



# 2023

**INTERIM REPORT**

1 January – 30 June

**elicera**  
THERAPEUTICS

# Elicera Therapeutics AB (publ) Interim report

1 January – 30 June 2023

## Second quarter (April–June 2023)

- Operating profit/loss amounted to SEK -4 466 286 (-3,641,800).
- Loss for the period amounted to SEK -4,335,852 (-3,667,200).
- Cash flow from operating activities totaled SEK -2,146,178 (-3,877,975).
- Earnings per share before dilution totaled SEK -0.22 (-0.19). Earnings per share after dilution totaled SEK -0.22 (-0.19).

## Period (January–June 2023)

- Operating profit/loss amounted to SEK -6,372,143 (-8,382,851).
- Loss for the period amounted to SEK -6,602,181 (-8,421,815).
- Cash flow from operating activities totaled SEK -4,181,989 (-9,211,200).
- Earnings per share before dilution totaled SEK -0.33 (-0.43). Earnings per share after dilution totaled SEK -0.33 (-0.43).

## Key events during the second quarter

- Elicera Therapeutics receives conditional approval from the Medical Products Agency on its CAR T-cell Clinical Trial Application to test ELC-301 (CARMA-study).
- Elicera AGM re-elects the board.

## Key events during the period

- Elicera continues phase I/IIa study with oncolytic virus as planned, following safety review in cohort 3.
- Elicera submits Clinical Trial Application to evaluate its CAR T-cell therapy in B-cell lymphoma.
- Elicera appoints Anna Koptina Gültekin as Head of Regulatory Affairs.
- Elicera recruits LifeSci Consulting as transaction advisor to assist the company in evaluating strategic partnering initiatives.
- Elicera hires Erik Penser Bank as market maker.
- Elicera, with its existing bank balances and expected EU grant, has full financing for various trials at least through the end of 2024.

## Key events after the end of the period

- Elicera receives Notice of Allowance for European patent protecting the iTANK™ platform.
- Elicera publishes a scientific article in Nature Communications about the CAR T construct in the ELC-401 program.
- No events that impact earnings or the financial position occurred after the end of the period.





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Cell and gene therapies  
for immune-based  
cancer treatments

# Condensed earnings and cash flow plus key performance indicators

(AMOUNTS IN SEK UNLESS OTHERWISE INDICATED)	2023 3 MOS APR-JUNE	2022 3 MOS APR-JUNE	2023 6 MOS JAN-JUNE	2022 6 MOS JAN-JUNE	2022 12 MOS JAN-DEC
Other operating income	1,771,388	2,673	3,182,575	377,268	1,268,141
Operating expenses	-6,237,674	-3,644,473	-9,914,718	-8,760,119	-20,643,055
Operating loss	-4,466,286	-3,641,800	-6,732,143	-8,382,851	-19,374,914
Loss for the period after net financial items	-4,335,852	-3,667,200	-6,602,181	-8,421,815	-19,438,631
Cash flow from operating activities	-2,146,178	-3,877,975	-4,181,989	-9,211,200	-8,570,820
<b>KEY PERFORMANCE INDICATORS</b>					
Working capital	26,179,594	43,302,628	26,179,594	43,302,628	32,291,711
Quick asset ratio, %	276	2,931	276	2,931	339
Equity/asset ratio, %	64	97	64	97	71
Earnings per share before dilution	-0.22	-0.19	-0.33	-0.43	-0.98
Earnings per share after dilution	-0.22	-0.19	-0.33	-0.43	-0.98
Average number of shares	19,782,000	19,782,000	19,782,000	19,782,000	19,782,000
Average number of warrants	0	7,750,000	0	7,750,000	7,091,781
Average no. of shares after dilution	19,782,000	23,657,000	19,782,000	23,657,000	23,327,890

## Definitions of key performance indicators

### Working capital

Sum total of current assets (including cash in hand) minus current liabilities.

### Quick asset ratio

Sum total of current assets (including cash in hand) as a percentage of current liabilities.

### Equity/asset ratio

Equity in relation to the balance sheet total.

### Earnings per share before dilution

Earnings after tax divided by the average number of shares.

### Average number of shares

The number of shares, on average, counted from the registration date of the issuance.

### Average number of shares after dilution

The number of shares, on average, counted from the registration date of the issuance plus the average number of shares after full redemption of warrants.

# CEO Comments

## The Swedish Medical Products Agency approves clinical trial application for the CARMA study after conditional validation of the GMP process

In late April, the Swedish Medical Products Agency (Läkemedelsverket) announced that it had approved our application to conduct clinical trials of our CAR T-cell therapy, ELC-301, in the treatment of B-cell lymphoma. The clinical trial, which we also call the CARMA study, is intended to evaluate the safety and efficacy of a dose of CD20-targeted CAR T-cells, armed with bystander immune-activating properties using the iTANK platform – in patients with B-cell lymphoma relapsed and/or refractory B-cell malignancies, by studying tolerance, toxicity, biological effects and anti-tumor responses. The approval is conditional on Elicera conducting certain further validations of its GMP process, which was previously expected to be completed and given final approval during the third quarter of the year but which we now, after additional dialogue with the Agency, is instead expected to be completed in the fourth quarter of the year. First patient is expected to be treated in the beginning of 2024

### Broad product portfolio yields many opportunities

We have made progress in our ongoing clinical phase I/IIa study with our oncolytic virus, ELC-100, in the treatment of neuroendocrine tumors and will shortly treat patient number 11. Thus, we only have one patient left to treat in the dose escalation phase, which we expect to be able to do by the turn of the year. Regarding our second oncolytic virus program, ELC-201, we have numerous alternatives for action that must be carefully considered before we make any final decisions on the continued development of this drug candidate. As also previously mentioned, we have completed our indication analysis together with an external party and identified several relevant forms of cancer where there is both robust scientific logic and good positioning for ELC-201. The issues we are currently examining include whether a clinical trial with ELC-201 is to be conducted in one cancer indication or several – known as a basket trial – and whether ELC-201 can and/or should be combined with other drugs. While we are engaged in responding to these and other vital questions concerning the content of the programs, GMP production of the oncolytic virus is taking place in parallel so that we – or a potential future partner – can commence patient trials with ELC-201 as soon as possible after decisions are made on the path ahead and financing is secured.

For ELC-401 – our CAR T program in glioblastoma – GMP production is also occurring in parallel with the analysis of our treatment alternatives. In contrast to ELC-201, the ELC-401 analysis partially entails preclinical trials for purposes including being able to better determine how the CAR T-cell therapy is to be administered. The objective for both ELC-201 and ELC-401 during the year is to produce clinical development plans, including trial design and costs for the forthcoming Phase I/II trials, and thereafter to decide how the programs should best be advanced and financed – by Elicera alone or potentially together with a partner. Having our efforts on the CAR T structure in ELC-401 recently accepted for publication in the renowned journal Nature Communications is gratifying. This is yet another sign that the work being pursued by our team of researchers maintains a very high level of scientific quality.

Once again, I would like to thank our team who, with hard work, and a great deal of commitment, has successfully pursued the development of our various drug programs – and I would also like to thank our committed shareholders for your continued support and confidence.

### Jamal El-Mosleh

CEO and co-founder



CEO and co-founder  
Jamal El-Mosleh

"Having our efforts on the CAR T structure in ELC-401 recently accepted for publication in the renowned journal Nature Communications is gratifying."

# Introduction to Elicera Therapeutics

Elicera Therapeutics AB is a clinical stage immuno-oncology company developing armed cell and gene therapies.

The attempt to fight cancer using the patient's own immune system has been ongoing for decades, but it is only within the last ten years that cancer immunotherapy (immuno-oncology) has been successfully used. In only a few years, immuno-oncology has revolutionized how we treat cancer. In contrast to traditional cancer therapies such as radiation, surgery and chemotherapy, immuno-oncology deals with training the body's own immune system to fight cancer. This occurs in mainly two ways: by triggering the immune system against cancer, primarily by activating tumor-killing T-cells (Elicera's focus), and by removing the tumor's suppressive activity on the immune system.

The company's product portfolio consists of four drug candidates, of which two are in the field of oncolytic viruses (ELC-100 and ELC-201) and two are in the field of CAR T-cell treatments (ELC-301 and ELC-401). Additionally, Elicera has developed a platform technology called iTANK (Immunotherapies Activated with NAP for Efficient Killing) that could be used for further boosting the immunity of all CAR T-cell treatments under development.

The ELC-100 and ELC-301 projects have come farthest in their development towards becoming drugs:

**1. ELC-100** is an oncolytic virus that has the capacity to selectively kill cancer cells but leave healthy cells alone. It is now being used in a patient study (clinical Phase I/II

testing) for treatment of neuroendocrine tumors, meaning tumors that originate in the neuroendocrine system.

**2. ELC-301** is a CAR T-cell therapy based on genetically modifying the patient's T-cells so that they recognize targets on the tumor cells in order to attack and kill them. ELC-301 was developed for treating B-cell lymphoma, a cancer that originates in the lymphatic system.

## Elicera's strengths and competitive advantages

Elicera's operation is founded on years of research conducted by Professor Magnus Essand, who has a sterling reputation in the field, and his research group at Uppsala University. Elicera's strengths are based on a profound understanding of how cells and viruses can be genetically modified to trigger a robust immune response to cancer. Building on this competence, the company has developed a technology platform called iTANK (Immunotherapies Activated with NAP for Efficient Killing) that enables the arming of CAR T-cells with an immunoactivated protein from *Helicobacter pylori* (NAP), which gives rise to a multi-faceted attack on the tumors. Elicera believes it has a unique position with its iTANK platform, which the company also believes could be used to arm all CAR T-cells under development by other companies as well (see Table 1 below). Preclinical proof of concept data confirming the mechanism of action for the iTANK platform was published in one of the world's foremost scientific journals, *Nature Biomedical Engineering*, in April 2022.<sup>1</sup>

	WHAT?	WHY?	PROBLEM?	ELICERA'S SOLUTION
Immuno-oncology	Treating cancer via the immune system	Curative potential	Individual therapies insufficient, combination treatments required	Development of CAR T-cells and OV's that can be combined with other immunotherapies
CAR T-cells	Train T-cells via genetic modification to recognize targets on the tumor cell	Demonstrated curative potential in blood cancer	Challenges in solid tumors: 1. Hostile micro-environment 2. Shortage of relevant targets	iTANK platform answers challenges 1) and 2) for all CAR T-cells
The iTANK platform	Boosting CAR T-cells so that they give rise to a parallel broad cancer attack via CD8+ T-cells	CAR T-cells perform poorly in solid tumors		
Oncolytic viruses/OV	Viruses that selectively infiltrate, and propagate in, cancer cells but not healthy cells	Selective cancer attack and natural activation of the immune system	Individual therapies insufficient, combination treatments required	Development of the next generation of OV with three combined mechanisms of action → extra activation of immune system

Table 1: Elicera's iTANK platform and drug candidates solve many problems for health care and other drug developers/potential partners.

<sup>1</sup> Jin C. et al, Nat. Biomed. Eng., 2022



**E**licera's drug candidates can be combined with other immunotherapies such as checkpoint inhibitors (CPIs) to achieve a concurrent effect. This makes the company's CAR T-cells and oncolytic viruses of potential interest as combination therapies for many other players in immuno-oncology, especially those who are developing different treatments that inhibit the tumor's undesirable inhibition of the immune system. CAR T-cells, which are under development for treatment of solid tumors, have in general encountered two major problems:

**1. A hostile micro-environment in the tumor**, which counteracts the function of the CAR T-cell.

**2. A highly varied set of targets** (antigens) in the tumor cell, which makes it difficult for the CAR T-cell to find and attack cancer.

The iTANK platform counteracts this hostile micro-environment and strengthens the function of the CAR T-cell. In addition, it activates the patient's own CD8+ T-cells, which gain the ability to target the entire set of relevant targets in the tumor cells; this makes the technology platform of potential interest to every company developing proprietary CAR T-cells against different types of solid tumors.

Since all of Elicera's drug candidates give rise to a multi-stage attack on cancer through genetic modification, they have the potential to offer cancer patients broader, more effective immunotherapy. Moreover, ELC-301 has the possibility of offering continued treatment for the large proportion of patients who relapse in conventional CAR T-cell therapies and are thus beyond current treatment alternatives.

The work of Professor Essand's research group in genetic and immunotherapy against cancer has led to two ongoing clinical trials with oncolytic viruses (one of which is using ELC-100), and one concluded and one ongoing academic study with CD19 CAR T-cells (not included in Elicera's product portfolio). These studies provide Elicera with access to valuable experience ahead of planning and implementation of the company's future CAR T-cell studies with ELC-301 and ELC-401.

Furthermore, Elicera's management group and Board of Directors has previous experience from drug development in immuno-oncology, with a focus on cell therapies. The Board's fields of expertise also include business development, health economy, regulatory strategy, business law and corporate governance in a listed environment.

### Business concept and strategy

Elicera develops innovative immunotherapies for the purpose of prolonging the lives of, and improving the quality of life for, cancer patients. Its business concept is built on generating revenue from commercial partnerships by:

- Benefiting from the company's world-leading competence in cell and tumor immunology in order to develop drugs that address major medical needs that are not being met.
- Continuing to build on its strong patent portfolio and work up valuable know-how.
- Implementing well-designed preclinical and clinical trials for projects that can then be included in commercial partnerships with large drug and/or biotech companies.
- Outlicensing the iTANK platform to other companies that are developing CAR T-cells.



# Product portfolio

The company's product portfolio consists of four drug candidates: two in the field of oncolytic viruses (ELC-100 and ELC-201) and two are in the field of CAR T-cell treatments (ELC-301 and ELC-401), as well as a platform technology, iTANK (ELC-001) for further boosting immunity in conjunction with CAR T-cell treatments. A description of each project follows below.

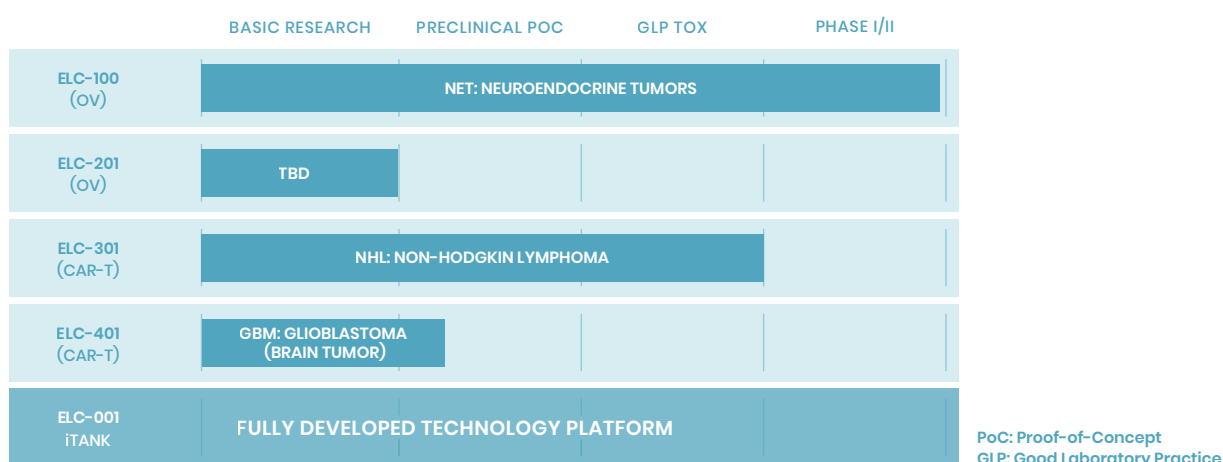


Figure 1: Elicera's product portfolio.

## ELC-001: the iTANK technology platform for CAR T-cell optimization and parallel immune activation against cancer

Elicera has developed a technology platform called iTANK (Immunotherapies Activated with NAP for Efficient Killing) that could be used for optimizing CAR T-cells by activating a parallel attack on cancer using CD8+ T-cells. Development of the platform is complete, and it is being used to arm the company's CAR T-cell therapies ELC-301 and ELC-401. Additionally, the iTANK technology is currently being used in ELC-201, Elicera's next generation of oncolytic virus. The platform has potential for application in all CAR T-cells under development by all companies, and is expected to be able to meet the two major challenges below faced by all CAR T-cells in the treatment of solid tumors:

1. A hostile micro-environment in the tumor, which counteracts the function of the CAR T-cell.
2. A highly varied set of targets (antigens) in the tumor cell, which makes it difficult for the CAR T-cell to find and attack cancer.

The iTANK platform has the capacity to strengthen the function of the CAR T-cell while directly counteracting the hostile micro-environment in the tumor. Arming with the iTANK platform also leads to a process that releases an entire set of relevant immunostimulants, not just individual ones, that together provide a highly robust and broad activation of the immune system and the patient's CD8+ T-cells against cancer (see Figure 2 below). The patient's own CD8+ T-cells are also activated against the entire set of relevant targets in the tumor cell, which creates the conditions for a broad attack on cancer (see Figure 3 below).

The iTANK technology is used to incorporate a transgene in CAR T-cells that codes for a neutrophil-activating protein (NAP) from *Helicobacter pylori* bacteria. Upon activation, the NAP has demonstrated the ability to:

- Recruit neutrophils and inflammatory cells<sup>1</sup> (publications by others).
- Trigger an adaptive immune response based on CD8+ T-cells<sup>2</sup> (publications by others).

<sup>1</sup> D'Elios et al, FEMS Immunol Med Microbiol 2007  
<sup>2</sup> D'Elios et al, FEMS Immunol Med Microbiol 2007



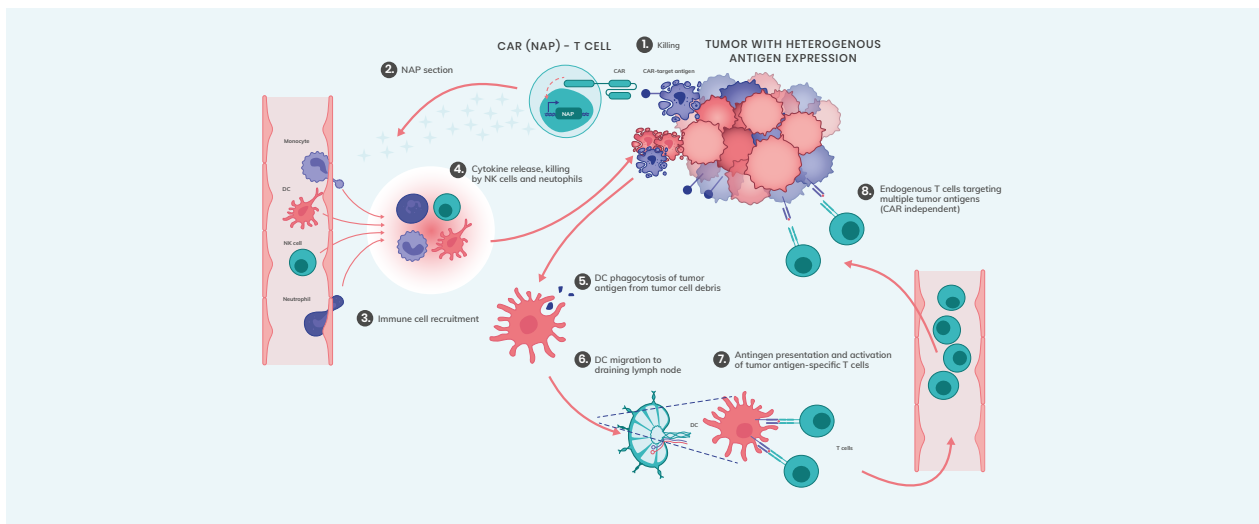


Figure 2: NAP-boosted CAR T-cells activate the innate immune system and a parallel attack on cancer via CD8+ T-cells.

- Function as a vaccine adjuvant and trigger an immune response against “weak” antigens as well<sup>3</sup> (publications by others).
- Improve the anti-tumor effect of the oncolytic measles virus<sup>4</sup> (publications by others).
- Create a pro-inflammatory micro-environment rich in cytokines and chemokines<sup>4</sup> (publications by Essand group).
- Recruit neutrophils that can kill cancer cells directly<sup>5</sup> (publications by Essand group).
- Activate dendritic cells and induce their migration to draining lymph nodes<sup>5</sup> (publications by Essand group).

Figure 2 above illustrates how NAP-boosted CAR T-cells trigger the innate immune system and a parallel attack on cancer via CD8+ T-cells. When the CAR T-cell comes in contact with a cancer cell via the target on the surface

of the tumor cell, NAPs are activated and released. In turn the NAPs recruit immune cells that release cytokines and chemokines, which create a pro-inflammatory environment that triggers the immune system against cancer. This occurs through the recruitment and activation of antigen-presenting cells such as dendritic cells (DCs). The DCs then pick up the set of various tumor antigens that are released after the CAR T-cell attack and move to the lymph nodes. There they present various tumor antigens to the T-cells, which are thereby activated and become cytotoxic, cancer-killing CD8+ T-cells.

Figure 3 below illustrates the advantages of the iTANK platform and highlights how NAP-boosted CAR T-cells generate another mechanism of action through CD8+ T-cells that focus on the entire set of relevant tumor antigens in cancer cells – not just one single target, as often is the

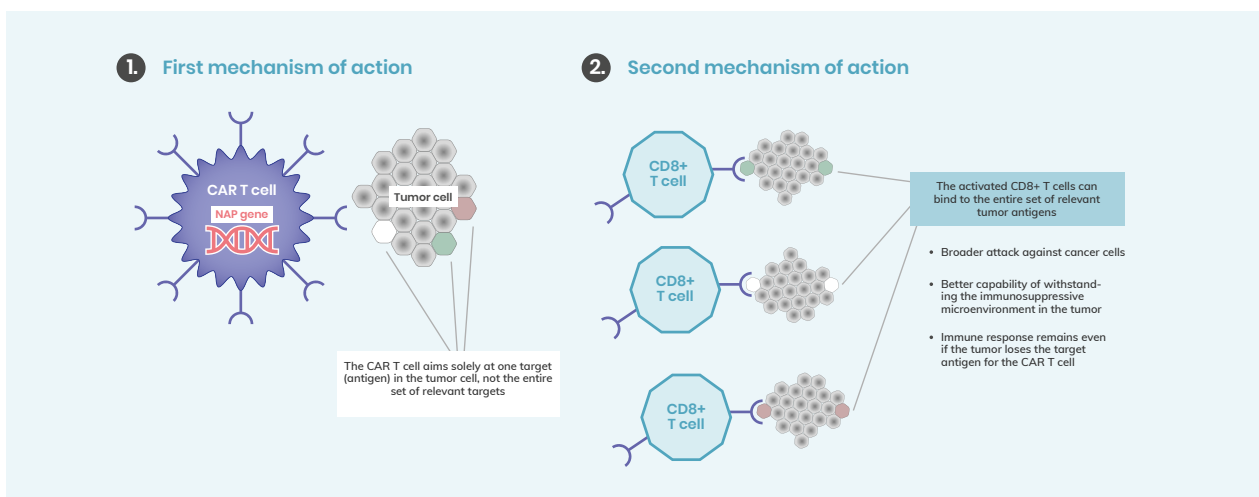


Figure 3: The iTANK platform results in a second parallel mechanism of action and a broad attack on tumor cells via CD8+ T-cells. The CD8+ T-cells are activated against the entire set of relevant targets on the tumor cell.

<sup>3</sup> Iankov I et al, Vaccines 2011, Iankov I et al, Mol Ther 2012, Iankov I et al, Vaccines 2013  
<sup>4</sup> Ramachandran M et al, Mol Ther 2013, Ramachandran M et al, J Immunol 2014

case for conventional CAR T-cells. According to Dr. Terry Fry, the co-author of "Mechanism of resistance to CAR T-cell therapy" (published in *Nature Review Clinical Oncology*<sup>5</sup>), the greatest problem with CAR T-cell therapies is the large proportion of patients who suffer a relapse after effective treatment. As much as 30–50 percent of patients who are treated with CD19 CAR-T cells and whose tumors regress initially see their cancer return, most of them within one year. The two challenges for CAR T-cells discussed above in the treatment of solid tumors are also likely explanations for the relapse after treatment with CAR T-cells for blood cancer<sup>6</sup>. As mentioned above, Elicera's iTANK platform can address both challenges by stimulating the immune system to attack other targets on tumor cells as well by activating neoantigen-reactive T-cells.

Elicera has generated preclinical data that demonstrates proof of concept for the various stages in the mechanism of action described above; this data was published in one of the world's most highly-regarded scientific journals, *Nature Biomedical Engineering* (April 2022)<sup>7</sup>. Other experiments were conducted, including on mice, in which the treatment with NAP-armed CD19 CAR T-cells was compared with conventional CD19 CAR T-cells in mice that had been injected with 50% CD19-positive tumor cells and 50% CD19-negative tumor cells. NAP-boosted CAR T-cells proved to limit tumor growth and prolong survival compared with conventional CAR T-cells. Further experiments analyzed CD8+ T-cells from mice and their CD19 reactivity, and only mice treated with NAP-boosted CAR T-cells showed CD8+ T-cells activated against CD19-negative

tumor cells, which clearly indicates the iTANK platform's capacity to trigger a parallel attack on the entire set of relevant tumor antigens and targets.

The following is a summary of proof-of-concept data for iTANK's mechanism of action, which was published in *Nature Biomedical Engineering* in April 2022:

- NAP is secreted only when CAR T-cells bind to tumor cells.
- NAP induces a "bystander" immune response that counteracts the problem of antigen heterogeneity. Several studies in vivo with different mouse models showed that only mice treated with iTANK-boosted CAR T-cells demonstrated an ability to attack tumors that lacked the CAR T-cell's target antigen, which resulted in increased tumor defense and increased survival compared with treatment with conventional CAR T-cells that were not boosted with the iTANK platform.
- CAR T-cells boosted with the iTANK platform showed less distress and improved activity compared with conventional CAR T-cells.
- Boosting CAR T-cells with the iTANK platform yields a more effective cancer treatment compared with conventional "unarmed" CAR T-cells independent of the choice of CAR molecule, tumor type or mouse model, which indicates that the technology is universally compatible with other CAR T-cell treatments.

### ELC-100: AdVince – Oncolytic virus in an ongoing Phase I/II study of the treatment of neuroendocrine tumors

Elicera's oncolytic virus AdVince (ELC-100) is based on a genetically modified adenovirus, Ad5PTD, and has been optimized with regard to its ability to enter specifically neuroendocrine cancer cells and not healthy cells, where they propagate until the tumor cell bursts and dies in a process

known as oncolysis. During oncolysis, an immune response against tumor cells is also initiated through tumor neoantigens (mutated antigens, the antigens that provoke the strongest immune response) being released and captured by the patient's dendritic cells, which then teach the T-cells

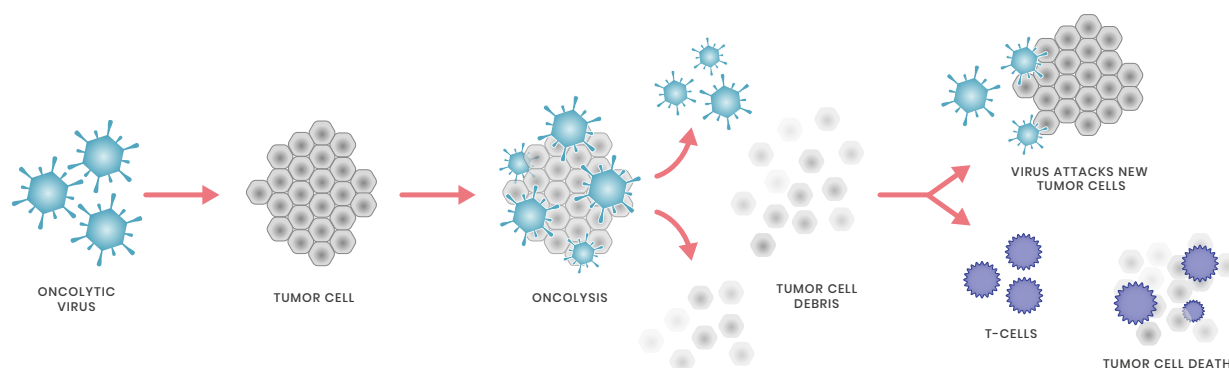


Figure 4: Oncolytic viruses selectively infiltrate, and propagate in, cancer cells. The process triggers an immune reaction and activates the patient's T-cells to attack cancer cells in parallel with the oncolytic viruses.

<sup>5</sup> Shah NN, Fry TJ. Mechanisms of resistance to CAR T cell therapy. *Nat Rev Clin Oncol*. doi: 10.1038/s41571-019-0184-6

<sup>6</sup> <https://www.cancertherapyadvisor.com/home/cancer-topics/hematologic-cancers/cart-cell-therapy-cancer-limitations-treatment/2/>

<sup>7</sup> Jin C. et al, *Nat. Biomed. Eng.*, 2022

to attack cancer cells wherever they are found in the body. AdVince is thus expected to achieve a tumor-killing effect in the cancer cells where it propagates while a long-term, systematic immune response is set in motion to attack cancer cells in other parts of the body as well (see Figure 4 above). In addition to selective propagation in neuroendocrine tumors (NETs), ELC-100 has also been genetically modified specifically not to propagate in liver cells, for the purpose of reducing the risk of side effects.

ELC-100 is currently being tested in a clinical Phase I/II trial (ClinicalTrials.gov identifier: NCT02749331) with Uppsala University as the sponsor (Elicera has the right to use data for continued development of ELC-100). The study is being conducted in two steps, where the primary goal of step 1 is to investigate the safety of the treatment and determine

the maximum tolerated dosage. This will then be tested in step 2 on a further 12 patients, where the primary goal is to study the efficacy of the treatment. The first step of the study has four dosage levels, with three patients at each level. In addition to determining the maximum tolerated dosage, the study is also investigating whether the patients respond to the treatment in the form of slowed tumor growth, or if the tumors have decreased in size. A complete treatment consists of four injections over approximately seven weeks. ELC-100 is either injected into the liver via blood vessels in the groin or directly into tumor lesion using an ultra-sound based technique. The patient is evaluated a month later using combined advance medical technology (CT, MR, PET). At present, ten of the 12 planned patients have been treated (patient 11 is scheduled for treatment) (see Figure 5 below).

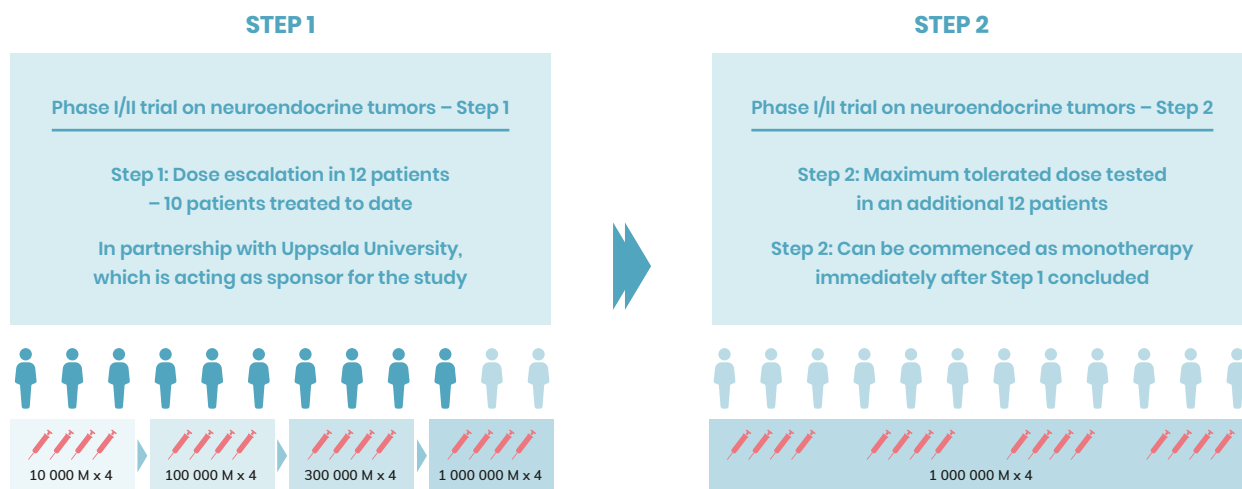


Figure 5: Ongoing Phase I/II trial on neuroendocrine tumors is being carried out in two step, where the first involves finding the maximum tolerated dosage, which will be tested in step 2.

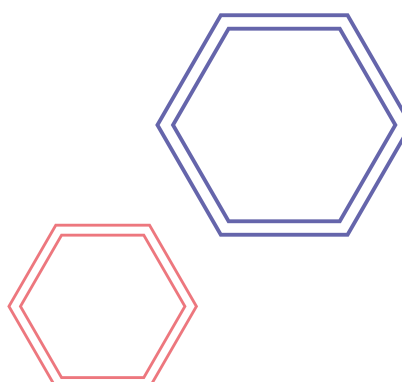
### ELC-201: the next generation of oncolytic virus, with three combined mechanisms of action

ELC-201, Elicera's next generation of oncolytic immunotherapy, is based on a genetically modified adenovirus vector with three combined mechanisms of action that have been developed to trigger an immune response that will lead to the activation of neoantigen-reactive T-cells. The treatment is expected to function synergistically, with established checkpoint inhibitors (CPIs), and can theoretically be used in the treatment of most forms of cancer.

ELC-201 is in the preclinical development phase.

### ELC-301: CAR T-cell therapy in the treatment of non-Hodgkin B cell lymphoma

ELC-301 is Elicera's iTANK-boosted CAR T-cell therapy in the treatment of non-Hodgkin B cell lymphoma (NHL), a form of blood cancer. Currently, NHL is treated primarily with cytotoxins in combination with the anti-CD20 antibody rituximab. Over 50 percent are cured, but between 20-50



percent of these patients stop responding to standard treatment or suffer a relapse after a complete response<sup>8</sup>. Three CAR T-cell therapies have been approved by the European Medicines Agency (EMA) between 8/2020 and 03/2022: Tecartus<sup>®</sup> (2020), Abcema<sup>®</sup> (2021) and Breyanzi<sup>®</sup> (2022). All three target CD19. The proportion of patients who have a complete tumor response is high, but “only” approximately 40 percent of these patients have a sustained complete response<sup>9</sup>. Elicera’s iTANK-boosted CAR T-cell therapy ELC-301 focuses on another target, CD20, and thereby supplements treatment with conventional CD19 CAR T-cell therapy. ELC-301 thus has the potential to more than double the number of B cell lymphoma patients who have a sustained complete tumor response.

Since NHL can have an immunosuppressive micro-environment and, moreover, there is a potential problem with patients becoming resistant to their treatment owing to the cancer cells often losing the target antigen with a relapse<sup>10</sup> it is important that a CAR T-cell treatment is able to induce a robust immune response based on neoantigen-reactive CD8+ T-cells that are able to kill cancer cells that do not express CD20 or CD19. ELC-301 has thus been boosted, via the iTANK platform, with an immunostimulant factor (NAP) that in preclinical studies has been shown to induce an immune response that also kills the cancer cells that do not express the target antigen that the CAR T-cell is directed against. At the end of April, Elicera received conditional approval to start a clinical phase I/IIa trial (the CARMA study) for the treatment of B-cell lymphoma. The conditional approval means that Elicera must complete the validation process of the GMP production, which is estimated to take place during the fourth quarter with expected first patient treatment in early 2024.

About the CARMA-study: The clinical phase I/IIa-study aims to evaluate the safety and efficacy of one dose of

CD20 directed CAR T-cells, armed with bystander immune activating properties, using the iTANK-platform, in patients with relapsed and/or refractory B-cell malignancies, by studying tolerance, toxicity, biological effects, and anti-tumor responses. The clinical trial will be conducted at the Academic hospital in Uppsala and at Karolinska University Hospital in two stages: a dose escalation stage (Phase I) to minimize the risk of serious side effects and to identify the appropriate testing dosage, followed by treatment in Phase IIa of the remaining six patients with the optimal dose identified in Phase I. A total of 12 patients are expected to be able to evaluate for safety and efficacy with the maximum tolerable dose.

### ELC-401 – a new CAR T-cell therapy in the treatment of glioblastoma, with immunity boosting via the iTANK platform

ELC-401 is a CAR T-cell therapy that targets IL13Ra2, a receptor that is overexpressed in 75 percent of patients with glioblastoma (GBM)<sup>11</sup>, as well as in a number of other solid tumors<sup>12</sup>. The drug candidate has been boosted with the iTANK platform, and is expected to meet the two aforementioned challenges for CAR T-cell treatment of solid tumors.

Via the iTANK platform, ELC-401 is expected to be able to activate CD8+ T-cells against the entire set of relevant tumor antigens and targets in GBM cells, thus offering a broader attack on cancer (the expectation has support from preclinical data published in Nature Biomedical Engineering in 2022). ELC-401 is expected to give rise to a pro-inflammatory environment in the tumor that counteracts the otherwise immunosuppressive micro-environment found in solid tumors.

ELC-401 is in the preclinical development phase.



<sup>8</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5649550/>

<sup>9</sup> Nature Medicine | 1344 VOL 25 | SEPTEMBER 2019 | 1341–1355

<sup>10</sup> Xu, X., et al. Mechanisms of Relapse After CD19 CAR T-Cell Therapy for Acute Lymphoblastic Leukemia and Its Prevention and Treatment Strategies. *Front Immunol* 10, 2664 (2019).

<sup>11</sup> IL13RA2 targeted alpha particle therapy against glioblastomas, *Oncotarget*. 2017 Jun 27; 8(26): 42997–43007.

<sup>12</sup> Interleukin-13 receptor α2 is a novel marker and potential therapeutic target for human melanoma, *Scientific Reports* volume 9, Article number: 1281 (2019)



# Financial information

## Financial performance during the first quarter, April 1–June 30, 2023

### Operating loss

Operating loss for the quarter totaled SEK -4,466,286 (-3,641,800), which is a change of SEK -824,486 compared to the year-earlier period. The change is due primarily to an SEK -2,593,201 increase in costs and SEK 1,768,715 in increased grants received.

### Loss for the quarter

Loss for the period amounted to SEK -4,335,852 (-3,667,200). Earnings per share totaled SEK -0.22 (-0.19).

### Liquidity and cash flow

- Cash flow from operating activities totaled SEK -2,146,178 (-3,877,975).
- Cash flow from investing activities totaled SEK +484,170 (0) SEK.
- Cash flow from financing activities totaled SEK 0 (0).
- Cash flow for the quarter amounted to SEK -1,662,008 (-3,877,975).
- At the end of the period, the company's cash and cash equivalents totaled SEK 40,124,490 (43,181,929).

## Financial performance during the period, January 1–June 30, 2023

### Operating loss

Operating loss for the period totaled SEK -6,732,143 (-8,382,851), which is a change of SEK +1,650,708 compared to the year-earlier period. The change is due primarily to an SEK -1,154,599 increase in costs and SEK 2,805,307 in increased grants received.

### Loss for the period

Loss for the period amounted to SEK -6,602,181 (-8,421,815). Earnings per share totaled SEK -0.33 (-0.43).

### Liquidity and cash flow

- Cash flow from operating activities totaled SEK -4,181,989 (-9,211,200).
- Cash flow from investing activities totaled SEK +484,170 (0) SEK.
- Cash flow from financing activities totaled SEK 0 (0).
- Cash flow for the quarter amounted to SEK -3,697,819 (-9,211,200).
- At the end of the period, the company's cash and cash equivalents totaled SEK 40,124,490 (43,181,929).

Elicera, with its existing bank balances and expected EU grant, has full financing for various trials at least through the end of 2024.

## Eu accelerator program

In June Elicera is selected, in very hard competition, for a grant from EU accelerator program amounting to SEK 2.5 m (about SEK 27 m). EU has paid the first part amounting at SEK 12.1 m. The remaining part will be paid during two coming years.

The amount is booked as prepaid income. The income will be booked as the costs occur in the project and the prepaid income will be reduced.

## Investments

Elicera's investments for the period totaled SEK +484,170 (0). Financial investments have been sold.

## Personnel and organization

The number of employees at the end of the period was 2. Elicera's organization comprises all the competence and experience that is necessary to run the company. Close collaboration has been established with a number of key consultants in patents, preclinical, clinical trials, development of pharmaceuticals, regulatory expertise for manufacture and documentation, quality assurance, finance, and law.

## Annual General Meeting 2023

The Annual General Meeting was held on May 16, 2023 in Stockholm. The AGM resolved to re-elect its Board of Directors: Agneta Edberg (chair), Magnus Essand, Christina Herder, Margareth Jorvid, Jan Zetterberg as ordinary members and Di Yu as deputy member. Board fees was fixed SEK 200,000 for Chairman of the Board Agneta Edberg and SEK 120,000 for the other members. RSM Göteborg KB, with signatory auditor Kristoffer Håkansson, was re-elected as auditor. The Board of Directors was authorized to conduct a private placement of a maximum of 20 % of the number of shares (3,956,400 shares)

## Risks and uncertainties

In addition to the general uncertainty related to research and development operations, the coronavirus, and delays in the start of clinical trials, there are no known tendencies, uncertainties, potential receivables or other demands, commitments or events that could be expected to have a material impact on the company's future prospects. A detailed account of various risks is presented on pages 30–31 of the Annual Report.

## Equity

Equity was impacted by the new share issue from the preceding year and earnings during the period. At the end of the period, equity totaled SEK 26,197,254 (43,816,251).

## The share

The Elicera share was listed on Nasdaq First North Growth Market on June 11, 2021. The share register is managed by Euroclear.

Erik Penser Bank AB, assume Certified Adviser duties from January 10, 2023.

Agreement was made with Erik Penser Bank as market maker on March 1, 2023. The market maker commitment is provided in accordance with Nasdaq Stockholm AB's rules for market making and means that the market maker will continuously place trading records on each purchase and sales page in the order book. A market maker aims to create a more accurate price picture in a company's share, which in turn gives a more accurate valuation of the company and allows for an improved trading volume in the share.

Loss after tax divided by the average number of shares for the period totaled SEK -0.33 (-0.43) for the reporting period. At the end of the period Elicera had approximately 2,400 shareholders. The number of shares at the end of the period was 19,782,000.

NAME	NUMBER OF SHARES	SHARE OF VOTES/ CAPITAL (%)
Magnus Essand	3,314,475	16.8
Di Yu	3,312,600	16.8
Jamal El-Mosleh	2,700,000	13.7
Nordnet	1,200,776	6.1
Six Sis AG	738 600	3.7
Other owners	8,515,549	43.0
<b>Total number of shares</b>	<b>19,782,000</b>	<b>100.0</b>

### Transactions with affiliated parties

Board member Jan Zetterberg, in addition to his work on the Board, received remuneration for consulting services in legal counselling through his company Zedur AB totaling SEK 11,000 SEK (3,000).

The pricing took place under market conditions.

### Events after the end of the period

No other key events that impact the financial statements occurred after the end of the period.

### Accounting policies

This interim report has been prepared in accordance with K3. The accounting policies are presented on page 36 of the Annual Report.

### Audit

This interim report has not been audited.

## ASSURANCE OF THE BOARD

The Board of Directors and CEO give their assurance that this interim report provides a true and fair overview of the company's operations, financial position, and earnings, and that it describes the material risks and uncertainties faced by the company.

Gothenburg, August 29, 2023

The Board of Directors of Elicera Therapeutics (publ)

Agneta Edberg, Chairman

Magnus Essand

Christina Herder

Jan Zetterberg

Margareth Jorvid

Jamal El-Mosleh, CEO

# Condensed statement of income and other comprehensive

(AMOUNTS IN SEK)	2023 3 MOS APR-JUNE	2022 3 MOS APR-JUNE	2023 6 MOS JAN-JUNE	2022 6 MOS JAN-JUNE	2022 12 MOS JAN-DEC
Other income	1,771,388	2,673	3,182,575	377,268	1,280,173
<b>Operating expenses</b>					
Other external expenses	-4,620,280	-2,705,615	-6,882,495	-6,896,258	-16,195,366
Personnel expenses	-1,614,448	-935,912	-3,026,331	-1,857,969	-4,435,881
Depreciation of property, plant and equipment	-2,946	-2,946	-5,892	-5,892	-11,776
<b>Total operating costs</b>	<b>-6,237,674</b>	<b>-3,644,473</b>	<b>-9,914,718</b>	<b>-8,760,119</b>	<b>-20,642,923</b>
<b>Operating loss</b>	<b>-4,466,286</b>	<b>-3,641,800</b>	<b>-6,732,143</b>	<b>-8,382,851</b>	<b>-19,362,750</b>
Interest income and similar profit/loss items	142,044	-	141,468	-	53,459
Interest expenses and similar profit/loss items	-11,610	-25,400	-11,506	-38,964	-129,205
<b>Loss before taxes</b>	<b>-4,335,852</b>	<b>-3,667,200</b>	<b>-6,602,181</b>	<b>-8,421,815</b>	<b>-19,438,631</b>
Tax	-	-	-	-	-
<b>Loss for the period</b>	<b>-4,335,852</b>	<b>-3,667,200</b>	<b>-6,602,181</b>	<b>-8,421,815</b>	<b>-19,438,631</b>
<b>Other comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
<b>Comprehensive income for the period</b>	<b>-4,335,852</b>	<b>-3,667,200</b>	<b>-6,602,181</b>	<b>-8,421,815</b>	<b>-19,438,631</b>

# Condensed balance sheet

(AMOUNTS IN SEK)	JUN 30 2023	JUN 30 2022	DEC 31 2022
<b>ASSETS</b>			
<b>Intangible assets</b>			
Software	17,660	29,436	23,552
<b>Total intangible assets</b>	<b>17,660</b>	<b>29,436</b>	<b>23,552</b>
<b>Financial assets</b>			
Securities	-	484,187	484,171
<b>Total financial assets</b>	<b>-</b>	<b>484,187</b>	<b>484,171</b>
<b>Total non-current assets</b>	<b>17,660</b>	<b>513,623</b>	<b>507,723</b>
Other receivables	123,813	115,586	330,567
Other interim receivables	766,615	1,534,485	1,647,373
Cash and bank	40,124,490	43,181,929	43,822,309
<b>Total current assets</b>	<b>41,014,918</b>	<b>44,832,000</b>	<b>45,800,971</b>
<b>TOTAL ASSETS</b>	<b>41,032,578</b>	<b>45,345,623</b>	<b>46,307,971</b>
<b>EQUITY</b>			
<b>Restricted equity</b>			
Share capital	830,844	830,844	830,844
<b>Total restricted equity</b>	<b>830,844</b>	<b>830,844</b>	<b>830,844</b>
<b>Non restricted equity</b>			
Share premium reserve	31,968,591	66,786,691	66,786,690
Profit or loss carried forward	-	-15,379,469	-15,379,469
Loss of the year	-6,602,181	-8,421,815	-19,438,631
<b>Total non-restricted equity</b>	<b>25,366,410</b>	<b>42,985,407</b>	<b>31,968,591</b>
<b>Total equity</b>	<b>26,197,254</b>	<b>43,816,251</b>	<b>32,799,434</b>
<b>Current liabilities</b>			
Account payables	2,348,280	715,041	731,933
Tax liabilities	-	-	5 437
Other current liabilities	208,266	92,193	236,229
Accrued expenses and prepaid income	12,278,778	722,138	12,535,125
<b>Total current liabilities</b>	<b>14,835,324</b>	<b>1,529,372</b>	<b>13,508,537</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>41,032,578</b>	<b>45,345,623</b>	<b>46,307,971</b>



# Condensed statement of changes in equity

(AMOUNTS IN SEK)	SHARE CAPITAL	SHARE PREMIUM RESERVE	RETAINED EARNINGS	LOSS FOR THE YEAR	TOTAL EQUITY
<b>Opening balance at January 1, 2022</b>	<b>830,844</b>	<b>66,786,691</b>	<b>-2,259,026</b>	<b>-13,120,443</b>	<b>52,238,066</b>
Proposed appropriation of earnings to AGM			-13,120,443	13,120,443	-
Loss for the period	-	-	-	-4,754,615	- 4,754,615
<b>Closing balance at March 31, 2022</b>	<b>830,844</b>	<b>66,786,691</b>	<b>-15,379,469</b>	<b>-4,754,615</b>	<b>47,483,450</b>

(AMOUNTS IN SEK)	SHARE CAPITAL	SHARE PREMIUM RESERVE	RETAINED EARNINGS	LOSS FOR THE YEAR	TOTAL EQUITY
<b>Opening balance at April 1, 2022</b>	<b>830,844</b>	<b>66,786,691</b>	<b>-15,379,469</b>	<b>-4,754,615</b>	<b>47,483,450</b>
Loss for the period	-	-	-	-3,667,200	-3,667,200
<b>Closing balance at June 30, 2022</b>	<b>830,844</b>	<b>66,786,691</b>	<b>-15,379,469</b>	<b>-8,421,815</b>	<b>43,816,251</b>

(AMOUNTS IN SEK)	SHARE CAPITAL	SHARE PREMIUM RESERVE	RETAINED EARNINGS	LOSS FOR THE YEAR	TOTAL EQUITY
<b>Opening balance at July 1, 2022</b>	<b>830,844</b>	<b>66,786,691</b>	<b>-15,379,469</b>	<b>-8,421,815</b>	<b>43,816,251</b>
Loss for the period	-	-	-	-11,016,816	-11,016,816
<b>Closing balance at December 31, 2022</b>	<b>830,844</b>	<b>66,786,691</b>	<b>-15,379,469</b>	<b>-19,438,631</b>	<b>32,799,435</b>

(AMOUNTS IN SEK)	SHARE CAPITAL	SHARE PREMIUM RESERVE	RETAINED EARNINGS	LOSS FOR THE YEAR	TOTAL EQUITY
<b>Opening balance at January 1, 2023</b>	<b>830,844</b>	<b>66,786,691</b>	<b>-15,379,469</b>	<b>-19,438,631</b>	<b>32,799,435</b>
Proposed appropriation of earnings to AGM		-34,818,100	15,379,469	19,438,631	-
Loss for the period	-	-	-	-2,266,329	-2,266,329
<b>Closing balance at March 31, 2023</b>	<b>830,844</b>	<b>31,968,591</b>	<b>-</b>	<b>-2,266,329</b>	<b>30,533,106</b>

(AMOUNTS IN SEK)	SHARE CAPITAL	SHARE PREMIUM RESERVE	RETAINED EARNINGS	LOSS FOR THE YEAR	TOTAL EQUITY
<b>Opening balance at April 1, 2023</b>	<b>830,844</b>	<b>31,968,591</b>	<b>-</b>	<b>-2,266,329</b>	<b>30,533,106</b>
Loss for the period	-	-	-	-4,335,852	-4,335,852
<b>Closing balance at June 30, 2023</b>	<b>830,844</b>	<b>31,968,591</b>	<b>-</b>	<b>-6,602,181</b>	<b>26,197,254</b>

DISCLOSURES ON SHARES	NUMBER OF SHARES
Number at beginning of the year	19,782,000
Number at June 30, 2023	19,782,000
Number of warrants at June 30, 2023	0

# Condensed cash flow statement

(AMOUNTS IN SEK)	2023 3 MOS APR-JUNE	2022 3 MOS APR-JUNE	2023 6 MOS JAN-JUNE	2022 6 MOS JAN-JUNE	2022 12 MOS JAN-DEC
<b>OPERATING ACTIVITIES</b>					
Operating loss before financial items	-4,466,286	-3,641,800	-6,732,143	-8,382,851	-19,362,734
Reversal of depreciation	2,946	2,946	5,892	5,892	11,792
Interest received	142,044	-	141,468	-	53,459
Interest paid	-11,610	-25,400	-11,506	38,964	-129,340
Taxes paid	-	-	-	-	2,168
<b>Cash flow from operating activities</b>	<b>-4,332,906</b>	<b>-3,664,254</b>	<b>-6,596,289</b>	<b>-8,415,923</b>	<b>-19,424,671</b>
Increase/Decrease in prepaid expenses and accrued income	662,423	60,811	1,087,512	175,490	-152,378
Increase/Decrease in account payable	1,657,451	-357,437	1,616,348	-1,331,103	-1,316,211
Increase/Decrease in other current liabilities	-133,146	82,906	-289,560	362,336	12,322,440
<b>Cash flow from operating activities</b>	<b>-2,146,178</b>	<b>-3,877,975</b>	<b>-4,181,989</b>	<b>-9,211,200</b>	<b>-8,570,820</b>
<b>Investing activities</b>					
Investments in intangible assets	-	-	-	-	-
Change in non-current financial assets	484,170	-	484,170	-	-
<b>Cash flow from investing activities</b>	<b>484,170</b>	<b>-</b>	<b>484,170</b>	<b>-</b>	<b>-</b>
<b>Financing activities</b>					
New share issue	-	-	-	-	-
<b>Cash flow from financing activities</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>
Cash flow for the period	-1,662,008	-3,877,975	-3,697,819	-9,211,200	-8,570,820
Cash and cash equivalents at the beginning of the period	41,786,498	47,059,904	43,822,309	52,393,129	52,393,129
<b>Cash and cash equivalents at the end of the period</b>	<b>40,124,490</b>	<b>43,181,929</b>	<b>40,124,490</b>	<b>43,181,929</b>	<b>43,822,309</b>

## Financial calendar

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Year-end Report 2023 ..... Februari 13, 2024

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### Adress

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The background features a dark, teal-toned abstract design. A prominent DNA double helix structure is visible, with its sugar-phosphate backbones rendered as thick, dark, textured bands. The base pairs are represented by smaller, glowing blue and pinkish-red spheres connected by thin, light blue lines. Additionally, a complex network of thin, light blue lines connects various small, glowing pinkish-red spheres, creating a molecular or data-like structure that spans the entire frame.

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