

BioWin

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Wallonia—a cell therapy and regenerative medicine powerhouse

Since 2006, BioWin, the health cluster of the Belgian region of Wallonia, has powered a renaissance of technological and scientific excellence in cell therapy and regenerative medicine.

Research and development in cell therapy and regenerative medicine is exploding in Belgium's Wallonia region thanks to an increasing number of initiatives and companies active in this fast-developing field. Driving this success is BioWin, one of Europe's most innovative health clusters. Its unique ecosystem comprises 130 companies, 5 universities (Université Catholique de Louvain (UCL), Université Libre de Bruxelles (ULB), Université de Liège (ULg), Université de Mons (UMONS) and Université de Namur (UNamur)) and 4 registered research centers. In total, the cluster includes 11,000 researchers (Fig. 1).

Since its creation, BioWin has witnessed a 71% growth in the employment rate among members, the establishment of five new companies, the launch of over 32 R&D projects, the filing and/or granting of 78 patents, rapid progress on 23 other projects and services and increasing international attention. According to Sylvie Ponchaut, BioWin's managing director, "The government of Wallonia provides strong financial and fiscal support for the biopharmaceutical industry, which has attracted over €800 million [US\$872 million] of private capital since 2006. A unique ecosystem has been fostered by the presence of large players with strong roots in the region, such as GSKVaccines, Baxter, UCB, IBA and Eurogentec-Kaneka, and an unusually high concentration of small- and medium-sized enterprises, universities and research institutes. This has instilled a culture of technological, scientific and entrepreneurial excellence."

An ecosystem driving cell therapy R&D

With over €303.87 million generated from public and private funds since 2006 for cell therapy R&D, and with the transfer of technology from 30 research laboratories to five companies, Wallonia lays claim to a level of innovation and drive seen in few other regions in Europe. BioWin recognized early on that against a European backdrop of strong fundamental science in cell therapy and regenerative medicine, a fully integrated academic and industrial ecosystem was a prerequisite for addressing issues of safety, scaling and manufacturing to deliver on the potential of cell therapies to transform the future of medicine.

In 2013, Novadip Biosciences, a UCL spin-off, was established to support the development of a platform to transform fat cells into bone cells. The same year, cellular therapy company Celyad raised €23 million through a successful initial public offering (IPO) on the Paris and Brussels Euronext exchanges. This enabled the company



Figure 1: Wallonia's health cluster BioWin has been instrumental in putting Belgium on the map as a powerhouse in cell therapies and regenerative medicine.

to advance its autologous heart-failure therapy, C-Cure, into phase 3 pivotal trials, and to expand into oncology with the acquisition of a portfolio of chimeric antigen receptor T cell (CAR-T) products for solid and liquid tumors that will move into clinical development in 2016.

In 2015, Bone Therapeutics raised €37 million in a successful oversubscribed IPO in support of clinical programs in bone fracture repair and prevention, and Promethera Biosciences, a UCL spin-off active in liver regeneration and functional repair, raised €25.3 million in a series C financial round to pursue phase 2b studies in urea-cycle disorders and to develop new indications in congenital and acquired liver diseases.

Excellence in technology and manufacturing

Key to accelerating the translation of scientific breakthroughs into the clinic are maintaining the investment momentum, developing the technological and manufacturing infrastructure and addressing the need for specialized skill sets. In 2011, BioWin supported the creation of MaSTherCell, the first advanced-therapy medicinal product contract manufacturing and development organization for cell therapies in Wallonia. MaSTherCell was recently acquired by US cellular therapy specialist Orgenesis.

In April 2015, a large public-private partnership including Bone Therapeutics and Promethera opened a high-tech, large-scale manufacturing facility for cell therapies in Gosselies, Belgium. "We are excited to be starting the transition to our new facilities, situated in the heart of the thriving Belgian biotech environment," said Enrico Bastianelli, CEO of Bone Therapeutics. "After the rapid expansion of our clinical programs last year and the recent IPO, this is an important step to

secure the company's commercial readiness and continued growth."

International partnerships

BioWin, in collaboration with the Wallonia Foreign Trade and Investment Agency, actively pursues opportunities for its members to establish partnerships and other collaborative agreements outside of Wallonia. As an example, Promethera and EMD Millipore recently obtained funding to jointly develop a long-term liver drug-toxicity screening platform. Funding was made possible under a BioWin partnership with the Massachusetts Life Sciences Center. "Our company specializes in isolating, expanding and characterizing human liver progenitor cells for the treatment of congenital and acquired liver diseases," explained Etienne Sokal, founder, board director and CSO of Promethera. "BioWin helped us from the initial characterization and isolation of cells, core to driving the growth and clinical application of stem cell research, to what is now an internationally recognized biotech of excellence."

BioWin has representatives in Boston, Shanghai and a number of European capitals, as well as partnerships with many other centers of excellence around the world to support its members. At the heart of this approach lies a philosophy of open innovation, reflecting the dynamism of a region that not only is open to technological partnerships but also offers a vibrant and supportive ecosystem.

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