



# Q2

INTERIM REPORT OCTOBER 1<sup>ST</sup> 2022 – DECEMBER 31<sup>ST</sup> 2022

The "Company" or "SelectImmune Pharma" refers to SelectImmune Pharma AB,  
corp. reg. no. 559104-6874

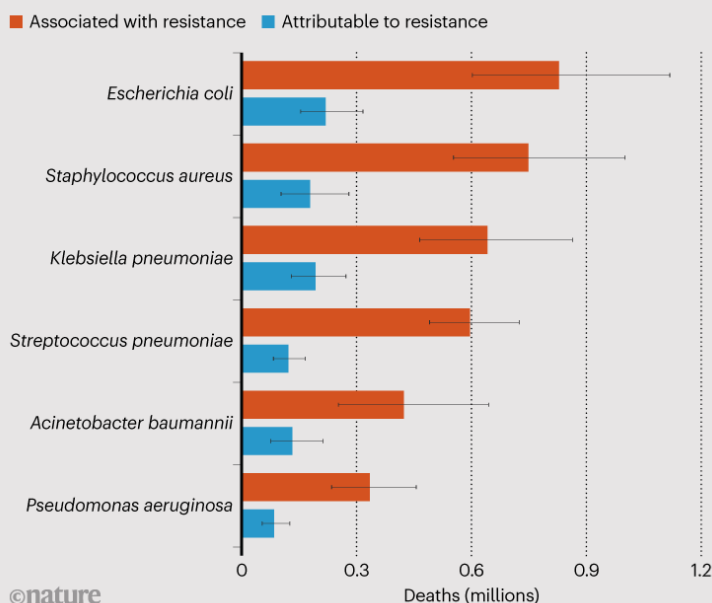
**SelectImmune**  
PHARMA

# SELECTIMMUNE PHARMA IN BRIEF

- SelectImmune Pharma is an innovative biotech company that develops novel immunotherapies against infection.
- Excessive innate immune responses to infection cause symptoms and pathology in acute pyelonephritis and acute cystitis. Immunomodulation is therefore a realistic option for treating these conditions as alternatives or complements to antibiotics.
- Several of the company's drug candidates have shown protective effects against bacterial infection in animal models, including acute cystitis, severe kidney infection and urosepsis.
- One drug candidate, Interleukin-1 receptor antagonist (IL1-RA) has successfully been used in the clinic to treat bladder pain syndrome and is currently being investigated in controlled Phase II trials.
- Furthermore, IL1-RA treatment is being investigated in a Phase II trial in patients with recurrent cystitis.
- SelectImmune Pharma is a research based company with an agreement with LU.
- The discoveries are protected by four patent families. Patents have been approved in the US, Europe and Australia. Group I includes known immunomodulatory substances and pain inhibitors. Group II includes molecules from "good" bacteria that rebalance the immune system and Group III small RNA inhibitors that target excessive inflammation and reduce the risk of sepsis or kidney damage.
- The drug candidates address important medical needs in large patient groups. The markets for the treatment of infections are extensive, both nationally and internationally.
- Antibiotic resistance is a global, rapidly growing health concern. The World Health Organization (WHO) has declared antibiotic resistance a major threat to global health.

## DEADLY INFECTIONS

These 6 pathogens were responsible for almost 80% of the 1.27 million deaths attributed directly to antimicrobial resistance in 2019.



The image summarizes data for infections caused by bacteria with multi-resistance to currently available drugs. The numbers show patient mortality due to the lack of treatment options (source Nature, <https://www.nature.com/articles/d41586-022-00228-x>).

# ONGOING CLINICAL TRIALS DEVELOP ACCORDING TO PLAN

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This quarter has seen the continued development of SelectImmune Pharma's project portfolio. The strategy includes the completion of the ongoing clinical Phase II trial for recurrent acute cystitis and the start of a placebo-controlled Phase II trial in patients with bladder pain syndrome. The first patients have been recruited. In both cases the immunotherapeutic drug Kineret, which is an IL-1 receptor antagonist (IL-1RA), is being used. SelectImmune Pharma owns the patent rights to use Kineret for both of these indications and the potential for helping these patients is significant. Kineret treatment has shown great promise for severely handicapped patients with bladder pain syndrome.

The company is also taking the drug candidate NlpD, through the drug development process, including GMP production and toxicology testing, and planning for clinical trials. NlpD is a protein from "nice" bacteria, which is beneficial for different tissues and prevents exaggerated inflammatory responses to infection. The recombinant protein shows potent anti-infective and anti-inflammatory activity in animal models of cystitis and kidney infection. NlpD promotes bacterial clearance and inhibits the inflammatory response that causes disease. In view of these properties, NlpD has the potential to add a new approach to the treatment of infection and potentially a wide range of inflammatory conditions. In addition, structural studies of NlpD may open up for 2nd generation drug candidates or new production methods, in the future.

Additionally, the company will focus on developing IRF7 inhibitors for use primarily in the treatment of kidney infections and urosepsis. IRF7 inhibitors have

the potential to significantly add to antibiotic therapy for these indications and the company is exploring novel ways of inhibiting IRF7. Urosepsis is a major cause of death world-wide and treatments is made very difficult by wide-spread antibiotic resistance.

Overall, the company's continued development strategy is focused on bringing new and innovative drugs to market, and on improving patient outcomes through the use of these new treatments. The engagement in partnership and market access discussions, all play a critical role in achieving this goal.

The company has sufficient funding for this fiscal year ending 30 June 2023 and is actively seeking solutions to raise additional funds for the next development phase.

We understand that it is in the interest of all shareholders that the clinical trials are completed as soon as possible and the company is making every effort to run the studies safely and efficiently. We thank our colleagues, consultants and partners for their contributions and our shareholders for their confidence and continued support.

**Catharina Svanborg**  
Chairman

**Gabriela Godaly**  
CEO (acting)

# SIGNIFICANT EVENTS DURING THE SECOND QUARTER

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## Q2

2022-10-10

### **The Phase II trial of recurrent acute cystitis is proceeding according to plan**

SelectImmune Pharma is conducting a randomized single-center Phase II trial in patients with recurrent acute cystitis, investigating the effects of the IL-1 receptor antagonist (IL-1RA). The clinical trial is led by key opinion leaders in the field of urinary tract infection therapy in Giessen, Germany and at Lund University. The efficient study organization includes physicians, monitors, other clinical and laboratory staff. Patient recruitment is proceeding according to plan, and we envisage completion of enrolment by the end of this year (See the WHO registry at <https://trialsearch.who.int/> and insert the EudraCT number 2019-004209-28).

2022-11-11

### **Magnus Nylén proposed as new member of the SelectImmune Pharma board**

SelectImmune Pharma has proposed Magnus Nylén for election to the board of SelectImmune Pharma at the Annual General Assembly on November 23rd, 2022. Magnus Nylén has extensive experience from national and international capital markets including The Royal Bank of Scotland, Alfred Berg Fondkommission, HSBC and Aros Fondkommission. Since 2013, Magnus Nylén is one of the owners of Partner Fondkommission, with offices in Göteborg and Stockholm.

2022-11-14

### **First patient in – a new treatment option for patients with bladder pain**

SelectImmune Pharma has announced the start of a controlled clinical trial for patients with bladder pain syndrome, using the drug Kineret, an Interleukin1 (IL-1) receptor antagonist and the first patient has been included in the study. The study will include a larger number of patients and clinical centers in Sweden, and aims to evaluate the treatment effect with greater precision. The trial will initially take place in two centers in Sweden, which have extensive experience with this patient group, with the goal of reducing pain and improving quality of life for those affected. The company has received permission from the Swedish Medicines Agency and Swedish Ethical Review Authority, and has established the study organization in Sweden. The possibility of treating this patient group is of great medical interest.

2022-11-24

### **Communiqué from the Annual General Meeting of SelectImmune Pharma AB**

SelectImmune Pharma published a Communiqué from the Annual General Meeting of SelectImmune Pharma AB held November 23rd in Malmö. The board was granted freedom from liability. Catharina Svanborg was elected chairman. It was decided that the board should consist of the chairman, Carl-Johan Wachtmeister, Helena Lomberg, Magnus Nylén and Gabriela Godaly. All decisions were unanimous.

2022-11-29

### **SelectImmune Pharma held a digital investor meeting**

SelectImmune Pharma held a digital investors' meeting via Zoom on Tuesday November 29th for existing shareholders, other investors, and interested parties. The purpose of the meeting was to provide updates on the company's developments and to allow for a question-and-answer session.

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## **Significant events after the period**

2023-01-23

### **SelectImmune Pharma AB publishes video from digital investor meeting**

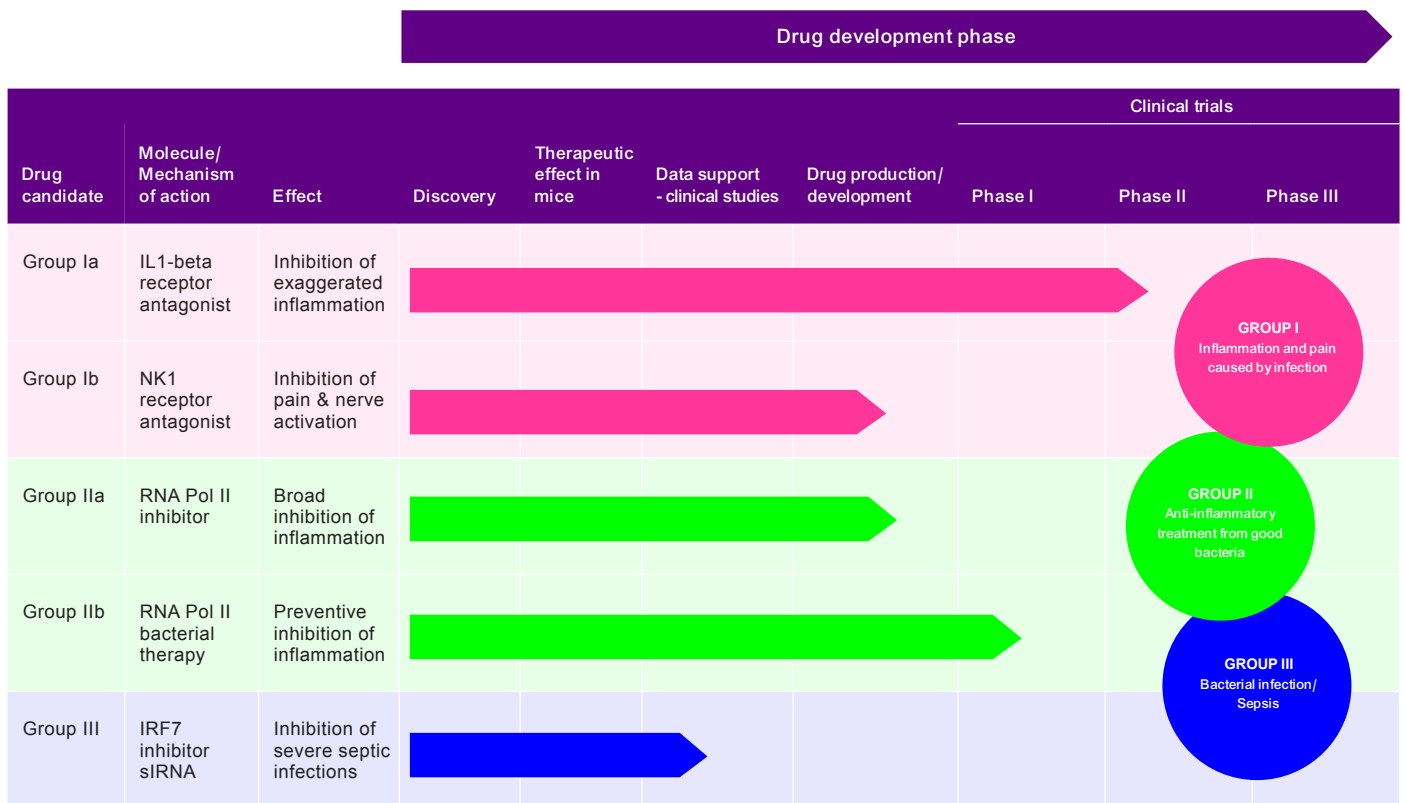
SelectImmune Pharma AB has published a video from the digital investors' meeting held in conjunction with the company's Annual General Meeting in November 2022. The video is available on the company's website.

## Patent portfolio overview

An updated overview of the SelectImmune Pharma patent portfolio for the fiscal year is shown below. SelectImmune Pharma was recently granted patent protection in Australia for IRF-7 Inhibitors for treatment of antibiotic resistant Enterobacteriaceae. This adds to patents already granted in Europe and the US for this invention.

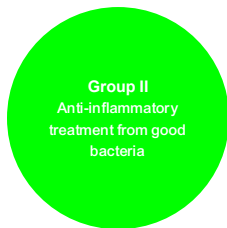
Title	Filing Date	Country	Patent Application No.	Granting Date	Comments
IL-1 receptor antagonists	January 2016	Australia	2016205864	13 May 2021	IL-1 receptor antagonists for the treatment of cystitis. NB: This US patent covers IL-1 receptor antagonists and MMP inhibitors for the treatment of cystitis in a single patent.
		Europe (CH, DE, DK, FI, FR, NL, SE, GB)	16703357.0	13 October 2021	
		USA	15/542,041	25 May 2021	
MMP7 inhibitors	January 2016	Australia	2021202603	Pending	MMP-7 inhibitors for the treatment of cystitis.
		Europe (CH, DE, DK, FI, FR, NL, SE, GB)	19186921.3	18 Aug 2021	
ASC / NLRP-3	January 2016	Europe	19186921.3	Pending	ASC or NLRP-3 proteins for the treatment of cystitis.
		USA	17/313,463	Pending	
IRF7 inhibitors	March 2016	Australia	2016241555	9 Dec 2022	IRF-7 inhibitors for the treatment of Enterobacteriaceae infections.
		Europe (CH, DE, DK, FI, FR, NL, SE, GB)	16715897.1	16 Sep 2020	
		USA	10,287,585	14 May 2019	
NK1 Antagonists	July 2017	Europe	17740488.6	Pending	NK1 antagonists for treating bacterial infection or management of pain caused by bacterial infections.
		Hong Kong	19132137.1	Pending	
		USA	16/316,324	Pending	
Pol II inhibitors	October 2017	Australia	2017344453	Pending	Inhibitors of polymerase II, which can be used for immunosuppression, anti-inflammation, and/or anti-infection.
		Europe (CH, DE, DK, FI, FR, NL, SE, GB)	17797991.1	1 Dec 2021	
		Hong Kong	19132176.9	Pending	
		India	20194718316	Pending	
		Singapore	11201903336U	Pending	
		USA	16/341,962	Pending	
Bladder Pain	June 2019	Europe	20734114.0	Pending	IL-1 receptor antagonists for the treatment of bladder pain.
		USA	17/617,204	Pending	
		Australia	2020288361	Pending	
		China	202080049659.X	Pending	
		Japan	2021-572575	Pending	
Pyelonephritis	Jan 2022	GB initial filing	2201139.9	Pending	Treatment or prevention of acute pyelonephritis and/or urosepsis.

## Project portfolio overview



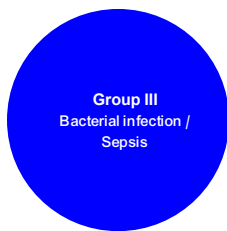
### Group I

- Based on the initial successful off-label study of IL1-RA treatment of patients with bladder pain syndrome, we have initiated a placebo-controlled clinical trial.
- The IL1-RA Phase II clinical trial in recurrent acute cystitis is being performed in Giessen, Germany, and the patient enrollment continues as foreseen.
- SelectImmune Pharma has been seeking patent protection for modulators of the IL-1 pathway for treatment of chronic inflammatory conditions in the lower urinary tract and chronic pelvic/bladder pain syndrome. The company has recently extended the geographical scope by filing for patent protection in Europe, the US, Australia, China, and Japan.
- While the IL1-RA compound is effective against pain, the company is also pursuing the pain inhibitor NK1-RA, neurokinin receptor antagonist, which is efficient in animal models.
- Dialogues for potential project partnering are pursued internationally.



## Group II

- The polymerase inhibitor NIpD is a potent drug candidate. The protective properties of this molecule have been confirmed and extended in cellular assays and animal models.
  - Technology transfer and small-scale production of the NIpD protein have been successfully completed at the pharmaceutical manufacturing partner Lonza corporation's UK site. Select-Immune Pharma is testing small-scale quantities for further development work.
  - SelectImmune Pharma has filed patent applications for further indications of this interesting active protein.
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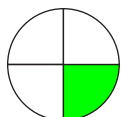
## Group III

- Continued studies in animal models are performed for the IRF7 inhibitor to support and develop the obtained results. Additional molecules are being explored for this indication.

# THE PERIOD IN SUMMARY

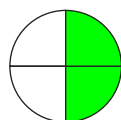
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Amounts in parentheses indicate the corresponding value in the preceding year.



## SECOND QUARTER 2022-10-01–2022-12-31

- Net sales totaled kSEK 0 (0)
- Loss before tax amounted to kSEK -1 338 (-4 498)
- Loss after tax amounted to kSEK -1 338 (-4 498)
- Loss per share\* was SEK -0,0766 (-0,2576)



## FIRST HALF 2022-07-01–2022-12-31

- Net sales totaled kSEK 0 (0)
- Loss before tax amounted to kSEK -2 750 (-7 630)
- Loss after tax amounted to kSEK -2 750 (-7 630)
- Loss per share\* was SEK -0,1575 (-0,437)
- On december 31, 2022, the equity/assets ratio\*\* was 88 (86)%

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\* Profit/loss after tax for the period divided by 17,459,225 (17,459,225) shares, where 17,459,225 is the number of shares outstanding on December 31, 2022. The comparative figure in parentheses was the number of shares on December 31, 2021.

\*\* Equity divided by total capital.

# SelectImmune

## PHARMA

### SelectImmune Pharma AB

SelectImmune Pharma AB is a company that performs drug development. The company's development aims to offer effective alternatives to antibiotics. Instead of killing the bacteria directly, the body's immune system is strengthened and balanced. The company is developing new drug candidates for the treatment of bacterial infections.

The technology agreement between SelectImmune Pharma and Linnane Pharma from 2021 ensures the company's access to advanced science and technology. The agreement runs for two years and the technology platform is available to SelectImmune Pharma on a subscription basis. This is an effective way to gain access to cutting-edge expertise and new technology at low cost. The agreement does not contain any further financial commitments to Linnane Pharma.

### Revenue and earnings

As SelectImmune Pharma is a development company in life science, future income will primarily consist of various forms of royalty income such as advance payments, milestone-based payments and ongoing royalties. The longer the company runs its projects under its own auspices, the better bargaining power the company will have in business negotiations with potential future partners. The company has assessed that continued development under its own auspices will increase value and has therefore chosen not to enter into any cooperation agreements yet.

Net sales during the second quarter amounted to kSEK 0 (0), and the profit after tax amounted to kSEK -1,338 (-4,498). The lower negative result is explained by an uneven distribution of costs between the quarters and specifically lower costs for the clinical trials during this quarter.

### Financial position

At the end of the quarter, the equity/assets ratio was 88 (86) %, and the company's cash and cash equivalents were kSEK 9 158 (19 411). The equity at the same time amounted to kSEK 9 035 (18 237).

### Cash flow and investments

During the period July 1 2022 to December 31 2022, cash flow amounted to kSEK -2 033 (-7 158). No intangible assets were capitalized during the period, since the company is in an R&D stage. R&D costs are therefore recognized as operating expenses in the income statement. No new investments in tangible assets were capitalized during the quarter.

### Depreciation

During the quarter, depreciation of equipment amounted to kSEK 100 (100), and during the first half, depreciation of equipment amounted to kSEK 200 (199).

### Employees

The company had the corresponding of 2 (2) full-time employees during the quarter.

### The share

The number of registered shares as of December 31, 2022 amounted 17,459,225 (17,459,225), of which 2,000,000 (2,000,000) Series A shares and 15,459,225 (15,459,225) Series B shares. Each Series A share entitles to ten votes and Series B shares to one vote.

SelectImmune Pharma's Series B shares have been admitted to trading on Spotlight Stock Market since June 26, 2019. The share is traded under the short name "SELECT B" with ISIN code SE0012622785.

### Transactions with related parties

During the first half, there were costs to Linnane Pharma AB of kSEK 750 (750) for the technology platform and kSEK 240 (240) for license costs. The corresponding amounts for the quarter are kSEK 375 (375) for the technology platform and kSEK 120 (120) for license costs. Furthermore, salaries and remuneration to the Board and management were paid during the period. Transactions with related parties are on market terms.

In addition to the collaboration with Lund University, SelectImmune Pharma needs access to current and innovative cutting-edge expertise. Linnane Pharma offers a collaboration to solve these needs. A technology platform provides access to a unique combination of cutting-edge expertise, large-scale analysis methods such as proteomics, RNA and DNA sequencing, methods for analysis of clinical materials and animal models for the design of clinical studies for drug development, etc.

### Significant risks and uncertainties

The Board's assessment of significant risks and uncertainties is unchanged compared with the most recent financial year and is described in the most recently published annual report (2022-06-30).

### Basis of preparation for the interim report

The company prepares its accounts in accordance with the Swedish Annual Accounts Act and the K3 framework (BFNAR 2012:1) of the Swedish Accounting Standards Board (Bokföringsnämnden).

The company's accounting principles are unchanged compared with the most recent financial year and are described in the most recent published annual report 2021-2022.

### Review

This interim report has not been audited.

### Financial calendar

Interim report for Q3, 2022/2023	2023-05-25
Interim report for Q4, 2022/2023	2023-08-29
Year end report 2022/2023	2023-11-01
Interim report for Q1, 2023/2024	2023-11-16
Annual General Meeting 2022/2023	2023-11-22

# INCOME STATEMENT

SEK	2022-10-01 2022-12-31	2021-10-01 2021-12-31	2022-07-01 2022-12-31	2021-07-01 2021-12-31	2021-07-01 2022-06-30
Net sales	0	0	0	0	0
Other operating income	0	0	0	0	5 099
<b>Operating income</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5 099</b>
Other external costs	-740 272	-3 647 803	-1 690 971	-6 015 439	-10 914 204
Employee benefit expenses	-496 814	-743 551	-852 155	-1 398 491	-2 745 884
Depreciation of tangible assets	-99 834	-99 834	-199 668	-199 131	-398 797
Other operating expenses	-829	-6 685	-7 343	-16 683	-27 305
<b>Operating loss</b>	<b>-1 337 748</b>	<b>-4 497 872</b>	<b>-2 750 137</b>	<b>-7 629 744</b>	<b>-14 081 092</b>
Financial items	-124	0	-124	0	0
<b>Loss before tax</b>	<b>-1 337 872</b>	<b>-4 497 872</b>	<b>-2 750 261</b>	<b>-7 629 744</b>	<b>-14 081 092</b>
Tax on loss for the period	0	0	0	0	0
<b>Loss after tax</b>	<b>-1 337 872</b>	<b>-4 497 872</b>	<b>-2 750 261</b>	<b>-7 629 744</b>	<b>-14 081 092</b>

# BALANCE SHEET

SEK	2022-12-31	2021-12-31	2022-06-30
<b>ASSETS</b>			
<b>Fixed assets</b>			
Tangible assets	922 494	1 321 828	1 122 162
<b>Total fixed assets</b>	<b>922 494</b>	<b>1 321 828</b>	<b>1 122 162</b>
<b>Current assets</b>			
Other receivables	0	266 506	599 681
Prepaid expenses	148 008	114 848	93 259
Cash and bank balances/financial investments	9 157 803	19 410 814	11 190 810
<b>Total current assets</b>	<b>9 305 810</b>	<b>19 792 168</b>	<b>11 883 750</b>
<b>Total assets</b>	<b>10 228 304</b>	<b>21 113 996</b>	<b>13 005 912</b>
<b>EQUITY &amp; LIABILITIES</b>			
<b>Restricted equity</b>			
Share capital	872 961	872 961	872 961
<b>Total restricted equity</b>	<b>872 961</b>	<b>872 961</b>	<b>872 961</b>
<b>Non-restricted equity</b>			
Share premium reserve	49 348 206	49 348 206	49 348 206
Retained earnings	-38 435 808	-24 354 717	-24 354 717
Loss for the period	-2 750 261	-7 629 744	-14 081 092
<b>Total non-restricted equity</b>	<b>8 162 136</b>	<b>17 363 745</b>	<b>10 912 397</b>
<b>Total equity</b>	<b>9 035 098</b>	<b>18 236 707</b>	<b>11 785 358</b>
<b>Current liabilities</b>			
Accounts payable	105 799	837 739	493 883
Tax liabilities	11 523	21 273	42 546
Other liabilities	428 668	108 873	62 410
Accrued expenses	647 216	1 909 404	621 714
<b>Total current liabilities</b>	<b>1 193 207</b>	<b>2 877 289</b>	<b>1 220 553</b>
<b>Total Equity &amp; Liabilities</b>	<b>10 228 304</b>	<b>21 113 996</b>	<b>13 005 912</b>

# CASH FLOW STATEMENT

SEK	2022-07-01 2022-12-31	2021-07-01 2021-12-31	2021-07-01 2022-06-30
<b>Operating activities</b>			
Loss after financial items	-2 750 261	-7 629 744	-14 081 092
Adjusted for non-cash items, etc.	199 668	199 131	398 797
<b>Cash flow from operating activities before changes in working capital</b>	<b>-2 550 593</b>	<b>-7 430 613</b>	<b>-13 682 295</b>
<b>Cash flow from changes in working capital</b>			
Change in current receivables	544 932	414 443	102 857
Change in current liabilities	-27 347	-141 847	-1 798 583
<b>Cash flow from operating activities</b>	<b>-2 033 007</b>	<b>-7 158 017</b>	<b>-15 378 021</b>
<b>Financing activities</b>			
New share and subscription warrant issues	0	0	0
Issuance costs	0	0	0
<b>Cash flow from financing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Cash flow for the period</b>	<b>-2 033 007</b>	<b>-7 158 017</b>	<b>-15 378 021</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>11 190 810</b>	<b>26 568 831</b>	<b>26 568 831</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>9 157 803</b>	<b>19 410 814</b>	<b>11 190 810</b>

# EQUITY

SEK	Share capital	Share premium reserve	Retained earnings	Loss for the period	Total
<b>Opening balance July 1, 2022</b>	<b>872 961</b>	<b>49 348 206</b>	<b>-24 354 717</b>	<b>-14 081 092</b>	<b>11 785 358</b>
Transfer of prior year's loss			-14 081 092	14 081 092	0
Loss for the period, Q1				-1 412 389	-1 412 389
Loss for the period, Q2				-1 337 872	-1 337 872
<b>Equity December 31, 2022</b>	<b>872 961</b>	<b>49 348 206</b>	<b>-38 435 808</b>	<b>-2 750 261</b>	<b>9 035 098</b>

# KEY FIGURES AND DATA PER SHARE

	2022-10-01 2022-12-31	2021-10-01 2021-12-31	2022-07-01 2022-12-31	2021-07-01 2021-12-31	2021-07-01 2022-06-30
Net sales, kSEK	0	0	0	0	0
Earnings after financial items, kSEK	-1 338	-4 498	-2 750	-7 630	-14 081
Equity/assets ratio, %	88%	86%	88%	86%	91%
Number of shares	17 459 225	17 459 225	17 459 225	17 459 225	17 459 225
Of which Series A	2 000 000	2 000 000	2 000 000	2 000 000	2 000 000
Of which Series B	15 459 225	15 459 225	15 459 225	15 459 225	15 459 225
Loss per share, SEK	-0,0766	-0,2576	-0,1575	-0,4370	-0,8065
Cash and cash equivalents, kSEK	9 158	19 411	9 158	19 411	11 191
Equity, kSEK	9 035	18 237	9 035	18 237	11 785

Malmö, February 23<sup>rd</sup> 2023

Catharina Svanborg  
Chairperson of the Board

Gabriela Godaly  
CEO (acting)  
Board member

Helena Lomberg  
Board member

Carl-Johan Wachtmeister  
Board member

Magnus Nylén  
Board member



# SelectImmune

PHARMA

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