BIOVICA

Best possible treatment from day one

About

BIOVICA

Biovica develops and commercializes blood-based biomarker assays that improve the monitoring of modern cancer therapies and helps to predict patient outcome. Biovica's initial focus is breast cancer, where approximately 1,600 new cases are diagnosed every day in the EU and US alone.

By collaborating with world-leading cancer institutes as well as pharmaceutical companies launching next-generation therapies, Biovica actively promotes the growing drive towards personalized medicine. Improved patient survival and lower healthcare costs are two anticipated and welcome outcomes.

Biovica's clinical validation plan has been selected to receive funding in the Horizon 2020 phase 2 program, which is a European Commission initiative.

PATENTS IN **49** COUNTRIES	**16** PUBLICATIONS	**10** ONGOING STUDIES
ISO **13485** CERTIFICATE	DIVITUM CE-MARKING	LISTED ON FIRST NORTH PREMIER BIOVIC B

SELECTED PARTNERSHIPS

BIG Breast International Group · IBCSG · Karolinska Institutet · City of Hope · DANA-FARBER CANCER INSTITUTE · Penn University of Pennsylvania · KU The University of Kansas · Johns Hopkins University · Lunds Universitet · ITT Istituto Toscano Tumori

TODAY'S PRESENTER

Anders Rylander
CEO
Anders Rylander holds a MSc in Mechanical Engineering from the Swedish Royal Institute of Technology. He has been a management consultant for over 15 years in companies such as Accenture and Andersen Consulting. Additionally, Anders has an entrepreneurial background as he founded two companies; Axholmen and Arinvest.

Jarl Ulf Jungnelius
Director
Ulf is a board-certified oncologist trained at the Karolinska Institute. He has over 20 years of experience in pharmaceutical drug development and has held top positions at Clinical Research and Development, Oncology, Celgene, Pfizer, Eli Lilly, and Takeda Pharmaceuticals.

Karin Mattsson
R&D Director
Karin has a PhD in cell and tumor biology from the Karolinska Institute. She has over 20 years' experience of working within academic research within the biomedical industry. She has held various technical and managerial positions within in R&D and has significant experience of in-vitro diagnostic assay development.

Cecilia Driving
CFO
Cecilia holds a LLM and BSc in Business Administration from Stockholm University. She has held several CFO positions in life-science, private equity, research and telecom companies. Cecilia joined Biovica in 2016. She also serves as Chairman of Adom AB.

History of Biovica

2008

Biovica is founded

The company was founded to develop and commercialize innovative methods to measure cell proliferation

2009

Re-start

During the financial crisis of 2008, Biovica was unable to find sufficient financing and the patents and the name Biovica was acquired by Rönnerbol Holding AB

2010

First EU-funding

Rönnerbol Holding AB changed name to Biovica International AB and the company received 1.9 MEUR in funding from the European Union

2011

New CEO

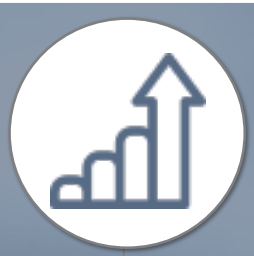
Anders Rylander takes office as CEO

Clinical collaboration with Karolinska Institute starts

2012

Winner of NSA

Biovicas research has gained international recognition by winning the Network Stars Award for the best research project within EU



2014

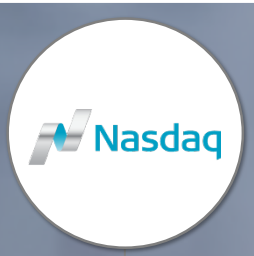
Business takes off

A dramatic increase in sales (driven by research institutes and hospitals) is seen and the product quality is improving steadily

2016

cSens Acquisition

The firm acquires bio-tech company cSens to complement its existing technology. The company raises 30 MSEK in equity, partially to finance the acquisition



2017

Nasdaq First North IPO

On March 29, Biovica is introduced on the Swedish stock exchange First North, resulting in a 60 MSEK capital raise

2018

Positive clinical results

Several positive results from clinical studies including positive response from FDA regarding analytical validation for supplement #1

Extended and approved patent in the US, China and India

2019

US office opened

Biovica Inc. is established and sets up headquarters in Boston, MA, as DiviTum closes in on FDA approval

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Cancer diagnosis – a prerequisite for efficient cancer treatment

OVERVIEW OF CANCER DIAGNOSTICS

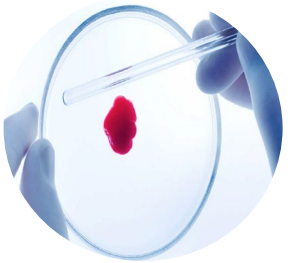
CANCER DIAGNOSIS

Primary aim with cancer diagnosis is to determine type of treatment
Clinicians may use one or several approaches to diagnose cancer incl. laboratory tests, imaging tests and biopsy

Early detection of the cancer and relevant treatment is key to survival
5-year survival rate for women with breast cancer in Stage I is 100% and 22% when the cancer is in Stage IV (metastasized)

Improved cancer diagnostic tools can save lives and money
Early detection and feedback on treatment response makes it easier for clinicians to decide on the right treatment, improving outcome and mitigates the risk of spending money on an inefficient treatment

OVERVIEW OF BIOMARKERS AND WHY THEY ARE NEEDED



CANCER BIOMARKERS

Biomarkers are traceable substances used as an indicator of biological state
Cancer biomarkers are molecules that indicates the presence of cancer or gives information about the likely future behaviour of cancer (i.e likelihood of progression or response to therapy)[1]

Profound approach for obtaining rapid results for treatments
Cancer biomarkers are used for diagnostic, predictive, prognostic and monitoring purposes

Biomarkers can be the answer to an efficient personalized cancer treatment
Biomarkers can be used for better risk assessment, prediction of outcome, selection of individual therapy and monitoring of therapy efficacy

 Source: (**1**) Duffy et al. Med. Princ. Pract., 2013, 22,p.4-11.

Case study: Pfizer – Ibrance in metastatic breast cancer

AREA OF PROBLEM

- Ibrance (Palbociclib) belongs to a new class of drugs (CDK-inhibitors), which have achieved extraordinary results in clinical studies with patients suffering from metastatic breast cancer (MBC). The drug class inhibits the cell cycle, which prevents tumour growth. Ibrance can be given to about 80% of patients with MBC (all HR+)

- The costs for Ibrance currently amount to approximately USD $12,000 / patient & month, which makes Ibrance one of the world's most expensive cancer drugs[1]
- However, 40% of the patients who receive the drug do not respond, which results in the patient risking an expensive and ineffective treatment[2]

- Today there is no biomarker that can identify patients who will respond to the treatment or evaluate whether the drug has desired effect on the patient

BIOVICA'S SOLUTION – DIVITUM®

- DiviTum® is a blood test that makes it possible to evaluate whether Ibrance treatment gives the desired effect on the patient

- By using DiviTum®, oncologists can quickly exclude non-responders and thereby avoid expensive and ineffective treatments.
- Additional clinical results on DiviTum and CDK inhibitors will be presented at the AACR annual meeting in Atlanta, 29 March-3 April.

- DiviTum® can be used by pharmaceutical companies as a biomarker in pre-clinical and clinical studies for the development of cell-cycle regulating pipeline compounds

Source: (**1**) Available online: www.goodrx.com/breast-cancer/drugs, Accessed 19 Mar. 2019; (**2**) Finn R et al, "Palbociclib and Letrozole in Advanced Breast Cancer", NEJM 2016 Nov 17;375(20):1925-1936

Large unmet need for selecting and evaluating cancer treatment

Urgent need for a tool to predict and monitor treatment response

+43m

People in the world living with cancer

There are estimated to be more than 43 million people in the world living with cancer and more than 14 million diagnosed with cancer each year[1]

c.80%

Patients do not respond to the treatment

The first line of treatment in cancer patients often proves inefficient with up to 80% of the treated cancer patients showing no response to the initial treatment[2]

The treatment needs to be personalized

The main reason behind the low efficacy in cancer treatments is that each patient has unique treatment response. Hence, it is critical to quickly detect whether the patient responds to the treatment and adapt it accordingly

PROBLEM WITH CURRENT METHODS

- Difficult for the clinicians to determine correct therapy for the patient at an early stage
- Risk of exposing a patient with a prolonged toxic treatment that proves ineffective
- Risk that the patient develops resistance against the therapy, creating a need to quickly switch treatment once signs of resistance is detected

A tool to determine how well patients respond to treatment means that ineffective therapies could quickly be replaced with more efficacious ones

KOLs have acknowledged the problem and calls for a solution

"With the goals of therapy focused on improving quality of life and overall survival, the challenge has been finding a test that is safe, non-invasive and reliable to assess response"

"In the metastatic setting, for those undergoing treatment, it is crucial to determine responders versus non-responder in order to help guide treatment decisions"

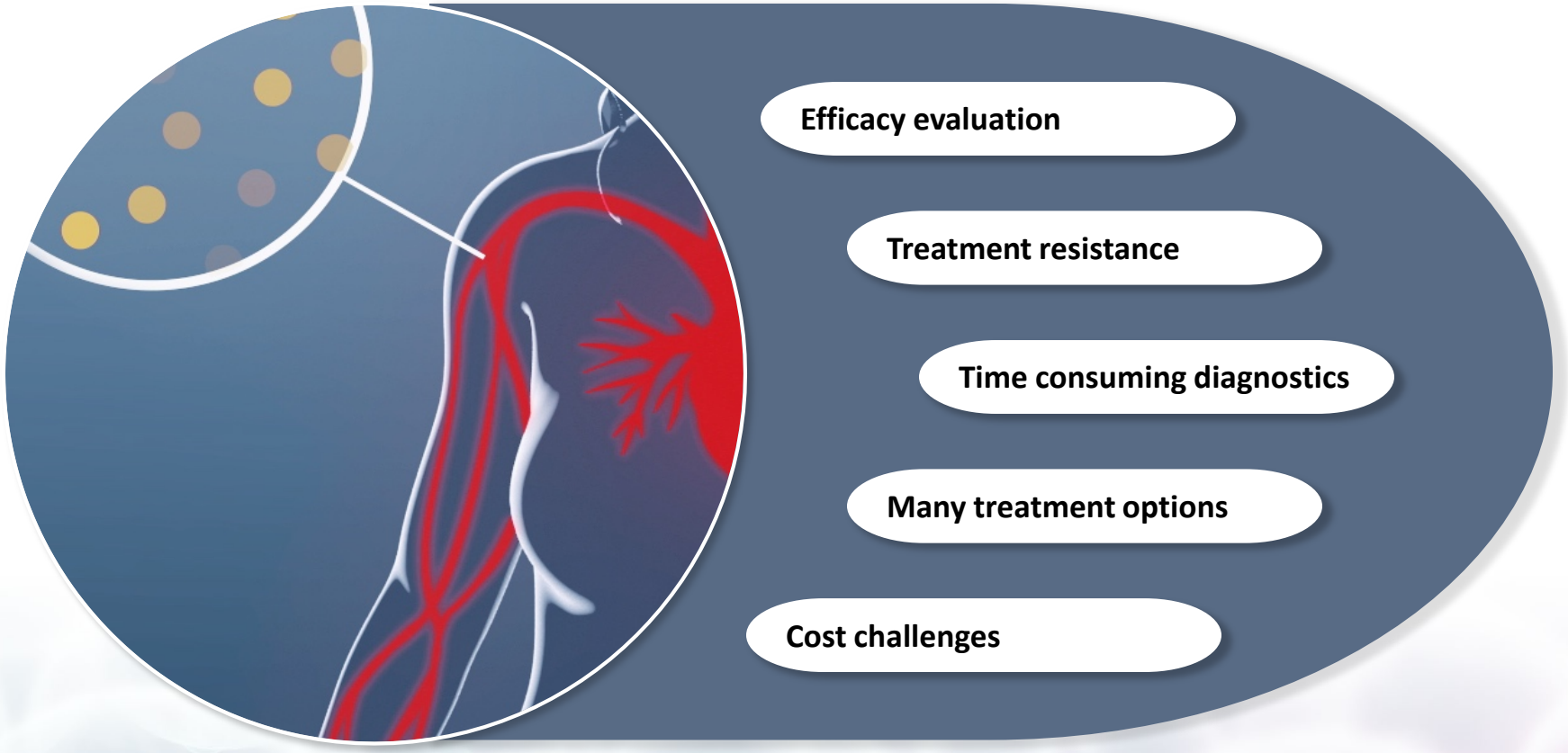
- Lindsey J. Graham et al.[3]

"We still have a desperate need for biomarkers to identify tumors that are most likely to benefit from these novel approaches"

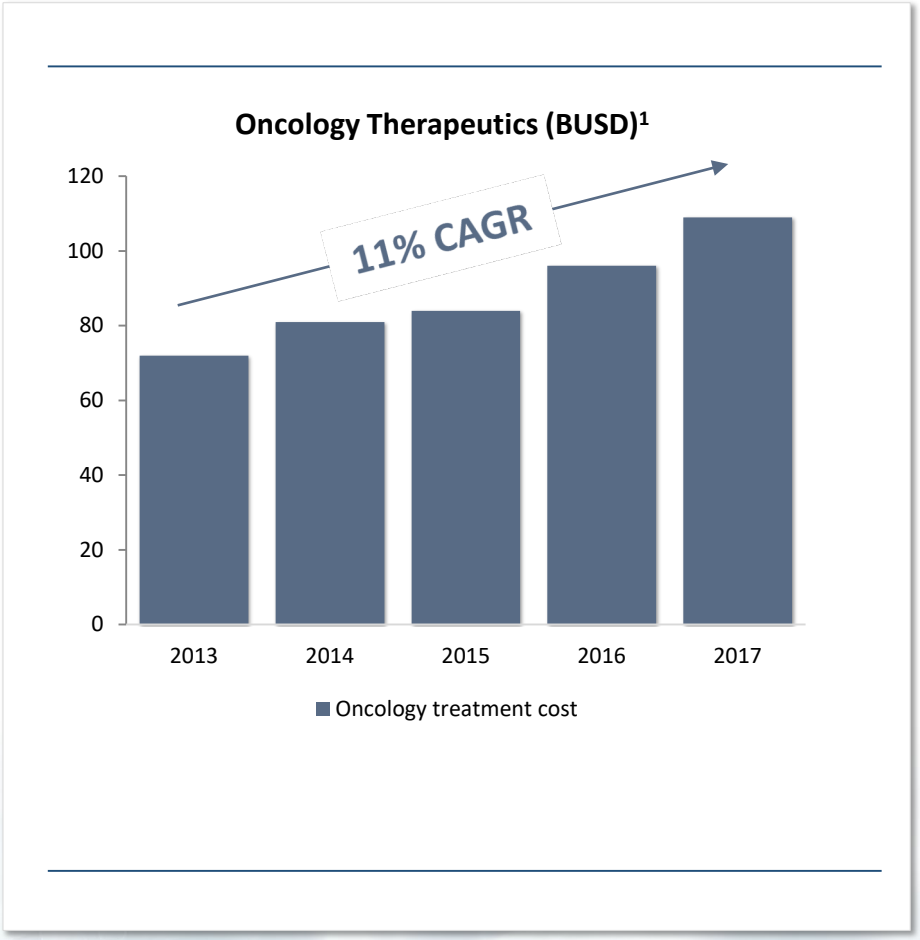
- Professor Hope Rugo, UCSF[4]

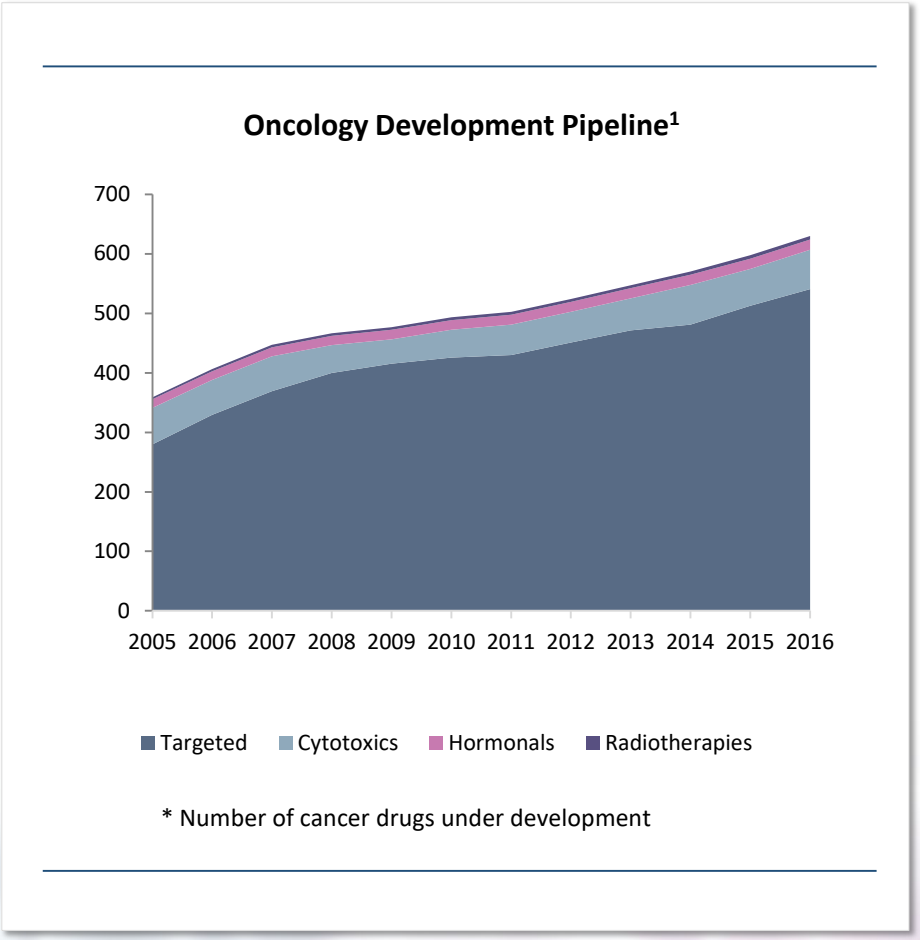
Note: (**1**) Globocan, 2018. (**2**) Norbert Avril et al, "Response to Therapy in Breast Cancer", The journal of nuclear medicine, 2009. (**3**) Graham LJ, et al. Current approaches and challenges in monitoring treatment responses in breast cancer. J Cancer 2014; 5(1):58–68.; (**4**) http://www.ascopost.com/issues/november-1-2014/novel-agents-may-address-endocrine-therapy-resistance/#.XJC07xmDMOY.email

Unmet need for biomarkers for personalized cancer treatments



Cost for cancer treatments exceeds USD 100 billion





≥ 90% OF NEW TREATMENTS ARE TARGETED OR HORMONALS

 Source: (1) IQVIA Oncology cost report 2018.

Biovica focuses primarily on metastatic breast cancer

LARGE ADDRESSABLE MARKET

450,000 patients

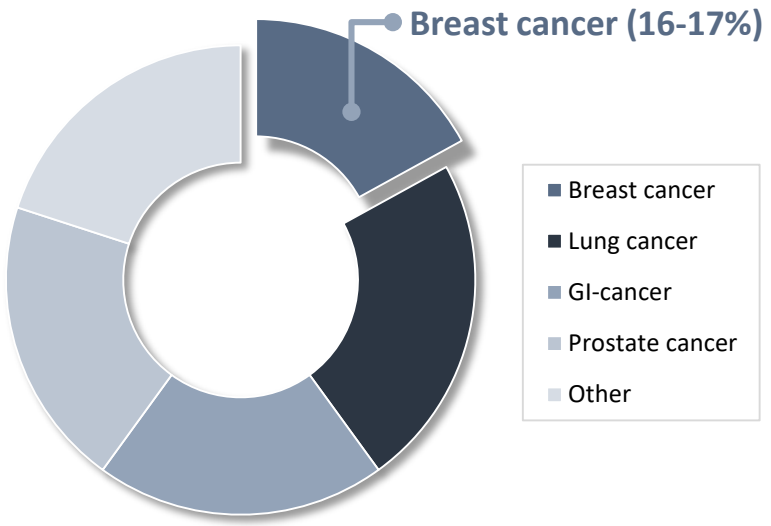
There are currently approximately 450,000 patients with metastatic breast cancer in US and Europe[1]

SEK **6bn**

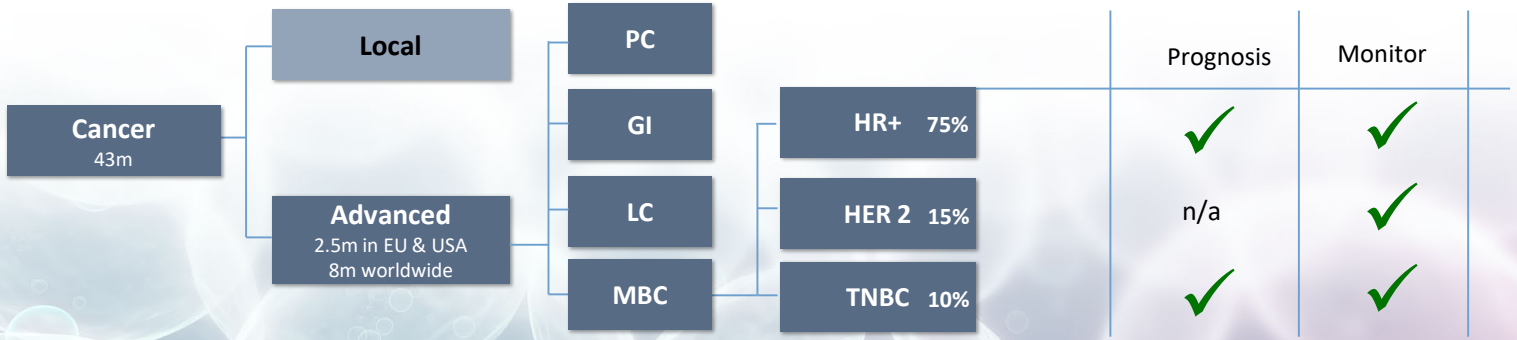
The addressable market for DiviTum® in metastatic breast cancer alone amounts to SEK 6 billion per year in the US and Europe[2]

Breast cancer only comprise 16-17% of all metastatic cancer types providing a significant upside potential for Biovica by expanding into the other metastatic cancers as well as into local cancer types and CDx

Distribution of metastatic cancer types



Metastatic Breast Cancer – Focus area for Biovicas first clinical application

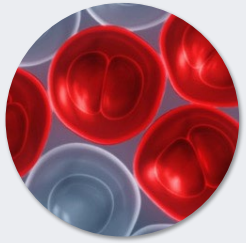


 Source: (**1**). Metastatic Breast Cancer Network, "Most Common Statistics Cited for MBC 2016"; (**2**) Based on the size of the patient group, number of test per patient and a company estimate on the price per patient test.

Competing technologies suffer from various drawbacks

DIRECT COMPETITORS

BLOOD BASED BIOMARKERS



The technology
- Includes e.g. CA 15-3 and CEA.[1]
- Identifies specific proteins in the blood.[1]

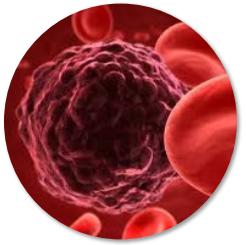
Pros
- Blood based and can be performed frequently

Cons
- Low sensitivity and may be confused with other inflammatory conditions.[2]
- Cannot be the basis for treatment assessment standalone.[2]
- Not standardized and lacking qualitative data.[3]
- Inadequate for endocrine treatment monitoring.[2]

Active TK companies
- Diasorin - TK activity test
- Beckman Coulter - TK activity test
- Arocell TK concentration

OTHER COMPETING DIAGNOSTIC METHODS

CIRCULATING TUMOR CELLS



The technology
- Quantifies circulating tumor cells in the blood

Pros
- Blood-based

Cons
- Not recommended to be used for monitoring due to its unknown clinical use.[4]
- Because of the rarity of the tumor cells, a blood sample may not reflect the actual occurrence in the body.[4]
- Inconsistent results in clinical studies.[4]

Active companies
- CellSearch

IMAGING DIAGNOSTICS

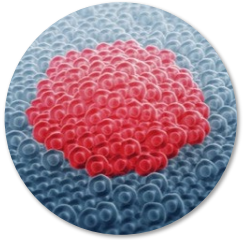
The technology
- Includes PET, CT and MRI.[1]
- Measures tumor volume.[5]

Pros
- Non-invasive

Cons
- Most are radioactive[1]
- 40% of patients develop a metastasis that cannot be measured.[1]
- 2-4 months before response can be evaluated
- Measures differences in tumor volume
- Expensive and time consuming

Active companies
- GE Healthcare
- Siemens
- Philips

BIOPSY



The technology
- Used e.g. a for hormone receptor analysis, HER2 status and Ki-67

Pros
- Allows analysis of genetic set

Cons
- Difficult to access metastases in the skeleton.[1]
- Cannot be used frequently to evaluate the effect of treatment.[6]
- Inconsistent responses due to where in the tumour biopsy is performed.[6]

Active companies
- Sigma Aldrich
- Dako
- Immunotech

Source: (**1**). Graham et al. "Current Approaches and Challenges in Monitoring Treatment Responses in Breast Cancer", Journal of cancer, 2014; (**2**) R. Bartsch, "Prognostic value of monitoring tumour markers CA 15-3 and CEA during fulvestrant treatment", BioMed Central, 2006 ;(**3**) cancer.net, "Biomarkers to Guide Treatment for Metastatic Breast Cancer" (**4**) 6.B. Hong, "Detecting Circulating Tumor Cells: Current Challenges and New Trends", Theranostics, 2013; (**5**) N. Avril et al, "Response to Therapy in Breast Cancer", The journal of nuclear medicine, 2009; (**6**) M. Dowsett, "Assessment of Ki67 in Breast Cancer: Recommendations from the International Ki67 in Breast Cancer Working Group", JNCI, 2011

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DiviTum® a blood based biomarker assay

- **Blood based**
- **ELISA – standardized platform**
- **Monitor and predict treatment response**
- **Patented method and kit**
- **CE-marked**

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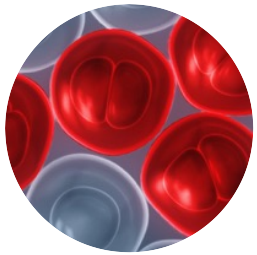
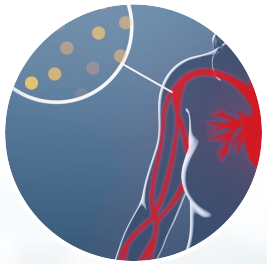
DiviTum® – enables best possible treatment from day one

DiviTum® helps to determine the efficacy of the cancer therapy



DiviTum® measures cell growth rate …

- Divitum® is an innovative biomarker test developed to provide prognosis and monitor therapy response in treatment of solid tumors
- Measures the activity in the enzyme thymine kinase-I (TK), in serum or in cell cultures. The TK-activity is low in normal cells and high in active tumors, providing a good biomarker for tumor aggressiveness

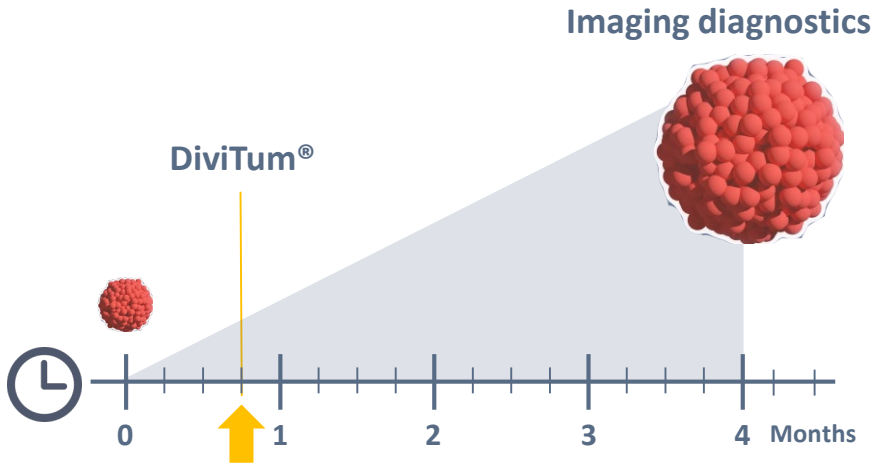


… and provides quick data on patient's tumor response

- As patients respond differently to different cancer treatments, it is crucial to early on in the process get an insight in the patient's treatment response
- DiviTum® provides the clinicians with a diagnostic tool that quickly tells them whether the patient respond to the cancer treatment

Response rate is superior to regular imaging diagnostic

DiviTum® can determine a tumor response in 2-4 weeks compared to 2-4 months with regular medical imaging diagnostics[1,2]



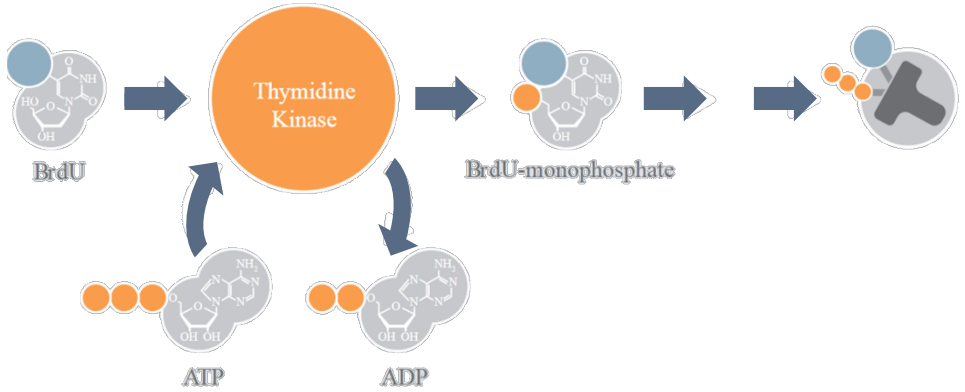
Comments

- The major disadvantage with today's standard diagnostic method – m*edical imaging diagnostics* – is that it measures the change in tumor volume, a slow and expensive method to detect tumor response
- DiviTum® helps clinicians to evaluated the targeted treatment strategy much earlier than other diagnostic method available, resulting in an optimized treatment for each individual patient

Source: (**1**) Gold, L.S., et al., Imaging Techniques for Treatment Evaluation for Metastatic Breast Cancer: Technical Brief No. 17.2014: Rockville (MD); (**2**) Liu N et al, San Antonio Breast Cancer Symposium 2016.

Unique proprietary technology to determine cell proliferation

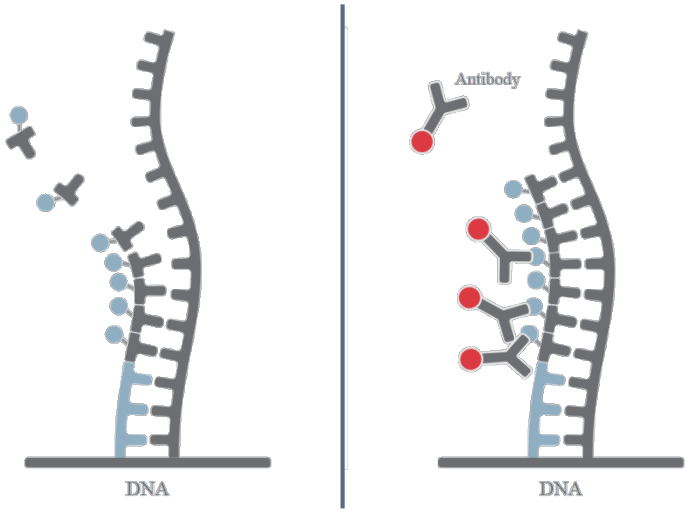
DiviTum® measures and analyses the enzymatic activity of TK



Comments

- Analysis is performed using a 96-well microtiter plate
- A sample is incubated with a substrate; BrdU (a thymidine analogue) and a phosphate donor; ATP
- If Thymidine Kinase (TK) is present in the sample it will phosphorylate BrdU, forming BrdUMP (BrdU-monophosphate)
- Additional phosphorylation steps will form BrdUTP (BrdU-triphosphate)
- A set of reference samples with known TK activity (Calibrators), as well as three controls (low, middle, high) are added to the plate for each run
- The Calibrators are used for determining the TK activity in the sample

Detection of TK activity



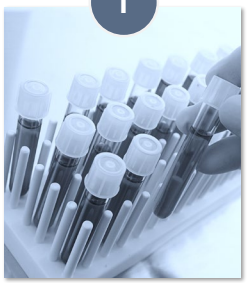
Comments

- Formed BrdUTP is incorporated via a DNA polymerase into polynucleotide strands attached to the microtiter plate. Non-bound components are washed away
- The incorporated BrdUTP is quantified using a BrdU antibody conjugated with AP (alkaline phosphatase). Non-bound antibodies are washed away
- Incubation with a substrate for AP will turn the substrate color from colorless to yellow. The change in color (absorbance) is determined using a spectrophotometer
- The color developed is proportional to the amount of BrdUMP formed by TK, which is proportional to the initial TK activity in the sample

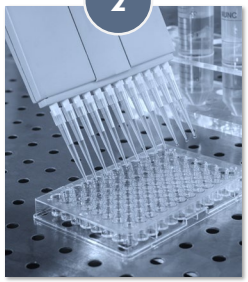
Quick non-invasive test performed during routine blood tests

IMPLEMENTATION OF BIOVICA'S TEST

MEASUREMENT OF TK-AKTIVITY



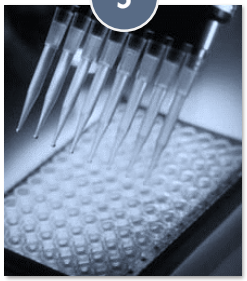
- A blood sample is drawn from the patient
- Serum is separated



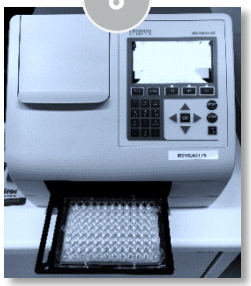
- Serum samples are mixed and incubated with a reaction mix in a 96-well microplate
- The thymidine kinase (TK) in serum phosphorylates the thymidineanalog BrdU
- Additional enzymatic steps form a DNA strand of the phosphorylated BrdU molecules

- The plate is washed using an ELISA microplate washer

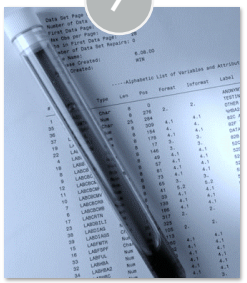
- Incubation with anti-BrdU antibodies
- With antibodies, the amount of BrdU DNA formed is determined and the TK activity can be calculated



- Following another wash, the plate is incubated with a Substrate



- Absorbance is measured using an ELISA- microplate reader (spectrophotometer)
- TK activity is calculated



- The Oncologist gets the result and can evaluate the response to therapy

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DiviTum® is validated in 16 published studies

Indication	Studies	Patients
Breast cancer	5	635
Breast and Colorectal cancer (GI)	1	79
Lung cancer	2	281
Kidney cancer (GI)	2	230
Pancreatic cancer (GI)	1	404
Blood cancer	4	440
Method	1	368
Total	**16**	**2,437**

16 articles, peer reviewed and published in oncology journals

Results within major oncology areas (Breast, Lung, Gastro Intestinal, Blood malignancies)

Ongoing program within breast cancer with world leading cancer institutes

DiviTum®– strong evidence within breast cancer

Summary of results from published (or presented) breast cancer studies

Study	Stage	#Pat	Results[1]
BRCA	High risk	80	DiviTum able to predict which high-risk-patients (BRCA-positive) that would develop cancer.
BC early	I,II	161	DiviTum able to predict risk for recurrence within 5 years.
TEX	III, IV	287	DiviTum prognostic for progression and survival. Better than CA 15-3 (golden standard marker breast cancer).
Wash-U	II, III	48	DiviTum able to assess changes caused by targeted treatment , 2 weeks after treatment start. Correlated to biopsy proliferation marker.
Pilot Prato	IV	31	DiviTum able to identify patients responding to hormonal treatment both before and after one month of treatment.
Lund	IV	142	DiviTum able to identify patients responding to 3 types of treatments both before and during treatment.
EFECT	IV	244	DiviTum able to identify patients responding to hormonal treatment (2nd line) both before and after one month of treatment.
TREnd	IV	45	DiviTum can be used to evaluate the efficacy of palbociclib in metastatic breast cancer.
8 studies	**All stages**	**1,038**	

ALL STUDIES SHOW STATISTICALLY SIGNIFICANT RESULTS

 Source: (1) Please refers to appendix or http://biovica.com/technology/publications/

Ongoing collaborations with world-leading institutes

Collaboration	Study	Stage	Patients	Endpoints
BIG Breast International Group / IBCSG	PYTHIA	IV	120	TK-activity for targeted drug response
Karolinska Institutet	PREDIX	III	200	TK for targeted drug response and survival
Lunds Universitet	LUND MBCT	IV	142	TK activity prognostic for PFS and OS, correlates with KI-67.
The University of Kansas	FELINE	III	120	TK for targeted drug response and correlation to other biomarkers
City of Hope	PALBO+ PEMBRO	IV	18	Pilot two targeted drugs
	EFECT	IV	244	TK activity is prognostic for TTP
Penn	RIBO+PACL	IV	28	Pilot chemo & targeted drug
Johns Hopkins	PALBO	IV	100	Biomarker for targeted drug resistance
	TREnd	IV	45	TK can evaluate the efficacy of palbociclib
Dana-Farber Cancer Institute	PALBO/ MEK	IV	139	TK for targeted drug response
	10 studies	**III-IV**	**1,156**	

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Clear strategy for commercialization of DiviTum®

STEP 1: CREATE DEMAND

- By utilizing clinical results from leading research groups, such as Dana Farber and IBCSG, and through health economic studies, Biovica collects data for reimbursement
- Continue work on expanding the Key opinion leader network (KOL) in Europe and the US
- KOLs publishes data and presents the technology at oncology conferences with high impact
- Studies with KOLs are the basis for inclusion in national treatment guidelines and recommendations

STEP 2: SECURE ACCESS TO KEY MARKETS

- Sales in the EU and the US (outside reimbursement) to pharmaceutical companies and research groups to generate early reveneues for DiviTum®
- Analytical and clinical validation of assay to generate data for FDA 510k application
- Studies for regulatory approval
- FDA 510k submission by end of 2019

STEP 3: ESTABLISH PARTNERSHIP FOR SALES AND MARKETING

- FDA approval in the United States. Clinical evidence from the FDA application complements data for reimbursement
- Reimbursement is obtained in selected European countries as well as the USA in 2020
- Establish commercial partnership for sales and marketing in US and selected markets in Europe

STEP 4: FULL SCALE COMMERCIALIZATION AND EXPANISION OF INDICATIONS

- Sales in key markets through commercial partners (clinical laboratories and diagnostic companies)
- Extend DiviTum ® - to include additional indications and tumors
  - Collaboration at Dana Farber initiated in lung cancer - 500,000 new cases per year (US and Europe)
  - Evaluation of future treatments (focus cell-cycle regulating targeted drugs)
  - Next Generation Endocrine Drugs (SERDs) and Immunotherapies

2019 | **2020** | **2021-**

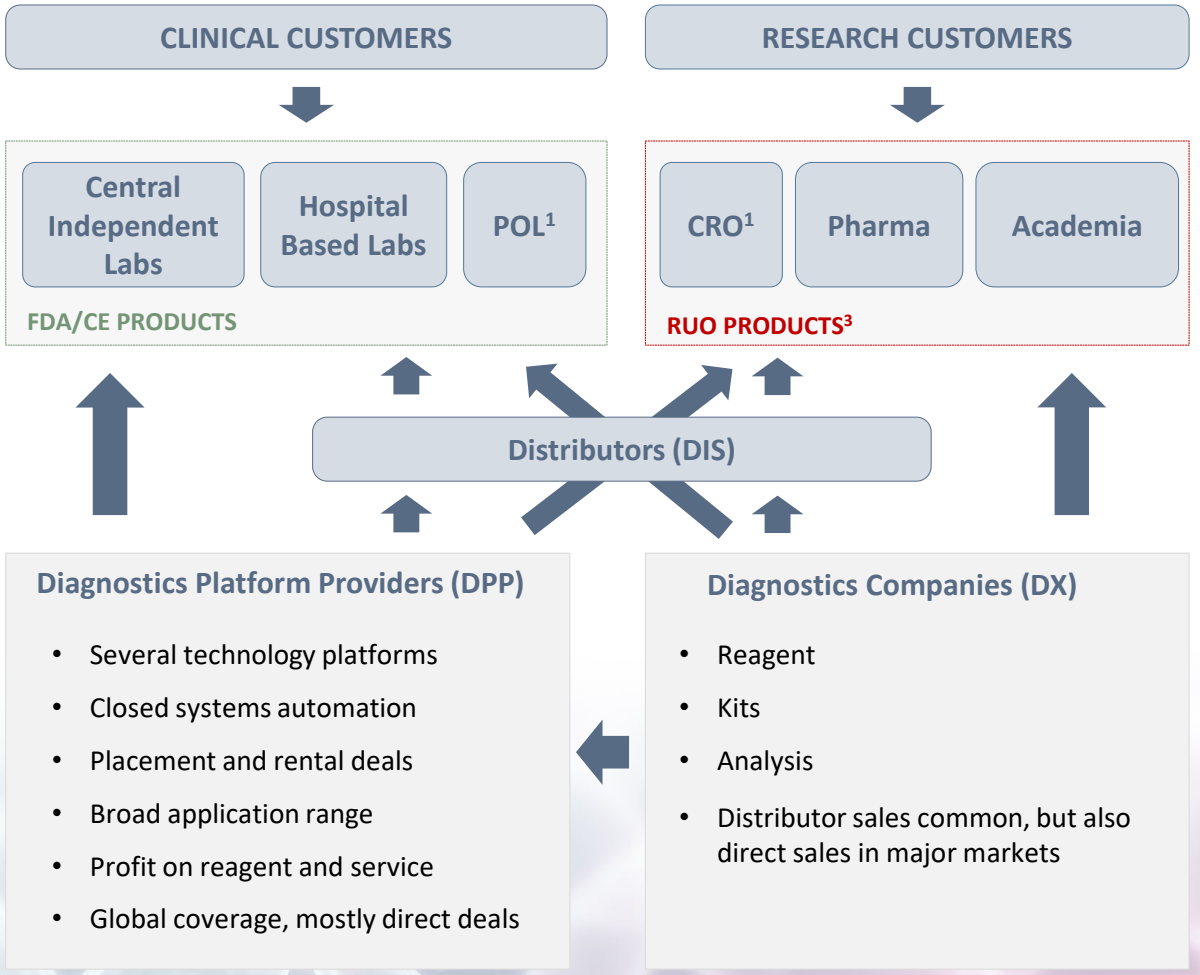
BIOVICA

Business model

Comments

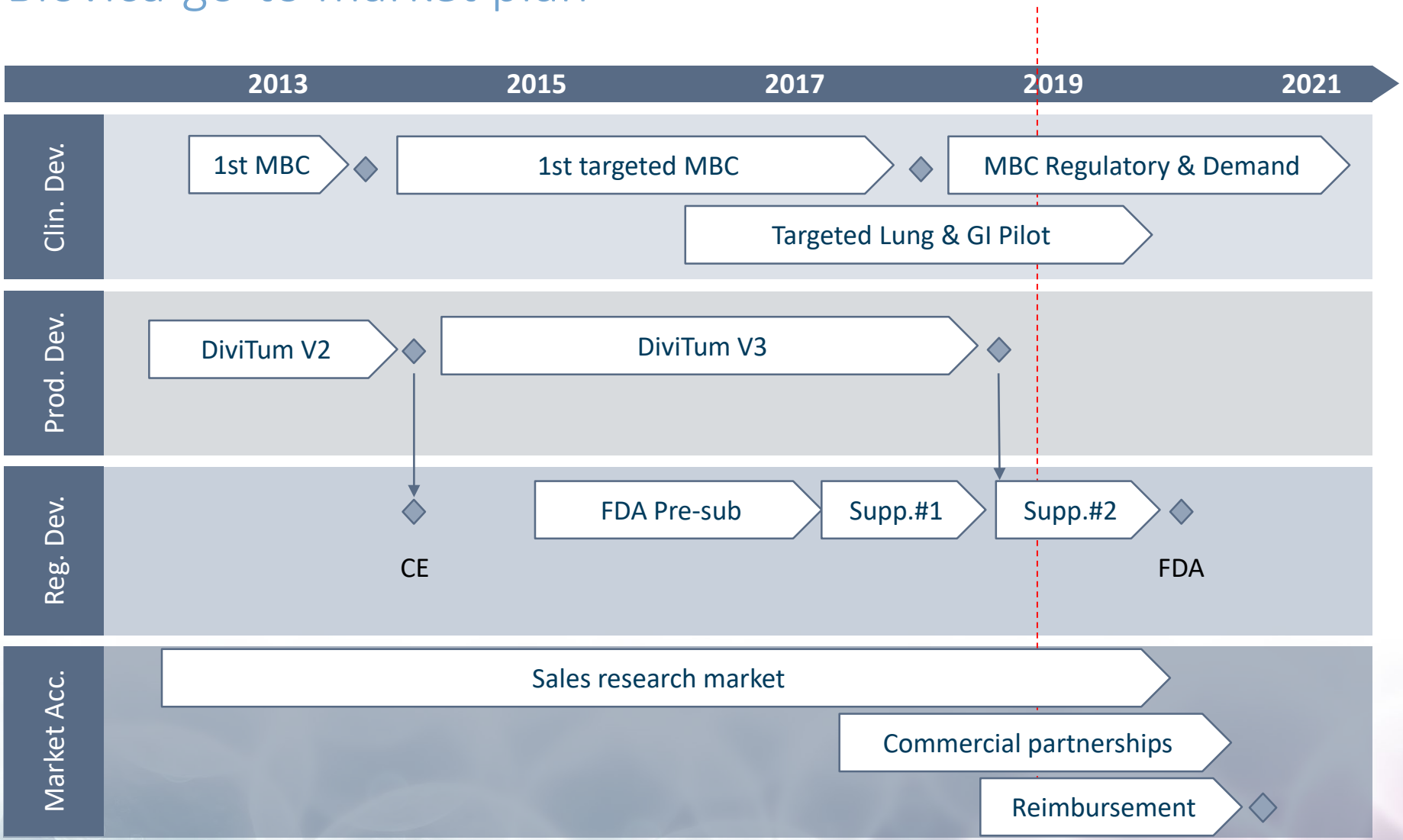
- Biovica is currently a diagnostic supplier selling directly to the Research Market
- Biovica's main target is the clinical market. The strategy to commercialize this segment is to establish partnership with diagnostic suppliers
- Diagnostic suppliers can be categorised into two main groups:
  1) Smaller diagnostic companies supplying analysis, reagents and kits – both own and OEM-kits. They typically use distributors
  2) Multinational diagnostic companies with large automated diagnostic platforms, i.e. Diagnostic Platform Providers (DPP)
- DPP help improve efficiency for large central and hospital labs, by offering automated laboratory solutions
- Collaboration with a DPP can be very beneficial as they have all the regulatory resources, sales and marketing functions as well as large installed base of automated systems
- DPPs of interest are companies such Roche Diagnostics, Siemens Healthineers, Abbott Laboratories, Beckman-Coulter. (Danaher), Sysmex and others

Market structure/value chain



 Note: (**1**) POL is an abbreviation of Physicians' Office Laboratory; (**2**) CRO is an abbreviation of Contract Research Organization; (**3**) RUO products refers to products that are for "Research Use Only".

Biovica go-to market plan



BIOVICA

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Several near term value triggers

2019

Clinical Trails

- Results from CDK-inhibitor trials
- Publication from Lund trial on metastatic breast cancer - 144 patients

Market Access

- 510k application submitted
- Health Economic Model established

Commercial Partnership

- Partnership for research market sales

2020

Clinical Trails

- Results from prospective trials on CDK inhibitors
  - PYTHIA – IBSCG & BIG
  - PREDIX – Karolinska
- Results from FELINE trial, CDK Inhibitors, stage III

Market Access

- 510k approval
- First reimbursement on US market
- Inclusion in first US guideline

Commercial Partnership

- Partners for clinical sales on US and European market

Biovica – the investment case in short

BIOVICA IN SUMMARY

Addressing a large unmet clinical need

- 450,000 patients is estimated to live with metastatic breast cancer in EU and US
- Up to 80% of breast cancer patients do not respond to the treatment
- A SEK 6bn market potential per year in metastatic breast cancer in EU and US alone

Innovative and proprietary diagnostic technology

- The unique biomarker technology provide quick data on patient treatment response (2-4 weeks vs. to 3-4 months with traditional imaging)
- Quick, non-invasive test that can be performed during routine blood tests
- Beneficial for cancer patients and payers

Strong clinical evidence for DiviTum®

- 16 published clinical studies across a broad range of cancer types (9 within breast cancer)
- 10 ongoing studies with world leading institutions and oncologists

Clear commercialization strategy

- Four-step commercialization strategy to achieve full scale commercialization strategy by 2020/21
- Successful commercialization within the breast cancer area create opportunities for commercial deal with large diagnostic platform provider

Strong pipeline of upcoming milestones

- Clinical trial results in 2019 and 2020
- FDA 510k application in 2019 and expected approval in 2020
- Commercial sales partnerships for research market (2019) and clinical market (2020)

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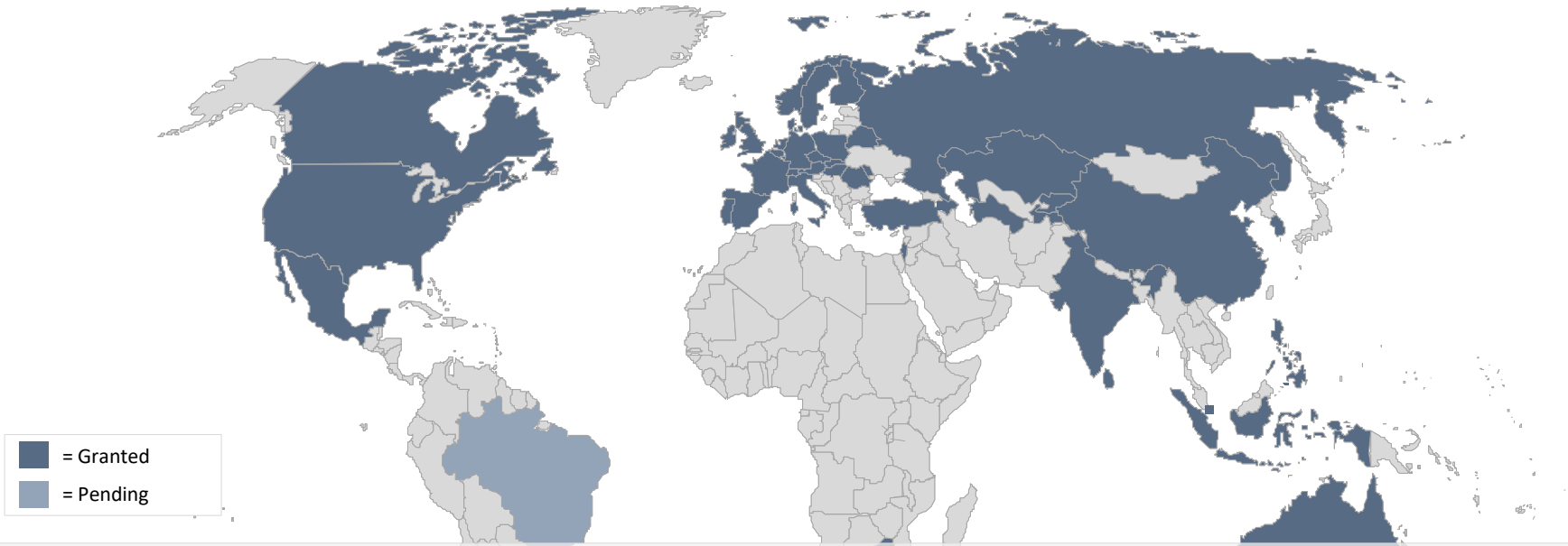
Biovica patent portfolio – protection until 2031



Application date	Description	Valid until	Europe	US	China	Japan	Other
2006-02-24	Kit for determination of thymidine kinase activity and use thereof	2026-02-24	G[1]	G	G	G	G[3] P[4]
2011-05-13	Patent to measure deoxynucleoside kinase activity	2031-05-13[5]	G[2]	G	G	G	

G: Granted
P: Pending

1 Belgium, Denmark, England, Finland, France, Netherlands, Ireland, Italy, Luxembourg, Norway, Poland, Portugal, Switzerland, Spain, Sweden, Turkey, Germany, Austria
2 Belgium, Denmark, England, Finland, France, Netherlands, Ireland, Italy, Luxembourg, Switzerland, Sweden, Germany
3 Australia, Canada, Hong Kong, India, Israel, Mexico, New Zealand, Singapore, South Africa, South Korea, Armenia, Azerbaijan, Belarus, Czech Republic, Hungary, Indonesia, Kazakhstan, Kyrgyzstan, Moldova, Philippines, Romania, Russia, Slovakia, Tajikistan, Turkmenistan
4 Pending: Brazil
5 USA patent (9,429,518) valid until 2032-07-16

Management

ANDERS RYLANDER

CEO

Holdings: 3,575,640 A-, 360,956 B-shares

Anders has been a management consultant for over 15 years in companies such as Accenture and Andersen Consulting. Additionally, Anders has an entrepreneurial background as he founded two companies; Axholmen (management consulting) and Arinvest (private equity).

CECILIA DRIVING

CFO

Holdings: 9,000 B-shares, 40,000 warrants

Cecilia holds a LLM and BSc in Business Administration from Stockholm University. She has held several CFO positions in life-science, private equity, research and telecom companies. Cecilia joined Biovica in 2016. She also serves as Chairman of Adom AB.

KARIN MATTSSON

R&D DIRECTOR

Holdings: 1,000 B-shares, 40,000 warrants

Karin has a PhD in cell and tumor biology from the Karolinska Institute. She has over 20 years' experience of working within academic research within the biomedical industry. She has held various technical and managerial positions within in R&D and has significant experience of in-vitro diagnostic assay development.

WING CHENG

MARKET ACCESS & QA DIRECTOR

Holdings: 2,500 B-shares, 20,000 warrants

Wing has held leading positions within the Regulatory and Reimbursement area from Competent Authorities e.g The Dental and Pharmaceutical Benefits Agency (TLV), the Medical Products Agency (MPA), European Medicine Agency (EMA) and the European Commission.

PONTUS NOBREUS

BUSINESS DEV. DIRECTOR

Holdings: 6,000 B-shares, 20,000 warrants

Pontus has had commercial roles for 20 years, especially in diagnostics and laboratory industries. He has long international experience and has been stationed in the United States and South Africa. Pontus has also held regional sales responsibility for HemoCue and comes from a service as Global Export Manager at Euro Diagnostica.

MATTIAS BERGQVIST

CLINICAL DEV. DIRECTOR

Holdings: 106,560 B-SHARES, 20,000 warrants

During his more than 20 years of experience in the pharmaceutical and biotechnology industry, he has launched oncology drugs with tailored diagnostics and co-authored publications. He previously worked as Nordic TA Director in Specialty Care and Oncology at AstraZeneca and in the Global Marketing Division at AstraZeneca UK.

ADAM GERMUNDER

OPERATIONS DIRECTOR

Holdings: 3,600 B-shares, 20,000 warrants

Adam has experience from production management and process development in the life science business. Before joining Biovica Adam worked as a production manager at Fiomi Diagnostics AB and as teamleader at Fresenius Kabi.

Board of directors

LARS HOLMQVIST

CHAIRMAN

Holdings: 410,630 B-shares

MSc in Business Administration. Former Senior Advisor within healthcare at Bain Capital. Senior management positions in pharma and medtech companies including Agilent, Dako, Applied Biosystems Inc., Medtronic Europe Sarl. Board member in the Lundbeck Foundation, H Lundbeck A/S, ALK-Abelló A/S, Tecan AG and BPL Plc-UK.

MARIA HOLMLUND

DIRECTOR

Holdings: 9,750 B-shares

Maria has 30 years of experience in the life science and diagnostic industry and she has previously held senior management positions as CEO, business area manager and marketing manager at international diagnostic companies such as Pharmacia Diagnostics, Boehringer Mannheim, Roche Scandinavia, Phadia and Thermo Fisher.

JESPER SÖDERQVIST Ph.D.

DIRECTOR

Holdings: 41,085 A-, 32,700 B-aktier, 3,000 warrants

Jesper is currently CEO at Arcoma AB. Previously Vice President of Elekta's Neuroscience division, he was General Manager, Mammography, at Philips Healthcare and the CEO of Sectra Mamea, AB, from 2004 until it was acquired by Philips in 2011.

JARL ULF JUNGNELIUS

DIRECTOR

Holdings: -

Ulf is a board-certified oncologist trained at the Karolinska Institute. He has over 20 years of experience in pharmaceutical drug development and has held top positions at Clinical Research and Development, Oncology, Celgene, Pfizer, Eli Lilly, and Takeda Pharmaceuticals in the US.

ANDERS RYLANDER

CEO

Holdings: 3,575,640 A-, 360,956 B-shares

Please, see description on previous page.

Overview of Biovica's key opinion leaders

Matt Ellis

M.D, Ph.D

Director for Lester and Sue Smith Breast Cancer at Baylor Collage of Medicine. Ellis is considered a pioneer within breast cancer genomics. He has made a great contribution by genomic mapping of receptor positive breast cancer.

Matthew P. Goetz

M.D

Goetz is currently co-principal investigator at Mayo Clinic Breast Cancer Specialized Program of Research Excellence (SPORE). The research focus of Matthew P. Goetz, is on estrogen receptor positive breast cancer and the development of novel therapeutics for endocrine-resistant breast cancer.

Richard Finn,

M.D

Professor at the Geffen School of Medicine at UCLA and Director of the Translational Research Laboratory at the Division of Hematology / Oncology. Prof. Finn was also participating in the preclinical trials of the world-leading drug trastuzumab (Herceptin).

Vered Stearns

M.D

Dr. Stearns joined the faculty at the Breast Cancer Program at the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins in 2002. She was appointed as co-Director of the Breast Cancer Program in 2010, and to full Professor in 2013 and co-Director of the Breast and Ovarian Cancer Program in 2014.

Angelo Di Leo

M.D, Ph.D

Head of Sandro Pitgliani Medical Oncology Department at Prato Hospital. Angelo's main area of research is breast cancer and he's led several important phase III trials regarding new adjuvant therapies. Angelo also studies molecular biomarkers with potentially predictive value for treatment of breast cancer.

Cynthia Ma

M.D, Ph.d

Professor within medicine and Clinical Director for the Breast Cancer Program at Washington University School of Medicine. Cynthia's main research area includes preclinical and clinical trials regarding molecular targeted cancer therapies against resistant breast cancer.

Geoffrey Shapiro

M.D, Ph.D

Associate Professor in Medicine at Harvard Medical School and Dana-Farber. He is also Director for Early Drug Development Center and member of Dana Farber Thoracic Oncology Program and Dana Farber/Harvard Cancer Center SPORE (Specialized Program of Research Excellence) in Lung Cancer.

Kent Osborne

M.D

Dr. Osborne's research interests have focused on the biology and treatment of breast cancer. He has published extensively on the role of growth factors in breast cancer pathogenesis, and he has also investigated the mechanisms of action and resistance to ER and HER2 targeted therapies in breast cancer.

Overview of Biovica's key opinion leaders

William Gradishar

M.D

Chief of Hematology and Oncology in the Department of Medicine at Northwestern Memorial Hospital, Betsy Bramsen Professorship of Breast Oncology. Dr. Gradishar clinical research focuses on the development of novel therapies for the treatment of breast cancer. He is a co-author of the NCCN Guidelines for breast cancer published in 2018.

Jonas Bergh

M.D, PhD

Jonas Bergh is Professor in Oncology at Karolinska Institutet (KI) and is senior consultant at Karolinska University Hospital in Stockholm, Sweden. He has recently been appointed Director for the Strategic Research Program in Cancer at KI. Professor Bergh's research is mainly focused on tailored breast cancer treatment. Jonas Bergh was Chair of the Swedish Breast Cancer Group between 1995 and 2016.

Samuel Rotstein

M.D, PhD

Samuel Rotstein is Associate Professor at Karolinska Institutet (KI) and is senior consultant at Karolinska University Hospital in Stockholm, Sweden. He as authored 80 publications, focusing on breast cancer and has acted as Head of Oncology Department at Danderyd Hospital for many years.

Henrik Lindman

M.D, PhD

Henrik Lindman is Associate Professor in Oncology at Uppsala University and a senior registrar at Deparment of Oncology, Akademiska Sjukhuset, Uppsala. He has authored more than 60 publications, focusing on breast cancer. He is also the Chairman of the Uppsala-Örebro region Breast Group, Chairman of the Uppsala-Örebro region Breast Oncology Group, Vice chairman of the Swedish Breast Cancer Group (SweBCG).

Martine J. Piccart

M.D, PhD

Prof. Piccart served as Head of the Department of Medicine at the Jules Bordet Institute and has also founded the Breast International Group (BIG) in 1996 and serves as its chairman, uniting 47 academic research groups from around the world and running over 30 trials under its umbrella. She has been Chairman of Clinical Advisory Board at Immutep Limited since June 01, 2017.

Daniel F. Hayes

M.D

Dr. Hayes is the Stuart B. Padnos Professor of Breast Cancer Research, Professor of Internal Medicine, UM Rogel Cancer Center. He is an authority in the field of breast cancer translational and clinical research and clinical care. His research focus is on the identification and validation of tumor biomarker tests. He was previously the president of ASCO and chairman of SWOG. He is the co-author of ASCO guidelines for use of biomarkers to guide treatment decisions in metastatic breast cancer.

Thomas Hatschek

M.D, PhD

Thomas Hatschek is Associate Professor at Karolinska Institutet (KI) and is senior consultant at Karolinska University Hospital in Stockholm, Sweden. He has authored 77 publications, focusing on breast cancer and acted as Principal Investigator for many pioneering clinical breast cancer trials.

Shareholder list as per 2018-12-31

Name	A-Shares	B-Shares	Share Capital (%)	Votes (%)
Anders Rylander	3,575,640	360,956	22.40	33.64
Gunnar Rylander	931,185	52,112	5.60	8.63
Avanza Pension		718,774	4.09	2.18
LYM Consulting AB		493,810	2.81	1.50
Kristina Gronowitz	411,660		2.34	3.75
Lars Holmqvist[1]		410,630	2.34	1.25
Mats Danielsson[1]	244,025	62,000	1.74	2.41
Nordnet Pensionsförsäkring		303,635	1.73	0.92
Danica Pension		296,900	1.69	0.90
Per Stålhandske		291,723	1.66	0.88
Total 10 largest shareholders	*5,162,510*	*2,990,540*	*46.39*	*56.06*
Others	*2,532,739*	*6,887,583*	*53.61*	*43.94*
Total	**7,695,249**	**9,878,123**	**100.00**	**100.00**

 Note: (1) Direct and through company.

Income statement

(TSEK)	Q3 2018/2019	Q3 2017/2018	May-Jan 2018/2019	May-Oct 2017/2018	May-Apr 2017/2018
Net sales	288	51	1 269	1 290	2 723
Other income	320	129	666	323	494
Work performed by the company and capitalized	1 713	1 784	4 565	4 949	6 596
Change in WIP inventory	174	69	101	103	132
	2 495	**2 034**	**6 600**	**6 665**	**9 945**
Materials cost	-122	-265	-637	-722	-1 148
Other external costs	-3 247	-2 709	-7 484	-7 023	-9 503
Employee benefit expenses	-4 051	-4 327	-11 554	-10 689	-14 495
Depreciation/amortization	-834	-749	-2 249	-2 055	-2 738
Other expenses	-20	-	-22	-	-17
Operating loss	**-5 780**	**-6 016**	**-15 346**	**-13 824**	**-17 956**
Other interest income and similar p/l items	0	0	0	0	0
Interest expenses and similar items	-265	-3	-291	-9	-54
Loss after financial items	**-6 045**	**-6 020**	**-15 636**	**-13 833**	**-18 010**
Tax expense	-	-	-	-	-
Net loss for the year	**-6 045**	**-6 020**	**-15 636**	**-13 833**	**-18 010**

Balance sheet

(TSEK)	Jan 31 2019	Jan 31, 2018	Apr 30, 2018
ASSETS			
Intangible assets	36 577	31 425	33 778
Property, plant and equipment	2 542	1 711	2 616
Financial assets	-13	-18	0
Total fixed assets	**39 106**	**33 118**	**36 394**
Inventories	519	341	403
Accounts receivable	303	0	1 068
Current receivables	923	697	779
Cash and bank	24 203	55 099	42 127
Total current assets	**25 949**	**56 138**	**44 377**
TOTAL ASSETS	**65 055**	**89 257**	**80 771**

(TSEK)	Jan 31 2019	Jan 31, 2018	Apr 30, 2018
EQUITY			
Share capital	1 172	1 172	1 172
Other contributed capital	133 776	133 776	133 776
Retained earnings (losses), including net loss for the year	-76 930	-51 098	-61 235
Total equity	**58 018**	**83 850**	**73 713**
LIABILITIES			
Other non-current liabilities	571	468	387
Current liabilities	6 466	4 939	6 672
TOTAL EQUITY AND LIABILITIES	**65 055**	**89 257**	**80 771**

Cash flow statement

(TSEK)	Q3 2018/2019	Q3 2017/2018	May-Oct 2018/2019	May-Oct 2017/2018	May-Apr 2017/2018
Cash flow from operating activities before changes in working capital	-5 329	-5 487	-13 267	-11 483	-15 009
Changes in working capita	102	577	242	109	127
Cash flow from operating activities	**-5 227**	**-4 910**	**-13 025**	**-11 374**	**-14 882**
Cash flow from investing activities	-1 838	-2 833	-4 899	-6 738	-8 459
Cash flow from financing activities	0	0	0	0	0
Cash flow for the period	**-7 065**	**-7 743**	**-17 924**	**-18 112**	**-23 342**
Cash and cash equivalents at the beginning of the period	31 268	60 954	42 127	65 469	65 469
Cash and cash equivalents at the end of the period 2	24 203	53 212	24 203	47 357	42 127

List of DiviTum® publications

Breast Cancer

1. Bonechi M, Galardi F, Biagioni C, 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 2018; Mar; 9 (23): 16389-16399.
2. Bagegni N, Thomas S, Liu 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; Nov 21;19(1):123.
3. Bjohle J, Bergqvist J, Gronowitz JS, et al. Serum thymidine kinase activity compared with CA 15-3 in locally advanced and metastatic breast cancer within a randomized trial. Breast Cancer Res and Treat 2013; 139(3):751-8.
4. Nisman B, Kadouri L, Allweis T, et al. Increased proliferative background in healthy women with BRCA1/2 haploinsufficiency is associated with high risk for breast cancer. Cancer Epidemiol Biomarkers Prev. 2013; Nov; 22(11):2110-5.
5. Nisman B, Allweis T, Kadouri L, et al. Serum thymidine kinase 1 activity in breast cancer. Cancer Biomark. 2010; 7(2):65-72.

Lung Cancer

6. Nisman B, Nechushtan H, Biran H, et al. Serum Thymidine Kinase 1 Activity in the Prognosis and Monitoring of Chemotherapy in Lung Cancer Patients. J Thorac Oncol 2014; Oct; 9(10):1568-1572.
7. Korkmaz T, Seber S, Okutur K et al. Serum thymidine kinase 1 levels correlates with FDG uptake and prognosis in patients with non small cell lung cancer. Biomarkers 2013; Feb;18(1):88-94.

Pancreatic Cancer

8. Felix K, Hinz U, Dobiasch S, Hackert T, et al. Preoperative Serum Thymidine Kinase Activity as Novel Monitoring, Prognostic, and Predictive Biomarker in Pancreatic Cancer. Pancreas. 2017; Nov 16.

Breast and Colorectal Cancer

9. Bolayirli M, Papila C, Korkmaz G, et al. Serum thymidine kinase 1 activity in solid tumor (breast and colorectal cancer) patients treated with adjuvant chemotherapy. J Clin Lab Anal. 2013; May;27(3):220-6.

Renal Cell Carcinoma

10. Nisman B, Appelbaum L, Yutkin V, et al. Serum Thymidine Kinase 1 Activity Following Nephrectomy for Renal Cell Carcinoma and Radiofrequency Ablation of Metastases to Lung and Liver. Anticancer Res. 2016; Apr;36(4):1791-7.
11. Nisman B, Yutkin V, Nechushtan H, et al. Circulating Tumor M2 pyruvate kinase and thymidine kinase 1 are potential predictors for disease recurrence in renal cell carcinoma after nefrectomy. Urology; 76 (2), 513. e1-e6, 2010.

Blood Malignancies

12. Stelmach P, Blonski JZ, Wawrzyniak E, et al. Prognostic value of thymidine kinase activity in patients with chronic lymphocytic leukemia. Postepy Hig Med Dosw. 2016; 70(0):1321-1330.
13. Bacovsky J, Myslivecek M, Minarik J, et al. Analysis of thymidine kinase serum levels by novel method DiviTum™ in multiple myeloma and monoclonal gammopathy of undetermined significance – comparison with imaging methods 99mTc-MIBI scintigraphy and 18F-FDG PET/CT. Biomed Pap Med Fac Univ Palacky Olomouc Czech Repub. 2015; Mar;159(1):135-8.
14. Procházka V, Faber E, Raida L, et al. High baseline serum thymidine kinase 1 level predicts unfavorable outcome in patients with follicular lymphoma. Leuk Lymphoma 2012; Jul;53(7):1306-10.
15. Rivkina A, Vitols G, Murovska M, et al. Identifying the stage of new CLL patients using TK, ZAP-70, CD38 levels. Exp. Oncology 2011; 33(2), 99-103.

Method

16. Nisman B, Allweis T, Kadouri L, et al. Comparison of diagnostic and prognostic performance of two assays measuring thymidine kinase 1 activity in serum of breast cancer patients. Clin Chem Lab Med. 2013; 51(2):439-47.

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