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EP Vantage interview – MediGene sets out to roll up German biotech

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It must be hard to head up a promising biotech company based in Europe – a region that seems almost completely immune to the wild frenzy of investor enthusiasm going on in the US. But one boss sees things clearly and is not afraid to say what he thinks the answer is: consolidation.

“It makes a lot of sense to bring Germany’s small biotech companies together, and we are very active here,” Frank Mathias, the chief executive of MediGene, tells *EP Vantage*. “We are in discussions.”

Indeed, a roll-up strategy of Germany’s fragmented biotech sector is something that Mr Mathias has pursued for some time, but so far without much success. *EP Vantage* understands, for instance, that MediGene had at one point approached its cross-town Munich rival Wilex with a merger proposal.

But the chief executive thinks things have now moved on sufficiently to make another push. “The financial background has changed. There is less finance from the [European] markets, and companies will need to go into consolidation because of this lack of funding,” he says.

Little enthusiasm

It is disappointing to many in Europe that, in contrast to the biotech boom of 1999/2000, the wave of US investor enthusiasm has not been mirrored across the Atlantic this time around. UK and German biotechs have struggled, with some going out of business and others fighting hard to raise ever-decreasing amounts of cash.

“If you look back five to 10 years there is not really any German biotech that has made it through to the market with a product. Veregen [MediGene’s niche genital warts treatment] is an exception,” Mr Mathias says, though he singles out MorphoSys as a company that clearly has been successful.

One problem is that too many biotechs started enlarging their pipelines too soon, for what he calls “de-risking reasons. This brings the company to the limit. There is too much to do.” It has resulted in a hodgepodge of early to mid-stage assets in the hands of a disparate array of biotechs, each struggling to raise cash.

But despite the obvious need in such an environment for M&A just about the only European biotech that has consolidated in recent years is the UK’s BTG. And one reason M&A is difficult is the unrealistic valuation expectations on the part of many chief executives – the “big issue in our industry”, says Mr Mathias.

Another is ego: “Lots of CEOs and other board members have difficulties accepting that consolidation can change the board’s composition.”

That said, recent management shake-ups, like at Berlin’s Epigenomics, might be eliminating many of these ego issues. 4SC, another biotech in the Munich area, recently saw its chief executive depart, and should thus feature prominently on deal bankers’ radars.

Investable entity

As well as wanting to create a more investable entity with something approaching critical mass, Mr Mathias says he wants to “bring pipeline sustainability” to MediGene.

With Veregen marketed, a royalty on the prostate cancer therapy Eligard monetised and EndoTAG-1 positioned for development in triple-negative breast cancer thanks to a strategic deal with Syncore Biotechnology, MediGene’s internal focus in now almost exclusively on its CD80-antagonist RhuDex.

RhuDex had initially been targeted at rheumatoid arthritis, but the company has now decided to pursue an orphan use – primary biliary cirrhosis (PBC) – and is seeking a regional partner, for instance in Asia, to provide additional funding.

“We are financed to the beginning of 2015,” says Mr Mathias, “but we always want to start a study when fully financed.” The planned phase II RhuDex trial in PBC is expected to begin in the second quarter of next year but

will not be completed until late 2015, although Mr Mathias says he is also working on alternatives.

Apart from big pharma's obvious interest in rare diseases, why was PBC chosen? For one thing the competitive landscape was not so strong, says the chief executive, and indeed *EvaluatePharma* shows just six clinical-stage projects. For another, there are many immune therapy-naive patients – in contrast to RA.

Clinical pipeline for primary biliary cirrhosis

Project	Companies	Mechanism	Status	Trial ID
Obeticholic acid	Intercept Pharmaceuticals/Genextra	Farnesoid X receptor agonist	Phase III	NCT01473524
NI-0801	NovImmune	Anti-Interferon gamma-induced protein 10 MAb	Phase II	NCT01430429
Stelara	Johnson & Johnson/Bristol-Myers Squibb	Anti-IL-12 & IL-23 MAb	Phase II	NCT01389973
RhuDex	MediGene/Active Biotech	CD80 antagonist	Phase II-ready	–
LUM001	Pfizer/Lumena Pharmaceuticals	Apical sodium-dependent bile acid transporter inhibitor	Phase I	–
DSP-1747	Dainippon Sumitomo Pharma	Farnesoid X receptor agonist	Phase I	–

The only marketed drug for PBC is the off-patent ursodeoxycholic acid, but this is merely symptomatic, as in Mr Mathias's view is Intercept's obeticholic acid. "This indication is very strongly linked to CD80, the main mechanism of action of our project. By acting on CD80 [RhuDex] might have disease-modifying properties."

The planned phase II study will test three RhuDex doses against placebo, with change in serum alkaline phosphatase – a key PBC indicator – as the primary endpoint.

But first a partnering alliance must be struck. This, added to Mr Mathias's M&A remit, should make him a hot target for investment bankers.

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