member since 2011.
Born: 1956.
Current assignments: Chairman of Ignitus, Cinclus Pharma Holding 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, Biovitrum and KabiGen. PhD in genetic from Umeå University.
Holdings: Indirect holdings of 432,000 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 660,000 shares, 333,333 warrants (LTIP 2020) and 1,930,700 employee stock options (LTIP 2021).

PERNILLA SANDWALL
Chief Operating Officer (COO) since 2012. Board member of InDex Pharmaceuticals and InDex Diagnostics.
Born: 1963.
Current assignments: Board member of Alzinova and Innovativa Mindre Life science-företag (part of Läkemedelsindustriföreningen).
Experience: Managerial positions within clinical operations at Merck (MSD).
Holdings: Direct holdings of 130,000 shares, 133,333 warrants (LTIP 2020) and 772,300 employee stock options (LTIP 2021).

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 240,000 shares, 133,333 warrants (LTIP 2020) and 772,300 employee stock options (LTIP 2021).

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

DR. THOMAS KNITTEL
Chief Medical Officer (CMO) since 2012.
Born: 1962.
Current assignments: Board member of Heparegenix and CMO at EPM Group.
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, 66,667 warrants (LTIP 2020) and 257,500 employee stock options (LTIP 2021).

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

Holdings per December 30, 2021.

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 2021.

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 being evaluated in the phase III study CONCLUDE as a novel treatment of moderate to severe ulcerative colitis – a debilitating, chronic inflammation of the large intestine.

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 advanced drugs. Sales of advanced treatments of ulcerative colitis amount to more than USD 6 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 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 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, cobitolimod is now being evaluated in the pivotal phase III study CONCLUDE. Phase III is the final stage of development before application for market approval can be submitted to regulatory authorities.

Based on regulatory guidance InDex is conducting 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 first induction study CONCLUDE will include 440 patients. The first patient was enrolled in the study end of 2021, and the results are expected to be presented during H2 2023. CONCLUDE is a randomised, double-blind, placebo-controlled, global phase III study to evaluate cobitolimod as a novel treatment for patients with moderate to severe left-sided ulcerative colitis. The primary endpoint will be

clinical remission 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, the phase III study will 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 phase IIb study.

When approximately 30% of the participants in the study have been randomised and have eligible data for the primary endpoint, 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. Patients responding to cobitolimod in the induction study will be eligible to continue in a one-year maintenance study, where they will be treated with either cobitolimod or placebo.

InDex has entered into an agreement for services with the leading global clinical research organisation (CRO) Parexel Biotech for the phase III study CONCLUDE. Parexel Biotech has considerable experience managing phase III studies in inflammatory bowel disease. Parexel Biotech was the CRO that InDex successfully collaborated with in the phase IIb study CONDUCT.

SIGNIFICANT EVENTS DURING THE REPORTING PERIOD

- On January 14, 2021, the Board 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 Fjärde AP-fonden.
- 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 were thus not utilized. InDex received, through the rights issue, approximately SEK 488 million after 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.
- InDex announced on May 31, 2021, that patient recruitment for the phase III study CONCLUDE was planned to be initiated after the summer. The study will evaluate the efficacy and safety of the drug candidate cobitolimod for the treatment of moderate to severe left-sided ulcerative colitis.
- InDex announced on July 21, 2021, that the Swedish Medical Products Agency (MPA) has given approval to start the phase III clinical study CONCLUDE with cobitolimod in Sweden.
- InDex announced on August 24, 2021 that the U.S. Food and Drug Administration (FDA) has given clearance to start the phase III clinical study CONCLUDE with cobitolimod in the United States.
- InDex announced on November 9, 2021, that a new method of use patent for the drug candidate cobitolimod has been granted by the United States Patent and Trademark Office (USPTO). The patent provides protection for the use of certain dosage regimens of cobitolimod for treating inflammatory bowel disease, including the 250 mg dose which was successful in the phase IIb study CONDUCT.
- InDex announced on November 16, 2021, that a new method of use patent for the drug candidate cobitolimod has been granted by the Canadian Intellectual Property Office (CIPO). The patent provides additional protection for the use of certain dosage regimens of cobitolimod for treating chronic active ulcerative colitis in patients that are not responding or are intolerant to anti-inflammatory therapy.
- InDex announced on November 24, 2021 that the first patient was enrolled in the pivotal phase III study CONCLUDE.

SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

- InDex announced on March 13, 2022, that the company is planning for self-commercialisation of the drug candidate cobitolimod in the US with strategic collaborations in other regions. Launch is expected in 2027, with the potential for annual sales to reach more than USD 1 billion, in moderate to severe left-sided ulcerative colitis.

OTHER EVENTS

- InDex announced on March 30, 2021, that the company signed an agreement for services with global clinical research organisation (CRO) Parexel Biotech for the phase III study CONCLUDE.
- InDex announced on April 7, 2021, that a patent covering 19 compounds from the company's DIMS platform has been granted by the European Patent Office. The new European patent covers both the composition-of-matter and method-of-use of 19 different DIMS compounds for the treatment of inflammatory diseases, cancer and infectious diseases. The patent provides an exclusivity period until December 2031, with the possibility of up to 5 years term extension after market approval.
- The annual general meeting in InDex Pharmaceuticals Holding AB was held on June 3, 2021. Board members Wenche Rolfsen (also chairman), Marlene Forsell, Uli Hacksell and Lennart Hansson were re-elected. Yilmaz Mahshid and Stig Løkke Pedersen had ahead of the annual general meeting declined re-election. The annual general meeting also resolved, in accordance with the Board's proposal, on the implementation of a long-term incentive program in the form of employee stock options to senior executives and other key persons of the group.
- InDex announced on August 19, 2021, that the company will conduct a clinical pharmacokinetic study (PK study) with cobitolimod in Sweden. The Swedish Medical Products Agency has given approval to start the study. The purpose of the study is to evaluate the systemic uptake of cobitolimod in local treatment of colonic inflammation. The study will include at least 6 patients with moderate to severe ulcerative colitis treated with doses of 500 mg of cobitolimod administered rectally.
- InDex announced on August 23, 2021, that two new employees have been appointed in the clinical development organisation in preparation of the start of the phase III study CONCLUDE with cobitolimod. Anders Bröijersén has joined InDex as Senior Medical Director Clinical Operations and Johan Levin as Project Manager Clinical Operations.
- InDex announced on December 8, 2021 that the first patient has been enrolled in the clinical pharmacokinetic study (PK study) with cobitolimod.

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, 2021 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, 2021.

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	2021	2020	2019	2018	2017
Net sales	0.0	0.0	0.1	0.1	0.1
Operating loss	–102.9	–57.3	–87.7	–82.0	–73.2
Result after tax	–103.0	–57.4	–87.8	–82.1	–72.7
Earnings per share before and after dilution, SEK[1]	–0.21	–0.24	–0.45	–0.48	–0.44
Cash flow from operating activities	–124.1	–70.6	–85.1	–78.6	–67.3
Cash and cash equivalents at the year-end	428.4	53.8	126.8	83.0	125.1
Weighted average number of shares (thousands)[1]	483,365	236,750	197,001	169,846	166,697
Number of shares at the year-end (thousands)[1]	532,688	236,750	236,750	183,417	166,700

[1] 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 2021 amounted to SEK 0.0 (0.0) million. The net sales previous year were 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 12.7 (0.4) million refers to grants received from Vinnova and foreign exchange gains of SEK 12.3 (0) million related to cash and cash equivalents in foreign currency. InDex purchased during the second quarter 2021 USD to be used for future payments related to signed contracts denominated in USD.

Operating expenses for the period amounted to SEK 115.6 (57.8) million. The increase is attributable to, as expected, higher costs for the phase III study CONCLUDE.

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

Costs for the personnel during the reporting period amounted to SEK 12.3 (9.6) million. The increase is partly related to general salary increases and an increase in number of employees.

Cash and cash equivalents as of December 31, 2021 amounted to SEK 428.4 million, which is SEK 374.6 million higher than as of December 31, 2020. 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 approximately SEK 488 million after deduction of the transaction related costs for financial and legal services and for costs for registration and practical management.

Parent company

The net sales amounted to SEK 10.2 (11.3) million during the period January to December 2021 and consisted of invoicing of group wide expenses to InDex Pharmaceuticals AB.

The operating expenses amounted during the reporting period to SEK 17.6 (17.3) 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 2021 a shareholder contribution of in total SEK 200 (50) million. A write-down of shares in subsidiaries were made simultaneously.

FINANCIAL SUMMARY AFTER THE REPORTING PERIOD

Russia's invasion of Ukraine may impact the health care system and the global economy and at the same time there is continued uncertainties how the Covid-19 pandemic will develop globally. It is at present difficult to assess the wider impact of these factors. The Board of Directors, however, assess that there is no impact on the company's financial position as of December 31, 2021, due to events after the reporting period.

THE BOARD OF DIRECTORS AND CEO

The Board in InDex Pharmaceuticals Holding AB was elected at the Annual General Meeting on June 3, 2021, and consists of the chairman Wenche Rolfsen, Marlene Forsell, Uli Hacksell and Lennart Hansson.

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 9 (7) and the number of people closely associated with InDex through consultancy arrangements amount to 10 (9).

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 with rigorous oversight of permits, quality assurance and environmental obligations.

Annual General Meeting in the parent company

The annual general meeting of InDex Pharmaceuticals Holding AB to be held on June 1, 2022 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 23, 2022 or, in the case of shares registered in the name of a nominee, the shareholder must request temporary entry in the transcription of the register of the shareholders well in advance of May 25, 2022. In addition, the shareholders must announce their intention to attend the meeting no later than May 31, 2022 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	740,133,518
Net result	–207,546,095
	532,587,423
The Board's suggestion to be carried forward	532,587,423

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

The Board does not propose a dividend for 2021. 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	2021	2020	2019
Revenues				
Net sales	5	–	35	88
Other income	8	12,720	380	–
Total revenues		**12,720**	**415**	**88**
Operating expenses				
Raw material and consumables		–14,383	–16,021	–3,903
Other external expenses	6, 7	–87,737	–30,990	–70,189
Personnel costs	7	–12,258	–9,561	–12,769
Depreciations/amortisations of fixed assets and right-of-use assets	14, 15	–1,252	–1,192	–939
Total expenses		**–115,630**	**–57,764**	**–87,800**
Operating loss		**–102,910**	**–57,349**	**–87,712**
Result from financial investments				
Financial income	9	–	46	–
Financial expenses	9	–133	–115	–61
Financial items – net		**–133**	**–69**	**–61**
Earnings before tax		**–103,043**	**–57,418**	**–87,773**
Taxes for the period	10	–	–	–
LOSS FOR THE PERIOD		**–103,043**	**–57,418**	**–87,773**
Earnings per share, attributable to the shareholders of the parent company:				
Earnings per share, before and after dilution, SEK[1]		–0.21	–0.24	–0.45

[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, 2021	December 31, 2020	December 31, 2019
ASSETS				
Fixed assets				
Tangible fixed assets				
Equipment, tools and installations	14	639	818	11
Total tangible fixed assets		**639**	**818**	**11**
Right-of-use assets	15	**1,520**	**2,593**	**464**
Financial assets				
Other financial assets	16	1	1	1
Total financial assets		**1**	**1**	**1**
Total fixed assets		**2,160**	**3,412**	**476**
Current assets				
Current receivables				
Accounts receivable	17	–	–	4
Other current receivables	18	2,400	907	1,343
Prepaid expenses and accrued income	19	12,187	3,031	474
Cash and cash equivalents	20	428,449	53,834	126,790
Total current receivables		**443,036**	**57,772**	**128,611**
Total current assets		**443,036**	**57,772**	**128,611**
TOTAL ASSETS		**445,196**	**61,184**	**129,087**
EQUITY AND LIABILITIES				
Equity	21			
Share capital		10,654	1,776	1,776
Additional paid in capital		863,433	384,557	384,314
Retained earnings (including profit/loss for the year)		–440,048	–337,005	–279,587
Total equity attributable to the shareholders of the parent company		**434,039**	**49,328**	**106,503**
Provisions				
Other provisions		116	–	–
Total provisions		**116**	**–**	**–**
Liabilities				
Non-current liabilities				
Non-current lease liabilities	15	475	1,578	–
Total non-current liabilities		**475**	**1,578**	**–**
Current liabilities				
Current lease liabilities	15	807	763	484
Account payables		4,497	3,023	3,153
Other current liabilities	23	1,693	852	1,138
Accrued expenses and prepaid income	24	3,569	5,640	17,809
Total current liabilities		**10,566**	**10,278**	**22,584**
Total liabilities		**11,041**	**11,856**	**22,584**
TOTAL EQUITY AND LIABILITIES		**445,196**	**61,184**	**129,087**

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, 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**
Opening balance January 1, 2021	**1,776**	**384,557**	**–337,005**	**49,328**
Profit/loss for the period equal to total comprehensive income	–	–	–103,043	–103,043
Total comprehensive income for the year	**–**	**–**	**–103,043**	**–103,043**
Transactions with shareholders of the parent company:				
Issue of shares	8,878	523,809	–	532,687
Transaction costs	–	–45,192	–	–45,192
Value of the employees' employment	–	258	–	258
Total transactions with shareholders of the parent company	**8,878**	**478,875**	**–**	**487,753**
Closing balance December 31, 2021	**10,654**	**863,433**	**–440,048**	**434,039**

Consolidated cash flow

SEKk	Note	2021	2020	2019
Operating activities				
Operating result		–102,910	–57,349	–87,712
Adjustment for non-cash items:				
Depreciations/amortisations		1,252	1,192	939
Interest paid and received		–133	–70	–61
Income tax paid		–	–	–
Other adjustments		–11,907	–	–
Cash flow from operating activities before changes in working capital		**–113,698**	**–56,227**	**–86,834**
Cash flow in working capital				
Decrease/increase of current receivables		–10,648	–2,117	151
Decrease/increase of current liabilities		288	–12,306	1,602
Cash flow from changes in working capital		**–10,360**	**–14,423**	**1,753**
Cash flow from operating activities		**–124,058**	**–70,650**	**–85,081**
Investing activities				
Investments in tangible assets		–	–909	–
Cash flow from investment activities		**–**	**–909**	**–**
Financing activities				
Amortisation of lease liabilities	15	–1,103	–1,639	–947
Issue of shares, net after transaction costs	21	487,495	–	129,784
Issue of warrants	7	–	242	–
Cash flow from financing activities		**486,392**	**–1,397**	**128,837**
Cash flow for the period		**362,334**	**–72,956**	**43,756**
Decrease/increase of cash and cash equivalents				
Cash and cash equivalents at the beginning of the year		53,834	126,790	83,034
Currency translation difference in cash and cash equivalents		12,281	–	–
Cash and cash equivalents at the end of the year		**428,449**	**53,834**	**126,790**

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 6, 2022.

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, 2021, or later. None 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, 2022, 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.

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. No sale of services has occurred during 2021.

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 CURRENT AND DEFERRED TAX

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

The group has large tax loss carry-forwards and the current assessment is that the tax loss carry-forwards will not be utilised against taxable profits in a foreseeable future.

2.7 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.

2.8 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.

2.9 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. On December 31, 2021 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.

2.10 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.

2.11 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) 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 receivables 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.

2.12 ACCOUNTS RECEIVABLE

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

2.13 CASH AND CASH EQUIVALENTS

Cash and cash equivalents include bank balances in both the balance sheet and the cash flow statement.

2.14 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.

2.15 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.

2.16 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.

(iii) Share-based payments

The group has share-based payment programs where the company receives services from the employees as a compensation via the group's equity instruments. Information regarding these programs can be found in note 7.

Employee stock options program

Fair value of the employment that entitles the employees to be granted options through InDex employee stock option program is accounted for as personnel costs with a corresponding increase of equity in accordance with IFRS 2. The total amount to be expensed is based on the fair value per grant date based on the Black&Scholes model.

The total amount is accounted for over the vesting period. At the end of each reporting period the group assesses how many shares that is expected to be vested. Any potential deviations compared to the original assessment will be accounted for in the consolidated statements of total comprehensive income with a corresponding effect on equity.

Social security costs attributable to the value of the potential taxable benefit related to granted employee stock options are expensed in line with the vesting period. The value is calculated based on the fair value of the vested options at the end of the reporting period, which is in line with UFR 7.

2.17 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. The group has however purchased foreign currency (USD) for future payments of accounts payable in USD.

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 3,347k (December 31, 2020: SEK 1,293k, December 31, 2019: SEK 2,149k). 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, 2021, 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 and USD 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 2021 would have been SEK 988k (2020: SEK 400k, 2019: SEK 600k) lower/higher mostly as a result of gains/losses on translation of accounts payable. This calculation does not include the impact of cash and cash equivalents in foreign currencies.

(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 receivables 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, 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**

THE GROUP'S FINANCIAL LIABILITIES ON DECEMBER 31, 2021

On December 31, 2021	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	447	–	–	1,520	1,282
Accounts payable	4,497	–	–	–	–	4,497	4,497
Other liabilities	1,693	–	–	–	–	1,693	1,693
Accrued expenses	3,569	–	–	–	–	3,569	3,569
Total	**10,027**	**805**	**447**	**–**	**–**	**11,279**	**11,041**

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

	2021	2020	2019
Research and analysis services	–	35	88
Total	**–**	**35**	**88**

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

	2021	2020	2019
Sweden	–	35	88
Total	**–**	**35**	**88**

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

	2021	2020	2019
PwC			
– Audit engagement	260	265	194
– Other services	10	663	254
Total	**270**	**928**	**448**

NOTE 7 PERSONNEL COSTS

EMPLOYEE BENEFITS

	2021	2020	2019
Salaries and other benefits	6,982	5,496	8,307
Social security charges	3,022	2,384	2,596
Pension expenses – defined contribution plans	1,694	1,572	1,510
Fees	7,589	7,845	6,742
Total remuneration	**19,287**	**17,297**	**19,155**

REMUNERATION, OTHER BENEFITS AND SOCIAL SECURITY CONTRIBUTIONS

	2021		2020		2019	
	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	4,578	2,583 (1,019)	4,241	2,175 (998)	6,093	2,721 (992)
Other employees	3,647	1,727 (675)	2,523	1,245 (574)	3,214	1,529 (518)
Total group	**8,225**	**4,310 (1,694)**	**6,764**	**3,420 (1,572)**	**9,307**	**4,250 (1,510)**

AVERAGE NUMBER OF EMPLOYEES SPLIT BY COUNTRY

	2021		2020		2019	
	At year-end	Whereof men	At year-end	Whereof men	At year-end	Whereof men
Sweden	9	3	7	1	7	1
Total group	**9**	**3**	**7**	**1**	**7**	**1**

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

	2021		2020		2019	
	At year-end	Whereof men	At year-end	Whereof men	At year-end	Whereof men
Board of Directors	4	2	6	4	4	3
CEO and other senior executives	4	3	4	3	4	3
Total group	**8**	**5**	**10**	**7**	**8**	**6**

REMUNERATION AND OTHER BENEFITS 2021

	Basic salary/ Board remuneration	Variable remuneration	Sharebased payments	Pension expenses	Fees	**Total**
Chairman of the Board – Wenche Rolfsen	430	–	–	–	–	**430**
Member of the Board – Marlene Forsell	215	–	–	–	–	**215**
Member of the Board – Uli Hacksell	215	–	–	–	–	**215**
Member of the Board – Lennart Hansson	215	–	–	–	–	**215**
Member of the Board – Yilmaz Mahshid	84	–	–	–	–	**84**
Member of the Board – Stig Lökke Pedersen	84	–	–	–	–	**84**
CEO – Peter Zerhouni	1,830	162	83	620	–	**2,695**
Other senior executives (3 people)	1,123	60	77	399	3,157	**4,816**
Total group	**4,196**	**222**	**160**	**1,019**	**3,157**	**8,754**

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

REMUNERATION AND OTHER BENEFITS 2020

	Basic salary/ Board remuneration	Variable remuneration	Sharebased payments	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	3,105	**4,621**
Total group	**4,241**	**–**	**–**	**998**	**3,105**	**8,344**

REMUNERATION AND OTHER BENEFITS 2019

	Basic salary/ Board remuneration	Variable remuneration	Sharebased payments	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	3,006	**4,866**
Total group	**3,879**	**2,213**	**–**	**992**	**3,006**	**10,090**

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 is no severance pay agreements.

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

WARRANTS

Set out below is a summary of the warrants granted by the group during any of the financial years included in annual report 2021:

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 fair 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 (LTIP 2020)
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 valuation 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 fair value.

After the completed rights issue the exercise price and the number of shares each warrant represents have been recalculated in accordance with the 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, 2021 666,667
- December 31, 2020 666,667
- December 31, 2019 0

LTIP 2020

	2021		2020		2019	
	Average exercised price per warrant	Warrants	Average exercised price per warrant	Warrants	Average exercised price per warrant	Warrants
Per January 1	7.804	958,388	–	–	–	–
Granted	–	–	7.804	958,388	–	–
Forfeited	–	–	–	–	–	–
Exercised	–	–	–	–	–	–
Expired	–	–	–	–	–	–
Per December 31	**7.804**	**958,388**	**7.804**	**958,388**	**–**	**–**

Weighted average remaining contractual life of warrants outstanding at end of period is 1.58 years (2020 2.58 years, 2019 0.75 years).

EMPLOYEE STOCK OPTIONS
Set out below is a summary of the employee stock options granted by the group during any of the financial years included in annual report 2021.

TO 2021/2024 (LTIP 2021)
At the Annual General Meeting held on June 3, 2021 it was resolved to issue 7,200,000 employee stock options to transfer to employees and other key persons within InDex. In addition, 2,262,240 warrants were issued to cover potential cash flow effects from social security costs arising from allotted employee stock options. The options have a strike price of SEK 4 per share and can be exercised during July-December 2024.

In July 2021 the Board allocated 5,731,800 employee stock options to employees and other key persons free of charge. A total of 13 employees and other key persons were offered and subsequently subscribed for their allotted employee stock options. The employee stock options will vest with 1/3 per year. In October 2021 the Board allocated an additional 676,000 employee stock options to two new employees. The remaining employee stock options will be terminated.

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

- December 31, 2021 3 732 800
- December 31, 2020 0
- December 31, 2019 0

The assessed fair value at grant date of options granted during 2021 (LTIP 2021) was SEK 0.14 and SEK 0.10 per employee stock option respectively. The fair value at grant date has been calculated using the Black&Scholes valuation model, which takes into account the exercise price, the term of the option, the impact of dilution (where material), the share price at grant date and expected price volatility of the underlying share, the expected dividend yield, and the risk-free interest rate for the term of the option.

The model inputs for options granted during 2021 include:

- Exercise price: SEK 4.00 (2020 and 2019, not applicable)
- Grant date: July 6, 2021 and October 26, 2021 respectively (2020 and 2019, not applicable)
- Expiry date: July 1-December 31, 2024 (2020 and 2019, not applicable)
- Share price at grant date: SEK 1.48 and SEK 1.38 respectively (2020 and 2019, not applicable)
- Expected price volatility of the company's shares: 50% (2020 and 2019, not applicable)
- Expected dividend yield: 0% (2020 and 2019, not applicable) and
- Risk-free interest rate: 0% (2020 and 2019, not applicable)

The expected price volatility is based on expected changes to future volatility.

LTIP 2021

	2021		2020		2019	
	Average exercised price per option	Employee stock option	Average exercised price per option	Employee stock option	Average exercised price per option	Employee stock option
Per January 1	–	–	–	–	–	–
Granted	4.00	6,407,800	–	–	–	–
Forfeited	–	–	–	–	–	–
Exercised	–	–	–	–	–	–
Expired	–	–	–	–	–	–
Per December 31	**4.00**	**6,407,800**	**–**	**–**	**–**	**–**

Weighted average remaining contractual life of employee stock options outstanding at end of period is 2.75 years.

Expenses arising from share-based payment transactions
Employee stock option program (LTIP 2021) – SEK 374k

NOTE 8 OTHER INCOME

	2021	2020	2019
Government grants	440	380	–
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate	12,280		
Total	**12,720**	**380**	**–**

NOTE 9 FINANCIAL ITEMS

	2021	2020	2019
Interest income	–	46	–
Other financial income	–	0	0
Total financial income	**–**	**46**	**0**
Interest expense	–133	–113	–61
Exchange rate differences	–	–	–
Other financial expenses	–	–2	–
Total financial expenses	**–133**	**–115**	**–61**
Financial items – net	**–133**	**–69**	**–61**

NOTE 10 TAXES

	2021	2020	2019
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:

	2021	2020	2019
Earnings before tax	**–103,043**	**–57,418**	**–87,773**
Tax as per applicable tax rate for parent company in Sweden (2021: 20.6%, 2020 and 2019: 21.4%)	21,227	12,287	18,783
Tax effects due to:			
Non-taxable income	–	–	–
Non-deductible expenses	–9	–7	–79
Tax effect related to unrecognised tax losses carried forward	–21,218	–12,280	–18,704
Taxes	**–**	**–**	**–**

The weighted average tax rate for the group was 0% (2020: 0%, 2019: 0%).

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

	2021	2020	2019
Other income – (note 8)	12,280	–	–
Other external expenses	–	–	–
Financial items – (note 9)	–	–	–
Total	**12,280**	**–**	**–**

NOTE 12 EARNINGS PER SHARE

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

InDex has pending ordinary shares through warrants. The warrants have no dilution effect during 2019, 2020 and 2021 as a conversion to ordinary shares would lead to a lower negative earnings per share.

	2021	2020	2019
Result after tax attributable to the shareholders of the parent company	–103,043	–57,418	–87,773
Total	**–103,043**	**–57,418**	**–87,773**
Weighted average number of shares (thousands)[1]	**483,365**	**236,750**	**197,001**
Earnings per share, SEK	**–0.21**	**–0.24**	**–0.45**

[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, 2021:

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 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**
Fiscal year 2021	
Opening net book amount	818
Investments	–
Divestments/scrapping	–
Depreciations	–179
Closing net book amount	**639**
Per December 31, 2021	
Acquisition cost	2,038
Accumulated depreciations	–1,399
Net book amount	**639**

NOTE 15 LEASING AGREEMENTS

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

	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Right-of-use assets			
Office space	1,520	2,593	464
Total	**1,520**	**2,593**	**464**
Leasing liabilities			
Non-current	475	1,578	–
Current	807	763	484
Total	**1,282**	**2,341**	**484**

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:

	2021	2020	2019
Amortisation of right-of-use assets			
Office space	–1,073	–1,090	–929
Total	**–1,073**	**–1,090**	**–929**
Interest expense (included in financial expenses)	–96	–82	–41
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	–31	–23	–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 1,177k (2020: SEK 1,198k, 2019: SEK 1,000k). For information on the maturity of the lease liability, see Note 3.

NOTE 16 FINANCIAL INSTRUMENTS PER CATEGORY

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**

December 31, 2021	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
Other current receivables	–	2,400	2,400
Prepaid expenses and accrued income	–	12,187	12,187
Cash and cash equivalents	–	428,449	428,449
Total	**1**	**443,036**	**443,037**

December 31, 2021		Financial liabilities measured at amortised cost	Total
Liabilities on the balance sheet			
Accounts payable	–	4,497	4,497
Other current liabilities	–	1,693	1,693
Accrued expenses and deferred income	–	3,569	3,569
Total	**–**	**9,759**	**9,759**

NOTE 17 ACCOUNTS RECEIVABLE

	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Accounts receivable	–	–	4
Less: Provision for loss allowance	–	–	–
Accounts receivable - net	**–**	**–**	**4**

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, 2021	Dec 31, 2020	Dec 31, 2019
Tax receivable	164	–	–
Other	2,236	907	1,343
Total	**2,400**	**907**	**1,343**

NOTE 19 PREPAID EXPENSES AND ACCRUED INCOME

	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Prepaid insurance premiums	2	72	89
Other	12,185	2,959	385
Total	**12,187**	**3,031**	**474**

NOTE 20 CASH AND CASH EQUIVALENTS

	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Bank accounts	**428,449**	**53,834**	**126,790**
Total	**428,449**	**53,834**	**126,790**

NOTE 21 SHARE CAPITAL AND ADDITIONAL PAID IN CAPITAL

	No of shares (thousands)	Share capital	Additional paid in capital
Per January 1, 2019	**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**
Issue of shares	443,906	8,878	478,617
Value of the employees' employment	–	–	258
Per December 31, 2021	**532,688**	**10,654**	**863,433**

The share capital as of December 31, 2021, consisted of 532,687,650 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, 2019		
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		
Net results and total comprehensive income for the year	–	–
Per December 31, 2021	**–**	**–**

Unutilised loss carry-forwards for which no deferred tax assets have been reported amount to SEK 747,132k as of December 31, 2021 (December 31, 2020: SEK 631,158k, December 31, 2019: SEK 586,788k). The loss carry-forwards can be carried forward indefinitely.

Deferred tax assets are recognised for tax loss carry-forwards 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, 2021	Dec 31, 2020	Dec 31, 2019
Tax liabilities	6	–	90
Other	1,687	852	1,038
Total	**1,693**	**852**	**1,138**

NOTE 24 ACCURED COSTS AND DEFERRED INCOME

	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Accrued vacation salaries	1,244	1,405	1,318
Accrued social security charges	390	442	414
Accured costs, clinical trials	–	–	8,987
Other items	1,935	3,793	7,090
Total	**3,569**	**5,640**	**17,809**

NOTE 25 PLEDGED ASSETS

	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Bank guarantee, Euroclear	50	50	50
Bank guarantee, Akademiska Hus	537	537	–
Total	**587**	**587**	**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, the acquisition of warrants at market value in 2020 and the allocation of employee stock options in 2021. Remuneration to senior executives is disclosed in Note 7.

NOTE 27 CHANGES IN LIABILITIES FROM FINANCING ACTIVITIES

	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**

	January 1, 2021	Cash inflow	Cash outflow	Non-cash items	December 31, 2021
Lease liability	2,629	–	–1,146	95	1,578
Total	**2,629**	**–**	**–1,146**	**95**	**1,578**

NOTE 28 SIGNIFICANT EVENTS AFTER THE END OF THE FINANCIAL YEAR

RUSSIA'S INVASION OF UKRAINE

Russia's invasion of Ukraine has led to significant volatility in the global economy and on the financial markets. The consequences of the current geopolitical situation from macro-economic and political perspectives cannot be fully assessed. InDex has in its ongoing phase III study CONCLUDE not initiated patient recruitment in Russia and Ukraine. An assessment is currently ongoing to evaluate how the planned patients from these countries can be replaced. InDex is still estimating that the result from the first phase III study can be presented during H2 2023.

Statement of comprehensive income for the parent company

SEKk	Note	2021	2020	2019
Revenues				
Net sales	2	10,176	11,265	10,997
Total revenues		**10,176**	**11,265**	**10,997**
Operating expenses				
Other external expenses	3	–10,691	–11,485	–9,108
Personnel costs	4	–6,718	–5,754	–7,852
Depreciation	7	–179	–91	–
Total operating expenses		**–17,588**	**–17,330**	**–16,960**
Operating loss		**–7,412**	**–6,065**	**–5,963**
Net financial items				
Write-down of financial assets	5	–200,097	–50,000	–90,000
Financial income	5	–	46	–
Financial costs	5	–37	–6	–21
Total net financial items		**–200,134**	**–49,960**	**–90,021**
Profit or loss before tax		**–207,546**	**–56,025**	**–95,984**
Taxes for the period	6	–	–	–
PROFT OR LOSS FOR THE YEAR		**–207,546**	**–56,025**	**–95,984**

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, 2021	December 31, 2020	December 31, 2019
ASSETS				
Fixed assets				
Tangible fixed assets				
Equipment, tools and installations	7	639	818	–
Total tangible fixed assets		**639**	**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		**247,669**	**247,848**	**247,030**
Current assets				
Current receivables				
Intercompany receivables		196,921	779	563
Other receivables	9	1,237	219	58
Prepaid expenses and accrued income	10	410	1,247	366
Total current receivables		**198,568**	**2,245**	**987**
Cash and cash equivalents	11	**99,793**	**45,491**	**124,965**
Total current assets		**298,361**	**47,736**	**125,952**
TOTAL ASSETS		**546,030**	**295,584**	**372,982**
EQUITY AND LIABILITIES				
Equity				
Restricted equity				
Share capital	12	10,654	1,776	1,776
Total restricted equity		**10,654**	**1,776**	**1,776**
Non-restricted equity				
Share premium reserve		1,109,148	630,274	630,031
Retained earnings		–369,014	–312,989	–217,005
Profit or loss for the year		–207,546	–56,025	–95,984
Total non-restricted equity		**532,587**	**261,260**	**317,042**
Total equity		**543,241**	**263,036**	**318,818**
Provisions				
Other provisions		71	–	–
Total provisions		**71**	**–**	**–**
Current liabilities				
Account payables		446	1,114	243
Intercompany liabilities		–	28,800	47,262
Other current liabilities	13	462	323	1,222
Accrued expenses and deferred income	14	1,810	2,311	5,437
Total current liabilities		**2,718**	**32,548**	**54,164**
TOTAL EQUITY AND LIABILITES		**546,030**	**295,584**	**372,982**

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, 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**
Opening balance January 1, 2021	**1,776**	**630,274**	**–312,989**	**–56,025**	**263,034**
Disposition of last year's result	–	–	–56,025	56,025	–
Net results and total comprehensive income for the year	–	–	–	–207,546	–207,546
Total comprehensive income	**–**	**–**	**–**	**–207,546**	**–207,546**
Transactions with shareholders in their capacity as owners					
Issue of shares	8,878	523,809	–	–	532,687
Transaction costs	–	–45,192	–	–	–45,195
Value of the employees' employment	–	258	–	–	258
Transactions with shareholders of the parent company	**8,878**	**478,875**	**–**	**–**	**487,753**
Closing balance December 31, 2021	**10,654**	**1,109,148**	**–369,014**	**–207,546**	**543,241**

Statement of cash flows for the parent company

SEKk	2021	2020	2019
Operating activities			
Earnings before tax	–207,546	–56,025	–95,984
Adjustment for non-cash items:			
Write-down	200,097	50,000	90,000
Income tax paid	–	–	–
Depreciations	179	91	–
Other adjustments	328	–	–
Cash flow from operating activities before changes in working capital	**–6,942**	**–5,934**	**–5,984**
Cash flow in working capital			
Changes in current receivables	–196,323	–1,258	–268
Changes in current liabilities	–29,830	–21,616	9,045
Cash flow from changes in working capital	**–226,153**	**–22,874**	**8,777**
Cash flow from operating activities	**–233,095**	**–28,808**	**2,793**
Cash flow from investment activities			
Shareholders contribution	–200,097	–50,000	–90,000
Investment in tangible fixed assets	–	–909	–
Cash flow from investment activities	**–200,097**	**–50,909**	**–90,000**
Financing activities			
Issue of shares, net after transaction costs	487,495	–	129,784
Issue of warrants	–	243	–
Cash flow from financing activities	**487,495**	**243**	**129,784**
Cash flow for the year	**54,302**	**–79,474**	**42,577**
Decrease/increase in cash and cash equivalents			
Cash and cash equivalents at the beginning of the year	45,491	124,965	82,388
Cash and cash equivalents at the end of the year	**99,793**	**45,941**	**124,965**

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

	2021	2020	2019
Net sales, see note 16	10,176	11,265	10,997
Total	**10,176**	**11,265**	**10,997**

NET SALES PER COUNTRY

	2021	2020	2019
Sweden	10,176	11,265	10,997
Total	**10,176**	**11,265**	**10,997**

NOTE 3 FEES AND REMUNERATION TO AUDITORS

	2021	2020	2019
PwC			
– Audit engagement	260	265	194
– Other services	10	663	254
Total	**270**	**928**	**448**

NOTE 4 PERSONNEL COSTS

EMPLOYEE BENEFITS

	2021	2020	2019
Salaries and other benefits	3,335	2,973	5,093
Social security charges	1,295	1,139	1,586
Pension expenses – defined contribution plan	1,019	998	992
Fees	4,115	4,146	3,940
Total	**9,764**	**9,256**	**11,611**

REMUNERATION, OTHER BENEFITS AND SOCIAL SECURITY CONTRIBUTIONS

	2021		2020		2019	
	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	4,578	2,583 (1,019)	4,241	2,175 (998)	6,093	2,721 (992)
Other employees	–	–	–	–	–	–
Total parent company	**4,578**	**2,583 (1,019)**	**4,241**	**2,175 (998)**	**6,093**	**2,721 (992)**

AVERAGE NUMBER OF EMPLOYEES SPLIT BY COUNTRY

	2021		2020		2019	
	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

	2021		2020		2019	
	At year-end	Whereof men	At year-end	Whereof men	At year-end	Whereof men
Board of directors	4	2	6	4	4	3
CEO and other senior executives	4	3	4	3	4	3
Total parent company	**8**	**5**	**10**	**7**	**8**	**6**

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

NOTE 5 INTEREST INCOME, INTEREST EXPENSE AND SIMILAR ITEMS

	2021	2020	2019
Write-down of financial assets	–200,097	–50,000	–90,000
Interest costs	–37	–6	–21
Total interest expense and similar items	**–200,134**	**–50,006**	**–90,021**
Interest income	–	46	–
Total interest income	**–**	**46**	**–**
Financial items, net	**–200,134**	**–49,960**	**–90,021**

NOTE 6 TAXES

REPORTED TAX IN STATEMENT OF COMPREHENSIVE INCOME

	2021	2020	2019
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:

	2021	2020	2019
Pre-tax loss	**–207,546**	**–56,025**	**–95,984**
Income tax calculated according to the tax rate in Sweden (2021: 20.6%, 2020 and 2019: 21.4%)	42,754	11,989	20,541
Tax effects from:			
Non-taxable income	–	–	–
Non-deductible expenses	41,220	–10,697	–19,262
Unused tax credits for which no deferred tax is recognised	1,534	1,292	–1,279
Total reported tax	**–**	**–**	**–**

NOTE 7 EQUIPMENT, TOOLS AND INSTALLATIONS

	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Opening acquisition cost	909	–	–
Investments	–	909	–
Closing acquisition cost	**909**	**909**	**–**
Opening depreciations	–91	–	–
Depreciations	–179	–91	–
Closing depreciations	**–270**	**–91**	**–**
Net book amount	**639**	**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, 2021	Carrying value Dec 31, 2020	Carrying value Dec 31, 2019
InDex Pharmaceuticals AB	556704-5140	Stockholm, Sweden	60,281,586	247,030	247,030	247,030

InDex Pharmaceuticals AB	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Opening acquisition value	594,300	544,030	454,030
Shareholders contribution	200,097	50,000	90,000
Closing acquisition value	**794,127**	**594,030**	**544,030**
Opening accumulated depreciations/write-downs	–347,000	–297,000	–207,000
Depreciations/write-downs	–200,097	–50,000	–90,000
Closing accumulated depreciations/write-downs	**–547,097**	**–347,000**	**–297,000**
Carrying value	**247,030**	**247,030**	**247,030**

NOTE 9 OTHER RECEIVABLES

	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Tax account	1,237	160	58
Tax receivable preliminary tax	–	–	–
Other	–	59	–
Total	**1,237**	**219**	**58**

NOTE 10 PREPAID EXPENSES AND ACCRUED INCOME

	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Prepaid rent	296	289	243
Prepaid insurance premiums	–	33	6
Other	114	925	117
Total	**410**	**1,247**	**366**

NOTE 11 CASH AND CASH EQUIVALENTS

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

	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Bank accounts	99,793	45,491	124 965
Total	**99,793**	**45,491**	**124 965**

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, 2021	Dec 31, 2020	Dec 31, 2019
Calculated employee contribution on pensions	6	69	293
Liability to the Tax Authority (VAT, employee withholding tax and social contributions)	456	254	929
Current liabilities to employees	–	–	–
Other	–	–	–
Total	**462**	**323**	**1,222**

NOTE 14 ACCRUED COSTS AND DEFERRED INCOME

	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Accrued vacation salaries	574	929	851
Accrued social security charges	180	292	267
Other	1,056	1,090	4,319
Total	**1,810**	**2,311**	**5,437**

NOTE 15 PLEDGED ASSETS

	Dec 31, 2021	Dec 31, 2020	Dec 31, 2019
Bank guarantee, Euroclear	50	50	50
Bank guarantee, Akademiska Hus	537	537	–
Total	**587**	**587**	**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 1,154k (2020: SEK 1,048k and 2019: SEK 988k) for office leases are included in the statement of comprehensive income.

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

	2021	2020	2019
Within 1 year	1,146	1,048	988
Between 1 and 5 years	478	1,624	–
Beyond 5 years	–	–	–
Total	**1,624**	**2,672**	**988**

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

	2021	2020	2019
Revenue from services			
Sales to group companies	10,176	11,265	10,997
Total	**10,176**	**11,265**	**10,997**
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, 2021	Dec 31, 2020	Dec 31, 2019
Receivables from related parties:			
Receivables from group companies	196,921	779	563
Liabilities to related parties			
Liabilities to group companies	–	28,800	47,261
Total	**196,921**	**29,579**	**47,824**

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 receivables from related parties are largely related to sales transactions and fall due 1 month after the date of the sale.

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	740,133,518
Net result	–207,546,095
	532,587,423
The Board's suggestion to be brought forward	532,587,423

Signatures

The consolidated income statement and balance sheets will be submitted to the Annual General Meeting on June 1, 2022 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 6, 2022

Wenche Rolfsen
Chairman of the Board

Marlene Forsell

Uli Hacksell

Lennart Hansson

Peter Zerhouni
CEO

Our audit report was submitted on April 6, 2022

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

Unofficial translation

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 2021.

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 2021 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 2021 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 income statement and balance sheet for the parent company and the group.

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 ISA 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 2021 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 6 April 2022
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 bulletins 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 Annual General Meeting on June 1, 2021 it was decided 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.

The board of directors proposes that the general meeting resolves on principles for the appointment of and instructions for the nomination committee to apply until the general meeting decides otherwise. The nomination committee shall consist of the chairman of the board of directors and four members appointed by the four largest shareholders by votes at the end of the third quarter each year. The "the four largest shareholders by votes" shall hereinafter also include known shareholder groups. The chairman of the board of directors shall annually contact the shareholders who are entitled to appoint a member. Should any of the entitled shareholders waive their right to appoint a member to the nomination committee, the right is transferred to the fifth largest shareholder by votes, and so on. However, no more than five additional shareholders need be contacted, unless the chairman of the board of directors finds that there are special reasons for doing so. When a shareholder is contacted with a request to appoint a representative of the nomination committee, the chairman of the board of directors shall set out the requisite rules of procedure, such as the last date of response, etc.

The names of the members of the nomination committee and the names of the shareholders appointing members shall be made public no later than six months prior to the annual general meeting. The nomination committee appoints a chairman among its members. The chairman of the board of directors shall not be the chairman of the nomination

committee. Should a member resign before the work of the nomination committee is concluded, and if deemed appropriate by the nomination committee, a replacement member shall be appointed by the shareholder that appointed the member who resigned, or, if that shareholder no longer represents one of the four largest shareholders by votes, by the shareholder representing such group. If a shareholder who has appointed a certain member has substantially decreased its shareholding in the company, and the nomination committee does not deem it inappropriate in view of a potential need of continuity prior to an impending general meeting, the member appointed by such shareholder shall resign from the nomination committee and the nomination committee shall offer the largest shareholder who has not yet appointed a member of the nomination committee to appoint a new member.

The nomination committee shall further be composed and perform such tasks that from time to time are stated in the Swedish Corporate Governance Code. The members of the nomination committee shall not receive remuneration from the company. Any costs incurred in connection with the work of the nomination committee shall be paid by the company, provided that they have been approved by the chairman of the board of directors.

The nomination committee before the annual general meeting 2022, as communicated on November 10, 2021, has consisted of Karl Tobieson, chairman, and appointed by Linc, Ivo Staijen appointed by HBM Healthcare Investments, Jannis Kitsakis appointed by Fjärde AP-fonden, Björn Wasing appointed by SEB-Stiftelsen and S-E-B Utvecklingsstiftelse 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 and Lennart Hansson. 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 materialise. 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 Russia's invasion of Ukraine", "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 Russia's invasion of Ukraine and 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 headings "Risks related to Russia's invasion of Ukraine" and "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 Russia's invasion of Ukraine

At the date of the Board's approval of this annual report Russia's invasion of Ukraine is ongoing. It is at present difficult to assess the impact of the invasion on the global economy and if the current geopolitical situation may impact additional countries over time. InDex has in the ongoing phase III study CONCLUDE not initiated patient recruitment in Russia and Ukraine. An assessment is currently ongoing to evaluate how the planned patients from these countries can be replaced. If additional countries are affected by the geopolitical situation this can lead to limitations to patient access and may cause delay in the ongoing phase III program.

Risks related to the Covid-19 pandemic

The Covid-19 pandemic is still affecting the healthcare systems and investor sentiment globally and must be considered in the company's strategic planning. If the spread of Covid-19 does not subside, InDex may experience difficulties in conducting its ongoing phase III program for cobitolimod since it may affect patient access. This impact may both be a result of governments or authorities imposing new restrictions 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 ongoing 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 ongoing phase III program for cobitolimod. Furthermore, if persons engaged by InDex are infected by Covid-19 this may limit their possibilities to work with the ongoing phase III program, which in turn could delay the 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 nine full time employees and has established cooperation with about ten qualified consultants each specialised in different areas, such as regulatory affairs, statistics, medicine, preclinical, manufacturing, business development, quality assurance, finance, HR 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 a clinical study InDex needs to apply for approvals with the authorities 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 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 Russia's invasion of Ukraine and the continued development of the Covid-19 pandemic (see in more detail under the headings "Risks related to Russia's invasion of Ukraine" and "Risks related to the Covid-19 pandemic"). It is uncertain to what extent the economic development will be affected and the effects on the pharmaceutical market and consequently also on the company's future operations. 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.

PK STUDY (PHARMACOKINETIC STUDY)
A study that investigates a drug's absorption, distribution, metabolism and excretion.

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.

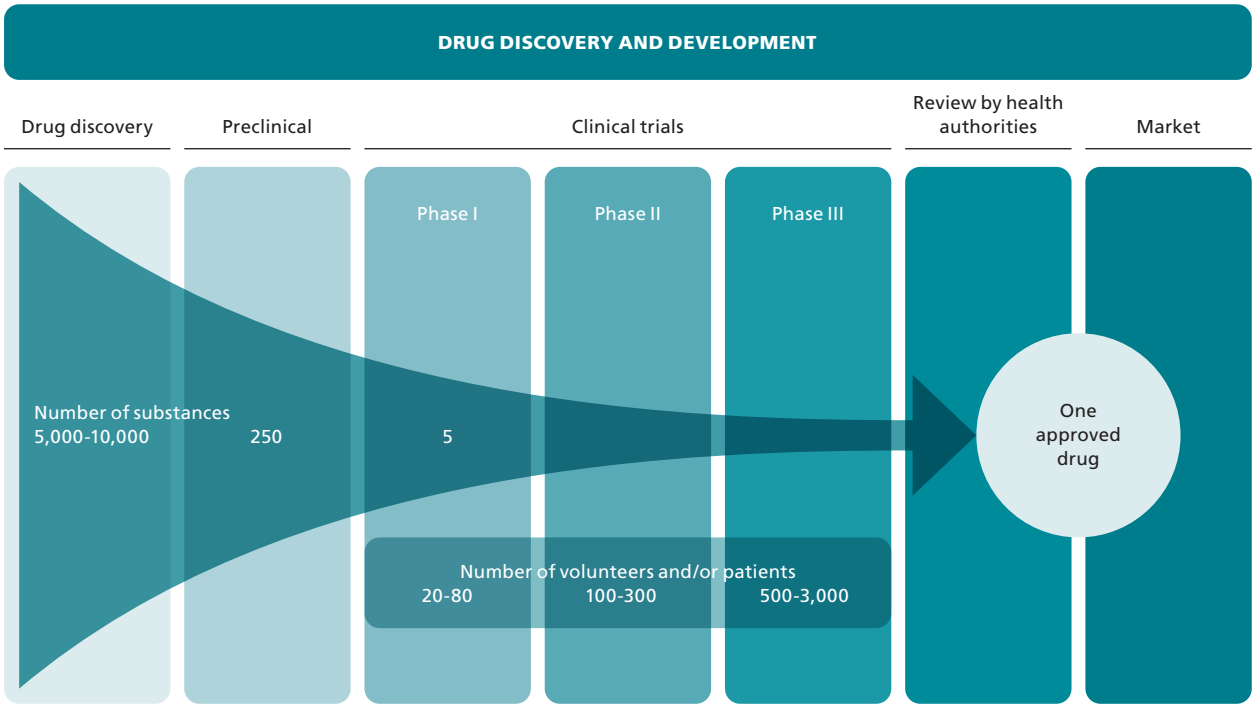
Phase II: Phase II trials are conducted in patients with the disease concerned, with the aim to establish an appropriate dosage for the phase III programme. The phase II studies also aim to obtain preliminary data on the efficacy of the substance. Safety is also carefully monitored. Phase II is usually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