

## COMPANY OVERVIEW

GILUPI is a specialised medtech company focused on the development and production of a medical device used in the upstream value chain of molecular diagnostics.

The Company has developed a unique and proprietary technology platform that combines the *in vivo* isolation of rare cells out of the circulating blood and their subsequent *in vitro* analysis, providing compelling and improved diagnostic value. This patent protected technology is currently tested within clinical studies to detect specific cells in oncological and prenatal diagnostic settings.

GILUPI is led by a seasoned management team with a long standing entrepreneurial experience: Dr. Klaus Lücke and Dr. Nils Morgenthaler. The Company was founded in 2006 by Dr. Klaus Lücke. He has a track record of more than 30 years of successfully translating innovative technologies into commercial opportunities. Dr. Nils Morgenthaler, MD, PhD, MBA, joined the Company in 2011, adding over 20 years of experience in clinical development, key opinion leader networking, and the diagnostics industry.

The Company has a staff of 29 employees, thereof 22 with higher education and operates two sites: GILUPI is headquartered in Potsdam, near Berlin and has a GMP-standard production and cancer development site in Greifswald, about 200 km North of Berlin.

## TRANSACTION OBJECTIVES

By offering a clinically proven technology that allows extracting rare cells from the patient's blood stream *in vivo* and thereby increasing the sensitivity compared to current methodologies by a **factor of up to 10**, GILUPI has the potential to take current diagnostic tests to the next level. GILUPI is convinced that its Functionalised and Structured Medical Wire (FSMW) is of highest value for the improvement of diagnostic test and associated therapeutic approaches and development of targeted therapeutics.

To further exploit the potential and increase the speed of development and deployment of its technology, GILUPI explores options for a strategic relationship with a premier pharmaceutical company.

## PRODUCT PIPELINE

Product	2011		2012		2013		2014		2015		Comment	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2		Q3
Cancer01 (AB: EpCam)				Market Launch								Marketed for laboratory use since 2010
Cancer02 (AB: EpCam + 2 <sup>nd</sup> AB)												
Cancer02L (2 <sup>nd</sup> AB: B7H3/MUC)								Market Launch				Lung cancer specific
Cancer02B (2 <sup>nd</sup> AB: MUC16/Her2)								Market Launch				Breast cancer specific
Prenatal01 (AB: ILA-2)												Status successfully completed
Prenatal02 (AB: ILA-2 + 2 <sup>nd</sup> AB)								Market Launch				
Prenatal03 (AB: ILA-2 + 2 <sup>nd</sup> AB)								Market Launch				
Advanced Leads												
Cancer02P (2 <sup>nd</sup> AB: NN, PSMA)												Prostate cancer specific
Cancer02M (2 <sup>nd</sup> AB: CSPG4/Her2)												Melanoma specific

AB = monoclonal antibody target

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 FON: +49 (331) 58 18 47 82, FAX: +49 (331) 58 18 47 80, EMAIL: [INFO@GILUPI.COM](mailto:INFO@GILUPI.COM)

[WWW.GILUPI.COM](http://WWW.GILUPI.COM)

## Facts & Figures

- Founded in 2006
- Private Equity and privately funded
- 29 Employees
- Headquarter and R&D:  
Potsdam, Germany
- GMP-Standard Manufacturing and Cancer Research:  
Greifswald, Germany

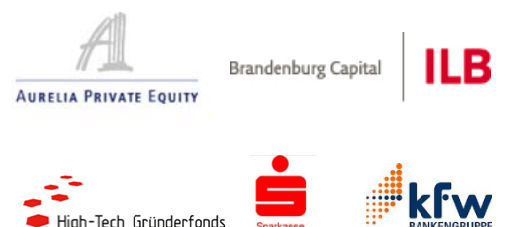
## Management

- Dr. Klaus Lücke  
(Founder and Chief Executive Officer)
- Dr. Nils Morgenthaler, MD, PhD, MBA  
(Chief Medical Officer)

## Scientific Advisors

- Prof. Dr. Klaus Pantel
- Prof. Dr. Nikolas Hendrik Stoecklein
- Prof. Dr. Udo Markert
- Prof. Dr. Grzegorz H. Breborowicz
- Prof. Dr. Maciej Zabel
- Prof. Dr. Manfred Schmitt
- Prof. Dr. Jürgen Rühle

## Investors



## Personal Contact

Dr. Klaus Lücke

GILUPI GmbH  
 Am Mühlenberg 11  
 D-14476 Potsdam  
 Germany

Fon: +49 (331) 58 18 47 81

Fax: +49 (331) 58 18 47 80

Email: [klaus.luecke@gilupi.com](mailto:klaus.luecke@gilupi.com)

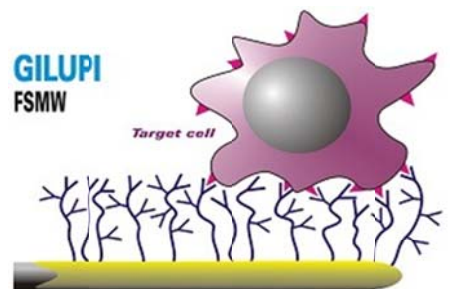
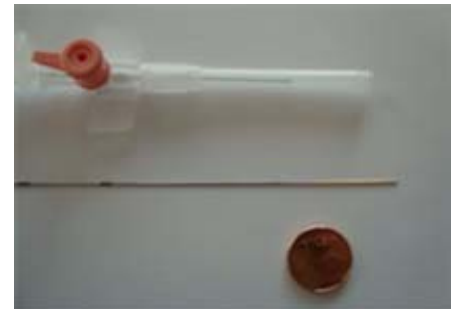
## TECHNOLOGY

The GILUPI technology is based on a FSMW, which is inserted in the patient's vein for a specific time to extract pre-defined cells from the patient's blood stream with particularly high sensitivity.

The "Nanodetector" utilizes a thin in-dwelling gold coated wire covered with polymer threads, making the tip of the wire smooth and biocompatible. The polymer layer supports the tight binding of antibodies with predetermined selectivity to increase the capture of circulating tumour cells (CTCs) and foetal cells. When inserted into a patient's vein these antibodies ensure the selection of the targeted bio molecules and bind them to the wire. These cells are subsequently used for the analysis of genetic and/or transduction pathway activation status of the isolated cells. Another option is the fluorescence microscopic analysis (enumeration) and molecular biologic analysis (characterization).

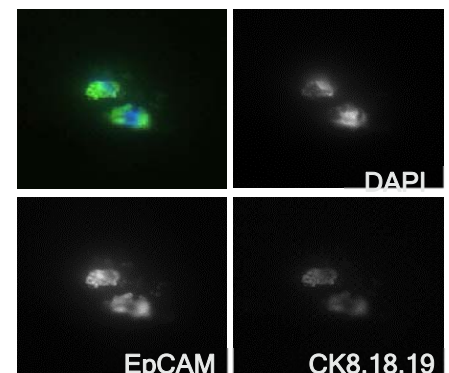
Due to the *in vivo* reaction time of approx. 30 minutes and high sensitivity, GILUPI's FSMW significantly increases extraction of target cells and allows for more reliable medical predictions and more educated decisions.

Currently, GILUPI conducts clinical studies and has developed a certification plan to receive the CE mark in the first diagnostic setting in cancer before year end. Additionally, GILUPI runs clinical trials for a second application in a prenatal diagnostic setting.



## TECHNOLOGY USPS

- **Higher hit rate:** Due to its unique *in vivo* approach, the FSMW maximises antibody reaction time with target cells and overcomes limitation of *in vitro* isolation
- **High sensitivity:** Successful isolation of rare cells (e.g. CTCs) even with particularly low number of cell count in patient's blood
- **Variability:** Application may be employed for a variety of diagnostic tests such as all major carcinoma types, i.e. breast, lung, colon, prostate
- **No side effects:** The FSMW eliminates risks associated with current standard of care (e.g. potentially lethal risks associated with an amniocentesis) and has no known side effects
- **Earlier results:** FSMW enables prenatal diagnostic tests as early as in 10<sup>th</sup> week of pregnancy, 2 weeks earlier than amniocentesis
- **Patient cost reduction:** Significantly lower costs for the patient due to targeted therapeutic approach
- **Higher patient satisfaction:** Better diagnostic tests allow for a more targeted therapeutic approach



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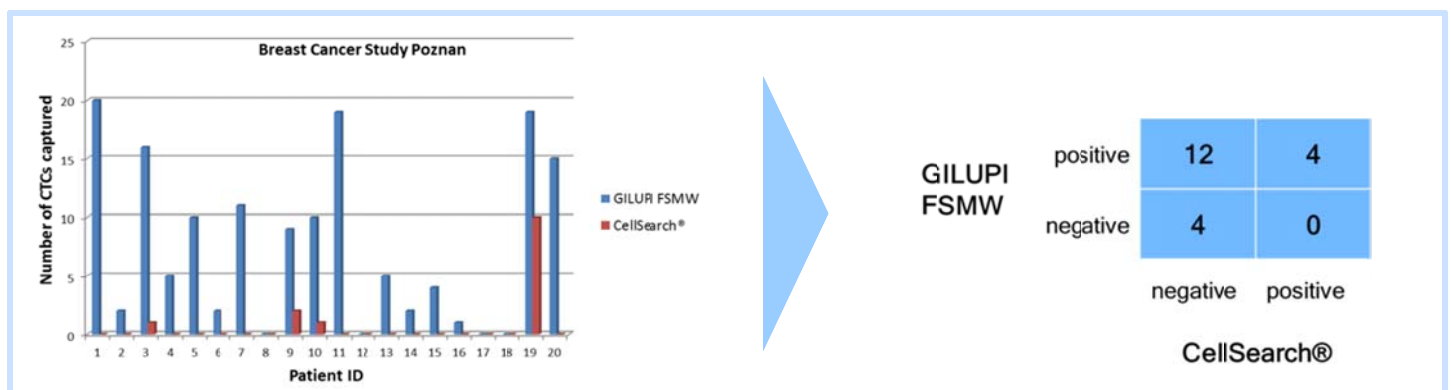
## ONCOLOGY PRODUCT

CTCs are extremely rare, comprising as few as one cell per  $10^9$  in the blood of patients with cancer. So far, in metastatic settings a number of molecular and clinical studies support the importance of detecting circulating tumour cells (CTCs). However, there is only one FDA-cleared methodology for enumerating CTCs which is performed on a blood sample of 7.5ml. Extensive studies using this methodology prove the prognostic potential but also show the technical challenge of extracting these rare cells from the patient. For this reason the capture, isolation and characterization by the GILUPI "Nanodetector" system represents a major technological advance with major implication on the diagnosis and rational treatment selection in patient's burdened with cancer.

The GILUPI technology allows extracting CTCs using the interaction of target CTCs with the FSMW mediated by an antibody directed against the epithelial cell adhesion molecule (EpCAM). EpCAM is an epithelial cell surface antigen which is expressed by many carcinomas. It is clinically proven for a variety of cancers such as breast and lung cancer. GILUPI currently conducts three clinical studies for the detection of CTCs originating from the following carcinomas:

- **NSCLC:** Clinical study for detection of NSCLC CTC in Poznan, Poland, with 60 participants and in collaboration with Bayer Healthcare/Prometheus. The study will be concluded in Q4 2011.
- **Mamma carcinoma:** Clinical study for detection of mamma carcinoma CTC in Poznan, Poland, with 42 participants and in collaboration with Bayer Healthcare/Prometheus. The study will be concluded in Q4 2011.
- **Prostate carcinoma:** Clinical study for detection of prostate carcinoma CTC in Halle, Germany, with 40 participants and in collaboration with Bayer Healthcare/Prometheus. The study will be concluded in Q4 2012.

Clinical results from over 48 breast and lung cancer patients resulted in a sensitivity of over 80%. This represents a **10-fold higher capturing rate** than the result using existing methods in the identical setting. The first oncology products are sold for use in the development of cancer therapeutics and market launch is planned for 2012. A direct comparison of the GILUPI FSMW against the current gold standard CellSearch® with 20 patients in a clinical setting is depicted below:



## PRENATAL PRODUCT

Embryonic trophoblast cells are very rare in the maternal blood stream (~1 cell per ml blood). So far, no practicable method is available for the isolation of foetal cells from maternal blood. The current standard to extract foetal cells (e.g. to measure chromosomal defects) is through amniocentesis, which is associated with an adverse risk profile. The GILUPI technology provides an easy and safe way to capture these rare cells *in vivo*. In combination with *in vitro* diagnostics for chromosomal defects, the FSMW has the potential to largely replace the widely used amniocentesis.

GILUPI's FSMW for prenatal diagnostics uses a combination of two specific antibodies against different trophoblast antigens: one (G233) is directed against the human leukocyte antigen G (HLA-G); the second was developed by GILUPI specifically for binding trophoblast cells.

Clinical studies have shown the proof of concept by detection trophoblast cells *in vivo*. Further studies are planned to start in Q4 2011 with market launch expected for 2013.

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