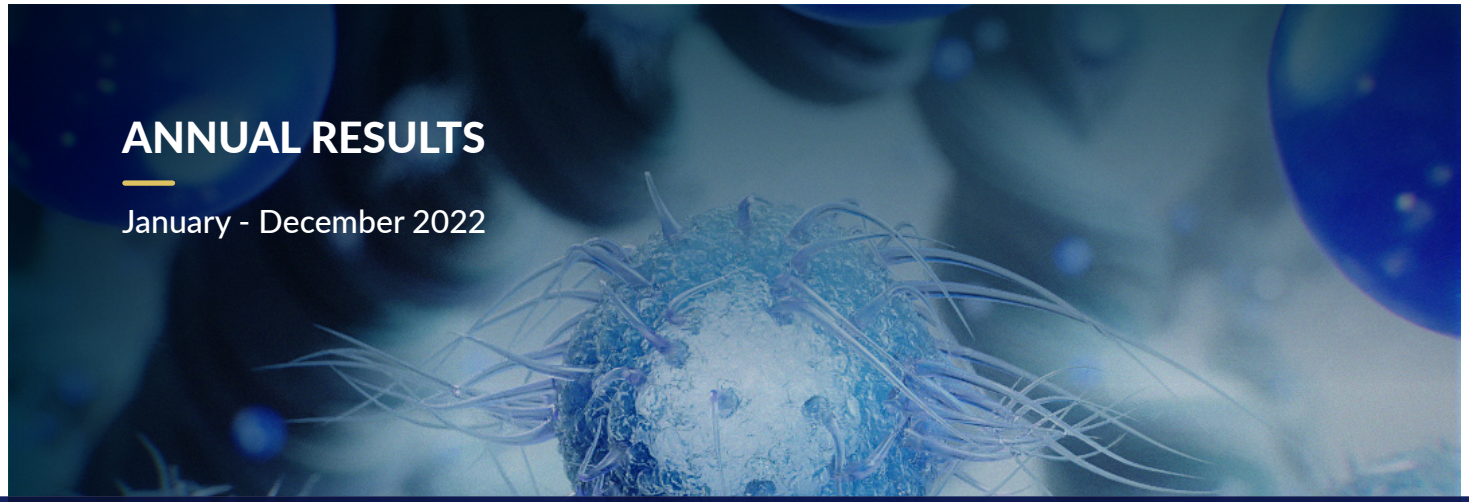

# ANNUAL RESULTS

January - December 2022

SYNACT PHARMA

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

# Q4

This English version of SynAct Pharma's Annual Results and 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**

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

**www.synactpharma.com**

# Interim report for the fourth quarter and annual results 2022


## Quarter 4 (October - December)

- 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 2024.
- Operating expenses amounted to SEK 30,523 (26,153) thousand, an increase of 16%, driven both by increased investments in R&D and higher administrative costs.
- The Group's loss after tax amounted to SEK 30,477 (26,210) 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 77 (-3) thousand in the quarter.
- The Group's earnings per share before and after dilution amounted to SEK -1.06 (-1.01).
- Cash flow from operating activities amounted to SEK -22,306 (-20,257) thousand.
- Cash flow from financing activities amounted to SEK 76,025 (-77) thousand.
- Cash flow for the period amounted to SEK 53,747 (-20,332) thousand.
- Cash and cash equivalents at the end of the period amounted to SEK 108,245 (23,997) thousand


## Twelve months (January – December)

- The Group's net sales amounted to SEK 0 (0) thousand.
- Operating expenses amounted to SEK 105,705 (76,699) thousand, an increase of 38%, 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 acquisition of TXP Pharma AG.
- The Group's loss after tax amounted to SEK 99,205 (69,304) 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 7,860 (7,505) thousand in 2022.
- The Group's earnings per share before and after dilution amounted to SEK -3.60 (-2.68).
- Cash flow from operating activities amounted to SEK -117,555 (-64,997) thousand.
- Cash flow from financing activities amounted to SEK 200,712 (74,323) thousand.
- Cash flow for the period amounted to SEK 83,184 (9,319) tho usand.

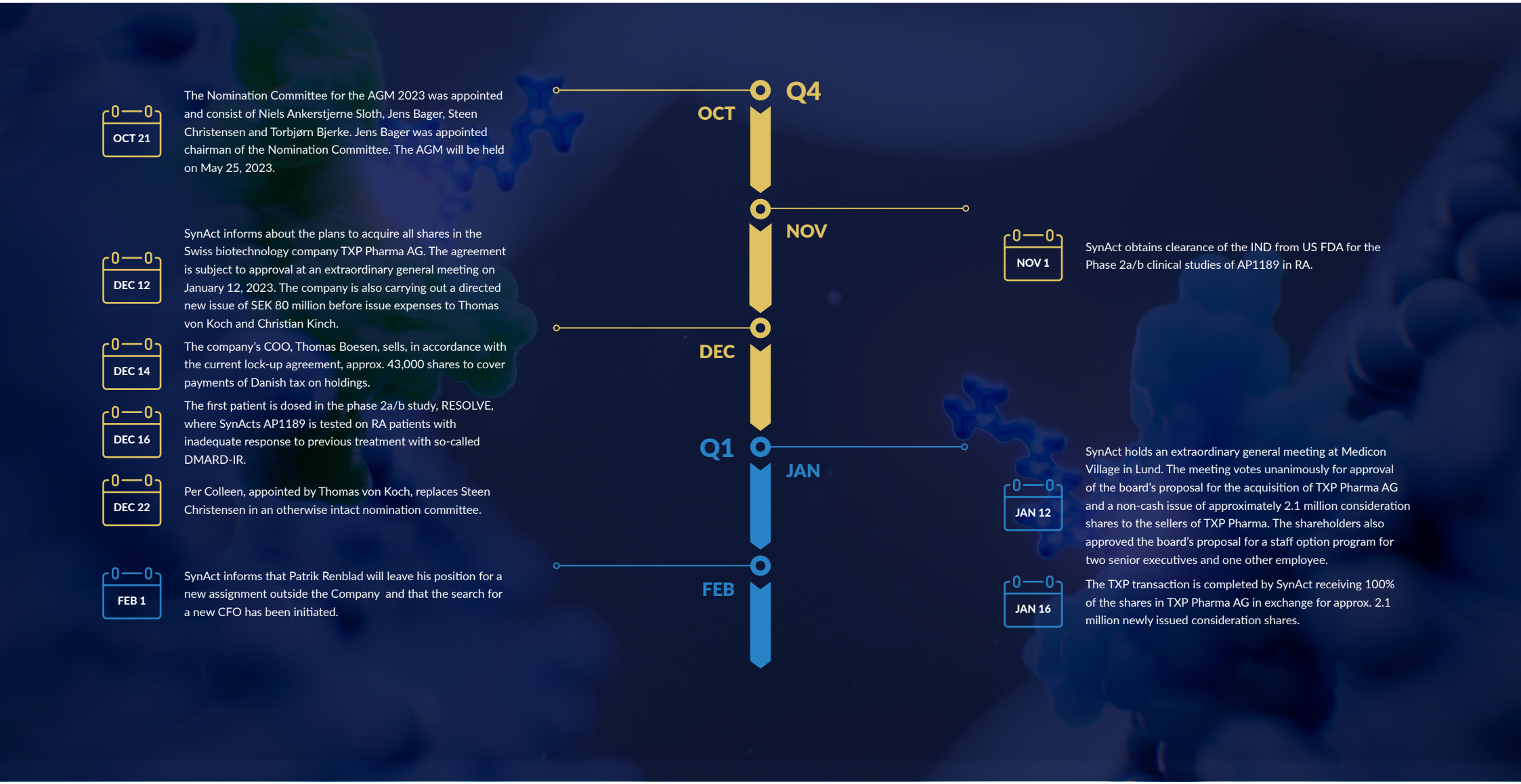
## The Group's financial performance per quarter

| (SEK thousand) | 2022 Q4 | 2022 Q3 | 2022 Q2 | 2022 Q1 | 2021 Q4 | 2021 Q3 | 2021 Q2 | 2021 Q1 |
|---|---|---|---|---|---|---|---|---|
| Net sales | - | - | - | – | – | – | – | – |
| Operating income | -30,523 | -26,461 | -26,417 | -22,304 | -26,153 | -20,885 | -15,603 | -14,058 |
| Profit before tax | -30,554 | -26,569 | -27,625 | -22,317 | -26,207 | -20,676 | -15,856 | -14,070 |
| Profit for the period | -30,477 | -23,919 | -24,754 | -20,055 | -26,210 | -18,222 | -13,137 | -11,735 |
| Total assets | 142,597 | 96,206 | 133,972 | 22,155 | 38,369 | 59,836 | 75,273 | 88,945 |
| Equity / asset ratio (%)[1] | 89% | 83% | 77% | 3% | 54% | 79% | 87% | 88% |
| Earnings per share (SEK) | -1.06 | -0.84 | -0.91 | -0.77 | -1.01 | -0.70 | -0.51 | -0.46 |
| Research & development cost / operating expenses (%)[1] | 71% | 78% | 54% | 60% | 77% | 78% | 83% | 79% |

1) Alternative performance measures - APM, ref. p. 23 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 fourth quarter of 2022 and after the end of the reporting period



# The CEO, Jeppe Øvlesen comments on the fourth quarter

## Strengthened pipeline from acquisition and progress on AP1189

**With a busy 2022 behind us, it is important to take a moment and reflect on the accomplishments made and give thanks to our investors who trusted us and our ability to execute on the company strategy.**

SynAct kept a fast pace during the year, working hard through the end of the fourth quarter. We advanced our pipeline with the lead compound AP1189, dramatically expanded our portfolio with the acquisition of TXP Pharma and bolstered the finances and shareholder base with a successful rights issue of SEK 150 million and the directed share issue of SEK 80 million. With our studies progressing and this broader portfolio, SynAct is in a fantastic position to drive shareholder value.

The company's acquisition of TXP Pharma and SEK 80 million investment from Thomas von Koch and Christian Kinch were momentous, and their knowledge within the industry and extensive network will be important for the company, lifting our attractiveness towards potential business partners.

Our leading position within therapies for resolution treatment through melanocortin biology is boosted by combining the pipeline and scientific capabilities of SynAct and TXP. We can now take on the full range of inflammatory and autoimmune diseases with two complementary platforms, highlighting SynAct's strength in developing pharmaceuticals to treat these severe and debilitating diseases where there is a great unmet medical need.

The development program in rheumatoid arthritis continues to be our main focus.

SynAct also advanced its efforts withing Rheumatoid Arthritis (RA) with the company's lead compound AP1189. The company received clearance from the US Food and Drug Administration (FDA) of its Investigational New Drug (IND) application for a Phase 2a/b study in RA with AP1189. It marks the start of regulatory and clinical processes in the US and allows us to work together with well renowned key opinion leaders in the further development of AP1189 in the US and in the conduct of the RESOLVE study.

At the end of the fourth quarter, the first patient with inadequate response to disease-modifying antirheumatic drugs (DMARD-IR) was dosed in part A of the clinical Phase 2a/b study RESOLVE. This was a big step for SynAct, and we expect results in the second half of 2023 if the recruitment goes as planned.

Including clinics in the US in the development program is key for our discussions with potential business partners. It also opens up the US market, the world's biggest and most important pharma market, where rheumatoid arthritis (RA) in itself has an estimated market value of approximately USD 20 billion annually.

In September, we enrolled our first patient in the Phase 2b EXPAND study in RA using our candidate drug AP1189. This first patient in Moldova was a nice milestone for the EXPAND study, and we will continue to enroll additional patients there and in Bulgaria.

The EXPAND study follows the successful results from the BEGIN study that showed AP1189 to be safe, well tolerated and induce a statistically significant reduction in disease. To bolster the position of AP1189 as a novel compound with a unique mode of action in resolution of inflammation, several exploratory endpoints are included in EXPAND, such as MRI-scanning of affected joints. Topline data is expected to be ready during the second half of 2023, assuming recruitment goes smoothly. EXPAND results will be pivotal in the ongoing interactions with potential partners and for the further development of AP1189.

SynAct also bolstered its board and management team during the year. Kerstin Hasselgren joined the board and adds a wealth of experience from the pharmaceutical industry. Patrik Renblad joined as CFO at the start of 2022 and was instrumental in our move to NASDAQ Stockholm and our capital raisings.

In the fourth quarter, our operating expenses were SEK 31 million, an increase of 16% over the same period last year. R&D investments were SEK 22 million or 7% higher than Q4 2021. Due to the acquisition of TXP Pharma, we incurred higher General and Administration costs than predicted, or SEK 9 million in the quarter, up 52% from the same period last year.

This year will also be crucial for the company. We will work hard to incorporate TXP and drive our portfolio. We are planning for a Capital Markets Day during the spring and will revert with a date in due course.

SynAct is in a strong position with its broader pipeline and new shareholder base. The team at SynAct is grateful for all the support we receive from investors and other stakeholders.

**"During the fourth quarter, we continued the development of AP1189 at a high pace. SynAct's pipeline was strengthened with the acquisition of TXP Pharma and our shareholder base was broadened through the private placement."**

**Jeppe Øvlesen**
CEO

# SynAct Pharma in Brief

## About SynAct Pharma AB

SynAct Pharma AB is a biotech company in clinical phase listed on Nasdaq Stockholm's main market. The company's leading 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 subsidiaries SynAct Pharma ApS and TXP Pharma AG, where the latter is consolidated into the group from January 16, 2023. In addition to the above, SynAct has no additional shareholdings in other companies.

## The acquisition of TXP Pharma AG

On December 12, 2022, SynAct announced the proposed acquisition of the privately owned Swiss biotech company TXP Pharma AG. The transaction, which was conditional upon the approval of the shareholders of SynAct Pharma AB on January 12 was formally closed on January 16, 2023.

TXP Pharma AG was incorporated in 2013 and has its base in Baar in the Zug kanton in Switzerland. It has generated a platform of more than 70 unique analogs to the naturally occurring melanocyte stimulating hormone (MSH). MSH is a melanocortin peptide that is produced by the body to help regulate immune and other systems. The peptides are modified using a proprietary technology to enhance receptor selectivity and stability.

TXP Pharma's patent portfolio is 100% owned and controlled by the company with the lead program being TXP-11. TXP-11 is currently in late pre-clinical phase, expected to enter into clinical testing within a year. Its primary indication is prevention of post-operative organ dysfunction and failure, which is associated with in-hospital mortality and high healthcare system costs.

In addition, TXP Pharma's pre-clinical pipeline consists of several promising assets that have potential to be developed for a wide range of indications where melanocortin receptor stimulating agents have been shown to work and that represents high unmet medical need and great value opportunities.

The acquisition significantly expands SynAct's melanocortin technology portfolio with complimentary peptide agonists that can be tailored to a wide range of autoimmune and inflammatory conditions.

Among the sellers of TXP Pharma AG were, directly and indirectly, Torbjørn Bjerke, chairman of the board of directors of SynAct, Jeppe Øvlesen, CEO of SynAct, Thomas Jonassen, board member and CSO of SynAct, Thomas Boesen, COO of SynAct and Jim Knight, CBO of SynAct. It has therefore been handled as a related party transaction governed by a committee composed of the four non-conflicted members of the board of directors, chaired by Uli Hacksell. In its work, the committee has been supported by legal and financial advisors and has also obtained a third-party valuation of TXP's assets as well as a so-called fairness opinion issued by Ernst & Young AB.

Following due diligence and negotiation, the agreed purchase price for the acquisition was composed of an initial purchase price of SEK 136 million and a potential additional purchase price of SEK 55 million. The initial purchase price was to be paid through the issuance of in the aggregate 2,172,523 new issued consideration shares in SynAct. In determining the number of shares issued, a settlement price of SEK 62.60 per share (corresponding to the volume-weighted average price of the Company's shares on Nasdaq Stockholm during 30 trading days up to and including the trading day prior to the date of signing of the share purchase agreement) was used.

The additional purchase price is a one-time amount of SEK 55 million which will be payable, in cash or in new shares in SynAct at the discretion of SynAct, if or when the first of a set of conditions are met; (i) SynAct's board of directors, following the completion of the first Phase 2 study with one of TXP's compounds, resolves to continue the development of said compound for a subsequent Phase 2b or a Phase 3 study or if an application to commence such studies is filed; (ii) TXP divests or licenses one of TXP's compounds; or (iii) SynAct divests the shares in TXP.

TXP Pharma AG will be consolidated into the financial reporting of SynAct Pharma AB from the first quarter 2023.

Please refer to note 12a to the financial statements for more information on the transaction.

## Review by the Company's Auditor

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

## Annual General Meeting

The Annual General Meeting will be held on May 25, 2023 at 1 p.m. at Setterwalls Advokatbyrå, Stortorget 23, 211 34 Malmö. Notice to attend will be announced in Post- och Inrikes Tidningar and on the Company website.

## Forward looking statements

This financial report contains statements that are forward-looking Such forward-looking statements necessarily involve known and unknown risks and uncertainties, which may cause actual performance and financial results in future periods to differ materially from any projections of future performance or result expressed or implied by such forward-looking statements.

# 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 | STATUS & NEXT MILESTONE |
|---|---|---|---|---|---|---|---|
| AP1189 | Rheumatoid arthritis - First line treatment | | | | | | • SynAct-CS007 (EXPAND):<br>• Status: Ongoing/Recruiting<br>• Topline data available – H2 2023 |
| | Rheumatoid arthritis - DMARD-IR | | | | | | • SynAct-CS006 (RESOLVE):<br>• Status: Ongoing/Recruiting<br>• Top line data (Part A) available - H2 2023 |
| | Nephrotic syndrome (iMN) | | | | | | • SynAct-CS003<br>• Status: Ongoing/Recruiting<br>• Top line data available - H2 2023 |
| | Virus-induced respiratory insufficiency | | | | | | • Pre-clinical viral disease models |
| TXP-11 | Prevention of organ failure in complicated surgey | | | | | | • Ready for start of clinical development - H2 2023 |
| Next generation molecules | Inflammatory diseases | | | | | | |

Completed phase

Ongoing phase

# Research and Development (continued)

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 adrenocorticotropic 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.

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.

## 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

SynAct has 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

The company has initiated two additional Phase 2 clinical studies in RA with AP1189.

### 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. The study also involves several exploratory endpoints that are expected to underscore the unique mode of action of AP1189. 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 conducts the study at clinics in Europe in a cost-efficient approach with the aim to report key results second half of 2023. The study started in September 2022 and patients are recruited according to plan.

### 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 the Company considers further clinical development in DMARD-IR to be both relevant and necessary.

Development of AP1189 in DMARD-IR patients is done under an IND (Investigational New Drug) application with clinical sites in the both the US and in European countries. The clinical study called RESOLVE is designed as a two-part safety and dose finding study with four weeks dosing in part A like in the BEGIN study, followed by a part B resembling EXPAND with 12 weeks once

# Research and Development (continued)

daily dosing. Recruitment of patients is ongoing and results from part A is expected in the second half of 2023.

### 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. The main efficacy read-out in the study is effect on urinary proteing excretion. Recruitment is ongoing.

### Virus Induced Respiratory Insufficiency (VIRI)

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 VIRI

As part of the RESOVIR collaboration, AP1189 was tested in a 60 patient placebo-controlled Phase 2a clinical trial of treatment of hospitalized COVID-19 infected patients who required supplemental oxygen (experiencing respiratory insufficiency). AP1189 or placebo was administered orally once-daily for 2 weeks.

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

Further clinical development in the COVID-19 infected patient population was deemed less viable.

There is still an unmet medical need in virus-induced respiratory insufficiency associated with common annual or seasonal viral infections such as viral pneumonia and or influenza. The company 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 did not reach a conclusion in 2022, as were expected, but pre-clinical studies with the aim to unlock AP1189's potential in this area are still ongoing in 2023.

### Peptide Agonists

SynAct expanded its melanocortin agonist portfolio through the acquisition of TXP Pharma. TXP was a privately held, Swiss-incorporated biotech company researching and developing pharmaceutical drugs for autoimmune and inflammatory diseases by stimulation of melanocortin receptors. TXP has created a platform of more than 70 unique analogs of the naturally occurring melanocyte stimulation hormone (MSH) with a range of melanocortin receptor selectivity. The TXP analogs have both increased stability as well as enhanced receptor binding and stimulation over MSH.

### TXP-11

TXP-11 has completed regulatory toxicology studies required to initiate Phase 1 studies in humans. TXP-11 is a peptide which is administered intravenously and is being developed for the prevention of organ failure and damage in connection with major surgeries. TXP-11 is expected to advance into Phase 1 clinical development in 2023.

# The SynAct Pharma Share

## Share information

SynAct Pharma's share has been listed on Nasdaq Stockholm in the Mid Cap segment since July 12, 2022. The stock is traded with the ticker or short name SYNACT. From the initial public offering in 2016 until July 11, 2022, the company's stock was traded on Spotlight.

In December 2022, SynAct Pharma AB successfully completed a directed share issue in which the number of shares increased by 1,277,954 to 29,648,457 and the share capital increased by SEK 159,744 to SEK 3,706,057.

The closing price of the SynAct share on the last trading day in 2022 was SEK 81.50.

## Share-based incentive programs

At the extraordinary general meeting on January 12, 2023, the board's proposal for a staff option program for two senior executives and one other employee was adopted. See note 12b to the financial statements for further information.

There have been no share-based incentive programs that have affected the reporting period.

## Ownership (December 31, 2022)

| Shareholder | Capital and votes(%) |
|---|---|
| Bioinvest ApS | 12.7% |
| Avanza Pension | 6.4% |
| Nordnet Pensionsförsäkring | 5.0% |
| Thomas von Koch | 3.8% |
| Torbjörn Bjerke | 2.8% |
| Handelsbanken fonder | 1.1% |
| Robert Sahlin | 1.0% |
| Henrik Stage | 0.9% |
| Swedbank Försäkring | 0.9% |
| Per Granath | 0.8% |
| **Total (top-10)** | **35.3%** |
| **Others** | **64.7%** |

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, 29,648,457.

## Lock-up agreement

The board with Torbjørn 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 allowed sales of a maximum of 10% for three months until October 24, 2022.

In connection with the directed share issue in December 2022, new lock-in agreements were entered into for all members of the board and management. The new agreements are valid until March 15, 2023 with similar conditions as before.

The agreements above were entered between the respective directors & executives and the banks ABG Sundal Collier AB and Van Lanschot Kempen N.V.

The lock-up agreements did not affect the Group financially or in terms of accounting.

## Analyst coverage

SynAct Pharma and its share is covered by two independent analysts:
- Gonzalo Artiach Castañón från ABG Sundal Collier AB
- Sebastian van der Schoot från Van Lanschot Kempen BV

## Financial reporting calendar

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

| Date: | Report: |
|---|---|
| 04/13/2023 | Annual Report 2022 |
| 05/05/2023 | Interim Report Q1 2023 |
| 05/25/2023 | Annual General Meeting 2023 |
| 08/04/2023 | Interim Report Q2 2023 |
| 11/03/2023 | Interim Report Q3 2023 |

# Comments on the financial development for the fourth quarter and the whole year of 2022

## Net sales
Net sales for the fourth quarter and the whole year 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 2 program involving the drug candidate AP1189, planned for 2024.

The parent company's sales are from services delivered to the Danish subsidiary and amounted to SEK 1,310 (408) thousand in the fourth quarter, and SEK 5,144 (1,637) thousand for the whole year.

## Research and development (R&D) costs
Total costs for R&D in the fourth quarter amounted to SEK 21,663 (20,205) thousand. For the whole year, R&D costs amounted to SEK 70,067 (60,490) 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 two main clinical Phase 2 studies with AP1189 in RA progresses, costs are expected to rise further.

## General & administration costs
Administrative expenses amounted to SEK 8,987 (5,917) thousand in the fourth quarter and SEK 35,611 (16,225) thousand for the whole year. 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 the TXP Pharma acquisition. The parent company follows the accounting guidelines in RFR 2, which for the treatment of acquisition costs, deviates from IFRS. Therefore, acquisition cost amounting to SEK 4,056 thousand is reported as pre-paid expenses and will be capitalized in the parent company.

## Financial items
Net financial items amounted to SEK -31 (-54) thousand in the fourth quarter and SEK -1,360 (-110) thousand for the whole year. The change is attributable to exchange rate adjustments and interest expenses from leasing liabilities.

In the Parent Company, net financial items amounted to SEK -1 (0) thousand in the quarter. Year-to-date, net financial items were SEK -110,299 (-50,005) thousand. The group reports no proprietary intangible assets because the criteria according to IAS 38 are not met. To be able to continue the development activities in Denmark, the Swedish parent company provides ongoing capital contributions to the company that conducts the development activities. Under normal circumstances, the parent company would capitalize the contribution as shares in subsidiaries, but since no part of these funds is capitalized in the balance sheet, the contribution is a cost to the parent company and this cost is reported as a financial cost in the income statement.

## Tax for the period
Tax revenues in the quarter amounted to SEK 77 (-3) thousand. For the twelve months the accrued tax credit amounted to SEK 7,860 (7,505) thousand. See Note 7 - Tax receivables for more information.

## Loss for the period
The Group's loss for the quarter amounted to SEK 30,477 (26,210) thousand and for the whole year, the reported loss was SEK 99,205 (69,304) thousand.

## Cash flow, financial position and going concern
Cash flow from operating activities amounted to SEK -22,306 (-20,257) thousand in the quarter. The increase is driven by increased activities and by initial start-up payments for the two new clinical trials. Full-year cash flow from operating activities amounted to SEK -117,555 (-64,997) thousand.

Cash flow from financing activities amounted to SEK 76,025 (-77) thousand in the quarter, driven by the directed issue that was completed in December. For the whole year, cash flow from financing activities amounted to SEK 200,712 (74,323) thousand.

Cash flow for the period amounted to SEK 53,747 (-20,332) thousand and SEK 83,184 (9,319) thousand for the year.

The Group's cash and cash equivalents as of December 31, 2022 amounted to SEK 108,245 (23,997) thousand.

The Board of Directors continuously assesses the Company's financial position and has determined that its current cash and cash equivalents is sufficient to fund ongoing clinical studies, other communicated activities and keep the company, including the recently acquired affiliate TXP Pharma AG, running until mid-2024.

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 7 - Tax receivables for more information) amounted to SEK 8,231 (7,564) thousand.

The Group applies IFRS 16 Leasing on leased office premises, which generated a right of use in the balance sheet of SEK 2,095 (3,179) thousand and the corresponding short- and long-term leasing liabilities of SEK 1,000 (979) thousand and SEK 1,064 (2,110) thousand, respectively.

## Employees
The number of employees was 5 (3). Three employees (2) were employed by the affiliate SynAct Pharma ApS.

## Corporate Governance
Since the listing on Nasdaq in July, 2022, the company complies with the Swedish Code of Corporate Governance and will publish a Corporate Governance Report as an integrated part of the Annual Report for 2022.

# Consolidated income statement

| SEK (thousand) | 2022 | 2021 | 2022 | 2021 |
|---|---|---|---|---|
| | Okt-Dec | Okt-Dec | Jan-Dec | Jan-Dec |
| Net sales | - | - | - | - |
| **Gross profit** | - | - | - | - |
| Research and development costs | -21,663 | -20,205 | -70,067 | -60,490 |
| General and administration costs | -8,987 | -5,917 | -35,611 | -16,225 |
| Other operating income/expenses | 127 | -30 | -28 | 16 |
| **Total operating expenses** | **-30,523** | **-26,153** | **-105,705** | **-76,699** |
| **Operating income** | **-30,523** | **-26,153** | **-105,705** | **-76,699** |
| Net financial items | -31 | -54 | -1,360 | -110 |
| **Profit after financial items** | **-30,554** | **-26,207** | **-107,065** | **-76,809** |
| Tax on profit/loss for the period | 77 | -3 | 7,860 | 7,505 |
| **Profit for the period** | **-30,477** | **-26,210** | **-99,205** | **-69,304** |
| Earnings per share (SEK) | -1.06 | -1.01 | -3.60 | -2.68 |
| Dilued earnings per share (SEK) | -1.06 | -1.01 | -3.60 | -2.68 |
| Average number of shares outstanding ('000) | 28,621 | 26,006 | 27,585 | 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 | 2022 | 2021 |
|---|---|---|---|---|
| | Okt-Dec | Okt-Dec | Jan-Dec | Jan-Dec |
| **Profit for the period** | **-30,477** | **-26,210** | **-99,205** | **-69,304** |
| **Items reclassifiable to profit or loss** | | | | |
| Translation differences from foreign operation | 646 | -139 | 3,164 | -94 |
| **Comprehensive income after tax for the period** | **-29,831** | **-26,348** | **-96,041** | **-69,398** |
| **Comprehensive income for the period** | **-29,831** | **-26,348** | **-96,041** | **-69,398** |

*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) | 12/31/2022 | 12/31/2021 |
|---|---|---|
| **Assets** | | |
| ***Non-current assets*** | | |
| Right-of-use assets | 2,095 | 3,179 |
| Financial assets | 270 | 274 |
| **Total non-current assets** | **2,365** | **3,454** |
| | | |
| ***Current assets*** | | |
| Tax credit | 8,231 | 7,564 |
| Other current receivables | 6,464 | 3,107 |
| Prepaid expenses | 17,293 | 247 |
| Cash and cash equivalents | 108,245 | 23,997 |
| **Total current assets** | **140,232** | **34,916** |
| | | |
| **Total assets** | **142,597** | **38,369** |

| SEK (thousand) | 12/31/2022 | 12/31/2021 |
|---|---|---|
| **Equity and liabilities** | | |
| Share capital | 3,706 | 3,251 |
| Other paid-in capital | 394,839 | 193,602 |
| Reserves | 2,765 | -399 |
| Retained earnings/losses including net profit | -274,790 | -175,585 |
| **Total equity** | **126,520** | **20,869** |
| | | |
| ***Non-current liabilities*** | | |
| Leasing liability | 1,064 | 2,110 |
| **Total non-current liabilities** | **1,064** | **2,110** |
| | | |
| ***Current liabilities*** | | |
| Accounts payable | 4,723 | 4,254 |
| Leasing liability | 1,000 | 979 |
| Other current liabilities | 4,381 | 2,267 |
| Accrued expenses | 4,909 | 7,889 |
| **Total current liabilities** | **15,012** | **15,390** |
| | | |
| **Total equity and liabilities** | **142,597** | **38,369** |

# Consolidated statement of changes in equity

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

| 01/01/2022 - 12/31/2022<br>SEK (thousand) | Share capital | Other paid-in capital | Reserves | Retained earnings, including profit for the period | Total |
|---|---|---|---|---|---|
| **Opening equity** | **3,251** | **193,602** | **-399** | **-175,585** | **20,869** |
| Profit for the period | - | - | - | -99,205 | -99,205 |
| Other comprehensive income | - | - | 3,164 | - | 3,164 |
| **Comprehensive income for the period** | **-** | **-** | **3,164** | **-99,205** | **-96,041** |
| **Transactions with owners** | | | | | |
| New share issue | 455 | 228,490 | - | - | 228,945 |
| Issue expenses | - | -27,252 | - | - | -27,252 |
| **Total transaction with owners** | **455** | **201,238** | **-** | **-** | **201,693** |
| **Closing equity** | **3,706** | **394,839** | **2,765** | **-274,790** | **126,520** |

# Condensed consolidated statement of cash flows

| SEK (thousand) | 2022 | 2021 | 2022 | 2021 |
|---|---|---|---|---|
| | Okt-Dec | Okt-Dec | Jan-Dec | Jan-Dec |
| **Cash flow from operations** | | | | |
| Operating income | -30,523 | -26,153 | -105,705 | -76,699 |
| Adjustment for non-cash items | -43 | 88 | 712 | 88 |
| Interest received | 1 | - | 47 | - |
| Interest paid | 136 | -54 | -119 | -110 |
| Corporate income tax received | 7,860 | 4,625 | 7,860 | 4,625 |
| **Cash flow from operations before change in working capital** | **-22,569** | **-21,494** | **-97,206** | **-72,096** |
| Change in working capital | 263 | 1,237 | -20,349 | 7,099 |
| **Cash flow from operating activities** | **-22,306** | **-20,257** | **-117,555** | **-64,997** |
| Cash flow from investing activities | 27 | 2 | 27 | -6 |
| Cash flow from financing activities | 76,025 | -77 | 200,712 | 74,323 |
| **Cash flow for the period** | **53,747** | **-20,332** | **83,184** | **9,319** |
| Cash and cash equivalents at beginning of period | 54,898 | 44,402 | 23,997 | 14,548 |
| Decrease/increase in cash and cash equivalents | 53,747 | -20,332 | 83,184 | 9,319 |
| Exchange rate difference in cash and cash equivalents | -400 | -73 | 1,063 | 130 |
| **Cash and cash equivalents at end of period** | **108,245** | **23,997** | **108,245** | **23,997** |

## Parent company's condensed income statement

| SEK (thousand) | 2022 | 2021 | 2022 | 2021 |
|---|---|---|---|---|
| | Okt-Dec | Okt-Dec | Jan-Dec | Jan-Dec |
| Net sales | 1,310 | 408 | 5,144 | 1,637 |
| **Gross profit** | **1,310** | **408** | **5,144** | **1,637** |
| General and administration costs | -3,054 | -4,256 | -25,726 | -12,571 |
| Other operating expenses | 99 | -5 | -90 | -27 |
| **Total operating expenses** | **-2,955** | **-4,261** | **-25,815** | **-12,598** |
| **Operating income** | **-1,645** | **-3,853** | **-20,671** | **-10,962** |
| Net financial items | -1 | - | -110,299 | -50,005 |
| **Profit after financial items** | **-1,646** | **-3,853** | **-130,970** | **-60,966** |
| Tax on profit for the period | - | - | - | - |
| **Profit for the period** | **-1,646** | **-3,853** | **-130,970** | **-60,966** |

## Parent company's statement of comprehensive income

| SEK (thousand) | 2022 | 2021 | 2022 | 2021 |
|---|---|---|---|---|
| | Okt-Dec | Okt-Dec | Jan-Dec | Jan-Dec |
| Profit for the period | -1,646 | -3,853 | -130,970 | -60,966 |
| Other comprehensive income | - | - | - | - |
| **Total comprehensive income** | **-1,646** | **-3,853** | **-130,970** | **-60,966** |

# Parent company's condensed balance sheet

| SEK (thousand) | 12/31/2022 | 12/31/2021 |
|---|---|---|
| **Assets** | | |
| *Non-current assets* | | |
| Financial assets | 24,419 | 24,419 |
| **Total non-current assets** | **24,419** | **24,419** |
| | | |
| *Current assets* | | |
| Other receivables | 2,231 | 865 |
| Prepaid expenses | 4,325 | 202 |
| Cash and cash equivalents | 88,250 | 19,849 |
| **Total current assets** | **94,806** | **20,915** |
| | | |
| **Total assets** | **119,225** | **45,334** |

| SEK (thousand) | 12/31/2022 | 12/31/2021 |
|---|---|---|
| **Equity and liabilities** | | |
| *Restricted equity* | | |
| Share capital | 3,706 | 3,251 |
| | | |
| *Non-restricted equity* | | |
| Other paid-in capital | 394,839 | 170,387 |
| Retained earnings/losses | -156,448 | -72,267 |
| Profit for the period | -130,970 | -60,966 |
| **Total equity** | **111,127** | **40,404** |
| | | |
| **Current liabilities** | | |
| Accounts payable | 1,072 | 1,136 |
| Other liabilities | 4,044 | 2,163 |
| Accrued expenses | 2,981 | 1,630 |
| **Total current liabilities** | **8,098** | **4,930** |
| | | |
| **Total equity and liabilities** | **119,225** | **45,334** |

# Notes and disclosures

## 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 Scheelevägen 2, 223 63 Lund, Sweden. This interim report was approved for publishing on February 17, 2023.

## 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.

## 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. In connection with the then proposed acquisition of TXP Pharma AG in December 2022, a directed issue of SEK 80 million, SEK 76.3 million net after issuing expenses, strengthened the Company’s financial position.

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 fourth 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 took mitigating steps to reduce the risk through placement of liquidity in EUR and DKK accounts. However, the depreciation of the Swedish currency against these major currencies has resulted in cost increases during 2022 and it cannot be ruled out that it could have negative impact on SynAct’s financial results during 2023.

SynAct Pharma conducts 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. To-date, SynAct and its collaborating partners have not encountered any difficulties that have not been overcome with only minor cost increases but without delays in the execution of the studies. 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 current study program, the assessment is that the pandemic (as it is currently occurring) should not significantly affect the recruitment to and implementation of the studies.

# Notes and disclosures (continued)

## Note 4 - Transactions and agreements with related parties

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

| SEK (thousand) | | 2022 | 2021 | 2022 | 2021 |
|---|---|---|---|---|---|
| **Related party** | **Service** | Oct-Dec | Oct-Dec | Jan-Dec | Jan-Dec |
| UST Leadership AB (Torbjørn Bjerke, chairman) | Consultancy | 525 | 480 | 525 | 654 |
| JSH Biotech ApS (John Haurum, f. board member) | Consultancy | - | - | - | 167 |

The Board of Directors resolved on October 7, 2022, to approve an agreement engaging UST Leadership (Torbjørn Bjerke, chairman of the board of directors) as consultant to perform certain, defined tasks.

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 11, Contingent liabilities for more information.

On December 12, SynAct Pharma AB entered into a conditional share purchase agreement with the owners of TXP Pharma AG. Among the sellers are, directly and indirectly, Torbjørn Bjerke, chairman of the board of directors of SynAct, Jeppe Øvlesen, CEO of SynAct, Thomas Jonassen, board member and CSO of SynAct, Thomas Boesen, COO of SynAct and Jim Knight, CBO of SynAct. Therefore the transaction and the agreement has been defined as a related party transaction. Please refer to note 12a for more information of the transaction.

## 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 SEK 125.1 million after issue expenses. 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.

In December 2022, the Company carried out a directed issue of 1,277,954 shares at a subscription price of SEK 62.60 per share shares, bringing approximately SEK 76.3 million in net proceeds. The number of shares and votes in the Company increases from 28,370,503 to 29,648,457 and the share capital increase by SEK 159,744 from SEK 3,546,313 to SEK 3,706,057.

## Note 6 - Number of registered shares

| Thousand | 2022 | 2021 | 2022 | 2021 |
|---|---|---|---|---|
| | Oct-Dec | Oct-Dec | Jan-Dec | Jan-Dec |
| Number of shares at the beginning of the period | 28,371 | 26,006 | 26,006 | 24,406 |
| Number of shares at the end of the period | 29,648 | 26,006 | 29,648 | 26,006 |
| Average number of shares outstanding in the period | 28,621 | 26,006 | 27,585 | 25,848 |

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

## Note 7 - Tax receivables

According to Danish tax law (the tax credit scheme), the subsidiary SynAct Pharma ApS is entitled to receive a current tax income for some of the expenses that are directly attributable to the company's research and development (R&D). Settled expenses for R&D 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 DKK 5.5 million 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 8,231 thousand (7,564). The Company's balance under the "Tax Credit Scheme" for 2021 was settled in the fourth quarter. The balance related to fiscal year 2022 with an amount of SEK 8,231 thousand is expected to be received in November 2023.

# Notes and disclosures (continued)

## Note 8 - 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 SEK 2 million, and accrued for the remaining amount of approximately SEK 1.6 million.

In December 2021, the Administrative Court ruled in the Company's favor in the case, whereby deductions were allowed. The Tax Agency appealed the Administrative Court's judgment to the Court of Appeal, which on 6 September 2022 rejected the appeal.

On November 3, 2022, the Tax Agency appealed the Court of Appeal's judgment and applied for leave to appeal in the Supreme Administrative Court (HFD). At the moment, it is unclear whether the case will be taken up for review on its merits because the HFD has not yet made a decision regarding the leave to review.

The company has continued to reserve for the full amount of VAT and tax surcharges of SEK 3,689 (1,614) thousand as an other short-term liability in the financial reporting pending a final judgment. The change since the previous year is due to the fact that at the beginning of 2022, after the judgment in the Administrative Court, the Tax Agency refunded the part of the dispute that the Company had previously paid.

## Note 9 - 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 approximately SEK 17 million to SEK 17,293 (247) thousand.

The company reports accrued expenses of SEK 4,909 (7,889) thousand. The change since the comparison period is mainly due to increased provisions for costs related to personnel (severance costs).

The parent company reports prepaid expenses of SEK 4 325 (202). The change against last year is derived from the acquisition related expenses of the TXP Pharma AG transaction of approximately SEK 4 million that are expensed at the Group, but will be capitalized in the parent company upon closing of the transaction.

## Note 10 - Financial assets and liabilities

| SEK (thousand) | 12/31/2022 | 12/31/2021 |
|---|---|---|
| **Financial assets** | | |
| Non-current financial assets | 270 | 274 |
| Cash and cash equivalents | 108,245 | 23,997 |
| **Total financial assets** | **108,515** | **24,271** |
| **Financial liabilities** | | |
| Accounts payable | 4,723 | 4,254 |
| Accrued expenses | 4,909 | 7,889 |
| **Total financial liabilities** | **9,632** | **12,143** |

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 11 - 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 DKK 4.5 million 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 2023 and have a cash flow effect no earlier than 2025.

## Note 12 - Events occuring after the reporting period

### 12 a - Acquisition of TXP Pharma AG

In the beginning of 2023, Synact Pharma AB acquired 100% of the issued share capital of TXP Pharma AG, a swiss biotech company. The acquisition were completed on the 16th of January 2023.

| The purchase price of the acquisition is as follows: | Fair value (SEK thousands) |
|---|---|
| Cash and cash equivalents | 0 |
| Ordinary shares issued | 189,879 |
| Provision for earnout | 7,077 |
| **Total purchase consideration** | **196,956** |

The initial purchase price was paid by SynAct issuing 2,172,523 consideration shares, equivalent to SEK 136 million at the time of signing of the deal and based on a share price of SEK 62.60. In accordance with IFRS 3, the acquirer must recognize the fair value of share-based payments on the acquisition date. The fair value was determined using a share price of SEK 87.40 to SEK 189,879 thousand. The acquisition was carried out on a debt- and cash-free basis.

The provision for earnout is based on a number of events and will be maximum SEK 55 million.
- Positive data in a Phase 2a Study (which leads to a Phase 2b Study or a Phase 3 Study)
- Divesting or out licensing one or more TXP-projects.
- Sale of TXP Pharma AG

The fair value of the earnout has been derived through discounting and probability adjusting to SEK 7,077 thousand.

**Preliminary purchase price allocation analysis**
The table to the right outlines a preliminary purchase price allocation analysis of tha TXP Pharma AG acquisition.

| Assets and Liabilities | Fair value (SEK thousand) |
|---|---|
| Intangible assets | 142,805 |
| Property, plant and equipment | 0 |
| Current receivables excl cash and bank | 100 |
| Cash and cash equivalents | 2,134 |
| Non-current liabilities | 0 |
| Deferred tax liability | -16,908 |
| Current liabilities | -1,950 |
| **Total net assets acquired excluding goodwill** | **126,180** |
| Goodwill | 70,776 |
| **Total net assets acquired** | **196,956** |
| Less | |
| Ordinary shares issued | 189,879 |
| Provision for earnout | 7,077 |
| **Net cash outflow on acquisition of business** | **196,956** |

The purchase price allocation is based on assumptions regarding fair values of intangible assets and earnouts among other things, which may be adjusted during the twelve-months period following the acquisition. Goodwill recognized in the acquisition is attributable to intellectual property rights which is not qualified as intangible assets.

Acquisition costs, related to valuation, tax and legal advisory etc, that for 2022 amounts to SEK 4 million has been expensed in the group but will be capitalized in the parent company.

### 12 b - Approval of Employee Option Program 2023

At the Extraordinary General Meeting of SynAct Pharma AB on January 12, 2023, the meeting resolved in accordance with the proposal from the board of directors to implement an employee option program for two senior executives and one other employee of the company.

The employee option program shall comprise a maximum of 195,000 employee options. The allotted employee options will vest with 1/3 as of the date that falls 12, 24 and 36 months after the date of allotment. Allotted and vested options can be exercised during 30 days from the day following after the announcement of the company's quarterly reports, the first time after the announcement of the quarterly report for the fourth quarter of 2025 and the last time after the announcement of the quarterly report for the fourth quarter of 2026. Each employee option entitles the holders a right to acquire one new share in the company against cash consideration at an exercise price amounting to

# Notes and disclosures (continued)

SEK 138.93, represeinting 175 per cent of the volume weighted average share price of the company's share on Nasdaq Stockholm during 30 trading days immediately prior to the extraordinary general meeting on January 12, 2023. The employee options shall be allotted without consideration and shall not constitute securities and shall not be possible to transfer or pledge.

In order to enable the company's delivery of shares under the employee option program, the meeting also resolved on a directed issue of a maximum of 195,000 warrants to the company or a subsidiary of the group. In addition, the meeting also resolved to approve that the company or another company of the group may transfer warrants to the participants without consideration in connection with the exercise of the employee options. If all warrants that are issued in relation to the employee option program are exercised for subscription of shares, a total of 195,000 shares will be issued, representing a dilution of approximately 0.61% after the increase in shares following the issue of new shares to fund the acquisition of TXP Pharma AG described in Note 12 a.

Employee Option Program 2023 is expected to incur costs for the Company partly from an accounting perspective in accordance with IFRS 2 and partly in form of social security charges for Swedish participants. Personnel costs in accordance with IFRS 2 do not affect the Company's cash flow. For participants in Sweden, social security charges will be expensed in the income statement during the vesting period.

The costs for the program is estimated to SEK 4,106 thousand, and refer to both the estimated cost of the value of the employees' services during the vesting period, valued at market value at the time of the allocation, and the estimated social security fees.

# 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) | 12/31/2022 | 12/31/2021 |
|---|---|---|---|
| | **Assets** | | |
| | Total non-current assets | 2,365 | 3,454 |
| | Total current assets | 140,232 | 34,916 |
| [1] | **Total assets** | **142,597** | **38,369** |
| | **Equity and liabilities** | | |
| [2] | **Total equity** | **126,520** | **20,869** |
| | Total non-current liabilities | 1,064 | 2,110 |
| | Total current liabilities | 15,012 | 15,390 |
| | **Total liabilities** | **16,077** | **17,500** |
| | **Total equity and liabilities** | **142,597** | **38,369** |
| [2] / [1] | **Equity / asset ratio (%)** | **89%** | **54%** |

## 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 Okt-Dec | 2021 Okt-Dec | 2022 Jan-Dec | 2021 Jan-Dec |
|---|---|---|---|---|---|
| [1] | Research and development costs | -21,663 | -20,205 | -70,067 | -60,490 |
| | General and administration costs | -8,987 | -5,917 | -35,611 | -16,225 |
| | Other operating income / expense | 127 | -30 | -28 | 16 |
| [2] | **Total operating expenses** | **-30,523** | **-26,153** | **-105,705** | **-76,699** |
| [1] / [2] | **Research and development costs / operating expenses (%)** | **71%** | **77%** | **66%** | **79%** |

# The CEO declaration

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 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. The interim report has not been reviewed by the company's auditors.

Lund, February 17, 2022

**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**
Adrenocorticotropic 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 it 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.

**ESMA**
European Securities and Markets Authority.

# Dictionary (continued)

### 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).

### Melanocyte-stimulating hormone (MSH
MSH is a group of peptide hormones with receptors on melanocytes. Three different molecules have been able to be verified: alpha-MSH, beta-MSH and gamma-MSH. The first variant, alpha-MSH, is the most active.

### 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.

### Magnetic resonance imaging (MRI)
Magnetic resonance imaging (MRI) is a medical imaging technique used in radiology to form pictures of the anatomy and the physiological processes of the body. MRI scanners use strong magnetic fields, magnetic field gradients, and radio waves to generate images of the organs in the body. MRI does not involve X-rays or the use of ionizing radiation, which distinguishes it from CT and PET scans.

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

### Peptide
A peptide is a molecule that consists of a chain of amino acids (also called monopeptides) joined together by peptide bonds to form a short chain. Peptides differ from proteins only in that they are smaller. Peptides occur naturally in the body, but can also be produced synthetically.

### 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.

### Synovial joint
A synovial joint joins bones with a fibrous capsule that is continuous with the periosteum of the joined bones. This joint unites long bones and permits free bone movement and greater mobility. The synovial cavity/joint is filled with synovial fluid. The joint capsule is made up of an outer layer of fibrous membrane, which keeps the bones together structurally, and an inner layer, the synovial membrane, which seals in the synovial fluid.

# 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 63 Lund, Sweden |
| Phone number | +45 28 44 75 67 |
| Homepage | www.synactpharma.com |
| 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 |

| **TXP Pharma AG** – affiliate | |
|---|---|
| Country of establishment | Switzerland |
| Country of operations | Switzerland |
| Firmennummer (Company registration id) | CHE-271.053.235 |
| Holding | 100 percent |

SYNACT PHARMA

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