

## Initial Coverage

### ELICERA THERAPEUTICS AB

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www.elicera.com

Bloomberg: ELIC: SS  
Reuters Eikon: ELIC.ST

Stock Exchange List: Nasdaq First North

Last share price: SEK 5.3  
Market Cap: SEK 105 million

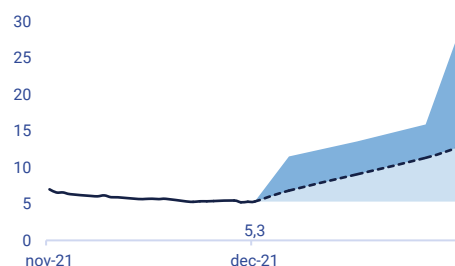
### SHARE PRICE GRAPH



	12M	YTD	3M	1M
Perf. (%)	-	-	-25	-24

Source: S&P Capital IQ

### VALUATION RANGE



	BEAR	BAS	BULL
Target price (SEK)	5.2	12.9	26.1
Share price potential (%)	-2	142	392

Source: S&P Capital IQ and Carlsquare estimates.

### CARLSQUARE EQUITY RESEARCH

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## Cell Therapy Company Under the Radar

Carlsquare Equity Research initiates coverage of Elicera Therapeutics and identifies a cancer research company with good potential. The Company is developing novel cell therapy therapies based on the enhancement of validated technologies. A primary focus is on the CAR-T area, where the market should multiply in the coming years. We estimate a risk-adjusted value of about SEK 13 per share. We see significant room for further appreciation upon clinical trials and business development progress.

### The First Listed Swedish CAR-T-company Out of the Starting Blocks

Elicera is developing, among other things, new cancer treatments in CAR-T cell therapy, an area that has generated strong clinical results in patients with difficult-to-treat cancer and whose market should grow strongly in the coming years. Leading scientists back the Company, and Elicera's candidates are differentiated with a proprietary technology to boost immune responses to cancer. So far, there is limited clinical data for Elicera's portfolio, but the success of similar external projects bodes well. The corporate cash position is sufficient for the next two years. If outstanding warrants are exercised next year, financial sustainability will improve.

### Benefitting from Regulatory and Financial support

Elicera intends to address rare cancers such as lymphoma and brain cancer, opening potentially faster clinical development than the average drug project. The projects have also received significant research funding. The aim is to license out projects and technology to essential partners, and examples of business development in the industry show that this can happen relatively early. At the same time, the risk of setbacks in clinical trials is high in drug development, as it is for Elicera's project portfolio. However, we believe that the prospects for the Company's immune-activating technology iTANK are not entirely dependent on a single project, which mitigates the technical risk to some extent.

### Weak Share Performance not Linked to Project Development

We believe that the low valuation, with a net asset value of over SEK 50 million, stands out compared to similar companies. An explanation is that Elicera already has one project in clinical development and is expected to add another in the coming year. The share price has been pressured by sell-offs related to a pre-IPO issue and, as expected, a somewhat limited news flow. We see the potential for more share price-driving news in 2022. We calculate a risk-adjusted justified value of SEK 13 in a base case scenario. In case of progress in clinical development, we estimate that the stock could double further in a bull scenario. The share is currently trading just above our bear scenario, where we only include the brain tumour project in our valuation.

### Financial Key Ratios (SEKm)

	2020	2021E	2022E	2023E	2024E	2025E
Net revenues	0,0	0,0	0,0	0,0	0,0	134,9
Total revenues	0,0	0,0	0,0	0,0	0,0	134,9
Gross profit	0,0	0,0	0,0	0,0	0,0	134,9
EBITDA	-2,8	-15,5	-25,6	-40,5	-42,8	112,8
EBIT	-2,9	-15,5	-25,6	-40,5	-42,8	112,8
EBT	-2,9	-15,5	-25,6	-40,5	-42,8	112,8
Earnings per share	0,3	-1,1	-1,3	-1,7	-1,5	4,0
Net revenue growth	NA	NaN	NaN	NaN	NaN	-
EBITDA-margin	Neg	Neg.	Neg	Neg	Neg	0,8
EBIT-margin	Neg	Neg.	Neg	Neg	Neg	0,8
EV/Sales (nov.)	NaN	NaN	NaN	NaN	NaN	0,4x
EV/EBITDA	NM	NM	NM	NM	NM	0,5x
EV/EBIT	NM	NM	NM	NM	NM	0,5x

Source: Company information and Carlsquare estimates.

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## Investment Case

Carlsquare Equity Research initiates coverage of Elicera Therapeutics and identifies a cancer research company with significant potential. The Company is developing novel cell therapy treatments based on enhanced validated technologies. A primary focus is on the CAR T area, where the market should multi-double in the coming years. We estimate a risk-adjusted share value of approximately SEK 13. We see significant room for further appreciation upon clinical trials and business development progress. Our assessment is in marked contrast to the current valuation of the stock on First North, which in our view, discounts a cautious scenario for clinical development.

## Investment Case

### A Differentiated Immunotherapy

Elicera's iTANK platform applies to several immunotherapies, and the Company is not entirely dependent on any single internal project. The Company's potent immune activator, NAP, is unique in cancer clinical development, and preclinical results are promising. Licensing deals in the sector underline the ability to out-license this type of technology independently of in-house drug development projects.

### Externally Validated Methods

Both CAR-T and oncolytic viruses (OV) are validated approaches for cancer treatment, albeit still in their infancy compared to other cancer therapies. However, CAR-T is gaining momentum and, as its use broadens to new indications, we believe there is potential for substantial long-term growth. The market for CAR-T cell therapies, currently worth about \$1.5 billion, is expected to multiply in the coming years. Solid tumours remain the major challenge for CAR-T. Whether the Company can develop a sufficiently safe and effective treatment for these cancers will probably determine whether CAR-T achieves the big successes commercially.

### iTANK a Possible Way Forward in Solid Tumors

Although the development is early and human studies have not yet started, Elicera hopes that iTANK can also be a therapeutic for solid tumours within the ELC-401 project.

Elicera's focus for solid tumours is on glioblastoma, a specific type of highly aggressive malignant brain tumour. Glioblastoma appears to be a potential therapeutic area for CAR-T as the prognosis is poor and there is a lack of effective therapies. Furthermore, specific target receptors, one example being IL13Ra2, are targeted by ELC-401. IL13Ra2 is overexpressed in 75% of all glioblastoma patients.

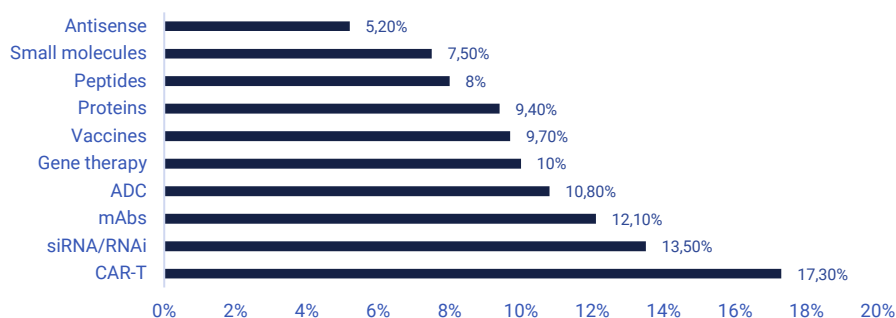
### Elicera Stands on a Solid Scientific Foundation

The founders of Elicera belong to the Department of Immunology at Uppsala University. They are among the leading experts in the country and well-cited internationally in oncolytic viruses and cell therapy for cancer treatment. They give Elicera access to a prominent academia and cancer care network, facilitating preclinical and clinical development. In addition, Elicera can indirectly reap the benefits of the substantial research support granted to the founders' research. Moreover, the Company can significantly reduce costs to produce preclinical and clinical material.

### Comparatively Short Way to Market

Most new CAR-T therapies in development focus on rare diseases and difficult-to-treat patient populations. They are thus eligible for one of the FDA's various Priority Review or Accelerated Approval programs. A practical consequence is that no controlled studies have been required for preliminary approval. It has led to significantly shorter than average development times in drug development in some cases. Kymriah, the first CAR-T therapy to receive market approval, took about three years from IND application (phase I, first time tested in humans) to market approval. However, many projects are run by or in collaboration with the academy, which may slow down development. Based on historical data, CAR-T cells are about three times more likely to be approved than oncology (Source Bio/Pharma Intelligence) in clinical development from Phase I.

### Likelihood of approval from Phase I, by modality



Source: Bio/Informa Pharma/QLS

### Good Prospects for Business Development

Immunotherapy and adoptive T-cell therapy are areas that have seen a high level of activity in terms of both licensing and acquisitions. Although competition from external projects is high, as CAR-T is a clinically proven and validated method, we believe that the demand for new projects is high. Many licensing deals are already struck in the early development phase (see below).

#### Licensing deals in the CAR-T area

	Partner	Project	Indication	Phase	Value (USDm)	Upfront (USDm)	Royalties
Collectis*	Pfizer	Allogeneic CAR-T	Oncology	Pre Clinical	200	20	Not specified
Collectis	Servier	UCART19	ALL	I	410	38	"Flat low double digit"
Juno	Celgene		NHL	Pre Clinical		1 000	Profit-sharing 70/30
Kite	Amgen	CAR-platform	Cancer	Pre Clinical	585	60	High single-digit to double-digit
Atata*	Bayer	Autologous+allogeneic anti-mesothelin	Solid tumours	I	335	30	Low double-digit
Legend Bio-tech	Janssen	LCAR-B38M	Multiple Myeloma	CFDA BLA review		350	Profit-sharing 50/50
Fate Therapeutics	Janssen	iPSC stem cells platform	Oncology	Pre Clinical	3 100	100	Double-digit
Ad-aPTimmune*	Astellas	-	Oncology	Pre Clinical	356	25	Average single-digit to double-digit
<b>Median</b>					<b>383</b>	<b>49</b>	

Source: Company information. \* Estimated mid-value per project.

### Additional Validation for iTANK Might Push the Share Price

During the autumn, Elicera has presented new preclinical findings for iTANK as an enhancer of cancer treatments. Promising results for CAR-T cells boosted with the immune activator NAP support the hypothesis that iTANK can activate a broad immune response against cancer and potentially provide an option for patients who do not respond to current immune therapies. We see the potential for iTANK to gain further attention, and Elicera intends to publish the results in a scientific article.

#### Intended development plan for Elicera

	Indication	Discovery	Preclinical PoC	Preclinical Tox	Phase I	Phase II	Phase III	BLA
ELC-100/AdVince	NET							2023
ELC-201	Solida Tumors		?					
ELC-301	Lymphoma							2022
ELC-401	Glioblastoma							2022

Sources Elicera and Carlsquare estima.

## Forecasts and Valuation

### High Value per Treatment Underpins Niche Strategy

Elicera's technology has potential applications in a variety of cancers. External research supports Elicera's focus on the cancer indications of lymphoma (blood cancer) and glioblastoma. Although competition in blood cancers is intense, we believe that the immune enhancer iTANK can help differentiate ELC-301 from today's leading CAR-T cell therapies in the field. Glioblastoma is rare and very difficult to treat cancer but a potential blockbuster opportunity for a more effective drug than today's limited treatment options (mainly chemotherapy). CAR-T cells are very highly-priced, upwards of \$400,000 per treatment even in Europe. Overall, we see a sales potential of between \$230 and \$1,080 million for each of the projects in the Elicera pipeline.

Provided that one or more of the planned clinical trials are successful, we see prospects for out-licensing the internal projects in a few years. In our base-case scenario, we expect this to happen in 2025.

### Elicera Funded to Expand Clinical Program

We expect costs to rise in the coming years due to increased clinical activity. With existing cash (SEK 53 million at the end of Q3), Elicera can further develop the project portfolio well down the road. Capital requirements are held back by relatively small studies and external research support. ELC-100 and ELC-301 are at the front of the development.

- For ELC-100, the focus is on completing the dose escalation, which is halfway complete. Elicera intends to open an additional clinical site in Germany to accelerate recruitment. The goal is to complete the study in the second half of 2022.
- ELC-301 is in preclinical development. Elicera is awaiting the delivery of virus vectors, among other things, where delivery times are long. The plan is to complete manufacturing by the summer and a Phase I/II study in H2 2022.
- The Company also aims to start clinical development with CAR-T in solid tumours in 2023, primarily glioblastoma.

Overall, we expect value-driven project updates going forward, emphasising next year.

### Research Support Alleviates Capital Needs

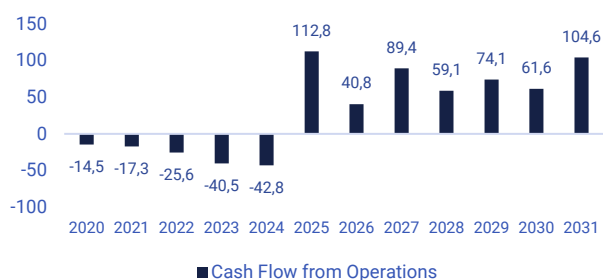
The Phase I study for ELC-100 is sponsored by Uppsala University, which has received earmarked funding from the Victory NET Foundation. Approximately 12 patients are expected to be enrolled in Phase 2a part.

Furthermore, the research team behind the Elicera project portfolio has received about SEK 10 million in grants for ELC-401 in brain tumours and also about SEK 10 million for the ELC-301 project.

### Possible Financing via Warrants

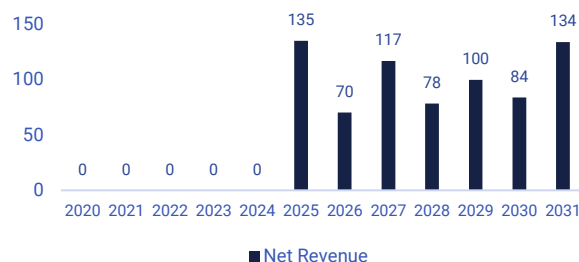
7.75 million subscription options (TO1) were issued in connection with the May 2021 IPO. The subscription period is in November 2022, and the subscription price is SEK 11.6. Two warrants are required to subscribe for one share. If fully exercised, these will raise approximately SEK 45 million before costs. At present, the share price is clearly below the exercise price, so this source of funding is uncertain. However, we believe that Elicera has financial sustainability until the second half of 2023.

#### Forecast Cash Flow (SEKm)



Sources: Company Information and Carlsquare estimates.

#### Net revenues (SEKm), risk-adjusted



Sources: Company Information and Carlsquare estimates.

## Shares Trading Close to a Bear-scenario

Elicera is valued significantly lower than similar cell therapy companies based on Enterprise Value. The difference is probably due to limited clinical evidence for Elicera's project portfolio. On the other hand, it suggests a significant upside potential as its clinical programs broaden and progress. In the coming year, the Company should take critical value-driving steps for their most advanced projects ELC-100 and ELC-301.

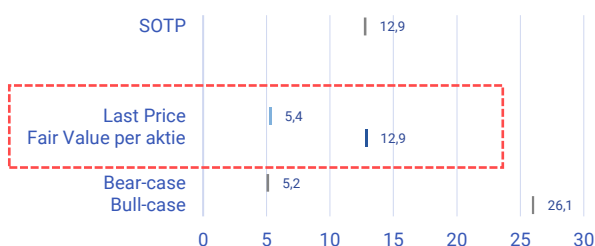
We estimate an EV of SEK 250 million or SEK 12.9 per fully diluted share in a base case scenario. Our bull scenario of SEK 26 per share brushes in that Elicera gets two internal projects in clinical development and that the Company strikes a licensing deal for the iTANK technology. In a bear scenario, we only include the brain cancer project ELC-401, and the justified value drops to SEK 5 per share.

### Summary, Sum-of-the-parts-valuation, Base scenario, SEK million

Projekt	Indication	LOA*, %	Royalty, %	Peak Sales, USDm	Launch	rNPV, SEKm
ELC-301	NHL	13.0%	15.0%	470	2028	279
ELC-401	Glioblastoma	2.9%	15.0%	1 080	2028	102
ELC-100	Neuroendocrine tumours	8.6%	15.0%	230	2030	82
<b>Technology value</b>						<b>462</b>
Overhead and Taxes						-212
<b>EV</b>						<b>250</b>
Net cash position (21'Q4E)						49
<b>Motivated value (SEK million)</b>						<b>299</b>
Number of shares. million						19.8
SEK per share						15.1
Estimated financing						61
Shareholder value after financing (SEK million)						360
Number of shares after dilution						27.9
<b>Motivated value per share. SEK</b>						<b>12.9</b>

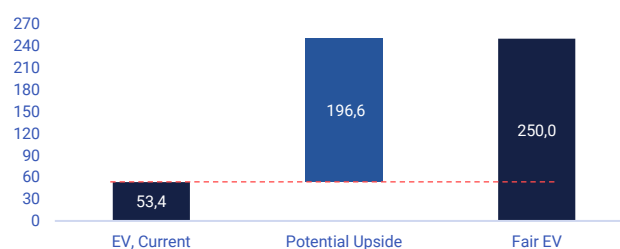
Source: Carlsquare \*LOA: Likelihood of a launch.

### The Fair Value within a Range, SEK



Source: Carlsquare estimates

### Visualisation, Base Scenario (SEKm)



Source: Carlsquare estimates

## Risks and Challenges

### Early Phase

The majority of the Company's projects, and all CAR-T programs, are in the preclinical phase. CAR T cells are expensive and complicated to produce, and the step into clinical development can be challenging for a small company. However, Elicera's scientific management team already has experience developing previous CAR T therapies from clinical development. The research group in Uppsala is a leader in Sweden with a strong international network.

### Long Lead Times in Manufacturing can Affect Timelines

There is a shortage of capacity among contract manufacturers in cell and gene therapy. Therefore, there is a not-insignificant risk that development times for Elicera may be adversely affected as a result. However, the Company has already contracted production for upcoming clinical trials with BioNTech of Germany.

### Competition could be Significant

According to Nature Reviews Drug Discovery, there are 2 073 cell therapy projects targeting oncology in preclinical or clinical development (April 2021), an increase of 38% compared to the previous year. More than half are CAR-T projects. Although only a fraction reaches the market, there is a strong indication that competition will intensify dramatically over time (there are currently five approved cell therapies in oncology in the US).

### Risks of Gene Therapy

There are still a relatively small number of patients who have been treated with gene or cell therapy. In the last year, unintended mutations possibly linked to CAR-T cell therapy, gene editing, and lentivirus have been reported from projects in clinical development. There is a risk of negative publicity or that some projects might be delayed or stopped due to concerns about side effects resulting from mutations.

### Missing a Robust External Owner

The founders own almost half of the Company. It lacks an external financially strong owner, making it challenging to finance clinical development.

## Company Description

Elicera is an early-stage cancer research company focused on cell therapy in oncology. The founder is a leading researcher in immuno-oncology and gene therapy at Uppsala University. In 2021, the Company listed on First North and raised 62 MSEK to advance projects in the fast-growing CAR-T area.

## Introduction to Elicera

### Research Progress at Uppsala University Sowed the Seed for Elicera

Elicera develops immunotherapies for cancer treatment based on cell therapy and oncolytic viruses. The Company has four drug candidates, one of which is in clinical development. The activity is based on research conducted by a research group led by Professor Magnus Essand at Uppsala University. The group received research funding in 2016 that led to the development of technology, iTANK, to enhance immune activation in cancer therapies with CAR-T cells and oncolytic viruses. The goal is to improve clinical efficacy because many cancer patients relapse despite advances in new immunotherapies.

The strategy is to start clinical development and enter commercial partnerships with larger biotech or pharmaceutical companies. In addition, the Company sees the possibility of licensing out the iTANK technology to external CAR-T projects.

The Company was formed in 2014 when Professor Magnus Essand and his colleague Di Yu sold the US patent for adenovirus to Immunicum. Elicera (then called VirEx) retained the right to use the viral vector in neuroendocrine tumours. With financial support from a foundation set up by the cancer-stricken British businessman Vince Hamilton, a clinical trial was started in Uppsala in patients with neuroendocrine tumours treated with this oncolytic virus.

### Pipeline Elicera Therapeutics

Project	Modality	Goal	Mechanism of operation	Indication	Phase
ELC-100	OV		Oncolysis, immune response	NET	I
ELC-201	OV	TBD	Oncolysis, iTANK	Solid tumours	Detection phase
ELC-301	CAR-T	CD20	CAR-T, iTANK	Lymphoma	Pre Clinical
ELC-401	CAR-T	IL13Ra2	CAR-T, iTANK	Glioblastoma	Pre Clinical

Source: Elicera Therapeutics, Carlsquare. OV: Oncolytic Viruses. NET: Neuroendocrine tumours.

The focus is on cell therapy and CAR-T, a validated method for modifying immune T-cells. The longest-running project, the oncolytic virus ELC-100/AdVince, was developed early in the Company's history and is not based on iTANK. It also does not target any specific protein but is encoded to replicate only in the presence of a protein (CgA) expressed by neuroendocrine tumours, making the treatment tumour targeted.

The intellectual property rights for iTANK are based on a patent application for a viral vector encoding CAR antigen receptors and the immune activator NAP. The patent protection for iTANK is of great importance for the '301 and '401 projects and the possibility of licensing the technology to external CAR T-cell developers. For ELC-401, a patent application for glioblastoma was filed in 2020; for ELC-301, there is no specific patent application, but the iTANK patent will protect the project if that application is granted.

For oncolytic viruses, patent protection is based on an approved product patent for AdVince (expiring in 2033) and an application for an adenovirus encoding NAP for ELC-201. The US patent for AdVince was sold to Immunicum in 2014. Still, Elicera retained the rights to develop a treatment for neuroendocrine tumours in exchange for an obligation to pay lower royalties on any future revenues in this indication.

## Management



CEO **Jamal El-Mosleh** holds a Master of Science in Industrial Economics from the Chalmers University of Technology. He has been the co-founder of Elicera and CEO since 2020. Jamal El-Mosleh was previously CEO of the cell therapy company Immunicum AB and Annexin Pharmaceuticals. Jamal is the third-largest shareholder (September 2021), with 2.7 million shares.



Head of Research **Magnus Essand** is co-founder, board member, and the largest shareholder with 3.3 million shares. He is a Professor of Gene Therapy and an Associate Professor of Immunology at Uppsala University. He has published more than 100 scientific papers and leads immunotherapy research programs focusing on CAR-T and oncolytic viruses, some of which have also entered clinical development.



**Di Yu** is Head of Development. He is an Associate Professor in Immunotherapy of Cancer at Uppsala University, Ph. D. in Medical Science from Uppsala University, and a BSc. in Bioscience and Biotechnology from Shaanxi Normal University China. He is a co-founder of Elicera and co-inventor of Elicera's patents. Di Yu owns 3.3 million shares.



**Ingvar Karlsson** is CFO (consultant) and CFO of Idogen. He has previously held similar roles at Doro and Perstorp AB. Ingvar owns 36,000 shares.

Source: Company information.

## Board of Directors

Elicera has a relatively large board consisting of founders and significant shareholders, and people with experience in the field of cell therapy. The majority have joined in 2020 or later.

**Agneta Edberg** has been Chairman of the Board since 2020 and has extensive experience from leading positions in the Life Science sector from Mylan AB, among others. She is also chairman of Idogen, Likvor AB, A+ Science, and AISAB. Edberg has previously served as chairman of Immunicum AB. She owns 120,291 shares.

**Margareth Jorvid** has been a board member since 2020 and an expert in regulatory affairs with experience from leading positions in that function from, among others, Immunicum, Hoechst Marion Roussel, and the MPA. She owns 68,600 shares.

**Christina Herder** has been a board member since 2020 and is COO of the listed biotech company Medivir. Previously, she was CEO of Modus Therapeutics and held senior positions at SOBI and Biovitrum. Christina is also a board member of PCI Biotech and Imogen. She owns 56,600 shares.

**Jan Zetterberg** has been a board member since 2020 and has many years of experience in various senior positions within AstraZeneca's legal department, including as Vice President, Strategy, Intellectual Property, Assistant General Counsel, and Head of Group Branding. He owns 71,500 shares.

**Karin Hoogendoorn** took office as a board member at the 2021 AGM. She holds an MSc in biology and biopharmaceutical sciences from Leiden University and a PharmD degree from Utrecht University. Karin has held various roles responsible for manufacturing medicinal products (CMC) and regulatory affairs. She is senior director of CMC portfolio management at the Dutch gene therapy company uniQure.

**Magnus Essand** (see Management above) has been a board member since 2014.

Source: Company information.

The Board has significant experience, a strong track record, and by all accounts broad and relevant knowledge in clinical and regulatory development, not least in the field of cell and gene therapy. There is a link to other Swedish cells therapy companies such as Immunicum and Idogen, different assignments, and ongoing collaborations.

We note that the President has five presidencies, which is about the maximum in our view. Magnus Essand, Head of Research, is also on the Board. We see it as desirable to separate these roles in the long term.

## The Ten Largest Shareholders

The largest individual owners are the founders of Elicera and executives of the Company. Together they control almost half of the capital. We welcome the fact that the founders are still owners and active in the Company. However, there is no primary financially strong owner besides the founders. It is uncertain whether the group of founders will contribute to the financing of further clinical development on a pro-rata basis. A strengthening of the ownership structure is probably a vital issue of long-term funding.

In connection with the listing issue, 7.75 million warrants (TO1) were issued with a subscription period during November 2022. Two options are required to subscribe for one share. The subscription price is SEK 11.60 per share. Thus, if fully exercised, the issue via these warrants could raise SEK 45 million.

### Ten Largest Shareholders

Owner	Share of capital	Share of votes	Verified
Magnus Essand	16.8%	16.8%	2021-07-05
Di Yu	16.8%	16.8%	2021-07-05
Jamal El-Mosleh	13.7%	13.7%	2021-07-05
Nordnet Pension Insurance	5.9%	5.9%	2021-09-30
Avanza Pension	4.1%	4.1%	2021-09-30
Rothsay Ltd	3.2%	3.2%	2021-09-30
Victory NET Foundation	3.1%	3.1%	2021-06-11
Futur Pension	1.8%	1.8%	2021-09-30
Polynom Investment AB (publ)	1.4%	1.4%	2021-09-30
Mikael Blihhagen	0.8%	0.8%	2021-09-30

Source: Holdings.se

## Shares Trading Sideways in Anticipation of Significant Milestones

Elicera was listed on First North on 11 June 2021 and, in connection in addition to that, carried out a listing issue of units corresponding to 7,750,000 new shares with a subscription price of SEK 8 per share, as well as 7,750,000 warrants of series TO1. The share issue thus raised a total of SEK 62 million before costs. The issue price corresponded to a valuation of SEK 96 million before cash.

The stock has had a weak start, falling about 40 per cent from the issue price in the early days. A possible contributing factor is sales from investors who previously participated in a pre-IPO issue in the autumn of 2020. After the initial fall, the stock has traded in a wide range from around SEK 4.5 to SEK 8.5. We do not believe that the volatile performance has been linked to any negative news. News flow has been sparse in anticipation of the expected clinical stock growth next year. However, Elicera has been able to report preclinical results that support the mechanism of action of iTANK. In addition, an agreement has been signed to supply viral vectors for Elicera's CAR-T project in glioblastoma (ELC-401).

### Share Price Development for Elicera



Source: S&P Capital IQ and Carlsquare estimates.

## Indications

### Medical Need for New Treatments for Aggressive Lymphoma

Non-Hodgkin's Lymphoma (NHL) is the most common form of blood cancer and comprises quite a wide range of malignancies in lymphatic tissue. Lymphoma presents in white blood cells, usually B-cells (i.e., anti-body-producing immune cells) and T-cells. It manifests as the uncontrolled growth of immature blood cells in the lymph nodes and the bone marrow.

Lymphoma is associated with certain infections, previous treatment with immune suppressors, exposure to radiation, and autoimmune disease. Symptoms include swelling of lymph nodes in the neck, the armpits, or the groin. If the bone marrow is affected, the patient will experience anaemia, increased risk of infections, and increased bruising and bleeding.

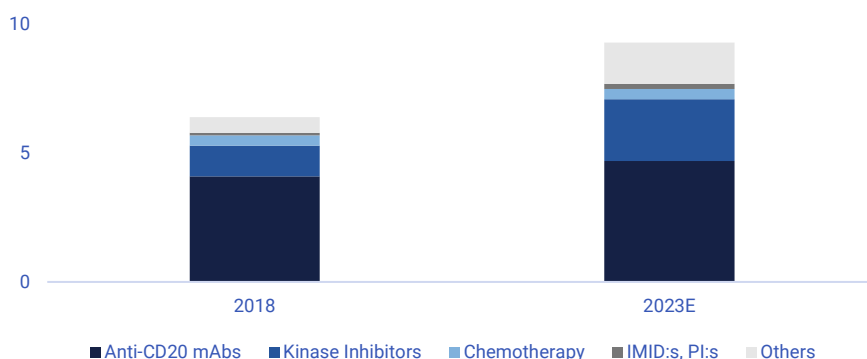
In the US, there are some 75,000 new cases diagnosed annually. Most are indolent, i.e., slow-growing cancers without apparent symptoms. However, 35 to 40 per cent of NHL patients have an aggressive form of the disease with a median survival of about five years. The most common aggressive sub-type is Diffuse Large B-cell Lymphoma (DLBCL).

So-called CD20-antibodies are widely used in different lines of treatment and different chemotherapy combinations. CD20 is a protein expressed on B-cells but not fully differentiated antibody-producing cells and is a feasible target for anti-tumour therapy. Even if healthy B-cells are also affected, this side effect is generally considered acceptable as the bone marrow B-cell production is typically restored following completed treatment. Still, many patients are refractory or relapse following anti-CD20 treatment.

### Rituximab Still Ubiquitous

Non-Hodgkin's Lymphoma drugs market is nearing USD 10bn and is dominated by anti-CD20 treatment rituximab. Protease Inhibitors and CAR-T:s are the drug classes expected to grow the fastest in the coming years.

### The Drug Market for Non-Hodgkin's Lymphoma (USD bn)



Source: Nature Reviews Drug Discovery

### Glioblastoma, the Most Common Primary Brain Tumor

Primary malignant brain tumours are a large group of different tumours of various severity and histological appearance. Gliomas represent 30 per cent of all primary brain tumours and 80 per cent of malignant forms.

### Still Grim Outlook for Patients

Gliomas are genetic diseases of single cells that manifest in the glia cells in the nervous system, which generally have supportive and connective functions in the brain. Glioblastomas are advanced forms of gliomas. The incidence of gliomas is 6.6 per 100,000, of which about half are glioblastomas (Weller, M., "Glioma", *Nature Reviews Disease Primers*, vol.1, 2015). The cause is often unclear, but genetic disposition and earlier radiation therapy are possible factors. The prognosis is dire, with median overall survival in clinical trials of twelve to 18 months in first-line treatment and two to nine months for patients treated for relapsed disease.

Suspicion of a brain tumour is often based on various neurological symptoms that have persisted for weeks or months or seizures in a previously healthy individual. Imaging with MRI is the first-line method of diagnosis.

If feasible, surgery is the first option to remove as much tumour tissue as possible without causing neurological symptoms. Subsequent first-line treatment is radiation therapy in combination with oral chemotherapeutic **temozolomide**. **Giladel Wafer** is also indicated for adjuvant first-line treatment following surgery and radiotherapy. It is an implant containing the chemotherapy drug carmustine. The antibody **Avastin** is approved for the treatment of relapsed glioblastoma.

The drug market for glioblastoma is estimated at some USD 1.5bn (Evaluate Pharma).

**Optune** is a medical device for treating glioblastoma with electric fields or "Tumour Treating Fields", emitted via ceramic plates attached to the scalp. It is approved as an adjuvant treatment to surgery, radiotherapy, and chemotherapy. Novocure, which markets Optune, states 2,200 prescriptions in the US in 2020. We estimate this equals a penetration of about 20 per cent. Optune has approved already in 2011 for patients with relapsed glioblastoma and has also been approved for newly diagnosed patients.

A handful of candidate drugs are in late-stage clinical development, with study updates next year. Examples include protease inhibitors, kinase inhibitors, and cell therapy. Checkpointinhibitoren nivolumab has failed to demonstrate improved survival in several clinical trials.

GBM Agile is a clinical trials network in the US focused on glioblastoma. Several new treatments are tried and compared to the current standard of care. The aim is to streamline and speed up clinical development in this field and generate sufficient filing data. To date, there are three active arms, Stivarga, paxalisib, and VAL-083 (a new chemotherapeutic).

## Neuroendocrine Tumors

Neuroendocrine tumours (NET), previously referred to as carcinoids, is a collective name for a type of hormone-producing tumour. These tumours often present in the gastrointestinal tract or the lungs. The terms "Gastrointestinal Carcinoid Tumors" eller "Gastroenteropancreatic neuroendocrine tumours" are often used in the literature.

NET are slow-growing tumours that develop into either benign or malignant forms. The latter may metastasise, mainly to the liver. NET affects the older population, primarily over 60 years, with women being somewhat over-represented. In the following text, we will discuss the malignant form.

NETs may present anywhere in the body, but common sites are the small intestine, the stomach, the colon, the pancreas, and the lungs. NETs produce hormones, serotonin, and other substances that affect the blood vessels. Symptoms are i) abdominal pain from tumour growth in the small intestine ii) the "carcinoid syndrome" (>50 per cent of patients) with watery diarrhoea, flushing, bronchospasm, hypotension, and right-sided heart disease correlated with serotonin hypersecretion.

The global incidence is 2.5 to five per 100,000. In Sweden, statistics indicate 400 to 500 new cases annually and a prevalence of some 35 to 40 per 100,000. The prognosis is quite favourable, and survival is often several decades. All in all, it indicates that the disease is probably underdiagnosed.

There are several treatment options for NET patients:

- Surgery: Tumour resection might be enough depending on location and presence of metastases. However, adjuvant treatment could be necessary.
- Symptomatic treatment such as opiate analogues and loperamide to reduce flush and diarrhoea symptoms
- Anti-hormonal treatment to reduce serotonin production from NETs with somatostatin analogues. In clinical trials, treatment with long-acting somatostatin analogues has improved tumour response and time to progression.

In 2019 EMA approved a novel class of treatment for the symptomatic disease in small intestine NET (telotristatetyl (Xermelo)). Chemotherapy is indicated for advanced, non-resectable NET.

Examples of targeted therapy include Peptide Receptor Radionuclide Therapy, i.e. delivery of tumour-killing radiotherapy directly to the cell via radio-labelled somatostatin analogues, such as Lutathera. Elicera's ELC-100 could also be considered a form of targeted therapy.

Interferon is a human protein, a cytokine, and modulates the immune response. Interferon-alpha has some anti-tumour effects as well as an easing of symptoms. However, it is seldom prescribed due to severe side effects and a poor risk-benefit profile.

So-called mTOR-inhibitors are approved for advanced pancreatic and gastrointestinal NETs based on a positive effect on progression-free survival in clinical trials. NETs with liver metastases are treated with surgery if resectable or locally ablative techniques.

We do not have a complete estimate for the drug market for NET. However, the market leader Novartis reported some USD 1.9bn of sales for its brands of NET drugs in 2020.

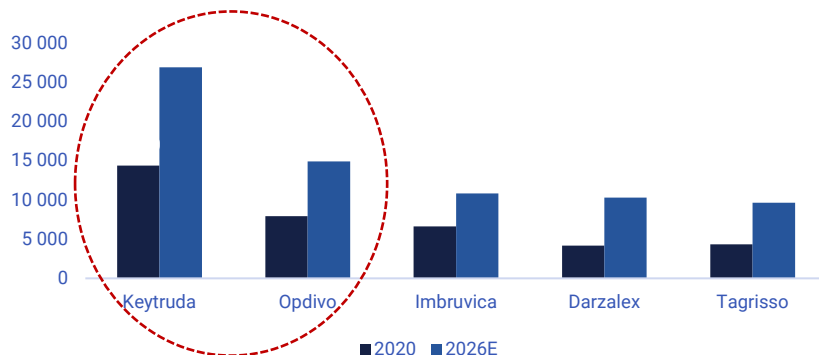
## Immuno-Oncology

### Hot Area but Success Concentrated in a Few Classes

It is fair to say that immuno-oncology represents the most significant breakthrough for cancer treatment, and maybe also for drug development in general, during the last decade. Sales of immuno-oncology drugs are growing by 20 per cent annually and are expected to reach USD 100bn in 2026 (Source: Evaluate Pharma). In general, immuno-oncology drugs are about enhancing the immune response to cancer. The most successful approaches so far are:

In **solid tumours**, checkpoint inhibitors are the modality with the most convincing results. They are antibodies blocking the tumours' ability to send checkpoint signals to dampen the response of T-cells (the "soldiers" of the immune system). Checkpoint inhibitors have demonstrated substantial clinical benefits in melanoma, lung cancer, and kidney cancer, among others, and there are many combination opportunities with, e.g., chemotherapy. The largest subclass, the so-called PD-1-inhibitors, is expected to record some USD 40bn in sales in 2026. In this scenario, the leading PD-1-inhibitors Keytruda and Opdivo will be the best selling cancer drugs, see below:

### The Best-Selling Cancer Treatments 2026E (USDm)



Source: Evaluate Pharma World Preview 2021

The most successful approach in blood cancers is to modify immune cells, such as T-cells, to make them more tumour-directed. The concept is called adoptive cell therapy, and the furthest developed approach is "Chimeric Antigen Receptor T-cells" or CAR-T. To simplify, CAR-T-cells could be described as a combination of T-cells and antibodies. The market for CAR-Ts is comparatively small; the five approved therapies currently sell for around USD 1.5bn. The market is expected to grow to USD 7bn in 2024, according to consensus estimates compiled by Evaluate Pharma. The main drivers are new CAR-Ts being approved and broadened indications for the current CAR-Ts on the market.

***Today's Immuno-Oncology Arsenal Needs To Be Completed***

Despite checkpoint inhibitors' clinical and commercial success, most patients do not respond to treatment. The effectiveness of checkpoint inhibitors is dependent on a baseline immune response and on unleashing pre-existing immunity. The need for complementary immunotherapy to improve the efficacy of current treatments is apparent. According to Informa, there are currently almost 4,700 open clinical trials in the immuno-oncology field (July 2021).

Effector T cells play a central part in the anti-tumour response of checkpoint inhibitors. Tumours are often classified as "hot" or "cold" immune tumours, depending on whether activated T cells are present in the tumour or not. If tumours can be rendered hot, the response to immune checkpoint inhibitors should improve.

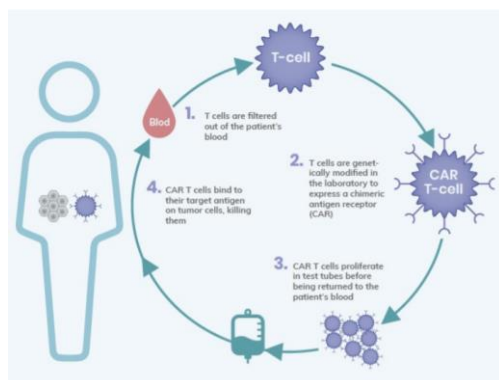
Broadly, such strategies consist of attempts to prime T cells to the tumours (e.g., vaccines and oncolytic viruses but also traditional chemotherapy and radiation), to expand the number of T-cells with tumour specificity (e.g., CAR-T cell therapy) and, lastly, to improve the trafficking to and infiltration of T-cells in the tumour.

**CAR-T the Most Successful Cell Therapy to Date**

To produce CAR-Ts, the manufacturer has to extract T-cells from the blood and modify them genetically to express a receptor that guides the T-cells to recognise and destroy tumour cells. The T-cells are subsequently transplanted into the patient for cancer treatment.

T-cells are a type of white blood cells that originate from stem cells in the bone marrow and then travels to mature in the thymus (hence the "T" to the "-cell"). They have a pivotal role in the adaptive immune system. There are different T-cells with specific tasks, but cytotoxic T-cells are perhaps the most well-known and are designed to kill cells infected by viruses and cancer cells.

## Illustration of the Production Process for CAR-T



Source: Elicera

Moreover, to find targets, T-cells have receptors that recognise pathogens. CAR-T-cells are engineered with gene therapy to express synthetic chimeric (i.e., composed of DNA from more than one individual) receptors for the specific antigen the drug is meant to bind. In addition, CAR-Ts also express co-receptors that enhance T-cell survival and proliferation. CAR-T cells thus combine the specificity of antibodies with the ability of T cells to kill cancer cells. Notably, the method allows the generation and delivery of many activated T cells to patients where the T cell response is depressed and insufficient for various reasons.

The development of CAR-T began at the end of the 1990s. Researchers at the National Cancer Institute began clinical trials in 2010 in lymphoma. In a phase I/II trial in 111 lymphoma patients who had relapsed from earlier treatment, tumour response was achieved in 82 per cent of patients, out of which 54 per cent had complete responses. The therapy was axi-cel (Yescarta), an autologous CAR-T targeting CD19 expressed on malignant B-cells. The anti-tumour effect was far better than the standard of care in advanced lymphoma. Based on these results, FDA approved Yescarta under the accelerated approval pathway in October 2017. Earlier that year, in August, another CAR-T, Kymriah, had already been approved in leukaemia patients up to 25 years old.

There are currently five approved CAR T therapies:

- **Yescarta** (axi-cel): Yescarta is indicated for advanced lymphomas in patients who have received at least two prior lines of treatment. The target is CD19.
- **Tecartus** (bre-cel): Tecartus has a similar design to Yescarta. However, the T-cell expansion process has been adapted specifically for Mantle Cell Lymphoma and Leukemia.
- **Kymriah** (tisa-cel): It was the first approved CAR-T-cell therapy. Similar to Yescarta, Kymriah targets CD19. It is indicated for acute lymphoblastic leukaemia (ALL) patients aged up to 25 years and third-line treatment in large B-cell lymphoma.
- **Abecma** (ide-cel). Abecma is targeting the BCMA antigen on B-cells. The treatment is approved for multiple myeloma patients that are refractory to or have relapsed following treatment with three different drug classes.
- **Breyanzi** (liso-cel). Breyanzi is an additional lymphoma treatment targeting CD19.

### Large and Growing Pipeline and Wider Use

According to Nature, over 500 CAR-T:s in clinical development. CAR-Ts are either autologous, i.e., developed from the patient's T-cells or transplanted from healthy individuals (allogeneic). Further, the CAR receptor has an extracellular part of antibody fragments that have been designed to target specific antigens. It is linked to an intracellular domain that consists of signalling components from a T-cell receptor and a stimulating co-receptor for enhanced effect. There are different manufacturing methods; however, in currently approved products, retroviruses or lentiviruses transfer the CAR T transgene to the T-cells.

When the first CAR-Ts were introduced in 2017, pundits had high sales expectations, as demonstrated by Gilead's USD 11.9bn acquisition of Kite (who developed Yescarta). In general, sales of the drug class have been somewhat slower than anticipated. Likely explanations are that the treatments have only been approved in relatively narrow indications and complex logistics.

Recently the clinical development of several CARTs has shown significant progress that opens for increased commercial potential. The FDA approved the first CAR-T for Multiple Myeloma, Abecma, in 2021. The modality is making inroads into this vast drug market. Topline results for Yescarta and Breyanzi in earlier lymphoma treatment lines are promising an underline the potential to broaden into new indications. According to results presented at the 2021 ASH Conference, Yescarta lowers the risk of progression or death by 60 per cent compared to the standard of care (chemotherapy and bone marrow transplantation) in second-line treatment. However, Kymriah has not demonstrated any similar improvement.

### ***New Promising Treatments in Development***

**Descartes-11** (Cartesian). It targets BCMA and is one of the first CAR-Ts evaluated in first-line treatment (in Multiple Myeloma). It is based on mRNA technology to achieve a transitory, as opposed to the ordinarily permanent, expression of CAR. The aim is a CAR-T with an improved side effect profile.

**LCAR-B38M/JNJ-4528** (Legend Biotech/J&J). A CAR-T also targets BCMA and is differentiated by binding to dual antigen epitopes for increased binding strength.

**CTX110/120/130** (CRISPR Therapeutics). CRISPR develops allogeneic CAR-Ts. A significant difference is that gene editing rather than virus vectors are used to express CAR. The T-cell receptors are also modified with gene editing to reduce the risk for "Graft vs Host Disease" (GVHD), i.e., the foreign T-cells will react to the patient's healthy tissue, leading to severe complications such as inflammation and fibrosis.

### **Allogeneic Therapies Have Not Convinced**

All approved CAR-Ts are autologous and require that the patients' T-cells be successfully harvested, modified and expanded. In addition to the logistical challenges, sometimes the specified quality, such as the share of viable T-cells, is not reached.

To address these challenges, so-called allogeneic CAR-Ts are under development. Ideally, allogeneic therapies can be produced from healthy donors' T-cells, stored and administered "off the shelf". However, the durability of response appears to be shorter with allogeneic CAR-Ts compared to autologous. Early clinical results from CRISPR Therapeutics and Allogene Therapeutics candidates in lymphoma indicate that more than half of responders relapse within six months. The risk for possible side effects from "gene scissors" such as CRISPR are not yet thoroughly examined. In theory, CRISPR may cut outside the intended gene and cause unwanted mutations. Recently, FDA put the whole clinical program of Allogene on hold due to the discovery of an unexpected chromosomal change in one patient.

CAR-T treatments are associated with severe side effects in almost all patients. The most severe symptoms include low blood cell counts, CRS (cytokine release syndrome) and neurotoxicity. CRS is an acute systemic inflammatory condition caused by hyperactive T-cells and a massive release of inflammatory signals. In the latter case, some symptoms are heightened blood pressure, shortness of breath, and cardiac arrest in severe cases. Immune suppressors such as tocilizumab (anti-IL-6R) are used to alleviate these symptoms.

CAR-Ts faces similar challenges as traditional antibodies in oncology in achieving tumour-specific effects and can only address antigens on the surface of the tumour cells. CD19 and BCMA are feasible targets as they are almost exclusively expressed on B-cells, and B-cell production typically recovers at the end of treatment.

### **Manufacturing is a Sticking Point**

Manufacturing CAR-T is complex as it requires handling of T-cells in many steps, including collection, modification and transfusion to the patient. Also, genes need to be incorporated into the T-cells.

First, leukocytes are taken from the patient's or donor's body using leukapheresis. That is, patients are connected to a device that separates blood components. The apheresis product is frozen and shipped to the manufacturing site. The T-cells are washed and selected for the crucial step of gene modification, e.g., by transduction via viral vectors, to express the CAR receptor. The modified T-cells are expanded (cultivated) with, e.g., cytokines into a sufficient dose. They are subsequently formulated with a fluid for cryopreservation and shipped back to the clinic for administration to the patient.

It has been challenging to automate the different manufacturing steps, labour is a large share of production costs, and economies of scale are somewhat elusive. Production costs exceed most other biological drugs. Estimates are between USD 20,000 and 100,000 per dose, depending on variables such as commercial quality. However, manufacturers such as Lonza have developed automated systems such as the Cocoon platform.

### A System for the Automated Production of Autologous CAR-T-Cells



Cocoon® Platform

Source: Lonza

Access to manufacturing capacity is a constraint, and many biotechs rely on contract manufacturers. Gene and cell therapy today corresponds to only about two per cent of global bioprocessing capacity while the demand is several factors higher. Rader, R et al. "Cellular and Gene Therapies Face a Manufacturing Capacity Crunch" *BioPharm International*, September 2020). Far from all hospitals can provide CAR-T treatment. The FDA's Risk Evaluation and Mitigation Strategy (REMS) program require hospitals to be certified to perform CAR-T therapy.

Elicera has contracted BioNTech to produce virus vectors and is planning to hire Vecura to manufacture CAR-T:s for the clinical trials. Vecura is a part of Karolinska University hospital and has a GMP production facility. We believe Elicera's close cooperation with academia is advantageous for establishing a network of suppliers and partners at this stage.

Elicera will probably need to work with a larger industrial processing partner in the longer term. It is uncertain whether such collaboration needs to be in place before any licensing can occur.

### **Elicera Aims to Address Challenges in Solid Tumor Treatment**

Developing CAR T-cells for solid tumours is a much more significant challenge than in blood cancers.

In solid tumours, it has been challenging to identify sufficiently "clean" targets, i.e. antigens on the tumour surface that are homogeneous and specific to the tumours to be targeted. This increases the risk of toxicity if the targets are also expressed on healthy cells. Clinical studies in solid tumours have been discouraging, with several cases of severe side effects on vision, hearing, liver, heart and other organs.

Many antigens are also expressed only on particular tumour cells. This increases the risk of resistance. Solid tumours are also generally surrounded by more barriers to the immune system than is the case in blood cancers. This includes physical barriers such as stromal tissue and an immunosuppressive environment around the tumour that discourages T-cell responses.

Some possible strategies to get around these challenges are

- CAR-Ts that are multivalent, i.e. targeted against multiple antigens simultaneously. This addresses heterogeneity in antigen expression and re-resistance due to "antigen escape", i.e. surviving tumours depressing the target antigen. Examples of bivalent CAR-T cells in blood cancers are CD19 x CD22 and CD19 x BCMA. In solid tumours, preclinical development of HER2 x IL13 Ra2 in glioblastoma or HER2 x MUC1 in breast cancer is ongoing. A potential concern with these approaches is the increased risk of toxicity, where healthy tissue is also affected as more target proteins become involved.
- Enhance T-cell infiltration and get through the tumour-protective environment by targeting CAR-T cells to signalling proteins that depress immune responses and cluster around tumours, such as TGFβ. Local or intratumoral injection is another possibility.
- Arming CAR-T cells with immune activators. In addition to H-NAP used in Eliceras iTANK are IL-12, IL-18 and IL-23. These pro-inflammatory cytokines direct immune cells (macrophages) to the tumour microenvironment or stimulate T-cell production.

### ***Specific Antigen in Combination with Local Injection Possible Route***

Elicera has selected IL13Ra2 as a target protein to develop CAR-T in solid tumours further. It is a receptor for interleukin-13 overexpressed in glioblastoma tumours and is a poor prognostic factor for survival in patients with glioblastoma. The target has been validated to some extent as US-based Mustang Bio is conducting clinical development with a CAR-T candidate called MB-101 targeting IL13Ra2 in collaboration with academia. About 60 patients have been evaluated in different treatment regimens, including combination therapies. Top-line results from the study have not been released, but two cases of complete response have been reported from the clinical program. MB-101 is administered locally in the brain's ventricles, reducing the risk of systemic side effects. Elicera states that ELC-401 will also be distributed locally. Glioblastoma very rarely spreads to the rest of the body, but unfortunately, the disease recurs locally in almost all cases.

## **iTANK - Elicera's backbone**

### **Mechanism of Action Based on Known Immune-Activating Protein**

iTANK is a technology used by Elicera to potentiate the effect of immunotherapy.

iTANK stands for "Immuno Therapies Activated with NAP for efficient Killing", where NAP stands for "Neutrophil-Activating Protein". To fully follow the iTANK platform, the concept of HP-NAP also needs to be explained. HP stands for "Helicobacter pylori," a bacterium identified as recently as 1989. HP was previously called *Campylobacter pylori*. In 2005, Warren and Marshall received the Nobel Prize in Medicine for the discovery that *H. pylori* cause gastritis.

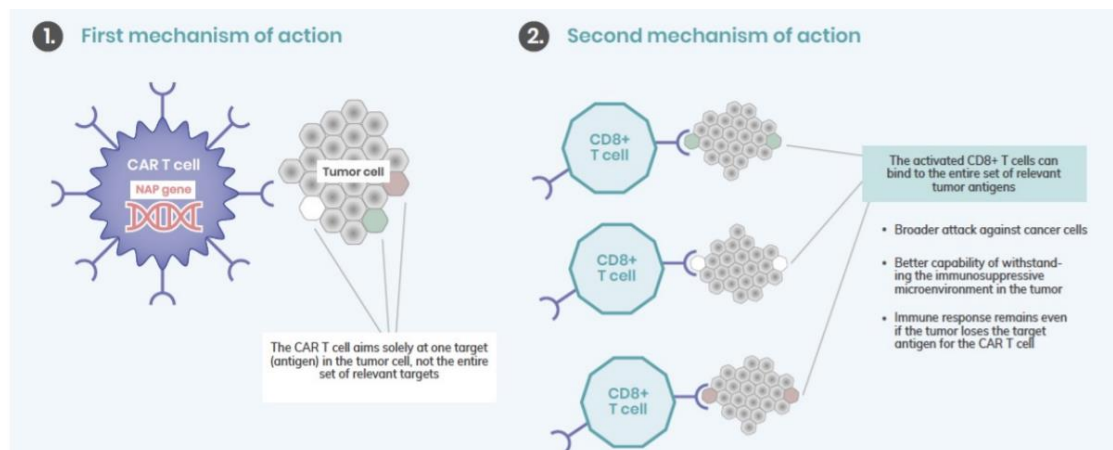
HP-NAP has been mentioned in the scientific literature since the mid-1990s. Professor Magnus Essand published results in 2013 indicating that adenovirus in combination with HP-NAP may have therapeutic effects on neuroendocrine tumours. A research team from Taiwan published a paper in 2015 summarising that HP-NAP is beneficial for various clinical applications such as vaccine development, diagnostics and new drugs to treat cancer. Professor Magnus Essand received a four-year research grant in 2016 to develop a cancer therapy based on CAR T cells and HP-NAP. This work has resulted in the iTANK platform.

NAP acts as an activator of neutrophils (about 60% of all white blood cells) and is an essential component of the innate immune system. When activated, neutrophils secrete various proteins that participate in the immune response. Cytokines and chemokines have a specific local role in recruiting more neutrophils. They make the blood vessel wall (endothelium) more permeable to neutrophils and other blood cells from the innate immune system, such as natural killer (NK) cells, monocytes and dendritic cells.

A second important component of NAP is the recruitment and activation of so-called dendritic cells. These dendritic cells are part of the body's immune system and pick up the specific tumour antigens (neoantigens) that are released when the CAR T-cells attack the tumour. Once the dendritic cells have picked up antigens in peripheral tissue where the tumour is located, they leave this tissue and move via lymphatic vessels to lymph nodes to

present the antigens to the body's T-cells. In this way, the tumour is attacked in two ways, directly via CAR T cells targeting the tumour and secondly via dendrites which, via the lymph, activate the immune system's T cells to recognise and attack the tumour's neoantigens (mutated proteins).

### Description of the Mechanism of Action of the Immune Activator iTANK



Source: Elicera

NAP also has an immunomodulatory effect by activating T-helper (Th1) cells, increasing the secretion of pro-inflammatory cytokines.

The iTANK platform is a potent enhancer of the CAR T cell/oncolytic virus technology. iTANK should be seen as an enhancer of the tumour cell killing effect, both by activating and recruiting neutrophils to the tumour site and by spreading the neoantigen from the tumour via lymph vessels/nodes using the activated dendritic cells to activate T cells and neutrophils at other sites in response to the neoantigen.

When iTANK is used with CAR T or oncolytic viruses, the T cell/adenovirus is modified with a gene encoding NAP. It is essential to point out and understand that *H. pylori* are not included in the iTANK/NAP platform.

## Potential Challenges with HP-NAP

### Side Effect Profile May Be Influenced by Immune Activation

potents is a potent activator of the body's immune system and is also pro-inflammatory; it is essential to closely monitor the early phase I/II trials to avoid unwanted over-activation of the immune system, resulting in cytokine storms.

### Neutrophils Have a Complex Role in Cancer

Neutrophils appear to have a complex role in cancer, supporting both pro-tumourigenic and tumour-eridical effects. In cancer, a high level of tumour-associated neutrophils (TANs) is often observed in the tumour tissue. An increased presence of TANs is associated with a poorer pro-inflammatory prognosis. Still, it is unclear whether the neutrophils themselves contribute to tumour growth or whether the accumulation is a secondary effect resulting from systemic inflammation in advanced cancer. The scientific literature seems to be dominated by the view that neutrophils have a tumour-driving impact (including through angiogenesis, i.e. stimulation of the tumour's ability to form blood vessels). However, Elicera states that neutrophils activated by NAP express high levels of myeloperoxidase (MPO), the phenotype sometimes referred to as N1 neutrophils. MPO-expressing neutrophils are usually a favourable prognostic factor.

### Antibody Response to HP-NAP

*H. pylori* infection is highly prevalent, with a prevalence between 30 and 50 per cent in developed countries. There is a risk that patients who have had infection may have developed antibody pairs to NAP which could reduce or eliminate the efficacy of iTANK-enhanced immunotherapy. Elicera states that studies in animal models show that even in the presence of anti-NAP antibodies, the effect of iTANK is not affected (observations with anti-CD20 CAR-T). However, these data have not yet been published in scientific journals.

## Oncolytic Viruses Can Complement Other Immunotherapies

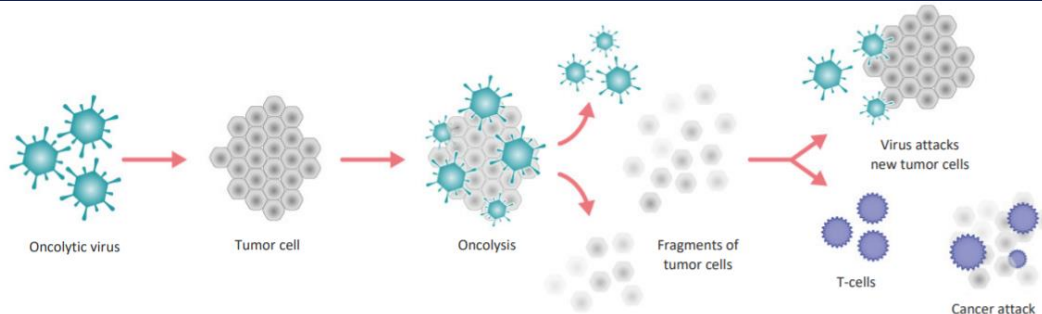
Oncolytic viruses are based on infecting cancer cells with a modified tumour-targeting virus. Since viruses are experts at entering host cells to replicate and killing the host cells in the process, the hypothesis is to exploit this property to kill only tumour cells. When tumour cells die, neoantigen is also released, which in turn can be taken up by antigen-presenting dendritic cells to activate neoantigen-targeted T cells. The idea is to boost the immune response to tumours in this way. Thus, the aim is to achieve both a local tumour-killing effect and activate the immune system.

Tumour cells appear to be less able to protect themselves against infection than healthy cells, which is an integral part of the rationale for oncolytic viruses, which thus spread more easily in cancer cells. New generations of oncolytic viruses are also programmed with transgenes to induce infecting cells to express proteins that enhance the treatment's effect. One example is the granulocyte-macrophage colony-stimulating factor (GM-CSF).

There are limitations. A viral infection normally triggers an immune response, as do oncolytic viruses. This causes the oncolytic virus to be attacked and risks counteracting the effect. A common way to get around virus degradation is to inject it directly into the tumour. The tumour environment often presents a physical barrier, such as fibrotic tissue, which can be difficult for oncolytic viruses to penetrate.

There are a variety of oncolytic viruses with different advantages and disadvantages. Larger viruses such as measles and herpes viruses can take a larger load of transgenes and thus potentially exert a broader mechanism of action. At the same time, they run a higher risk of immunogenicity and antibody response to treatment. Cold viruses (adenoviruses) are used relatively frequently. The only oncolytic virus approved so far in the US, Imlygic (T-VEC), is of the herpes simplex virus type.

### Illustration of the General Mechanism of Action of Oncolytic Viruses



Source: Elicera

We have tracked another NAP (oncolytic virus based on measles virus vector) project in early clinical development in advanced breast cancer. However, Elicera appears unique in using NAP to develop novel CAR-T therapies. The Company does not have a patent for NAP in oncolytic viruses specifically. However, NAP is included in the 201 patent application.

## Promising Data for the Project Portfolio

Elicera's pipeline consists of four projects. The most advanced is the oncolytic virus ELC-100 (AdVince). A Phase I/II study is currently underway in patients with neuroendocrine tumours whose disease has spread to the liver and other organs. The study is investigator-initiated and run by Uppsala University.

### Efficacy Signal with Oncolytic Virus

The study is in the dose-escalation phase, and seven patients have received treatment. According to Elicera, no severe side effects have been reported, and a partial response has been observed. AdVince is not built on the iTANK platform and has not been loaded with any transgenes. It is an adenovirus designed to replicate in neuroendocrine tumours selectively.

Although it is difficult to compare the outcome with previous external studies with other treatments given the differences in study design and patient population, we find the signal of tumour response to low-dose therapy in the dose-escalation phase promising. Tumour response is relatively rare in disseminated disease, underlining the difficulty of treating liver metastases. Existing treatments have tumour shrinking effects in 15 to 20% of patients in a similar population (e.g. targeted radionuclide therapy).

### **Preclinical Proof of Principle for iTANK**

Specifically, regarding iTANK, Elicera presented preclinical results at the ESGCT gene and cell therapy conference in October 2021 and PEGS Europe in November 2021. The results show that the iTANK concept can be combined with different CAR receptors. Treatment with CAR T cells boosted with NAP improves survival compared to a "naked" conventional CAR-T in solid tumours and lymphoma models. In an experiment using a cancer model with mixed CD19-positive and CD19-negative tumours treated with anti-CD19 CAR-T cells, the NAP-enhanced CAR T exhibited better anti-tumour efficacy. This supports the Company's hypothesis that the NAP-CAR-T has an additional mechanism of action beyond killing the tumours targeted by the CAR-T treatment. This is supported by the fact that endogenous T cells from mice treated with Elicera's CAR T are activated when mixed with CD19-negative tumours. An obvious explanation is that iTANK may activate the immune system "in a second wave" against several tumour antigens that are released when tumour cells die after the initial attack by CD19-targeted CAR T cells.

### **iTANK and Oncolytic Viruses**

The iTANK technology has been tested in oncolytic viruses in preclinical models for different types of tumours. The studies demonstrated that NAP does not affect the stability or replication ability of the viral vector, and biological effects include increased infiltration of neutrophils into tumour tissue and increased levels of cytokines. Last but not least, NAP-enhanced viral vectors appear to improve survival compared to oncolytic viruses lacking the transgene for NAP.

### **Good Rationale for ELC-301 in Lymphoma Despite Competition**

An important question is what Elicera and ELC-301 can bring to the lymphoma field, which is already the "home turf" for CAR-T therapies.

### **'Classmate' Shows Promising Results**

In addition to carrying iTANK, ELC-301 differs from approved therapies on the market for lymphoma in that it targets the CD20 target molecule. In terms of monovalent CAR-Ts (targeting one target), there is some limited competition in anti-CD20. Mustang Bio's candidate MB-106 has shown promising results in a small dose-escalation study (n=15) with tumour response in as many as 93% of lymphoma patients, including 67% complete response. Admittedly, the population was primarily of patients with follicular lymphoma (a relatively less aggressive form). However, these had undergone four previous lines of treatment (median) and, taken together, the results provide a proof of concept that CD20 treatment is effective.

### **Clinical Results for CD19 and CD20 CAR-T in Lymphoma**

Project	Phase	Patients	N (patients)	ORR	CR	DoR (months)
Yescarta (anti-CD19)	2	Lymphoma	111	82%	54%	8,1
MB-106 (anti-CD20)	1	Lymphoma	15	93%	67%	n.a.

Source: Company Information. ORR: Objective Tumor Response. CR: Complete Response. DoR: Durability of Response

Since it is reasonable to assume that most patients in the study had previously received the standard treatment rituximab, the results implicitly suggest that resistance to CD20 antibodies does not appear to affect the efficacy of anti-CD20 CAR-T treatment.

Overall, Mustang Bio's results, combined with the fact that ELC-301 is armed with an additional mechanism of action with the immune enhancer iTANK, give us high hopes for future clinical trials.

## Market and Competition

The market for cell therapy in oncology is, by all accounts, in its infancy. More treatment targets and wider use are expected to drive rapid growth for CAR-T medicines in the coming years. At the same time, competition is rapidly intensifying.

### CAR-T Makes Long-Awaited Progress

#### Expectations of a New Growth Phase for CAR-T

Yescarta and Kymriah have been on the market since 2017, but it took until this year for more CAR-T treatments to reach the market. Abecma, which targets BCMA on B cells, is a notable newcomer. With this treatment, CAR-T is entering the market niche for Multiple Myeloma, which commercially is larger than lymphoma. Legend Biotech and Janssen have filed for FDA approval of Cilta-cel for Multiple Myeloma, and a decision is expected in February 2022.

There are hopes that growth will now take off in earnest, with forecasts of a USD 7-10 billion market as early as 2024 (Evaluate Pharma (consensus) and McKinsey). Although these expectations seem optimistic, the assumptions are starting to fall into place.

#### CAR-T-Treatments, Sales by Quarter (USD million)



Source: Company information.

The CAR-T treatments are marketed by major pharmaceutical companies such as Bristol Myers, Gilead, and Novartis. The market structure results from acquisition activity, with Gilead buying Kite Pharma, the Company behind Yescarta (axis-cel), in 2017 for USD 11.9 billion. Bristol Myers acquired Celgene in 2019, which had bought Juno Therapeutics for USD 9 billion a year earlier. Juno had developed Breyanzi (liso-cel) and was a co-developer of Abecma (ide-cel) for lymphoma and multiple myeloma, respectively.

#### Business Development is Active

Below we present a selection of deals in the CAR-T area. The amounts have been adjusted because the contracts may include more candidates, in which case we assume an average per candidate/project. Except in exceptional cases, the amounts are not as high as in some other "hot" areas of oncology (e.g., antibodies and antibody conjugates), which may be since the market is still in its infancy. This is also reflected in the fact that many deals are struck at an early stage of development. Overall, business activity is high, which may be due to the validation of CAR-T cell therapy and many Chinese companies and projects active in this field.

## Licensing Deals in the CAR-T Space

	Partner	Project	Indication	Phase	Value (USDm)	Upfront (USDm)	Royalties
Collectis*	Pfizer	Allogenic CAR-T	Oncology	Preclinical	200	20	Not specified
Collectis	Servier	UCART19	ALL	I	410	38	"Flat low double digit"
Juno	Celgene		NHL	Preclinical		1000	Profit-sharing 70/30
Kite	Amgen	CAR platform	Cancer	Preclinical	585	60	High single-digit to double-digit
Atata*	Bayer	Autolog+allogeneic anti-mesothelin	Solid tumours	I	335	30	Low double-digit
Legend Bio-tech	Janssen	LCAR-B38M	Multiple Myeloma	CFDA BLA review		350	Profit-sharing 50/50
Fate Therapeutics	Janssen	iPSC stemcell platform	Oncology	Preclinical	3100	100	Double-digit
Adaptimmune*	Astellas	-"	Oncology	Preclinical	356	25	Average single-digit to double-digit
<b>Median</b>					<b>383</b>	<b>49</b>	

Source: Company information. \* Average value per project.

Many deals are about accessing a technology, such as gene editing, rather than a long-awaited project. Gene editing, such as CRISPR, has applications in allogeneic therapies to reduce rejection when donated T-cells are transplanted into the patient.

## Technology Licensing

Licensor	Partner	Project	Value (USDm)	Upfront (USDm)	Royalties
Transposagen	Janssen	Piggybac genediting	292	Not specified	Not specified
Alpine Immune Systems	Kite Pharma	Technology to strengthen the immune	535	5	Low single-digit
Caribou	Abbvie	CRISPR editing gens	340	40	Not specified
Noile-Immune	Adaptimmune	PRIME	312		Average single-digit
Noile-Immune	Legend Biotech	PRIME	70		Average single-digit
<b>Median</b>			<b>312</b>	<b>23</b>	

Source: Company information.

Japan's **Noile-Immune** has developed a PRIME technology (Proliferation-Inducing and Migration-Enhancing) to boost immune responses with immunotherapies, particularly solid tumours. In PRIME, CAR-T cells are programmed to express IL-7 and CCL19, proteins that regulate the immune response and are usually found in the lymphatic system. IL-7 stimulates the growth of T cells, and CCL19 drives the migration of T cells and antigen-presenting cells. Noile-Immune collaborates with several pharmaceutical and biotechnology companies such as Takeda, Adaptimmune, Autolus, and Legend Biotech, and Takeda has been an early partner. Although PRIME uses other immunostimulatory factors, it is a potential reference for iTANK. A Phase I clinical trial of PRIME technology in solid tumours is ongoing with Takeda.

## Despite Setbacks, There is Interest in Oncolytic Viruses

To date, neither oncolytic viruses' clinical nor commercial development has lived up to initial expectations. The herpes simplex virus T-VEC is approved for treatment in recurrent melanoma after surgery but has not demonstrated improved survival. A challenge is that the treatment has limited systemic efficacy in tumours where T-VEC has not been injected despite being armed with immunostimulatory GM-CSF. In addition, competition in melanoma is high as it is the "home turf" for checkpoint inhibitors. Pre-sales are by all accounts modest and are not separately reported by the manufacturer Amgen.

Given the mechanism of action, it has been speculated that it could be combined with checkpoint inhibitors to increase the infiltration of T-cells into tumours to make them "hot" and thus more susceptible to this type of immunotherapy. Preclinical and early clinical results have been promising. In a Phase III study, T-VEC has been evaluated as combination therapy with Keytruda in malignant melanoma. Still, no significant improvement in either progression-free survival or overall survival was demonstrated, and the study was prematurely terminated.

Despite a very modest market and setbacks in clinical development, there is still interest in the field, even if the activity is not overwhelmingly high. In recent years, Japanese companies have shown interest in the area in the form of two high-profile deals.

### Licensing Deals with Oncolytic Viruses

Licensor	Partner	Project	Phase	Value (USDm)	Upfront (USDm)	Royalties	Date
Kalivir Immunotherapeutics	Astellas	VET2-L2	Preclinical	363	56	Not specified	2020-12-07
Turnstone Biologics	Takeda	Flt3xCtLA4xIL-12	Preclinical	1020	120	Profit-sharing 50/50	2019-12-19

Source: Company information.

The collaboration between Takeda and Turnstone is an exciting reference, given that the project involves an oncolytic virus that encodes immune-activating proteins.

## Listed peers

Below we present valuations of several listed cells and gene therapy companies in early clinical development, most of which are focused on oncology.

### Antaganden om toppförsäljning ELC-100

Company	EV (SEKm)	Phase
Active Biotech AB (publ)	219	2
Autolus Therapeutics plc	2 780	2
CombiGene AB (publ)	171	Preclinical
Idogen AB (publ)	17	Preclinical
Immunicum AB (publ)	842	2
Mustang Bio, Inc.	683	1
Poseida Therapeutics, Inc.	2 645	1
Transgene SA	2 381	2
<b>Median</b>	<b>762</b>	
Elicera	51.8	

Source: S&P Capital IQ and Carlsquare estimates.

Compared to other companies in the sector, the valuation of Elicera appears very low on an Enterprise Value basis. We believe a key reason is that the Company is undiscovered and that there is no clinical evidence yet for the CAR-T projects to show. The international competitors above have also invested in their manufacturing capacity, have generally more extensive project portfolios, and much more influential organisations at their disposal.

## CAR-T-Companies

### Autolus Therapeutics

As its name suggests, a British company develops autologous CAR-T cell therapies. Autolus has two CAR-Ts in clinical development, both in leukaemia, with the lead project Obe-cel being evaluated in a potentially pivotal study. Obe-cel is designed to reduce the risk of the cytokine storm.

### Mustang Bio

Mustang Bio is one of the clearest competitors to Elicera. The Company works closely with academia and is developing CAR-Ts against CD20 and IL13Ra2. Early results in lymphoma and glioblastoma are promising. The stock has performed poorly, likely due to concerns about unrelated gene therapy projects.

### Poseida Therapeutics

This innovative Company is developing multiple technologies to improve CAR-T cell therapies and gene therapy. Clinical development is ongoing in both Multiple Myeloma and Prostate Cancer.

## Other Companies

### Active Biotech

Israeli NeoTx, in collaboration with Swedish Active Biotech, is developing immunotherapy (the fusion protein naptumomab) for cancer based on bacterial superantigens (SEA from staphylococcus bacteria) for a more robust immune response. Naptumomab's mechanism of action differs from iTANK in that it targets a pre-defined specific tumour-associated antigen (5T4). Naptumomab is being developed clinically in combination with the PD-L1 antibody durvalumab and chemotherapy, and preclinical development of a variety with CAR-T is ongoing.

### CombiGene

**CombiGene is developing gene therapy treatments for epilepsy and rare diseases. Earlier this autumn, a licensing agreement was signed with Spark Therapeutics for CG01 worth up to \$328 million. Idogen**

Idogen is developing tolerogenic cell therapies focusing on haemophilia and organ transplantation.

### Immunicum

Immunicum is developing cell therapies for oncology based on dendritic cells and has two candidates in phase II. The Company merged at the beginning of the year with Dutch DC Prime.

## Financial History and Carlsquare's forecasts

Historically, Elicera's costs have been very low due to research funding. We estimate that the Company's activities have sufficient funds for the next two years. The CAR-T field is developing rapidly, which could benefit Elicera, and we anticipate that the projects can be out-licensed after completing Phase I/II studies. We see a possible blockbuster potential.

## Revenue and Profitability Forecasts

### Estimated Sources of Funding Need to Be Completed

The operational focus is on completing production and preparing to apply for the start of clinical trials for ELC-301 in the second half of 2022. In addition, Elicera has ordered virus vectors to produce ELC-401 from contract manufacturer BioNTech. The phase I part of the study in neuroendocrine tumours is also due to be completed in the next year. This study is mainly funded externally (Victory NET Foundation).

During the first nine months of the year, costs have increased compared to the corresponding period in 2020 but remain at a modest level (just under SEK 11 million compared to SEK 232 thousand). As of 30 September, cash and cash equivalents amounted to SEK 53 million.

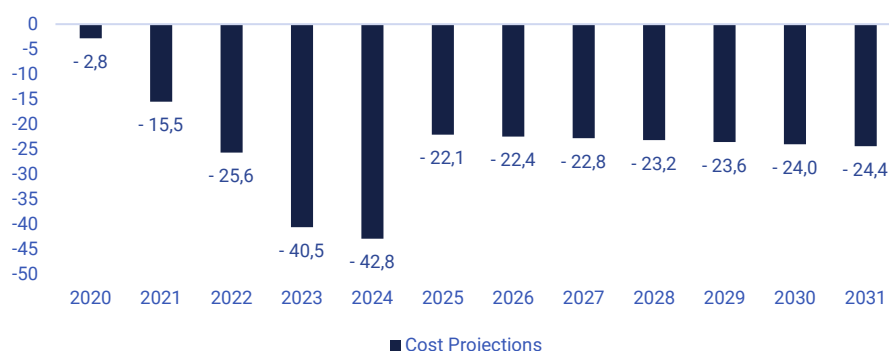
The research behind Elicera's drug candidates has primarily been funded by grants from, for example, the Swedish Cancer Foundation and the Sjöberg Foundation. In 2019 and 2020, Magnus Essand has received funding of SEK 4.5 million and SEK 6 million, respectively, to develop ELC-401 in glioblastoma. The ELC-301 project is also partly funded by a grant of SEK 10 million from the Swedish Cancer Foundation.

We believe that future clinical trials will drive costs in light of research grant funding. Therefore, we anticipate a gradual but apparent increase in prices from 2022 to 2023. In the prospectus, Elicera indicates a cost for further developing the CAR-T programs of around SEK 20m.

We assume that new funding will be required in the second half of 2023. If outstanding TO1 warrants are heavily exercised (subscription period in November 2022), the capital requirement may be further delayed.

### Cost Projections (SEK million)

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Source: Company information and Carlsquare estimates.

## Project Assumptions

### ELC-100

The only reference on the market for oncolytic viruses is Imlygic, where cost varies according to dosage. We estimate a list price of around USD 69,000 in the US. A more effective treatment than Imlygic could probably be priced higher. A higher value per treatment than Imlygic may also be justified because ELC-100 is likely to obtain orphan drug status in neuroendocrine tumours with liver metastases. We assume USD 100,000 (net) in the US and half in Europe.

Assuming a prevalence of neuroendocrine tumours of 35 per 100,000, this corresponds to up to 300,000 people affected in the US and Europe. We presume that AdVince is indicated for treating liver metastases from neuroendocrine tumours GEP-NET). The proportion with GEP-NET is estimated at 60%, and about 27% of these will, in turn, develop liver metastases of which about 30% can be treated with surgery (Frilling, A. "Recommendations for the management of patients with neuroendocrine liver metastases", Lancet Oncology, 2014). We see an addressable market of about 34,000 in Europe and the US receiving palliative care with these adjustments.

We expect ELC-100 to have a penetration of up to 10% as a second-line treatment (first-line treatment with, for example, radionuclides already results in relatively good survival). We use a reasonably conservative assumption as there is still limited clinical data from the project.

### Assumptions About Peak Sales ELC-100

2035E	USA	Europe	Total
Prevalence NET	115,932	181,199	297,131
Share GEP-NET	60%	60%	
Liver metastases	27%	27%	
Liver surgery	30%	30%	
Palliative care	13,147	20,548	33,695
Second lines	43%	43%	
ELC-100 market share	23%	23%	
ELC-100 patients	1,268	1,981	3,249
Sales, MUSD	127	99	226

Source: Frilling (2014)

An important question is whether ELC-100 should be combined with systemic therapies, and if so, which ones. For example, checkpoint inhibitors as monotherapies have not been convincing in clinical trials in neuroendocrine tumours. However, there is a theoretical rationale for combining oncolytic viruses with checkpoint inhibitors to activate T-cells and simultaneously break tumour tolerance to activated T-cells.

### ELC-201

We do not include ELC-201 in our projections or our valuation, given that the project is in early development and the mechanism of action is not presented except that iTANK will be included.

### ELC-301

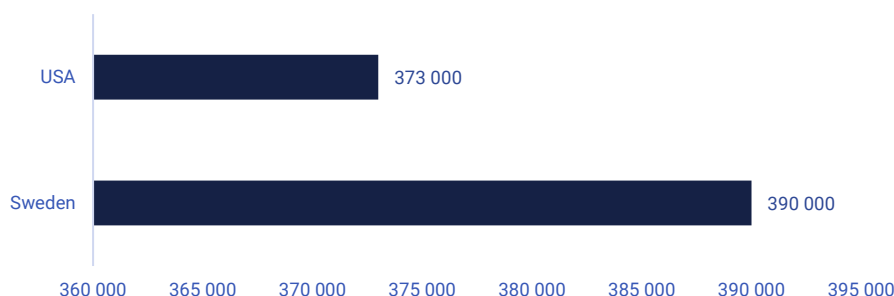
We assume that ELC-301 will primarily be evaluated in and potentially approved for CAR-T-naïve patients who have received at least two prior systemic therapies. That is, the same indication as currently applies to Yescarta. Eventually, the indication may be extended to patients in earlier lines of treatment. As mentioned, Gilead and Bristol Myers are expected to seek approval for Yescarta and Breyanzi, respectively, in second-line therapy shortly. It represents more significant commercial potential but requires more extensive controlled studies as the standard of care is already available.

If many patients receive CAR-T treatment already in the second line in the future, this may affect the possibilities in the third line. An important question is whether the same patient should receive additional CAR-T treatment in case of relapse after the first CAR-T treatment. The few (and small) studies that have been done show evidence of treatment benefit in retreatment but no substantial evidence. There are no guidelines on retreatment yet, but the high cost of treatment may be a limiting factor—the three CAR-T therapies currently approved for the treatment of lymphoma target the same antigen, CD19. About half of patients treated with anti-CD19 will relapse. Therefore, a possible way forward is to treat these patients with CAR-Ts that target other targets, such as CD20 for ELC-301.

Overall, in the context of a still volatile competitive situation, it is unclear when ELC-301 will be deployed and what market share might be reasonable. A standard estimate is that around 40% of all patients with late-stage B-cell lymphoma (relapsed or refractory disease in second-line or later) could be candidates for CAR-T treatment. If ELC-301 can take 15 per cent of that land-need potential, that would equate to 1,500 patients annually in the US, Europe, and Japan combined.

CAR-T treatments are very highly-priced, which is justified by the one-off nature of the treatment, proven efficacy in difficult-to-treat patients, the small patient groups in rare diseases addressed, and, not least, the high cost of manufacturing. The list price for Yescarta is USD 373,000 in the US. List prices in Europe do not appear to differ from those in the US, although manufacturers use different pricing strategies in other European countries. For example, reimbursement may be linked to treatment response.

### Pricing of the CAR-T-treatment Yescarta (USD)



Source: Company information and TLV

Assuming a net price (after discount) of USD 320,000 on average corresponds to peak sales of USD 470 million (at 15% market share).

### ELC-401

GBM is a very challenging indication to treat but, at the same time, a significant opportunity for the project that makes it to the end. Updated clinical results from the competing MB-101 project, which targets the same goal, may shed further light on the potential of ELC-401. We anticipate that ELC-401 will be used as a second-line treatment after relapse following chemotherapy and radiotherapy +/- surgery, reaching a penetration of approximately ten per cent of glioblastoma cases or 3,400 annually. Assuming the exact pricing as for ELC-301, this represents blockbuster potential.

### Technology platforms

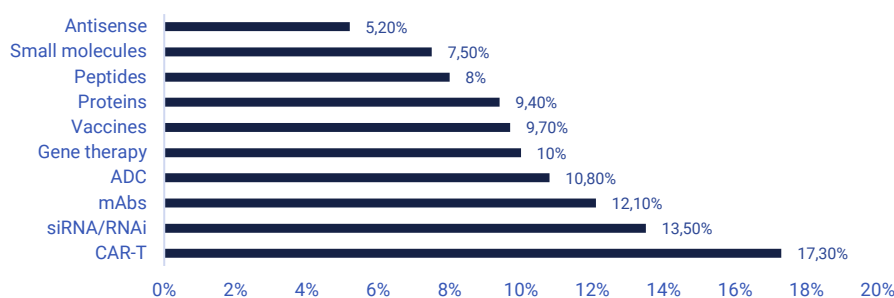
iTANK has broad applications and is not linked to any specific form of immunotherapy. This type of collaboration is popular in the CAR-T field when more prominent players complement the toolbox. As mentioned, Japanese Noile-Immune has several agreements for the immune enhancer PRIME.

However, we see a possible challenge in trying to license out the use of iTANK while using the technology in internal projects to enter into different partnerships for these as well. Difficulties in delineating rights may reduce opportunities. For the time being, therefore, we do not include any new projects from the technology in our forecasts or attribute any different value to the iTANK platform.

### Probability to market

Based on drug development statistics, the probability of reaching the market is estimated at 7.9% for an average Phase I drug project. For oncology, the corresponding possibility is 5.4% ("Clinical Development Success Rates and Contributing Factors 2011-2020", Bio/Informa Pharma/QLS). Factors influencing the likelihood are an indication, target molecule, and modality. For example, haematology is an indication area where it has historically been relatively easier to achieve success in clinical development. CAR-T as an approach is also relatively prosperous compared to, for example, antibody pairs and small molecules. All else being equal, this bodes well for ELC-301. This is reflected in our assumption of a relatively high probability of approval for this project.

#### The likelihood for approval from Phase I, by modality



Source: Bio/Informa Pharma/QLS

On the other hand, we are more cautious about the ELC-100 and ELC-401. We have no statistics for neuroendocrine tumours or glioblastoma, but both are challenging indications for drug development. Oncolytic viruses as a modality still have much to prove in terms of success in clinical development as only one project has been approved.

#### Assumptions Probability to Market

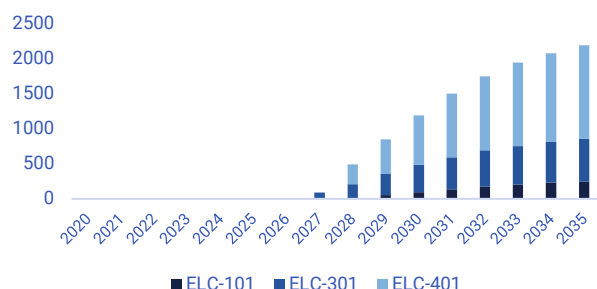
Project	Indication	Preclinical	Phase I	Phase II	Phase III	NDA	LOA
ELC-100	GEP-NET	100%	75%	25%	50%	92%	9%
ELC-301	Lymphoma	75%	44%	59%	67%	100%	13%
ELC-401	Glioblastoma	50%	50%	25%	50%	92%	3%

Source: Carlsquare LOA: Likelihood of launch.

### Our Forecasts are Based on Outlicensing in 2025

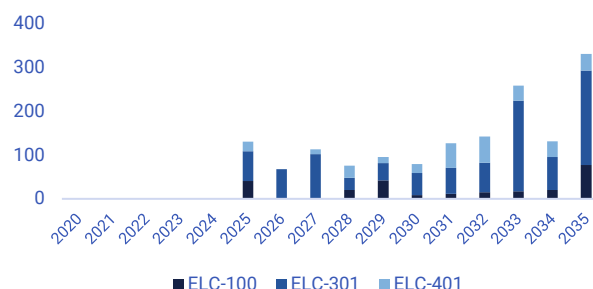
For our revenue assumptions, we assume that both the ELC-100 and CAR-T projects are out-licensed in 2025 after clinical proof of concept has been achieved. As mentioned above, we believe the potential is most significant for ELC-401 given the high medical need and little competition in the field; however, in our risk-adjusted projections, the lymphoma project ELC-301 carries more weight.

### Forecast Royalty Income (SEKm)



Source: Company information and Carlsquare estimates.

### Forecast Royalty and Milestone income, risk-adjusted (SEKm)



Source: Company information and Carlsquare estimates.

We have assumed licensing deals worth USD 400 million each for the CAR-T projects. It aligns with the median of the licensing agreement sample we have compiled above. We assume an upfront payment of 10% and a royalty rate of 15%. For ELC-100, we assume a lower value of a licensing deal, \$250 million. We have tracked only a few licenses deals in the area where the amounts have been reported. ELC-100 is also a comparatively "simple" design of an oncolytic virus that does not carry transgenes. Our assessment may change in a more optimistic direction should results from the ongoing clinical trial indicate a clear treatment benefit compared to what has historically been observed for current standard therapies.

## Valuation

### Fair value SEK 13 per share in a Base scenario

#### Broadening Portfolio and Financial Position Provides Valuation Support

Our base case valuation is based on the sales assumptions described in the forecasting section above. We have used a risk-adjusted DCF valuation, as described below. The risk adjustment is based on the development risks discussed below. We assume the probability of reaching a market of between three and thirteen per cent with the most significant risk adjustment for solid tumours. In our model, we have used a discount rate of 14.6 per cent. This is based on a risk-free rate of 0.3 per cent, a beta value of 1, and a risk premium of 14.2 per cent. The latter is based on PwC's 2021 Risk Premium Study and consists of a market risk premium of 6.7 per cent, a size-based premium of 4.2 per cent, and a company-specific premium of 3.4 per cent.

We estimate an operating value of just under SEK 250 million. We have assumed dilution because of an expected financing requirement in approximately two years. Here we have provisionally assumed an issue price of SEK 8, the same as the listing issue. We have not assumed that outstanding warrants will be exercised as they are out-of-the-money. In total, a justified value is approximately SEK 13 per share.

### Summary Sum-of-the-parts valuation, Base Case (SEKm)

Project	Indication	LOA*, %	Royalty, %	Peak Sales, USDm	Launch	rNPV, SEKm
ELC-301	NHL	13.0%	15.0%	470	2028	279
ELC-401	Glioblastoma	2.9%	15.0%	1 080	2028	102
ELC-100	Neuroendocrine tumours	8.6%	15.0%	230	2030	82
<b>Technology value</b>						<b>462</b>
Overhead and taxes						-212
<b>EV</b>						<b>250</b>
Net Cash position (21'Q4E)						49
<b>Motivated value</b>						<b>299</b>
Number of shares (million)						19.8
Per share. SEK						15.1
Estimated financing						61
Shareholder value after financing						360
Number of shares after full dilution (million)						27.9
<b>Motivated value per share (SEK)</b>						<b>12.9</b>

Source: Carlsquare \*LOA: Likelihood to launch.

### Valuation Range

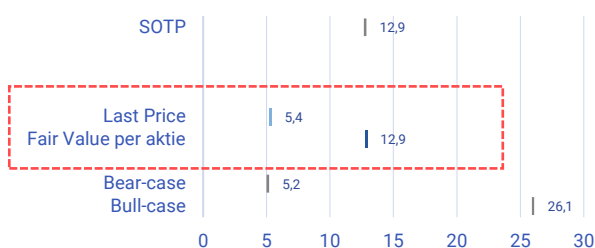
In an **optimistic bull scenario**, we expect that

- Elicera enters into a technology agreement with iTANK to develop a preclinical project. We assume a deal worth up to USD 300 million, plus five per cent royalties on future sales and an upfront payment of USD 15 million.
- We further anticipate the successful completion of the Phase I portion of the ongoing ELC-100 clinical trial
- ELC-301 enters the clinical phase.
- The T01 warrants are fully exercised, and no additional financing is required in the foreseeable future
- We lower our discount rate to 13%.

We estimate a justified value of SEK 575 million or around SEK 26 per share after dilution.

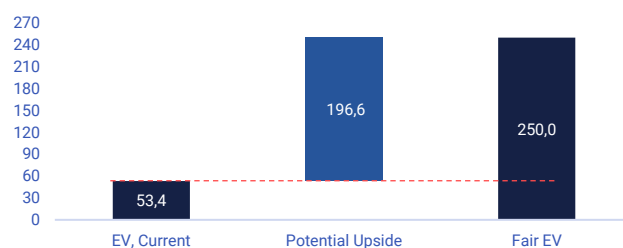
In a **conservative Bear scenario**, both ELC-100 and ELC-301 are terminated after setbacks in early clinical development. After dilution, we estimate a justified value of just over SEK 5 per share.

### The Fair Value within a Range, SEK



Source: Carlsquare estimates

### Visualisation, Base Scenario (SEKm)



Source: Carlsquare estimates

# Key Figures and Accounts

## Income Statement, Quarterly basis (SEKm)

	2021, Q1	2021, Q2	2021, Q3	2021, Q4E	2022, Q1E	2022, Q2E
<b>Net revenues</b>	0,0	0,0	0,0	0,0	0,0	0,0
Total revenues	0,0	0,0	0,0	0,0	0,0	0,0
<b>Gross profit</b>	0,0	0,0	0,0	0,0	0,0	0,0
Total operating costs	-2,4	-1,8	-6,8	-4,5	-4,7	-7,3
<b>EBIT</b>	-2,4	-1,8	-6,8	-4,5	-4,7	-7,3
<b>EBITDA</b>	-2,4	-1,8	-6,8	-4,5	-4,7	-7,3
<b>EBT</b>	-2,4	-1,8	-6,8	-4,5	-4,7	-7,3
<b>Earnings per share (SEK)</b>	-0,20	-0,35	-0,34	-0,23	-0,24	-0,37

Source: Company information and Carlsquare estimates.

## Income Statement (SEKm)

	2020	2021	2022E	2023E	2024E	2025E
<b>Net revenues</b>	0,0	0,0	0,0	0,0	0,0	134,9
Other operating income	0,0	0,0	0,0	0,0	0,0	0,0
<b>Total revenues</b>	0,0	0,0	0,0	0,0	0,0	134,9
Purchase of commodities	0,0	0,0	0,0	0,0	0,0	0,0
<b>Gross profit</b>	0,0	0,0	0,0	0,0	0,0	134,9
Adjusted gross profit	0,0	0,0	0,0	0,0	0,0	134,9
Other external costs	-1,8	-11,2	-18,7	-30,0	-28,5	-3,7
Personnel costs	-1,0	-4,2	-6,9	-10,6	-14,4	-18,3
Depreciation and amortisation	0,0	0,0	0,0	0,0	0,0	0,0
Other operating expenses	0,0	0,0	0,0	0,0	0,0	0,0
Total Operating costs	-2,8	-15,5	-25,6	-40,5	-42,8	-22,1
<b>EBIT</b>	-2,9	-15,5	-25,6	-40,5	-42,8	112,8
<b>EBITDA</b>	-2,8	-15,5	-25,6	-40,5	-42,8	112,8
Net finance	-0,1	0,0	0,0	0,0	0,0	0,0
<b>Pretax profit</b>	-2,9	-15,5	-25,6	-40,5	-42,8	112,8
Taxes	0,0	0,0	0,0	0,0	0,0	0,0
<b>Net profit</b>	-2,9	-15,5	-25,6	-40,5	-42,8	112,8
<b>Earnings per share</b>	-0,3	-1,1	-1,3	-1,7	-1,5	4,0

	2020	2021	2022E	2023E	2024E	2025E
<b>Growth</b>						
Net revenues	NA	NaN	NaN	NaN	NaN	n.m.
Total revenues	NA	n.m.	-100%	n.m.	n.m.	n.m.
Gross profit	NA	n.m.	-100%	n.m.	n.m.	n.m.
Adjusted gross profit	NA	n.m.	n.m.	n.m.	n.m.	n.m.
EBIT	NA	-440%	-66%	-58%	-6%	363%
EBITDA	NA	-449%	-66%	-58%	-6%	363%
EBT	NA	-428%	-66%	-58%	-6%	363%
Net profit	NA	-428%	-66%	-58%	-6%	363%
Earnings per share	NA	-514%	-16%	-35%	12%	363%

	2020	2021	2022E	2023E	2024E	2025E
<b>Margins</b>						
Gross margin	n.m.	100,0%	n.m.	n.m.	n.m.	100,0%
Adjusted gross margin	NaN	n.m.	n.m.	n.m.	n.m.	100,0%
EBIT-margin	n.m.	n.m.	n.m.	n.m.	n.m.	83,6%
EBITDA-margin	n.m.	n.m.	n.m.	n.m.	n.m.	83,7%
Net Profit margin	n.m.	n.m.	n.m.	n.m.	n.m.	83,6%

\*Adjusted gross profit = net revenues less purchase of commodities.

\*\*Adjusted gross margin = Net revenues less purchase of commodities, divided by net revenues.

Source: Company information and Carlsquare estimates.

## Balance Sheet (SEKm)

	2020	2021	2022E	2023E	2024E	2025E
<b>ASSETS</b>						
Intangible Assets	0,0	0,0	0,0	0,0	0,0	0,0
Tangible Fixed Assets	0,0	0,0	0,0	0,0	0,0	0,1
Financial Fixed Assets	0,5	0,5	0,5	0,5	0,5	0,5
Sum Tangible Assets	0,5	0,5	0,5	0,5	0,5	0,6
Inventory	0,0	0,0	0,0	0,0	0,0	0,0
Trade receivables	0,0	0,0	0,0	0,0	0,0	0,0
Other current receivables	0,5	0,0	0,0	0,0	0,0	0,0
Prepaid expenses and accrued income	0,0	0,0	0,0	0,0	0,0	0,0
Cash and bank	11,6	49,4	23,7	44,3	1,4	114,2
Total current assets	12,1	49,4	23,7	44,3	1,4	114,2
<b>Sum assets</b>	<b>12,5</b>	<b>49,9</b>	<b>24,2</b>	<b>44,8</b>	<b>2,0</b>	<b>114,7</b>
<b>EQUITY</b>						
Sum Equity	10,1	49,9	24,3	44,8	2,0	114,8
<b>LIABILITIES</b>						
Liabilities to credit institutions	0,0	0,0	0,0	0,0	0,0	0,0
Total long-term liabilities	0,0	0,0	0,0	0,0	0,0	0,0
Liabilities to credit institutions	0,0	0,0	0,0	0,0	0,0	0,0
Accounts payable	2,0	0,0	0,0	0,0	0,0	0,0
Other liabilities	0,1	0,0	0,0	0,0	0,0	0,0
Accrued expenses and deferred income	0,3	0,0	0,0	0,0	0,0	0,0
Total current liabilities	2,4	0,0	0,0	0,0	0,0	0,0
<b>Sum Equity and Liabilities</b>	<b>12,5</b>	<b>49,9</b>	<b>24,3</b>	<b>44,8</b>	<b>2,0</b>	<b>114,8</b>
<b>Liquidity</b>						
Current ratio	5,1	n.m.	n.m.	n.m.	n.m.	n.m.
Cash ratio	4,9	n.m.	n.m.	n.m.	n.m.	n.m.
<b>Indebtedness and Solvency</b>						
Net debt (-)/ Net Cash (+)	11,6	49,4	23,7	44,3	1,4	114,2
Net debt/EBITDA	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.
Net debt/Equity	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.
Debt/Equity	23%	0%	0%	0%	0%	0%
Solvency ratio	124%	100%	100%	100%	99%	100%
<b>Return on capital</b>						
ROA	Neg.	Neg.	Neg.	Neg.	Neg.	98,3%
ROE	Neg.	Neg.	Neg.	Neg.	Neg.	98,3%
ROIC	Neg.	Neg.	Neg.	Neg.	Neg.	78,1%

Source: Company information and Carlsquare estimates.

## Cash Flow (SEKm)

	2020	2021	2022E	2023E	2024E	2025E
CF ongoing operations	-13,3	-14,5	-25,6	-40,5	-42,8	112,8
CF investment activities	-1,5	0,0	0,0	0,0	0,0	-0,1
CF financing activities	19,5	55,1	0,0	61,1	0,0	0,0
Cash flow for the period	3,5	37,8	-25,6	20,6	-42,8	112,7
Cash, beginning of period	8,4	11,9	49,7	24,1	44,6	1,8
Cash, end of period	11,9	49,7	24,1	44,6	1,8	114,5
<b>Key ratios</b>						
CF ongoing operations/ Net revenues	NaN	NaN	NaN	NaN	NaN	0,8
CF ongoing operations/ Total Assets	-1,1	-0,3	-1,1	-0,9	-22,0	1,0
Dividend per share (SEK)	0,00	0,00	0,00	0,00	0,00	0,00

Källa: Bolagsinformation och Carlsquare prognoser

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