

Biovica

Sector: Diagnostics

DiviTum To Stir Some Blood

Redeye initiates coverage of cancer diagnostics firm Biovica with base case of SEK 24. The shares have spiked some 140 percent YTD on the back of increasing investor optimism ahead of a possible US launch next year. While we see room for a slight pull-back short-term, a potential marketing approval in the US for blood-based cancer diagnostic test DiviTum within the next 6-12 months is a major catalyst for significant further upside to our valuation. Ongoing clinical validation to complete the submission to the FDA could provide important clues already in the next few months.

Focus on Breast Cancer Monitoring

New therapies for advanced breast cancer increase the need for fast and reliable monitoring tools to guide treatment decisions. Evidence supports that TK1 enzyme is an early marker for cell proliferation and treatment response and we view Biovica as a leader in advancing TK1 markers for breast cancer monitoring. We estimate a potential target population of some 100,000 patients annually in the US alone for DiviTum. We calculate potential peak sales of about USD 200m.

US Presence Pays Off

Extensive clinical evidence in breast cancer trials with more than 1,800 patients as well collaborations with leading US institutions provide important validation for DiviTum, in our view. For the pivotal clinical validation ahead of filing for market approval, an agreement with the leading cancer trial network SWOG to use patient samples significantly reduces time and costs for Biovica.

Risks are balanced, in our view

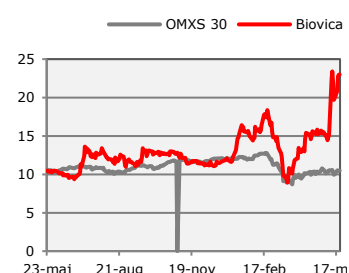
If the ongoing clinical validation does generate strong data, we see about **50 percent further upside to our base case, to SEK 37 (our bull case)**. Besides expected progress in the FDA process, news regarding potential commercial collaborations could drive the share price. While we believe Biovica is well prepared to meet requirements for market clearance, there is a risk for slow market uptake if results in the ongoing clinical validation are weaker than expected. In the medium term, additional financing will also be needed.

KEY FINANCIALS (SEKm)	17/18	18/19	19/20E	20/21E	21/22E	22/23E
Net sales	3	3	2	3	27	68
EBITDA	-16	-19	-24	-34	-30	-5
EBIT	-18	-22	-29	-34	-30	-5
EPS (adj.)	-1.0	-1.2	-1.2	-1.5	-1.3	-0.2
EV/Sales	43.9	59.7	NA	NA	25.7	10.4
EV/EBITDA	NA	NA	NA	NA	NA	NA
EV/EBIT	NA	NA	NA	NA	NA	NA
P/E	NA	NA	NA	NA	NA	NA

FAIR VALUE RANGE

BEAR	BASE	BULL
10.6	24.0	37.0

VERSUS OMXS30



REDEYE RATING



KEY STATS

Ticker	BIOVICb.ST
Market	First North
Share Price (SEK)	28.2
Market Cap (MSEK)	665
Net Debt 20E (MSEK)	-37
Free Float	77 %
Avg. daily volume ('000)	50

ANALYSTS

Niklas Elmhammer
niklas.elmhammer@redeye.se

Investment Thesis

The changing landscape for cancer drugs increases the need for faster diagnostics to guide treatment decisions. Clinical evidence supports the view that Biovica's minimally invasive DiviTum test is an especially relevant biomarker in metastatic breast cancer and is well positioned to benefit from this trend.

Biovica eyes to enter the US market for clinical use already next year. In the last twelve months, Biovica has reported significant progress towards meeting FDA requirements for technical and clinical validation. In 2019, Biovica agreed with the SWOG group, the largest cancer trial network within the US National Cancer Institute, to access patient samples from a large breast cancer trial to perform the clinical validation. This has shortened the clinical development significantly. The company plans to file a 510(k)-submission in Q3, 2020. This could open for a market clearance in the first half of 2021.

For clinical development Biovica has collaborated with some very renowned institutions in the field of oncology such as Dana-Farber, Johns Hopkins, SWOG and the Mayo Clinic. We believe it provides a stamp of quality and working with leading US institutions increases the chances of gaining vital support from key opinion leaders ahead of market launch. Also, Biovica has during the last two years expanded the management and board with experienced industry competence with proven track record in developing, marketing and business development in cancer diagnostics.

We see very limited, if any, short-term impact from the Covid-19 pandemic as no active clinics are needed to generate the data for 510(k)-filing.

Assuming an 80 percent likelihood of successful clinical validation and subsequent marketing clearance from the FDA, we calculate a base case value of SEK 24 per share. We see further upside to SEK 35-40 per share if pivotal clinical validation data is strong and DiviTum gets approved for clinical use on the US market.

Key Catalysts

Filing for marketing approval in the US. Biovica plans to submit a 510(k) application for DiviTum to FDA in Q3 2020. This could open up for marketing clearance on the US market in the first half of next year, a very significant milestone towards commercialization of DiviTum on the largest cancer drug market globally. In our view, this should entail significant de-risking of the DiviTum project and drive valuation higher.

Further clinical validation. Currently, DiviTum is evaluated in breast cancer clinical trials involving some 1,300 patients. Results from large trials could further strengthen clinical evidence. The most important trial currently is the SWOG collaboration which will serve as documentation for the application for market approval in the US.

Commercial partnerships. For a successful launch of DiviTum for clinical use, Biovica needs to team up with larger partners. As clinical evidence for the prognostic value of DiviTum continues to build and with the possibility of clearing important regulatory hurdles in the coming twelve months, the likelihood for attracting strong partners increases.

Counter Thesis

Capital need to advance commercialization process. While we believe Biovica has enough funding to complete the ongoing 510(k)-process for marketing approval in the US, further capital will be needed to support the launch on key markets.

Market uptake could be more protracted than expected. Even following a marketing clearance in the US, market uptake could be slow initially until reimbursement policies come into place. More clinical evidence might be needed for adoption into guidelines.

Company Overview

Biovica International ("Biovica" or "The company") develops tests to monitor the efficacy of standard cancer therapies. Its patented blood-based biomarker, DiviTum®, measures the activity of an enzyme involved in cell proliferation. It can be used to measure how rapid tumor cells are growing and has the potential to detect response to cancer treatment. The aim is to develop DiviTum as a minimally invasive, simple and reliable test for earlier evaluation of treatment response than current methods, thus providing oncologists with a new tool to guide decisions already at an early stage whether to continue or change current course of treatment. Possible advantages are improved survival, reduction of unnecessary exposure to inefficient and toxic drugs and a better allocation of resources in cancer care.

Biovica is mainly focusing on advanced hormone-receptor positive breast cancer. For this disease, there are several drug treatment options and thus a clear need for reliable decision-making tools to select the most promising treatment for each individual patient. The success of a new class of drugs, so-called CDK inhibitors, in recent years increases the relevance of DiviTum and could in our view facilitate market penetration. So far, the test has been sold to contract research organizations and pharmaceutical companies for drug development. Before Biovica can successfully address the much larger market for clinical use, it needs marketing clearance and reimbursement in place for DiviTum.

This requires evidence to validate reliability, robustness and support health economics. DiviTum has already demonstrated promising results in predicting response and showing correlation with established biomarkers in several prospective breast cancer clinical trials involving both endocrine therapy as well as CDK inhibitors.

Larger controlled trials are ongoing and DiviTum is currently being evaluated in seven clinical trials. Biovica is collaborating with several very reputable institutions such as Johns Hopkins, The Mayo Clinic, Dana Faber and the SWOG group as well as Karolinska Institute. The International Breast Cancer Study Group (IBCSG) and Breast International Group (BIG).

Biovica plans to submit a 510(k) application for marketing clearance of DiviTum in the US in Q3, 2020, upon successful completion of technical and clinical validation tests. In parallel, Biovica is working to have commercial partnerships and reimbursement in place in 2021.

History and Milestones

Already in 1982, the researchers Simon Gronowitz and Claes Källander at Uppsala University invented a method to measure the enzyme thymidine kinase which has a key role in DNA synthesis and hence cell proliferation.

However, it was not until the 2000's when the first clinical collaborations were initiated, and the method was patented. The company Biovica originally acquired the license. After a dispute between the founders and the minority shareholders a newly started company, Biovica International, acquired the patent in 2009.

In 2011, a new management and strategy was put in place. The first clinical trial with DiviTum was started in collaboration with the Karolinska Institute and the results were published in 2013. In 2014-2015 new clinical investigations were initiated with the Dana Farber Cancer Institute in Boston, International Breast Cancer Study Group, Breast International Group as well as Karolinska.

In 2016, Biovica acquired cSens and gained access to technology for real time analysis of TK-activity for PCR instruments. During the year Japanese pharmaceutical giant Eisai ordered DiviTum tests to be used in development of new cancer drugs.

Maturing Clinical Data provides Proof of Concept

Since 2016, the results from several clinical trials evaluating DiviTum in treatment of breast cancer has been presented at science conferences as well as published in scientific papers. These includes evidence of prognostic value for histological as well as clinical effect of standard of care drug treatments in mainly metastatic breast cancer but also operable breast cancer. In total, DiviTum has been evaluated in 11 clinical trials in more than 1,800 patients.

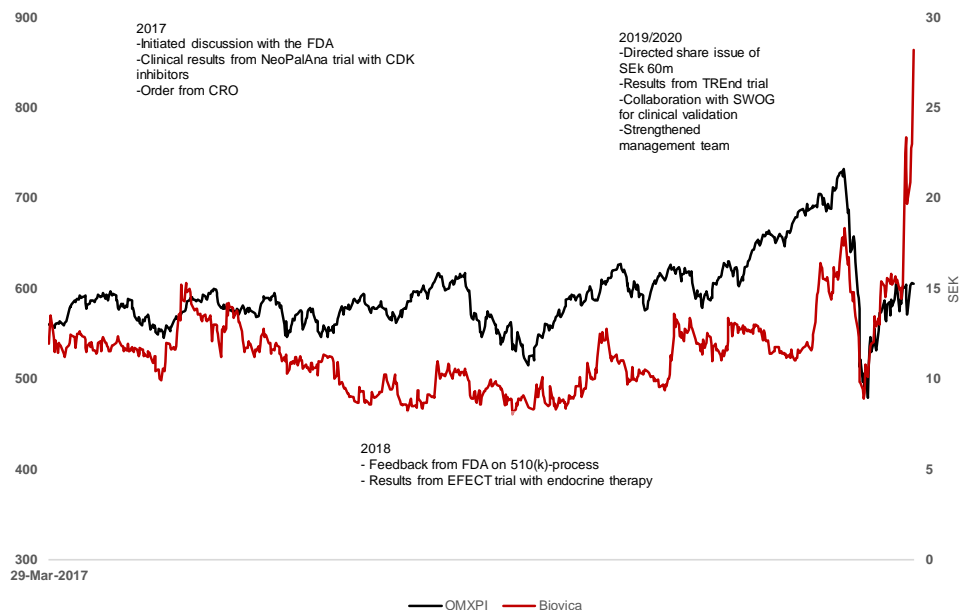
Pathway to FDA Approval Defined

In 2017, Biovica initiated discussions with the FDA regarding the path to market approval and completed a pre-submission. The regulator's feedback in 2018 confirmed that the 510(k) pathway was applicable for DiviTum and outlined the required steps for technical as well as clinical validation. To meet FDA's specifications, Biovica developed a new version of DiviTum. In 2019, SWOG, the largest clinical trial cooperative group within the US National Cancer Institute, agreed to provide Biovica with blood samples from a trial investigating endocrine therapy in over 700 patients with advanced breast cancer. This clinical material will be used to validate DiviTum prior to submitting a 510(k) application.

The revenue so far has consisted of sales to the research market. Biovica has also received research grants from the EU (Eurostar and Horizon 2020) and has raised some SEK 190m in equity.

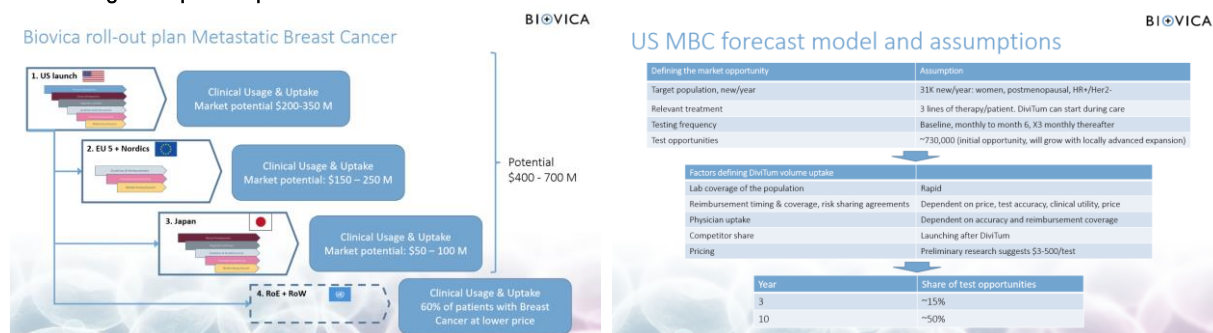
Share Price Development

Biovica was listed on Nasdaq First North in March 2017 and raised SEK 60m at a subscription price of SEK 12.5 per share (a pre-money valuation of SEK 160m). In April 2019, the company raised a further SEK 60m at SEK 10 per share in a directed issue.



The share price has risen sharply lately in the wake of the Capital Markets Day on May 11, 2020. We believe this has been driven by the announced goal to reach 50 percent penetration in targeted markets, with an interim target of 15 percent three years after market launch. Further, Biovica presented preliminary market research indicating possible acceptance for pricing of 300-500 USD per DiviTum test in the US, which was higher than we had previously anticipated. The company sees a potential market totalling USD 400m to 700m for metastatic breast cancer in the US, EU-5 and Japan. Also, the company reiterated its plans to file a 510(k)-submission to the FDA in Q3, 2020, which we believe is reassuring in the light of some supply issues cited in the recent quarterly report, as well as general uncertainty due to the covid-19 pandemic.

Biovica targets 50 percent penetration in an estimated USD 400 -700m market



Source: Redeye Research

Further contributing to the rise, DiviTum has recently been acknowledged in renowned scientific journals as a potential biomarker for the growing class of CDK 4/6-inhibitors (McCartney, A. et al, "Potential through simplicity: thymidine kinase-1 as a biomarker for CDK4/6 inhibitors, *British Journal of Cancer*, May 2020; Knudsen, E. et al, "Selective CDK4/6 Inhibitors: Biologic Outcomes, Determinants of Sensitivity, Mechanisms of Resistance, Combinatorial Approaches, and Pharmacodynamic Biomarkers, *2020 ASCO Educational Book*). These are further signs that DiviTum is on the radar of key opinion leaders in the field. At the same time, the authors see the need for further validation in larger prospective trials as well as studies establishing thresholds to determine what changes in TK1-activity are clinically relevant.

Early Detection of Dividing Tumors

DiviTum measures the activity of the thymidine kinase enzyme. Thymidine Kinase is a catalyst for DNA synthesis by phosphorylation of the nucleoside thymidine to form one of the building blocks of DNA. This enzyme is upregulated during the “S”-phase when DNA replicates.

There are two forms in mammals, TK1 and TK2, but only TK1 is relevant for measuring cell proliferation. The level of TK1 in blood sera is normally very low as superfluous TK1 is degraded in the cells. However, rapidly growing cells, such as tumor cells, entail an increase the level of TK1 and tumor cells also possibly release TK1 to the circulation. Abnormal levels of TK1 and its activity could therefore be a sign of cancer disease.

It is a challenge to measure TK1 concentration as it forms protein complexes in blood. In DiviTum, the enzyme *activity* is used as an alternative measurement. In a DiviTum assay, synthetic DNA strands are bound to a microtiter well. The blood sample is added to the well in combination with bromodeoxyuridine (BrdU), a synthetic analogue to thymidine. The higher the activity of the TK1 in the blood sample, the more BrdU is incorporated into the DNA. BrdU antibodies are added to the test. By using standard ELISA technique, antibody binding to the well can be measured and thus, TK1-activity can be indirectly estimated. Biovica is also developing a method for real time analysis for PCR (Polymerase Chain Reaction) -instruments. If successful, this will enable faster analysis with fewer manual steps compared to ELISA-based testing.

DiviTum test kit



Source: Biovica

Other TK biomarkers have been developed for blood cancers by e.g. Diasorin and Beckman-Coulter. The Diasorin test is not sold in the US. Arocell of Sweden has developed TK210, which differs from most TK1 biomarkers as it measures the concentration of TK1. This is clearly a different approach from DiviTum as a high concentration of TK1 is considered a sign of treatment efficacy (dying tumor cells releasing TK1). In 2018, Arocell signed a non-exclusive license deal (terms not disclosed) with diagnostics giant Roche to develop a version of the TK210 for the cobas instrument platform.

Still Unmet Medical Need in Advanced Breast Cancer

We believe the intended use of DiviTum in the clinical setting will be to monitor treatment of metastatic hormone-receptor positive breast cancer. Breast Cancer represents some 15 percent of new cancer cases diagnosed annually. The National Cancer Institute estimates some 276,000 new cases the US in 2020. The prognosis is generally relatively favorable in the developed world where most cases are detected early due to screening. The five-year survival rate overall is close to 90 percent in the US. However, if the cancer has metastasized the corresponding rate drops to about 27 percent.

Surgery is first line of treatment. Normally, this is followed by chemotherapy or endocrine therapy depending on stage or risk assessment. Some 80 percent of all breast cancers have tumors that are hormone receptor positive ("ER+"), i.e., they grow in response to estrogen. They are candidates for drugs that block either estrogen production or estrogen receptors. Some aggressive cancers (15-30 percent) are characterized by tumors where receptors of important growth factors are overexpressed (so-called HER2-positive or "HER2+" tumors) (from human epidermal growth factor receptor 2)). They are eligible for treatment with antibody therapy such as trastuzumab.

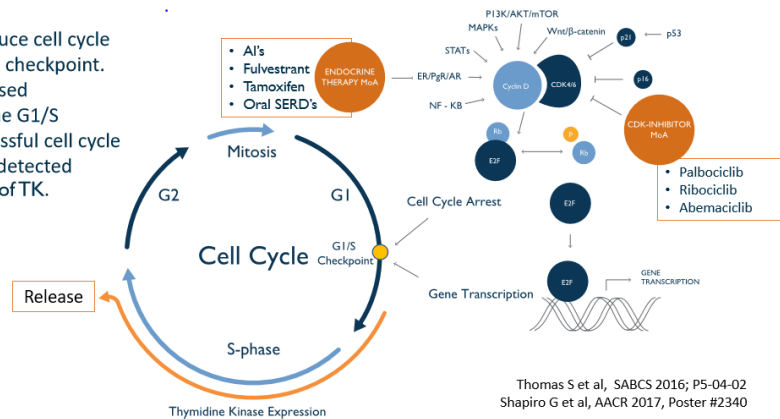
Why is TK1-Activity Relevant in Breast Cancer?

TK1-activity is likely not very precise for monitoring clinical effect of chemotherapy since such therapies by their mechanism of action interfere directly with TK1-expression, e.g. through the disruption of synthesis of deoxy-thymidine-monophosphate.

However, endocrine therapy affects tumor growth more upstream compared to chemotherapy. Thus, TK1-activity in this case can be used as an independent marker of tumor proliferation. In metastatic breast cancer, there is a growing pipeline of treatments in development. In recent years, the so called CDK (Cyclin Dependent Kinase)-inhibitors have been approved and rapidly gained wide adaption. This class of cancer drugs block the phosphorylation of CDK of the RB-protein, thereby inhibiting signals necessary for gene transcription to enable cell division. One such signal is TK1.

DiviTum® TK - Scientific Rationale for Efficacy Evaluation of Cell Cycle Regulating Drugs

Specific drugs induce cell cycle arrest at the G1/S checkpoint. Since TK is expressed downstream of the G1/S checkpoint, successful cell cycle inhibition can be detected as changed levels of TK.



Source: Biovica

Thus, TK1 is a relevant biomarker for two classes of standard of care drug treatments in advanced breast cancer.

- In our view, the main advantage of TK1 testing would be for early feedback on response to endocrine therapy. During monitoring of therapy addition or change of therapies should be initiated when proliferation increases and DiviTum values increase.
- As is evident from tumor response and survival data below for leading CDK-inhibitor Ibrance (palbociclib), only about half of patients respond to treatment with CDK inhibitors, but there are still no approved biomarkers to select likely

responders. The high cost for treatment (some USD 10,000 per month in the US) in addition to increased side effects underlines the need for better tools for patient selection and treatment monitoring.

PALOMA-2 study results in ER-positive, HER2-negative advanced or metastatic breast cancer, first line

Table 8. Efficacy Results – Study 1 (Investigator Assessment, Intent-to-Treat Population)

	IBRANCE plus Letrozole	Placebo plus Letrozole
Progression-free survival for ITT	N=444	N=222
Number of PFS events (%)	194 (43.7)	137 (61.7)
Median progression-free survival (months, 95% CI)	24.8 (22.1, NE)	14.5 (12.9, 17.1)
Hazard ratio (95% CI) and p-value	0.576 (0.463, 0.718), p<0.0001	
Objective Response for patients with measurable disease	N=338	N=171
Objective response rate* (%; 95% CI)	55.3 (49.9, 60.7)	44.4 (36.9, 52.2)

CI=confidence interval; ITT=Intent-to-Treat; N=number of patients; NE=not estimable.

* Response based on confirmed responses.

Source: Pfizer

Palbociclib (brand name: Ibrance) was in 2015 the first CDK inhibitor approved for advanced ER+/HER2- breast cancer, in combination with anti-estrogen therapy. It won accelerated approval on a phase II study showing a strong benefit on progression-free survival compared to hormone therapy alone. In 2019, Pfizer recorded some USD 5bn in sales for palbociclib, confirming its position as one of the most successful launches in oncology in recent years. Several clinical trials are ongoing to evaluate palbociclib in earlier stages of breast cancer to increase the addressable market. In addition to palbociclib, two more CDK inhibitors have been approved (ribociclib and adamaciclib). Sales for CDK 4/6 inhibitors in breast cancer is expected to amount to some USD 8-10bn in the next couple of years.

All in all, as more treatments for breast cancer become available, monitoring TK1-activity becomes increasingly relevant, in order to help select the best therapy.

Current Diagnostics Leave a Gap

Breast cancer is today monitored by clinical examination, imaging and biopsy analysis. These methods are improving and will most likely continue to be the backbone of cancer diagnostics in the foreseeable future. There is however a clear need for additional biomarkers for earlier and more frequent assessment of treatment response.

There are already some biomarkers in clinical use. Ki-67 is an established biomarker for cell proliferation. However, it is invasive (biopsy) and the tumor needs to be localized. There is a large variability in Ki-67 scoring, and it is not recommended to determine patient-care decisions in clinical practice.

- **CA (Carcinoma Antigen) 15-3** is a blood-based biomarker measuring antigen produced by the cancer-associated MUC1 gene. According to the American Association of Clinical Oncology (ASCO), data is insufficient to assess the clinical utility of CA 15-3.
- Measuring **circulating tumor cells** have demonstrated a generally prognostic value for survival. However, no such biomarkers have yet shown predictive value, i.e. utility in guiding cancer treatment.

Despite limited support from guidelines, the use of blood-based biomarkers such as CA 15-3 has historically been widespread in the US, even in earlier stages of breast cancer (over 40 percent penetration according to some surveys).

Molecular diagnostics and DNA sequencing based on so called liquid biopsies (i.e. blood draws) instead of tumor tissue could pose direct competition in the future. The interest in this field is underlined by Illumina spinoff GRAIL having raised USD 2bn since 2016 to develop a multi-cancer early detection test. We are however not aware of any development specifically for tools for monitoring treatment efficacy.

Oncotype DX Case Study Supports Ambitions for Market Penetration

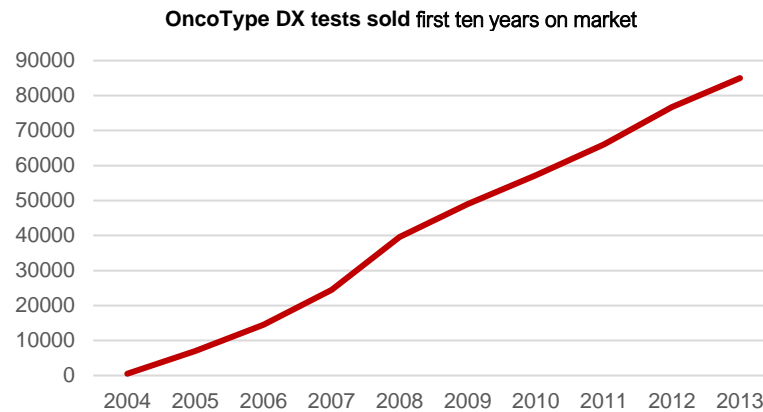
In contrast, tumor profiling based on histological analysis of tumors has since long been accepted as a key component to guiding breast cancer treatment, e.g. for identifying subtypes of patients likely to respond to hormone therapy or to targeted therapy such as anti-HER2. Gene expression profiling and molecular diagnostics are also rapidly gaining ground promising to further increase precision. One drawback is that these tests normally still need to be performed in centralized labs.

An interesting case study is Oncotype DX, a commercially available gene expression assay that provides prognostic information for early-stage invasive hormone-receptor-positive breast cancer. It is used to help select patients that will benefit from the addition of chemotherapy to adjuvant endocrine therapy. This is based on a Breast Recurrence Score, i.e. a risk assessment of the cancer recurring from analyzing 21 genes from tumor tissue. Patients that score high are more likely to benefit from added chemotherapy.

We believe Oncotype DX is a useful parallel to DiviTum as it is an aid for clinicians to recommend treatment. An important difference however is that it is a predictive test to select treatment prior to initiation unlike DiviTum which we believe is primarily suited to monitor ongoing treatment. Since it is indicated for early breast cancer, we do not consider Oncotype DX competing with DiviTum.

Oncotype DX has been a notable success for developer Genomic Health, primarily in breast cancer but also to some extent in prostate cancer. Genomic Health recorded sales of USD 394m in 2018. In 2019, it was acquired by Exact Sciences for around USD 2.5bn in cash and stock.

Oncotype DX became available in 2004. During the first ten years over 400,000 Oncotype DX tests were performed, the majority in the US:



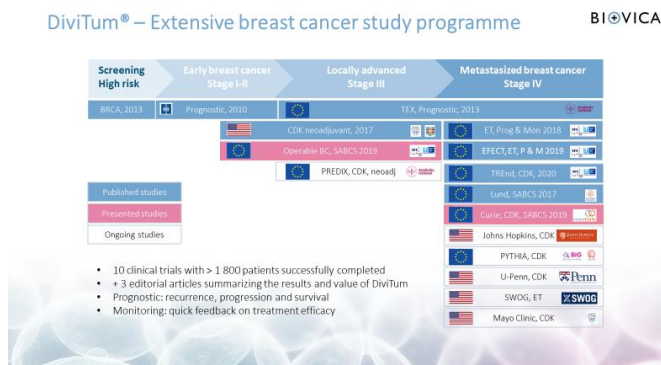
Source: Genomic Health, Redeye Research

The test was originally indicated for early invasive hormone-receptor positive cancer (the most common breast cancer at diagnosis), representing some 140,000 new cases annually in the US. The sales development above implies that Genomic Health achieved roughly 50 percent penetration in the US after ten years on the market (in the rest of the world, penetration is yet considerably lower). Oncotype DX is a so called “Laboratory Developed Test” regulated under the CLIA and is not considered a diagnostic kit that needs to be cleared for marketing by the FDA. The tests can only be performed at Genomic Health’s own labs.

Clinical Evidence for DiviTum

DiviTum has been evaluated in 11 clinical trials in breast cancer.

Biovica's Clinical Program in Breast Cancer



Source: Biovica

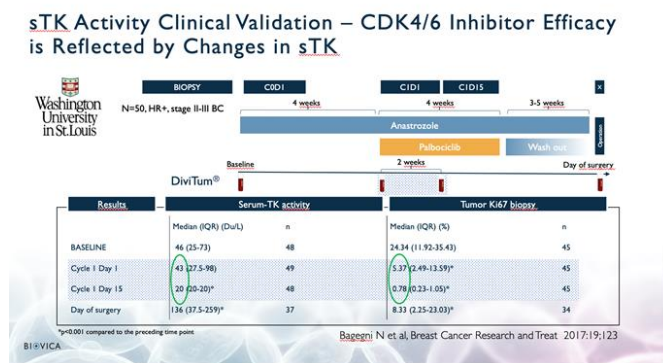
A further five trials are still ongoing, including the clinical validation in cooperation with the SWOG group, where another 1,000 patients in total is expected to be included. Also, DiviTum is used in trials in other cancers. Below we summarize the most important findings in breast cancer:

- Prognostic marker for clinical response to endocrine therapy:** In metastatic breast cancer patients treated with endocrine therapy, it was shown that a reduction in TK1-activity after one month predicted response, as manifested by significantly longer progression-free survival compared to patients with increased TK1-activity (Bonechi, M., et al., " Plasma thymidine kinase-1 activity predicts outcome in patients with hormone receptor positive and HER2 negative metastatic

breast cancer treated with endocrine therapy” *Oncotarget* vol 9(23), 2018). In the *EFFECT trial* (n=244) low baseline TK1-activity as well as a drop in TK1 activity following treatment was prognostic of improved time to progression following treatment with endocrine therapies fulvestrant or exemestane.

- **Early detection of response to targeted therapy:** In a study in patients with locally advanced breast cancer treated with palbociclib before surgery (n=50), TK1 activity as measured with DiviTum correlated with high accuracy with early signs of response according to the established tumor biopsy biomarker Ki-67. The correlation could be observed already two weeks after treatment was initiated. Sensitivity was 94 % and specificity was 84 %.

TK1-activity as measured with DiviTum correlates with tumor biomarker Ki-67.



Source: Bagegni N, et al, “Serum thymidine kinase 1 activity as a pharmacodynamic marker of cyclin-dependent kinase 4/6 inhibition in patients with early-stage breast cancer receiving neoadjuvant palbociclib”, *Breast Cancer Res and Treat.* 2017).

- **Prognostic marker for clinical response to CDK-inhibitors:** In the Phase II “TREnd” trial, DiviTum was used to evaluate TK1-activity in in patients with metastatic breast cancer receiving CDK4/5-inhibitor palbociclib with or without endocrine therapy (N=46) . An increase in TK1 activity after one cycle of treatment correlated with significantly shorter median progression-free survival (3.1 vs 9 months). Baseline TK1-activity showed a trend of correlation with clinical outcome, though not statistically significant. In another study (n=115) presented at the 2019 San Antonio Breast Cancer Symposium, baseline and four-week TK1-activity was significant prognostic factors for survival in patients receiving CDK inhibitor in addition to endocrine therapy. In contrast to previous studies, changes in TK1-activity was however not a significant prognostic factor.

TK1 activity and clinical outcome in breast cancer patients treated with Ibrance +/- endocrine therapy.

(McCarney, A. et al, " Plasma Thymidine Kinase Activity as a Biomarker in Patients with Luminal Metastatic Breast Cancer Treated with Palbociclib within the TReND Trial, *Clinical Cancer Research*, 2020)

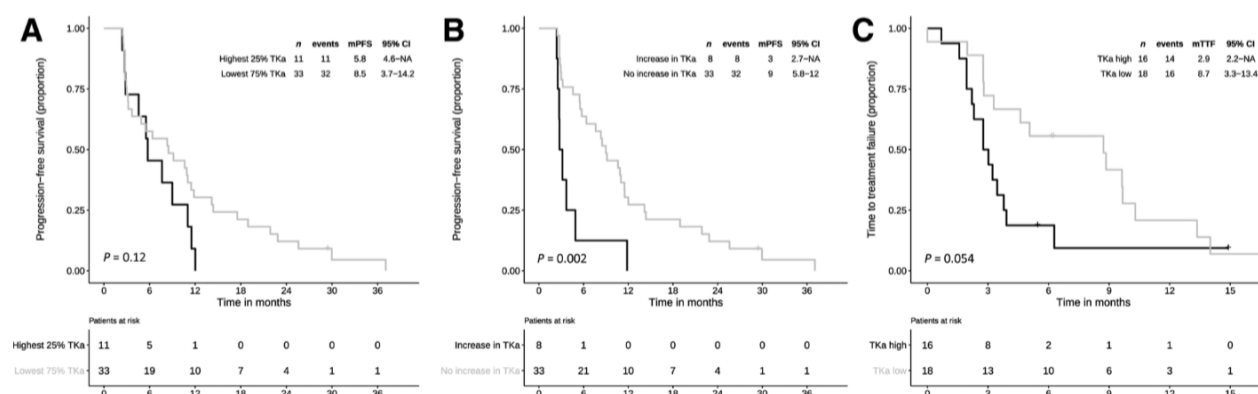


Figure 4.

Outcome of patients in the TReND study according to pTKa. **A**, Baseline (T0) pTKa divided according to the top quartile, correlated to mPFS. **B**, On-treatment pTK changes after one cycle of palbociclib therapy (T1), correlated to mPFS. **C**, mTTF on the line of treatment received immediately after exiting TReND according to pTK at the point of progression on trial (T2) using the median value as threshold.

- **Prognostic marker in operable breast cancer:** A retrospective analysis of samples from 644 patients with stage II-IIIb breast cancer with adjuvant treatment with ER-blocker tamoxifen showed that baseline TK1-activity as measured by DiviTum was a prognostic factor for disease free survival.

In our view, clinical results so far indicate that base line, as well as changes in, TK1-activity are both prognostic factors for monitoring treatment. Determining what should be considered as high and low baseline TK1-activity, respectively, is however somewhat of a challenge as it differs significantly between patient groups. Therefore, we believe change in TK 1-activity is likely the most useful parameter to monitor in the clinic. The results in operable breast cancer are promising, but the clinical utility needs to be further evaluated and competition from molecular diagnostics is more tangible here, we believe.

Other Cancer Indications

DiviTum is being evaluated in other cancers as well. A retrospective study with the University of Heidelberg on blood samples from patients with pancreatic cancer showed that TK1-activity correlated with survival. Biovica also collaborates with the Dana Farber institute for evaluating DiviTum in a trial in lung cancer with combination therapies with CDK inhibitors. So far, however, CDK inhibitors are only approved for breast cancer.

Patents

The patent protection for DiviTum rests on two patent platforms; method and kits for analysis of TK-activity with ELISA, as well as corresponding patents for real time analysis. These patents expire in 2026 and 2031, respectively.

Market

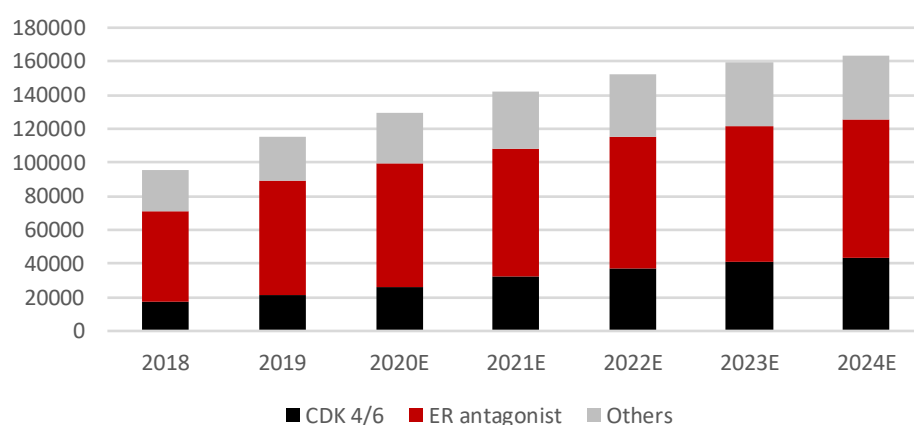
TK1 Marker Relevant for a Large Population in Metastatic Breast Cancer

We believe advanced breast cancer is the appropriate starting point to assess the potential of DiviTum. In this indication there is a clear utility for TK1 biomarkers to guide treatment decisions, in our view. Ongoing clinical trials in other cancers indicates a prognostic value but it is yet unclear whether it is useful for comparing treatment options. We do not know the current market for TK1 biomarkers, but we assume it is small as clinical use seems to be limited.

Some twelve per cent of all women will be affected by breast cancer in their lifetime. In the US, some 3.4m women are living with or have a history of breast cancer. In most cases, the cancer is local at diagnosis. Some 20 to 30 percent of early breast cancer eventually progress to metastatic disease. In the US, the prevalence of metastatic breast cancer is 155,000, of which three quarters have been previously diagnosed at earlier stages (Source: Mariotto, A., et al., "Estimation of the Number of Women Living with Metastatic Breast Cancer in the United States" *Cancer Epidemiology, Biomarkers & Prevention*, 26(6), 2017).

We assume the primary indication for DiviTum is hormone-receptor positive, HER2-negative metastatic breast cancer. Datamonitor estimates some 130,000 US patients in this indication will receive branded drug treatment in 2020 (all lines of treatment). The majority (77 per cent) will receive ER antagonists or CDK inhibitors.

Drug Treated patients, ER+, HER2- Metastatic Breast Cancer (US)



Source: Datamonitor

We assume that patients receiving either CDK-inhibitors and/or ER antagonists is the most relevant target population, since these are the treatments where DiviTum so far has demonstrated the best evidence of clinical utility. According to Datamonitor, this currently represents a market of 100,000 patients annually in the US. As only branded drugs are included, this might be a somewhat conservative assumption, e.g. with regards to endocrine therapy. We lack detailed estimates for the European market, however assuming a similar prevalence we calculate a primary target population in the same patient setting of 155,000 in the region.

Various surveys and company estimates indicate that successful biomarkers such as CA 15-3 or Oncotype DX have reached 40-70 percent adoption in relevant target populations on the US market. Taking possible future competition from other TK1 biomarkers into account, we assume an adoption for DiviTum of 30 percent in the US. For Europe, we have

assumed a lower penetration of 20 percent on the back of a more heterogeneous market. For Japan we assume 24 percent penetration.

Biovica's goal is to achieve 15 percent penetration in targeted markets three years after launch and a 50 percent penetration in the longer run.

Pricing for diagnostic tests in cancer varies considerably. For blood-based biomarkers such as CA 15-3 we estimate around USD 100 per test in the US, while tests measuring circulating tumor cells exceed USD 300. For molecular diagnostics testing the cost is about significantly higher, however, these are often performed just once on tumor tissue. Genomic Health reported a list price of USD 4,620 in the US for its invasive breast cancer test Oncotype DX for 2019.

In the end, reimbursement and pricing will be highly dependent on demonstrated accuracy in larger clinical trials and perceived clinical utility. According to Biovica, preliminary market research indicates possible market acceptance for a cost between 300 and 500 USD per test in the US. We assume a cost of 300 USD per test in the US and 150 USD in Europe and Japan, and 8-9 tests per patient and year. Based on our assumed market penetration rates stated above, this renders a peak sales estimate (gross) of about USD 190m.

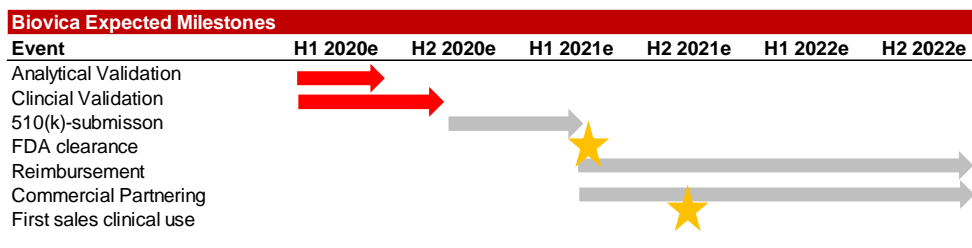
Important Regulatory Hurdle Could Be Cleared in Coming Year

DiviTum has a CE-marking in Europe allowing for sales to clinical laboratories and diagnostic companies. For successful commercialization, reimbursement in key markets is also essential. As reimbursement systems vary considerably between European countries, this is a lengthy process. In addition, Biovica will have to register DiviTum according to the new IVD (In Vitro Diagnostics) directive. As a consequence, Biovica plans to first obtain market clearance in the US and subsequently use the same documentation for a registration in the EU.

In the US, FDA need to approve diagnostic tests for clinical use. Following a pre-submission in June 2017, FDA has communicated that DiviTum is considered a class II device (i.e. moderate to high risk for the patient/user) and that it was possible to refer to an already approved predicate device. Thus, the 510(k) process was applicable. In August 2018, Biovica reported positive feedback from FDA regarding proposed intended use and the protocols and documentation needed to validate technical and clinical performance.

- The technical or analytical validation concerns documenting the stability and performance of the test on several production lots.
- For the clinical validation, Biovica will use samples from a large phase II clinical trial (more than 700 patients) conducted by the SWOG Cancer Research Network in metastatic ER+ breast cancer. Hence, the trial will be performed retrospectively, significantly reducing time and costs for the clinical development. If the analytical and clinical validation is successful, the goal is to submit the 510(k)-application in Q3, 2020.

FDA review times for a 510(k) are stipulated at three months, but in reality, the average review time is some six months. The three-month deadline is met for 20-25 percent of all submissions. Our impression is that Biovica preemptively initiated discussions at an early stage and has made thorough preparations to meet FDA requirements, possibly mitigating the risk for a drawn-out review.



Source: Redeye Research

Currently the analytical validation of DiviTum is ongoing. In its recent Q3 2019/20 report, Biovica reported that delays in the supply of DiviTum components meant that completion of the analytical validation had been postponed to the second quarter. The company also stated that the completed steps (about two thirds) of the analytical validation so far has met the specified requirements.

The analytical validation is necessary to subsequently perform the process of clinical validation with the "FDA-version" of DiviTum. Biovica has received and analyzed all the samples from SWOG.

The original trial conducted by SWOG compared two groups receiving either standard-dose aromatase inhibitor anastrozole alone or anastrozole plus fulvestrant (a blocker of estrogen receptors). Aromatase is an enzyme necessary for the forming of estrogen. The large study population with several relevant subgroups (for example cross over was permitted during the trial) and the long follow up times (median follow up 7 years) provides a strong foundation for the clinical validation, we believe.

Biovica may already sell DiviTum to CLIA certified laboratories regardless of FDA marketing clearance (for research use only). Biovica has already generated some sales on its own despite a limited sales force. For the US market, IBL-America has non-exclusive distribution rights since April 2019.

Forecasts

Commercial Collaboration with Larger Partners A Likely Strategy

Biovica is not planning to build a large sales force on its own. Instead it, aims to strike commercial partnerships with larger partners such as distributors, laboratories or diagnostic companies.

Out-licensing: Lower Risk but Not Most Lucrative Option

There are several possible options for commercial structure. Direct out-licensing deals is one possibility. Out-licensing would limit Biovica's own costs and capital requirements, but also likely meaning having to refrain from the lion's share of revenue from DiviTum.

There is limited publicly available information on licensing deals for cancer diagnostics. Below we have listed some reference deals:

With one exception, (Epigenomics/Companion Dx) these are exclusive deals. We calculate a median value of USD 17m in total and USD 5m in up-front payments, and generally double-digit royalty rates on sales.

Licensing deals cancer diagnostics							
Company	Partner	Project	Indication	Market?	Value (USDm)	Upfront (USDm)	Royalties
Exact Sciences	LabCorp	PreGen-Plus	Colorectal cancer	No	40	0	15-17%
Cleveland Diagnostics	Genomic Health	IsoPsa	Prostate cancer	No	10	2	ND
Almac Group	Genomic Health		Breast cancer	No	ND	9	ND
Epic Sciences	Genomic Health	AR-V7	Prostate cancer	No	14	7,5	Income sharing
Epigenomics	Companion DX	Septin 9	Colorectal cancer	Yes	ND	ND	"double digits"
MabCure	Biotech Invest.	Anti-body	Prostate cancer	No	ND	ND	12,5%
Veracyte	J&J Innovation		Lung cancer	No	20	5	ND
Average					21	5	
Median					17	5	

ND: Not Disclosed.

In our view, this indicates that out-licensing is not a preferred option, unless Biovica can strike a more favorable deal than the ones cited above. As we believe Biovica already has enough production capacity for at least the initial launch phase and is also expanding its commercial organization in the US, we do not see out-licensing as a first-hand choice for Biovica.

Finding the Right Partner is Key in Fragmented Market

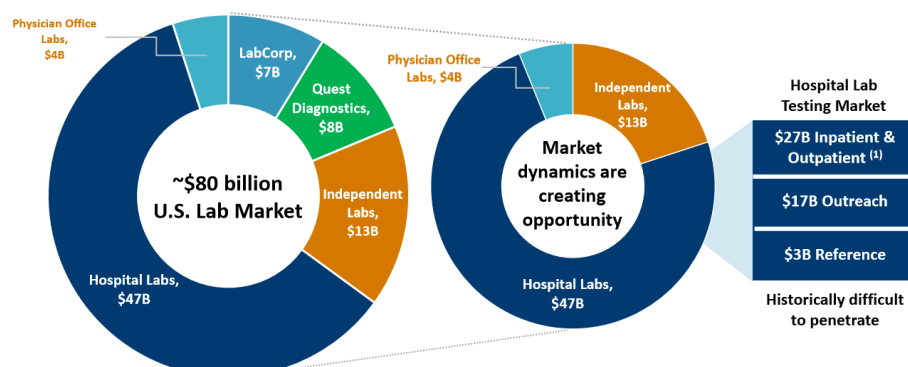
In theory, building one's own sales force is the most value-generating alternative, but it is also riskier as it means investing in a large commercial organization with significant fixed costs. We also believe Biovica would have to raise significant capital for this task.

We assume a "middle-ground" will be the way forward were Biovica will supply DiviTum kits to a partner/distributor and that the revenue split will be roughly 50/50.

Possible partners include diagnostics companies such as Roche, Abbott Laboratories, Danaher and Siemens. Generally, the largest Roche has a 20 percent market share in In Vitro Diagnostics (we do not have a share estimates of the oncology segment). Oncology-focused diagnostic group Exact Sciences seems like the a possible "best fit", at least on the US market. As we have mentioned above Exact Sciences subsidiary Genomic Health achieved some 50 percent penetration in early breast cancer for Oncotype DX in the U.S. in ten years.

Alternatively, laboratory groups such as Labcorp of America and Quest Diagnostics are also possible partners with some 10 percent each of the US lab market (20-25 percent if the hospital lab testing market is excluded). There are also a number of smaller independent labs.

US Lab market



Source: LabCorp.

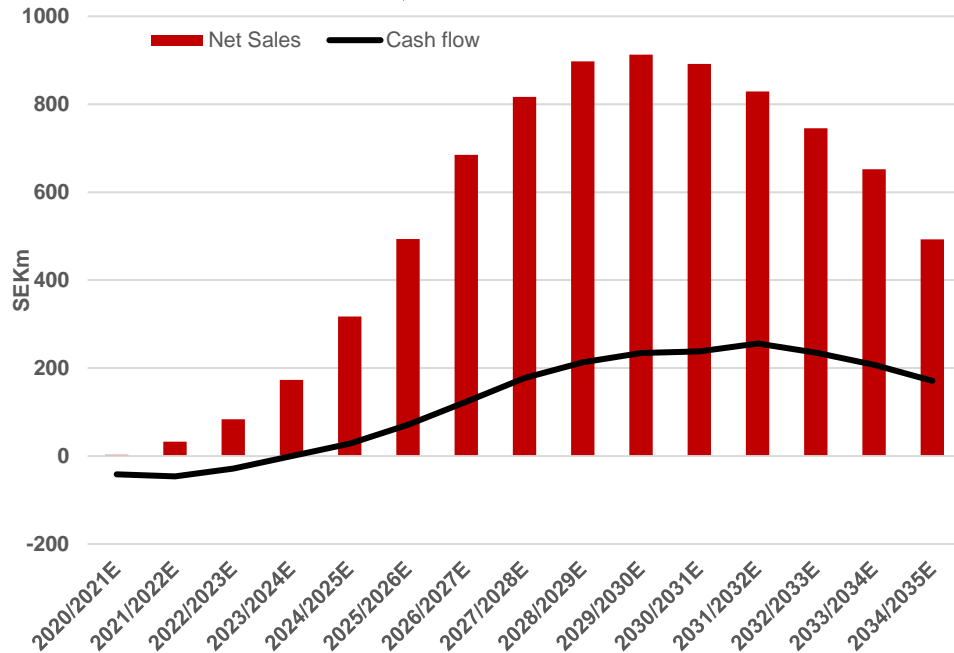
Key Forecast Assumptions

- We calculate that DiviTum will be launched in the US in the second half of 2021, one year later in Europe and two years later in Japan. Due to patent expirations, we have assumed that sales will peak towards the end of the 2020's. In our forecasts, we have included some research income as well (see below).

Assuming gross peak sales of USD 186m, this would result in peak income from clinical use of about SEK 900m for Biovica (non-risked).

- Relevant peers such as Exact Sciences and Genomic Health enjoy gross margins of 82 to 84 percent on average. We assume some 80 percent on average for Biovica. We have assumed opex corresponding to 40-50 percent of sales in the long run, generating an operating margin of 35-40 percent (32 percent average for the forecast period).

Biovica Net Sales and Cash Flow Estimates, Non-Riskd

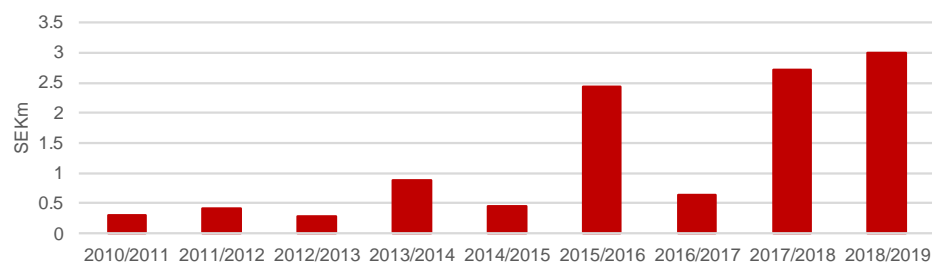


Source: Redeye Research.

Still Some Growth Potential in Research Market

As mentioned above, Biovica already addresses the research market. During the last couple of years, Biovica has made several deals with CROs concerning use in preclinical and clinical development. The larger deals have amounted to some USD 100,000. The potential market could be illustrated by the amount of targeted cancer therapies in clinical development (over 500). While the addressable market for DiviTum for clinical use in advanced breast cancer alone is likely > 10 times larger, research deals could in the long run open up for new applications and generate further interest for DiviTum. In our model, we have assumed that DiviTum will eventually penetrate some 5-10 per cent of the research market, corresponding to SEK 10m in sales per year. Research sales could be boosted by a marketing approval for the US, in our view.

Historical Net Sales



Source: Biovica

Financials

Costs have been increasing at a steady orderly pace over recent years as the company has ramped up research and regulatory activities in preparation for filing for marketing approval in the US. Biovica has developed a new version of the DiviTum test to fully comply with FDA requirements. The organization has also expanded and Biovica has established an office in Boston.

Net sales have historically been rather stable. Currently, Biovica is focussed on completing the documentation for the 510(k) application, and not much internal effort is directed on marketing DiviTum to the research market. Biovica has a distribution agreement for the US market which has yet to make any substantial impact on sales.

We believe Biovica made a major step forward last year in securing access to patient material from SWOG for the clinical validation. It reduced time and costs to reach the market, as the collaboration lays the foundation for a solid retrospective analysis, as opposed to having to conduct a prospective trial for possibly many years.

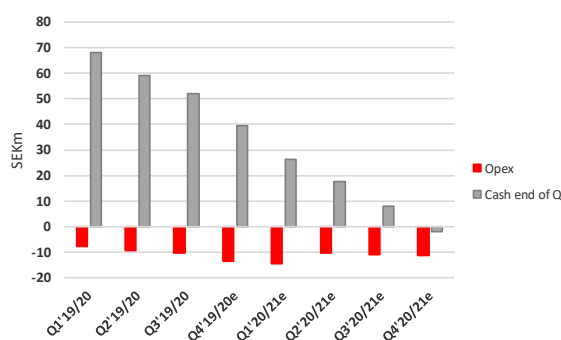
For the coming year, we expect costs to go up as the analytical and clinical validation is completed and an increase in staff mainly in the US.

At the end of Q3 2019/20, Biovica held some SEK 52m in cash. According to our forecasts, this provides Biovica with about twelve months of financial runway.

Financial Forecasts

Risk-adjusted full-year income statement forecast					
	2017/18	2018/19	2019/20e	2020/21e	2021/22e
Net revenue	2.7	3.0	1.9	3.0	27.3
Other operating income	7.2	7.4	10.7	10.2	
Total income	9.9	10.4	12.6	13.2	27.3
Materials cost	-1.1	-0.9	-0.2	-1.2	-5.5
Other external expenses	-9.5	-12.0	-17.4	-17.0	-24.0
Personnel costs	-14.5	-16.2	-19.4	-26.4	-28.8
Depreciation/Amortization	-2.7	-3.0	-4.1	-4.0	-4.0
Other operating expenses	0.0	-0.1	0.0	0.0	0.0
Operating expenses	-27.9	-32.2	-41.0	-47.4	-56.9
EBITDA	-15.2	-18.7	-24.3	-30.2	-25.6
EBIT	-17.9	-21.7	-28.4	-34.2	-29.6
Financial net	-0.1	0.2	0.0	0.0	0.0
EBT	-17.9	-21.5	-28.4	-34.2	-29.6
Tax	0.0	0.0	0.0	0.0	0.0
Net profit	-17.9	-21.6	-28.4	-34.2	-29.6

Source: Redeye Research



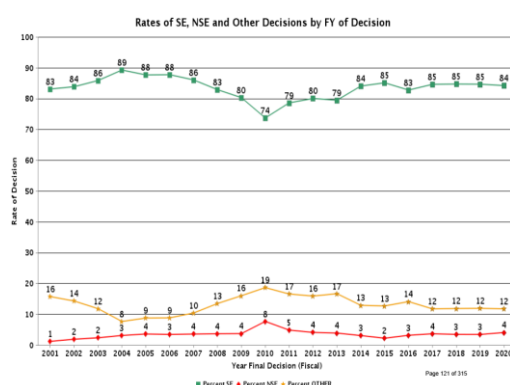
Valuation

Our approach to valuing Biovica is based on risk-adjusted discounted project values.

Likelihood of Approval

According to FDA statistics, historically some 84 percent of 510(k)-submissions are considered as substantially equivalent and receive market clearance and only three percent are rejected outright. This implies some 90 percent likelihood of clearance, in our view. Taking into account that the analytical and clinical validations are not completed, and the submission not yet filed, we assume 80 per cent likelihood of reaching the market (i.e. we calculate with about 80 per cent chance that Biovica will pass analytical and clinical validation).

FDA statistics on 510(K)-submissions



Source: FDA

Other assumptions:

- We have derived a WACC of 13 percent from the Redeye Rating model.
- We assume a USD of 9.7 SEK

Based on our sales forecasts, and the assumptions above, we calculate a shareholder value of some SEK 570m.

DCF-Valuation			
Risk premium	11% Growth f'cast 20-30e, CAGR	82% rNPV forecast period, SEKm	357
Assumed beta	1.0 Growth f'cast 30-35e, CAGR	-12% rNPV terminal, SEKm	168
Risk free rate	2% Long Term growth	0% Net cash, SEKm	40
WACC	13% Long Term EBIT-margin	35% Shareholder value, SEKm	566
		Shareholder value (SEK)	24.0

Source: Redeye Research

Scenario Analysis

Biovica faces major catalysts in the coming 6-12 months, which will have a major impact on valuation. To illustrate the effects, we consider optimistic and pessimistic scenarios.

In our **optimistic bull case scenario**, we make the following assumptions about critical factors:

- Analytical and clinical validation is completed and the 510(k)-submission is filed in Q3 2020 according to communicated plans. Convincing results from the clinical

validation is presented by KOL:s at a scientific conference. As a consequence, we raise the likelihood of market launch to 95 per cent.

- We assume a faster roll-out and 15 percent penetration in three years.
- Peak sales (gross) rises to about USD 200m.

Our bull case fair value amounts to SEK 37.

In our **cautious bear case scenario**, we assume an out-licensing strategy is pursued. We pencil royalties of 20 percent and upfront and license payments of USD 11m. Compared to the base case, we assume 25 percent lower pricing and penetration, rendering peak sales (gross) of some USD 100m, with Biovica net sales of roughly SEK 200m. Our bear case fair value amounts to SEK 10.6.

"Frothy" Valuation of Cancer Diagnostics could Help Propel Biovica Shares

Since Biovica so far has generated only limited sales, traditional key ratios are not applicable. Below we have listed technology value (EV) of some listed Nordic diagnostics companies which are still in the pre-revenue phase. We believe however that a comparison does not provide much guidance at this point as valuations differs considerably. Notably, the closest peer Arocell has a much lower valuation than Biovica at present.

Peer valuation					
(SEKm)	Market Cap	Share Price	Net Cash	EV	Phase
Arocell	108	1.42	56	52	Clinical validation
Immunovia	2850	145	186	2664	Clinical validation
Prolight Diagnostics	298	2.345	9	290	Product development
2cureX	162	13.05	34	128	Clinical validation
Biovica	665	28.2	40	625	Clinical validation
Average (ex Biovica)	854			783	
Median (ex Biovica)	230			209	
	Market Cap			EV	EV/Sales 20e (X)
Exact (USDM)	12460			12895	10.5
EpiGenomics (EURm)	57			47	13.4
Illumina (USDm)	50340			48901	13.7
Veracyte (USDm)	1324			1184	11.9
MdxHealth (EURm)	58			50	2.1
CareDx (USDm)	1420			1407	9.1
Average					10.1
Median					11.2

Sources: Company Financials, Redeye Research, Bloomberg

Innovative established cancer diagnostics companies enjoy high valuations. Applying the median EV/Sales multiple of 11.2x to our base case sales forecast in five years (SEK 317m) translates into a EV of about SEK 3.6bn. Using a risk factor of 80 percent and a discount rate of 13 percent renders a present value of *SEK 1.5bn or some 65 SEK per share*. We believe some caution is warranted, however due to the possible short term impact of the Covid-19 pandemic on sales estimates, and hence valuations.

Owners and Management

The CEO is The Largest Owner

CEO Anders Rylander is also the largest owner. There are two classes of shares, the A-shares has three times the voting power of the B-shares. Rylander controls some 29 per cent of the votes.

The largest institutional shareholder is Coeli, who participated in the directed share issue in 2019.

Ownership structure as of 30/4 2020	Holdings	Capital	Votes
Anders Rylander	3 955 396	16,61%	28,98%
Gunnar Rylander	1 503 297	6,38%	8,95%
Coeli	1 169 782	4,91%	3,05%
Nordnet Pension Insurance	806 262	3,42%	2,14%
Avanza Pension	784 014	3,33%	2,09%
LYM Consulting AB	49 381	2,09%	1,31%
Henrik Osvald	474 106	1,99%	1,24%
Kristina Gronowitz	411 660	1,75%	3,29%
Lars Holmqvist	410 630	1,72%	1,07%
Eccenovo AB	300 000	1,27%	0,80%
Other shareholders	13 952 520	58,58%	58,58%
Total	23 817 048	100,00%	100,00%

Management

The management team has expanded in the recent year, as Biovica has recruited to positions in R&D, Business Development and Marketing.

Name	Position	Experience
Management		
Anders Rylander	CEO	Anders Rylander is the CEO since 2010. He has a MSc in Mechanical Engineering and has long experience from management consulting at e.g. Accenture and Axholmen. He is the largest shareholder in Biovica, owning 3.58 million A-shares and 369,000 B-shares as well as 20,000 warrants.
Otti Bengtsson Gref	R&D Director	Otti holds a Med Lic in Immunology from Uppsala University and has more than 20 years of experience working within academic research and product development within the biomedical industry, e.g. Thermo Fischer. Previously, Otti served as Research and Development Director at Cavid. She holds 20,000 warrants.
Henrik Winther	SVP Business Development	Henrik has a background as associate professor at the University of Copenhagen and Danish diagnostic company Dako that were later acquired by Agilent. At Dako, Henrik was R&D Director before heading up the Companion Diagnostics Business Area. Previous to joining Biovica, Henrik had the role as SVP Business Development at Swedish diagnostic company Immunovia. He holds 20,000 warrants.
Cecilia Dröving	CFO	Cecilia holds a LL.M and BSc in Business Administration from Stockholm University. She has held several CFO positions in life-science, private equity, research and telecom companies. She also serves as Chairman of Adom AB. She holds 10,000 B-shares as well as 60,000 warrants.
Robert Dann	SVP Marketing	Robert Dann holds an MA in Russian Civilization from the University of Chicago, and an MBA from Columbia University. He has over 20 years' experience in the healthcare industry, in roles spanning country management, global product launches, and strategy. He has concentrated strongly on cancer care AstraZeneca, GE Healthcare and IBM Watson Health.

Sources: Biovica, Redeye Research

Chairman Brings Highly Relevant Experience

Lars Holmqvist has been the CEO of diagnostics company Dako and held senior management positions at Agilent and Medtronic. He is also on the board of the Lundbeck Foundation, H Lundbeck A/S, ALK-Abelló A/S, Tecan AG, BPL Plc-UK and Vitrolife AB. Holdings: 410 630 B-shares, 50 000 warrants 2019/2023 (TO4). He participated in the listing issue in 2017 and became a Senior Adviser in 2018. In 2019, he assumed the role of Chairman of the Board.

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: 4

The CEO Anders Rylander is also the largest owner. The chairman Lars Holmqvist has extensive experience from senior management positions in the medtech/diagnostics industry at e.g. Dako and Agilent.

Business: 2

Cancer care is expected to become more tailored to individual patients, increasing the need for fast and reliable diagnostic tools. To access the wider market for clinical use Biovica needs to team, and share revenue, with larger partners.

Financials: 2

Profitability is dependent on market approval and a successful launch of DiviTum on the US market, and is still some years away. Additional financing is needed within the next twelve months.

INCOME STATEMENT	17/18	18/19	19/20	20/21	21/22
Net sales	3	3	2	3	27
Total operating costs	-18	-22	-26	-37	-57
EBITDA	-16	-19	-24	-34	-30
Depreciation	0	0	0	0	0
Amortization	-2	-3	-4	0	0
Impairment charges	0	0	0	0	0
EBIT	-18	-22	-29	-34	-30
Share in profits	0	0	0	0	0
Net financial items	0	0	0	0	0
Exchange rate dif.	0	0	0	0	0
Pre-tax profit	-18	-22	-29	-34	-30
Tax	0	0	0	0	0
Net earnings	-18	-22	-29	-34	-30

BALANCE SHEET	17/18	18/19	19/20	20/21	21/22
Assets					
Current assets					
Cash in banks	42	17	40	0	0
Receivables	1	2	0	0	0
Inventories	0	0	0	0	3
Other current assets	1	1	0	0	0
Current assets	44	20	40	0	3
Fixed assets					
Tangible assets	3	3	4	0	0
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
O intangible rights	34	38	44	50	50
O non-current assets	0	0	0	0	0
Total fixed assets	36	41	47	50	50
Deferred tax assets	0	0	0	0	0
Total (assets)	81	61	87	50	53
Liabilities					
Current liabilities					
Short-term debt	0	0	0	0	0
Accounts payable	7	8	5	0	0
O current liabilities	0	0	0	0	0
Current liabilities	7	8	5	0	0
Long-term debt	0	1	0	4	37
O long-term liabilities	0	0	0	0	0
Convertibles	0	0	0	0	0
Total Liabilities	7	9	5	4	37
Deferred tax liab	0	0	0	0	0
Provisions	0	0	0	0	0
Shareholders' equity	74	52	80	46	16
Minority interest (BS)	0	0	0	0	0
Minority & equity	74	52	80	46	16
Total liab & SE	81	61	87	50	53

FREE CASH FLOW	17/18	18/19	19/20	20/21	21/22
Net sales	3	3	2	3	27
Total operating costs	-18	-22	-26	-37	-57
Depreciations total	-2	-3	-4	0	0
EBIT	-18	-22	-29	-34	-30
Taxes on EBIT	0	0	0	0	0
NOPLAT	-18	-22	-29	-34	-30
Depreciation	2	3	4	0	0
Gross cash flow	-16	-19	-24	-34	-30
Change in WC	0	0	0	-5	-3
Gross CAPEX	-8	-7	-11	-2	0
Free cash flow	-24	-26	-35	-42	-33

CAPITAL STRUCTURE	17/18	18/19	19/20	20/21	21/22
Equity ratio	91%	86%	92%	92%	31%
Debt/equity ratio	1%	2%	3%	9%	223%
Net debt	-42	-16	-37	4	37
Capital employed	32	36	41	50	53
Capital turnover rate	0.0	0.0	0.0	0.1	0.5

GROWTH	17/18	18/19	19/20	20/21	21/22
Sales growth	0%	10%	-37%	60%	810%
EPS growth (adj)	NA	NA	NA	NA	NA

DCF VALUATION	
WACC (%)	13.0 %
Fair value e. per share. SEK	24
Share price. SEK	28.2

PROFITABILITY	17/18	18/19	19/20E	20/21E	21/22E
ROE	NA	NA	NA	NA	NA
ROCE	NA	NA	NA	NA	NA
ROIC	NA	NA	NA	NA	NA
EBITDA margin	NA	NA	NA	NA	NA
EBIT margin	NA	NA	NA	NA	NA
Net margin	NA	NA	NA	NA	NA

DATA PER SHARE	17/18	18/19	19/20E	20/21E	21/22E
EPS	-1.02	-1.23	-1.21	-1.45	-1.25
EPS adj	-1.02	-1.23	-1.21	-1.45	-1.25
Dividend	0.00	0.00	0.00	0.00	0.00
Net debt	-2.38	-0.90	-1.59	0.17	1.56
Total shares	17.57	17.57	23.57	23.57	23.57

VALUATION	17/18	18/19	19/20E	20/21E	21/22E
EV	119.6	178.3	627.3	668.9	701.5
P/E	-9.0	-9.0	-23.3	-19.4	-22.5
P/E diluted	-9.0	-9.0	-23.3	-19.4	-22.5
P/Sales	59.2	65.1	NA	NA	24.4
EV/Sales	43.9	59.7	NA	NA	25.7
EV/EBITDA	NA	NA	NA	NA	NA
EV/EBIT	NA	NA	NA	NA	NA
P/BV	NA	NA	NA	NA	NA

SHARE PERFORMANCE		GROWTH/YEAR	18/20E
1 month	78.5 %	Net sales	-17.1 %
3 month	53.7 %	Operating profit adj	26.1 %
12 month	168.6 %	EPS, just	8.7 %
Since start of the year	139.0 %	Equity	4.3 %

SHAREHOLDER STRUCTURE %	CAPITAL	VOTES
Anders Rylander	16.6 %	29.0 %
Gunnar Rylander	6.4 %	8.8 %
Coeli	5.0 %	3.1 %
Rbc Investor Services Bank S.A	5.0 %	3.1 %
Nordnet Pensionsförsäkring	3.5 %	2.2 %
SEB Life International	3.4 %	2.1 %
Avanza Pension	3.2 %	2.0 %
LYM Consulting AB	2.1 %	1.3 %
Henrik Osvald	2.0 %	1.3 %
Kristina Gronowitz	1.8 %	3.2 %

SHARE INFORMATION	
Reuters code	BIOVICb.ST
List	First North Premier
Share price	28.2
Total shares. million	23.6
Market Cap. MSEK	664.8

MANAGEMENT & BOARD	
CEO	Anders Rylander
CFO	Cecilia Driving
IR	Cecilia Driving
Chairman	Lars Holmqvist

FINANCIAL INFORMATION	
FY 2020 Results	June 12, 2020
Q1 report	August 27, 2020
Q2 report	December 03, 2020

ANALYSTS	
Niklas Elmhammer	Redeye AB
niklas.elmhammer@redeye.se	Mäster Samuelsgatan 42, 10tr
	111 57 Stockholm

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.

Redeye Equity Research team

Management

Björn Fahlén

bjorn.fahlen@redeye.se

Håkan Östling

hakan.ostling@redeye.se

Technology Team

Jonas Amnesten

jonas.amnesten@redeye.se

Henrik Alveskog

henrik.alveskog@redeye.se

Havan Hanna

havan.hanna@redeye.se

Kristoffer Lindström

kristoffer.lindstrom@redeye.se

Erika Madebrink

erika.madebrink@redeye.se

Fredrik Nilsson

fredrik.nilsson@redeye.se

Tomas Otterbeck

tomas.otterbeck@redeye.se

Eddie Palmgren

eddie.palmgren@redeye.se

Oskar Vilhelmsson

oskar.vilhelmsson@redeye.se

Viktor Westman

viktor.westman@redeye.se

Editorial

Eddie Palmgren

eddie.palmgren@redeye.se

Mark Siöstedt

mark.siostedt@redeye.se

Life Science Team

Gergana Almquist

gergana.almquist@redeye.se

Oscar Bergman

oscar.bergman@redeye.se

Anders Hedlund

anders.hedlund@redeye.se

Arvid Necander

arvid.necander@redeye.se

Erik Nordström

erik.nordstrom@redeye.se

Jakob Svensson

jakob.svensson@redeye.se

Ludvig Svensson

ludvig.svensson@redeye.se

Niklas Elmhammer

niklas.elmhammer@redeye.se

Mats Hyttinge

mats.hyttinge@redeye.se

Disclaimer

Important information

Redeye AB ("Redeye" or "the Company") is a specialist financial advisory boutique that focuses on small and mid-cap growth companies in the Nordic region. We focus on the technology and life science sectors. We provide services within Corporate Broking, Corporate Finance, equity research and investor relations. Our strengths are our award-winning research department, experienced advisers, a unique investor network, and the powerful distribution channel redeye.se. Redeye was founded in 1999 and since 2007 has been subject to the supervision of the Swedish Financial Supervisory Authority.

Redeye is licensed to; receive and transmit orders in financial instruments, provide investment advice to clients regarding financial instruments, prepare and disseminate financial analyses/recommendations for trading in financial instruments, execute orders in financial instruments on behalf of clients, place financial instruments without position taking, provide corporate advice and services within mergers and acquisition, provide services in conjunction with the provision of guarantees regarding financial instruments and to operate as a Certified Advisory business (ancillary authorization).

Limitation of liability

This document was prepared for information purposes for general distribution and is not intended to be advisory. The information contained in this analysis is based on sources deemed reliable by Redeye. However, Redeye cannot guarantee the accuracy of the information. The forward-looking information in the analysis is based on subjective assessments about the future, which constitutes a factor of uncertainty. Redeye cannot guarantee that forecasts and forward-looking statements will materialize. Investors shall conduct all investment decisions independently. This analysis is intended to be one of a number of tools that can be used in making an investment decision. All investors are therefore encouraged to supplement this information with additional relevant data and to consult a financial advisor prior to an investment decision. Accordingly, Redeye accepts no liability for any loss or damage resulting from the use of this analysis.

Potential conflict of interest

Redeye's research department is regulated by operational and administrative rules established to avoid conflicts of interest and to ensure the objectivity and independence of its analysts. The following applies:

- For companies that are the subject of Redeye's research analysis, the applicable rules include those established by the Swedish Financial Supervisory Authority pertaining to investment recommendations and the handling of conflicts of interest. Furthermore, Redeye employees are not allowed to trade in financial instruments of the company in question, from the date Redeye publishes its analysis plus one trading day after this date.
- An analyst may not engage in corporate finance transactions without the express approval of management and may not receive any remuneration directly linked to such transactions.
- Redeye may carry out an analysis upon commission or in exchange for payment from the company that is the subject of the analysis, or from an underwriting institution in conjunction with a merger and acquisition (M&A) deal, new share issue or a public listing. Readers of these reports should assume that Redeye may have received or will receive remuneration from the company/companies cited in the report for the performance of financial advisory services. Such remuneration is of a predetermined amount and is not dependent on the content of the analysis.

Redeye's research coverage

Redeye's research analyses consist of case-based analyses, which imply that the frequency of the analytical reports may vary over time. Unless otherwise expressly stated in the report, the analysis is updated when considered necessary by the research department, for example in the event of significant changes in market conditions or events related to the issuer/the financial instrument.

Recommendation structure

Redeye does not issue any investment recommendations for fundamental analysis. However, Redeye has developed a proprietary analysis and rating model, Redeye Rating, in which each company is analyzed and evaluated. This analysis aims to provide an independent assessment of the company in question, its opportunities, risks, etc. The purpose is to provide an objective and professional set of data for owners and investors to use in their decision-making.

Redeye Rating (2020-05-24)

Rating	People	Business	Financials
5p	14	11	4
3p - 4p	105	81	30
0p - 2p	7	34	92
Company N	126	126	126

Duplication and distribution

This document may not be duplicated, reproduced or copied for purposes other than personal use. The document may not be distributed to physical or legal entities that are citizens of or domiciled in any country in which such distribution is prohibited according to applicable laws or other regulations.

Copyright Redeye AB.

CONFLICT OF INTERESTS

Niklas Elmhammer owns shares in Biovica : No
Redeye performs/have performed services for the Company and receives/have received compensation from the Company in connection with this.