

# INTERIM REPORT

January - June 2022

SYNACT  PHARMA

**Research** and  
**development** in  
inflammatory  
diseases

# Q2

This English version of SynAct Pharma's Interim Report has been prepared by the Company as a service to its non-Swedish stakeholders. In case of differences, the original Swedish report prevails.

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

# CONTENT

|  |    |
|--|----|
| Summary of interim report                | 3  |
| Significant events in the second quarter | 4  |
| CEO comments                             | 5  |
| Research and Development                 | 6  |
| SynAct Pharma AB in brief                | 9  |
| Financial development                    | 10 |
| Income statement                         | 11 |
| Report on financial position             | 12 |
| Report on changes in equity              | 13 |
| Report on cash flow                      | 14 |
| The parent company's income statement    | 15 |
| The parent company's balance sheet       | 16 |
| Notes and disclosures                    | 17 |
| Alternative performance measures         | 20 |
| The CEO declaration                      | 21 |
| Dictionary                               | 22 |
| Other company information                | 24 |

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Significant events in  
the second quarter  
of 2022

p. 4

CEO Jeppe Øvlesen  
comments on the  
second quarter

p. 5



SynAct Pharma is a clinical stage biotechnology company  
focused on resolving inflammation with melanocortin biology

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

# Interim report for the second quarter and first half of 2022



## Quarter 2 (April - June)

- The Group's net sales amounted to SEK 0 (0) thousand, which is in line with expectations given the phase the company's research portfolio is in. The Company is not expected to generate any revenues until after the completion of the clinical phase 2 program for the drug candidate AP1189 planned for the end of 2023.
- Operating expenses amounted to SEK 26,417 (15,603) thousand, an increase of 69%, driven both by increased investments in R&D and higher administrative costs for the application for listing on Nasdaq Stockholm.
- The Group's loss after tax amounted to SEK 24,754 (13,137) thousand.
- Profit after tax is improved by the effect that arises because of the Danish tax credit scheme, which means an early tax refund related to part of the research and development costs incurred. The effect of this tax credit was SEK 2,871 (2,719) thousand in the quarter.
- The Group's earnings per share before and after dilution amounted to SEK -0.91 (-0.51).
- Cash flow from operating activities amounted to SEK -36,922 (-16,114) thousand.
- Cash flow from financing activities amounted to SEK 125,158 (0) thousand.
- Cash flow for the period amounted to SEK 88,236 (-16,114) thousand.
- Cash and cash equivalents at the end of the period amounted to SEK 96,466 (62,532) thousand



## H1 (January - June)

- The Group's net sales amounted to SEK 0 (0) thousand.
- Operating expenses amounted to SEK 48,722 (29,661) thousand, an increase of 64%, driven both by increased investments in R&D and higher administrative costs for the application for listing on Nasdaq Stockholm and expenses related to the rights issue that was decided in the first quarter of 2022.
- The Group's loss after tax amounted to SEK 44,809 (24,872) thousand.
- Profit after tax is improved by the effect that arises because of the Danish tax credit scheme, which means an early tax refund related to part of the research and development costs incurred. The effect of this tax credit was SEK 5,133 (5,054) thousand in the first six months.
- The Group's earnings per share before and after dilution amounted to SEK -1.68 (-0.97).
- Cash flow from operating activities amounted to SEK -53,913 (-26,491) thousand.
- Cash flow from financing activities amounted to SEK 124,916 (74,400) thousand.
- Cash flow for the period amounted to SEK 71,003 (47,907) thousand.

## The Group's financial performance per quarter

| (SEK thousand)  | 2022 Q2 | 2022 Q1 | 2021 Q4 | 2021 Q3 | 2021 Q2 | 2021 Q1 |
|---|---------|---------|---------|---------|---------|---------|
| Net sales   | -       | -       | -       | -       | -       | -       |
| Operating income  | -26 417 | -22 304 | -26 153 | -20 885 | -15 603 | -14 058 |
| Profit before tax   | -27 625 | -22 317 | -26 207 | -20 676 | -15 856 | -14 070 |
| Profit for the period   | -24 754 | -20 055 | -26 210 | -18 222 | -13 137 | -11 735 |
| Total assets  | 133 972 | 22 155  | 38 369  | 59 836  | 75 273  | 88 945  |
| Equity / asset ratio (%) <sup>1</sup>                             | 77%     | 3%      | 54%     | 79%     | 87%     | 88%     |
| Earnings per share (SEK)  | -0,91   | -0,77   | -1,01   | -0,70   | -0,51   | -0,46   |
| Research & development cost / operating expenses (%) <sup>1</sup> | 54%     | 60%     | 77%     | 78%     | 83%     | 79%     |

1) Alternative performance measures - APM, ref. p. 20 for definitions



"SynAct Pharma AB" means the parent company SynAct Pharma AB with corporate registration number 559058-4826. The "Company" or "SynAct" means the Group i.e., SynAct Pharma AB and its wholly owned affiliate SynAct Pharma ApS. Numbers in this report are, with a few explicit exceptions, presented rounded to thousand SEK. Due to rounding, deviations (<1 TSEK) may occur in row totals.

## Significant events during the second quarter of 2022 and after the end of the reporting period



## The CEO, Jeppe Øvlesen comments on the second quarter

### Continued progress

### in the development

### of AP1189

**Boosted by the successful rights issue that was completed in the second quarter, SynAct continued to drive progress in its clinical development pipeline for AP1189 and deliver on the commitments on corporate activities.**

Shareholders continued to show support for the company, helping us raise SEK 150 million that allows us to plan for and finance the continued clinical program with AP1189 in rheumatoid arthritis (RA), development of AP1189 for kidney disease, explore new research into new molecules and cover general administration costs. This financing was critical for us to reach our full potential. We remain confident and are grateful for the trust given us.

SynAct submitted its clinical trial application (CTA) to enable the start of the Phase 2b study EXPAND with drug AP1189 in patients with newly diagnosed RA in the very near future.

The purpose of the EXPAND study is to confirm the encouraging effects of AP1189 demonstrated in the previous BEGIN study showing very good safety and a clinically meaningful effect on both primary and secondary efficacy readouts already after four weeks treatment. A major aim is to identify the full treatment potential of the compound, i.e. how large a proportion of patients that respond to the compound and to generate safety data during prolonged treatment of 12 weeks. This truly could be a gamechanger for the

management of RA, and we expect the study to be completed in the second half of 2023.

Before the end of the quarter, we announced that the Company was granted and received written response from the FDA on the request for a Type B pre-IND meeting on the planned development of AP1189 oral tablets for treatment of rheumatoid arthritis in patients with an inadequate response to methotrexate (DMARD-IR). The FDA's guidance is critical as it will help us align with the agency's expectations but is also valuable for discussions with potential partners. The response enables us to continue our preparations for the clinical Phase 2a/b study (RESOLVE) which we, subject to approval of the investigational new drug (IND) application, expect to initiate in the second half of 2022, according to plan.

The development program in RA for AP1189 is our top priority, but we are confident that AP1189 has a potential as a safe and effective treatment in kidney diseases associated with proteinuria and NS. During the quarter we therefore re-assessed and re-designed our clinical Phase 2a study in idiopathic membranous nephropathy (iMN) patients, (SynAct-CS003). Through the new design, when duly approved, we believe that recruitment to the study can be accelerated and hope to obtain proof-of-concept in a third disease for AP1189 during 2023.

The company hit another major milestone during the quarter when Nasdaq Stockholm approved SynAct for listing on the Main Market, and subsequently trading started on July 12. Moving to Nasdaq Stockholm's main list will help us take the company to the next level, giving us greater access to the Swedish and international capital markets as well as additional international and institutional investors. We listed on Spotlight Stock Market in 2016 and have had a fantastic journey for which I want to extend my sincere thanks and appreciation to our shareholders and to the Spotlight Group.

In the second quarter, our operating expenses were SEK 26.4 million, an increase by 69% from the same period last year. R&D investments were at SEK 14.3 million or +10% compared with the

second quarter 2021. We expect slightly higher costs for our R&D activities starting from the third quarter driven by the two new studies in RA.

Driven mainly by the Nasdaq uplift, our G&A expenses grew by SEK 9.4 million to SEK 12.1 million in the quarter. I expect significantly lower costs as we are now on Nasdaq.

With the proceeds from the rights issue, our cash-on-hand improved significantly, and we ended the quarter with approximately SEK 96 million which gives us a runway of approximately 18 months, to the end of 2023.

It was an incredibly busy period for us, and we are happy to see the company is progressing as planned. The programs are on time and our business development activities continue on an ongoing basis. SynAct is in a strong financial position with a strong pipeline, and we are all grateful for the support and look forward to the second half of the year.

**"SynAct is in a strong financial position with a strong pipeline, and we are all grateful for the support and look forward to the second half of the year."**

Jeppe Øvlesen  
CEO



## Research and Development

### Inflammation resolution

Inflammation is the immune system's way of responding to infections or injuries. Normally an inflammatory response is self-limiting. The immune system will "deactivate" itself and the inflammation will be resolved after the invading pathogen has been removed or the injury has begun to heal.

However, in some cases, the inflammation can be excessive or chronic and it can overwhelm the immune system's ability to resolve the inflammation. This can lead to pain, tissue destruction, and loss of function.

When the immune system is overwhelmed, therapies like AP1189 may help resolve inflammation by providing both anti-inflammatory activity and by triggering the immune system's natural inflammatory resolution mechanisms.

Most available treatments used to treat inflammation are immunosuppressive. They suppress the immune system by removing key signaling molecules or by depleting certain immune cells. Both strategies can lead to a heightened risk of serious infections and other significant side effects and safety issues. These therapies are anti-inflammatory, but they do not resolve the underlying uncontrolled inflammation.

SynAct seeks to stimulate the body's natural resolution mechanisms and resolve excessive inflammation without suppressing the immune system's ability to respond to new infections or injuries.

### Melanocortin biology

The melanocortin system is an ancient modulatory system comprising a family of 5 melanocortin receptors and a set of

naturally occurring melanocortin peptides that bind to and activate these receptors. The melanocortin receptors (MC1R-MC5R) are located on many cell types and are spread throughout most organs.

MC1R and MC3R are believed to be the key receptors involved in direct effects on the immune system and these receptors are located on immune cells and associated structural and supportive cells. When activated, MC1R and MC3R provide both direct anti-inflammatory effects, such as causing immune cells to produce fewer pro-inflammatory molecules and stimulating pro-resolution effects such as switching cells to perform inflammation 'cleanup' or regulatory functions. Through these dual effects, targeted melanocortin therapies can help the immune system resolve excessive or chronic inflammation.

## Pipeline overview

| ASSET                     | INDICATION  | PRECLINICAL    | PHASE 1 | PHASE 2A | PHASE 2B | PHASE 3 | MILESTONES  |
|---------------------------|---|----------------|---------|----------|----------|---------|---|
| AP1189                    | Rheumatoid arthritis<br>First line treatment in select patients | [Progress bar] |         |          |          |         | <ul style="list-style-type: none"> <li>Initiate study - H2 2022.</li> <li>Topline data available - H2 2023</li> </ul>   |
|                           | Rheumatoid arthritis<br>DMARD-IR                                | [Progress bar] |         |          |          |         | <ul style="list-style-type: none"> <li>File IND - H2 2022.</li> <li>Initiate study - H2 2022</li> <li>Dose range data (Part A) available - H2 2023</li> </ul> |
|                           | Nephrotic syndrome (iMN)  | [Progress bar] |         |          |          |         | <ul style="list-style-type: none"> <li>Implement redesign in ongoing Phase 2a - H2 2022</li> </ul>  |
|                           | Virus-induced respiratory insufficiency                         | [Progress bar] |         |          |          |         | <ul style="list-style-type: none"> <li>Data from viral disease models - H2 2022</li> </ul>  |
| Next generation molecules | Inflammatory diseases   | [Progress bar] |         |          |          |         |   |

MC2R also exerts anti-inflammatory effects but these effects are indirect. MC2R is predominantly located in the adrenal glands and its stimulation causes the adrenals to release cortisol, the body's 'natural' steroid—a powerful anti-inflammatory and immunosuppressive molecule. Some melanocortin peptides like adrenocorticotrophic hormone (ACTH) are potent MC2R activators and can cause significant safety, side effect, and tolerability issues that are common with steroid therapies like prednisone. SynAct's selective melanocortin agonists do not activate MC2R and do not cause cortisol release.

### **AP1189 - a selective, biased MC1R / MC3R agonist**

SynAct is developing selective melanocortin therapeutics to address inflammatory and autoimmune diseases characterized by excessive or chronic inflammation. SynAct's lead drug candidate, AP1189, is an oral selective melanocortin agonist that was designed to stimulate MC1R and MC3R, but not MC2R, to help resolve excessive inflammation without steroid side effect and safety issues. AP1189 is a biased agonist that stimulates MC1R and MC3R through the activation of the pERK signaling pathway rather than the cAMP pathway which is the classical approach. The cAMP pathway is believed to be responsible for certain off-target activity such as skin hyperpigmentation which are avoided with AP1189. Over stimulation of the cAMP pathway via MC1R has also been proposed as a potential risk factor for skin cancer.

The Company is evaluating AP1189 in three Phase 2 clinical programs: rheumatoid arthritis (RA), idiopathic membranous nephropathy (iMN), a form of nephrotic syndrome, and virus-induced respiratory insufficiency (VIRI) like that seen in COVID-19.

In 2021, SynAct successfully completed P2a trials in early severe RA and in hospitalized patients with COVID-19-induced respiratory insufficiency. Also in 2021, SynAct successfully tested a new oral solid tablet formulation of AP1189 in healthy volunteers and filed additional patents that should provide exclusivity past 2040.

### **Rheumatoid arthritis (RA)**

Rheumatoid arthritis (RA) is a chronic inflammatory disorder that typically affects more than just your joints. RA is an autoimmune disorder, a disease where the immune system mistakenly attacks your body's own tissues. RA affects the lining of the joints, causing a painful swelling that can result in cartilage and bone erosion and joint deformity. RA is often associated with symptoms involving other parts of the body including the skin, eyes, lungs, heart, and blood vessels. While new types of medications have improved treatment options, significant unmet needs still exist. For most patients, RA still progresses, and damage accumulates. Patients cycle through therapies and classes of therapies and must deal with periods of acute disease activity called flares, which can occur several times per year and drive the need to adjust the dose of current drugs or to change to a new therapy to maintain control of the disease.

### **Clinical development of AP1189 in RA**

In November 2021, SynAct announced results from the phase 2a study of AP1189 in newly diagnosed and previously untreated RA patients presenting with severe disease activity. The study, called BEGIN, was a randomized, double-blind, placebo controlled multicenter study in previous treatment naïve RA patients where either 50 mg or 100 mg of AP1189 or placebo was administered in addition to methotrexate (MTX). MTX is a disease modifying anti-rheumatic drug (DMARD) that is typically used as a first line therapy. MTX tends to work well in most patients, but it can take up to 6-8 weeks for the drug to take full effect, and up to 40% of patients will not achieve a full response to MTX therapy and will require dose escalation or the addition of additional drugs like biological therapies which can induce a higher degree of immunosuppression.

AP1189 given once-daily for four weeks was safe and well tolerated in the applied patient population. 100 mg of AP1189 demonstrated a statistically significant mean reduction in the clinical disease activity index (CDAI), the primary study endpoint, from baseline to four weeks that was more than 65% higher than the effect seen in the placebo-treated control group (mean reduction in CDAI: AP1189 100 mg (n=33): 15.5 points compared

with placebo (n=30): 9.3%, p = 0.0394). The 100 mg AP1189 group also demonstrated a significantly higher fraction of patients achieving ACR20 than placebo treated patients (ACR20: AP1189 (n=33) 100 mg: 60.6%; Placebo (n=30): 33.3%, P=0.0437) within the 4 weeks.

### **Continued development**

Based upon the results of the BEGIN RA study, the company intends to initiate two additional Phase 2 clinical studies in RA with AP1189 in 2022.

### **EXPAND - A 12-week P2b study of daily AP1189 in MTX-naïve patients with severe disease activity**

The EXPAND study is designed to test the treatment effect of 12-weeks of AP1189 on disease activity as measured by the ACR20 response rate as well as other RA disease measures and to confirm the safety profile of the molecule. This study will utilize the newly developed solid tablet formulation of AP1189 and will dose for 12-weeks as opposed to the 4-weeks of dosing in the BEGIN trial. The Company plans to conduct the study at clinics in Europe in a cost-efficient approach. The submission of the Clinical Trial Application (CTA) was completed in June 2022. Subject to approval by authorities, the Company intends to initiate the study in Q3 2022 with the aim to report key data in the second half of 2023.

### **RESOLVE - A 12-week P2a/b study of daily AP1189 in patients with an incomplete response to first-line disease modifying anti-rheumatic drugs (DMARD-IR) who are experiencing moderate to severe disease activity**

A large percentage of patients treated with DMARDs never achieve the full desired effect, have a diminishing treatment effect, or suffer from side effects that can prevent further treatment. These patients who experience an inadequate response to DMARDs are referred to as DMARD-IR (inadequate responder).

The Company believes that AP1189 could be very well suited for DMARD-IR patients given the emerging profile of an efficacious,

safe, and well tolerated once-daily oral therapy. The DMARD-IR patient population has high commercial attractiveness and SynAct considers further clinical development in DMARD-IR to be both relevant and necessary.

The intention is to develop AP1189 in DMARD-IR patients under an IND (Investigational New Drug) application. In June 2022, the Company obtained scientific and regulatory feedback from the FDA in a pre-IND process and expect to submit the application in the third quarter and, subject to approval by the agency, start the study in 2022.

### **Idiopathic Membranous Nephropathy - Nephrotic Syndrome (NS)**

Nephrotic Syndrome (NS) is a condition associated with increased loss of protein into the urine resulting in tissue swelling and eventually development of edemas. The edemas can develop in the hands, feet, ankles, and face. Edemas can even develop in the lungs where it is associated with dyspnea (shortness of breath). Untreated or insufficiently treated NS will in many cases be associated with hypercholesterolemia, increased risk for blood clots, increased risk for infections and can develop into chronic kidney disease that is associated with increased risk of development of cardiovascular disease and risk of development of end stage kidney disease and thereby need for renal replacement therapy (dialysis or transplant).

Idiopathic Membranous nephropathy (iMN) is one of the frequent causes of NS. iMN can be primary or it can be secondary to other diseases, including systemic lupus (lupus nephritis), cancer or seen following treatment with certain drugs.

### **Clinical development of AP1189 in iMN**

AP1189 is being tested in an exploratory, randomized, double-blind, multicenter, placebo controlled P2a study with repeated once-daily 100 mg dosing to assess the safety, tolerability, pharmacokinetics, and efficacy of AP1189. The study population consists of patients with iMN who are on an ACE inhibitor or angiotensin II receptor blocker treatment. In November 2021, SynAct announced its intention to amend the iMN P2a protocol.

This amendment will allow for the use of the new oral tablet as well as a longer 3-month dosing duration. The benefit of this redesign is that it increases the likelihood to show significant treatment effect on urinary protein excretion, the main efficacy read-out in the study, and increase patient compliance as a once-daily dosing with a tablet is much more convenient than daily intake of an oral suspension. The application to relevant authorities in Denmark, Sweden and Norway occurred in July 2022.

### **Virus Induced Respiratory Insufficiency**

Virus infected patients can develop a variety of symptoms, but lung involvement is very common and in some viral infections like COVID-19 it can be the leading cause of death. Patients can develop respiratory insufficiency where they are unable to provide enough oxygen to the body and these patients require oxygen supplementation in order to maintain adequate levels. As respiratory insufficiency continues it can cause severe pneumonia and can also develop into acute respiratory distress syndrome (ARDS), a very serious condition where patients often require mechanical ventilation in order to breathe adequately.

Viral or secondary bacterial infections can also cause the immune system to be highly overly active and produce excessive quantities of pro-inflammatory molecules (a 'cytokine storm', also known as Systemic Inflammatory Distress Syndrome or SIDS) which can cause damage to key organ systems like the lungs, kidneys and heart.

Viral infections can cause significant respiratory issues. In order to prevent the inflammation-associated damage that viral infections can cause, it is important to resolve the excessive inflammation without suppressing the immune system's ability to fight the viral infection. The goal of therapy would be to arrest the excessive inflammation and prevent severe disease.

### **Clinical development of AP1189 in Virus-induced respiratory insufficiency**

Working within the RESOVIR collaboration, SynAct designed and executed a 60 patient Phase 2a clinical trial in Brazil. Hospitalized

COVID-19 infected patients were enrolled in the study who required supplemental oxygen (experiencing respiratory insufficiency). These patients were hospitalized, and all received steroids (dexamethasone) at an average dose of 6mg/day. After an initial open-label safety run-in of 6 patients, the blinded placebo-controlled portion of the trial dosed an additional 36 patients with 100mg of AP1189 and 18 patients with placebo, each given orally once-daily for 2 weeks.

The trial concluded in Q2 of 2021. Patients treated with 100mg AP1189 orally once-daily for 2-weeks achieved respiratory recovery (no longer requiring oxygen therapy) on average 3.5 days (35%) quicker than placebo treated patients (6.4 days and 9.9 days on average respectively). All AP1189 treated patients (including the first 6 open-label safety patients) recovered respiratory recovery on average 4.0 days (40%) quicker than placebo treated patients (5.9 days and 9.9 days on average respectively). AP1189 patients were discharged on average 3.3 days earlier than placebo and by day 4, 41% of AP1189 patients had been discharged vs 0% for placebo.

### **Next Steps for AP1189 in virus-induced respiratory insufficiency**

After the completed study, SynAct explored various opportunities for further development of AP1189 for use in patients suffering from COVID-19. The Company has had an advisory meeting with the Brazilian health authority ANVISA (Agência Nacional de Vigilância Sanitária) and prepared an application for clinical trial authorization for a confirmatory study.

At about this time, the rapid spread of the omicron and subsequent COVID-19 variants, changed the way in which patients were affected. The Company therefore decided to look more broadly at virus-induced respiratory insufficiency associated with common annual or seasonal viral infections such as viral pneumonia and or influenza. SynAct has initiated pre-clinical pharmacological studies in virus models with the aim of informing decisions on next steps for the program including the design of any potential next clinical study. The Company will make its decision on further development when the pre-clinical trials are completed during the second half of 2022.

# SynAct Pharma AB in brief

## About SynAct Pharma AB

SynAct Pharma AB is a biotech company in clinical phase listed on Nasdaq. The company's drug candidate AP1189 is a "First-in-Class" melanocortin receptor agonist focused on active inflammatory and autoimmune diseases. The company's research and patents are based on the endogenous hormone, melanocortin, which is activated in inflammatory conditions and contributes anti-inflammatory effects, which are important components of the healing process and for recovery to normal tissue function.

## Business model

SynAct's business strategy is to drive projects into clinical development in order to secure proof-of-concept, i.e. support for clinical relevance. The company's ambition is to conduct phase 2 clinical studies, and then to sign commercial agreements with one or more major pharmaceutical companies.

## Group relationship and shareholding

SynAct Pharma AB is the parent company of a group that includes the wholly owned subsidiary SynAct Pharma ApS. In addition to the above, SynAct has no additional shareholdings in other companies.

## Ownership (June 30, 2022)

| Shareholder                | Capital and votes(%) |
|----------------------------|----------------------|
| Bioinvest ApS              | 13.3%                |
| Avanza Pension             | 6.6%                 |
| Nordnet Pensionsförsäkring | 5.4%                 |
| Torbjörn Bjerke            | 2.9%                 |
| Henrik Stage               | 1.4%                 |
| Robert Sahlin              | 1.1%                 |
| Peter Nordwall             | 0.8%                 |
| Patrik Strempl             | 0.8%                 |
| Per Granath                | 0.8%                 |
| Niklas Borgquist           | 0.8%                 |
| <b>Total (top-10)</b>      | <b>34.0%</b>         |
| Others                     | 66.0%                |

Compiled and processed data from the share register of SynAct Pharma AB kept by Euroclear AB. Share of capital and votes is based on the number of shares outstanding at the time, 28,370,503.

## Lock-up agreement

The board with Torbjörn Bjerke, Kerstin Hasselgren, Terje Kalland, Uli Hacksell, Marina Bozilenko and Thomas Jonassen and the management with Jeppe Øvlesen, Patrik Renblad, Thomas Boesen and Jim Knight have all entered into lock-in agreements, that with certain exceptions prohibited the sale of shares until the end of July 2022 and allows sales of a maximum of 10% for three months until the end of October 2022.

The agreements above are entered between the respective executives and the banks ABG Sundal Collier AB and Van Lanschot Kempen N.V. The lock-up agreements do not affect the Group financially or in terms of accounting.

## Review by the Company's Auditor

This report has not been reviewed by the Company's Auditor.

## Forward looking statements

This financial report contains statements that are forward-looking and actual future results may differ materially from those stated. In addition to the factors discussed, factors that may affect the results are development in research programs.



## The Share

The share in SynAct Pharma AB was listed on Nasdaq Stockholm on July 12, 2022. The share is traded under the ticker "SYNACT" and is included in the Mid-Cap segment of the stock exchange.

In the second quarter of 2022, SynAct Pharma AB successfully completed a rights issue in which the number of shares increased by 2,364,208 to 28,370,503 shares and the share capital by SEK 295,526 to SEK 3,546,313.



## Financial reporting calendar

SynAct prepares and publishes a quarterly financial report. Upcoming reports are planned as follows:

**Date:**  
2022-11-04  
2023-02-17  
2023-05-05

**Report:**  
Interim Report Q3 2022  
Annual Results 2022  
Interim Report Q1 2023

# Comments on the financial development for the second quarter and first six months of 2022

## Net sales

Net sales for the second quarter and first six months of 2022 amounted to SEK 0 (0) thousand. The company is not expected to generate any revenue until at the earliest after the completion of the planned phase II program regarding the drug candidate AP1189 planned for the end of 2023.

The parent company's sales are from services delivered to the Danish subsidiary and amounted to SEK 1,262 (409) thousand in the second quarter, and SEK 2,556 (818) thousand for the first six months of the year.

## Research and development (R&D) costs

Total costs for R&D in the second quarter amounted to SEK 14,275 (12,952) thousand. For the first six months, R&D costs amounted to SEK 27,765 (24,025) thousand. The main reasons for the cost increase are increased activity in the clinical studies, investments in clinical manufacturing and control ("CMC") and pre-clinical activities that support both the drug candidate, AP1189 and projects in the early research phase.

As the planned clinical trials with AP1189 in RA start during the second half of the year, costs are expected to rise further.

SynAct's research and development is led and managed by the Company and its management, but in all essentials the activities are carried out by consultants and contract suppliers.

## General & administration costs

Administrative expenses amounted to SEK 12,127 (2,686) thousand in the second quarter and SEK 20,885 (5,653) thousand for the first six months. The increase is driven by activities related to the preparations for and the actual listing of the company's share on Nasdaq Stockholm's Main Market and by activities related to the rights issue which cannot be reported as issue expenses, off-setting the proceeds as equity. Administrative expenses are expected to be significantly reduced after the successful completion of the listing project.

## Financial items

Net financial items amounted to SEK -1,208 (-253) thousand in the second quarter and SEK -1,221 (-265) thousand for the first six months. The change is attributable to exchange rate adjustments and interest expenses from leasing liabilities.

In the Parent Company, net financial items amounted to SEK -96,059 (3) thousand in the quarter. Year-to-date, net financial items were SEK -110,296 (-3) thousand. Shareholders' contributions provided to subsidiaries that intend to cover the subsidiary's costs for research are expensed and the cost is reported in the income statement in net financial items. The accounting treatment in the parent company thus reflects the principle in the Group, where all expenses for research are charged to the income statement.

## Tax for the period

Tax revenues in the second quarter amounted to SEK 2,871 (2,719) thousand. For the first six months the accrued tax credit amounted to SEK 5,133 (5,054) thousand. See Note 8 - Tax receivables for more information.

## Loss for the period

The Group's loss for the second quarter of 2022 amounted to SEK 24,754 (13,137) thousand and for the first six months, the reported loss was SEK 44,809 (24,872) thousand.

## Cash flow and balance sheet

Cash flow from operations amounted to SEK -36,922 (-16,114) thousand in the quarter. The increase is driven by increased activities and by initial start-up payments for the two new clinical trials made to the vendor. Year-to-date cash-flow from operations amounted to SEK -53,913 (-26,491) thousand.

Cash flow from financing activities amounted to SEK 125,158 (0) thousand in the quarter, driven by the rights issue slightly off-set by the cash flow impact of leasing. For the first six months, cash flow from financing activities amounted to SEK 124,916 (74,400) thousand.

Cash flow for the period amounted to SEK 88,236 (-16,114) thousand and SEK 71,003 (47,907) thousand for the first six months.

The Group's cash and cash equivalents as of June 30, 2022 amounted to SEK 96,466 (62,532) thousand.

Receivables from the Danish tax authorities that follow from the so-called "Tax Credit Scheme" (see Tax on profit for the period above and Note 8 - Tax receivables for more information) amounted to SEK 13,129 (9,654) thousand.

The Group applies IFRS 16 Leasing on leased office premises, which generated a right of use in the balance sheet of SEK 2,209 thousand and the corresponding short- and long-term leasing liabilities of SEK 850 thousand and SEK 1,322 thousand, respectively.

## Employees

The number of employees was 4 (0). The Company's CEO, CSO and COO are employed by the affiliate, SynAct Pharma ApS and the CFO is employed by the parent company, SynAct Pharma AB. The CBO performs their duties based on a consultancy contract.

## Corporate Governance

The company chose not to publish a Corporate Governance Report for 2021, which is a requirement for companies listed on a regulated market but not on Spotlight Stock Market. With the only exception, SynAct follows the Swedish Code of Corporate Governance and will, after listing the Company's share on the regulated market (Nasdaq), publish the Corporate Governance Report for 2022.

## Consolidated income statement

| SEK (thousand)                              | 2022           |                | 2021           |                | 2021           |
|---|----------------|----------------|----------------|----------------|----------------|
|   | Apr-Jun        | Apr-Jun        | Jan-Jun        | Jan-Jun        |                |
| Net sales                                   | -              | -              | -              | -              | -              |
| <b>Gross profit</b>                         | -              | -              | -              | -              | -              |
| Research and development costs              | -14,275        | -12,952        | -27,765        | -24,025        | -60,490        |
| General and administration costs            | -12,127        | -2,686         | -20,885        | -5,653         | -16,225        |
| Other operating income/expenses             | -16            | 35             | -72            | 17             | 16             |
| <b>Total operating expenses</b>             | <b>-26,417</b> | <b>-15,603</b> | <b>-48,722</b> | <b>-29,661</b> | <b>-76,699</b> |
| <b>Operating income</b>                     | <b>-26,417</b> | <b>-15,603</b> | <b>-48,722</b> | <b>-29,661</b> | <b>-76,699</b> |
| Net financial items                         | -1,208         | -253           | -1,221         | -265           | -110           |
| <b>Profit after financial items</b>         | <b>-27,625</b> | <b>-15,856</b> | <b>-49,942</b> | <b>-29,926</b> | <b>-76,809</b> |
| Tax on profit/loss for the period           | 2,871          | 2,719          | 5,133          | 5,054          | 7,505          |
| <b>Profit for the period</b>                | <b>-24,754</b> | <b>-13,137</b> | <b>-44,809</b> | <b>-24,872</b> | <b>-69,304</b> |
| Earnings per share (SEK)                    | -0.91          | -0.51          | -1.68          | -0.97          | -2.68          |
| Diluted earnings per share (SEK)            | -0.91          | -0.51          | -1.68          | -0.97          | -2.68          |
| Average number of shares outstanding ('000) | 27,305         | 26,006         | 26,659         | 25,688         | 25,848         |

The result for the period is attributable in its entirety to the owners of the parent company

## Consolidated statement of comprehensive Income

| SEK (thousand)  | 2022           |                | 2021           |                | 2021           |
|---|----------------|----------------|----------------|----------------|----------------|
|   | Apr-Jun        | Apr-Jun        | Jan-Jun        | Jan-Jun        |                |
| <b>Profit for the period</b>                                    | <b>-24,754</b> | <b>-13,137</b> | <b>-44,809</b> | <b>-24,872</b> | <b>-69,304</b> |
| <b>Items reclassifiable to profit or loss</b>                   |                |                |                |                |                |
| Exchange rate differences from conversion of foreign operations | 1,231          | -32            | 1,175          | 126            | -94            |
| <b>Comprehensive income after tax for the period</b>            | <b>-23,523</b> | <b>-13,169</b> | <b>-43,634</b> | <b>-24,746</b> | <b>-69,398</b> |
| <b>Comprehensive income for the period</b>                      | <b>-23,523</b> | <b>-13,169</b> | <b>-43,634</b> | <b>-24,746</b> | <b>-69,398</b> |

The total comprehensive income for the period is attributable in its entirety to the owners of the parent company

## Consolidated statement of financial position

| SEK (thousand)                  | 06/30/2022     | 06/30/2021    | 12/31/2021    |
|---------------------------------|----------------|---------------|---------------|
| <b>Assets</b>                   |                |               |               |
| <i>Non-current assets</i>       |                |               |               |
| Right-of-use assets             | 2,209          | -             | 3,179         |
| Financial assets                | 286            | 268           | 274           |
| <b>Total non-current assets</b> | <b>2,495</b>   | <b>268</b>    | <b>3,454</b>  |
| <i>Current assets</i>           |                |               |               |
| Tax credit                      | 13,129         | 9,654         | 7,564         |
| Other current receivables       | 7,283          | 2,496         | 3,107         |
| Prepaid expenses                | 14,599         | 322           | 247           |
| Cash and cash equivalents       | 96,466         | 62,532        | 23,997        |
| <b>Total current assets</b>     | <b>131,476</b> | <b>75,004</b> | <b>34,916</b> |
| <b>Total assets</b>             | <b>133,972</b> | <b>75,273</b> | <b>38,369</b> |

| SEK (thousand)                                | 06/30/2022     | 06/30/2021    | 12/31/2021    |
|---|----------------|---------------|---------------|
| <b>Equity and liabilities</b>                 |                |               |               |
| Share capital                                 | 3,546          | 3,251         | 3,251         |
| Other paid-in capital                         | 318,725        | 193,602       | 193,602       |
| Reserves                                      | 776            | -178          | -399          |
| Retained earnings/losses including net profit | -220,394       | -131,153      | -175,585      |
| <b>Total equity</b>                           | <b>102,654</b> | <b>65,521</b> | <b>20,869</b> |
| <i>Non-current liabilities</i>                |                |               |               |
| Leasing liability                             | 1,322          | -             | 2,110         |
| <b>Total non-current liabilities</b>          | <b>1,322</b>   | <b>-</b>      | <b>2,110</b>  |
| <i>Current liabilities</i>                    |                |               |               |
| Accounts payable                              | 15,353         | 6,600         | 4,254         |
| Leasing liability                             | 850            | -             | 979           |
| Other current liabilities                     | 4,315          | 1,680         | 2,267         |
| Accrued expenses                              | 9,478          | 1,471         | 7,889         |
| <b>Total current liabilities</b>              | <b>29,996</b>  | <b>9,751</b>  | <b>15,390</b> |
| <b>Total equity and liabilities</b>           | <b>133,972</b> | <b>75,273</b> | <b>38,369</b> |

## Consolidated statement of changes in equity

| 01/01/2021 - 12/31/2021<br>SEK (thousand)  | Share capital | Other paid-in<br>capital | Reserves | Retained earnings, including<br>profit for the period | Total   |
|--|---------------|--------------------------|----------|---|---------|
| <b>Opening equity</b>                      | 3,051         | 119,401                  | -304     | -106,281  | 15,868  |
| Profit for the period                      | -             | -                        | -        | -69,304   | -69,304 |
| Other comprehensive income                 | -             | -                        | -94      | -   | -94     |
| <b>Comprehensive income for the period</b> | -             | -                        | -94      | -69,304   | -69,398 |
| <b>Transactions with owners</b>            |               |                          |          |   |         |
| New share issue                            | 200           | 79,800                   | -        | -   | 80,000  |
| Issue expenses                             | -             | -5,600                   | -        | -   | -5,600  |
| <b>Total transaction with owners</b>       | 200           | 74,200                   | -        | -   | 74,400  |
| <b>Closing equity</b>                      | 3,251         | 193,602                  | -399     | -175,585  | 20,869  |

| 01/01/2022 - 06/30/2022<br>SEK (thousand)  | Share capital | Other paid-in<br>capital | Reserves | Retained earnings, including<br>profit for the period | Total   |
|--|---------------|--------------------------|----------|---|---------|
| <b>Opening equity</b>                      | 3,251         | 193,602                  | -399     | -175,585  | 20,869  |
| Profit for the period                      | -             | -                        | -        | -44,809   | -44,809 |
| Other comprehensive income                 | -             | -                        | 1,175    | -   | 1,175   |
| <b>Comprehensive income for the period</b> | -             | -                        | 1,175    | -44,809   | -43,634 |
| <b>Transactions with owners</b>            |               |                          |          |   |         |
| New share issue                            | 296           | 148,650                  | -        | -   | 148,945 |
| Issue expenses                             | -             | -23,526                  | -        | -   | -23,526 |
| <b>Total transaction with owners</b>       | 296           | 125,124                  | -        | -   | 125,419 |
| <b>Closing equity</b>                      | 3,546         | 318,725                  | 776      | -220,394  | 102,654 |

## Condensed consolidated statement of cash flows

| SEK (thousand)  | 2022           | 2021           | 2022           | 2021           | 2021           |
|---|----------------|----------------|----------------|----------------|----------------|
|   | Apr-Jun        | Apr-Jun        | Jan-Jun        | Jan-Jun        | Jan-Dec        |
| <b>Cash flow from operations</b>                                  |                |                |                |                |                |
| Operating income  | -26,417        | -15,603        | -48,722        | -29,661        | -76,699        |
| Adjustment for non-cash items                                     | 259            | -              | 530            | -              | 88             |
| Interest received   | 0              | 0              | 46             | 0              | 0              |
| Interest paid   | -102           | -16            | -147           | -27            | -110           |
| Corporate income tax received                                     | -              | -              | -              | -              | 4,625          |
| <b>Cash flow from operations before change in working capital</b> | <b>-26,261</b> | <b>-15,619</b> | <b>-48,293</b> | <b>-29,689</b> | <b>-72,096</b> |
| Change in working capital   | -10,662        | -495           | -5,621         | 3,198          | 7,099          |
| <b>Cash flow from operating activities</b>                        | <b>-36,922</b> | <b>-16,114</b> | <b>-53,913</b> | <b>-26,491</b> | <b>-64,997</b> |
| Cash flow from investing activities                               | -              | -              | -              | -3             | -6             |
| Cash flow from financing activities                               | 125,158        | -              | 124,916        | 74,400         | 74,323         |
| <b>Cash flow for the period</b>                                   | <b>88,236</b>  | <b>-16,114</b> | <b>71,003</b>  | <b>47,907</b>  | <b>9,319</b>   |
| Cash and cash equivalents at beginning of period                  | 6,806          | 78,883         | 23,997         | 14,548         | 14,548         |
| Decrease/increase in cash and cash equivalents                    | 88,236         | -16,114        | 71,003         | 47,907         | 9,319          |
| Exchange rate difference in cash and cash equivalents             | 1,424          | -237           | 1,466          | 78             | 130            |
| <b>Cash and cash equivalents at end of period</b>                 | <b>96,466</b>  | <b>62,532</b>  | <b>96,466</b>  | <b>62,532</b>  | <b>23,997</b>  |

## Parent company's condensed income statement

| SEK (thousand)                      | 2022            |               | 2021            |               | 2021           |
|-------------------------------------|-----------------|---------------|-----------------|---------------|----------------|
|                                     | Apr-Jun         | Apr-Jun       | Jan-Jun         | Jan-Jun       |                |
| Net sales                           | 1,262           | 409           | 2,556           | 818           | 1,637          |
| <b>Gross profit</b>                 | <b>1,262</b>    | <b>409</b>    | <b>2,556</b>    | <b>818</b>    | <b>1,637</b>   |
| General and administration costs    | -10,637         | -2,516        | -18,135         | -5,273        | -12,571        |
| Other operating expenses            | -112            | -8            | -168            | -15           | -27            |
| <b>Total operating expenses</b>     | <b>-10,749</b>  | <b>-2,524</b> | <b>-18,303</b>  | <b>-5,288</b> | <b>-12,598</b> |
| <b>Operating income</b>             | <b>-9,487</b>   | <b>-2,115</b> | <b>-15,747</b>  | <b>-4,470</b> | <b>-10,962</b> |
| Net financial items                 | -96,059         | 3             | -110,296        | -3            | -50,005        |
| <b>Profit after financial items</b> | <b>-105,546</b> | <b>-2,112</b> | <b>-126,044</b> | <b>-4,473</b> | <b>-60,966</b> |
| Tax on profit for the period        | -               | -             | -               | -             | -              |
| <b>Profit for the period</b>        | <b>-105,546</b> | <b>-2,112</b> | <b>-126,044</b> | <b>-4,473</b> | <b>-60,966</b> |

## Parent company's statement of comprehensive income

| SEK (thousand)                    | 2022            |               | 2021            |               | 2021           |
|-----------------------------------|-----------------|---------------|-----------------|---------------|----------------|
|                                   | Apr-Jun         | Apr-Jun       | Jan-Jun         | Jan-Jun       |                |
| Profit for the period             | -105,546        | -2,112        | -126,044        | -4,473        | -60,966        |
| Other comprehensive income        | -               | -             | -               | -             | -              |
| <b>Total comprehensive income</b> | <b>-105,546</b> | <b>-2,112</b> | <b>-126,044</b> | <b>-4,473</b> | <b>-60,966</b> |

## Parent company's condensed balance sheet

| SEK (thousand)                  | 06/30/2022    | 06/30/2021     | 12/31/2021    |
|---------------------------------|---------------|----------------|---------------|
| <b>Assets</b>                   |               |                |               |
| <i>Non-current assets</i>       |               |                |               |
| Financial assets                | 24,419        | 54,295         | 24,419        |
| <b>Total non-current assets</b> | <b>24,419</b> | <b>54,295</b>  | <b>24,419</b> |
| <i>Current assets</i>           |               |                |               |
| Other receivables               | 2,403         | 557            | 865           |
| Prepaid expenses                | 239           | 205            | 202           |
| Cash and cash equivalents       | 24,666        | 45,467         | 19,849        |
| <b>Total current assets</b>     | <b>27,308</b> | <b>46,229</b>  | <b>20,915</b> |
| <b>Total assets</b>             | <b>51,727</b> | <b>100,523</b> | <b>45,334</b> |

| SEK (thousand)                      | 06/30/2022    | 06/30/2021     | 12/31/2021    |
|-------------------------------------|---------------|----------------|---------------|
| <b>Equity and liabilities</b>       |               |                |               |
| <i>Restricted equity</i>            |               |                |               |
| Share capital                       | 3,546         | 3,251          | 3,251         |
| <i>Non-restricted equity</i>        |               |                |               |
| Other paid-in capital               | 295,510       | 170,387        | 170,387       |
| Retained earnings/losses            | -133,233      | -72,267        | -72,267       |
| Profit for the period               | -126,044      | -4,473         | -60,966       |
| <b>Total equity</b>                 | <b>39,779</b> | <b>96,898</b>  | <b>40,404</b> |
| <i>Current liabilities</i>          |               |                |               |
| Accounts payable                    | 5,196         | 481            | 1,136         |
| Other liabilities                   | 3,990         | 1,680          | 2,163         |
| Accrued expenses                    | 2,762         | 1,464          | 1,630         |
| <b>Total current liabilities</b>    | <b>11,949</b> | <b>3,625</b>   | <b>4,930</b>  |
| <b>Total equity and liabilities</b> | <b>51,727</b> | <b>100,523</b> | <b>45,334</b> |

## Notes and disclosures

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### Note 1 - General information

This interim report covers the Swedish parent company SynAct Pharma AB (publ) ("SynAct" or the "Parent Company"), corporate identity number 559058-4826 and its subsidiaries (collectively, the "Group"). The Group's main business is to conduct the development of pharmaceuticals. The parent company is listed on Nasdaq Stockholm, with ticker SYNACT. The Parent Company is a limited liability company registered with its registered office in Lund, Sweden. The address of the head office is Schelevägen 2, 223 81 Lund, Sweden. This interim report was approved for publishing on August 5, 2022.

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### Note 2 - Accounting principles

The interim report has been prepared in accordance with IAS 34 Interim Reporting. The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) with interpretations from the IFRS Interpretation Committee, approved by and implemented in the European Union.

The accounting principles applied in this interim report are aligned with the ones used for the Annual Report 2021, note 2 pages 32 to 36. No new or changed standards implemented on or after January 1, 2022, have had any significant impact on the company's financial reporting.

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### Note 3 - Significant risks and uncertainties

The risks and uncertainties to which SynAct's operations are exposed are, in summary, related to, among other things, drug development, competition, technology development, patents, regulatory requirements, capital requirements, currencies and interest rates.

The Group's overall risk management focuses on identifying, analyzing and evaluating risks that could affect the business and the Company's overall goals with the intention of minimizing potential adverse effects. The most significant risks and uncertainties are described below. See the Annual Report for 2021, pages 18-21 for further information on the Group's general risk management.

As the company does not have approved products on the market that can generate positive cash flow, the business presupposes additional capital. After analyzing and evaluating various financing alternatives, the Board decided on March 28, 2022 to carry out a fully guaranteed rights issue of SEK 150

million, which added approximately SEK 125 million after deduction of issue expenses. It is the Board's assessment that after this capital injection, the Company has the necessary financial means to finance the planned and communicated clinical studies and run the Company until the end of 2023.

Even if this financing risk is mitigated in the short term, the Company's operations presuppose new capital injections in the medium term, which is why this refinancing risk cannot be considered negligible.

The macroeconomic situation with rising inflation and interest rates did not have a significant impact on SynAct's operations in the second quarter. Our suppliers and partners have been able to produce and deliver according to the plans we work with and without any significant cost increases. However, it cannot be ruled out that increased inflation and rising interest rates may lead to price increases for goods and services that could have a negative impact on the Company's future financial results and position.

The Group's operation is exposed to currency risks with its financing in SEK and main operations in DKK and EUR. SynAct has as taken mitigating steps to reduce the risk through placement of liquidity in EUR and DKK accounts at the expense of, for the time being, negative interest expense.

SynAct Pharma will conduct clinical trials at clinics in Eastern Europe in the vicinity of the conflict in Ukraine, including in neighboring Moldova. The risks of this have been considered and action plans in the scenario where the conflict spreads and further affects the neighboring countries have been developed. Minor delays and / or minor impact on the Company's operating costs cannot be completely ruled out.

The COVID-19 pandemic affected clinical trials ongoing in 2020 and 2021 with delays in patient recruitment. With regard to the new studies that are planned to start in the second half of 2022, the assessment is that the pandemic (as it is currently occurring) should not be able to significantly affect the recruitment to and implementation of the studies.

#### Note 4 - Transactions with related parties

In addition to salaries and other remuneration (including invoiced) to the Company's management and board remuneration, according to the resolution of the Annual General Meeting, to the board, the following transactions have taken place with related parties:

| SEK (thousand)                                    |             | 2022    | 2021    | 2022    | 2021    | 2021    |
|---|-------------|---------|---------|---------|---------|---------|
| Related party                                     | Service     | Apr-Jun | Apr-Jun | Jan-Jun | Jan-Jun | Jan-Dec |
| UST Leadership AB<br>(Torbjørn Bjerke, chairman)  | Consultancy | -       | -       | -       | 174     | 654     |
| JSH Biotech ApS<br>(John Haurum, f. board member) | Consultancy | -       | 72      | -       | 119     | 167     |

In addition to the transactions described above, the Company has entered into an agreement with Boesen Biotech ApS regarding the transfer of intellectual property rights. The agreement did not involve any financial transactions in reported periods. See Note 12, Contingent liabilities for more information.

#### Note 5 - Share issues

In February 2021, the Company carried out a directed new issue of SEK 80 million, net SEK 74.4 million after issue expenses. Through the issue, the number of shares and votes in the Company increased by 1,600,000 from 24,406,295 to 26,006,295, and the share capital increased by SEK 200,000 from SEK 3,050,787 to SEK 3,250,787.

On March 28, 2022, the Company's board of directors resolved on a fully guaranteed rights issue that provided the Company with approximately SEK 150 million before issue expenses of approximately SEK 24 million. Through the rights issue that was completed in the second quarter 2022, the number of shares increased by 2,364,208 to 28,370,503 shares. The share capital increased by SEK 295,526 to SEK 3,546,313.

#### Note 6 - Number of registered shares

| Thousand  | 2022    | 2021    | 2022    | 2021    | 2021    |
|---|---------|---------|---------|---------|---------|
|   | Apr-Jun | Apr-Jun | Jan-Jun | Jan-Jun | Jan-Dec |
| Number of shares at the beginning of the period | 26,006  | 26,006  | 26,006  | 24,406  | 24,406  |
| Number of shares at the end of the period       | 28,371  | 26,006  | 28,371  | 26,006  | 26,006  |

All shares are freely traded and the Company does not hold any shares.

#### Note 7 - Leasing

As of Q4 2021, the Group changed the assessment of lease agreements for office premises, which were previously assessed as short-term contracts and therefore were exempted from the main principle in IFRS 16 (Leasing agreements).

As of December 2021, the principle is fully applied to leased premises, which has generated a right of use in the balance sheet at the reporting date of SEK 2,209 (0) thousand and the corresponding short- and long-term lease liabilities amounting to SEK 850 (0) thousand and SEK 1,322 (0) thousand, respectively.

#### Note 8 - Tax receivables

According to Danish tax law (the tax credit scheme), the subsidiary SynAct Pharma ApS can receive a current tax income for some of the expenses that are directly attributable to the company's research and development. Settled expenses for research and development that result in tax revenue received reduce the company's tax loss carryforwards with the corresponding amount. SynAct Pharma ApS can settle a maximum of tax deficits attributable to research and development up to DKK 25 million per year. This corresponds to 5.5 MDKK as possible tax revenue, as the tax rate in Denmark is 22%.

The claim on the Danish tax authorities that follows from this scheme amounted to SEK 13,129 thousand (9,654). The company's balance under the "Tax Credit Scheme" for 2021 with an amount of SEK 7,896 thousand is expected to be paid in November 2022.

## Note 9 - VAT

SynAct Pharma has previously been denied a deduction for input VAT for the years 2018 and earlier. The Company disputed the Swedish Tax Agency's decision and appealed to the first instance, the Administrative Court. During the process SynAct agreed to pay part of the disputed amount to the Swedish Tax Agency, approximately 2 MSEK, and accrued for the remaining amount of approximately 1.6 MSEK.

In December 2021, the Administrative Court in Malmö announced a ruling in the Company's favor in the case, whereby a deduction was granted. However, the Swedish Tax Agency has appealed the decision to the Court of Appeal, which is why the Company continues to report the liability, SEK 3,689 (1,614) thousand, under other liabilities in the consolidated and the parent company's balance sheets. The change from previous reporting is due to the fact that the Swedish Tax Agency, following the court ruling in December 2021, refunded the amounts previously paid-in by the Company early 2022.

## Note 10 - Prepaid and accrued expenses

SynAct has made initial payments to the CRO handling the two new clinical studies SynAct-CS006 (RESOLVE) and SynAct-CS007 (EXPAND). The costs will be recognized during the active treatment period and three months before and after. Hence the increase in prepaid expenses by more than SEK 14 million to SEK 14,599 (322) thousand.

The company reports accrued expenses of SEK 9,478 (1,471) thousand. The change since the comparison period of approximately SEK 8 million is mainly due to increased activity in the clinical studies and thus increased accrued clinical costs of SEK 5.8 million, partly on increased provisions for costs related to personnel (bonus, pension and holidays) and board fees totaling SEK 2 million and other accrued expenses of SEK 0.2 million.

## Note 11 - Financial assets and liabilities

| SEK (thousand)                     | 06/30/2022    | 06/30/2021    | 12/31/2021    |
|------------------------------------|---------------|---------------|---------------|
| <b>Financial assets</b>            |               |               |               |
| Non-current financial assets       | 286           | 268           | 274           |
| Cash and cash equivalents          | 96,466        | 62,532        | 23,997        |
| <b>Total financial assets</b>      | <b>96,752</b> | <b>62,801</b> | <b>24,271</b> |
| <b>Financial liabilities</b>       |               |               |               |
| Accounts payable                   | 15,353        | 6,600         | 4,254         |
| Accrued expenses                   | 9,478         | 1,471         | 7,889         |
| <b>Total financial liabilities</b> | <b>24,831</b> | <b>8,071</b>  | <b>12,143</b> |

SynAct Pharma does not hold any financial instruments that are valued at fair value. For all financial assets and liabilities, the reported value above is deemed to be an approximation of fair value. No change in classification of financial instruments has occurred over the reported periods.

## Note 12 - Contingent liabilities

In March 2021, the subsidiary SynAct Pharma ApS acquired the rights to a number of innovative chemical molecules from Boesen Biotech ApS, a company controlled by COO Thomas Boesen. The transfer took place free of charge, but according to the agreement, Boesen Biotech ApS is entitled to receive milestone payments and royalties in the future related to any progress in the Company's development and commercialization of products based on these rights. Upon successful achievement of defined milestones, Boesen Biotech ApS may receive up to a maximum of 4.5 MDKK in payment. In the event of any future commercialization of a product where these IP rights are used, Boesen Biotech ApS is entitled to royalties amounting to 3% of net sales for 10 years from launch and with a maximum amount of DKK 500 million.

As the remunerations that may be paid to Boesen Biotech is not considered to be secure or probable commitment for SynAct, they are not reported as a liability (accrual or provision). Based on current plans, a first milestone payment may be charged to the income statement and balance sheet at the earliest at the end of 2022 and have a cash flow effect no earlier than 2024.

## Alternative performance measures - APM

The use of Alternative Performance Measures in financial reports is regulated by the European Securities and Markets Authority (ESMA) in guidelines issued in 2015. According to these guidelines, an alternative key ratio refers to a financial measure of historical or future earnings development, financial position, financial result or cash flows. It is not such a financial measure that is defined or specified in the applicable rules for financial reporting.

SynAct Pharma uses alternative key figures to increase the understanding of the information provided in financial reports, both for external analysis, comparison and internal evaluation. The company has chosen equity / assets ratio and research and development costs / operating expenses as alternative key figures in its reporting. Definitions and tables for deriving these are shown below.

### Equity / asset ratio

The equity ratio is a financial ratio indicating the relative proportion of equity used to finance a company's assets. The two components are taken from the SynAct Pharma's balance sheet or statement of financial position (so-called book value). Equity divided by total assets.

| #         | SEK (thousand)                      | 06/30/2022     | 06/30/2021    | 12/31/2021    |
|-----------|-------------------------------------|----------------|---------------|---------------|
|           | <b>Assets</b>                       |                |               |               |
|           | Total non-current assets            | 2,495          | 268           | 3,454         |
|           | Total current assets                | 131,476        | 75,004        | 34,916        |
| [1]       | <b>Total assets</b>                 | <b>133,972</b> | <b>75,273</b> | <b>38,369</b> |
|           | <b>Equity and liabilities</b>       |                |               |               |
| [2]       | <b>Total equity</b>                 | <b>102,654</b> | <b>65,521</b> | <b>20,869</b> |
|           | Total non-current liabilities       | 1,322          | -             | 2,110         |
|           | Total current liabilities           | 29,996         | 9,751         | 15,390        |
|           | <b>Total liabilities</b>            | <b>31,318</b>  | <b>9,751</b>  | <b>17,500</b> |
|           | <b>Total equity and liabilities</b> | <b>133,972</b> | <b>75,273</b> | <b>38,369</b> |
| [2] / [1] | <b>Equity / asset ratio (%)</b>     | <b>77%</b>     | <b>87%</b>    | <b>54%</b>    |

### Research and development costs / operating expenses

Total cost of Research and Development as a percentage of total operating expenses. Indicates the share of total investment allocated to R&D. Subsequently, the residual (1 - R&D/Operating Expenses), indicates share of total invested into General & Administration activities.

| #         | SEK (thousand)   | 2022           | 2021           | 2022           | 2021           | 2021           |
|-----------|--|----------------|----------------|----------------|----------------|----------------|
|           |  | Apr-Jun        | Apr-Jun        | Jan-Jun        | Jan-Jun        | Jan-Dec        |
| [1]       | Research and development costs                                 | -14,275        | -12,952        | -27,765        | -24,025        | -60,490        |
|           | General and administration costs                               | -12,127        | -2,686         | -20,885        | -5,653         | -16,225        |
|           | Other operating income / expense                               | -16            | 35             | -72            | 17             | 16             |
| [2]       | <b>Total operating expenses</b>                                | <b>-26,417</b> | <b>-15,603</b> | <b>-48,722</b> | <b>-29,661</b> | <b>-76,699</b> |
| [1] / [2] | <b>Research and development costs / operating expenses (%)</b> | <b>54%</b>     | <b>83%</b>     | <b>57%</b>     | <b>81%</b>     | <b>79%</b>     |

## The CEO declaration

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The CEO assures that this interim report provides a true and fair view of the development and the Group's and the Parent Company's operations, position and results, and describes significant risks and uncertainties that the Parent Company and the companies included in the Group face. The interim report has not been reviewed by the company's auditors. The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) adopted by the EU and the interim report has been prepared in accordance with IAS 34 - Interim Financial Reporting.

Lund, August 5, 2022

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**Jeppe Øvlesen**  
Chief Executive Officer (CEO)

# Dictionary

## ACE inhibitor

A group of drugs that lower blood pressure by inhibiting the enzyme angiotensin-converting enzyme (ACE).

## Agonist

An agonist is a chemical that activates a receptor to produce a biological response. Receptors are cellular proteins whose activation causes the cell to modify what it is currently doing. In contrast, an antagonist blocks the action of the agonist, while an inverse agonist causes an action opposite to that of the agonist.

## Angiotensin

Angiotensin is a peptide hormone important for the regulation of blood pressure.

## ACTH

Adrenocorticotrophic hormone (ACTH; also adrenocorticotropin, corticotropin) is a polypeptide tropic hormone produced by and secreted by the anterior pituitary gland. It is also used as a medication and diagnostic agent.

## AP1189

The mechanism of action of SynAct Pharma's leading drug candidate AP1189 is the promotion of inflammatory resolution by the selective activation of melanocortin receptors 1 and 3. These receptors are found on all immune cells, including macrophages and neutrophils. Activation of these receptors leads to two direct anti-inflammatory effects: it affects these cells to produce fewer inflammation-driving molecules and is also able to change them to initiate cleaning of the inflammation, also known as efferocytosis (J Immun 2015, 194: 3381-3388). This process has been shown to be effective in models of inflammatory and autoimmune diseases and the clinical potential is tested in clinical programs in patients with rheumatoid arthritis (RA), nephrotic syndrome (NS) and COVID-19. The safety and efficacy of AP1189 have not been reviewed by any global regulator.

## APM

Alternative Performance Measures. An alternative key figure refers to a financial measure of historical or future earnings development, financial position, financial result or cash flows. It is not such a financial measure that is defined or specified in the applicable rules for financial reporting.

## Autoimmune disease

An autoimmune disease is a condition arising from an abnormal immune response to a functioning body part.

## BEGIN

The BEGIN study was a multi-center, two-part, double-blind, placebo-controlled study, in which two doses of AP1189 (50 mg and 100 mg orally administered once daily) was evaluated against placebo as adjunctive therapy to methotrexate in newly diagnosed patients with acute, active RA. The study's primary endpoint is a reduction in disease activity from high (defined as clinical disease activity > 22) to moderate or low activity during its four-week treatment period. Key data from the study were presented on November 30, 2021.

## cAMP

Cyclic adenosine monophosphate (cAMP, cyclic AMP, or 3',5'-cyclic adenosine monophosphate) is a second messenger important in many biological processes. cAMP is a derivative of adenosine triphosphate (ATP) and used for intracellular signal transduction in many different organisms, conveying the cAMP-dependent pathway.

## Clinical study

Clinical studies are performed to test the efficacy and safety of new drugs, diagnostic tests, products or treatments. Before studies on humans begin, tests have already been performed in several different ways in laboratory experiments and in animal studies. Clinical studies are conducted with both healthy volunteers and individuals with the disease being studied.

## CMC

CMC is an acronym for chemistry, manufacturing and controls, which are crucial activities in the development of new pharmaceutical products. In addition to the processes themselves, CMC also refers to practices and specifications that must be followed and complied with to ensure product safety and consistency between batches.

## Contract Research Organization (CRO)

In the life sciences, a contract research organization (CRO) is a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. A CRO may provide such services as biopharmaceutical development, biologic assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence.

## DMARD

Disease-modifying anti-rheumatic drugs (DMARDs) are a category of otherwise unrelated drugs that are defined by their use in rheumatoid arthritis and other rheumatic diseases. The term often finds its meaning in contrast to non-steroidal anti-inflammatory drugs and steroids. The term overlaps with antirheumatics, but the two terms are not synonyms.

## Dictionary continued

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### **ESMA**

European Securities and Markets Authority.

### **FDA**

The United States Food and Drug Administration (FDA or USFDA) is the US Food and Drug Administration responsible for food (for humans and animals), dietary supplements, medicines (for humans and animals), cosmetics, medical equipment (for humans and animals), radioactive radiation equipment and blood products.

### **iMN**

Idiopathic membranous nephropathy is an autoimmune disease in which the membranes of the glomerulus are attacked by generated autoantibodies, resulting in progressive deterioration of kidney function.

### **IND (Investigational New Drug) Application**

An application to the FDA that must be submitted and approved before a drug can be tested on humans, so-called permit application for drug testing.

### **Melanocortin**

Melanocortin is a body-specific hormone that acts by activating specific melanocortin receptors on the cell surface of certain white blood cells.

### **Melanocortin receptors**

When these receptors are activated, processes start in the body that lead to reduced release of pro-inflammatory mediators (slowed inflammation) and stimulation of healing processes (dead cells and cell debris are cleaned away and the tissue heals).

### **Methotrexate (MTX)**

Methotrexate is a folic acid antagonist that belongs to the group of chemotherapy drugs. Today it is used in rheumatoid arthritis, psoriasis and Crohn's disease as a disease-modifying drug but can also be used as a cancer treatment.

### **Nephrotic Syndrome (NS)**

Nephrotic syndrome (sometimes abbreviated NS) is a syndrome (a collection of symptoms) due to a change in the kidneys.

### **pERK pathway**

The pERK pathway (also known as the MAPK/ERK or Ras-Raf-MEK-ERK pathway) is a chain of proteins in the cell that communicates a signal from a receptor on the surface of the cell to the DNA in the nucleus of the cell.

### **Pharmacokinetics (PK)**

Pharmacokinetics is the study of the metabolism of drugs in the body, i.e., how the levels of a drug in the body change through absorption, distribution, metabolism and excretion.

### **RA**

Rheumatoid arthritis, is an autoimmune disease characterized by chronic inflammation (arthritis) and pain (arthralgia) in the joints of the body. Inflammation has a strong ability to break down cartilage, adjacent bones, tendons and arteries.

### **RESOVIR (Resolution Therapy for Viral Inflammation Research) collaboration**

RESOVIR is a scientific and clinical collaboration between Professor Mauro Teixeira, MD, PhD, Universidade Federal de Minas, Belo Horizonte, Brazil, Professor Mauro Perretti, PhD William Heavy Research Institute, Barts and the London School of Medicine, Queen Mary University, London, UK, and SynAct Pharma AB. The aim of the RESOVIR collaboration is to investigate the utility of resolution therapy to resolve the cytokine storm inflammation associated with significant viral infections.

### **Respiratory insufficiency**

Means that breathing does not work as it should, which leads to a lack of oxygen.

## Other company information

### SynAct Pharma AB – parent company

|                                |   |
|--------------------------------|---|
| Company name                   | SynAct Pharma AB  |
| Trade name/Ticker              | SynAct Pharma/SYNACT. Shares are traded at Nasdaq Stockholm.        |
| ISIN-kod                       | The ISIN-code of the share is SE0008241491.                         |
| LEI-kod                        | 549300RRYIEFEQ72N546  |
| Registered office and domicile | Skåne County, Lund Municipality, Sweden                             |
| Corporate registration number  | 559058-4826   |
| Date of incorporation          | 2016-04-12  |
| Date of operation              | 2016-04-12  |
| Jurisdiction                   | Sweden  |
| Association form               | Public limited liability company                                    |
| Legislation                    | Swedish law and Swedish Companies Act                               |
| Company address                | Scheelevägen 2, 223 81 Lund, Sweden                                 |
| Phone number                   | +45 28 44 75 67   |
| Homepage                       | <a href="http://www.synactpharma.com">www.synactpharma.com</a>      |
| Auditor                        | KPMG AB (Box 227, 201 22 Malmö), auditor in charge Linda Bengtsson. |

### SynAct Pharma ApS – affiliate

|                                      |             |
|--------------------------------------|-------------|
| Country of establishment             | Denmark     |
| Country of operations                | Denmark     |
| CVR-number (Company registration id) | 34459975    |
| Holding                              | 100 percent |



SYNACT  PHARMA

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