

# InDex Pharmaceuticals Holding AB (publ)

Interim report January-June 2022



# PMDA supports InDex's development plan for cobitolimod in Japan

#### **PERIOD APRIL-JUNE 2022**

- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –21.7 (–42.6) million
- Result after tax amounted to SEK –21.7 (–42.6) million, corresponding to SEK –0.04 per share (–0.08) before and after dilution
- Cash flow from operating activities amounted to SEK –53.0 (–45.1) million

#### SIGNIFICANT EVENTS DURING THE QUARTER

- Peter Zerhouni stepped down as CEO of InDex. The company's CFO Johan Giléus has been appointed acting CEO while a new CEO is being recruited
- InDex strengthened the organisation with Eva Arlander as Chief Development Officer and presented a new management team

### SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

InDex got a new patent for cobitolimod granted in Europe

All comparative amounts in brackets refer to the outcome during the corresponding period 2021.

#### **PERIOD JANUARY-JUNE 2022**

- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –40.6 (–51.9) million
- Result after tax amounted to SEK –40.6 (–52.0) million, corresponding to SEK –0.08 per share (–0.11) before and after dilution
- Cash flow from operating activities amounted to SEK –71.4 (–53.6) million
- Cash and cash equivalents at the end of the period amounted to SEK 395.6 (478.8) million
- Number of employees at the end of the period was 7 (7)
- Number of shares at the end of the period was 532,687,650

### **OTHER EVENTS**

- InDex participated with a booth at the Digestive Disease Week (DDW) in San Diego
- The annual general meeting in InDex Pharmaceuticals Holding AB was held on June 1, 2022

"With great interest from the clinics for our phase III study CONCLUDE and cobitolimod, our successful interactions with the Japanese regulatory authority PMDA, as well as with a strengthened patent portfolio, InDex is strongly equipped for cobitolimod's path towards market approval", says Johan Giléus, acting CEO of InDex Pharmaceuticals.

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.

# CEO statement

We remain fully focused on the implementation of the phase III study CONCLUDE, which evaluates the drug candidate cobitolimod as a new and unique treatment for patients with moderate to severe left-sided ulcerative colitis. The study is progressing according to plan, i.e. we expect the results to be available during H2 2023. We see great interest in the study and cobitolimod when we, together with our experienced CRO, Parexel Biotech, visit the participating clinics. In the beginning of July, we invited all CRAs of the study, i.e. Parexel's employees who have ongoing contact with the participating clinics, to a two-day meeting in Stockholm. The purpose of the meeting was to jointly discuss the CONCLUDE study and the benefits of cobitolimod.

At the end of June, the planned consultation meeting with the Japanese regulatory authority, PMDA, was held. It was very encouraging that the PMDA supports our proposed clinical development plan for cobitolimod and that they agree to include Japanese patients in our second induction study in the phase III program, without conducting any specific clinical studies in Japanese subjects. In addition, complementary pharmacokinetic data for cobitolimod in Japanese patients can be collected during the remaining phase III program. This is a unique decision by the PMDA, indicating great potential for cobitolimod and a need for new treatment options that can help more patients with moderate to severe ulcerative colitis. In addition, the positive feedback from PMDA is advantageous for discussions with potential candidates for strategic collaborations in Japan.

At the end of May, InDex participated with a booth at the premier medical congress in the world in gastroenterology, the Digestive Disease Week (DDW) in San Diego, USA. Our participation was very successful and resulted in many valuable contacts, and several new clinics expressed interest to join our phase III study with cobitolimod. We will take the experience with us when we now plan for our participation in the United European Gastroenterology Week (UEGW) in October.

In parallel with the global clinical phase III study CONCLUDE, InDex is conducting a smaller clinical pharmacokinetic study (PK study) with cobitolimod in Sweden. The patient recruitment in the PK study has gone faster than expected and the study is well underway. The aim of the study is to confirm that the systemic uptake of cobitolimod 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. A limited systemic uptake is a significant advantage compared to competing drugs for ulcerative colitis that act on the whole body and can cause severe side effects outside the inflamed colon.



In July, we announced that a new patent for cobitolimod has been granted in Europe. The patent provides additional protection for the use of cobitolimod in the treatment of inflammatory bowel disease. The patent provides an exclusivity period until August 2040, and further strengthens, broadens and extends our robust intellectual property position for cobitolimod in Europe. Corresponding patent applications have been filed in the strategically most important patent territories globally.

With great interest from the clinics for our phase III study and cobitolimod, our successful interactions with the Japanese regulatory authority, as well as with a strengthened patent portfolio, I look forward to an exciting and eventful fall where we will take important steps forward for InDex.

Johan Giléus, acting CEO

# **Business overview**

#### INTRODUCTION

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 Immuno-Modulatory Sequences (DIMS), with the potential to be used in the treatment of various immunological diseases. InDex is based in Stockholm, Sweden. The company's shares are traded on Nasdaq First North Growth Market Stockholm.

#### **COBITOLIMOD**

Cobitolimod is a potential new medication for patients with moderate to severe ulcerative colitis. Ulcerative colitis is a chronic disease caused by inflammation of the colon. Today, about two million people in Europe and the US suffer from ulcerative colitis, a disease that has a major impact on the patient's quality of life. Ulcerative colitis is characterised by blood- and mucus-mixed diarrhea, frequent stools, pain, fever, weight loss, and anemia. Patients also have a significant 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 via the rectum 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.

# 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

#### THE MOST IMPORTANT ADVANTAGES WITH COBITOLIMOD



Illustrations: Freepik

20-30%, corresponding to global peak annual sales of more than USD 1 billion.

## Phase III study - CONCLUDE

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 initial induction study CONCLUDE will include 440 patients and be conducted in over 30 countries in Europe, the Americas and the Asia-Pacific region. The first patient was enrolled into the study end of 2021. CONCLUDE is a randomised, double-blind, placebo-controlled, 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.

# **Commercialisation strategy for cobitolimod**

InDex has together with external experts analysed the commercialisation options for cobitolimod in the US and Europe. 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

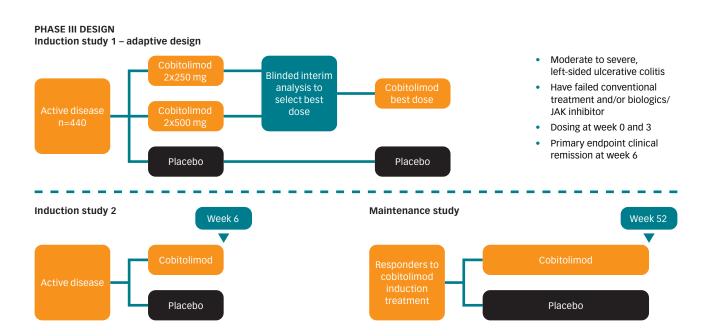
Results from the ongoing first phase III study with cobitolimod are expected to be available during H2 2023. The complete phase III program, including a second induction study and a one-year maintenance study, is expected to be completed during 2026. Applications for marketing approval will then be submitted to the regulatory authorities, with an expected launch of cobitolimod in 2027.

## 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 optimise 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.

## **OTHER DIMS**

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.

# SIGNIFICANT EVENTS DURING THE QUARTER

- InDex announced on April 11, 2022 that CEO Peter Zerhouni
  has decided to leave his position after more than seven
  years. The company's CFO Johan Giléus has been appointed
  acting CEO while a new CEO is being recruited, and he also
  continues his position as CFO.
- InDex announced on May 2, 2022 that the company has strengthened the organisation with Eva Arlander as Chief Development Officer. Eva is also part of the new management team, together with acting Chief Executive Officer and Chief

Financial Officer Johan Giléus, Chief Medical Officer Anders Bröijersén and Chief Scientific Officer Charlotte Admyre.

### SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

 InDex announced on July 13, 2022 that a new method of use patent for the drug candidate cobitolimod has been granted by the European Patent Office (EPO). The patent provides additional protection for the use of cobitolimod in the treatment of inflammatory bowel disease.

### **OTHER EVENTS**

- InDex participate with a booth at Digestive Disease Week (DDW) May 21-24, 2022 in San Diego to inform about cobitolimod and the phase III study CONCLUDE. DDW is the premier medical congress in the world in gastroenterology.
- The annual general meeting in InDex Pharmaceuticals Holding AB was held on June 1, 2022. Board members Wenche Rolfsen (also chairman), Marlene Forsell, Uli Hacksell and Lennart Hansson were re-elected, and Karin Bernadotte af Wisborg and Anna-Kaija Grönblad was elected as new ordinary board members for the time until the end of the next annual general meeting. The annual general meeting also resolved, in accordance with the board of directors' proposal, on the implementation of a long term incentive program by way of granting employee stock options to senior executives and other key persons of the group.



# **Financial overview**

#### FINANCIAL SUMMARY FOR THE GROUP

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

#### FINANCIAL DEVELOPMENT DURING APRIL-JUNE 2022

Net sales for the period April to June 2022 amounted to SEK 0.0 (0.0) million.

Other operating income SEK 31.8 (0.0) million refers to grants received from Vinnova and foreign exchange gains of SEK 31.3 (0.0) 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 53.5 (42.7) 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 3.5 (2.9) million. The increase is partly related to general salary increases and an increase in number of employees.

Cash and cash equivalents as of June 30, 2022 amounted to SEK 395.6 million, which is SEK 21.9 million lower than as of March 31, 2022.

## FINANCIAL DEVELOPMENT DURING JANUARY-JUNE 2022

Net sales for the period January to June 2022 amounted to SEK 0.0 (0.0) million.

Other operating income SEK 39.6 (0.0) million refers to grants received from Vinnova and foreign exchange gains of SEK 39.0 (0.0) 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 80.2 (52.1) 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 7.3 (5.5) million. The increase is partly related to general salary increases and an increase in number of employees.

Cash and cash equivalents as of June 30, 2022 amounted to SEK 395.6 million, which is SEK 32.9 million lower than as of December 31, 2021.

### 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 are 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 however, assess that there is no impact on the company's financial position as of June 30, 2022, due to events after the reporting period.

#### **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.

## PARENT COMPANY

The net sales amounted to SEK 5.7 (5.7) million during the period January to June 2022 and consisted of invoicing of group wide expenses to InDex Pharmaceuticals AB.

The operating expenses amounted to SEK 8.9 (8.7) million and consisted of personnel expenses and other operating expenses relating to the administration of InDex.

FINANCIAL SUMMARY					
SEK million	Apr-Jun 2022	Apr-Jun 2021	Jan-Jun 2022	Jan-Jun 2021	Full year 2021
Revenues	-	-	-	-	-
Operating result	-21.7	-42.6	-40.6	-51.9	-102.9
Result after tax	-21.7	-42.6	-40.6	-52.0	-103.0
Earnings per share before and after dilution, SEK	-0.04	-0.08	-0.08	-0.11	-0.21
Cash flow from operating activities	-53.0	-45.1	-71.4	-53.6	-124.1
Cash and cash equivalents at the end of the period	395.6	478.8	395.6	478.8	428.4

Note: Earnings per share – Net result divided by weighted number of shares.

# Other information

#### **EMPLOYEES**

The number of employees at the end of the period was 7 (7).

#### THE SHARE

The share is listed on Nasdaq First North Growth Market Stockholm since October 11, 2016.

#### Number of Percentage of capital shares 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 Fonder 24,862,134 4.7 Avanza Pension 19,659,255 3.7 SFR-Stiftelsen 19,047,617 3.6 SEB Life International 13,927,350 26 SEB Venture Capital 12,994,367 24 2.4 Stiftelsen Industrifonden 12,865,296 Nordnet Pensionsförsäkring 11,014,920 2.1 2.0 Swedbank försäkring AB 10.370.243 S-E-Bankens Utvecklingsstiftelse 1.9 10.000.000 1.7 Staffan Rasiö 8.898.097 Originat AB 1.3 7,000,000 Ponderus Invest AB 5,719,085 1.1 Other 201,177,978 37.7 Total 532,687,650 100.0

# INCENTIVE PROGRAMMES

At the annual general meeting held on April 20, 2020 it was resolved to issue 3,965,000 warrants to transfer to employees and other key persons within InDex. The warrants had an exercise price of SEK 20 per share and can be exercised during May-October 2023. The Board allocated in July 2020 958,388 warrants to employees and other key persons that were purchased for SEK 0.2522 per warrant. A total of 13 employees and other key persons were offered to subscribe for warrants and 12 of these individuals subscribed for their full allotment.

After the completed rights issue in February 2021 the exercise price and the number of shares that each warrant represents have been recalculated in accordance with the applicable terms. The new exercise price amounts to SEK 7.804 and each warrant entitles the holder to subscribe for 2.5627 shares. The remaining warrants have been terminated. Repurchase of 106,667 warrants have been completed in accordance with the applicable terms. These warrants will be terminated.

#### 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 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. 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 together with the employee stock options not to be vested. The total number of outstanding employee stock options to employees and other key persons within InDex amounts 4,193,867 at end of the reporting period.

LTIP 2021 is accounted for in accordance with *IFRS 2 – Share-based payments*. IFRS 2 stipulates that the employee stock options should be expensed as personnel costs over the vesting period. Personnel costs in accordance with IFRS 2 do not affect the company's cash flow. Social security costs will in accordance with UFR 7 be expensed in the income statement during the vesting period.

## **LTIP 2022**

At the annual general meeting held on June 1, 2022 it was resolved to issue 8,000,000 employee stock options to transfer to employees and other key persons within InDex. In addition, 2,513,600 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 2025. In July 2022 the Board allocated 5,500,200 options to employees and other key persons free of charge. A total of 15 employees and other key persons were offered and subsequently subscribed for their allotted employee stock options. The remaining employee stock options will be terminated together with the employee stock options not to be vested.

LTIP 2022 will be accounted for in accordance with *IFRS 2 – Share-based payments*. IFRS 2 stipulates that the employee stock options should be expensed as personnel costs over the vesting period. Personnel costs in accordance with IFRS 2 do not affect the company's cash flow. Social security costs will in accordance with UFR 7 be expensed in the income statement during the vesting period.

## **REVIEW BY THE AUDITOR**

This interim report has not been limited reviewed by the company's auditor.

## FINANCIAL CALENDER

Interim report Q3 November 23, 2022 Year-end report 2022 February 23, 2023

Stockholm, August 26, 2022 Johan Giléus, acting CEO

# FOR MORE INFORMATION, PLEASE CONTACT:

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The information in this interim report is information that InDex Pharmaceuticals Holding AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication by the contact person stated above on August 26, 2022 at 8:00 CET.

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

# Condensed consolidated statement of total comprehensive income

		Apr 1-Jun 30,	Apr 1-Jun 30,	Jan 1-Mar 31,	Jan 1-Mar 31,	Full year
SEKK	Note	2022	2021	2022	2021	2021
Revenues						
Net sales		-	=	-	=	-
Other operating income	5	31,803	121	39,642	156	12,720
Total revenues		31,803	121	39,642	156	12,720
Operating expenses						
Raw material and consumables		-9,284	-491	-9,851	-825	-14,383
Other external expenses		-40,474	-30,627	-62,439	-36,792	-87,737
Personnel costs		-3,460	-2,937	-7,322	-5,476	-12,258
Depreciations/amortisations of tangible fixed assets and right-of-use assets		-314	-317	-630	-634	-1,252
Other operating expenses	5	-	-8,368	-	-8,368	_
Total expenses		-53,532	-42,740	-80,243	-52,095	-115,630
Operating loss		-21,729	-42,619	-40,601	-51,939	-102,910
Result from financial investments						
Financial income		-	=	-	=	=
Financial expenses		-13	-26	-28	-54	-133
Financial items – net		-13	-26	-28	-54	-133
Earnings before tax		-21,742	-42,645	-40,629	-51,993	-103,043
Taxes for the period		-	-	-	-	-
LOSS FOR THE PERIOD		-21,742	-42,645	-40,629	-51,993	-103,043

# Earnings per share, based on the net result attributable to the shareholders of the parent company:

SEK	Note	Apr 1-Jun 30, 2022	Apr 1-Jun 30, 2021	Jan 1-Mar 31, 2022	Jan 1-Mar 31, 2021	Full year 2021
Earnings per share before and after dilution	7	-0.04	-0.08	-0.08	-0.11	-0.21

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 equity holders of the parent company.

# **Condensed consolidated balance sheet**

SEKK	Jun 30, 2022	Jun 30, 2021	Dec 31, 2021
ASSETS			
Fixed assets			
Tangible fixed assets			
Equipment, tools and installations	545	720	639
Total tangible fixed assets	545	720	639
Right-of-use assets	984	2,056	1,520
Financial assets			
Other financial assets	1	1	1
Total financial assets	1	1	1
Total fixed assets	1,530	2,777	2,160
Current assets			
Current receivables	2.007	2.040	0.400
Other current receivables Prepaid expenses and accrued income	2,906 7,362	2,010 16,719	2,400 12,187
Cash and cash equivalents	395,570	478,792	428,449
Total current receivables	405,838	497,521	443,036
Total culterit receivables	403,636	477,321	443,030
Total current assets	405,838	497,521	443,036
TOTAL ASSETS	407,368	500,298	445,196
EQUITY AND LIABILITIES			
Equity			
Share capital	10,654	10,654	10,654
Additional paid-in capital	863,534	863,174	863,433
Retained earnings (including profit/loss for the period)	-480,677	-388,998	-440,048
Total equity attributable to the shareholders of the parent company	393,511	484,830	434,039
Provisions			
Other provisions	62	-	116
Total provisions	62	-	116
Liabilities			
Non-current liabilities			
Non-current lease liabilities	_	1,305	475
Total non-current liabilities	-	1,305	475
Current liabilities			
Current lease liabilities	737	516	807
Account payables	9,126	9,127	4,497
Other current liabilities	925	1,132	1,693
Accrued expenses and deferred income	3,007	3,389	3,569
Total current liabilities	13,795	14,163	10,566
Total liabilities	13,795	15,467	11,041
TOTAL EQUITY AND LIABILITIES	407,368	500,298	445,196

# Condensed consolidated statement of changes in equity

	Equity attributable to the equity holders of the parent company					
SEKK	Share capital	Additional paid in capital	Retained earnings, including loss for the period	Total equit		
Opening balance, January 1, 2021	1,776	384,557	-337,005	49,32		
Profit/loss for the period equal to total comprehensive income	-	=	-51,993	-51,99		
Total comprehensive income for the year	-	-	-51,993	-51,99		
Transactions with shareholders of the parent company:						
Issue of shares	8,878	523,809	=	532,68		
Transaction costs	-	-45,192		-45,19		
Total transactions with shareholders of the parent company	8,878	478,617	-	487,49		
Closing balance, June 30, 2021	10,654	863,174	-388,998	484,830		
Opening balance, January 1, 2021	1,776	384,557	-337,005	49,32		
Profit/loss for the period equal to total comprehensive income	=	-	-103,043	-103,04		
Total comprehensive income for the year	-	-	-103,043	-103,04		
Transactions with shareholders of the parent company:						
Issue of shares	8,878	523,809	-	532,68		
Transaction costs Value of the employees' employment	_	-45,192 258	_	-45,19 25		
Total transactions with shareholders of the parent company	8,878	478,875		487,75		
Closing balance, December 31, 2021	10,654	863,433	-440,048	434,03		
Opening balance, January 1, 2022	10,654	863,433	-440,048	434,03		
Profit/loss for the period equal to total comprehensive income	_	-	-40,629	-40,62		
Total comprehensive income for the year	-	-	-40,629	-40,62		
Transactions with shareholders of the parent company:						
Value of the employees' employment	=	101	_	10		
Total transactions with shareholders of the parent company	-	101	-	10		
Closing balance, June 30, 2022	10,654	863,534	-480,677	393,51		

# **Condensed consolidated cash flow**

	Apr 1-Jun 30,	Apr 1-Jun 30,	Jan 1-Jun 30,	Jan 1-Jun 30,	Full year
SEKk	2022	2021	2022	2021	2021
Operating activities					
Operating result	-21,729	-42,619	-40,601	-51,939	-102,910
Adjustments for non-cash items:					
Depreciations/amortisations	314	317	630	634	1,252
Interest paid and received	-13	-	-28	-	-133
Income tax paid	-	-	-	-	_
Other adjustments	-31,204	8,368	-38,981	8,368	-11,907
Cash flow from operating activities before changes in working capital	-52,632	-33,934	-78,980	-43,937	-113,698
<b>.</b>					
Changes in working capital					
Decrease/Increase of current receivables	-1,959	-15,795	318	-14,791	-10,648
Decrease/Increase of current liabilities	1,588	4,669	3,230	4,133	288
Cash flow from changes in working capital	-371	-11,126	7,548	-10,658	-10,360
Cash flow from operating activities	-53,003	-45,060	-71,432	-53,595	-124,058
Investing activities					
Investments in tangible assets	_	_	_	_	_
Cash flow from investing activities	-	-	-	_	-
Financing activities					
Amortisation of lease liabilities	-191	-287	-475	-574	-1,103
Issues of shares, net after transaction costs	_	_	_	487,495	487,495
Cash flow from financing activities	-191	-287	-475	486,921	486,392
Cash flow for the period	-53,194	-45,347	-71,907	433,326	362,334
Decrease/increase of cash and cash equivalents	447.510	500 507	400.410	50.63	E0.001
Cash and cash equivalents at the beginning of the period	417,513	532,507	428,449	53,834	53,834
Currency translation difference in cash and cash equivalents	31,251	-8,368	39,028	-8,368	12,281
Cash and cash equivalents at the end of the period	395,570	478,792	395,570	478,792	428,449

# Statement of comprehensive income for the parent company

SEKk	Apr 1-Jun 30, 2022	Apr 1-Jun 30, 2021	Jan 1-Jun 30, 2022	Jan 1-Jun 30, 2021	Full year 2021
Revenues					
Net sales	2,853	2,184	5,670	5,661	10,176
Total revenues	2,853	2,184	5,670	5,661	10,176
Operating expenses					
Other external expenses	-3,309	-2,592	-6,189	-5,370	-10,691
Personnel costs	-1,157	-1,785	-2,616	-3,273	-6,718
Depreciations/amortisations of tangible fixed assets and right-of-use assets	-45	-49	<b>-94</b>	-98	-179
Total expenses	-4,512	-4,426	-8,899	-8,741	-17,588
Operating loss	-1,659	-2,242	-3,229	-3,080	-7,412
Net financial items					
Write-down of financial assets	-28	-100,000	-47	-100,000	-200,097
Financial costs	-	-	-	_	-37
Total net financial items	-28	-100,000	-47	-100,000	-200,134
Profit or loss before tax	-1,686	-102,242	-3,276	-103,080	-207,546
Taxes for the period	-	-	-	-	-
PROFIT OF LOSS FOR THE PERIOD	4 (0)	400.010	0.674	400.000	007.511
PROFIT OR LOSS FOR THE PERIOD	-1,686	-102,242	-3,276	-103,080	-207,546

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

# **Balance sheet for the parent company**

SEKK	Jun 30, 2022	Jun 30, 2021	Dec 31, 2021
ASSETS			
Fixed assets			
Tangible fixed assets			
Equipment, tools and installations	545	720	639
Total tangible fixed assets	545	720	639
Financial assets Shares in subsidiary	247,030	247,030	247,030
Total financial assets	247,030	247,030	247,030
Total manetal assets	247,030	247,030	247,030
Total fixed assets	247,575	247,750	247,669
Current assets			
Current receivables			
Intercompany receivables	226,204	286,036	196,921
Other receivables	1,728	1,125	1,237
Prepaid expenses and accrued income	530	521	410
Total current receivables	228,462	287,682	198,568
Cash and cash equivalents	65,812	114,107	99,793
Total current assets	294,274	401,789	298,361
TOTAL ASSETS	541,849	649,539	546,030
FOURTY AND LIABILITIES			
EQUITY AND LIABILITIES Equity			
Restricted equity			
Share capital	10,654	10,654	10,654
Total restricted equity	10,654	10,654	10,654
, ,			
Non-restricted equity			
Share premium reserve	1,109,249	1,108,891	1,109,148
Retained earnings	-576,561	-369,014	-369,014
Profit or loss for the period	-3,276	-103,080	-207,546
Total non-restricted equity	529,412	636,796	532,587
Total equity	540,066	647,451	543,241
Provisions			
Other provisions	38	-	71
Total provisions	38	-	71
Liabilities			
Liabilities  Current liabilities			
Accounts payable	168	428	446
Other liabilities	297	264	462
Accrued expenses and deferred income	1,280	1,396	1,810
Total current liabilities	1,745	2,088	2,718
TOTAL EQUITY AND LIABILITIES	541,849	649,539	546,030

# Statement of change in equity parent company

	Restricted equity	Non-	restricted equit	:y	
SEKK	Share capital	Share premium	Retained earnings	Net result	Total equity
Opening balance, January 1, 2021	1,776	630,274	-312,989	-56,025	263,036
Disposition of last year's result	-	_	-56,025	56,025	-
Net results and total comprehensive income for the year	-	-	-	-103,080	-103,080
Total comprehensive income for the year	-	-	_	-103,080	-103,080
Transactions with shareholders of the parent company:					
Issue of shares	8,878	523,809	-	_	532,687
Transaction costs		-45,192	_	_	-45,192
Total transactions with shareholders of the parent company	8,878	478,617	-	-	487,495
Closing balance, June 30, 2021	10,654	1,108,891	-369,014	-103,080	647,451
Opening balance, January 1, 2021	1,776	630,274	-312,989	-56,025	263,036
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 for the year	-	-	-	-207,546	-207,546
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  Total transactions with shareholders of the parent company	8,878	258 <b>478,875</b>			258 <b>487,753</b>
Closing balance, December 31, 2021	10,654	1,109,148	-369,014	-207,546	543,241
Opening balance, January 1, 2022	10,654	1,109,148	-369,014	-207,546	543,241
Disposition of last year's result	-	_	-207 546	207 546	-
Net results and total comprehensive income for the year	-	_	_	-3,276	-3,276
Total comprehensive income for the year	-	-	-	-3,276	-3,276
Transactions with shareholders of the parent company:		404			40.0
Value of the employees' employment	=	101	_	=	101
Total transactions with shareholders of the parent company	-	101	_	_	101
Closing balance, June 30, 2022	10,654	1,109,249	-576,561	-3,276	540,066

# Statement of cash flow for the parent company

SEKK	Apr 1-Jun 30, 2022	Apr 1-Jun 30, 2021	Jan 1-Jun 30, 2022	Jan 1-Jun 30, 2021	Full year 2021
Operating activities					
Profit or loss before tax	-1,686	-102,242	-3,276	-103,080	-207,546
Adjustments for non-cash items:	,	- ,	-,	,	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Write downs	28	100,000	47	100,000	200,097
Income tax paid	_	· –	_	-	_
Depreciations/amortisations	45	49	94	98	179
Other adjustments	60	-	68	=	328
Cash flow from operating activities before changes in working capital	-1,553	-2,193	-3,067	-2,982	-6,942
Changes in working capital					
Changes in current receivables	-13,873	60,609	-29,894	-285,438	-196,323
Changes in current liabilities	-1,324	-3,155	-973	-30,459	-29,830
Cash flow from changes in working capital	-15,197	57,454	-30,867	-315,897	-226,153
Cash flow from operating activities	-16,750	55,261	-33,934	-318,879	-233,095
Investing activities					
Shareholder's contribution	-27	-100,000	-47	-100,000	-200,097
Investment of leases	_	_	_	_	-
Cash flow from investing activities	-27	-100,000	-47	-100,000	-200,097
Financing activities					
Issues of shares, net after transaction costs	_	_	_	487,495	487,495
Cash flow from financing activities	-	-	-	487,495	487,495
Cash flow for the period	-16,777	-44,739	-33,981	68,616	54,302
Decrease/increase in cash and cash equivalents					
Cash and cash equivalents at the beginning of the period	82,589	158,846	99,793	45,491	45,491
Cash and cash equivalents at the end of the period	65,812	114,107	65,812	114,107	99,793
out and out of characters at the one of the period	00,012	117,107	00,012	117,107	,,,,,,

# **Development of parent company's share capital**

SEK		Change in	Total	Number of	Total number	Paid in
Date	Transaction	share capital	share capital	new shares	of shares	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

# Notes

## NOTE 1 GENERAL INFORMATION

This interim report includes the parent company InDex Pharmaceuticals Holding AB (publ), Corp. Reg. No. 559067-6820, the subsidiary InDex Pharmaceuticals AB and the sub-subsidiary InDex Diagnostics AB ('InDex', 'the company' or 'the group'). InDex Pharmaceuticals Holding AB (publ) is a parent company registered in Sweden with its registered office in Stockholm with the address Berzelius väg 13, 171 65 Solna, Sweden.

Unless otherwise stated, all amounts are in thousands of Swedish kronor (SEKk). Figures in parentheses refer to the comparative period.

#### FINANCIAL RISK MANAGEMENT

InDex may also need to raise additional capital in the future. Both the size and timing of InDex's possible need for capital in the future depend on several factors, including the possibility of entering into collaboration or licensing arrangements and the progress made in research and development projects. There is a risk that the necessary financing of the operations is unavailable at the right time and at a reasonable cost.

For a detailed description of significant risks, refer to InDex's annual report for 2021. The annual report is available on the company's website.

### ACCOUNTING POLICIES

InDex applies International Financial Reporting Standards (IFRS) as adopted by the EU. This report is prepared in accordance with IAS 34 Interim Financial Reporting and the Annual Accounts Act. The parent company prepares financial reports in accordance with the Swedish Financial Reporting Board's recommendation RFR 2 Accounting for Legal Entities and the Swedish Annual Accounts Act.

Applied accounting principles and calculation methods are the same as in the annual report for 2021.

None of the IFRS or IFRIC interpretations that have yet to come into legal effect are expected to have any significant impact on InDex.

NOTE 4 IMPORTANT ESTIMATES AND JUDGEMENTS

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.

# RISKS AND UNCERTAINTIES

## **OPERATIONAL RISK**

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 will obtain the necessary approvals to conduct the clinical trials that InDex would like to conduct, 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 pharmaceuticals 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.

# (iii) Estimates and assessments linked to development costs

An important assessment in financial reporting refers to the point in time for capitalizing pharmaceutical development costs. Based on the accounting policies set out under note 2 in the annual report for 2021, 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 OTHER OPERATING INCOME/OTHER OPERATING EXPENSES

Other operating expenses	_	_
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate*	-	-
Other operating income	7,839	31,803
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate*	7,777	31,251
Grants from Vinnova	62	552
SEKK	Jan-Mar 2022	Apr-Jun 2022

SEKK	Jan-Mar 2021	Apr-Jun 2021	Jul-Sep 2021	Oct-Dec 2021	Full year 2021
Grants from Vinnova	36	121	246	37	440
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate*	_	_	11,062	9,587	20,649
Other operating income	36	121	11,308	9,624	21,089
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate*	_	-8,368	-	_	-8,368
Other operating expenses	_	-8,368	_	-	-8,368

<sup>\*</sup> Revaluation of cash and cash equivalents at closing-day rate has been reported net in the accumulated period.

# NOTE 6 RELATED PARTY TRANSACTIONS

No related party transactions have occured from a group perspective.

InDex Pharmaceuticals Holding AB invoices InDex Pharmaceuticals AB for overall group functions.

# NOTE 7 EARNINGS PER SHARE

Earnings per share is calculated by dividing the result for the period by the weighted average number of outstanding ordinary shares during the period.

InDex had potential ordinary shares in the form of warrants. However, these did not give rise to any dilution effect in 2021 or 2022 as a conversion to ordinary shares decreases loss per share.

SEK million	Jan-Jun 2022	Jan-Jun 2021	Full year 2021
Net result attributable to the equity shareholders of the parent company	-40.6	-52.0	-103.0
Total:	-40.6	-52.0	-103.0
Weighted average number			
of shares (thousands)	532,688	465,280	483,365
Earnings per share, SEK	-0.08	-0.11	-0.21