

# Elicera Therapeutics AB (publ) Yearend Report 1 January – 31 December 2022

## Fourth quarter (October-December 2022)

- Operating profit/loss totaled SEK -3,951,799 (-2,142,267).
- Loss for the period totaled SEK -3,898,340 (-2,142,267).
- Cash flow from operating activities totaled SEK 5,516,307 (-879,846).
- Earnings per share before dilution totaled SEK -0.20 (-0,11). Earnings per share after dilution amounted to SEK -0.20 (-0,11).
- Proposed dividend of SEK 0.00 per share (0.00 for the preceding year)

### Period (January-December 2022)

- Operating profit/loss totaled SEK -19,362,750 (-13,119,368).
- Loss for the period totaled SEK -19,438,631 (-13,120,443).
- Cash flow from operating activities totaled SEK -8,570,820 (-14,293,102).
- Earnings per share before dilution totaled SEK -0.98 (-0.82). Earnings per share after dilution amounted to SEK -0.98 (-0.82).

### Key events during the fourth quarter

- Elicera Therapeutics' co-founders receive additional grants totalling 7,65 MSEK from the Swedish Cancer Society to support CAR T research.
- Elicera employees awarded "Doctoral Thesis of the Year" in Sweden (in gene and cell therapy research) for their description of the iTANK platform.
- Agreements were signed with Erik Penser Bank AB, which will assume Certified Adviser duties on January 10, 2023.
- Elicera Therapeutics enters first international collaboration involving the iTANK platform with a Spanish research institution
- Nomination Committee for Elicera Therapeutics appointed
- Elicera Therapeutics attended the Cell Therapy Durability Response Summit in Boston, MA (US)

## Key events during the period

- Elicera Therapeutics boosted IP protection for ELC-100 through the acquisition of patents from Immunicum.
- Elicera Therapeutics secured SEK 5 million in grant financing from Vinnova to develop an automated manufacturing process of CAR T-cells.
- Elicera Therapeutics published a scientific article in Nature Biomedical Engineering on the iTANK platform's mechanism of action, and data indicating its universal compatibility with other CAR T-cell therapies.
- Elicera Therapeutics successfully concluded preclinical proof-of-concept studies for oncolytic virus ELC-201 confirming the mechanism of action.

- Elicera Therapeutics received EUR 2.5 million in EU funding to fully finance a clinical phase I/II-trial with its CAR T-cell therapy, ELC-301.
- Elicera Therapeutics, with its cash and bank balances and EU support, has full financing for various trials through the first half of 2024.

### Key events after the end of the period

- Election Committee proposes re-election of the Board of Directors.
- Elicera Therapeutics continues Phase I/IIa trial with oncolytic virus as planned, following safety review in cohort 3.
- Elicera submits Clinical Trial Application to evaluate its CAR T-cell therapy in B-cell lymphoma.
- Elicera appoints Anna Koptina Gültekin as Head of Regulatory Affairs.
- Elicera recruits LifeSci Consulting as transaction advisor to assist the company in evaluating strategic partnering initiatives.
- No key events that impact earnings or the financial position occurred after the end of the period

#### **CEO Comments**

### Continued significant interest in the iTANK platform

Like the rest of the year, the final quarter of 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, Elicera signed its first agreement that is built on a collaboration around the iTANK platform in October – a significant milestone in the company's business development. 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. During the quarter, we experienced 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, so this is the first of several agreements 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, and we are looking forward very much to our partnership.

#### 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 ELC-401 program in the CAR T field. 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 a patient group with B-cell lymphoma that is either difficult to treat or has metastasized. The plan is to conduct the study in two stages: a dose escalation stage to minimize the risk of potential serious side effects and to identify a suitable dose for the study, which will then be followed by the next treatment stage in which the remaining patients receive the identified maximum tolerable dose. It is the same type of study design being used in the Phase I/IIa trial in which the company is evaluating clinical parameters regarding the treatment of neuroendocrine cancer with the ELC-100 oncolytic virus.

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 iTANK 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 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. What we reported from the ELC-100 study is that two out of a total of nine patients who have so far completed treatment and evaluation have shown signs of clinical activity through the reduction in size of certain metastases. The first patient was included in the first cohort of the study, where the patients were treated with the lower of four dosage levels, and the second patient was treated in the third patient cohort with the second-highest dosage.

Naturally, it is encouraging to receive reports of these clinical indications of efficacy, but a great deal remains before we can draw more far-reaching conclusions around the ELC-100 study.

Recently, 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 goahead to recruit the remaining three patients in the final cohort.

#### Full focus on new and ongoing initiatives

The CEO comments for the third quarter of 2022 concluded with three priorities for the near future and in my opinion, we made progress in all three areas during the fourth quarter:

- 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 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.

Naturally, Elicera will focus on the above priorities in 2023 as well. Moreover, we have begun initiatives in additional fields that will entail an expansion of both our organization and our clinical pipeline.

First, the company recently recruited Anna Koptina Gültekin as Head of Regulatory Affairs. Anna is an independent consultant with an extensive resumé in regulatory affairs and the development of cell and gene therapies for immuno-oncology in both the US and the EU. Her experience includes regulatory strategies and government agency programs for accelerated registration processes such as regenerative medicine advance therapy (RMAT), fast track, and orphan drug designations.

Second, the analysis to determine which cancer indication will initially be considered and evaluated has been concluded for our ELC-201 program, which is studying the effect of oncolytic viruses. Based on this analysis, the focus is now fully on evaluating and deciding on our treatment alternatives, as well as the impact they will have on Elicera's clinical program 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. It means that all our current clinical programs have been fully financed.

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

The interim report has been approved by the board and the CEO for publication. The information was submitted for publication distributed through the contact person below at 08;08 CET on February 17, 2023.

Elicera Therapeutics AB's interim report for January to December 2022 is available at the company home page: <a href="https://www.elicera.com/investors-2/financial-reports">https://www.elicera.com/investors-2/financial-reports</a>.

#### For further information please contact:

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#### About the iTANK platform

The iTANK- (immunoTherapies Activated with NAP for efficient Killing) platform is the company's own fully developed commercially available technology platform for arming and enhancing CAR T-cells to meet two of the major challenges CAR T-cell therapies face in the treatment of solid tumors: tumor antigen heterogeneity and a hostile tumor microenvironment. The technology is used to incorporate a transgene into CAR T-cells encoding a neutrophil activating protein (NAP) from the bacterium Helicobacter pylori. Upon activation, NAP secreted from the CAR(NAP) T-cells has been shown to be able to enhance the function of the CAR T-cell in addition to activating a parallel immune response via CD8+ killer T-cells. This is expected to lead to a broad attack against most antigen targets on cancer cells. The iTANK-platform is used to enhance the company's own CAR T-cells but can also be universally applied to other CAR T-cell therapies under development. More information about iTANK-platform is available here: https://www.elicera.com/technology

#### **About Elicera Therapeutics AB**

Elicera Therapeutics AB is a clinical stage cell and gene therapy company that develops next generation immuno-oncology treatments based on enhanced oncolytic viruses and CAR T-cells. The work is based on high-profile long-standing research conducted by Professor Magnus Essand's research group at Uppsala University and has resulted in the development of four drug candidates, including two CAR T-cells and two oncolytic viruses. In addition, Elicera has developed a technology platform called iTANK that can be used to optimize all CAR T-cells in development and activate killer T-cells against cancer. The company's share (ELIC) is traded on Nasdaq First North Growth Market.

G&W Fondkommission has been appointed the Company's Certified Adviser. E-mail: <a href="mailto:ca@gwkapital.se">ca@gwkapital.se</a>, tel: +468-503 000 50.

For more information, please visit www.elicera.com