

Interim report  
January-September 2023



# InDex Pharmaceuticals discontinues cobitolimod phase III program

## PERIOD JULY-SEPTEMBER 2023

- Net sales amounted to SEK 0.0 (0.0) million
- Operating loss amounted to SEK –42.1 (–4.5) million
- Result after tax amounted to SEK –37.9 (–3.5) million, corresponding to SEK –0.07 per share (–0.01) before and after dilution
- Cash flow from operating activities amounted to SEK –47.8 (–23.8) million

## SIGNIFICANT EVENTS DURING THE QUARTER

- A new patent has been granted in Europe for the commercial formulation of cobitolimod

## SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD

- InDex discontinues cobitolimod phase III program

## PERIOD JANUARY-SEPTEMBER 2023

- Net sales amounted to SEK 97.5 (0.0) million
- Operating result amounted to SEK 0.6 (–45.0) million
- Result after tax amounted to SEK 10.3 (–44.0) million, corresponding to SEK 0.02 per share (–0.08) before and after dilution
- Cash flow from operating activities amounted to SEK 9.0 (–95.2) million
- Cash and cash equivalents at the end of the period amounted to SEK 363.7 (398.3) 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

- The positive results from PK study with cobitolimod selected as one of the best abstracts for poster presentation at UEGW

All comparative amounts in brackets refer to the outcome during the corresponding period 2022.

*“This surprising and disappointing news confirms the complexity of the disease and the need for further research within this field, especially as moderate to severe ulcerative colitis is an indication with high unmet medical need for new treatment options. We are incredibly grateful to all the patients, investigators and study personnel for their engagement to date. We will conduct a comprehensive analysis of all the study data before announcing next steps,” said Jenny Sundqvist, CEO of InDex Pharmaceuticals.*

InDex Pharmaceuticals has a vision to help patients with immunological diseases where there is a high unmet medical need. The company is focusing on the drug candidate cobitolimod, a first in class mode-of-action, with the aim to offer an effective and safe treatment option. Cobitolimod was being evaluated in the phase III program CONCLUDE for moderate to severe left-sided ulcerative colitis – a debilitating, chronic inflammation of the large intestine. InDex Pharmaceuticals is based in Stockholm, Sweden. The company’s shares (ticker INDEX) are traded on Nasdaq First North Growth Market Stockholm.

# CEO statement

Clearly, anything that happened in Q3 feels rather insignificant in light of the advice we received from the Data Monitoring Committee (DMC) on Nov 21 that we should stop Induction Study 1 of the CONCLUDE phase III program. We have therefore decided to discontinue our ongoing phase III program.

Our dose selection analysis served, among other things, the purpose of being able to stop the study if there was a low likelihood of cobitolimod (irrespective of dose) showing a statistically significant benefit over placebo in terms of clinical remission at study completion.

The news that DMC advises that we stop the study reached us a couple of days ago, so we are still in shock, truly disappointed and surprised.

It is important to note that we will not make any decisions on next steps until we fully understand the reason for the DMC advice. We do not want to rush to any conclusions, and we have seen many examples of companies changing their view on a study or compound after having analyzed and understood data.

What happens now?

No more doses (neither cobitolimod nor placebo) will be administered to patients in the phase III program. The study will be unblinded and all patients will be followed up as per protocol. All available data will be collected and quality controlled. After that, we will analyze the data and ensure we understand it completely before making any decisions on how to proceed. At this point, it serves no purpose to speculate what might be the reason for the DMC outcome or what we shall do next.

Approximately 40% of phase III trials fail. It varies somewhat by therapy area and company, but failure happens both at small biotechs and big pharma. If we knew the outcome of a phase III trial, we would not have to do it. This shows the true complexity and challenge of drug development.

It is heartbreaking to see what so many co-workers, patients, medical staff and partners have hoped for not pan out as we wished. All data from the around 400 patients treated with cobitolimod to date pointed to an efficacious and safe treatment, so this result was not expected.

I want to extend my sincere gratitude to everyone who has devoted their dedication, grit and perseverance to date.



Jenny Sundqvist, CEO

# Business overview

## INTRODUCTION

InDex Pharmaceuticals has a vision to help patients with immunological diseases where there is a high unmet medical need. The company is focusing on the drug candidate cobitolimod, a first in class mode-of-action, with the aim to offer an effective and safe treatment option. Cobitolimod was being evaluated in the phase III program CONCLUDE for moderate to severe left-sided ulcerative colitis – a debilitating, chronic inflammation of the large intestine. InDex Pharmaceuticals is based in Stockholm, Sweden. The company's shares (ticker INDEX) are traded on Nasdaq First North Growth Market Stockholm.

## COBITOLIMOD

Ulcerative colitis is a chronic disease with no cure 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 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, many patients with ulcerative colitis still suffer from severe symptoms, and current therapies can cause serious side effects. For those patients who 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 is administered directly to the inflamed colon using an enema without systemic exposure and off-target effects.

Cobitolimod met the primary endpoint in the phase IIb study CONDUCT and data from four previously completed placebo-controlled clinical trials support the efficacy and safety demonstrated in the CONDUCT study. Cobitolimod was being evaluated in the pivotal phase III program CONCLUDE as a novel treatment for moderate to severe left-sided ulcerative colitis. Phase III is the final stage of clinical development before application for market approval can be submitted to regulatory authorities.

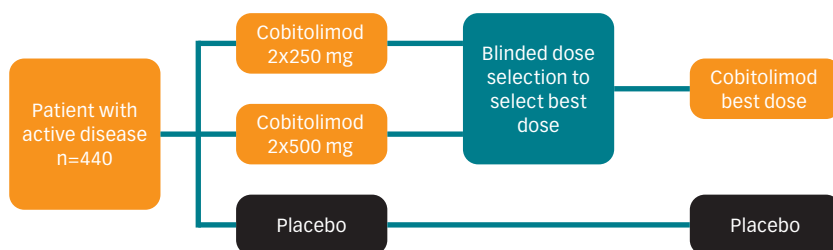
## Phase III program – CONCLUDE

Based on regulatory guidance InDex was conducting a phase III program consisting of two sequential induction studies which both fed into a maintenance study, in which patients who had responded to cobitolimod as induction therapy, received maintenance treatment with cobitolimod or placebo.

Induction Study 1 of the CONCLUDE program was planned to include approximately 440 patients and was being conducted in 30 countries in Europe, the Americas and the Asia-Pacific region. Induction Study 1 was 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 was clinical remission at week 6. In the first part of the study, two doses of cobitolimod were evaluated in an adaptive study design, 250 mg x 2, which was the highest dose and the dose that showed the best efficacy in the phase IIb study CONDUCT, and a higher dose of 500 mg x 2. After the first 133 patients (i.e., approximately 30% of the total 440 patient enrollment in Induction Study 1) had completed Induction Study 1, a dose selection analysis was performed by an independent Data Monitoring Committee (DMC) consisting of external and

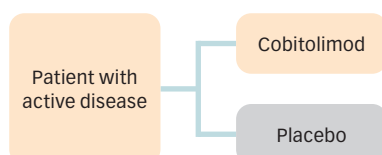
## PHASE III DESIGN

### Induction Study 1 – adaptive design, 6 weeks/patient (stopped)



- Moderate to severe, left-sided ulcerative colitis
- Have 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, 46 weeks/patient (stopped)



\* Induction Study 2 was planned to be initiated upon a positive result in Induction Study 1.

independent experts in the field. As part of the analysis, the DMC performed a safety review and a futility assessment based on the primary endpoint clinical remission at week 6. A futility assessment is performed to stop a trial if the chance for a significant primary endpoint at the end of the study is too low. The DMC advised that cobitolimod was unlikely to meet the primary endpoint upon completion of Induction Study 1. The advice to stop the study was not based on safety concerns. InDex discontinues the phase III program according to DMC's recommendation. More information regarding next steps will be provided once a thorough analysis of the data from Induction Study 1 has been completed.

#### **SIGNIFICANT EVENTS DURING THE QUARTER**

- InDex announced on August 2, 2023 that a new formulation patent for the drug candidate cobitolimod has been granted by the European Patent Office. The patent provides protection of the enema formulation of cobitolimod, that is currently under evaluation in the ongoing phase III program CONCLUDE. The patent will provide an exclusivity period until September 2042, with the possibility of up to five years extension upon market approval.

#### **SIGNIFICANT EVENTS AFTER THE REPORTING PERIOD**

- InDex announced on November 21, 2023 that an independent Data Monitoring Committee advises that cobitolimod is unlikely to meet the primary endpoint upon completion of Induction Study 1. The advice to stop the study was not based on safety concerns. InDex discontinues the phase III program according to DMC's recommendation. More information regarding next steps will be provided once a thorough analysis of the data from Induction Study 1 has been completed.

#### **OTHER EVENTS**

- InDex announced on August 22, 2023 that the positive results from the pharmacokinetic (PK) study with cobitolimod in patients with moderate to severe ulcerative colitis will be presented at one of the leading gastroenterology conferences, the United European Gastroenterology Week (UEGW). The abstract was selected as one of the best abstracts for poster presentation and was therefore also chosen to be presented orally in one of the moderated poster sessions.

# 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 JULY-SEPTEMBER 2023

Net sales for the period July to September 2023 amounted to SEK 0.0 (0.0) million.

Other operating income SEK 0.0 (26.8) million refers mainly to foreign exchange gains of SEK 0.0 (26.6) million related to cash and cash equivalents in foreign currency.

Operating expenses for the period amounted to SEK 42.1 (31.3) million. The increase is attributable to higher costs for Induction Study 1 of the phase III program CONCLUDE.

Other operating expenses SEK 0.7 (0.0) million refers foreign exchange losses of SEK 0.7 (0.0) million related to cash and cash equivalents in foreign currency.

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

Costs for the personnel during the reporting period amounted to SEK 3.5 (3.0) million. The increase is partly related to general salary increases.

InDex has during the period accrued interest income of SEK 4.1 (1.0) million related to cash and cash equivalents in foreign currency.

Cash and cash equivalents as of September 30, 2023 amounted to SEK 363.7 million, which is SEK 48.8 million lower than as of June 30, 2023.

## FINANCIAL DEVELOPMENT DURING JANUARY-SEPTEMBER 2023

Net sales for the period January to September 2023 amounted to SEK 97.5 (0.0) million. Net sales originate from the upfront fee from Viatrix Japan related to the out-licensing of cobitolimod in Japan. For additional information see Note 5.

Other operating income SEK 10.5 (66.4) million refers mainly to foreign exchange gains of SEK 10.5 (65.6) million related to cash and cash equivalents in foreign currency.

Operating expenses for the period amounted to SEK 107.5 (111.4) million. The decrease is attributable to lower costs for Induction Study 1 of the phase III program CONCLUDE during the period.

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 9.7 (10.3) million. The decrease is partly related to fewer number of employees during the period and general salary increases.

InDex has during the period accrued interest income of SEK 9.9 (1.0) million related to cash and cash equivalents in foreign currency.

Cash and cash equivalents as of September 30, 2023 amounted to SEK 363.7 million, which is SEK 18.8 million higher than as of December 31, 2022.

## FINANCIAL SUMMARY AFTER THE REPORTING PERIOD

The Board assess that there is no impact on the company's financial position as of September 30, 2023, due to events after the reporting period.

Events after the reporting period will be assessed during the fourth quarter 2023 and potential impacts on the company's financial position will be reported per December 31, 2023.

## EXPECTED FUTURE DEVELOPMENT

The company's cash and cash equivalents as of November 24, 2023 amounts to SEK 319.0 million. Quantification of costs for closing the phase III program CONCLUDE and other running costs is ongoing.

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.

## PARENT COMPANY

The net sales amounted to SEK 9.9 (8.2) million during the period January to September 2023 and consisted of invoicing of group wide expenses to InDex Pharmaceuticals AB.

The operating expenses amounted to SEK 15.5 (12.8) million and consisted of personnel expenses and other operating expenses relating to the administration of InDex.

## FINANCIAL SUMMARY

SEK million	Jul-Sep 2023	Jul-Sep 2022	Jan-Sep 2023	Jan-Sep 2022	Full year 2022
Net sales	–	–	97.5	–	–
Operating result	–42.1	–4.5	0.6	–45.0	–103.2
Result after tax	–37.9	–3.5	10.3	–44.0	–100.3
Earnings per share before and after dilution, SEK	–0.07	–0.01	0.02	–0.08	–0.19
Cash flow from operating activities	–47.8	–23.8	9.0	–95.2	–129.4
Cash and cash equivalents at the end of the period	363.7	398.3	363.7	398.3	344.9

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.

### LARGEST SHAREHOLDERS PER SEPTEMBER 30, 2023

	Number of shares	Percentage of capital and votes, %
Linc AB	69,920,567	13.1
Fjärde AP-fonden	52,314,074	9.8
HBM Healthcare Investments	51,300,670	9.6
Avanza Pension	23,469,315	4.4
SEB Life International	21,287,104	4.0
SEB-Stiftelsen	19,047,617	3.6
Staffan Rasjö	17,048,939	3.2
Stiftelsen Industrifonden	12,865,296	2.4
Swedbank försäkring AB	12,224,919	2.3
Nordnet Pensionsförsäkring	10,643,586	2.0
S-E-Bankens Utvecklingsstiftelse	10,000,000	1.9
Originat AB	7,000,000	1.3
Ponderus Invest AB	6,319,085	1.2
Försäkringsbolaget Skandia	5,679,043	1.1
Edward Thornberg	4,620,544	0.9
Other	208,946,891	39.2
<b>Total</b>	<b>532,687,650</b>	<b>100.0</b>

## INCENTIVE PROGRAMMES

### LTIP 2020

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.

The total number of outstanding warrants to employees and other key persons within InDex amounts 832,276 at end of the reporting period. LTIP 2020 expired on October 31, 2023 and no warrants were exercised.

### 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 total number of outstanding employee stock options to employees and other key persons within InDex amounts 3,517,867 at end of the reporting period. Remaining employee stock options have been terminated.

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. In December 2022 the Board allocated an additional 1,930,700 employee stock options to the incoming CEO, which were subscribed in January 2023.

The total number of outstanding employee stock options to employees and other key persons within InDex amounts 5,982,600 at end of the reporting period. Remaining employee stock options have been terminated.

LTIP 2022 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 2023**

At the annual general meeting held on May 24, 2023 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 2026. In July 2023 the Board allocated 6,658,600 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 not allocated during 2023 will be terminated together with the employee stock options not to be vested.

LTIP 2023 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.

**REVIEW BY THE AUDITOR**

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

**FINANCIAL CALENDER**

Year-end report 2023

February 21, 2024

Stockholm, November 28, 2023

Jenny Sundqvist, CEO

**FOR MORE INFORMATION, PLEASE CONTACT:**

Jenny Sundqvist, CEO

Phone: +46 (0) 8 122 038 50

Email: [jenny.sundqvist@indexpharma.com](mailto:jenny.sundqvist@indexpharma.com)

Johan Giléus, CFO and Deputy CEO

Phone: +46 (0) 8 122 038 50

Email: [johan.gileus@indexpharma.com](mailto:johan.gileus@indexpharma.com)

InDex Pharmaceuticals Holding AB (publ)

Berzelius väg 13, 171 65 Solna, Sweden

[www.indexpharma.com](http://www.indexpharma.com)

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 November 28, 2023 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

SEKK	Note	Jul 1-Sep 30, 2023	Jul 1-Sep 30, 2022	Jan 1-Sep 30, 2023	Jan 1-Sep 30, 2022	Full year 2022
<b>Revenues</b>						
Net sales	5	–	–	97,505	–	–
Other operating income	6	–	26,791	10,522	66,433	47,887
<b>Total revenues</b>		<b>–</b>	<b>26,791</b>	<b>108,027</b>	<b>66,433</b>	<b>47,887</b>
<b>Operating expenses</b>						
Raw material and consumables		–1,560	–409	–3,036	–10,260	–10,287
Other external expenses		–35,967	–27,720	–93,861	–90,109	–126,530
Personnel costs		–3,527	–2,991	–9,662	–10,314	–13,231
Depreciations/amortisations of tangible fixed assets and right-of-use assets		–304	–132	–912	–761	–1,066
Other operating expenses	6	–701	–	–	–	–
<b>Total expenses</b>		<b>–42,059</b>	<b>–31,252</b>	<b>–107,472</b>	<b>–111,444</b>	<b>–151,114</b>
<b>Operating result</b>		<b>–42,059</b>	<b>–4,461</b>	<b>554</b>	<b>–45,011</b>	<b>–103,227</b>
<b>Result from financial investments</b>						
Financial income		4,124	1,032	9,876	1,032	3,013
Financial expenses		–	–23	–178	–52	–120
<b>Financial items – net</b>		<b>4,124</b>	<b>1,009</b>	<b>9,698</b>	<b>980</b>	<b>2,893</b>
<b>Earnings before tax</b>		<b>–37,935</b>	<b>–3,452</b>	<b>10,253</b>	<b>–44,031</b>	<b>–100,333</b>
Taxes for the period		–	–	–	–	–
<b>RESULT FOR THE PERIOD</b>		<b>–37,935</b>	<b>–3,452</b>	<b>10,253</b>	<b>–44,031</b>	<b>–100,333</b>

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

SEK	Note	Jul 1-Sep 30, 2023	Jul 1-Sep 30, 2022	Jan 1-Sep 30, 2023	Jan 1-Sep 30, 2022	Full year 2022
Earnings per share before and after dilution	8	–0.07	–0.01	0.02	–0.08	–0.19

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	Sep 30, 2023	Sep 30, 2022	Dec 31, 2022
<b>ASSETS</b>			
<b>Fixed assets</b>			
<i>Tangible fixed assets</i>			
Equipment, tools and installations	318	500	454
<b>Total tangible fixed assets</b>	<b>318</b>	<b>500</b>	<b>454</b>
<b>Right-of-use assets</b>	<b>2,759</b>	<b>3,793</b>	<b>3,535</b>
<i>Financial assets</i>			
Other financial assets	1	1	1
<b>Total financial assets</b>	<b>1</b>	<b>1</b>	<b>1</b>
<b>Total fixed assets</b>	<b>3,078</b>	<b>4,294</b>	<b>3,990</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Other current receivables	1,806	2,878	2,129
Prepaid expenses and accrued income	20,539	1,460	286
Cash and cash equivalents	363,717	398,263	344,931
<b>Total current receivables</b>	<b>386,062</b>	<b>402,601</b>	<b>347,346</b>
<b>Total current assets</b>	<b>386,062</b>	<b>402,601</b>	<b>347,346</b>
<b>TOTAL ASSETS</b>	<b>389,140</b>	<b>406,895</b>	<b>351,336</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
Share capital	10,654	10,654	10,654
Additional paid-in capital	863,876	863,669	863,686
Retained earnings (including profit/loss for the period)	-530,128	-484,138	-540,381
<b>Total equity attributable to the shareholders of the parent company</b>	<b>344,402</b>	<b>390,185</b>	<b>333,959</b>
<b>Provisions</b>			
Other provisions	15	22	16
<b>Total provisions</b>	<b>15</b>	<b>22</b>	<b>16</b>
<b>Liabilities</b>			
<i>Non-current liabilities</i>			
Non-current lease liabilities	1,862	2,871	2,626
<b>Total non-current liabilities</b>	<b>1,862</b>	<b>2,871</b>	<b>2,626</b>
<i>Current liabilities</i>			
Current lease liabilities	700	637	626
Account payables	26,578	5,374	6,561
Other current liabilities	2,026	977	689
Accrued expenses and deferred income	13,557	6,829	6,859
<b>Total current liabilities</b>	<b>42,861</b>	<b>13,817</b>	<b>14,735</b>
<b>Total liabilities</b>	<b>44,723</b>	<b>16,688</b>	<b>17,361</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>389,140</b>	<b>406,895</b>	<b>351,336</b>

# Condensed consolidated statement of changes in equity

SEKK	Equity attributable to the equity holders of the parent company			
	Share capital	Additional paid in capital	Retained earnings, including loss for the period	Total equity
<b>Opening balance, January 1, 2022</b>	<b>10,654</b>	<b>863,433</b>	<b>-440,048</b>	<b>434,039</b>
Profit/loss for the period equal to total comprehensive income	-	-	-44,031	-44,031
<b>Total comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>-44,031</b>	<b>-44,031</b>
<b>Transactions with shareholders of the parent company:</b>				
Value of the employees' employment	-	177	-	177
<b>Total transactions with shareholders of the parent company</b>	<b>-</b>	<b>177</b>	<b>-</b>	<b>177</b>
<b>Closing balance, September 30, 2022</b>	<b>10,654</b>	<b>863,610</b>	<b>-484,079</b>	<b>390,185</b>
<b>Opening balance, January 1, 2022</b>	<b>10,654</b>	<b>863,433</b>	<b>-440,048</b>	<b>434,039</b>
Profit/loss for the period equal to total comprehensive income	-	-	-100,333	-100,333
<b>Total comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>-100,333</b>	<b>-100,333</b>
<b>Transactions with shareholders of the parent company:</b>				
Value of the employees' employment	-	253	-	253
<b>Total transactions with shareholders of the parent company</b>	<b>-</b>	<b>253</b>	<b>-</b>	<b>253</b>
<b>Closing balance, December 31, 2022</b>	<b>10,654</b>	<b>863,686</b>	<b>-540,381</b>	<b>333,959</b>
<b>Opening balance, January 1, 2023</b>	<b>10,654</b>	<b>863,686</b>	<b>-540,381</b>	<b>333,959</b>
Profit/loss for the period equal to total comprehensive income	-	-	10,253	10,253
<b>Total comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>10,253</b>	<b>10,253</b>
<b>Transactions with shareholders of the parent company:</b>				
Value of the employees' employment	-	191	-	191
<b>Total transactions with shareholders of the parent company</b>	<b>-</b>	<b>191</b>	<b>-</b>	<b>191</b>
<b>Closing balance, September 30, 2023</b>	<b>10,654</b>	<b>863,876</b>	<b>-530,128</b>	<b>344,402</b>

# Condensed consolidated cash flow

SEKK	Jul 1-Sep 30, 2023	Jul 1-Sep 30, 2022	Jan 1-Sep 30, 2023	Jan 1-Sep 30, 2022	Full year 2022
<b>Operating activities</b>					
Operating result	-42,059	-4,461	554	-45,011	-103,227
<i>Adjustments for non-cash items:</i>					
Depreciations/amortisations	304	132	912	761	1,066
Interest paid and received	4,124	-	9,698	-	2,893
Income tax paid	-	-	-	-	-
Other adjustments	743	-25,439	-10,333	-65,072	-46,517
<b>Cash flow from operating activities before changes in working capital</b>	<b>-36,888</b>	<b>-29,768</b>	<b>831</b>	<b>-108,749</b>	<b>-145,783</b>
<b>Changes in working capital</b>					
Decrease/Increase of current receivables	-10,825	5,930	-19,930	10,249	12,172
Decrease/Increase of current liabilities	-82	22	28,126	3,251	4,169
<b>Cash flow from changes in working capital</b>	<b>-10,907</b>	<b>5,952</b>	<b>8,196</b>	<b>13,500</b>	<b>16,341</b>
<b>Cash flow from operating activities</b>	<b>-47,795</b>	<b>-23,816</b>	<b>9,027</b>	<b>-95,249</b>	<b>-129,442</b>
<b>Financing activities</b>					
Amortisation of lease liabilities	-260	-98	-764	-573	-818
<b>Cash flow from financing activities</b>	<b>-260</b>	<b>-98</b>	<b>-764</b>	<b>-573</b>	<b>-818</b>
<b>Cash flow for the period</b>	<b>-48,055</b>	<b>-23,914</b>	<b>8,263</b>	<b>-95,822</b>	<b>-130,260</b>
<b>Decrease/increase of cash and cash equivalents</b>					
Cash and cash equivalents at the beginning of the period	412,473	395,570	344,931	428,449	428,449
Currency translation difference in cash and cash equivalents	-701	26,607	10,522	65,636	46,742
<b>Cash and cash equivalents at the end of the period</b>	<b>363,717</b>	<b>398,263</b>	<b>363,717</b>	<b>398,263</b>	<b>344,931</b>

# Statement of comprehensive income for the parent company

SEKK	Jul 1-Sep 30, 2023	Jul 1-Sep 30, 2022	Jan 1-Sep 30, 2023	Jan 1-Sep 30, 2022	Full year 2022
<b>Revenues</b>					
Net sales	3,665	2,533	9,940	8,203	10,735
<b>Total revenues</b>	<b>3,665</b>	<b>2,533</b>	<b>9,940</b>	<b>8,203</b>	<b>10,735</b>
<b>Operating expenses</b>					
Other external expenses	-2,541	-2,883	-10,079	-9,071	-12,367
Personnel costs	-1,928	-988	-5,278	-3,605	-4,209
Depreciations/amortisations of tangible fixed assets and right-of-use assets	-45	-45	-136	-139	-184
<b>Total expenses</b>	<b>-4,514</b>	<b>-3,917</b>	<b>-15,493</b>	<b>-12,815</b>	<b>-16,760</b>
<b>Operating loss</b>	<b>-849</b>	<b>-1,383</b>	<b>-5,553</b>	<b>-4,612</b>	<b>-6,025</b>
<b>Net financial items</b>					
Write-down of financial assets	-34	-45	-50,099	-93	-108
Financial costs	-	-	-	-	-
Financial income	0	25	4	25	27
<b>Total net financial items</b>	<b>-34</b>	<b>-20</b>	<b>-50,096</b>	<b>-68</b>	<b>81</b>
<b>Profit or loss before tax</b>	<b>-883</b>	<b>-1,404</b>	<b>-55,649</b>	<b>-4,680</b>	<b>-6,106</b>
Taxes for the period	-	-	-	-	-
<b>PROFIT OR LOSS FOR THE PERIOD</b>	<b>-883</b>	<b>-1,404</b>	<b>-55,649</b>	<b>-4,680</b>	<b>-6,106</b>

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	Sep 30, 2023	Sep 30, 2022	Dec 31, 2022
<b>ASSETS</b>			
<b>Fixed assets</b>			
<i>Tangible fixed assets</i>			
Equipment, tools and installations	318	500	454
<b>Total tangible fixed assets</b>	<b>318</b>	<b>500</b>	<b>454</b>
<i>Financial assets</i>			
Shares in subsidiary	247,030	247,030	247,030
<b>Total financial assets</b>	<b>247,030</b>	<b>247,030</b>	<b>247,030</b>
<b>Total fixed assets</b>	<b>247,348</b>	<b>247,530</b>	<b>247,484</b>
<b>Current assets</b>			
<i>Current receivables</i>			
Intercompany receivables	229,962	234,371	247,536
Other receivables	503	779	1,335
Prepaid expenses and accrued income	717	1,886	457
<b>Total current receivables</b>	<b>231,182</b>	<b>236,792</b>	<b>249,328</b>
Cash and cash equivalents	6,561	56,872	42,490
<b>Total current assets</b>	<b>237,743</b>	<b>293,663</b>	<b>291,818</b>
<b>TOTAL ASSETS</b>	<b>485,091</b>	<b>541,194</b>	<b>539,302</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<i>Restricted equity</i>			
Share capital	10,654	10,654	10,654
<b>Total restricted equity</b>	<b>10,654</b>	<b>10,654</b>	<b>10,654</b>
<i>Non-restricted equity</i>			
Share premium reserve	1,109,594	1,109,325	1,109,401
Retained earnings	-582,666	-576,561	-576,560
Profit or loss for the period	-55,649	-4,680	-6,106
<b>Total non-restricted equity</b>	<b>471,279</b>	<b>528,085</b>	<b>526,734</b>
<b>Total equity</b>	<b>481,933</b>	<b>538,739</b>	<b>537,389</b>
<b>Provisions</b>			
Other provisions	6	11	7
<b>Total provisions</b>	<b>6</b>	<b>11</b>	<b>7</b>
<b>Liabilities</b>			
<i>Current liabilities</i>			
Accounts payable	887	609	861
Other liabilities	1,411	521	415
Accrued expenses and deferred income	854	1,314	630
<b>Total current liabilities</b>	<b>3,152</b>	<b>2,444</b>	<b>1,906</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>485,091</b>	<b>541,194</b>	<b>539,302</b>

# Statement of change in equity parent company

SEKK	Restricted equity	Non-restricted equity			Total equity
	Share capital	Share premium	Retained earnings	Net result	
<b>Opening balance, January 1, 2022</b>	<b>10,654</b>	<b>1,109,148</b>	<b>-369,014</b>	<b>-207,546</b>	<b>543,241</b>
Disposition of last year's result	-	-	-207,546	207,546	-
Net results and total comprehensive income for the year	-	-	-	-4,680	-4,680
<b>Total comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-4,680</b>	<b>-4,680</b>
<b>Transactions with shareholders of the parent company:</b>					
Value of the employees' employment	-	177	-	-	177
<b>Total transactions with shareholders of the parent company</b>	<b>-</b>	<b>177</b>	<b>-</b>	<b>-</b>	<b>177</b>
<b>Closing balance, September 30, 2022</b>	<b>10,654</b>	<b>1,109,325</b>	<b>-576,561</b>	<b>-4,680</b>	<b>538,739</b>
<b>Opening balance, January 1, 2022</b>	<b>10,654</b>	<b>1,109,148</b>	<b>-369,014</b>	<b>-207,546</b>	<b>543,241</b>
Disposition of last year's result	-	-	-207,546	207,546	-
Net results and total comprehensive income for the year	-	-	-	-6,106	-6,106
<b>Total comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-6,106</b>	<b>-6,106</b>
<b>Transactions with shareholders of the parent company:</b>					
Value of the employees' employment	-	253	-	-	253
<b>Total transactions with shareholders of the parent company</b>	<b>-</b>	<b>253</b>	<b>-</b>	<b>-</b>	<b>253</b>
<b>Closing balance, December 31, 2022</b>	<b>10,654</b>	<b>1,109,401</b>	<b>-576,560</b>	<b>-6,106</b>	<b>537,389</b>
<b>Opening balance, January 1, 2023</b>	<b>10,654</b>	<b>1,109,401</b>	<b>-576,560</b>	<b>-6,106</b>	<b>537,389</b>
Disposition of last year's result	-	-	-6,106	6,106	-
Net results and total comprehensive income for the year	-	-	-	-55,649	-55,649
<b>Total comprehensive income for the year</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-55,649</b>	<b>-55,649</b>
<b>Transactions with shareholders of the parent company:</b>					
Value of the employees' employment	-	192	-	-	192
<b>Total transactions with shareholders of the parent company</b>	<b>-</b>	<b>192</b>	<b>-</b>	<b>-</b>	<b>192</b>
<b>Closing balance, September 30, 2023</b>	<b>10,654</b>	<b>1,109,594</b>	<b>-582,666</b>	<b>-55,649</b>	<b>481,933</b>

# Statement of cash flow for the parent company

SEKK	Jul 1-Sep 30, 2023	Jul 1-Sep 30, 2022	Jan 1-Sep 30, 2023	Jan 1-Sep 30, 2022	Full year 2022
<b>Operating activities</b>					
Profit or loss before tax	-883	-1,404	-55,649	-4,680	-6,106
<i>Adjustments for non-cash items:</i>					
Write downs	34	45	50,099	93	108
Income tax paid	-	-	-	-	-
Depreciations/amortisations	45	45	136	139	185
Other adjustments	37	81	192	202	190
<b>Cash flow from operating activities before changes in working capital</b>	<b>-767</b>	<b>-1,233</b>	<b>-5,222</b>	<b>-4,246</b>	<b>-5,623</b>
<b>Changes in working capital</b>					
Changes in current receivables	-9,885	-8,330	18,146	-38,224	-50,760
Changes in current liabilities	-366	699	1,246	-274	-812
<b>Cash flow from changes in working capital</b>	<b>-10,251</b>	<b>-7,631</b>	<b>19,392</b>	<b>-38,498</b>	<b>-51,572</b>
<b>Cash flow from operating activities</b>	<b>-11,018</b>	<b>-8,864</b>	<b>14,170</b>	<b>-42,744</b>	<b>-57,195</b>
<b>Investing activities</b>					
Shareholder's contribution	-34	-76	-50,099	-177	-108
<b>Cash flow from investing activities</b>	<b>-34</b>	<b>-76</b>	<b>-50,099</b>	<b>-177</b>	<b>-108</b>
<b>Cash flow for the period</b>	<b>-11,052</b>	<b>-8,940</b>	<b>-35,929</b>	<b>-42,921</b>	<b>-57,303</b>
<b>Decrease/increase in cash and cash equivalents</b>					
Cash and cash equivalents at the beginning of the period	17,613	65,812	42,490	99,793	99,793
<b>Cash and cash equivalents at the end of the period</b>	<b>6,561</b>	<b>56,872</b>	<b>6,561</b>	<b>56,872</b>	<b>42,490</b>



# Development of parent company's share capital

SEK 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

# 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 (SEK). Figures in parentheses refer to the comparative period.

## NOTE 2 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 2022.

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 3 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.

## 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 2022. The annual report is available on the company's website.

## 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.

### (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 2022, 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 REVENUES FROM CONTRACTS WITH CUSTOMERS**

InDex net sales for the period January to September 2023 consisted of up-front fee from Viatrix Japan for the out-licensing of the commercial rights to cobiltolimod in Japan.

Revenue for out-licensing is reported when control over the intangible asset is transferred to the counterparty occurs, which was at the time when the agreement with Viatrix Japan was signed, i.e. May 31, 2023. Variable remuneration (for example, attributable to future milestones regarding completed development step or regulatory approval) is recognized when there is no longer any significant uncertainty as to whether these will occur.

Compensation attributable to sales-based milestones or royalties is not recognized until the commercial sales that results in the right to milestones or royalties arise.

InDex has identified one specific performance commitment under the license agreement related to the upfront fee of USD 10m – a pharmacokinetic study (PK study) in Japan with Japanese patients designed to show a pharmacokinetic profile comparable to that generated in the PK study conducted earlier by InDex with Swedish UC patients. The share of the upfront fee attributable to this performance commitment has not been recognized as revenues yet and has been calculated based on the estimated cost (USD 1m) to complete the study. The proportion recognized as revenues (USD 9m) during the period January to September 2023 has therefore been calculated as a residual of the transaction price after deduction of the cost related to the performance commitment.

**NOTE 6 OTHER OPERATING INCOME / OTHER OPERATING EXPENSES**

SEKK	Jan-Mar 2023	Apr-Jun 2023	Jul-Sep 2023
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate*	–	13,244	–
<b>Other operating income</b>	<b>–</b>	<b>13,244</b>	<b>–</b>
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate*	–2,022	–	–701
<b>Other operating expenses</b>	<b>–2,022</b>	<b>–</b>	<b>–701</b>

SEKK	Jan-Mar 2022	Apr-Jun 2022	Jul-Sep 2022	Oct-Dec 2022	Full year 2022
Grants from Vinnova	62	552	184	348	1,146
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate*	7,777	31,251	26,607	–	65,635
<b>Other operating income</b>	<b>7,839</b>	<b>31,803</b>	<b>26,791</b>	<b>348</b>	<b>66,781</b>
Revaluation of cash and cash equivalents in foreign currency at the closing-day rate*	–	–	–	–18,894	–18,894
<b>Other operating expenses</b>	<b>–</b>	<b>–</b>	<b>–</b>	<b>–18,894</b>	<b>–18,894</b>

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

**NOTE 7 RELATED PARTY TRANSACTIONS**

No related party transactions have occurred from a group perspective.

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

**NOTE 8 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 2022 or 2023 as a conversion to ordinary shares decreases loss per share.

SEK million	Jan-Sep 2023	Jan-Sep 2022	Full year 2022
Net result attributable to the equity shareholders of the parent company	10.3	-44.1	-100.3
<b>Total:</b>	<b>10.3</b>	<b>-44.1</b>	<b>-100.3</b>
<b>Weighted average number of shares (thousands)</b>	<b>532,688</b>	<b>532,688</b>	<b>532,688</b>
<b>Earnings per share, SEK</b>	<b>0.02</b>	<b>-0.08</b>	<b>-0.19</b>