



Progress across the board

Two days across Belgium and the Netherlands, visiting 3 company sites and meeting with 8 management teams provided an opportunity to re-assess the progress happening across the European small and mid-cap biotech space.

Companies are innovating across the spectrum: **new modalities, targets and insights in disease biology**. This progress is close to academia and at the leading edge of research.

This can represent **huge investment opportunities, but selectivity is key**: Not all trials will work, not all companies have the same level of understanding and rigour.

Not all of the innovation makes it to the headlines: progress crucial to development speed but also cost efficiency across the healthcare system is happening behind the scenes in two areas: **clinical trial design** and **process innovation**.

Clinical trial design is where the understanding of disease biology, current patient needs and treatment patterns all come together.

Process innovation is not always associated with drug discovery and development companies. As molecules became more complex to tackle harder problems, so too do the processes to screen, manufacture and develop them.

The secret sauce: clinical trial design

Clinical trial design is a key factor in the drug development process. This is where the understanding of the disease biology, current treatment patterns and patient needs all come together. Done right, it can allow more cost-effective drug development, producing medicines which are more tailored to patient needs and ultimately increase the “pipette-to-pharmacy” success rate. How can this manifest itself?

Understanding the biology of the disease helps in choosing the metrics by which to assess the level of drug activity or help anticipate certain side effects. Understanding treatment algorithms is crucial to select a patient population which reflects real-life patient journeys.

Constant process improvement

Behind the scenes, research is not only being done to understand biology and discover new molecules, but also to improve processes. Process manufacturing is not typically associated with drug discovery and development, but the huge increase in the complexity of the drugs being now investigated has seen a proportional increase in the manufacturing complexity.

Nowhere is this more apparent than in cell therapy. Originally the idea was to manufacture every dose centrally due to complexities of the culture of patient white blood cells. Some companies have now developed thorough solutions for decentralized manufacturing based on pre-prepared kits and protocols.

Radiopharmaceuticals are another example of the logistical and manufacturing challenges that have arisen due to the development of more complex molecules. In fact, this area has seen consolidation, partly due to the need to secure supply arrangements.

Conclusion

Even though there are more than 7 times as many listed small and mid-cap biotech companies in the US than in the EU, the latter is by no mean lacking the former. Holistic research efforts pave the way for sustainable and scalable growth.

From an investment perspective, selectivity remains key – not all trials will work, and not all companies have the same diligent approach to drug development.

Yours sincerely,

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