



# Q1

INTERIM REPORT 1 JULY 2022 – 30 SEPTEMBER 2022

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

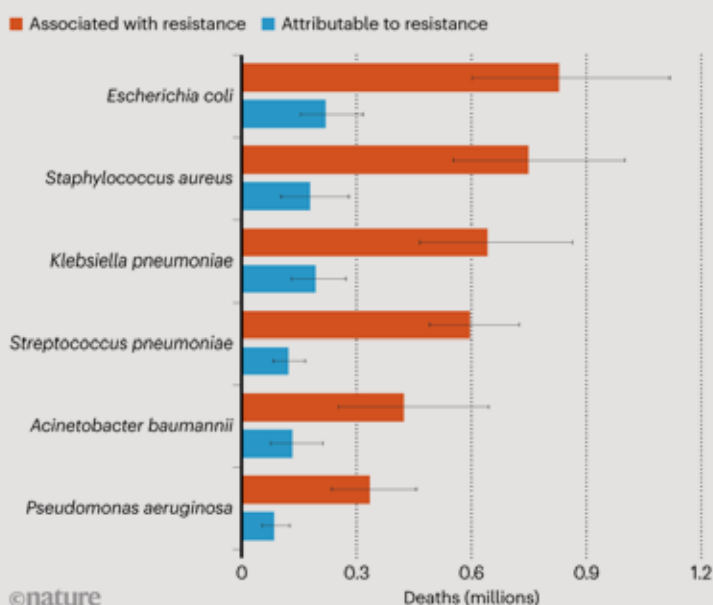
**SelectImmune**  
PHARMA

# 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 research-based and the company has an agreement with Lund University.
- 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 issue. 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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Our focus this quarter has been on the two ongoing clinical Phase II trials. The first study on patients with recurrent acute cystitis is proceeding according to plan, in Giessen Germany. The study organization is highly competent and the collection of clinical data and samples for laboratory test is well controlled, and samples are continuously analyzed. The study is a so-called double-blind study, which means that the company will not be able to know about results until the study is completed. The company will therefore not be able to publish 'interim reports' describing the study results. In a press release on October 10, 2022 the company announced that the study is proceeding according to plan, and that we estimate the last patient to be admitted at the end of this year.

The placebo-controlled study of patients with bladder pain has been initiated. The study is based on the finding that this group of severely handicapped patients experience significant improvement when treatment off label with Kineret, an IL-1 receptor antagonist with potent immunotherapeutic effects. A long-term improvement with a significant reduction in symptom score and improved quality of life was seen in the treated patients.

The placebo-controlled trial protocol has now been approved by the Swedish regulatory authorities (Läkemedelsverket), has received ethical approval and the first patients have been recruited.

Kineret has been developed and registered by the international biopharmaceutical company Sobi and is widely used to treat hyperinflammatory disorders, such as rheumatoid arthritis, and more recently treatment of COVID pneumonia. SelectImmune Pharma has patented the treatment with IL-1RA for the indications of cystitis and bladder pain. Sobi will provide the study

drug and placebo for the controlled clinical trial in patients with bladder pain. A supply agreement between SelectImmune and Sobi was signed on March 29, 2022.

SelectImmune has an efficient strategy for the development of new drugs against bacterial infections. High rates of resistance have been observed for common bacterial infections, including urinary tract infections and sepsis, and finding alternative treatments is the company focus. An overview of the immunotherapy approach is given in a recent review, published in Nature Reviews Urology (DOI: 10.1038/s41585-022-00602-4). (<https://rdcu.be/cP963>).

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 FIRST QUARTER

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## Q1

2022-08-11

The patent protecting the use of IL-1RA (Kineret) in patients with bladder pain was published in the USA

2022-08-18

### **Clinical study ready to start – a new treatment option for patients with bladder pain**

SelectImmune Pharma has successfully completed the preparations to start a controlled clinical trial in patients with bladder pain syndrome (severe pain in the bladder). The patients will be treated with the drug Kineret, which is an Interleukin-1 (IL-1) receptor antagonist (IL-1RA). The company can now announce that all permits are in place and that the recruitment of patients can start.

August/September

The development of the new NlpD molecule (Group II) is making significant progress. In addition to the preparations for large-scale production in collaboration with the international manufacturer Lonza, a screen for peptide fragments has been initiated. Fragments that retain key activities of the whole molecule would be of significant interest, to facilitate production by peptide synthesis rather than recombinant technology. Peptides may also be developed for increased activity or tissue specific properties.

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## Significant events after the period

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://trialssearch.who.int/> and insert the number 2019-004209-28).

2022-11-11

### **Magnus Nylén was proposed as a new member of SelectImmune Pharma's board**

Magnus Nylén has been proposed for election to the board of SelectImmune Pharma at the annual general meeting on 23 November 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 Gothenburg and Stockholm.

2022-11-14

### **Clinical trial initiated – a new treatment option for patients with bladder pain**

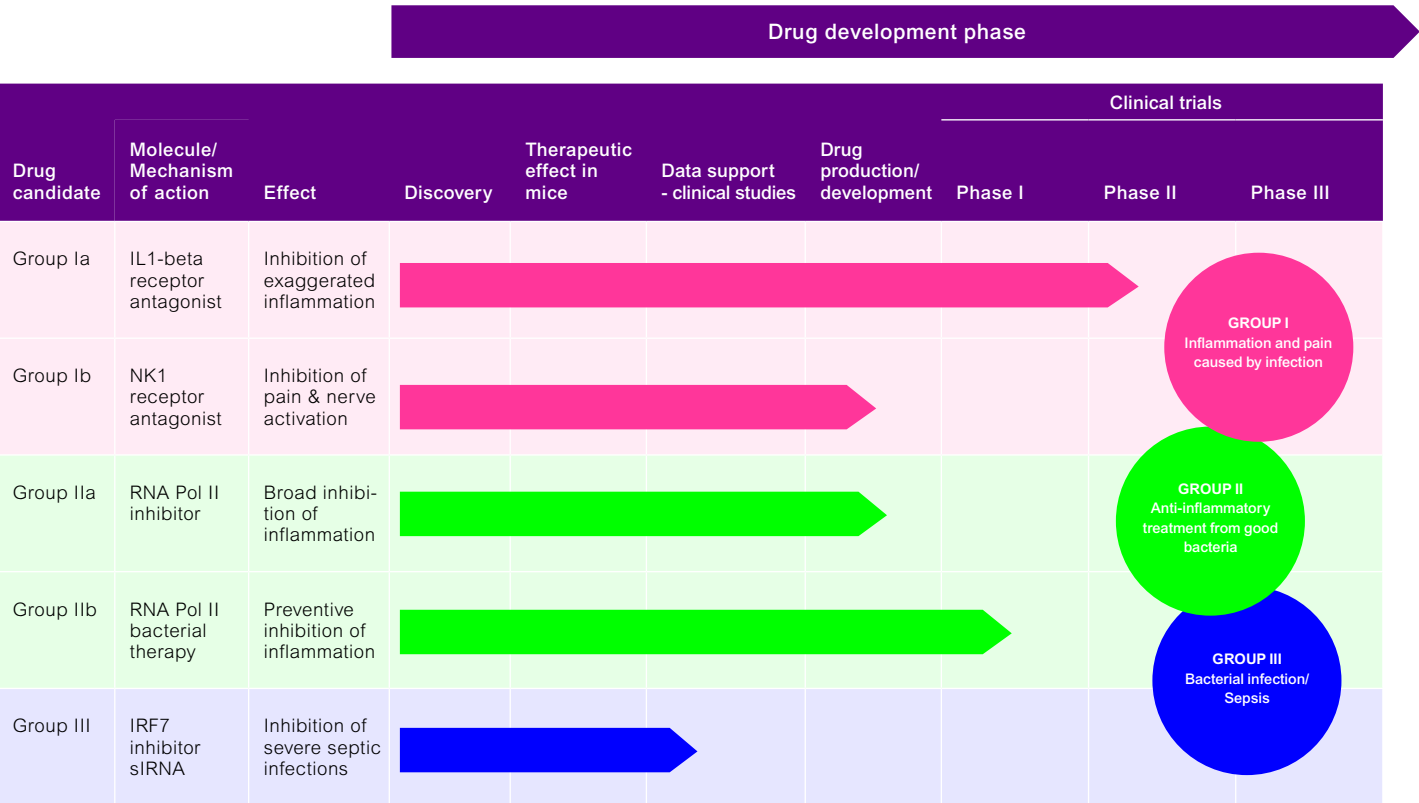
As previously announced, SelectImmune Pharma has successfully completed preparations to start a controlled clinical trial in patients with bladder pain syndrome (severe pain in the bladder). We can now announce that the study has started and the first patient has been included in the study. The patients will be treated with the drug Kineret, which is an Interleukin1 (IL-1) receptor antagonist (IL-1RA).

## 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.

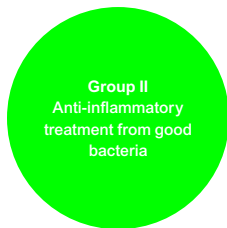
Title	Filing Date	Country	Patent Application No.	Granting Date	Comments
IL-1 receptor antagonists	January 2016	Australia	2016205864	13 May 2021	IL-1 receptor antagonists for the treatment of cystitis.  NB: This US patent covers IL-1 receptor antagonists and MMP inhibitors for the treatment of cystitis 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



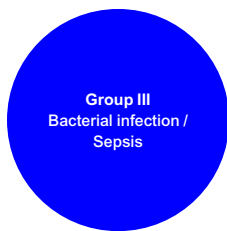
Group I

- Based on the initial successful off-label study of IL1-RA treatment of patients with bladder pain syndrome, we have initiated the 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 NlpD 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 NlpD protein have been successfully completed at the pharmaceutical manufacturing partner Lonza corporation's UK site. SelectImmune Pharma is testing small-scale quantities for further development work.
- SelectImmune Pharma has filed patent applications for further indications of this interesting active protein.



## 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.

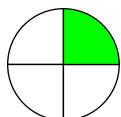
### THE COVID-19 PANDEMIC

The Covid pandemic has affected the infrastructure for clinical trials world-wide. The pandemic caused certain delays in the early part of the clinical study in Germany, but patient enrollment is now proceeding according to plan.

# THE Q1 PERIOD IN SUMMARY

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



## FIRST QUARTER 2022-07-01--2022-09-30

- Net sales for the quarter totaled kSEK 0 (0)
- Loss before tax amounted to kSEK -1 412 (-3 132)
- Loss after tax amounted to kSEK -1 412 (-3 132)
- Loss per share\* was SEK -0.0809 (-0.1794)
- On September 30, 2022, the equity/assets ratio\*\* was 93 (83)%

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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 September 30, 2022. The comparative figure in parentheses was the number of shares on September 30, 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 to kill the bacteria itself. The company is developing new drug candidates for the treatment of bacterial infections.

### Revenue and earnings

As SelectImmune Pharma is a life science development company, 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.

This means that the company had net sales of kSEK 0 (0) during this quarter. Profit after tax for the corresponding period amounted to kSEK -1 412 (-3 132) kSEK.

### Financial position

At the end of the quarter, the equity/assets ratio was 93 (83) %, and the company's cash and cash equivalents were kSEK 7 873 (24 997). The equity at the same time amounted to kSEK 10 373 (22 735).

### Cash flow and investments

During the period July 1, 2022 to September 30, 2022, cash flow amounted to kSEK -3 318 (-1 572). 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 (99).

### Employees

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

### The share

The number of registered shares as of September 30, 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. Spotlight Stock Market is the secondary name of ATS Finans AB, a securities company under supervision by the Swedish Financial Supervisory Authority (Finansinspektionen).

### Transactions with related parties

Salaries and remuneration to the Board and management were paid during the period. Transactions with related parties are on market terms. Catharina Svanborg does not receive remuneration as Chairman of the board.

In addition to the collaboration with Lund University, SelectImmune Pharma needs access to current and innovative cutting-edge expertise. The R&D company Linnane Pharma offers access to a technology platform, which provides 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. During the quarter, there were costs to Linnane Pharma AB of kSEK 375 (375) for the technology platform and kSEK 120 (120) for license costs for patents.

The technology agreement between SelectImmune Pharma and Linnane Pharma 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.

### 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

Annual General Meeting for 2021/2022	November 23, 2022
Interim report for Q2 (half-year), 2022/2023	February 23, 2023
Interim report for Q3, 2022/2023	May 25, 2023

# INCOME STATEMENT

SEK	2022-07-01 2022-09-30	2021-07-01 2021-09-30	2021-07-01 2022-06-30
Net sales	0	0	0
Other operating income	0	0	5 099
<b>Operating income</b>	<b>0</b>	<b>0</b>	<b>5 099</b>
Other external costs	-950 700	-2 367 636	-10 914 204
Employee benefit expenses	-355 341	-654 941	-2 745 884
Depreciation of tangible assets	-99 834	-99 297	-398 797
Other operating expenses	-6 514	-9 998	-27 305
<b>Operating loss</b>	<b>-1 412 389</b>	<b>-3 131 871</b>	<b>-14 081 092</b>
Financial items	0	0	0
<b>Loss before tax</b>	<b>-1 412 389</b>	<b>-3 131 871</b>	<b>-14 081 092</b>
Tax on loss for the period	0	0	0
<b>Loss after tax</b>	<b>-1 412 389</b>	<b>-3 131 871</b>	<b>-14 081 092</b>

# BALANCE SHEET

SEK	2022-09-30	2021-09-30	2022-06-30
<b>ASSETS</b>			
<b>Fixed assets</b>			
Tangible assets	1 022 328	1 421 662	1 122 162
<b>Total fixed assets</b>	<b>1 022 328</b>	<b>1 421 662</b>	<b>1 122 162</b>
<b>Current assets</b>			
Other receivables	88 880	240 385	599 681
Prepaid expenses	2 219 336	678 686	93 259
Cash and bank balances/financial investments	7 873 026	24 996 987	11 190 810
<b>Total current assets</b>	<b>10 181 242</b>	<b>25 916 058</b>	<b>11 883 750</b>
<b>Total assets</b>	<b>11 203 570</b>	<b>27 337 720</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	-1 412 389	-3 131 871	-14 081 092
<b>Total non-restricted equity</b>	<b>9 500 008</b>	<b>21 861 618</b>	<b>10 912 397</b>
<b>Total equity</b>	<b>10 372 970</b>	<b>22 734 579</b>	<b>11 785 358</b>
<b>Current liabilities</b>			
Accounts payable	78 142	1 899 747	493 883
Tax liabilities	17 087	21 273	42 546
Other liabilities	62 446	116 467	62 410
Accrued expenses	672 926	2 565 654	621 714
<b>Total current liabilities</b>	<b>830 600</b>	<b>4 603 141</b>	<b>1 220 553</b>
<b>Total Equity &amp; Liabilities</b>	<b>11 203 570</b>	<b>27 337 720</b>	<b>13 005 912</b>

# CASH FLOW STATEMENT

SEK	2022-07-01 2022-09-30	2021-07-01 2021-09-30	2021-07-01 2022-06-30
<b>Operating activities</b>			
Loss after financial items	-1 412 389	-3 131 871	-14 081 092
Adjusted for non-cash items, etc.	99 834	99 297	398 797
<b>Cash flow from operating activities before changes in working capital</b>	<b>-1 312 555</b>	<b>-3 032 574</b>	<b>-13 682 295</b>
<b>Cash flow from changes in working capital</b>			
Change in current receivables	-1 615 277	-123 274	102 857
Change in current liabilities	-389 953	1 584 005	-1 798 583
<b>Cash flow from operating activities</b>	<b>-3 317 784</b>	<b>-1 571 843</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>-3 317 784</b>	<b>-1 571 844</b>	<b>-15 378 021</b>
Cash and cash equivalents at the beginning of the period	11 190 810	26 568 831	26 568 831
Cash and cash equivalents at the end of the period	7 873 026	24 996 987	11 190 810

# 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 - Preliminary			-14 081 092	14 081 092	0
Loss for the period, Q1				-1 412 389	-1 412 389
<b>Equity September 30, 2022</b>	<b>872 961</b>	<b>49 348 206</b>	<b>-38 435 808</b>	<b>-1 412 389</b>	<b>10 372 970</b>

# KEY FIGURES AND DATA PER SHARE

kSEK	2022-07-01 2022-09-30	2021-07-01 2021-09-30	2021-07-01 2022-06-30
Net sales, kSEK	0	0	0
Earnings after financial items, kSEK	-1 412	-3 132	-14 081
Equity/assets ratio, %	93%	83%	91%
Number of shares	17 459 225	17 459 225	17 459 225
Of which Series A	2 000 000	2 000 000	2 000 000
Of which Series B	15 459 225	15 459 225	15 459 225
Loss per share, SEK	-0,0809	-0,1794	-0,8065
Cash and cash equivalents, kSEK	7 873	24 997	11 191
Equity, kSEK	10 373	22 735	11 785

Malmö, November 16 2022

**Catharina Svanborg**  
Chairperson of the Board

**Gabriela Godaly**  
CEO (acting)  
Board member

**Helena Lomberg**  
Board member

**Carl-Johan Wachtmeister**  
Board member





# SelectImmune

PHARMA

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