



# 2022

## ANNUAL REPORT

**elicera**  
THERAPEUTICS

Fiscal Year January 1–December 31, 2022

Elicera Therapeutics AB  
Corp. Reg. No. 556966–4955

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**elicera**  
THERAPEUTICS

Cell and gene therapies  
for immune-based  
cancer treatments



# CEO Comments

## Many advances in 2022



CEO and co-founder  
Jamal El-Mosleh

### We are putting a productive 2022 behind us

2022 offered many advances for Elicera. Our success is built on the basis of a small but efficient and dedicated organization as well as a well-established network of experts that also rests on a solid scientific foundation.

As we informed our readers in the previous interim report, in October Elicera signed its first agreement that is built on a collaboration around the iTANK platform. More specifically, Elicera signed a material transfer agreement (MTA) with the Josep Carreras Leukemia Research Institute (JCLRI) in Spain, which is developing CAR T-cell treatments for Ewing Sarcoma, a condition that is very difficult to treat.

We are experiencing continued significant interest from both new and existing contacts who are looking for a solution to the challenges of T-cell receptors and CAR T-cell treatments. In examining the market to identify innovative platforms for the development of their proprietary solutions, these contacts are beginning to see the potential of iTANK as just such an opportunity.

Elicera's strategy is built on signing partnership and licensing agreements for the iTANK platform, where the Spanish partnership agreement is the first of several partnerships that we are working to establish in the future. As a stage in these continuing efforts, Elicera has engaged LifeSci Consulting, which will assist us in accelerating our business development initiatives and intensifying our discussions with potential partners. LifeSci Consulting is a leading life science strategy and transaction adviser with a global reach and broad experience from transactions in oncology. We are looking forward very much to our partnership with them, but naturally we cannot provide any guarantees for when we will conclude any transactions in the near future.

**“Not only because it would be the first time the company enters into clinical studies with a CAR T-cell therapy, but also the first time that the immunoactivated properties of the iTANK platform will be clinically tested.”**

### Boosts to and advances in the CAR T program

In November, Elicera's co-founders Professor Magnus Essand and senior lecturer Di Yu received a total of SEK 7.65 million from Cancerfonden, the Swedish Cancer Fund, as financing for the Group's CAR T-cell research at Uppsala University. Both Professor Essand and Doctor Yu applied for funds in their capacities as researchers at Uppsala University, which means that Elicera itself is not the direct recipient of the financing, but the results of this research have the potential to enable the simplified administration of the company's pending clinical trials in CAR T with ELC-401. We are proud of the groundbreaking research that our co-founders are pursuing, and look forward to monitoring the project.

As regards our most advanced CAR T-cell candidate, ELC-301, Elicera recently submitted an application for clinical trials to the Swedish Medical Products Agency and documentation to the Swedish Ethical Review Authority for the purpose of obtaining approval to evaluate its drug candidate in the treatment of B-cell lymphoma, which is a disease that largely still lacks viable treatment alternatives. The study is intended to evaluate the safety and efficacy of a dose of CD20-targeted CAR T-cells, which are armed with immunoactivated properties via the iTANK platform, in patients with B-cell lymphoma that is either difficult to treat or has metastasized.

More information about the design of the 301 study will be presented if the application is approved, which would be a major milestone for Elicera. Not only because it would be the first time the company enters into clinical studies with a CAR T-cell therapy, but also the first time that the immunoactivated properties of the iTANK platform will be clinically tested.

### Encouraging data and progress in the ELC-100 study

In December, Elicera's co-founder Doctor Di Yu participated in the Oncolytic Virotherapy Summit in Boston to present proof-of-concept data from the company's preclinical studies involving the ELC-201 oncolytic virus. Doctor Di Yu also presented new data from the ongoing clinical Phase I/IIa trial that is evaluating the ELC-100 oncolytic virus for treatment of neuroendocrine tumors.

In January, we were able to announce that the Data Safety and Monitoring Board (DSMB), an independent group of experts whose functions include monitoring patient safety and how studies are conducted, concluded its third assessment of the ELC-100 study and recommended that the study continue in accordance with the plan established by the company. This means that Elicera has thus been given the go-ahead to recruit the remaining three patients in the final cohort.

### Full focus on new and ongoing initiatives

In my opinion, we made progress in all three areas we prioritized in 2022:

- We are experiencing continued interest in the iTANK platform and are maintaining contacts we previously made as well as targeting new ones.
- As the only Swedish R&D company that is developing CAR T-cell therapies from the ground up in Sweden, we have taken a significant step with the submission of clinical trial applications for ELC-301 toward meeting a significant unmet medical need for patients who currently do not have the possibility of treatment with market-approved conventional CAR T-cell therapies. We expect feedback from the authorities in the first half of 2023, and provided that the application is approved, we expect to be able to commence the trial immediately and treat the first patient shortly thereafter.

- We have begun recruitment of the last three patients in the final cohort of the ELC-100 study in light of the DSMB's recommendation to continue the trial in accordance with plans.

Elicera will focus on the above priorities in 2023 as well.

As regards our program that is researching the effect of the ELC-201 oncolytic virus, the analysis to determine which cancer indication will initially be considered and evaluated has been concluded. Based on this analysis, the focus is now fully on evaluating our treatment alternatives and what impact they will have on Elicera's programs and plan.

In conclusion, I would like to thank my colleagues for their fantastic efforts in 2022 – without their devotion, Elicera would not have come as far in its clinical work or successfully ensured the soft financing totaling over SEK 30 million that has been received from both the EU and Vinnova. This means that our ongoing clinical trial with ELC-100 and our planned clinical trial with ELC-301 have been fully financed. We also recently signed agreements with Erik Penser Bank regarding liquidity guarantees, meaning that the liquidity guarantor sets the bid and ask prices for the purpose of creating a truer and fairer picture of the share price. This in turn ought to provide a more reliable assessment of the company and promote the liquidity of the share.

I would also like to extend my sincerest thanks to Elicera's shareholders for their confidence during the year. Considering the plan we have established, I look forward to leading the company into yet another exciting and eventful year in pace with Elicera driving its clinical programs forward. All this so that people who are suffering from cancer will be able to avail themselves of the next generation of cell and gene therapies for immune-based cancer treatment.

**Jamal El-Mosleh**  
CEO and co-founder



# 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 multifaceted 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:<br>1. Hostile micro-environment<br>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.

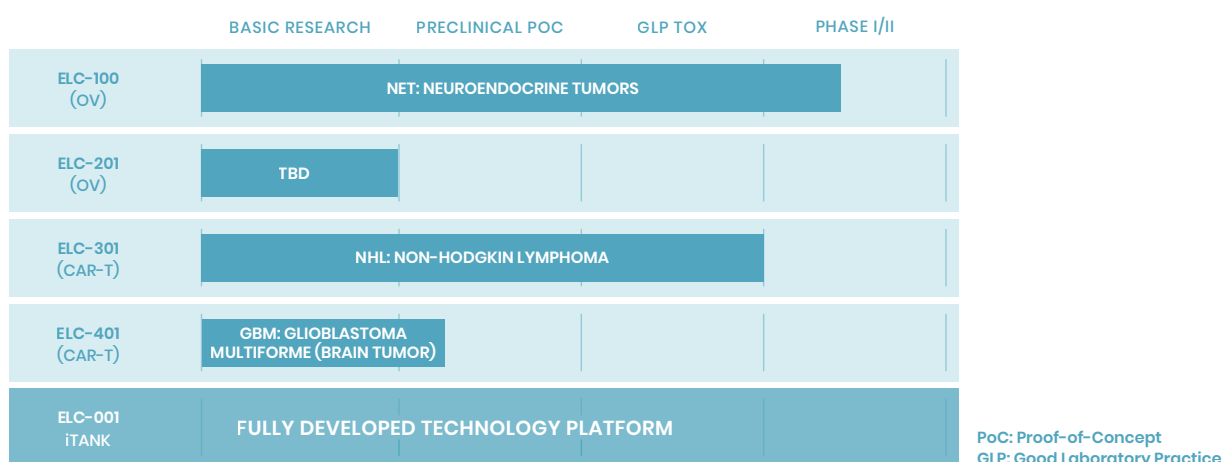


Figure 1: Elicera's product portfolio.

## 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>2</sup> (publications by others).
- Trigger an adaptive immune response based on CD8+ T-cells<sup>3</sup> (publications by others).

<sup>2</sup> D'Ellos et al, FEMS Immunol Med Microbiol 2007  
<sup>3</sup> D'Ellos et al, FEMS Immunol Med Microbiol 2007



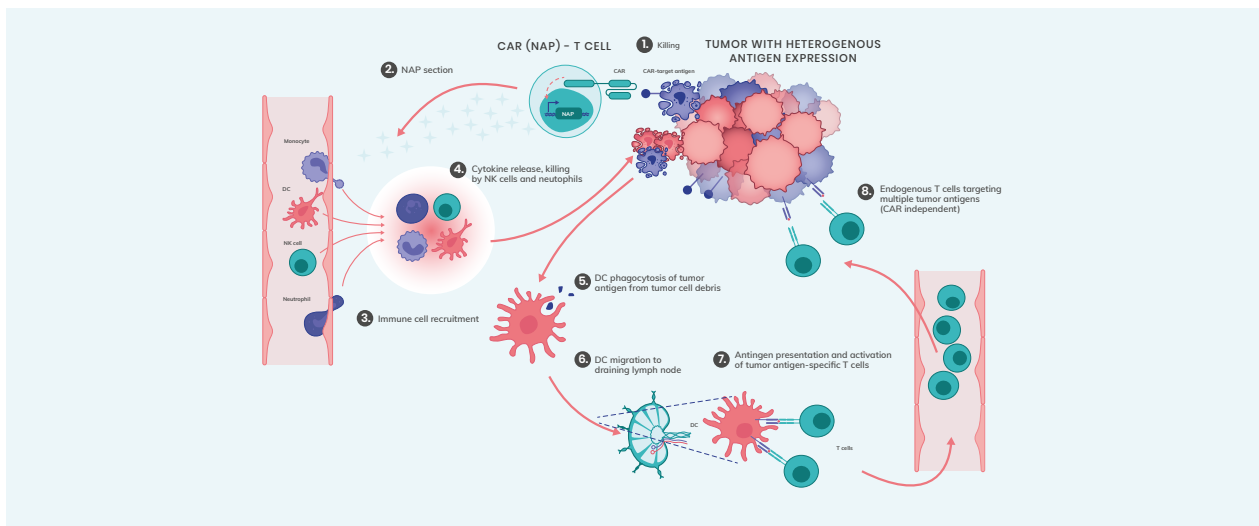


Figure 2: NAP-boosted CAR T-cells activate the innate immune system and a parallel attack on cancer via CD8+ T-cells.

- Function as a vaccine adjuvant and trigger an immune response against “weak” antigens as well<sup>4</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>5</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

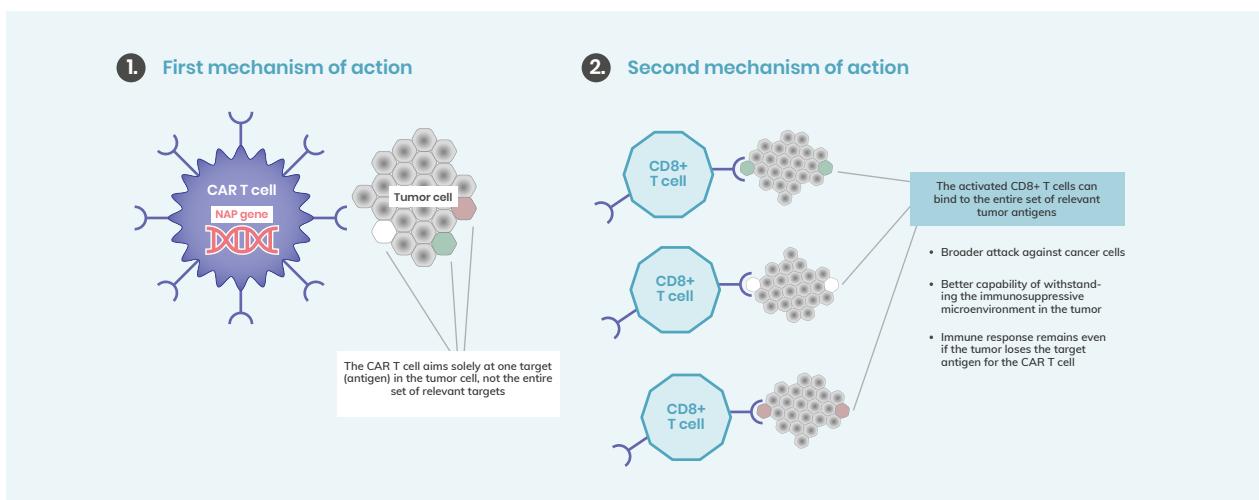


Figure 3: The iTANK platform results in a second parallel mechanism of action and a broad attack on tumor cells via CD8+ T-cells. The CD8+ T-cells are activated against the entire set of relevant targets on the tumor cell.

<sup>4</sup> Iankov I et al, Vaccines 2011, Iankov I et al, Mol Ther 2012, Iankov I et al, Vaccines 2013  
<sup>5</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>6</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>7</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>8</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

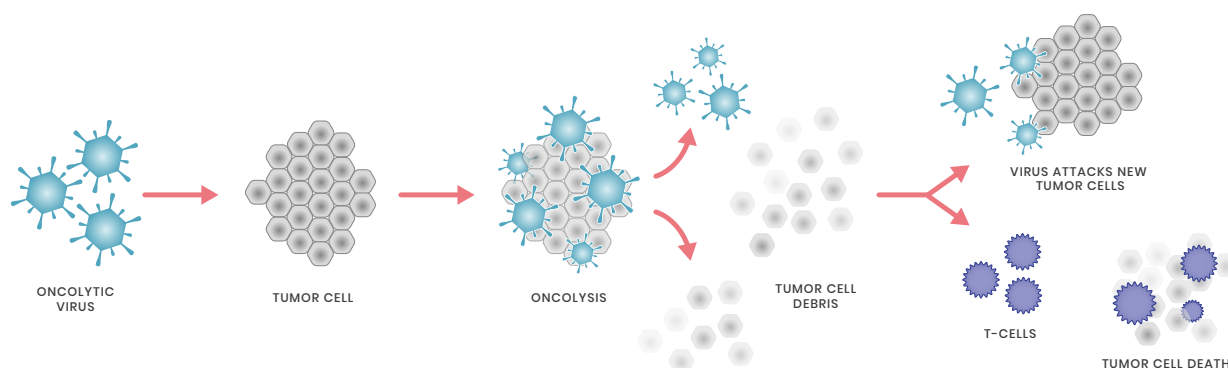


Figure 4: Oncolytic viruses selectively infiltrate, and propagate in, cancer cells. The process triggers an immune reaction and activates the patient's T-cells to attack cancer cells in parallel with the oncolytic viruses.

<sup>6</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>7</sup> <https://www.cancertherapyadvisor.com/home/cancer-topics/hematologic-cancers/cart-cell-therapy-cancer-limitations-treatment/2/>

<sup>8</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, nine of the 12 planned patients have been treated (see Figure 5 below).

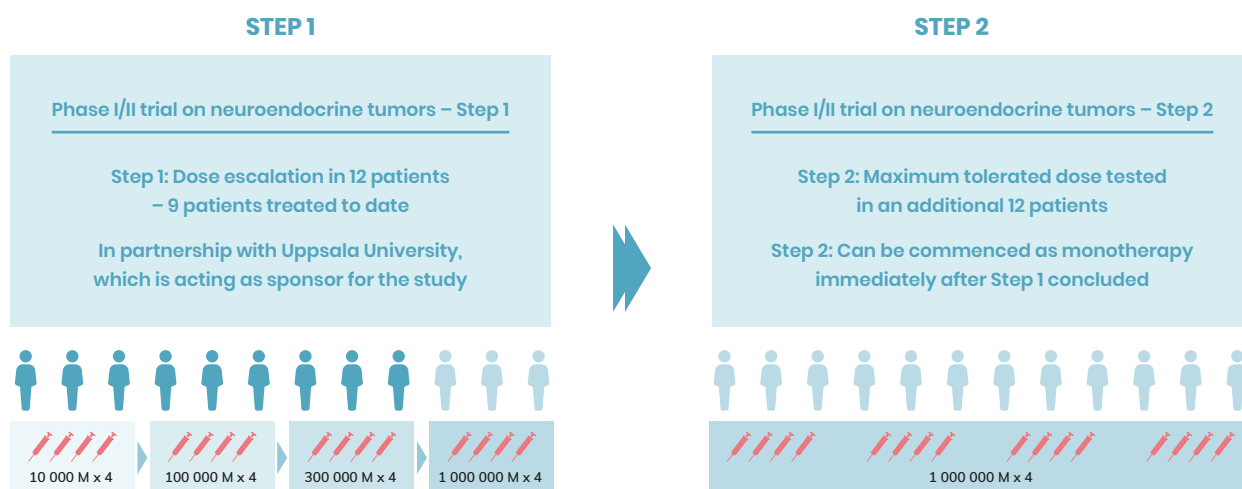
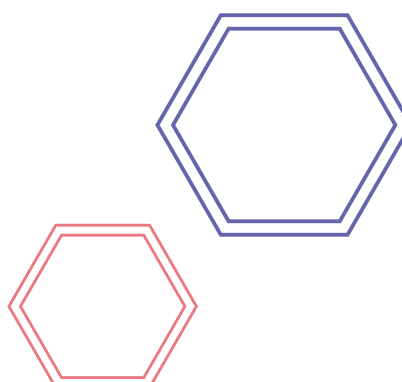


Figure 5: Ongoing Phase I/II trial on neuroendocrine tumors is being carried out in two step, where the first involves finding the maximum tolerated dosage, which will be tested in step 2.

### 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, and an analysis on relevant clinical cancer indications to treat has recently been completed. Based on this analysis, the company will evaluate its clinical trial alternatives going forward.



### 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>9</sup>. Three CAR T-cell therapies have been approved by the European Medicines Agency (EMA) between 8/2020 and 03/2022: Tecartus® (2020), Abcema® (2021) and Breyanzi® (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>10</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>11</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. Elicera submitted an application for clinical testing to the Swedish Medical Products Agency and the Swedish Ethical Review Authority in January.

### ELC-401 – a new CAR T-cell therapy in the treatment of glioblastoma multiforme, 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 multiforme (GBM)<sup>12</sup>, as well as in a number of other solid tumors<sup>13</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 injected locally into the tumor, and is expected to give rise to a pro-inflammatory environment that counteracts the otherwise immunosuppressive micro-environment found in solid tumors. Additionally, ELC-401 is injected directly into the tumor, thereby ensuring that the CAR T-cells reach the tumor location itself in order to bind to the tumor cells.

ELC-401 is in the preclinical development phase.



<sup>9</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5649550/>

<sup>10</sup> *Nature Medicine* | 1344 VOL 25 | SEPTEMBER 2019 | 1341–1355

<sup>11</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>12</sup> IL13RA2 targeted alpha particle therapy against glioblastomas, *Oncotarget*. 2017 Jun 27; 8(26): 42997–43007.

<sup>13</sup> Interleukin-13 receptor  $\alpha 2$  is a novel marker and potential therapeutic target for human melanoma, *Scientific Reports* volume 9, Article number: 1281 (2019)



# Market overview

## The market for neuroendocrine tumors

Neuroendocrine tumors (NETs) arise from specialized cells in the neuroendocrine system. The tumors can be found anywhere in the body, but occur primarily in the gastrointestinal tract (43 %) as well as in the lungs (30 %) and in the pancreas (7 %)¹⁴.

Approximately 450,000 people were living with NETs in 2017 in the seven major markets (7MM: the US, Japan, France, Germany, England, Italy and Spain), and the total market is valued at approximately USD 3.6 billion¹⁵.

The drugs most used in treating NETs consist of somatostatin analogues (SSAs) that inhibit the production of certain hormones that help the cancer to grow, followed by treatment with various types of kinase inhibitors and cytotoxins¹⁶. The choice of NET treatment depends on where the primary tumor is located, which also has a major impact on expected survival. A study published in 2018 shows that median survival for patients with NET is 41 months, and that the five-year survival rate is 39.4%¹⁷. The three largest Big Pharma companies in the NET field are Pfizer, Boehringer Ingelheim and Novartis¹⁸. According to a recently published report by Datamonitor, most industry-sponsored clinical trials in NET are in Phase I, with only one clinical trial in Phase III¹⁹ being conducted by the Chinese company Hutchison MediPharma with the kinase inhibitor sulfanitib.

Elicera has identified a competitor that is developing oncolytic viruses for treatment of NET (SVV-001): Seneca Therapeutics (ST). SVV-001 has, in contrast to ELC-100, not been modified with NET-specific replication or for enhanced infective capacity. The company has concluded a Phase I/II trial with initial indications of efficacy²⁰ and is now planning a Phase I/II trial in combination with a checkpoint inhibitor.

## The market for B cell NHL

Non-Hodgkin Lymphoma (NHL) can be divided up into several subgroups, where diffuse large B cell lymphoma (DLBCL) is the most common. NHL affects approximately 1.5 million people around the world every year²¹. DLBCL comprises over 85 percent of all NHL cases. Treatment alternatives vary depending on which type of NHL patient is affected and by how far the disease has progressed, but for NHL patients whose treatment is difficult, there is still a great medical need²².

The market for B cell NHL in the 7MM was valued at USD 5.7 billion in 2017, and is expected to increase to USD 9.2 billion by 2027²³. Growth is driven primarily by CAR T-cell therapies, the launch of new products that are still under development, and new areas of application for previously established drugs in the treatment of subgroups of B cell NHL.

Chemotherapy combined with the anti-CD20 antibody rituximab comprise the first line of treatment of NHL for the purpose of curing the disease, but relapses are unfortunately common. According to an international NHL study that retrospectively evaluated the results in patients with DLBCL that was difficult to treat, the objective frequency of response for the second line of treatment was only 26 percent and the total median survival was only 6.3 months²⁴. Only 20 percent of the patients were alive after two years, and the results in subgroups of patients in the study were consistently poor.

Younger patients who suffered relapses were frequently offered high-dosage chemotherapy (cytotoxins) with autologous stem cell transplants (ASCT), but more than half experienced new relapses and the effects of treatment for such patients are unfortunately very poor. Older patients with relapses that were not entitled to ASCT were offered palliative treatment only intended to alleviate symptoms.

**“The market for B cell NHL in the seven major markets was valued at USD 5.7 billion in 2017, and is expected to increase to USD 9.2 billion by 2027.”**

14 <https://www.cancer.net/cancer-types/neuroendocrine-tumors/introduction>

15 Global Neuroendocrine Tumors (NETs) Market Report 2019, Research and Markets

16 <https://mordorintelligence.com/industry-reports/neuroendocrine-tumor-treatment-market>

17 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6239108/>

18 <https://mordorintelligence.com/industry-reports/neuroendocrine-tumor-treatment-market>

19 <https://pharmastore.informa.com/product/market-spotlight-neuroendocrine-tumors-net/>

20 [https://www.researchgate.net/publication/49820092\\_Phase\\_I\\_Clinical\\_Study\\_of\\_Seneca\\_Valley\\_Virus\\_SVV-001\\_a\\_Replication-Competent\\_Picornavirus\\_in\\_Advanced\\_Solid\\_Tumors\\_with\\_Neuroendocrine\\_Features](https://www.researchgate.net/publication/49820092_Phase_I_Clinical_Study_of_Seneca_Valley_Virus_SVV-001_a_Replication-Competent_Picornavirus_in_Advanced_Solid_Tumors_with_Neuroendocrine_Features)

21 <https://www.ihealthcareanalyst.com/global-non-hodgkin-lymphoma-market/>

22 <https://decisionresourcesgroup.com/report/725293-biopharma-non-hodgkins-lymphoma-and-chronic-lymphocytic/>

23 <https://www.ccsentinel.com/life-style/2019-b-cell-non-hodgkins-lymphoma-market-share-global-trends-key-players-analysis-growth-factors-industry-opportunities-development-status-and-outlook-2023/>

24 Crump, M., et al. Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study. Blood 130, 1800-1808 (2017).

Today, the therapeutic cornerstones are still primarily chemotherapy combined with rituximab and radiation treatment, but new treatment strategies are emerging. Two CAR T-cell products that target the CD19 molecule, Yescarta® (Gilead) and Kymriah® (Novartis), have been approved in Europe as a second line of treatment for DLBCL. A third product, Tecartus (Gilead), for treatment of mantle cell lymphoma (MCL), a form of non-Hodgkin B cell lymphoma, was also approved in the US and in the EU. The total objective response rate (ORR) and complete response rate (CR) for Yescarta are 83% and 54% respectively<sup>25</sup>. A somewhat lower ORR (52%) and CR (40%) have been documented for Kymriah<sup>26</sup>. Even though the initial response rate is high, a majority of the patients experience relapse after CD19 CAR T-cell treatment, and when relapse occurs the tumor cells are often CD19-negative<sup>27</sup>. This means that patients who suffer a relapse become resistant to continued treatment with conventional CD19 CAR T-cell therapies (read more above about how Elicera is addressing these problems with its iTANK-boosted CAR T-cells/ELC-301, which targets CD20).

ELC-301 is initially intended to be developed as a third-line treatment for DLBCL, where Elicera estimates that a total of approximately 5,400 patients are in continued need of new therapies in the US and Europe. Epcoritamab, a bispecific antibody being developed by Genmab and Abbvie, is expected to be approved as a third-line treatment in DLBCL in 2023. Epcoritamab, unlike ELC-301, needs repeated dosing and is also not expected to provide as broad an anti-tumor response.

Cytokine release syndrome (CRS) and neurotoxicity are the two largest side effects. CRS is largely manageable at the clinic, but neurotoxicity can sometimes be fatal. The cause of neurotoxicity is considered to be a disruption of the blood-brain barrier, with infiltration of cytokines into the central nervous system (CNS)<sup>28</sup>, and by CAR T-cells that bind to CD19 in blood vessels in the brain. CD20 is not expressed in blood vessels in the brain, which indicates that treatment using CAR T-cells that target CD20 (such as ELC-301) are safer to use<sup>29</sup>.

### The market for glioblastoma

Glioblastoma (GBM) is an aggressive form of brain cancer that often leads to death within 15 months of diagnosis<sup>30</sup>. The standard treatment consists of surgery followed by radiation and chemotherapy. Approximately 300,000 people around the world suffered from GBM in 2018, according to Globocan. The market was valued at USD 662 million in 2017, and is expected to increase to USD 1.4 billion by 2027<sup>31</sup>.

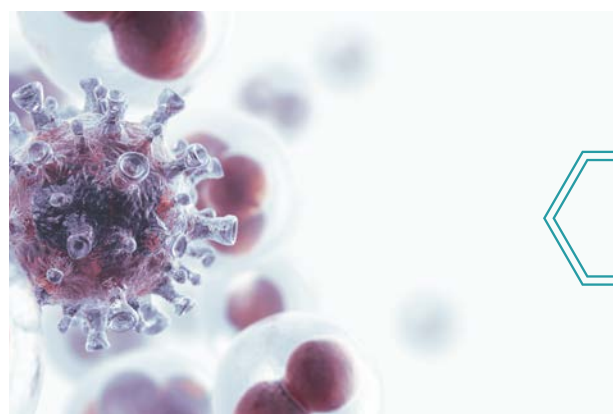
Owing to the inability of most drugs to pass the blood-brain barrier, there is a significant shortage of effective treatments. The only approved targeted therapy consists of Roche's tyrosine kinase inhibitor Avastin, despite the fact

that the treatment has not demonstrated prolonged survival in GBM patients<sup>32</sup>. It is expected that new treatments that can demonstrate a prolonged survival effect could capture significant market shares and immunotherapy has proven promising in this indication. Below are three examples of immunotherapies that are under development for the treatment of GBM:

- PD1-checkpoint inhibitor Opdivo (BMS): reported negative Phase III data in late 2020<sup>33</sup>.
- Cancer vaccine DCVAX-L (Northwest Biotherapeutics): promising survival data has been reported in Phase I/II trials, and the treatment is currently being tested in Phase III<sup>34</sup>.
- CAR T-cell MB-101 (Mustang Bio): promising effect data, including a patient who displayed complete response, in a small Phase I/II trial<sup>35</sup>. MB-101 is now being tested in combination with immune checkpoint inhibitors (Opdivo + Yervoy) in a Phase I/II trial.

MB-101 focuses on the same target – IL13Ra2 – as ELC-401, but the products differ in two important areas:

- ELC-401 has been boosted with the iTANK platform to activate CD8+ T-cells against cancer (read more about the iTANK platform above), while MB-101 has not been boosted with transgenes.
- ELC-401 and MB-101 bind to different parts of the IL13Ra2 antigen. MB-101 uses an IL13 ligand that also binds to targets outside IL13Ra2, and thus not specifically. This means that the product cannot be used outside the central nervous system in other indications. Moreover, the IL13 ligand binds to an area that competes with soluble IL13, whereas ELC-401 binds outside this area and thus does not compete with soluble IL13. All together, this gives ELC-401 great potential for good treatment effects not only in GBM but in other indications as well.



25 Locke, F.L. et al. Long-term safety and activity of axicabtagene ciloleucel in refractory large B-cell lymphoma (ZUMA-1): a single-arm, multicentre, phase 1-2 trial. *Lancet Oncol* **20**, 31-42 (2019).

26 Schuster, S.J. et al. Tisagenlecleucel in Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma. *N Engl J Med* **380**, 45-56 (2019).

27 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).

28 Gust, J., Taraseviciute, A. & Turtle, C.J. Neurotoxicity Associated with CD19-Targeted CAR-T Cell Therapies. *CNS Drugs* **32**, 1091-1101 (2018).

29 Parker, K.R. et al. Single-Cell Analyses Identify Brain Mural Cells Expressing CD19 as Potential Off-Tumor Targets for CAR-T Immunotherapies. *Cell* **183**, 126-142 e117 (2020).

30 <https://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments/Glioblastoma-Multiforme>

31 Glioblastoma Multiforme (GBM) Opportunity Analysis and Forecasts to 2027, GlobalData

32 [https://www.annalsofoncology.org/article/S0923-7534\(19\)34896-3/fulltext](https://www.annalsofoncology.org/article/S0923-7534(19)34896-3/fulltext)

33 <https://www.thepharmaletter.com/article/bms-says-checkmate-548-trial-of-opdivo-in-glioblastoma-will-not-meet-goal>

34 <https://nwbio.com/dcvax-l/>

35 <https://drug-dev.com/mustang-bio-presents-clinical-preclinical-data-on-mb-101-for-treatment-of-glioblastoma/>

# Immuno-oncology

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 greatest breakthrough in immuno-oncology comes from checkpoint inhibitors, or CPIs, that block immunosuppressive signaling in T-cells, thereby providing them with greater scope for attacking cancer cells. Not only is a high level of T-cell infiltration a positive factor in prognosis, but patients with tumors that have been infiltrated by T-cells additionally respond significantly better when they are treated with checkpoint inhibitors. In a way, this is logical since checkpoint inhibitors do not induce new T-cells but help already existing T-cells by blocking their brakes. An overall goal for the research field is now to get more patients to respond to treatment with checkpoint inhibitors.

To achieve this, T-cell infiltration into tumors must be improved both through breaking down barriers in cases where there are T-cells on the outer edge of the tumor but they have not successfully broken in, and through inducing an antitumoral T-cell response de novo in cases where T-cells are entirely absent. Elicera is developing two different types of therapies: oncolytic viruses and CAR T-cell treatments, both of which directly attack and kill cancer cells but have also been genetically modified via the company's iTANK (Immunotherapies Activated with NAP for Efficient Killing) technology platform in such a way that they also activate the patient's T-cells to infiltrate tumors and attack cancer cells.

## CAR T-cell therapies

The American Society of Clinical Oncology (ASCO), one of the world's largest cancer organizations, named CAR T-cell treatment as the "Advance of the Year" for 2018 owing to the remarkably high proportion of patients with difficult-to-treat blood cancers who were cured by CAR T-cells. Treatment with CAR T-cells often goes by the name "adoptive immunotherapy" and normally entails removing,

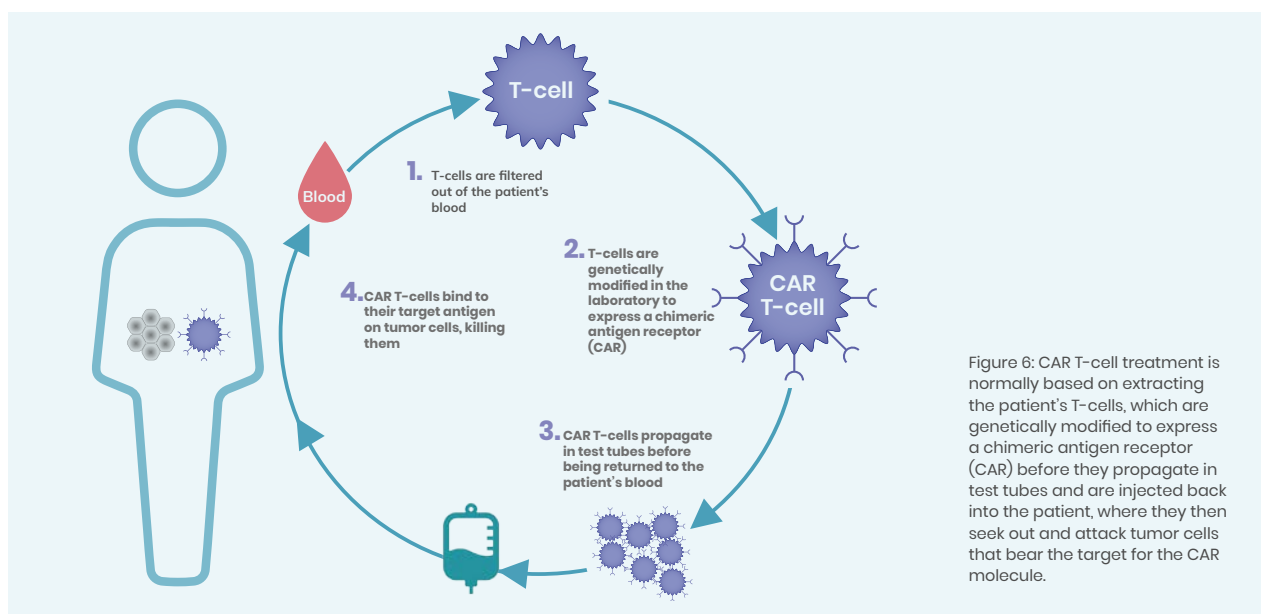


Figure 6: CAR T-cell treatment is normally based on extracting the patient's T-cells, which are genetically modified to express a chimeric antigen receptor (CAR) before they propagate in test tubes and are injected back into the patient, where they then seek out and attack tumor cells that bear the target for the CAR molecule.



genetically modifying and expanding the patient's T-cells before they are returned to the patient intravenously to find and kill cancer cells. The treatment is based on using a chimeric antigen receptor (CAR) that is placed on the surface of the T-cell so that it recognized a specific target (an antigen) in the tumor cells and can then attack and kill the tumor cell (see Figure 6 below).

The first approved CAR T-cell treatments target CD19, a molecule found on the cell surface in B cells that have been transformed into tumor cells and thus on lymphoma and leukemia cells that are based on the B lymphocyte line.

Successes in this type of treatment for blood cancer have been tremendous. Clinical trials with CAR T-cells in severe cases of blood cancer have demonstrated tumor response in upwards of 94% of the patients, which is particularly impressive considering that most CAR T-cell studies recruit patients who are no longer responding to available treatments<sup>36</sup>. CAR T-cell treatment has not been without its challenges, however, primarily concerning the high frequency with which patients' illnesses recur (see more below) and the serious side effects that many patients experience. These serious side effects include several reported fatalities attributable to CAR T-cells that target the CD19 antigen found on the immune systems' B cells, which comprise the most frequently studied target in the CAR T-cell field. Nearly 50% of all CAR T-cell studies focus solely on CD19<sup>37</sup>.

#### The iTANK platform answers two of the greatest challenges for CAR T-cells in the treatment of solid tumors

The successes in treating various types of blood cancer have confirmed the potential and effect of CAR T-cells, and

sparked great interest in this type of therapy. Serious effort is now being made to achieve success in the treatment of solid tumors as well, but currently there are no approved CAR T-cell therapies in this field, a fact that is attributable to the following challenges<sup>38</sup>:

- Solid tumors express a highly varied set of tumor antigens, which makes it difficult to find relevant targets for CAR T-cells.
- A solid tumor has an extremely immunosuppressive micro-environment that counteracts the effect of CAR T-cells against cancer.

Elicera's iTANK platform technology (see more below) is expected (with support from preclinical data published in Nature Biomedical Engineering in 2022) to improve CAR T-cell function while the technology also activates the patient's innate immune system and CD8+ T-cells against the entire set of relevant tumor antigens expressed in the tumor cells. The iTANK platform can thus answer the two aforementioned challenges in treating solid tumors with CAR T-cells. The technology is considered to be applicable to all CAR T-cells under development, not only the company's own.

“The iTANK platform can thus answer the two aforementioned challenges that impact the effect of traditional treatment of solid tumors with CAR T-cells. The technology is considered to be applicable to all CAR T-cells under development, not only the company's own.”

| CHALLENGES FOR CAR T-CELLS IN THE TREATMENT OF SOLID TUMORS |                       |   |
|---|-----------------------|---|
|   | Antigen heterogeneity | Immunosuppressive tumor micro-environment |
| iTANK   | ✓                     | ✓   |
| ELC-401 (GBM)   | ✓                     | ✓   |
| Conventional CAR T-cells                                    | ✗                     | ✗   |

Table 2: Elicera's iTANK platform is applicable in theory to all CAR T-cells under development, and answers two of the greatest challenges in the treatment of solid tumors. ELC-401 is expected to answer all challenges in the primary indication of glioblastoma multiforme (GBM).

<sup>36</sup> <https://www.labiotech.eu/features/car-t-therapy-cancer-review/>

<sup>37</sup> Global CAR-T Cell Therapy Market – \_Market Size, Forecasts, Trials & Trends, Bioinformant.

<sup>38</sup> <https://stemcellres.biomedcentral.com/articles/10.1186/s13287-020-02128-1>

“NAP activation leads to a process that releases an entire set of relevant immunostimulants that together provide a highly robust and broad activation of the immune system and the patient’s CD8+ T-cells against cancer.”

**Many different CAR T-cells under development, but very few activate the innate immune system and CD8+ T-cells against cancer like Elicera’s products do**

CAR T-cells have been developed and gradually improved for many years. The first generation of CAR T-cells most often demonstrated poor effects owing to insufficient propagation and survival in the body after infusion<sup>39</sup>. The second and third generations of CAR T-cells contained respectively one and two extra costimulatory domains, which improved function, survival and immune activation (see Figure 7 below). Approximately 70% of all CAR T-cells currently under development belong to the second generation, including the three aforementioned market-approved products<sup>40</sup>. The fourth generation of CAR T-cells is built on the second generation, but adds a transgene that codes for individual immunostimulants. The intention is thus to trigger the innate immune system and activate

the patient’s CD8+ T-cells to attack cancer. Via the iTANK platform, Elicera’s drug candidates ELC-301 and ELC-401 belong to an optimized version of the fourth generation of CAR T-cells since they have been genetically modified with a transgene that, instead of individual immunostimulants (cytokine), code for a neutrophil-activating protein (NAP). NAP activation 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. Approximately 16% of CAR T-cells currently under development belong to the fourth generation, and the majority of these are being developed in academic environments – that is, not commercially by companies. Elicera knows of another company that is developing the fourth generation of CAR T-cells with a focus on activating CD8+ T-cells (Noile-Immune Biotech).

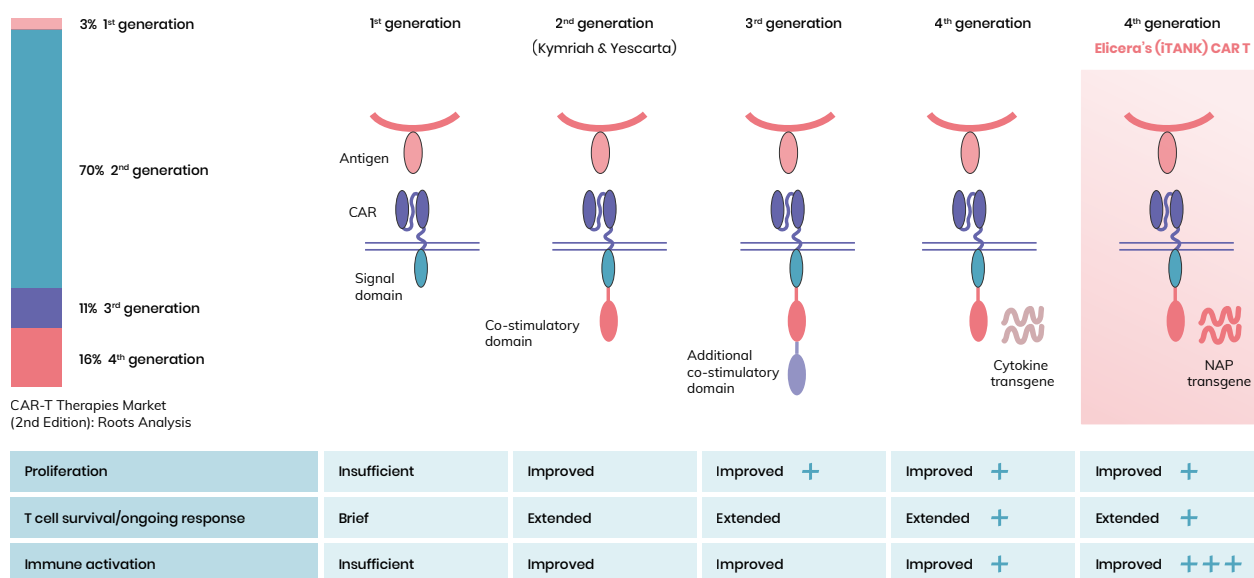


Figure 7: CAR T-cells have gradually improved over the years, but the majority still belong to the second generation.

39 Global CAR-T Cell Therapy Market – „Market Size, Forecasts, Trials & Trends | BioInformant.com  
40 CAR-T Therapies Market (2nd Edition): Roots Analysis.

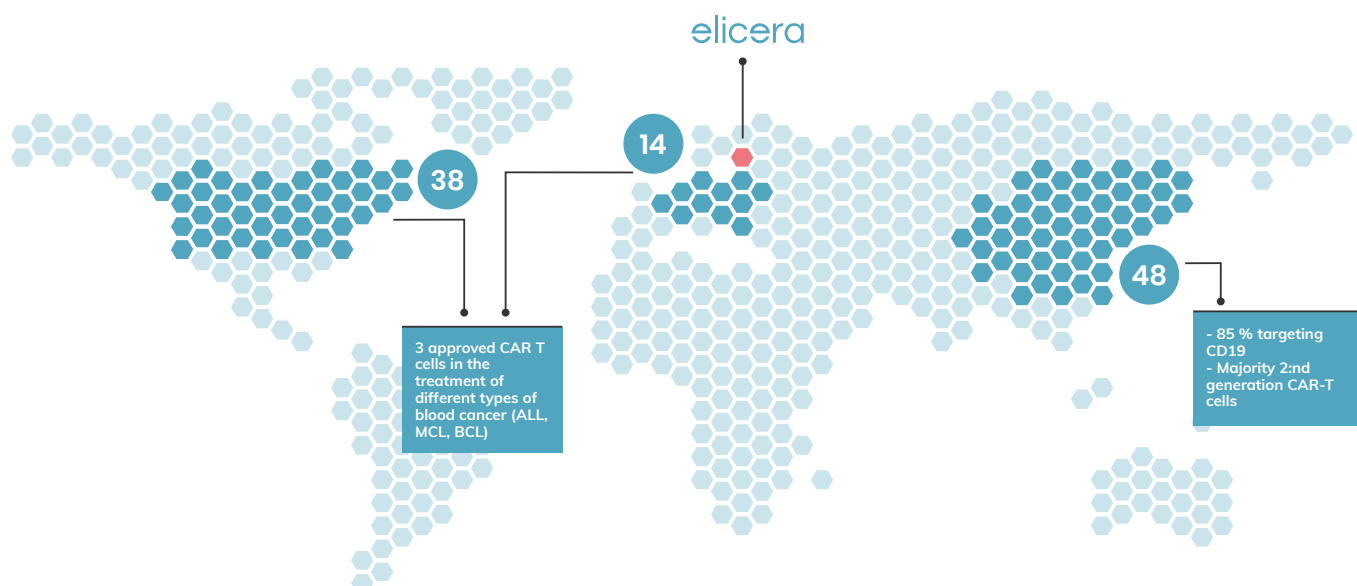


Figure 8: Hundreds of companies around the world, most of which are in the US and China, are developing CAR T-cells. Only a few CAR T companies in Europe; Elicera stands alone in Sweden.

#### Elicera has a unique position among competing CAR T-cells

Approximately 100 companies are developing CAR T-cells around the world, the majority in the US (38) and in China (48),<sup>41</sup> see Figure 8 above. Only 14 companies are developing CAR T-cells in Europe and, as far as Elicera is aware, the company is alone in Sweden in this field (not including Big Pharma presence). As previously mentioned, the majority of CAR T-cells under development are still second generation<sup>42</sup> and approximately half of all CAR T-cells target solely CD19<sup>43</sup>, which is expressed in most of the different types of blood cancer.

CAR T-cell companies are developing various types of products with their own unique properties, but in general it could be said that the focus in developing unique CAR T-cells is on one of the four areas below (see Figure 9):

1. Function of the T-cell.
2. The chimeric antigen receptor (CAR molecule).
3. Boosting (for example, with a transgene).
4. Manufacture.

#### 4. Manufacture

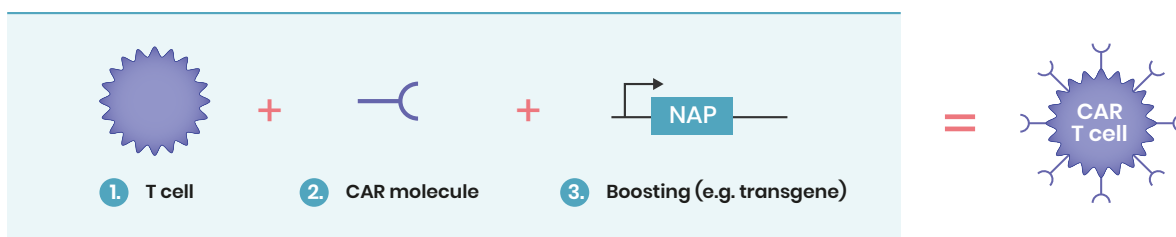


Figure 9: Different approaches to developing CAR T-cells.

<sup>41</sup> Global CAR-T Cell Therapy Market – „Market Size, Forecasts, Trials & Trends | BioInformant.com

<sup>42</sup> CAR-T Therapies Market (2nd Edition): Roots Analysis.

<sup>43</sup> Global CAR-T Cell Therapy Market – „Market Size, Forecasts, Trials & Trends | BioInformant.com



| AREAS OF FOCUS                          |                              |   | BYSTANDER IMMUNE ACTIVATION |
|---|------------------------------|---|-----------------------------|
|   | Technologies                 | Companies   |                             |
| <b>Safety</b> 1. 2.                     | mRNA modification            | MaxCyte   | No 3.                       |
|   | Replaceable CAR              | Calibr, AbbVie  | No 3.                       |
|   | ON/OFF button                | Cell Design Labs  | No 3.                       |
|   | Suicide gene                 | Belicium, Autolus Limited                               | No 3.                       |
| <b>Effect</b> 1. 2.                     | Preselected T-cell           | Posedia Therapeutics                                    | No 3.                       |
|   | Fab-CAR                      | Sorrento  | No 3.                       |
| <b>Specificity</b> 2.                   | Different targets            | JUNO, NOVATIS, Kite Pharma, Autolus, CARsgen            | No 3.                       |
| <b>Production (off the shelf)</b> 1. 4. | Universal (allogeneic) CAR T | Allogene, Atara Bio, Fate, Celyad, Precision Bio, Shire | No 3.                       |

Table 3: Examples of CAR T-cell companies and their areas of focus.

The table above lists a number of CAR T-cell companies that have garnered attention, as well as their areas of focus.

As Table 3 above shows, there are many different ways to develop different types of CAR T-cell therapies. The list is not exhaustive as regards approaches or relevant companies that are developing CAR T-cells, but is intended to highlight a selection of the most outstanding companies in the field and their methods.

Since CAR T-cells are often associated with severe side effects, a number of companies are working with the T-cell and/or CAR molecule to regulate their side effect profiles in various ways (not including optimizing their effects). As previously mentioned, most CAR T-cells under development target primarily blood cancer and CD19, but a number of companies are also developing CAR T-cells against

“Elicera’s iTANK platform technology is expected to generate more effective recruitment and activation of immune system cells than competing technologies owing to the comparatively more comprehensive release of immunostimulants, which are important for optimizing the immune response to cancer.”

other targets in the treatment of blood cancer and targets in solid tumors. Most of the CAR T-cells under development are still also autologous, meaning that they are based on the patient’s own T-cells filtered out

of the patient’s blood. This involves a costly and complex production process, which is why a number of companies have also begun working with allogeneic T-cells, meaning T-cells that are taken from healthy blood donors and can be mass produced rather than needing to be tailored for each individual patient. Even though allogeneic CAR T-cells have a comparatively simplified production process, it is generally more difficult to achieve as positive an effect as with autologous CAR T-cells. Elicera’s CAR T-cells are autologous, but the iTANK platform can be applied to both allogeneic and autologous CAR T-cells. Additionally, there are companies that are developing CAR T-cells that have been modified with checkpoint inhibitors, or with genes that code as cytokines, which improve the CAR T-cell’s capacity for infiltrating cancer cells.

As Table 3 shows, none of the companies discussed as examples are working to boost their CAR T-cells for parallel activation of the innate immune system and CD8+ T-cells against cancer, which Elicera is doing via its iTANK platform. Elicera has identified one company that is developing a platform technology with a similar approach: Noile-Immune Biotech. The company’s PRIME T platform is compared with Elicera’s iTANK platform in Table 4 below, together with other examples of fourth-generation CAR T-cells that are being developed primarily in academic environments, as far as Elicera is aware. Armning with iTANK is expected to add only a negligible increase to manufacturing costs.

|  | COMPANIES WITH PLATFORM TECHNOLOGY FOR 4TH GENERATION CAR T-CELLS                             |                                       | EXAMPLES OF CYTOKINES CODED BY COMMONLY OCCURRING TRANSGENES IN 4TH GENERATION CAR T-CELLS |                           |                           |                           |
|--|---|---------------------------------------|--|---------------------------|---------------------------|---------------------------|
|  | Elicera (iTANK platform)  | Noile-Immune Biotech (PRIME platform) | IL-12  | CD40L                     | IL-18                     | Flt3L                     |
| CAR T function   | <sup>+</sup><br>(IFN- $\gamma$ ; IL-16)   | <sup>+</sup><br>(IL-7)                | +  | +                         | +                         | +                         |
| Bystander immune activation  | <sup>++</sup><br>(IL-12, IL-1 $\alpha$ ; IL-1 $\beta$ ; IL-6; G-CSF; M-CSF; TNF- $\alpha$ )   | <sup>+</sup> <sup>2</sup>             | N/A <sup>1</sup>   | <sup>+</sup> <sup>2</sup> | <sup>+</sup> <sup>2</sup> | <sup>+</sup> <sup>2</sup> |
| Toxicity   | TBD, low <sup>3</sup>   | TBD                                   | Strong <sup>4</sup>  | TBD                       | TBD                       | TBD                       |
| Recruitment of immune cells  | <sup>++</sup><br>(CCL2; CCL3; CCL4; CCL5; CCL12; CXCL1; CXCL2; CXCL9; CXCL10; CXCL12; CXCL13) | <sup>+</sup><br>(CCL19)               | Not demonstrated   | +                         | +                         | +                         |
| Non-host factor  | Yes <sup>5</sup>  | No                                    | No   | No                        | No                        | No                        |
| <sup>1</sup> No data   <sup>2</sup> Requires pre-treatment and combination, for example, with cytotoxins in animal studies   <sup>3</sup> Patients infected with H. pylori suffered no side effects   <sup>4</sup> Clinical data shows strong toxicity associated with IL-12   <sup>5</sup> Immunomodulation factors from bacteria |   |                                       |  |                           |                           |                           |

Table 4: Elicera's iTANK platform technology is expected to generate more effective recruitment and activation of immune system cells than competing technologies owing to the comparatively more comprehensive release of immunostimulants, which are important for optimizing the immune response to cancer.

As Table 4 shows, Elicera's iTANK platform differs from Noile-Immune Biotech's PRIME platform and the other examples in that the iTANK platform initiates a process that releases an entire set of different relevant cytokines and chemokines to trigger the immune system, in contrast to only one or two that otherwise frequently occur in competing CAR T-cells that were developed in the fourth generation. Since the fourth generation of CAR T-cells are intended to trigger a parallel attack on cancer cells via CD8+ T-cells, the platform technology will likely be of interest to other companies that are developing CAR T-cells against solid tumors, where the CAR T-cells have demonstrated difficulty in achieving sufficient effect on their own. This assumption is strengthened by the fact that between 2019 and 2022, Noile-Immune Biotech established several partnerships and licensing deals around its PRIME T platform with both small and medium-size CAR T-cell developers in the field of solid tumors<sup>44</sup>.

### Oncolytic viruses

Oncolytic viruses (OVs) are viruses that selectively infiltrate and kill tumor cells (via propagation in the tumor cell, or oncolysis) while normal cells are left undamaged. As part of this process, the oncolytic viruses also stimulate the immune system to fight cancer cells via T-cell activation (see Figure 4 on page 9 above). OVs specifically have the ability to transform an immunological "cold" tumor with few immune effector cells (tumor-activated T-cells) into a "hot" tumor with increased infiltration of T-cells, which has led to several ongoing clinical trials combining oncolytic viruses with CPI treatment.

The global OV market was valued at USD 94 million in 2018, and is expected to increase to USD 571 million by 2026<sup>45</sup>. There are over 3,000 types of virus, but not all of them are suitable to use for oncolysis<sup>46</sup>. The oncolytic virus has to be non-pathogenic and have an innate tumor-specific killing capacity, or can otherwise be genetically modified with these properties. At present, there is only one commercially available oncolytic virus in the two most important drug markets (the US and Europe): T-VEC/Imlygic (for treatment of melanoma)<sup>47</sup>. A further oncolytic virus (Oncorine) has been approved in China for the treatment of head and throat cancer. Table 5 below lists the most frequently used OVs in clinical trials<sup>48</sup>.

Since the herpes simplex virus (HSV) is naturally extremely pathogenic, it must be genetically modified to limit its replication only to cancer cells. Additionally, T-VEC has been genetically modified to express GM-CSF (to stimulate dendritic cells) and to promote antigen presentation. These genetic modifications are ultimately intended to trigger an immune system via CD8+ T-cells, just as ELC-201 is intended to do via methods such as the iTANK platform and incorporating a transgene that codes for NAP. As described above, boosting with the iTANK platform is expected to give rise to more complete immune activation via an entire set of different immunostimulant cytokines and chemokines.

<sup>44</sup> <https://www.noile-immune.com/en/news.html>

<sup>45</sup> Global Oncolytic Virus Therapy Market, Verified Market Research

<sup>46</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6557159/>

<sup>47</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6557159/>

<sup>48</sup> Clinical CAR-T Cell and Oncolytic Virotherapy for Cancer Treatment, Molecular Therapy Vol. 29 No 2 February 2021.





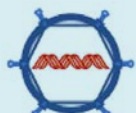
|                                     | HERPES VIRUS   | ADENOVIRUS  | VACCINIA VIRUS   | MEASLES VIRUS   | REOVIRUS  |
|-------------------------------------|--|---|--|---|---|
| <b>Structure</b>                    |                           |  |                           |  |  |
| <b>Genome</b>                       | 152kb dsDNA  | 36kb dsDNA  | 190kb dsDNA  | 16ss(-)RNA  | 23kb dsDNA  |
| <b>Products and drug candidates</b> | T-VEC (Amgen, approved)  | ELC-100, ELC-201, Oncorine (Shanghai Sunway Biotech, approved)                    | Pexa-Vec (SillaJen, Phase II)  | Measovir (Oncovita, preclinical)  | Reolysin (Oncolytics Biotech, Phase II)   |
| <b>Advantages</b>                   | Strong infiltration capacity, applicable to many tumor types, large genome, easy to genetically manipulate | Extensively studied, easy to genetically manipulate, safe to use                  | Strong infiltration capacity, applicable to many tumor types, large genome, easy to genetically manipulate | Extensively studied, easy to genetically manipulate, safe to use                    | Extensively studied, naturally infiltrates cancer cells, safe to use                |
| <b>Disadvantages</b>                | Extremely virulent, established immune response to the virus   | Established immune response to the virus  | Quickly neutralized, poor understanding  | Established immune response to the virus through vaccination                        | Sensitive to antiviral immune response  |

Table 5: The most frequently used OV in clinical trials.

Adenoviruses are among the most-studied OV and, like HSV, can easily be genetically manipulated. Most often, it is an issue of genetic modifications that limit replication in cancer cells, but genes that code for GM-CSF, for example, to trigger the immune system are sometimes also used<sup>49</sup>. Oncorine, which has been approved in China for the treatment of head and neck cancer, is based on an adenovirus and is currently being tested in a Phase III trial in China for the treatment of liver cancer.

The Vaccinia virus has a large genome, which means that large transgenes can be inserted and there is thus greater possibilities for genetic manipulation. The most frequently studied Vaccinia virus is Pexa-Vec, which was developed by Transgene and SillaJen. Like T-VEC, Pexa-Vec expresses GM-CSF for further immunostimulation. In December 2019, negative Phase III data was reported for Pexa-Vec in the

treatment of liver cancer, but the drug candidate is currently being studied in a clinical trial in combination with CPI for various solid tumors<sup>49</sup>.

The measles virus is a serious human pathogen, which is why 86 percent of all children around the world have been vaccinated against the virus. All OV based on the measles virus must thus manage the problem of an active immune response to the virus. Measovir, developed by Oncovita, is based on the measles virus and is in a preclinical development phase.

Reovirus is a well-studied virus that is safe to use, and replicates naturally in cancer cells. Oncolytics Biotech is developing Reolysin, which is currently being tested in several clinical trials for various indications and in combination with different immunotherapies from other companies.

<sup>49</sup> Clinical CAR-T Cell and Oncolytic Virotherapy for Cancer Treatment, Molecular Therapy Vol. 29 No 2 February 2021.

# Intellectual property rights

Elicera works continually on protecting its drug candidates and its platform technology through patent applications.

**E**LC-100 is protected by an approved US patent, which was repurchased from Mendus in early 2022.

Elicera also intends to investigate the possibility of applying for *orphan drug status* for drug candidates that target unusual diseases, since approval could confer such advantages as sole rights in the European market for ten years and sole rights in the US market for seven years.

Table 6 below lists Elicera's current patent portfolio.

- The iTANK platform: The patent application is in the national phase; it protects a vector that codes for a CAR and NAP.
- ELC-100 (AdVince): Approved product patent in the US.

- ELC-201 (the next generation of oncolytic virus, with three combined mechanisms of action): The patent application was submitted in 2021.
- ELC-301 (the next generation of CAR T-cells, initially for treatment of NHL): The product is protected by a patent application that was submitted for the iTANK platform, and the company believes that ELC-301 is not dependent on the patents of others.
- ELC-401 (the next generation of CAR T-cells, initially for treatment of glioblastoma): The product patent was submitted in April 2020. ELC-401 also includes the iTANK platform to achieve a broad and robust immune response to the tumor.

| DRUG CANDIDATE                           | TITLE  | YEAR OF APPLICATION | PATENT GRANTED | PERIOD OF VALIDITY |
|--|--|---------------------|----------------|--------------------|
| ELC-100/AdVince                          | Hexon TAT-PTD Modified Adenovirus and uses thereof | 2013                | US             | 2033               |
| ELC-201                                  | Adenovirus for treatment of cancer                 | 2021                | —              | 2041               |
| ELC-301 and ELC-001 (The iTANK platform) | T cell immunotherapy                               | 2016                | —              | 2036               |
| ELC-401                                  | CAR T IL-13Ra2                                     | 2020                | —              | 2040               |

Table 6: Elicera's patent portfolio.





# Board of Directors and management

## BOARD OF DIRECTORS

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**Agneta Edberg**

CHAIRMAN OF THE BOARD SINCE 2020

**Education:** Agneta Edberg has studied health economics at the Stockholm School of Economics and biomedicine at Mid Sweden University in Sundsvall.

**Experience:** Agneta Edberg (born 1956) has over 25 years of experience from senior positions in life science, including cell therapy companies. Her previous positions included Managing Director and Vice President of Mylan AB, Nordic countries; CEO of LFF Service AB, Svenska Läkemedelsförsäkringen AB and NM Pharma AB; as well as senior positions at the venture capital company LinkMed AB (Allenex), Pfizer, Pharmacia, Bactiguard and Cilag (Johnson & Johnson) AB. Her previous board assignments include Chairman of the Board of the immuno-oncology company Mendus AB (publ), Likvor AB, A+ Science AB and Ambulanssjukvården i Storstockholm AB (AISAB), Health Solutions AB, BioResonator Good Eye AB and BioMatCell – Vinn Excellence Center of Biomaterials and Cell Therapy, as well as a board member of TSS AB and TSS Holding AB. Other current board assignments include Chairman of the Board of CathPrint AB and A Edberg Consulting AB, and board member of XNK Therapeutics AB, the Start Up Life Science Foundation, the Centre for Advanced Medical Products (CAMP, a Swedish consortium) and NextGen NK (a skills center for development of NK-based cell therapies). She is also the Chairman of the Board of the cell therapy company Idogen AB (listed on Nasdaq First North).

**Independence:** Agneta Edberg is independent in relation to the company, its senior executives and major shareholders.

**Shares:** 120,291 (incl. related parties).



**Margareth Jorvid**

BOARD MEMBER SINCE 2020

**Education:** M.Sc. Pharma and MBA.

**Experience:** Margareth Jorvid (born 1961) has over 30 years of experience in regulatory affairs in pharmaceuticals and has worked at the Swedish Medical Products Agency as well as pharmaceutical companies both large and small such as Roussel Nordiska, Hoechst Marion Roussel (Stockholm and Paris, France) and Neopharma. She was previously Head of Regulatory Affairs and QA at the immuno-oncology company Mendus AVB (listed on Small Cap). Since 2006 she has also been a consultant in regulatory affairs and quality assurance for drugs and medtech products through her company Methra Uppsala AB, part of the LSM Group. She is a member and honorary member of the Organisation for Professionals in Regulatory Affairs (TOPRA), as well as a board member and President, 2005–2006.

**Independence:** Margareth Jorvid is independent in relation to the company, its senior executives and major shareholders.

**Shares:** 68,600 (incl. related parties).



**Christina Herder**

BOARD MEMBER SINCE 2020

**Education:** Christina Herder has a Ph.D. from the KTH Royal Institute of Technology in Stockholm, and an Executive MBA from Stockholm University.

**Experience:** Christina Herder (born 1961) has 30 years of experience in drug development and business development in the pharmaceuticals industry. Her previous assignments include several leading roles in companies such as Swedish Orphan Biovitrum AB (Sobi) and Biovitrum. She was previously EVP Strategic Business Development and Chief Operating Officer at Medivir AB (listed on Nasdaq Stockholm) and the CEO of Modus Therapeutics, a Swedish drug development company. Since 2015, she has been a board member of PCI Biotech Holding ASA (listed on Oslo Axess). She is currently acting CEO of the cell therapy company Idogen AB (listed on First North) and a Board member of company Beactica AB, Idogen AB and Ziccum AB.

**Independence:** Christina Herder is independent in relation to the company, its senior executives and major shareholders.

**Shares:** 56,500 (incl. related parties).



**Magnus Essand**

BOARD MEMBER SINCE 2014 AND CO-FOUNDER

**Education:** Professor of gene therapy and associate professor of immunology at Uppsala University.

**Experience:** Magnus Essand (born 1964) has been working as a professor of gene therapy at Uppsala University since 2009; prior to that, he worked for organizations including the US National Cancer Institute (NCI). He has published 95 scientific articles and been a driving force (first and last author) in 53 of them. On several occasions, he has been awarded prizes for his work and has received major research grants from the Swedish Research Council, Horizon 2020, the Swedish Cancer Society, the Swedish Childhood Cancer Fund, the Knut & Alice Wallenberg Foundation, the Sjöberg Foundation, and more. Currently, he is the sponsor of two clinical trials in immuno-oncology. Professor Essand is a co-founder of Elicera AB.

**Shares:** 3,314,475 (incl. related parties).



**Jan Zetterberg**

BOARD MEMBER SINCE 2020

**Education:** Jan Zetterberg earned a law degree in 1975. District court service and legal clerk, 1975–1979.

**Experience:** Jan Zetterberg (born 1951) has years of experience from various executive positions in AstraZeneca's legal department, including as VP Strategy, Intellectual Property, Assistant General Counsel and Head of Group Branding. He has over 35 years of experience from negotiations, agreements on technology transfers and licenses, product commercialization, patent strategies, business and project sales, due diligence and intellectual property rights. Since 2012, he has run his own consulting firm with a focus on life science companies.

**Independence:** Jan Zetterberg is independent in relation to the company, its senior executives and major shareholders.

**Shares:** 71,500 (incl. related parties).



**Jamal El-Mosleh**  
CEO AND CO-FOUNDER

**Education:** M.Sc., Industrial Engineering and Management (focus on biotech) from Chalmers University of Technology, and a Master's degree in Innovation and Entrepreneurship from Chalmers School of Entrepreneurship, 2006.

**Experience:** Jamal El-Mosleh (born 1981) comes most recently from a position as CEO of the First North-listed biotech company Annexin Pharmaceuticals AB (publ), 2017–2019. Prior to that, he was CEO of the Small Cap-listed immuno-oncology company Mendus AB (formerly Immunicum) for nearly ten years (2007–2017). As the first employee in 2007, he served as a co-founder of the company and was responsible for Immunicum's listing on Nasdaq First North in 2013 as well as for initiating a broad international clinical program. Jamal El-Mosleh was also a board member of the cancer diagnostics company Elypta AB.

**Shares:** 2,700,000 (incl. related parties).



**Ingvar Karlsson**  
CHIEF FINANCIAL OFFICER

**Education:** Ingvar Karlsson has a Master's degree in economics from Lund University.

**Experience:** Ingvar Karlsson (born 1956) has broad experience from qualified positions at several companies. He has been working as an independent consultant since 2014, and is currently part-time CFO of Idogen AB (publ). At Idogen, he carried out share issues and led the work on the switch of the share listing from Spotlight to First North Growth Market. Board member of Oxcia AB.

Before stepping into the role of CFO at Idogen, he was the CFO of Lekolar Group. Prior to that, he was the CFO of Doro AB (listed on Nasdaq Stockholm). His previous assignments included roles as controller at Gambro Group as well as CFO and controller at Perstorp AB.

**Shares:** 36,000 (incl. related parties).





### Magnus Essand

CHIEF SCIENCE OFFICER AND CO-FOUNDER

**Education:** Professor of gene therapy and associate professor of immunology at Uppsala University.

**Experience:** Magnus Essand (born 1964) has been working as a professor of gene therapy at Uppsala University since 2009; prior to that, he worked for organizations including the US National Cancer Institute (NCI). He has published 95 scientific articles and been a driving force (first and last author) in 53 of them. On several occasions, he has been awarded prizes for his work and has received major research grants from the Swedish Research Council, Horizon 2020, the Swedish Cancer Society, the Swedish Childhood Cancer Fund, the Knut & Alice Wallenberg Foundation, the Sjöberg Foundation, and more. Currently, he is the sponsor of two clinical trials in immuno-oncology. Professor Essand is a co-founder of Elicera AB.

**Shares:** 3,314,475 (incl. related parties).



### Di Yu

HEAD OF TRANSITIONAL RESEARCH AND TECHNICAL OPERATIONS, AND CO-FOUNDER

**Education:** Scientist in cancer immunotherapy at Uppsala University; Ph.D. in Medical Science from Uppsala University, and a B.Sc. in Life Sciences and Biotechnology from Shaanxi Normal University in China.

**Experience:** Di Yu (born 1985) is a scientist at Uppsala University and conducts research in immunotherapy at the Department of Immunology, Genetics and Pathology; he is also a co-founder of Elicera AB. He is the co-inventor of Elicera's patents and has been awarded several prizes and grants from organizations including the Sjöberg Foundation, Vinnova and Uppsala University Innovation. He was also awarded the Göran Gustavsson Prize for 2020 by KTH Royal Institute of Technology.

**Shares:** 3,312,600 (incl. related parties).

# The share

Elicera Therapeutics AB is a public company that has been listed on Nasdaq First North Growth Market since June 11, 2021. The company has 2,400 shareholders. In November 2020, a 20:1 split was carried out. One stock dividend issue and one new share issue.

A new share issue of 7,750,000 new shares was conducted in June 2021 in conjunction with the listing. In addition to the shares, 7,750,000 warrants were issued. Two warrants conferred the right to purchase one share in November 2022 for SEK 11.60 per share. Since the share price was around SEK 4, no one exercised the opportunity. There were thus no warrants at year-end, and the number of shares remains unchanged.

## Ownership structure

List of the 10 largest shareholders as of December 31, 2022.

| YEAR              | NUMBER OF SHARES  | SHARE OF VOTES AND CAPITAL (%) |
|-------------------|-------------------|--------------------------------|
| Magnus Essand     | 3,314,475         | 16.8                           |
| Di Yu             | 3,312,600         | 16.8                           |
| Jamal El-Mosleh   | 2,700,000         | 13.7                           |
| Nordnet AB        | 1,304,063         | 6.6                            |
| Six Sis AG        | 738,600           | 3.7                            |
| Avanza Pension AB | 660,703           | 3.3                            |
| Göran Persson     | 336,530           | 1.7                            |
| Kaj Rintala       | 230,000           | 1.2                            |
| Lars Blihhagen    | 191,423           | 1.0                            |
| Agneta Edberg     | 120,291           | 0.6                            |
| Other             | 6,873,315         | 34.7                           |
| <b>Total</b>      | <b>19,782,000</b> | <b>100.0</b>                   |

## Share capital

- The share capital will comprise at least SEK 500,000 and at most SEK 2,000,000.
- The number of shares will be a minimum of 12,000,000 and a maximum of 48,000,000.
- The registered share capital totals SEK 830,844.00.
- There is one class of share. Each share confers an equal right to a portion of the company's assets and earnings, and the right to one vote at the Annual General Meeting. One share equals one vote.
- The company's share register is maintained by Euroclear Sweden AB (formerly VPC AB), box 7822, SE-103 97 Stockholm, Sweden.

## Development of share capital

| YEAR | EVENT                | QUOTIENT VALUE | INCREASE IN NUMBER OF SHARES | INCREASE IN SHARE CAPITAL | TOTAL NUMBER OF SHARES | TOTAL SHARE CAPITAL |
|------|----------------------|----------------|------------------------------|---------------------------|------------------------|---------------------|
| 2014 | Founding             | 100            | 500                          | 50,000.00                 | 500                    | 50,000.00           |
| 2019 | Split 1:1,000        | 0.10           | 500,000                      | —                         | 500,000                | 50,000.00           |
| 2020 | New share issue      | 0.10           | 101,600                      | 10,160.00                 | 601,600                | 60,160.00           |
| 2020 | Stock dividend issue | 0.84           | —                            | 445,184.00                | 601,600                | 505,344.00          |
| 2020 | Split 1:20           | 0.042          | 11,430,000                   | —                         | 12,032,000             | 505,344.00          |
| 2021 | New share issue      | 0.042          | 7,750,000                    | 325,500.00                | 19,782,000             | 830,844.00          |

# Board of Directors' report

The Board of Directors and CEO of Elicera Therapeutics AB, Corp. Reg. No. 556966-4955, with registered office in Uppsala, Sweden, hereby present the Annual Report for the fiscal year from January 1 to December 31, 2022.

Unless otherwise stated, all amounts are reported in SEK and information in parentheses pertains to the corresponding period in the preceding year.

## General information

Elicera Therapeutics develops cell and gene therapies for immune-based cancer treatments. Elicera Therapeutics AB is developing four drug candidates, two of which are in the field of **oncolytic viruses** and two in the field of **CAR T-cell treatments**, as well as a platform technology called iTANK (Immunotherapies Activated with NAP for Efficient Killing) for further boosting immunity in conjunction with treatments in the aforementioned fields.

## Ownership structure

Elicera Therapeutics AB is a public company that is listed on Nasdaq First North Growth Market. Listing took place on June 11, 2021 and brought 2,900 new shareholders into Elicera. Elicera's largest shareholders are the founders, Magnus Essand (with 16.8% of the shares) and Di Yu (with 16.8% of the shares), and CEO Jamal El-Mosleh (13.7%). For further details, refer to the page on the Elicera share and the web site.

## DEVELOPMENT OF THE COMPANY'S OPERATION, EARNINGS AND FINANCIAL POSITION

| (AMOUNTS IN SEK)              | DEC. 31, 2022 | DEC. 31, 2021 | DEC. 31, 2020 | DEC. 31, 2019 | DEC. 31, 2018 |
|-------------------------------|---------------|---------------|---------------|---------------|---------------|
| Net sales                     | —             | —             | —             | —             | —             |
| Operating margin, %           | —             | —             | —             | —             | —             |
| Loss for the period           | -19,362,750   | -13,119,368   | -2,828,545    | -194,250      | -3,325        |
| Balance sheet total           | 46,307,971    | 54,738,205    | 12,589,772    | 618,101       | 809,164       |
| Return on capital employed, % | -59.3         | -25.1         | -22.4         | -30.9         | -0.4          |
| Return on equity, %           | -59.3         | -25.1         | -27.6         | -31.1         | -0.4          |
| Equity/asset ratio, %         | 70.8          | 95.4          | 81.3          | 99.4          | 99.5          |
| Earnings per share            | -0.98         | -0.82         | -0.23         | -0.02         | —             |

Definitions: see Note 14

## Accounting policies applied:

For 2020 and 2021, the financial statements were prepared in accordance with K3 and the Swedish Annual Accounts Act. For previous periods, K2 was applied. No effects of the change have been noted.

The number of shares has been restated for previous periods with two reverse splits (1,000:1 and 20:1), and the profit per share is thus comparable.

## Key events during the fiscal year:

- IP protection for ELC-100 boosted through the acquisition of patents from Immunicum (Mendus)

- Elicera Therapeutics secured SEK 5 million in grant financing from Vinnova to develop an automated manufacturing process of CAR T-cells.
- Publication of a scientific article in Nature Biomedical Engineering on the iTANK platform and data indicating its universal compatibility with other CAR T-cell therapies.
- Preclinical proof-of-concept studies for oncolytic virus ELC-201 successfully concluded, confirming the mechanism of action.
- EUR 2.5 million in EU funding to fully finance a clinical phase I/II-trial with the CAR T-cell therapy ELC-301.

- Change of Certified Adviser to Erik Penser Bank AB.
- Doctoral thesis that describes the iTANK platform named best of the year in Sweden (in gene and cell therapy research) for 2021
- The first international partnership agreement around the iTANK platform was signed with a Spanish research institute.
- The co-founders received an additional grant totaling SEK 7.65 million at Uppsala University from the Swedish Cancer Society to support CAR-T research.
- Reports of additional signals of clinical activity from patients with neuroendocrine tumors in the study with ELC-100 were presented at the Oncolytic Virotherapy Summit in Boston.

#### Key events after the end of the fiscal year:

- Continuation of the Phase I/IIa study with the ELC-100 oncolytic virus as planned, following the safety review in cohort 3.
- A clinical trial application to evaluate the ELC-301 CAR T-cell therapy in B-cell lymphoma has been submitted.
- LifeSci Consulting recruited as transaction adviser to assist the company in evaluating strategic partnering initiatives.
- Liquidity guarantee agreement signed with Erik Penser Bank.

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

#### Research and development:

Elicera's work on research and development, including planning and conducting clinical trials, has proceeded according to plan.

#### Financial performance

##### Operating loss

Operating loss for the period totaled SEK -19,362,750 (-13,119,368), which is a change of SEK -6,243,382 compared to the year-earlier period.

The change is due primarily to Vinnova grants received (+1,280,173) and increased costs (-7,522,968).

##### Loss for the period

Loss for the period totaled SEK -19,438,631 (-13,120,443). Earnings per share totaled SEK -0.98 (-0.82).

##### Liquidity and cash flow

- Cash flow from operating activities totaled SEK -8,570,820 (-14,293,102).
- Cash flow from investing activities totaled SEK 0 (-1,000).
- Cash flow from financing activities totaled SEK 0 (55,122,453).

- Cash flow for the period totaled SEK -8,570,820 (40,828,351).
- At the end of the period, the company's cash and cash equivalents totaled SEK 43,822,309 (52,393,129).

With existing cash and bank balances, and the EU support that has been granted, Elicera has sufficient liquidity to finance ongoing projects through the first half of 2024.

#### ELC Accelerator program

Against fierce competition, Elicera was awarded EUR 2.5 million (approximately SEK 27 million) in support from the European Innovation Council's (EIC) accelerator program in June 2022. The EU has disbursed an initial installment of SEK 12.1 million. The remaining disbursements are expected over the next three years.

The payment has been recognized as deferred income. Deductions will be made from the deferred income in pace with the recognition of costs for the project.

#### Investments

Elicera's material investments were SEK 0 (0).

Financial investments were SEK 0 (1,000).

#### Key events after the end of the period

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

#### Personnel and organization

The average number of employees at December 31 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.

#### Remuneration to senior executives

Elicera will pay market-based, competitive salaries. Remuneration to employees consists of salary, bonuses, and pensions for employees on the management team. Remuneration to consultants consists of daily or hourly remuneration. Remuneration is reported in Note 3 (Board of Directors and senior executives).

#### Environmental information

Elicera conducts operations that are not subject to licensing or reporting obligations.

#### Annual General Meeting 2022

The Annual General Meeting (AGM) was held online on March 7, 2022. 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. Karin Hoogendoorn declined re-election.



Board fees remained unchanged at SEK 120,000 for Chairman of the Board Agneta Edberg and SEK 90,000 for the other members.

RSM Göteborg KB, with signatory auditor Kristofer Håkansson, was re-elected as auditor.

The Board of Directors was authorized to conduct a private placement of a maximum of 20 percent of the number of shares (3,956,400 shares).

### Nomination Committee

In accordance with the resolution of the Annual General Meeting, the three largest shareholders were asked at the end of the third quarter of 2022 to nominate their representatives on the Nomination Committee. The representatives elected are Magnus Essand (chairman), Di Yu and Jamal El-Mosleh. The proposals of the Nomination Committee were presented in January. The Nomination Committee proposes the re-election of the Board and auditor.

### Annual General Meeting 2023

The AGM will be held on May 16, 2023 at 3:00 p.m. CEST, at the offices of Advokatfirman Delphi, Mäster Samuelsgatan 17 in Stockholm.

Shareholders will be notified that the meeting has been called through an announcement in Post- och Inrikes Tidningar and on the company's web site, as well as through an announcement in Svenska Dagbladet, at the earliest six weeks and at the latest four weeks prior to the meeting.

Shareholders wishing to have a matter addressed at the AGM can submit a written request to Elicera Therapeutics AB, Attn: Board of Directors, World Trade Center Göteborg, Mössans gata 10, 7th floor, SE-412 51 Gothenburg, Sweden. The request must be received by the Board at the latest seven weeks prior to the AGM, or enough in advance so that the matter, if required, can be included in the notification to attend.

The Annual Report will be published on April 17.

### Proposal for appropriation of profits

The Board of Directors and the CEO propose that no dividend (SEK 0.0 per share, same as the previous year) be paid for the fiscal year January 1–December 31, 2022.

### Risks and uncertainties

#### Preclinical and clinical studies

As yet, none of the company's drug candidates have obtained marketing approval in any market, and all the drug candidates are depending on positive outcomes in preclinical and/or clinical studies to obtain marketing approval. Preclinical and clinical studies are associated with a great deal of uncertainty as pertains to aspects of time and cost as well as outcomes and results. This includes risks that ongoing or planned studies will be more expensive or take longer than planned, that they will not be considered sufficiently adequately designed to be carried out, or ultimately that they will not indicate sufficient safety and efficacy for the company to obtain the necessary

marketing approval to facilitate commercialization of the company's drug candidates.

#### Side effects

There is a risk that those participating in the clinical studies with Elicera's drug candidates or who otherwise come into contact with Elicera's drug candidates/future approved drugs will suffer side effects. The consequences of any side effects could ultimately hinder the commercial use of the product, and there is a risk that Elicera could be liable for damages in relation to study participants who suffer side effects. This could impact the company's operation and financial position negatively.

#### Production of biological drugs

Elicera develops biological drugs under complex manufacturing processes, with a risk that the drug candidates lose viability/survivability after production and cannot be used as intended in clinical studies. This could lead to production and/or studies having to be redone, supplementary studies needing to be carried out, or ultimately that planned or initiated studies are stopped completely, which could entail significant costs and delays or failures in registering one or more of the company's drug candidates. Elicera has no internal manufacturing capacity, nor does it intend to develop such capacity. The company is thus dependent on third parties for manufacture of the oncolytic viruses and CAR T-cells that are needed for studies, development and any future sales of the company's drug candidates. If Elicera cannot ensure production capacity in time, on satisfactory terms or in general, or if Elicera's contracted manufacturer cannot maintain a high level of quality in production or meet regulatory requirements, there are risks of personal injury, product shortages, product recalls, increased production costs or delays in clinical studies.

#### Commercialization and pricing of drugs

Even if one or more of the company's drug candidates obtain the required approval from the authorities to be marketed and sold in Europe or other markets, there is a risk that the company's products will not be commercially successful. Complete or partial failure in commercialization of the company's products would negatively impact the company's continued operation and earning capacity and thereby the company's earnings and financial position.

#### Future financing and capital requirements

Elicera is a company in the development phase and has not yet launched any products in the market, and has therefore not generated any continual revenue attributable to sales of approved products. Elicera depends on external financing in order to fund its projects. There are risks that the necessary capital cannot be raised as needed, that it cannot be raised on terms that are advantageous to the company, or that such capital raised is not sufficient to fund the operation in accordance with the plan drawn up by the company, which ultimately entails a risk that the company will be compelled to substantially limit its planned activities or to cease operations.

## Government permits and registration

In order to market and sell drugs, permits must be obtained and registration must take place with the authorities concerned in the respective markets. In the event the necessary permits and registrations cannot be obtained from the authorities regarding the company's drug candidates, the company may be negatively impacted through the inability to commercialize one or more of the company's drug candidates. In summary, deficiencies in compliance with applicable rules and/or negative decisions by the authorities could lead to future revenue for Elicera being reduced or completely eliminated.

## Patents and other intellectual property rights

Elicera's competitiveness depends significantly on its drug candidates having full patent protection. There is a risk that the company's present or future patent applications will not lead to patents being granted, or that the patents granted do not offer sufficient comprehensive protection for Elicera's drug candidates. There is also a risk that the patents will not confer a competitive advantage and that competitors will be able to circumvent patents that have been applied for or granted. As regards third-party patents that the company depends on for its drug candidates, the company may also deliberately or mistakenly violate applicable licensing terms, which could lead to licensing agreements being terminated. Disputes concerning patent rights could entail significant costs and disruptions to the company's operational activities in the event of both positive and negative outcomes, which could impact the company's operation, earnings and financial position negatively.

## Future performance

Elicera Therapeutics develops cell and gene therapies in immuno-oncology. The company is currently conducting projects in various stages of development, but sees an increased focus on clinical trials in its future.

## The Board of Directors

The overall tasks of the Board of Directors are its responsibility for the company's organization and the administration of company affairs. In carrying out its tasks, the Board is to take the interests of all its shareholders into account. The Articles of Association state that the Board shall consist of a minimum of three and a maximum of seven members, and at most three deputies. Board members are elected annually at the AGM for the period until the close of the next AGM.

The Board of Directors consisted of Agneta Edberg (chair), Magnus Essand, Christina Herder, Jan Zetterberg and Margareth Jorvid, with Di Yu as deputy member.

The Board held 9 meetings during the year (11 meetings the previous year). The Board monitored the results of the research, as well as other strategic issues, closely during the year.

## Equity

Equity was impacted by the new share issue and earnings during the year. At December 31, equity totaled SEK 32,799,434 (52,238,065).

## The share

A new share issue of units was conducted in May 2021, with one share and one warrant (TO1) in each unit. 7,750,000 new shares at a value of SEK 8.00 per share and 7,750,000 cost-free warrants (TO1) were issued. In total, Elicera received SEK 55.1 million less issue expenses.

The Elicera share was listed on Nasdaq First North Growth Market on June 11, 2021.

The warrant (TO1) conveyed the right during the period November 1–30, 2022 to subscribe for one (1) new share for every two (2) warrants at a price of SEK 11.60. No subscriptions took place, since the share price was around SEK 4.

G&W was appointed Certified Adviser/CA. In October, an agreement was signed with Erik Penser Bank AB, who assumed Certified Adviser duties on January 10, 2023.

Loss after tax divided by the average number of shares for the period totaled SEK -0.98 (-0.82) for the reporting period.

At the end of the period in 2022, Elicera had approximately 2,400 shareholders. The number of shares at the end of the period was 19,782,000. The share register is managed by Euroclear.

## Proposal for appropriation of the company's profit or loss

| Amounts in SEK  |                   |
|---|-------------------|
| The Board of Directors proposes that available funds: |                   |
| Share premium reserve                                 | 66,786,690        |
| Loss carried forward                                  | -15,379,469       |
| loss for the year                                     | -19,438,631       |
| <b>Total</b>  | <b>31,968,591</b> |

The Board proposes that the losses be appropriated so that the loss carried forward (SEK 15,379,469) and the loss for the year (SEK 19,438,631) are offset against the share premium reserve, and that the remaining reserve be carried forward:

|              |                   |
|--------------|-------------------|
| <b>Total</b> | <b>31,968,591</b> |
|--------------|-------------------|

As regards the earnings and general financial position, refer to the following income statement and balance sheet, the statement of changes in equity, and the cash-flow statements, as well as the accompanying comments to the financial statements and the accompanying notes.

# Income statement

| (AMOUNTS IN SEK)  | NOTE | JAN. 1–DEC.<br>31, 2022 | JAN. 1–<br>DEC. 31, 2021 |
|---|------|-------------------------|--------------------------|
| <b>Operating income</b>   |      |                         |                          |
| Other income  |      | 1,280,173               | 587                      |
| <b>Operating expenses</b>                                       |      |                         |                          |
| Other external expenses   | 4    | -16,195,266             | -8,956,811               |
| Personnel expenses  | 3    | -4,435,881              | -4,151,369               |
| Depreciation and amortization of tangible and intangible assets |      | -11,776                 | -11,776                  |
| <b>Total operating costs</b>                                    |      | <b>-20,642,923</b>      | <b>-13,119,955</b>       |
| <b>Operating loss</b>   |      | <b>-19,362,750</b>      | <b>-13,119,368</b>       |
| <b>Profit/loss from financial items</b>                         |      |                         |                          |
| Interest income and similar profit/loss items                   |      | 53,459                  | —                        |
| Interest expenses and similar profit/loss items                 |      | -129,340                | -1,075                   |
| <b>Loss after financial items</b>                               |      | <b>-19,438,631</b>      | <b>-1,075</b>            |
| <b>Loss before tax</b>  |      | <b>-19,438,631</b>      | <b>-13,120,443</b>       |
| Tax   | 5    | —                       | —                        |
| <b>Loss after tax</b>   |      | <b>-19,438,631</b>      | <b>-13,120,443</b>       |
| <b>STATEMENT OF COMPREHENSIVE INCOME</b>                        |      |                         |                          |
| <b>Loss for the year</b>  |      | <b>-19,438,631</b>      | <b>-13,120,443</b>       |
| Other comprehensive income                                      |      | —                       | —                        |
| <b>Comprehensive income for the year</b>                        |      | <b>-19,438,631</b>      | <b>-13,120,443</b>       |

# Balance sheet

| (AMOUNTS IN SEK)  | NOTE | DEC. 31, 2022     | DEC. 31, 2021     |
|---|------|-------------------|-------------------|
| <b>ASSETS</b>   |      |                   |                   |
| <b>Non-current assets</b>                                 |      |                   |                   |
| <b>Intangible assets</b>                                  |      |                   |                   |
| Concessions, patents, licenses, brands and similar rights | 6    | 23,552            | 35,328            |
| <b>Total intangible assets</b>                            |      | <b>23,552</b>     | <b>35,328</b>     |
| <b>Financial assets</b>                                   |      |                   |                   |
| Other securities held as non-current assets               | 7    | 484,187           | 484,187           |
| <b>Total financial assets</b>                             |      | <b>484,187</b>    | <b>484,187</b>    |
| <b>Total non-current assets</b>                           |      | <b>507,723</b>    | <b>519,515</b>    |
| <b>Current assets</b>                                     |      |                   |                   |
| <b>Short-term receivables</b>                             | 8    |                   |                   |
| Other receivables   |      | 330,567           | 204,344           |
| Prepaid expenses and accrued income                       | 9    | 1,647,373         | 1,621,217         |
| <b>Total short-term receivables</b>                       |      | <b>1,977,940</b>  | <b>1,825,561</b>  |
| Cash and bank balances                                    |      | 43,822,309        | 52,393,129        |
| <b>Total current assets</b>                               |      | <b>45,800,248</b> | <b>54,213,440</b> |
| <b>TOTAL ASSETS</b>                                       |      | <b>46,307,971</b> | <b>54,738,205</b> |
| <b>EQUITY</b>   |      |                   |                   |
| <b>Restricted equity</b>                                  |      |                   |                   |
| Share capital   |      | 830,844           | 830,844           |
| <b>Total restricted equity</b>                            |      | <b>830,844</b>    | <b>830,844</b>    |
| <b>Non-restricted equity</b>                              |      |                   |                   |
| Share premium reserve                                     |      | 66,786,691        | 66,786,691        |
| Profit or loss carried forward                            |      | -15,379,469       | -2,259,026        |
| Loss for the year   |      | -19,438,631       | -13,120,443       |
| <b>Total non-restricted equity</b>                        |      | <b>31,968,591</b> | <b>51,407,222</b> |
| <b>Total equity</b>                                       |      | <b>32,799,434</b> | <b>52,238,065</b> |
| <b>Current liabilities</b>                                | 11   |                   |                   |
| Accounts payable  |      | 731,933           | 2,048,144         |
| Tax liabilities   |      | 5,437             | 3,269             |
| Other current liabilities                                 |      | 236,541           | 138,870           |
| Accrued expenses and prepaid income                       |      | 12,534,626        | 309,857           |
| <b>Total current liabilities</b>                          |      | <b>13,508,537</b> | <b>2,500,140</b>  |
| <b>TOTAL EQUITY AND LIABILITIES</b>                       |      | <b>46,307,971</b> | <b>54,738,205</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, 2021</b>   | <b>505,344</b> | <b>11,989,738</b>     | <b>564,101</b>    | <b>-2,823,127</b>  | <b>10,236,056</b> |
| Appropriation of earnings by AGM            |                |                       | -2,823,127        | 2,823,127          | —                 |
| New share issue                             | 325,500        | 61,674,500            | —                 |                    | 62,000,000        |
| Capital-raising expenses                    |                | -6,877,547            |                   |                    | -6,877,547        |
| Loss for the period                         | —              | —                     | —                 | -13,120,443        | -13,120,443       |
| <b>Closing balance at December 31, 2021</b> | <b>830,844</b> | <b>66,786,691</b>     | <b>-2,259,026</b> | <b>-13,120,443</b> | <b>52,238,065</b> |

| (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>52,238,065</b> |
| Proposed appropriation of earnings to AGM   |                |                       | -13,120,443        | 13,120,443         | —                 |
| Loss for the period                         | —              | —                     | —                  | -19,438,631        | -19,438,631       |
| <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> |

| DISCLOSURES ON SHARES           | NUMBER OF SHARES |
|---------------------------------|------------------|
| Number at beginning of the year | 19,782,000       |
| Number at December 31, 2022     | 19,782,000       |

The share issue in June 2021 was registered on July 1, 2021.



# Condensed cash flow statement

| (AMOUNTS IN SEK)   | 2022<br>12 MOS.<br>JAN-DEC | 2021<br>12 MOS.<br>JAN-DEC |
|--|----------------------------|----------------------------|
| <b>OPERATING ACTIVITIES</b>                              |                            |                            |
| Operating loss before financial items                    | -19,362,734                | -13,119,368                |
| Reversal of depreciation                                 | 11,792                     | 11,776                     |
| Interest received  | 53,459                     | —                          |
| Interest paid  | -129,340                   | -1,075                     |
| Income tax paid  | 2,168                      | —                          |
| <b>Cash flow from operating activities</b>               | <b>-19,424,671</b>         | <b>-13,108,667</b>         |
| Increase/Decrease in prepaid expenses and accrued income | -152,378                   | -1,330,860                 |
| Increase/Decrease in accounts payable                    | -1,316,211                 | 96,068                     |
| Increase/Decrease in other current liabilities           | 12,322,440                 | 50,357                     |
| <b>Cash flow from operating activities</b>               | <b>-8,570,820</b>          | <b>-14,293,102</b>         |
| <b>Investing activities</b>                              |                            |                            |
| Investments in intangible assets                         | —                          | —                          |
| Change in non-current financial assets                   | —                          | -1,000                     |
| <b>Cash flow from investing activities</b>               | <b>—</b>                   | <b>-1,000</b>              |
| <b>Financing activities</b>                              |                            |                            |
| New share issue  | —                          | 55,122,453                 |
| <b>Cash flow from financing activities</b>               | <b>—</b>                   | <b>55,122,453</b>          |
| Cash flow for the period                                 | -8,570,820                 | 40,828,351                 |
| Cash and cash equivalents at beginning of the period     | 52,393,129                 | 11,564,779                 |
| <b>Cash and cash equivalents at end of the period</b>    | <b>43,822,309</b>          | <b>52,393,129</b>          |

# Notes

## Note 1. General information

Elicera Therapeutics is a public company registered in Sweden, with its head office located in Uppsala and an office in Gothenburg (World Trade Center, Mössans gata 10, 7th floor). The company's operations are indicated in the Board of Directors' report.

The Annual Report for the fiscal year ending December 31, 2022 was approved by the Board of Directors on April 17, 2023 and will be presented to the Annual General Meeting on May 16, 2023 for adoption.

## Note 2. Accounting policies

### Summary of significant accounting policies

The main accounting policies applied in the preparation of this Annual Report are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

The company's functional currency is the Swedish krona (SEK), which is also the company's reporting currency. This means that the financial statements are presented in SEK. All amounts are presented in SEK unless otherwise stated.

### General accounting policies

This Annual Report has been prepared in accordance with the Swedish Annual Accounts Act and Swedish Accounting Standards Board general guidelines 2012:1, Annual Reports and Consolidated Accounts (K3). The switch from K2 to K3 took place during the year with no changes to comparison figures.

### Measurement principles, etc.

Assets, provisions and liabilities have been measured at cost unless otherwise stated.

### Intangible assets

The cost model is applied in reporting expenditures for the development of research results or other knowledge produced, which means that all expenditures are recognized as costs when they arise.

Development expenditures are recognized as intangible assets when the following criteria are met:

- It is technically feasible to complete the intangible asset so that it will be available for use or sale.
- The intent is to complete the intangible asset and use or sell it.
- Conditions exist for the intangible asset to be used or sold.
- It is probable that the intangible assets will generate future economic advantages.
- The required technical, financial and other resources exist and are adequate to complete the development of and to use or sell the intangible asset.

- The expenditures attributable to the intangible asset can be reliably calculated.

The cost of an internally developed intangible asset consists of the directly attributable expenses required for the use of the asset in the manner intended by corporate management. Internally developed intangible assets are depreciated over their estimated useful life. At present there is no capitalization.

There has been no capitalization of patent costs, since the costs pertain to different applications.

### Depreciation

Depreciation is on a straight-line basis over the estimated useful life of the asset. Depreciation is recognized as a cost in profit or loss.

| <i>Intangible assets</i>               | <i>Years</i> |
|--|--------------|
| Internally developed intangible assets |              |
| Acquired intangible assets             |              |
| Computer programs.....                 | 5            |

### Income tax

Recognition of income tax includes current tax and deferred tax. Tax is recognized in profit or loss, except for cases where it pertains to items recognized directly against equity. In such cases, the tax is also recognized in equity.

Deferred tax assets are recognized to the extent it is likely that there is a future taxable surplus that can be used against the temporary differences. The tax rate for 2022 is 20.6%, which will be used for various calculations.

Deferred tax assets pertaining to unutilized tax loss carryforwards at December 31, 2022 totaled SEK 43,222,132 (23,786,673), which resulted in a deferred tax asset of SEK 8,903,759 (4,900,054). Deferred tax has not been recognized on the tax loss since management is not yet able to assess the point in time at which the loss can be utilized against future surplus. The company therefore does not have any tax expenses, nor does it have any measurement of deferred tax.

### Remuneration to employees

Remuneration to employees is in the form of salaries paid and vacation earned, with a provision for social security expenses. Pension is paid under the ITPI program. Pension is defined-contribution.

Remuneration to various persons in consultant roles is paid in accordance with the consultant agreement, under which the consultant bears responsibility for salary, pension and social security expenses as well as their own work equipment.

### Note 3. Employees and personnel expenses

| AVERAGE NUMBER OF EMPLOYEES | JAN. 1–<br>DEC. 31, 2022 | JAN. 1–<br>DEC. 31, 2021 |
|-----------------------------|--------------------------|--------------------------|
| Men                         | 1                        | 1                        |
| Women                       | 1                        | —                        |
| <b>Total</b>                | <b>2</b>                 | <b>1</b>                 |

| SALARIES, OTHER REMUNERATION<br>AND SOCIAL SECURITY EXPENSES,<br>INCLUDING PENSION COSTS | JAN. 1–<br>DEC. 31, 2022 | JAN. 1–<br>DEC. 31, 2021 |
|--|--------------------------|--------------------------|
| Salaries and remuneration:   | 3,395,459                | 3,140,851                |
| Social security contributions  | 1,031,787                | 980,473                  |
| (Of which pension costs) <sup>1</sup>  | 10,617                   | 11,798                   |

1) Of the company's pension costs, SEK 10,617 (11,798) pertain to the company's CEO and Board of Directors.

| PERSONNEL                   | DEC. 31, 2022 | DEC. 31, 2021 |
|-----------------------------|---------------|---------------|
| Average number of employees | 2             | 1             |
| <b>Total</b>                | <b>2</b>      | <b>1</b>      |

All employees are senior executives, so there is no reporting of personnel since it is the same value.

#### REMUNERATION TO SENIOR EXECUTIVES

|                        | JAN. 1–DEC. 31, 2021 |                       |          |                |
|------------------------|----------------------|-----------------------|----------|----------------|
|                        | FEES                 | OTHER<br>REMUNERATION | PENSION  | TOTAL          |
| Chairman of the Board  | 130,000              | —                     | —        | <b>130,000</b> |
| The Board of Directors | 282,500              | 8,500                 | —        | <b>291,000</b> |
| <b>Total</b>           | <b>412,500</b>       | <b>8,500</b>          | <b>—</b> | <b>421,000</b> |

|                        | JAN. 1–DEC. 31, 2020 |                       |          |                |
|------------------------|----------------------|-----------------------|----------|----------------|
|                        | FEES                 | OTHER<br>REMUNERATION | PENSION  | TOTAL          |
| Chairman of the Board  | 120,000              | —                     | —        | <b>120,000</b> |
| The Board of Directors | 330,000              | 116,250               | —        | <b>446,250</b> |
| <b>Total</b>           | <b>450,000</b>       | <b>116,250</b>        | <b>—</b> | <b>566,250</b> |

Details concerning other reimbursement provided in Note 12.

### Note 4. Auditor fees and remuneration of costs

|                        | JAN. 1–<br>DEC. 31, 2022 | JAN. 1–<br>DEC. 31, 2021 |
|------------------------|--------------------------|--------------------------|
| <b>RSM Göteborg AB</b> |                          |                          |
| Audit engagement       | 87,955                   | 73,248                   |

Audit engagement refers to the statutory audit of the annual accounts and accounting records as well as the Board of Directors' and Chief Executive Officer's management of the company, as well as audits and other reviews conducted by agreement or under contract.

This includes other duties incumbent on the auditors of the company as well as advice and other assistance occasioned by observations made in the course of such examinations or the carrying-out of such other duties.

### Note 5. Tax on net profit/loss for the year

|  | JAN. 1–<br>DEC. 31, 2022 | JAN. 1–<br>DEC. 31, 2021 |
|--|--------------------------|--------------------------|
| Loss                                   | -19,438,631              | -13,120,444              |
| Current tax cost                       | 4,004,357                | 2,702,811                |
| Deferred tax                           | —                        | —                        |
| Tax effect of non-taxable expenses     | -22                      | -62                      |
| Tax effect of non-deductible expenses  | 615                      | —                        |
| Tax effect of costs of raising capital | —                        | 1,416,775                |
| Non-valued loss carryforward (20.6%)   | 4,004,950                | 4,900,524                |
| <b>Unutilized loss carryforwards</b>   | <b>43,222,132</b>        | <b>23,786,673</b>        |

### Note 6. Concessions, patents, licenses, brands and similar rights

|                                    | DEC. 31, 2022 | DEC. 31, 2021 |
|------------------------------------|---------------|---------------|
| <b>Accumulated cost</b>            |               |               |
| Accumulated cost                   | 58,880        | 58,880        |
| Other investments                  | —             | —             |
| At year-end                        | 58,880        | 58,880        |
| <b>Accumulated depreciation</b>    |               |               |
| Opening planned depreciation       | -23,560       | -11,776       |
| Depreciation during the year       | -11,768       | -11,784       |
| At year-end                        | -35,328       | -23,560       |
| <b>Carrying amount at year-end</b> | <b>23,552</b> | <b>35,320</b> |

### Note 7. Other securities held as non-current assets

|                                    | DEC. 31, 2022  | DEC. 31, 2021  |
|------------------------------------|----------------|----------------|
| <b>Accumulated cost:</b>           |                |                |
| At beginning of year               | 484,187        | 483,187        |
| Added assets                       | —              | 1,000          |
| Deducted assets                    | —              | —              |
| <b>Carrying amount at year-end</b> | <b>484,187</b> | <b>484,187</b> |

#### Note 8. Short-term receivables

|   | DEC. 31, 2022 | DEC. 31, 2021 |
|---|---------------|---------------|
| Receivables falling due within one year of the balance sheet date | 280,943       | 200,344       |

#### Note 9. Prepaid expenses and accrued income

|                  | DEC. 31, 2022    | DEC. 31, 2021    |
|------------------|------------------|------------------|
| Prepaid expenses | 1,647,373        | 1,621,217        |
| <b>Total</b>     | <b>1,647,373</b> | <b>1,621,217</b> |

#### Note 10. Current liabilities

|  | DEC. 31, 2022 | DEC. 31, 2021 |
|--|---------------|---------------|
| Receivables falling due within one year of the balance sheet date: | 1,498,505     | 2,500,140     |

#### Note 11. Related-party transactions

Board member Jan Zetterberg, in addition to his work on the Board, received remuneration for consulting services in legal counseling through his company Zedur AB totaling SEK 8,500 (16,250 the preceding year).

Former Board member Karin Hoogendoorn, in addition to her work on the Board, received remuneration for consulting services pertaining to GMC production. The total remuneration for the consulting services totaled SEK 0 for the period (100,000).

The pricing took place under market conditions.

#### Note 12. Equity

One share in Elicera has a quota value of SEK 0.042.

The number of shares at the end of the fiscal year was SEK 19,782,000 (19,782,000) and share capital was SEK 830,844 (803,844).

#### Note 13. Significant events after the end of the fiscal year

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

#### Note 14. Definitions of key performance indicators

##### Operating margin:

Operating profit / Net sales.

##### Balance sheet total:

Total assets.

##### Return on capital employed:

(Operating profit + financial income) / capital employed.

##### Financial income:

Items in net financial items that are attributable to assets (included in capital employed).

##### Capital employed:

Total assets – interest-free liabilities.

##### Interest-free liabilities:

Liabilities that do not bear interest. Pension liabilities are considered to bear interest.

##### Return on equity:

Profit/loss after financial items / Adjusted equity.

##### Equity/asset ratio:

(Total equity + (100% – the current corporate tax rate of untaxed reserves)) / Total assets.

##### Earnings per share

Profit after tax divided by the average number of shares for the period.

## Signatures

Gothenburg, April 17, 2023

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**Agneta Edberg**

Chairman of the Board

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**Christina Herder**

Board member

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**Magnus Essand**

Board member

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**Jamal El-Mosleh**

CEO

Our audit report was submitted on April 17, 2023  
RSM Göteborg KB

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**Kristofer Håkansson**

Authorized Public Accountant

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**Margareth Jorvid**

Board member

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**Jan Zetterberg**

Board member

# Auditor's report

To the Annual General Meeting of shareholders in Elicera Therapeutics AB,  
corporate registration number 556966-4955.

## Statement on the Annual Report

### Opinions

We have audited the annual accounts of Elicera Therapeutics AB for 2022. The annual accounts of the company are included on pages 28–38 in this document.

In our opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of Elicera Therapeutics AB as of 31 December 2022 and its financial performance and cash flow for the year then ended in accordance with the Annual Accounts Act. The Board of Directors' report is consistent with the other parts of the annual accounts.

We therefore recommend that the general meeting of shareholders adopts the income statement and balance sheet.

### Basis for opinions

We conducted our audit in accordance with International Standards on Auditing (ISA) and generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibilities section. We are independent of Elicera Therapeutics AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### Responsibilities of the Board of Directors and the Chief Executive Officer

The Board of Directors and the Chief Executive Officer are responsible for the preparation of the annual accounts and that they give a fair presentation in accordance with the Annual Accounts Act. The Board of Directors and Managing Director are also responsible for such internal control as they determine is necessary to enable the preparation of annual accounts that are free from material misstatement, whether due to fraud or error.

In preparing the annual accounts, the Board of Directors and Managing Director are responsible for the assessment of the company's ability to continue as a going concern. They disclose, as applicable, matters related to going concern and using the going concern basis of accounting. The going concern basis of accounting is however not applied if the Board of Directors and the Chief Executive Officer intend to liquidate the company, to cease operations, or have no realistic alternative but to do so.

### Auditor's responsibilities

Our objectives are to obtain reasonable assurance as to whether the annual accounts as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinions. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and generally accepted auditing standards in Sweden will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these annual accounts.

As part of an audit in accordance with ISAs, we exercise professional judgement and maintain professional skepticism throughout the audit. We also:

- identify and assess the risks of material misstatement of the annual accounts, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- obtain an understanding of the company's internal control relevant to our audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control.
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors and the Managing Director.
- conclude on the appropriateness of the Board of Directors' and the Chief Executive Officer's use of the going concern basis of accounting in preparing the annual accounts. We also draw a conclusion, based on the audit evidence obtained, as to whether any material uncertainty exists related to events or conditions that may cast significant doubt on the company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the annual accounts or, if such disclosures are inadequate, to modify our opinion about the annual accounts. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future



events or conditions may cause a company to cease to continue as a going concern.

- evaluate the overall presentation, structure and content of the annual accounts, including the disclosures, and whether the annual accounts represent the underlying transactions and events in a manner that achieves fair presentation.

We must inform the Board of Directors of, among other matters, the planned scope and timing of the audit. We must also inform of significant audit findings during our audit, including any significant deficiencies in internal control that we identified.

## Report on other legal and regulatory requirements

### Opinions

In addition to our audit of the annual accounts, we have also audited the administration of the Board of Directors and CEO of Elicera Therapeutics AB for 2022 and of the proposed appropriation of the company's profit or loss.

We recommend to the general meeting of shareholders that the profit be appropriated in accordance with the proposal in the Board of Directors' report and that the members of the Board of Directors and the Chief Executive Officer be discharged from liability for the financial year.

### Basis for opinions

We conducted the audit in accordance with generally accepted auditing standards in Sweden. Our responsibilities under those standards are further described in the Auditor's Responsibility section. We are independent of Elicera Therapeutics AB in accordance with professional ethics for accountants in Sweden and have otherwise fulfilled our ethical responsibilities in accordance with these requirements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions.

### Responsibilities of the Board of Directors and the Chief Executive Officer

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss. At the proposal of a dividend, this includes an assessment of whether the dividend is justifiable considering the requirements which the company's type of operations, size and risks place on the size of the company's equity, consolidation requirements, liquidity and position in general.

The Board of Directors is responsible for the company's organization and the administration of the company's affairs. This includes, among other things, continuous assessment of the company's financial situation and ensuring that the company's organization is designed so that the accounting, management of assets and the company's financial affairs otherwise are controlled in a reassuring manner. The Managing Director shall manage the ongoing administration according to the Board of Directors' guidelines and instructions and among other matters take measures that are necessary to fulfill the company's accounting in accordance with law and handle the management of assets in a reassuring manner.

### Auditor's responsibilities

Our objective concerning the audit of the administration, and thereby our opinion about discharge from liability, is to obtain audit evidence to assess with a reasonable degree of assurance whether any member of the Board of Directors or the Chief Executive Officer in any material respect:

- has undertaken any action or been guilty of any omission which can give rise to liability to the company, or
- in any other way has acted in contravention of the Swedish Companies Act, the Annual Accounts Act or the Articles of Association.

Our objective concerning the audit of the proposed appropriations of the company's profit or loss, and thereby our opinion about this, is to assess with reasonable degree of assurance whether the proposal is in accordance with the Companies Act.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with generally accepted auditing standards in Sweden will always detect actions or omissions that can give rise to liability to the company, or that the proposed appropriations of the company's profit or loss are not in accordance with the Companies Act.

As part of an audit in accordance with generally accepted auditing standards in Sweden, we exercise professional judgement and maintain professional skepticism throughout the audit. The examination of the administration and the proposed appropriations of the company's profit or loss is based primarily on the audit of the accounts. Additional audit procedures performed are based on our professional judgement with a starting point in risk and materiality. This means that we focus the examination on such actions, areas and relationships that are material for the operations and where deviations and violations would have particular importance for the company's circumstances. We examine and test decisions undertaken, support for decisions, actions taken and other circumstances that are relevant to our opinion concerning discharge from liability. As a basis for our opinion on the Board of Directors' proposed appropriations of the company's profit or loss we examined whether the proposal is in accordance with the Companies Act.

**Gothenburg, April 17, 2023**

RSM Göteborg AB

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**Kristofer Håkansson**

Authorized Public Accountant

## Financial calendar

|  |                   |
|--|-------------------|
| Interim Report January–March.....      | May 16            |
| Annual General Meeting.....            | May 16            |
| Interim Report January–June.....       | August 29         |
| Interim Report January–September ..... | November 14       |
| Year-end Report 2024 .....             | February 13, 2024 |

If you have questions, please contact:

**Jamal El-Mosleh, CEO**

Tel: +46 (0) 703 319 051

E-mail: [jamal.elmosleh@elicera.com](mailto:jamal.elmosleh@elicera.com)

## Address

**Elicera Therapeutics AB**

World Trade Centre Gothenburg

Mässans gata 10, Fl. 7

SE-412 51 Gothenburg, Sweden

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





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