

2009 MILESTONES

In 2009, MediGene AG focused on its core competencies, set long-term goals, and drew up a strategic roadmap until 2015. The company also made progress with its drug candidates. MediGene's further path is challenging, but we are well prepared and have a rewarding goal.

COMMERCIALIZATION

German market approval for Veregen®

MediGene's first proprietary development obtains market approval for Germany and a statement from the regulatory authorities that the drug will also be approved in Austria and Spain.

COMMERCIALIZATION

European marketing partnerships for Veregen®

MediGene agrees partnerships for the commercialization in Germany, Austria, Switzerland, Spain, and Portugal. An important US patent is extended.

FINANCE & STRATEGY

Exit from early-stage research

MediGene closes down its Early-stage Development department. The freed-up staff and financial resources will be utilized to expand Clinical Development for late-stage drug candidates.

Focus

MediGene's core competency is clinical research and development of innovative cancer drugs up to market approval. The new Executive Board decides to further focus on this core competency, first of all with emphasis on liposome technology, and puts it into practice by means of reorganization measures and revised development plans.

FINANCE & STRATEGY

Progress of EndoTAG™-1

Orphan drug designation in the USA, important European patent granted, and patient recruitment into phase II breast cancer trial successfully completed.

DEVELOPMENT

RhuDex® – revised project plan

MediGene successfully completes the preclinical tests prescribed by the regulatory authorities. In the course of the company refocusing, MediGene decides to prepare the anti-rheumatic agent for out-licensing.

DEVELOPMENT

2010 ROADMAP

MediGene is accelerating in order to reach its planned milestones for 2010. The conclusion of one or more partnerships for the cancer drug EndoTAG™-1 is of vital strategic and financial importance. With this, MediGene will buy its ticket for an exciting journey leading to new scientific insight, improvements for patients, constructive partnerships, and profitable business.

COMMERCIALIZATION

For the first time, Eligard® generates over € 100 million revenue in Europe

MediGene receives royalties on sales of the product.

COMMERCIALIZATION

Launch of Veregen® in the first European countries

In March 2010, MediGene's partner Solvay launched Veregen® on the German market. In Austria, the product obtained market approval and will be launched at mid-year. Further market approval applications are to follow.

FINANCE & STRATEGY

Partnership for EndoTAG™-1

In 2010, MediGene is planning to conclude one or more partnerships for development and commercialization of the company's most important drug candidate EndoTAG™-1.

DEVELOPMENT

More efficient manufacturing process for EndoTAG™-1

In the fourth quarter of 2010, MediGene is planning to produce the first spray-dried material for the scheduled phase III trial.

EndoTAG™-1: results of the phase II trial for the indication of breast cancer

The trial results expected for the first half of the year may provide a second proof of concept.

DEVELOPMENT

Spin-off of oHSV and AAVLP

In the course of the company refocusing, MediGene is planning to spin off or out-license the oHSV and AAVLP technologies in 2010 and 2011, respectively.

FINANCE & STRATEGY

2011–2015 ITINERARY

An itinerary becomes more and more sketchy the farther it reaches into the future. We keep our goals in view, but remain flexible enough to bypass the unforeseen, to factor in traffic jams, or to strike new paths. Decisions will have to be made as to whether the fastest, the safest, or the most economical route should be chosen. At the end of this path, MediGene intends to be a sustainably profitable company, and both shareholders and patients should equally benefit from its innovative products.

DEVELOPMENT

EndoTAG™-1: initiation of phase III trial for the indication of pancreatic cancer

This trial is planned in collaboration with a partner in the first six months of 2011.

DEVELOPMENT

EndoTAG™-1: results of the phase III trial and market approval application

Upon successful completion of clinical development, a market approval application can be compiled and submitted to the regulatory authorities.

COMMERCIALIZATION

Market approval for EndoTAG™-1

MediGene expects market approval application and launch of EndoTAG™-1 in 2015.

RhuDex®: resumption of clinical development

Following a preclinical trial program in 2010, MediGene is planning to resume clinical development no later than in the first quarter of 2011.

DEVELOPMENT

Diversification of oncology portfolio

MediGene is planning to examine EndoTAG™-1 for other indications and to develop new candidates from its EndoTAG™ technology platform. In addition, in-licensing of oncology products may also extend the portfolio.

FINANCE & STRATEGY

RhuDex® out-licensing

MediGene aims to out-license the immunology drug candidate once clinical proof of concept has been furnished, if not before, and intends to receive royalties on future sales of the drug.

FINANCE & STRATEGY

OUR GOALS FOR 2015

Three drugs on the market: Eligard®, Veregen®, and EndoTAG™-1

Other cancer drugs in clinical development:

- e.g. EndoTAG™-1 for a new indication
- a new product derived from EndoTAG™ technology
- possibly a product from in-licensing or M&A

Break-even point reached for enduring profitability
 Company is financed mainly by product sales as well as license and milestone payments received under the terms of partnership agreements

ICON DEFINITIONS

- Approval
- Partnership
- Commercialization
- Strategies and objectives
- Manufacturing processes
- Development progress

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