

Clinical Laserthermia Systems

Sector: Medtech

Heating Up

With approvals already secured both in Europe and the US for its laser treatment of tumors, CLS offers significant long-term potential - particularly as recurring disposables will be its main source of sales. We view a 5% or higher market share in its cancer indications as achievable within 10 years, by when revenues should be up to SEK 1bn.

Unique treatment method

CLS was founded on the discovery that heat from laser beams not only destroys tumors locally, but also has the potential to stimulate the immune system to release antigens that attack similar cancer cells in other parts of the body. This led CLS to develop its TRANBERG® Thermal Therapy System, a mobile laser unit offering two minimally invasive treatments: imILT®, developed around its founder's research, and the well-known FLA/LITT.

New scanner opportunities

The new Thermoguide software that CLS expects to launch in Europe and the US late next year provides an integrated solution adapted to Siemens' Magnetom MRI scanners. We see good potential for CLS to adapt the TRANBERG® system to other leading suppliers' scanners, as well as scope to apply it in the neuroscience field.

Distribution deals starting to pay off

CLS's US distribution deal with MRI Interventions has already started to pay off this year. We look for further growth from the partnership following two initial orders totaling SEK 2.2m.

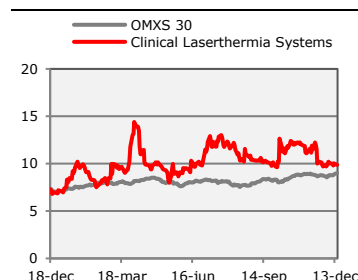
Potential catalysts in 2020

The CLS stock is trading with limited liquidity and high volatility. We believe that 2020 will include many interesting events and see the initiation of the proof-of-concept study in imILT®, the launch of TRANBERG® Thermoguide Software on the US and European markets as well as additional orders from the US as catalysts for the stock.

As Redeye is acting as Financial Advisor to CLS in connection with its rights issue, we present no research views on valuation ahead of and during the issue's exercise period, in line with general practice.

KEY FINANCIALS (SEKm)	2017	2018	2019E	2020E	2021E	2022E
Net sales	1	2	4	14	50	116
EBITDA	-21	-33	-42	-48	-30	-12
EBIT	-21	-33	-42	-49	-31	-12

CLS VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	CLSRb.ST
Market	First North
Share Price (SEK)	9.6
Market Cap (MSEK)	332
Net Debt 19E (MSEK)	4
Free Float	100 %
Avg. daily volume ('000)	69

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Investment Thesis

Minimally invasive tumor treatment

CLS has developed a system to treat cancer tumors through two thermal ablation methods, FLA/LITT and imILT®. Both are minimally invasive – indeed, patients treated with the proprietary and immune-stimulating imILT® should be able to leave hospital a few hours after treatment. We view this as a significant competitive advantage for CLS and see great potential in imILT®, although a larger proof-of-concept study is still needed to validate the method as safe and effective.

Exposed to growing market

While the global market for immunotherapies keeps growing and should be worth as much as USD 171bn by 2028, according to BIS Research, the indications that CLS focuses on (breast, pancreatic and prostate cancer) have a potential value of around EUR 2bn per year. We judge that CLS could achieve a 5-8% share of these markets within 10 years, giving potential sales of SEK 1bn.

Recurring revenues from disposables

The company's TRANBERG® system has been approved for sale in both Europe and the US, with the first sales made in 2017. Under its razor and blades model, the bulk of revenues will come from disposable products with high gross margins. We view this as a strong competitive advantage over many other medtech companies, whose revenue-generating product is the medical device.

Software launch to increase interest

The company's coming TRANBERG® Thermoguide Software should increase commercial interest in the TRANBERG® system. Over the longer term it also offers potential applications in the neuroscience field.

Catalysts ahead

An interesting and eventful 2020 ahead for the company should see it initiate the proof-of-concept study in imILT® and launch Thermoguide software in the US and Europe. These developments and additional orders from the US should provide catalysts for the stock.

Counter Thesis

Clinical trial challenges

CLS has to conduct a large proof-of-concept study with up to 100 patients to validate imILT® as safe and effective. Clinical trials are time-consuming, expensive and patient recruitment often takes longer than expected. Moreover, the company may fail to achieve its primary endpoint.

Highly competitive market

The global market for cancer therapies is highly competitive, with new drugs and treatments constantly in development. If imILT® fails to show efficacy benefits over established treatments, we expect it to struggle to gain market share.

Capital needs

Although CLS is already generating sales, we expect the company to remain unprofitable until 2023. Accordingly, it may need additional funding in the coming three years which may result in poor share price development

Company Description

Clinical Laserthermia Systems (CLS) is a Swedish medical technology company based in Lund, with subsidiaries in Germany and the US. The company develops thermal solutions to treat solid cancer tumors. CLS was founded in 2006 based on Professor Karl-Göran Tranberg's discovery that the heat from laser beams not only destroys tumors locally, but also has the potential to stimulate the immune system to release antigens that attack similar cancer cells elsewhere in the body. The company thus aims to treat patients suffering from metastatic cancer using this novel and unique treatment method.

CLS has developed TRANBERG® Thermal Therapy System, a mobile laser unit with monitoring capabilities and single-use products to treat solid cancer tumors. The TRANBERG® system uses two methods: immune stimulating interstitial laser thermotherapy (imILT®) and FLA/LITT. imILT® is a method based on Professor Tranberg's discovery while FLA/LITT is the commonly accepted method used for many years. CLS is currently focusing on validating the imILT® method and the TRANBERG® system via clinical trials. Since its inception, the company has entered into a several collaborations with hospitals around the world.

CLS's products have been granted both CE and FDA 510(k) approvals and have so far shown promising results in clinical trials. The company started to generate revenues in 2017 and has recently experienced increasing interest in its products in the US.

CLS currently has 12 employees, of whom nine work at the headquarters in Lund, one in Irvine, California and two in Berlin. The company went public in April 2009, listing its shares on Spotlight Stock Market (previously Aktietorget), and in March 2017, the shares were moved to Nasdaq First North.

History

CLS was founded in 2006 by Professor Karl-Göran Tranberg, Lars-Erik Eriksson (current CEO), and Pär Henriksson, based on Professor Tranberg's discovery that the heat from laser beams not only destroys tumors locally, but also stimulates the immune system to release antigens that attack similar cancer cells elsewhere in the body. Since its inception, CLS's vision has been to develop commercial products for use by oncologists around the world.

In 2007, CLS won Venture Cup Syd, a business plan competition designed to promote the realization of business ideas. Two years later, the company went public, listing its shares on Aktietorget (today Spotlight Stock Market) and also secured SEK 5m in a second round of funding.

In 2010, CLS presented its first prototype and also secured SEK 16m in a third round of funding. During the following two years, the company entered into several collaborations, and in 2013, CLS received CE approval for TRANBERG® | Cancer Immunotherapy System. Moreover, the company initiated its first clinical trial related to the development of treatment kits for outpatient use, and in 2014, it launched a treatment kit for percutaneous treatment of tumors located up to 35cm into the body. This was also the year when CLS applied for 510(k) approval, which was approved in 2015. Clinical trials of imILT® in pancreatic cancer were also initiated at Institut Paoli-Calmettes (Marseille, France) and University Hospital of Verona (Verona, Italy).

In 2016, CLS was granted SEK 20m as part of the EU initiative Horizon 2020, and the company also entered into a collaboration with the University of Texas Medical Branch relating to use of the TRANBERG® system within FLA/LITT. The following year, CLS received its first order as part of this collaboration and the first treatments with the system took place. CLS also acquired a German laser technology company, Laser- und Medizin-Technologie GmbH. In 2018, the company's extended patent application for imILT® was approved in the US, and CLS also received a CE certificate for FLA/LITT treatment with its TRANBERG® system in Europe. Another important event was the signing of a distribution agreement in the US with MRI Interventions.

In 2019, CLS signed an agreement with Siemens Healthineers, enabling a connection between TRANBERG® products and Siemens MRI Magnetom Scanners. Additionally, CLS received its first two orders as part of the distribution agreement with MRI Interventions, and in December, it filed for CE approval for its TRANBERG® Thermoguide Software.

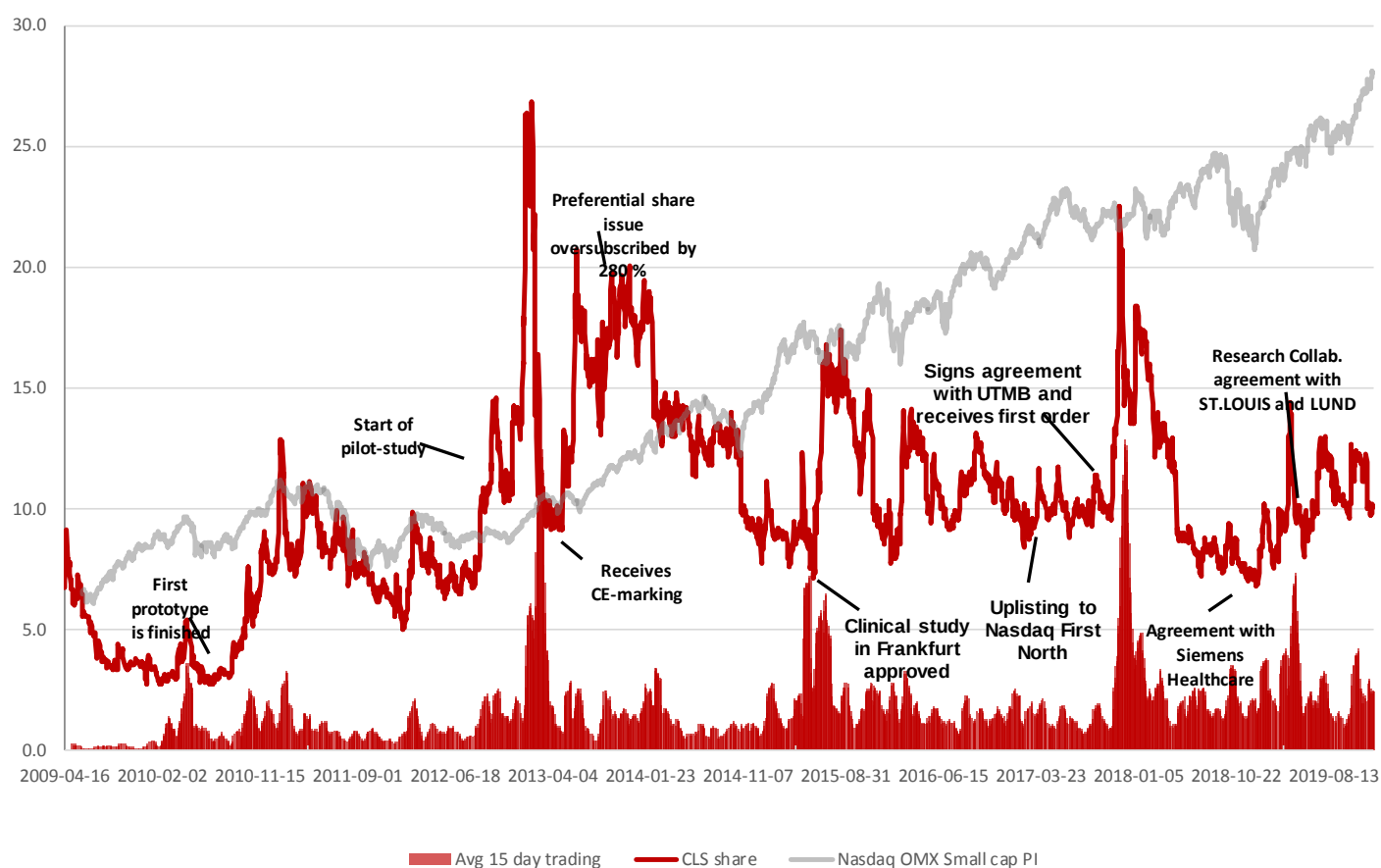
CLS - History of the company	
Year	
2006	- The company was founded by Karl-Göran Tranberg, Pär Henriksson and Lars-Erik Eriksson after Tranberg's scientific discovery.
2009	- The company was taken public on Aktietorget (now called Spotlight Stock Market). - Received funding of SEK 5m. - Successfully collected two patents on the Swedish market.
2010	- Received SEK 16m in a preferential rights issue. - Completed the first prototype.
2011	- Entered into new partnerships with the Spanish production partner, INTERmedic and an American laser fibre supplier.
2012	- INTERmedic produced CLS's first product. - Completed another round of funding, adding SEK 20m.
2013	- Received CE-marking for its TRANBERG system. - Launched its first clinical studies on supplementary treatment kits.
2014	- Launched treatment kit enabling percutaneous treatment of tumors. - Filed for 510(k) approval of TRANBERG and registered the subsidiary CLS Americas Inc.
2015	- Received 510(k) approval, allowing sales in the US.
2016	- Received SEK 20m in a grant from the EU Research and Innovation programme, Horizon 2020. - Completed its first post-market clinical follow-up report showing no significant side effects. - Entered into a cooperation with the Department of Radiology at the University of Texas Medical Branch (UTMB) for use of the TRANBERG system in FLA/LITT treatments.
2017	- UTMB placed its first order. - Announced up-listing to Nasdaq First North. - Received SEK 22m in share issue. - First treatments of prostate cancer using FLA/LITT were conducted. - Acquired the German company, Laser- Und Medizin Technologie GmbH providing CLS with important patents regarding the diffusion fibre technique. - Entered into collaboration with Swedish veterinary clinic to test the TRANBERG system on cancerous tumours in dogs.
2018	- Received approval for an extended patent application in the US. - Collected an extended CE certificate, permitting the use of TRANBERG in FLA/LITT treatments in Europe. - Collected SEK 61m in a preferential rights issue. - Received positive feedback from the FDA. - Signed important distribution agreement with MRI Interventions.
2019	- Signed agreement with Siemens Healthineers, enabling the connection between TRANBERG-products and Siemens MRI Magnetom Scanners. - Received two orders of SEK 0,7m and 1,5m from MRI Interventions regarding TRANBERG Laser Applicator Non-cooled.

Source: Redeye Research

Share Price Development

Since the IPO in 2009, the CLS share has seen a relatively flat development, with a few price jumps prompted by announcements of collaborations, study results, share issues, and regulatory approvals. Its liquidity has been fairly constant over the period, except for a few intervals with higher trade volumes.

Even though the last two years have included many interesting events, such as the signing of the distribution agreement with MRI Interventions and the collaboration with Siemens Healthineers, positive news have been neglected by rights issues and the share price has moved back to the same levels as before the positive announcements..



Products

TRANBERG®| Mobile Laser Unit

CLS has developed the TRANBERG® Mobile Laser Unit to provide medical professionals with high-precision, image-guided thermal therapy within oncology. The system is approved for soft tissue ablation, and the laser light and optical fiber applicators make it possible to use MR guidance as well as MR thermometry. The procedure is carried out without causing any disturbance to the surrounding tissue. In addition, the system has an integrated temperature system for precision in CT/US-guided procedures. The mobile unit consists of a computer with a touch screen, non-cooled laser applicators, as well as probe sensors and accessories specific to different indications.

Initially, TRANBERG® Mobile Laser Unit only supported imILT® treatments but CLS later decided to update it to support FLA/LITT treatments as well. This allows medical professionals to choose between the two treatment methods directly on the unit. The system has been designed to work solely with CLS's own products (fibers, inducer, and probe), making CLS the only alternative when it comes to purchasing disposable products. This facilitates the business model as the company can ensure recurring revenues once a unit has been sold. The disposable products are used regardless of treatment method and are sold as a kit. According to CLS, each kit is priced at approximately SEK 23,000 (EUR 2,200).



The TRANBERG® Mobile Laser Unit is sold in package including the following features:

- A compact, low-weight mobile laser unit
- Two integrated touch screens (19 inches)
- Options to control treatment power and time
- Ability to store patient information and procedure data
- Non-cooled laser applicators
- Radial and diffusing fiber technology that optimizes heat distribution in the tissue
- MR-compatible (3mm and 12mm) 15-gauge laser applicators
- A real-time feedback system that measures tissue temperature with external 17-gauge probes.

The list price of the laser unit is EUR 80,000–150,000, depending on if the system will be used in a MR setting or not, with the lower price range being outside MR and the higher range in an MR environment. However, we find it likely that units can be leased or, in some cases, provided to clinics for free since the company aims to generate sales mainly by selling the corresponding disposable products with high gross margins.

TRANBERG®| Laser Applicator Kit

As part of a razor and blades strategy, the lion's share of CLS's revenues will come from sales of the laser applicator kit. The laser applicator kit includes 3mm and 12mm non-cooled laser applicators, supporting MRI and almost all other kinds of image guiding. The fiber technology developed by CLS optimizes heat distribution in the treated tissue and eliminates the need for external cooling. This reduces the treatment time, which is a key benefit compared with competing products.

The introducers offer high precision when positioning the laser applicator using an image-guided percutaneous access technique. This can also be used in open surgery. The integrated feedback system provides the operator with real-time tissue temperature and the system supports simultaneous use of up to 6 sensors, which enhances temperature mapping in the treated area while also monitoring surrounding sensitive areas.



Source: CLS

The applicator kit includes three disposable products:

- **Probe**
During treatments, the probe measures the temperature in the tissue with high accuracy. At least one probe has to be used in every treatment in order to monitor temperature and to control the laser power and treatment time.
- **Laser applicator with an introducer**
The introducers offer accurate positioning of the fiber based on where the tumor is located, its size, and the access techniques. They allow for both minimally invasive treatments and open surgery.
- **Fibers**
Fibers are used to avoid burning the surrounding tissue when treating a patient with laser ablation. CLS has developed its own fibers, which it says are easier to use. These are designed for larger tumors (up to 1,600 mm²). The fibers have also been developed to fit systems other than TRANBERG®, offering additional sales potential.

CLS's fibers can be either radial or diffuse. When using a radial fiber, the laser beam is sent out radially and has a lower effect, making these fibers more suitable for treating smaller tumors. The diffuse fibers, on the other hand, send out the laser beam at a higher effect, making them more suitable for treating larger tumors. These products are used regardless of treatment method and are only sold as a kit. According to CLS, each kit is priced at approximately SEK 23,000 (EUR 2,200) and we expect a long-term gross margin of around 80%.

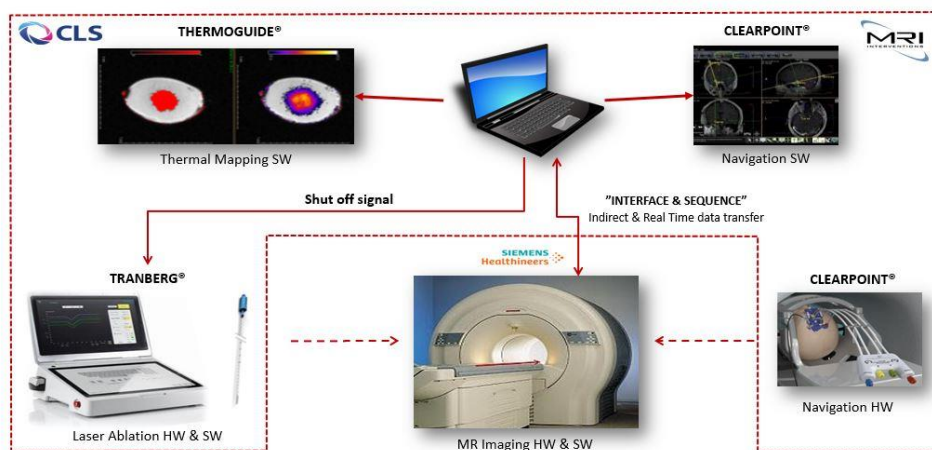
TRANBERG®| Thermoguide Software

CLS has announced that it will soon launch a new software called TRANBERG® Thermoguide Software in collaboration with Image Guided Therapy SA and Siemens Healthineers. The software will be integrated into the TRANBERG® system and is being developed to provide real-time tissue temperature and cell damage calculations, making the monitoring procedure safer and more accurate. The software accesses scanner sequences with minimal latency and provides the operator with guidance in choosing treatment size and margin. It is also intended to minimize the risk of damaging surrounding tissue, which renders the treatment safer.

The intention with the software is to provide hospitals with the ability to use the same one supplier for most of the products needed and to optimize the workflow. Through collaboration agreements with Image Guided Therapy and Siemens Healthineers, CLS can provide an integrated solution adapted to Siemens' generation of MRI Magnetom scanners. We believe there is great potential for CLS to further adapt the TRANBERG® system to MR scanners from other market-leading suppliers in the future.

According to CLS, the software will include the following features:

- Presentation of tissue temperature (graphically)
- Presentation of the calculated tissue damages (graphically)
- A function to choose maximum/minimum temperature
- Movement compensation
- An integrated laser unit control to adjust time and power
- Automatic alignment of the imaging plane
- Workflow assistance.



Source: CLS

Expected launch in 2020

CLS filed for CE approval for the software in December 2019 and we expect to see market approval in H1 2020. The company is also planning an FDA filing, but this has been slightly delayed, partly due to the company's ambition to establish the TRANBERG® system within neuro treatment, a new application area for CLS. However, we believe that it will make an FDA filing in early 2020 and that the software will be launched in both Europe and the US in late 2020 or during the early months of 2021. We believe that the Thermoguide software will increase the interest for the TRANBERG® system and expect the launch to be a key catalyst for the stock.

Patents

CLS has currently one Swedish, two European, one Chinese, one Australian, and two US patents. These focus on various innovative functions of the design and control of the heat probe, as well as the monitoring of tissue effect. Additionally, the patents have been strengthened by applications and approval of so-called departmental patents in the US, China, and Europe focusing on imiLT® treatment protocols. We show the scope of protection for the patents in the table below.

Number	Description	Regions of approval	Pending regions	Year of filing	Year of expiry
SE532142C	Device for determining thermal properties of a tissue	SE		2007	2027
EP 2532319 B1	Divided application to EP2532319A1	EP, DE		2008	2028
US 8,753,381 B2	Apparatus and methods for determining the property of a tissue	US		2007	2031
US 9,884,201	Divided application to US 8,753,381 B2	US		2007	2031
EP2192868 A4	Apparatus and methods for determining the property of a tissue	EP,DE		2007	2028
201510108207.5	Apparatus and methods for determining the property of a tissue	CN	HK	2007	2028
PCT/EP2014/058934	Apparatus and Method For Controlling Immunostimulating Laser Thermotherapy	EP	AU,BR,CN,JP,KR, US	2013	2033

Source: Redeye Research and CLS

We believe that CLS has a strong patent portfolio protecting its products and methods. This leads us to believe it can keep its potential competitors at bay in the coming years, providing a good window of opportunity within its targeted indications.

Market Opportunity

The second-largest cause of death

According to the World Health Organization (WHO), cancer is the second-largest cause of death globally, with almost 10 million deaths (~17% of all deaths) per year as of 2018. 18 million people were diagnosed with cancer globally in 2018 and the WHO expects this number to rise to 23.6 million by 2032. The most common indications in men are colorectal, stomach, lung, prostate, and liver cancer, while cervix, colorectal, lung, breast, and thyroid cancer are the most prevalent indications among women.

Incidence and mortality

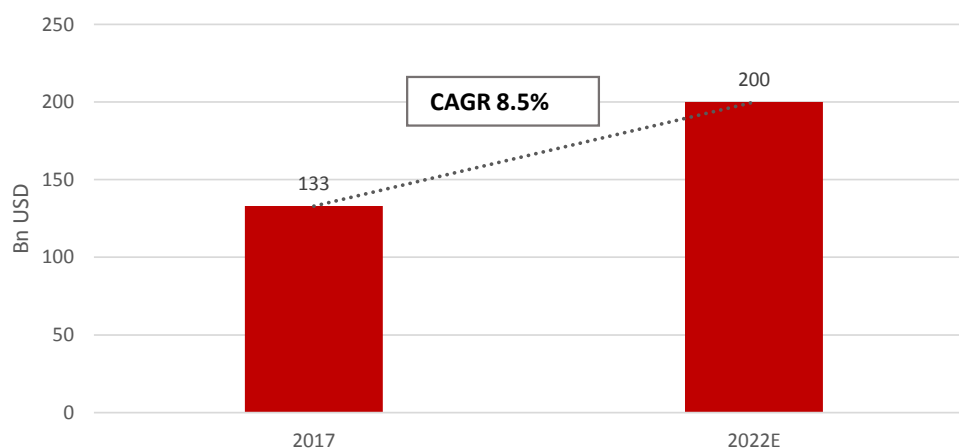
	Incidence						Mortality					
	Both sexes			Males			Both sexes			Males		
	New cases	Cum. risk 0-74 (%)	New cases	Cum. risk 0-74 (%)	New cases	Cum. risk 0-74 (%)	Deaths	Cum. risk 0-74 (%)	Deaths	Cum. risk 0-74 (%)	Deaths	Cum. risk 0-74 (%)
Eastern Africa	332 177	13.47	129 476	11.56	202 701	15.20	230 968	10.21	94 731	8.89	136 237	11.40
Middle Africa	95 735	10.86	41 407	10.62	54 328	11.23	68 763	8.30	30 852	8.01	37 911	8.66
Northern Africa	283 219	14.27	134 627	14.69	148 592	13.94	178 754	9.39	96 874	10.64	81 880	8.22
Southern Africa	114 582	19.93	50 814	22.35	63 768	18.54	61 670	11.33	30 106	13.54	31 564	9.84
Western Africa	229 459	11.42	90 232	10.10	139 227	12.72	153 332	8.26	63 968	7.36	89 364	9.14
Caribbean	111 933	20.23	57 728	22.41	54 205	18.28	63 075	10.42	34 354	11.69	28 721	9.29
Central America	256 782	14.70	115 751	14.53	141 031	14.90	119 168	6.86	57 609	6.83	61 559	6.89
South America	1 044 017	20.56	509 014	22.40	535 003	19.12	490 515	9.51	253 762	10.79	236 753	8.43
North America	2 378 785	33.13	1 274 306	36.25	1 104 479	30.31	698 266	9.64	367 738	10.82	330 528	8.58
Eastern Asia	5 622 367	21.54	3 108 655	24.23	2 513 712	18.91	3 456 734	12.88	2 136 217	16.36	1 320 517	9.35
South-Eastern Asia	989 191	15.29	478 093	16.33	511 098	14.52	631 190	10.14	345 482	11.95	285 708	8.57
South-Central Asia	1 739 497	10.26	859 799	10.57	879 698	10.02	1 167 183	7.22	619 488	7.84	547 695	6.62
Western Asia	399 877	17.51	210 004	19.94	189 873	15.55	221 957	10.17	130 276	12.75	91 681	7.81
Central and Eastern Europe	1 240 057	24.95	612 026	29.43	628 031	21.98	699 446	13.84	385 301	18.83	314 145	10.16
Western Europe	1 370 332	31.24	752 802	34.94	617 530	27.73	548 355	10.99	307 423	13.28	240 932	8.82
Southern Europe	933 181	27.55	516 339	31.78	416 842	23.72	422 054	10.60	246 579	13.53	175 475	7.91
Northern Europe	686 092	30.44	366 351	33.07	319 741	28.01	273 623	10.32	146 289	11.58	127 334	9.14
Australia and New Zealand	233 773	41.53	140 821	49.06	92 952	33.28	59 247	9.39	33 374	10.75	25 873	8.07
Melanesia	15 379	20.05	6 840	20.76	8 539	19.78	9 257	13.07	4 375	13.94	4 882	12.48
Polynesia	1 539	23.68	805	26.56	734	21.05	838	13.08	472	15.52	366	10.77
Micronesia	983	18.93	528	21.29	455	16.48	632	11.99	370	14.56	262	9.44
Low HDI	672 218	11.79	270 241	10.52	401 977	13.02	464 569	8.80	196 682	7.92	267 887	9.66
Medium HDI	2 828 475	11.94	1 364 853	12.30	1 463 622	11.67	1 861 723	8.21	984 221	9.08	877 502	7.42
High HDI	6 515 063	19.97	3 476 436	22.24	3 038 627	17.88	4 020 422	12.36	2 425 680	15.46	1 594 742	9.34
Very high HDI	8 054 578	29.05	4 340 394	32.72	3 714 184	25.88	3 204 212	10.52	1 776 814	12.81	1 427 398	8.47
World	18 078 957	20.20	9 456 418	22.41	8 622 539	18.25	9 555 027	10.63	5 385 640	12.71	4 169 387	8.70

Source: Redeye Research and Globocan

A disease with a huge economic impact

Cancer has a huge and constantly increasing economic impact on society; the cost burden of the disease was approximately USD 1.16 trillion in 2010. The majority of cancer-related deaths (~70%) take place in low- and middle-income countries, partly because only 20% of these countries have sufficient data and statistics to drive cancer policy.

Global spending on cancer treatments

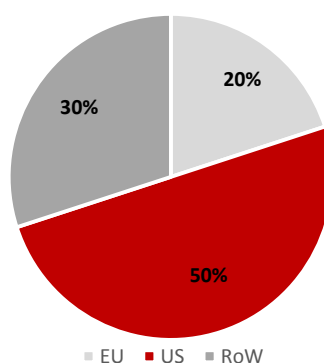


Source: PwC and Redeye Research

PwC estimates global spending on cancer treatments and care at USD 133bn in 2017 and expects this to increase to USD 200bn in 2022. This means that cancer-related treatments are expected to account for approximately 14% of total medical expenditure globally in 2022.

In 2017, US spending accounted for 46% of the total global spending, while Europe accounted for 20%. Furthermore, the US market is expected to account for approximately 50% in 2022, with the European market growing at a slower pace and still accounting for 20% of the total global spending.

Sales by region 2022E



Source: Redeye Research and IQVIA

Higher incidence in Europe and Asia

Geographically, Europe and Asia have higher incidence than the US. Around 15% of all new cases reported are in the US, while the corresponding numbers for Europe and Asia are approximately 25% and 50%, respectively. Of course, this is partly because Asian countries account for almost half of the total world population. However, the mortality rate is also higher in Asia. As of 2018, around 60% of all cancer-related deaths occurred in Asia, while Europe and North America accounted for around 20% and 8%, respectively. Given these factors, there will be huge potential for innovative and effective cancer treatments in the Asian markets in the coming years.

Immuno-oncology – a growing area

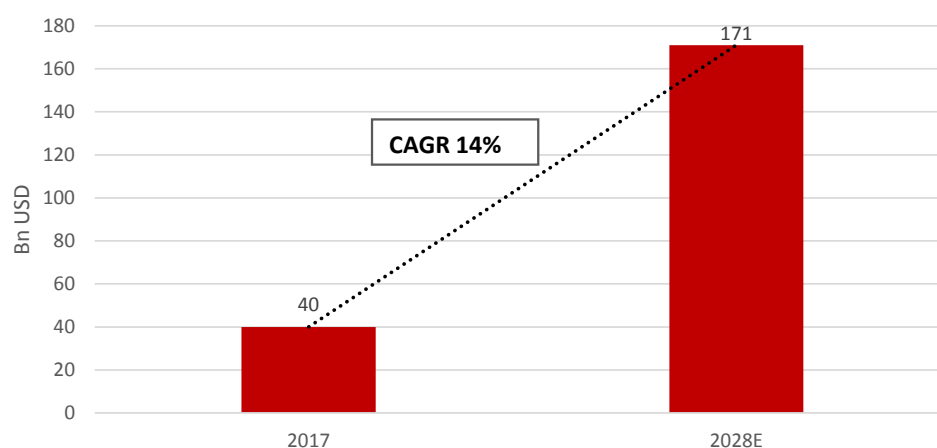
Even though oncology remains a challenging area, there have been many improvements over the last couple of years. One of the most interesting and fastest-growing areas within oncology treatment is immuno-oncology. The immune system is constantly assessing foreign compounds in the body and eliminating those it deems dangerous. Cancer treatments that are developed around this knowledge focus on stimulating the immune system to find, attack, and kill cancer cells within the human body. Immunotherapies can be used in both palliative and curative treatments and can be active, passive, or a combination of the two. Active treatment means that the immune system is directed to attack cancer cells by targeting antigens on the tumor, while passive treatment focuses on reinforcing already existing responses. Passive immunotherapies include the use of monoclonal antibodies, cytokines, and lymphocytes.

A market with huge potential

There is significant risk related to immunotherapies owing to the chance that the immune system not only attacks cancer cells, but also healthy cells and organs. Many clinical trials are currently being conducted to evaluate immunotherapies, and several therapies have been approved in recent years. When immunotherapies are proved safe and effective, patients tend to live longer than those on other treatments. European countries and the US have therefore been eager to implement these treatments, and the number of uses is constantly increasing.

BIS Research values the immunotherapy market at approximately USD 40bn for 2017 and expects it to be worth USD 171bn by 2028, implying a CAGR of 14% over this period.

Global immunotherapy market



Source: Redeye Research and BIS Research

Increasing demand for high-quality products

Technological improvements and better use of information are factors likely to drive further growth over the coming years, including improvements in drug development and better and more effective medical devices. Increasing demand for high-quality and innovative medical devices is thus likely in the coming years. Given the above, we believe there are good opportunities ahead for CLS and its TRANBERG® products.

Scientific Background

Hyperthermia treatments within oncology

Hyperthermia treatments take body temperature to a higher-than-normal level through a controlled procedure. Cells in the human body exposed to higher temperatures than normal undergo changes, making them more prone to be affected by external factors, such as different kinds of therapies. Very high temperatures can kill cells, but they also affect surrounding tissue. Hyperthermia treatments thus need to be controlled and conducted by medical professionals. Hyperthermia treatments can be divided into three subgroups: *local hyperthermia*, *regional hyperthermia*, and *whole-body hyperthermia*.

Local hyperthermia

When using local hyperthermia, a small area, such as a tumor, is heated with the intention of killing the cancerous cells. Treatment with very high temperatures is called thermal ablation and can be performed using different kinds of energy sources, such as microwaves, radio waves, laser beams, or ultrasound waves. Two commonly used methods to distribute the heat towards a tumor are either to send out high-frequency waves through an external device outside the body or to put a thin needle or probe into the tumor and then send out waves or laser beams via the probe.

Two well-known and commonly used methods of local thermal ablation are radio frequency ablation (RFA) and focal laser ablation (FLA/LITT). RFA is the most commonly used method. High energy waves are sent out towards the tumor via a probe for 10-30 minutes. The probe finds the tumor using ultrasound, CT scans, or MRI and then heats up cells within the targeted area. Following treatment, the dead cells become scar tissue and shrink after some time. RFA is commonly used on patients with tumors that cannot be removed with surgery or when surgery is not appropriate for other reasons. However, it can also be performed as a complement to surgery or other treatment methods, such as chemotherapy and radiation therapy. RFA can be used to treat tumors up to 5 cm across and for indications with solid tumors. Even though the long-term effects of RFA have not been determined, early results are promising. With FLA/LITT, the tumor is killed by heating it with laser beams sent via a probe that is inserted into the tumor.

Regional hyperthermia

Regional hyperthermia is performed by heating up a larger part of the body, for instance an organ. When treating such a large part of the body, the raised temperature is not sufficient to kill the cancer cells, but it weakens them and makes them susceptible to other treatments. Regional hyperthermia is often combined with radiation therapy or chemotherapy. One form of regional hyperthermia treatment is deep tissue hyperthermia, where specific devices are placed on the surface of the organ and send out high-frequency waves (microwaves or radio frequency waves) towards the targeted area until it heats up to the desired temperature.

Whole-body hyperthermia

Whole-body hyperthermia is intended as a complement to chemotherapy when treating metastatic tumors. The body temperature is raised using thermal chambers, warm-water immersion, or heating blankets. In some cases, patients who undergo this therapy receive light anesthesia to calm them. According to many researchers in the area, raising the body temperature makes cells more active and also increases the level of cell-killing compounds in the blood.

A promising area

Key opinion leaders and scientists agree that hyperthermia treatments are interesting and promising methods to treat cancer, especially in combination with other clinically accepted treatment methods, such as chemotherapy. Moreover, there is consensus that hyperthermia treatments work best if the treated area is maintained at a constant temperature range for a specific period of time, a factor that has posed a big challenge for many years. Measuring tumor temperature and keeping the surrounding tissue area unaffected is difficult. Some types of tissue are more sensitive to heat than others, meaning high demand for accurate temperature feedback systems (MRI) as well as for high-quality probes and disposable products. We consequently believe that CLS has a great opportunity in this area and we see good potential for the company going forward.

imILT®

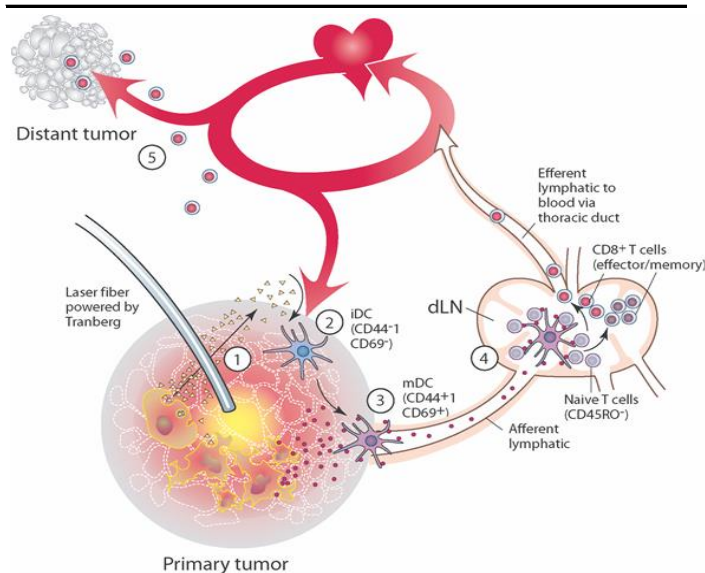
A unique treatment method

imILT® is the treatment method developed by CLS based on Professor Tranberg's discovery that the heat from laser beams not only destroys tumors locally, but also stimulates the immune system to release antigens that attack similar cancer cells in other parts of the body. imILT® is designed to kill solid cancer tumors while also to elicit an immunological defense against any remaining tumor cells, even those located outside or far from the treated area.

Stimulating the immune system

The treatment is carried out by inserting an optical laser fiber into the tumor. A laser light then heats the tumor up in a gentle and controlled manner, slowly killing it, usually over the next few days. As the tumor is heated up, anti-genes that stimulate the body's immune system are leaked from the cells of the tumor, triggering the immune system to attack other tumors and metastases in the body.

imILT overview



Source: CLS

Treatment at a lower temperature

Classic laser ablation, such as FLA/LITT, heats the whole tumor to at least 60°C to coagulate the tissue in the area, whereas imILT® is a local ablation method that works at non-coagulating temperatures, heating the tumor to a mere 46°C. This temperature is maintained for around 30 minutes, resulting in immunogenic cell death (ICD) at the tumor border. A damage-associated molecular pattern signals the body to produce antigens. These trigger an immune response, targeting similar tumor cells in other parts of the body. The method can be used to fight several types of cancer, such as prostate, breast, liver, pancreas, skin, lung, kidney, and prostate cancer. However, some types of cancer are considered more responsive than others. CLS is currently focused on proving the efficiency of the method in pancreatic and breast cancer, and interest in the method is increasing.

On July 1, 2019, CLS entered into a collaboration with Hospital da Luz, a private cancer clinic in Aveiro, Portugal, for treatment of solid cancer tumors using imILT®. The treatments will be performed under the guidance of Dr. Belarmino Gonçalves, who has experience in conducting clinical studies on imILT® treatment with the TRANBERG® system in pancreatic cancer.

The global addressable population for imILT® is estimated by CLS at approximately 8 million patients, while the US and European markets account for around 560,000 patients. According to CLS, this corresponds to a total annual market potential of SEK 9,200-14,700m (EUR 880-1,400m). The company's long-term ambition is to obtain a share of 5-8% of the global addressable market.

FLA/LITT

A clinically accepted treatment method

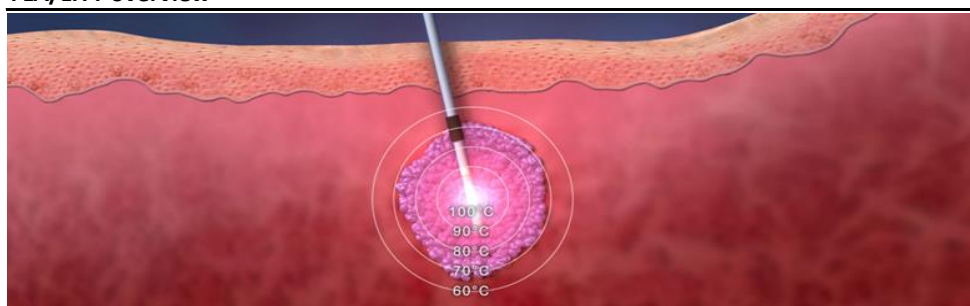
FLA/LITT is a clinically accepted treatment method, based on the same technique as imILT®. Focal therapy of tumors is an evolving treatment strategy that destroys the region harboring the clinically significant disease. Although long-term control is yet to be demonstrated, it has been shown to be associated with less treatment-related morbidity. A beam of electromagnetic radiation emitted from a laser heats the targeted tissue area for a short period to destroy the local tumor. However, this does not trigger the immune system, unlike imILT®. CLS's intention is to provide FLA/LITT treatments through its TRANBERG® system to treat early-stage prostate cancer in patients with local tumors that are too small to be removed by surgery. The market for prostate cancer in the US and Europe was valued by Research and Markets at USD 9.3bn in 2018 and is expected to reach USD 12.8bn in 2028.

Two treatment methods in one system

CLS provides minimally invasive imILT® and FLA/LITT treatments with short recovery time using its TRANBERG® system. With imILT®, the patient can, in some cases, leave the hospital just a couple of hours after treatment. We see this as a significant competitive advantage for CLS, offering good potential for the company over the coming years.

FLA/LITT treatment of early-stage prostate cancer with the TRANBERG® system is currently being studied at Toronto General Hospital, Canada. The study of 25 patients was initiated by the hospital. It is expected to be completed in 2022 and we believe the results could provide a good reference for CLS in future negotiations.

FLA/LITT overview



Source: CLS

Potential in combination with other treatments

As well as being used as stand-alone treatments, imILT® and FLA/LITT offer good potential in combination with other cancer therapies, we believe. CLS has recently entered into an agreement with Immunophotonics to conduct a clinical phase Ib/IIa study with the drug candidate IP-001. CLS's role is to provide the TRANBERG® system and associated disposable products. The study is interesting as it can provide evidence for imILT® as a combination treatment, which could bring new opportunities.

Even though we consider this partnership very interesting, we do not expect any significant revenues to be generated from it in the near future.

Business Strategy

Razor and blades

CLS has adopted a razor and blades strategy with the majority of revenues coming from sales of disposable one-time applicator kits. Thus, the company is focusing on generating recurring revenues. We believe that this is relatively unknown to many investors and see the business model as a competitive advantage compared to many other medtech companies, whose medical device is the revenue-generating product.

CLS says the disposable kits are priced at EUR 2,200, a level that relates to the health and economic benefits of imILT® and FLA/LITT treatment. Given this, they can be considered premium products with significant benefits for healthcare providers treating solid cancer tumors. The targeted customer group is hospitals providing cancer treatments, and the company is currently conducting clinical trials to prove the efficacy of the imILT® method and the TRANBERG® Laser Unit.

Business model



Recurring revenue

- Disposable treatment kits ensures a stable and recurring revenue of EUR 2,200 for each treatment
- Additional recurring revenue is generated via post-purchase technical services and fiber technology sales



Securing adoption

- Recurring sales from single-use products allows the system at financially favorable deals
- The TRANBERG® mobile laser units can be either sold, leased or financed by single-use product pricing structure



Targeted customers

- The targeted customers consist of hospitals and clinics involved in multidisciplinary cancer treatment
- CLS' products are marketed to medical specialists in surgical and interventional oncology

Source: CLS

CE and 510(k)

CLS aims to sell its products on the global market for cancer treatment. It received CE approval in 2013 and FDA 510(k) approval in 2015, meaning it can sell its TRANBERG® products in Europe and the US. However, selling medical technology products is difficult. A new company needs to generate interest and trust among decision-makers, which requires good clinical evidence. Treatment with imILT® is not yet covered by insurance companies, meaning it will be costly for patients who wish to undergo treatment with this method. To deal with this, CLS aims to create interest among key opinion leaders within oncology and to establish reference centers for the imILT® treatment solution, to help it gain traction. Once imILT® treatment costs start to be fully reimbursed, we expect to see a significant sales increase.

Local sales organizations and distribution partners

CLS's strategy is to sell its products through local sales organizations or distribution partners in Europe and the US. The company currently has its headquarters in Lund, Sweden, with subsidiaries in Irvine and Berlin. We consider this a good approach since selling medical technology products usually requires lengthy and thorough negotiations. Building a good relationship with customers is highly important and so local sales organizations are a widely used strategy. Since 2018, CLS has been collaborating with MRI Interventions on distribution in the US, and this collaboration started to generate revenues during 2019.

CLS has now received two orders amounting to a total value of SEK 2.2m as part of the collaboration and we expect to see further moves in 2020.

Future potential in Asia

Although CLS currently only operates on the European and US markets, we see good potential for it to enter the Asian markets in the future. According to the company, the Chinese, South Korean, and Japanese markets are of particular interest. Its sales strategy will likely be to work with local sales and distribution partners. However, we believe potential geographical expansion will begin in 2023. CLS first has to complete its clinical trials in order to validate the imILT® method and the TRANBERG® products.

Clinical Evidence

Clinical trials at five locations

In previously conducted studies, imILT® has been demonstrated as both safe and controllable in destroying tissues. imILT® was developed to achieve the maximum abscopal effect using heat from laser beams. The method has been thoroughly studied preclinically and is currently undergoing clinical studies in Europe.

Clinical trials		
Title	ClinicalTrials.gov Identifier	Location
Percutaneous Immunostimulating Interstitial Laser Thermotherapy in Pancreatic Cancer	NCT03187587	Portuguese Oncology Institute of Porto Porto, Portugal
Immunostimulating Interstitial Laser Thermotherapy in Pancreatic Cancer	NCT02973217	Institut J. Paoli et L. Calmettes (IPC) Marseille, France
Safety and Feasibility of imILT Locally Advanced Pancreatic Cancer (LAPC)	NCT02702986	University of Verona Hospital Verona, Italy
Intratumoral Injection of IP-001 Following Thermal Ablation in Patients With Advanced Solid Tumors.	NCT03993678	Kantonsspital Graubünden Chur, Switzerland, Centre hospitalier universitaire vaudois CHUV Lausanne, Switzerland and Kantonsspital St. Gallen St. Gallen, Switzerland

Source: Redeye Research and [Clinicaltrials.gov](https://clinicaltrials.gov)

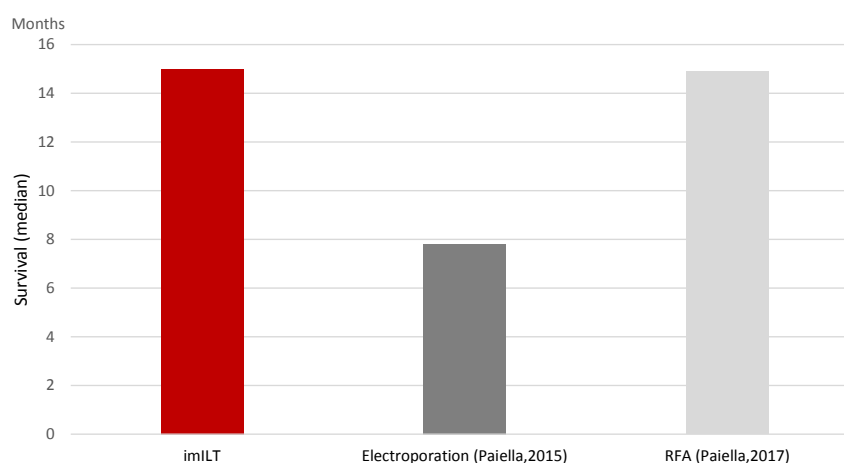
The pre-clinical studies showed that a temperature of 46°C in the periphery of a tumor provided greater abscopal effects than higher temperatures, while lower temperatures failed to cause complete tumor destruction during appropriate treatment times. However, using a temperature of 46°C requires a longer treatment time (~30 minutes) than other ablative methods.

In pre-clinical trials using a rat model, abscopal effects could be observed when treating colorectal cancer in the liver and the degree of metastasis was decreased compared to surgery. Moreover, intra-tumoral infiltration of cytotoxic T lymphocytes and macrophages in tumors in other parts of the body could be observed.

Horizon 2020

In 2016, CLS was granted SEK 20m in funding from the EU initiative Horizon 2020, which included clinical studies in pancreatic cancer at Institut Paoli-Calmettes (Marseille, France) and Portuguese Institute of Oncology (Porto, Portugal), plus clinical studies in breast cancer at Nottingham University Hospital (Nottingham, UK). The first report from the trials (released on November 30, 2018) showed that of the seven patients treated, five had a median overall survival rate of 17 months. This can be compared to other treatment methods where the median overall survival rates have been less than 12 months. In addition, only one serious adverse event has been reported, which is in line with other laser ablation and local ablative treatment methods.

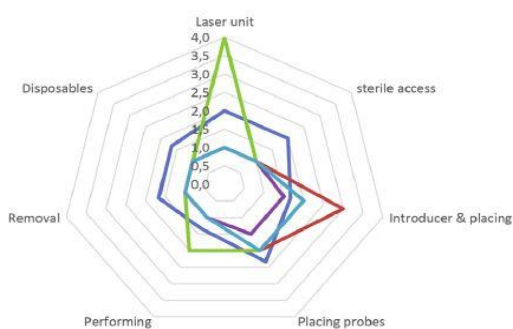
Overall survival rates



Source: CLS

During the clinical trials, the usability of the TRANBERG® Mobile Laser Unit has been evaluated (see below). A score of 1 means "easy", while a score of 4 means "difficult".

TRANBERG usability



Source: CLS

A safe and effective treatment method

Both pre-clinical and clinical results show that the imILT® method is safe and can be performed in a controlled manner. However, the results have not been statistically significant since the number of treated patients has been low. To overcome this issue, CLS is currently planning a larger proof-of-concept clinical trial including up to 100 patients, which is expected to start in late 2020. This study will be very important for the company to further validate the effect and safety of imILT® and we expect the initiation of the study to be a key catalyst for the stock.

Indications

Even though imILT® has potential in many cancer indications (such as pancreas, breast, lung, skin, liver, kidney, and prostate), we choose to only include breast and prostate cancer in our modelling, since these are the indications where CLS has ongoing clinical trials and has signed letters of intent with hospitals. As there is potential in other indications, we include these in our bull case only. For FLA/LITT, we only include early-stage prostate cancer as it is the company's only targeted indication with this treatment type in the US.

Indication	No. Patients (imILT)	Potential market value (SEKm)
Breast cancer	193,000	4,458
Pancreatic cancer	60,000	1,386
Lung cancer	175,000	4,043
Liver cancer	10,000	242
Malignant melanoma	18,000	420
Kidney cancer	28,000	651

Source: CLS and Redeye Research

Breast cancer

According to the WHO, around 2 million patients in the world are diagnosed with breast cancer every year and the indication accounts for approximately 15% of all cancer-related deaths among women. The global market for breast cancer treatments was valued at around USD 18bn in 2018 and is expected to reach USD 39bn by 2026, representing a CAGR of 10.2%. According to CLS, the targeted population for imILT® treatment on the European and US markets is 193,000 patients, which corresponds to market potential of approximately SEK 4.5bn.

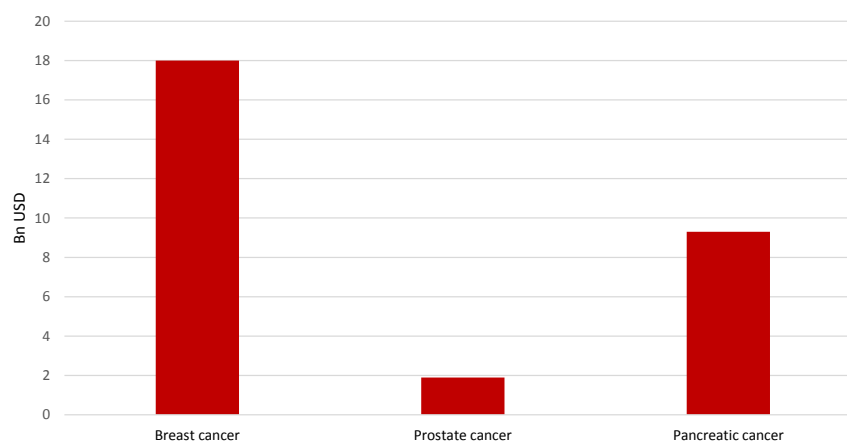
Pancreatic cancer

Pancreatic cancer is the seventh most common cause of cancer-related death globally, with 432,000 deaths in 2018. Around 460,000 patients globally are diagnosed with pancreatic cancer every year and the five-year survival rate is only 9%. The global market for pancreatic cancer treatments was worth USD 1.9bn in 2018 and is expected to reach USD 4.7bn by 2026, implying a CAGR of 10.6%. According to CLS, the target population for imILT® in Europe and the US is 60,000 patients, corresponding to market potential of roughly USD 1.4bn annually.

Prostate cancer

Prostate cancer is the fifth most common cause of cancer-related death globally and the second most common cancer diagnosis made in men. Globally, around 1.3 million new patients were diagnosed in 2018, while 360,000 people died from the disease. The global market for prostate cancer was valued at USD 9.3bn in 2018 and is expected to reach USD 12.8bn by 2028, which represents a CAGR of 3.3%. According to CLS, the target population in Europe and the US is 400,000, corresponding to market potential of SEK 9.2bn annually.

Global sales per indication 2018

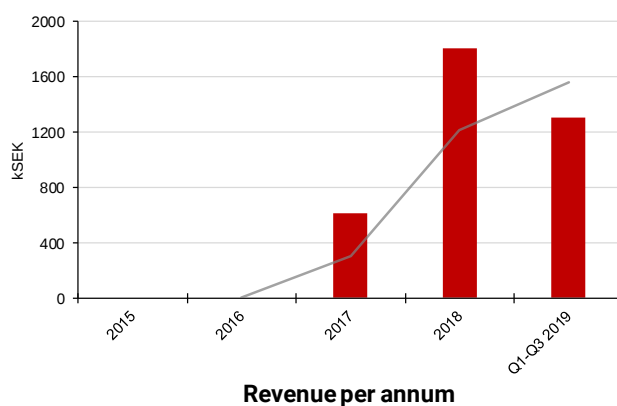
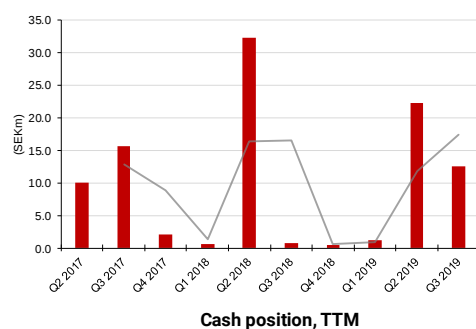
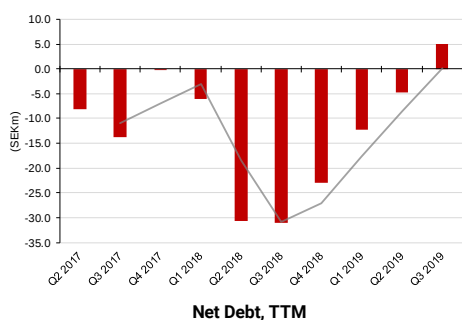
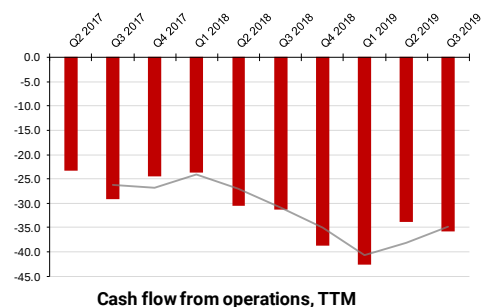
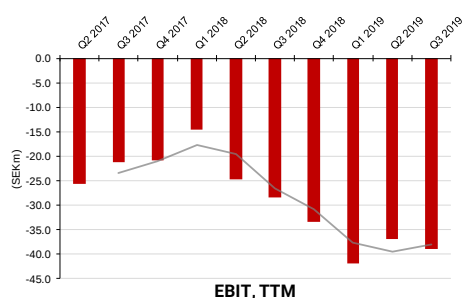


Source: Redeye Research

Neuroscience

CLS is constantly working to find new areas of application for its products and to improve its offering. Recently, the company presented scientific records in the neuroscience field where the TRANBERG® Thermal Therapy System and new TRANBERG® Thermoguide Software (expected launch in late 2020) had been used for tests performed on sheep brains. The conducted tests showed that fiber optics are also suitable for use in brain tissue, which we consider very interesting since it brings opportunities in a new area of treatment for the company. The results imply that CLS, together with MRI Interventions, can begin to plan for further trials in this field of application. However, given the early stage of research, we do not include neuroscience in our valuation of CLS for now. We will evaluate the potential further once more information has been released.

Financials



First sales generated in 2017

CLS generated its first sales in 2017 and is currently not generating profits because of its focus on establishing its products on the market and owing to the ongoing clinical trials intended to validate imILT®. Both EBIT and cash flow from operations have been negative since the company's inception and are likely to remain so in the coming three years.

In need of external capital

CLS has historically had a cash burn rate of around SEK 2m per month. In recent years it has used rights issues to address its liquidity need. This has caused the share price to remain at the same levels, even though many positive news have been announced. As of September 30, 2019, CLS had a cash position of SEK 12.5m, meaning it is in need of external financing. We expect the capital being raised in the current rights issue will finance the coming proof-of-concept study and the market launch of TRANBERG® Thermoguide Software in Europe and the US.

Forecasts

As mentioned above, we choose to only include breast and prostate cancer in our modelling, since these are indications where CLS has ongoing clinical trials and has signed letters of intent with hospitals. For FLA/LITT, we only include early-stage prostate cancer as it is the company's only targeted indication for this treatment type in the US.

FLA/LITT	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
No of patients	400,000	408,000	416,160	424,483	432,973	441,632	450,465	459,474	468,664	478,037	487,598	497,350
Growth (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Price per treatment (SEK)	23,100	23,562	24,033	24,514	25,004	25,504	26,014	26,535	27,065	27,607	28,159	28,722
Growth (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Market value (mSEK)	9,240	9,613	10,002	10,406	10,826	11,264	11,719	12,192	12,685	13,197	13,730	14,285
Penetration	0.03%	0.15%	0.50%	0.80%	1.00%	1.20%	1.40%	1.80%	2.30%	2.70%	3.00%	4.00%
Sales (mSEK)	2.8	14.4	50.0	83.2	108.3	135.2	164.1	219.5	291.7	356.3	411.9	571.4
imILT	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E	2027E	2028E	2029E	2030E
<i>Breast cancer</i>												
No of patients	193,000	196,860	200,797	204,813	208,909	213,088	217,349	221,696	226,130	230,653	235,266	239,971
Growth (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Price per treatment (SEK)	23,100	23,562	24,033	24,514	25,004	25,504	26,014	26,535	27,065	27,607	28,159	28,722
Growth (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Market value (mSEK)	4,458	4,638	4,826	5,021	5,224	5,435	5,654	5,883	6,120	6,368	6,625	6,892
Penetration	0.0%	0.0%	0.0%	0.5%	1.2%	1.4%	1.8%	2.0%	2.3%	2.8%	3.2%	4.0%
Sales (mSEK)	0	0.0	0.0	25.1	62.7	76.1	101.8	117.7	140.8	178.3	212.0	275.7
<i>Pancreatic cancer</i>												
No of patients	60,000	61,200	62,424	63,672	64,946	66,245	67,570	68,921	70,300	71,706	73,140	74,602
Growth (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Price per treatment (SEK)	23,100	23,562	24,033	24,514	25,004	25,504	26,014	26,535	27,065	27,607	28,159	28,722
Growth (%)	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%	2%
Market value (mSEK)	1,386	1,442	1,500	1,561	1,624	1,690	1,758	1,829	1,903	1,980	2,060	2,143
Penetration	0.0%	0.0%	0.0%	0.5%	1.4%	2.3%	2.8%	3.2%	4.0%	4.5%	5.5%	7.0%
Sales (mSEK)	0.0	0.0	0.0	7.8	22.7	38.9	49.2	58.5	76.1	89.1	113.3	150.0
Total imILT sales (mSEK)	0.0	0.0	0.0	32.9	85.4	114.9	151.0	176.2	216.9	267.4	325.3	425.7

Source: Redeye Research

Sales forecast using a top-down approach

We forecast sales for the next 10 years using a top-down approach. For FLA/LITT, we have computed the market potential using the targeted patient population within prostate cancer in the US and Europe multiplied by the price per treatment. We have also assumed inflation and patient growth rates of 2% annually. We have estimated a penetration rate for each year and thus forecast peak penetration of 4% in 2030, corresponding to sales of SEK 571m.

To assess the market potential for imILT®, we have divided the estimates into breast cancer and pancreatic cancer and computed the market potential using the addressed patient population in each of these indications in both the US and Europe. We have then multiplied this by the price per treatment. As with the FLA/LITT forecast, we have assumed inflation and patient growth rates of 2% annually. As CLS is planning to initiate a large proof-of-concept study in imILT®, which we believe will start in late 2020 and be concluded in 2022, we do not expect to see any revenues from this until 2022. We estimate peak penetration rates in 2030 of 4% and 7% in breast cancer and pancreas cancer, respectively. We consequently see peak sales potential of around SEK 426m.

Given the above, we believe sales can reach approximately SEK 1bn in 2030.

Competitors

CLS's main competitors can be considered those medtech companies that provide ablation products and radiation therapy. Below, we provide short descriptions of a few identified competitors. However, these can be seen as companies also proving the huge potential in the market for curative cancer treatments used against solid tumors.

Elekta

Elekta is a Swedish medical technology company founded in 1972 that specializes in the development of clinical solutions for the treatment of cancer and various brain diseases. Elekta's treatment systems and planning software for radiotherapy and radiation surgery are used in the hospital industry to identify and analyze different health conditions. The company is one of the global radiotherapy market leaders and its products can be found at almost 4,000 hospitals worldwide. Elekta is listed on Nasdaq OMX Stockholm Large Cap and has a market cap of SEK ~44bn. In 2018, its sales amounted to SEK 13.5bn.

Varian

Varian is a US medtech company founded in 1948. It provides medical devices using radiotherapy, proton therapy, radiosurgery, and brachytherapy to treat cancer. Varian has manufacturing at 70 sites globally and employs approximately 7,000 people. The company is listed on New York Stock Exchange and has a market cap of USD 13bn. In 2018, its sales amounted to USD 3.2bn.

Boston Scientific

Boston Scientific is a US medtech company founded in 1979. The company manufactures medical devices providing interventional cardiology, interventional radiology, neuromodulation, endoscopy, urology, and oncology treatment. It is listed on New York Stock Exchange and has a market cap of approximately USD 60bn. In 2018, its sales amounted to USD 9.8bn.

Shareholders

The CEO and co-founder Lars-Erik Eriksson and co-founder Karl-Göran Tranberg are both found among the ten largest shareholders in CLS, which we see as positive. However, none of the largest shareholders own more than 10% and there are no institutional owners holding a significant stake in the company. This lack of a strong owner is problematic, in our view, especially in times of uncertainty. However, we believe it will be easier for CLS to attract a more long-term institutional owner once the imILT® method has been validated and sales start to pick up.

#	Name or institution	Nr. of shares (A + B)	MSEK	Capital	Votes
1	Avanza Pension	3,147,303	20.80	9.07%	7.85%
2	Nordnet Pensionsförsäkring	2,587,780	17.10	7.46%	6.45%
3	Karl-Göran Tranberg	1,437,499	9.50	4.14%	8.07%
4	Lars-Erik Eriksson	969,597	6.40	2.79%	6.91%
5	Handelsbanken Liv Försäkring AB	682,918	4.50	1.97%	1.70%
6	AB Possessor	500,000	3.30	1.44%	1.25%
7	Sven Lennartsson	275,075	1.80	0.79%	0.69%
8	Livförsäkringsbolaget Skandia	249,518	1.60	0.72%	0.62%
9	Ingmar Värendh	244,661	1.60	0.71%	0.61%
10	Swedbank Försäkring	241,292	1.60	0.70%	0.60%
	Others	24,358,910	314	70.21%	65.24%

Source: MF Holdings (2019-12-19)

Management and Board

Name	Position	Shares and options	Experience
Management			
Lars-Erik Eriksson	Chief Executive Officer	200,000 shares and 743,916 shares via Elano AB	Eriksson has an MBA in Economics from Lund University and has, prior to joining CLS, worked in leadership positions in the financial sector. Apart from his engagement in CLS, Eriksson is a Board Member in Elano AB and Salitre AB.
Stephan Dymling	Chief Technical Officer	51,051 shares	Dymling has an MSc in Engineering Physics from Lund University and holds a PhD in Diagnostic Ultrasound. Previously, he have had several CTO and Technical Manager positions. Further, he is active as a Board Member of GPX Medical and BibbInstruments.
Christina Pantaleone	Technical Manager, Product Development	12,759 shares	Pantaleone has a solid background as an engineer having studied at Princeton University, Politecnico di Milano, and Lund University. She has been with CLS since 2012 and took on the position as Technical Manager, Product Development in 2015.
Gunilla Savring	Chief Investor Relations Officer	30,991 shares	Savring has a diverse background as Marketing Director, Communications Director, CEO, and Board Member. Apart from her commitment to CLS, she is a Board Member of Axichem. Savring has a degree in Commercial Law as well as an Executive MBA from Lund University.
Marie Grey	Director of Quality Assurance and Regulatory Affairs	200 shares	Grey has a MSc in Chemical Engineering with a specialization in biotechnology. Further, she holds a PhD and worked as a Post-doc at Lund University. Grey also works with Quality Assurance at BibbInstruments.
Dan J. Mogren	Chief Commercial Officer	40,815 shares	Mogren has a thorough background within Sales & Marketing and have been with CLS since 2013. Currently, he is also CEO of CLS' American organization. Mogren served as an Officer in the Navy and has a General Management Executive Education from IMD Business School.
Mats Ekelund	Chief Medical Officer	0 shares	Ekelund worked seven years for Region Skåne as Head of Surgery at Kristianstad Hospital and later as responsible for the R&D and Education of hospitals and primary care.

Source: Redeye Research, CLS, MF Holdings

Name	Position	Shares and options	Experience
Board of Directors			
Hans von Celsing	Chairman	30,000 shares	The Chairman, Hans von Celsing has an extensive background within in the industry and have had several leadership positions, including Executive Vice President of Elekta. Currently he is active as a Board Member in Peptonic, Gelexir Healthcare Ltd, Partner Fondkommission, and Sonowand A/S. Celsing has a MSc from Stockholm School of Economics and an MBA from Harvard Business School.
Lars-Erik Eriksson	Board member and CEO	200,000 shares and 743,916 shares via Elano AB	Eriksson has an MBA in Economics from Lund University and has, prior, to joining CLS worked in leadership positions in the financial sector. Apart from his engagement in CLS, Eriksson is a Board Member in Elano AB and Salitre AB.
Arne Ferstad	Board member since 2013	18,750 shares	Ferstad has been with CLS since 2013 and has in the past 15 years served as a Non executive board member, independent consultant, interim manager, business coach and mentor in small, and large companies in the sector. Companies include AroCell, FluoGuide AS, CombiGene, NeuroVive and many more. Ferstad holds an MBA from Insead Business School.
Rolf Kiessling	Board member since 2013	0 shares	Kiessling holds a PhD in Medicine and currently works as a professor within oncology and Chief Physician within cancer at Karolinska Institutet. He also serves as Chairman of the Board of ImmCon.
Karl-Göran Tranberg	Board member, founder and Senior Medical Advisor	200,000 shares and 1,237,499 via KG Tranberg Medical AB	Tranberg has previously worked as a Chief Physician at Lund University Hospital. He pursued his medical degree in Lund and holds a PhD in surgery. His scientific research and clinical activities provide the foundation of CLS.

Source: Redeye Research, CLS

Summary Redeye Rating

The rating consists of three valuation keys, each constituting an overall assessment of several factors that are rated on a scale of 0 to 1 points. The maximum score for a valuation key is 5 points.

Rating changes in the report

People: 3

CLS has an experienced Board and Management team with good knowledge of the industry. Several members of the Board and the Management team are found among the ten largest shareholders.

Business: 3

CLS is utilizing a razor and blades business model where the lion's share of revenues will be recurring. The company is operating on a profitable market and has a strong patent portfolio. CLS started to generate sales in 2017 and has interesting distribution agreements that have started to bear fruit.

Financials: 1

CLS is currently conducting clinical trials to validate its imILT® method and the company is not yet generating any profits.

INCOME STATEMENT	2017	2018	2019E	2020E	2021E
Net sales	1	2	4	14	50
Total operating costs	-21	-35	-46	-63	-80
EBITDA	-21	-33	-42	-48	-30
Depreciation	0	0	0	0	0
Amortization	0	0	0	0	0
Impairment charges	0	0	0	0	0
EBIT	-21	-33	-42	-49	-31
Share in profits	0	0	0	0	0
Net financial items	0	1	0	0	0
Exchange rate dif.	0	0	0	0	0
Pre-tax profit	-21	-33	-42	-48	-30
Tax	0	0	0	0	0
Net earnings	-21	-33	-42	-48	-30

BALANCE SHEET	2017	2018	2019E	2020E	2021E
Assets					
<i>Current assets</i>					
Cash in banks	16	25	0	0	0
<i>Receivables</i>	2	2	0	2	4
Inventories	3	5	0	1	5
Other current assets	0	0	0	0	0
Current assets	20	31	1	3	9
<i>Fixed assets</i>					
Tangible assets	1	1	0	1	2
Associated comp.	0	0	0	0	0
Investments	0	0	0	0	0
Goodwill	0	0	0	0	0
Cap. exp. for dev.	0	0	0	0	0
0 intangible rights	24	26	11	29	30
0 non-current assets	0	0	0	0	0
Total fixed assets	25	27	11	30	32
Deferred tax assets	0	0	0	0	0
Total (assets)	45	58	12	33	41
Liabilities					
<i>Current liabilities</i>					
Short-term debt	11	7	3	64	94
Accounts payable	0	0	0	1	5
0 current liabilities	0	0	0	0	0
Current liabilities	11	7	4	65	99
Long-term debt	1	1	0	9	13
0 long-term liabilities	0	0	0	0	0
Convertible	0	0	0	0	0
Total Liabilities	12	8	4	74	112
Deferred tax liab	0	0	0	0	0
Provisions	0	0	0	0	0
Shareholders' equity	33	50	8	-41	-71
Minority interest (BS)	0	0	0	0	0
Minority & equity	33	50	8	-41	-71
Total liab & SE	45	58	12	33	41

FREE CASH FLOW	2017	2018	2019E	2020E	2021E
Net sales	1	2	4	14	50
Total operating costs	-21	-35	-46	-63	-80
Depreciations total	0	0	0	0	0
EBIT	-21	-33	-42	-49	-31
Taxes on EBIT	0	0	0	0	0
NOPLAT	-21	-33	-42	-49	-31
Depreciation	0	0	0	0	0
Gross cash flow	-21	-33	-42	-48	-30
Change in WC	-5	-2	7	-2	-2
Gross CAPEX	-25	-2	15	-19	-2
Free cash flow	-50	-38	-20	-69	-34

CAPITAL STRUCTURE	2017	2018	2019E	2020E	2021E
Equity ratio	73%	86%	65%	-122%	-175%
Debt/equity ratio	36%	16%	49%	-178%	-150%
Net debt	-4	-16	4	72	107
Capital employed	29	34	12	32	36
Capital turnover rate	0.0	0.0	0.3	0.4	1.2

GROWTH	2017	2018	2019E	2020E	2021E
Sales growth	0%	200%	122%	261%	247%
EPS growth (adj)	0%	19%	28%	15%	-37%

DCF VALUATION	CASH FLOW, MSEK
WACC (%)	NPV FCF (2019-2020)
	NPV FCF (2021-2027)
	NPV FCF (2028-)
	Non-operating assets
	Interest-bearing debt
	Fair value estimate MSEK

Assumptions 2017-2023 (%)		Fair value estimate model
Average sales growth	107.0 %	Fair value e. per share, SEK
EBIT margin	-205.2 %	Share price, SEK

PROFITABILITY	2017	2018	2019E	2020E	2021E
ROE	0%	-80%	-146%	0%	0%
ROCE	-93%	-65%	-120%	-223%	-91%
ROIC	0%	-114%	-125%	-418%	-96%
EBITDA margin	-3453%	-1844%	-1050%	-336%	-61%
EBIT margin	-3483%	-1856%	-1050%	-336%	-61%
Net margin	-3550%	-1828%	-1050%	-336%	-61%

DATA PER SHARE	2017	2018	2019E	2020E	2021E
EPS	-0.80	-0.95	-1.21	-1.40	-0.88
EPS adj	-0.80	-0.95	-1.21	-1.40	-0.88
Dividend	0.00	0.00	0.00	0.00	0.00
Net debt	-0.14	-0.47	0.11	2.09	3.08
Total shares	26.70	34.60	34.60	34.60	34.60

VALUATION	2017	2018	2019E	2020E	2021E
EV	-3.7	-16.3	342.2	410.9	444.9
P/E	0.0	0.0	-8.1	-7.0	-11.1
P/E diluted	0.0	0.0	-8.1	-7.0	-11.1
P/Sales	0.0	0.0	84.6	23.5	6.8
EV/Sales	-6.2	-9.1	85.5	28.5	8.9
EV/EBITDA	0.2	0.5	-8.1	-8.5	-14.6
EV/EBIT	0.2	0.5	-8.1	-8.5	-14.6
P/BV	0.0	0.0	43.4	-8.3	-4.8

SHARE PERFORMANCE		GROWTH/YEAR	16/18E
1 month	-20.2 %	Net sales	158.2 %
3 month	-3.7 %	Operating profit adj	41.8 %
12 month	34.0 %	EPS, just	23.4 %
Since start of the year	35.5 %	Equity	-51.4 %

SHAREHOLDER STRUCTURE %	CAPITAL	VOTES
Avanza Pension	9.1 %	7.9 %
Nordnet Pensionsförsäkring	7.5 %	6.5 %
Karl-Göran Tranberg	4.2 %	8.1 %
Lars-Erik Eriksson	2.8 %	6.9 %
Handelsbanken Liv Försäkring AB	2.0 %	1.7 %
AB Possessor	1.4 %	1.3 %
Sven Lennartsson	0.8 %	0.7 %

SHARE INFORMATION	
Reuters code	CLSRB.ST
List	First North
Share price	9.8
Total shares, million	34.6
Market Cap. MSEK	338.4

MANAGEMENT & BOARD	
CEO	Lars-Erik Eriksson
CFO	-
IR	Gunilla Savring
Chairman	Hans Von Celsing

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Redeye Rating and Background Definitions

Company Quality

Company Quality is based on a set of quality checks across three categories; PEOPLE, BUSINESS, FINANCE. These are the building blocks that enable a company to deliver sustained operational outperformance and attractive long-term earnings growth.

Each category is grouped into multiple sub-categories assessed by five checks. These are based on widely accepted and tested investment criteria and used by demonstrably successful investors and investment firms. Each sub-category may also include a complementary check that provides additional information to assist with investment decision-making.

If a check is successful, it is assigned a score of one point; the total successful checks are added to give a score for each sub-category. The overall score for a category is the average of all sub-category scores, based on a scale that ranges from 0 to 5 rounded up to the nearest whole number. The overall score for each category is then used to generate the size of the bar in the Company Quality graphic.

People

At the end of the day, people drive profits. Not numbers. Understanding the motivations of people behind a business is a significant part of understanding the long-term drive of the company. It all comes down to doing business with people you trust, or at least avoiding dealing with people of questionable character.

The People rating is based on quantitative scores in seven categories:

- Passion, Execution, Capital Allocation, Communication, Compensation, Ownership, and Board.

Business

If you don't understand the competitive environment and don't have a clear sense of how the business will engage customers, create value and consistently deliver that value at a profit, you won't succeed as an investor. Knowing the business model inside out will provide you some level of certainty and reduce the risk when you buy a stock.

The Business rating is based on quantitative scores grouped into five sub-categories:

- Business Scalability, Market Structure, Value Proposition, Economic Moat, and Operational Risks.

Financials

Investing is part art, part science. Financial ratios make up most of the science. Ratios are used to evaluate the financial soundness of a business. Also, these ratios are key factors that will impact a company's financial performance and valuation. However, you only need a few to determine whether a company is financially strong or weak.

The Financial rating is based on quantitative scores that are grouped into five separate categories:

- Earnings Power, Profit Margin, Growth Rate, Financial Health, and Earnings Quality.

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Disclaimer

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Redeye Rating (2019-12-20)

Rating	People	Business	Financials
5p	11	11	2
3p - 4p	88	67	28
0p - 2p	9	30	78
Company N	108	108	108

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Erik Nordström owns shares in the company : No

Ludvig Svensson owns shares in the company : No

Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.