Global regenerative medicine market is poised for strong growth

*Europe, Japan, U.S. are pursuing different product development pathways*

- Regenerative medicine (RM) therapies have high potential to address a broad range of unmet medical needs.

- The RM sector today in Europe, Japan and the U.S. includes more than 640 privately held and publicly traded companies.

- A strong RM product pipeline is paving the way for a global market that could reach $68B by 2020.

- Cell therapy products account for 76% of the 915 RM products in development in Europe, Japan, and the U.S., with gene therapy products accounting for the balance.

- Despite divergent product development trajectories, Europe, Japan, and the U.S. share common challenges.

Regenerative medicine-enabling technologies—resulting from decades of research in transplantation science, biomechanics, stem cell biology, molecular biology, vector engineering, advanced materials, immunology and recombinant DNA technology—have taken a quantum leap forward with the introduction of cell- and gene-based therapies, and tissue engineering. As a result, the RM global market is positioned for strong growth, benefitting both developers looking to address unmet medical needs, and patients. According to the Alliance for Regenerative Medicine (ARM), in the U.S. alone, musculoskeletal-related conditions, an area of focus in RM, each year generate 132 million doctor’s office visits, 29 million emergency room visits, and 15 million hospital out-patient visits.

Although regulatory agencies in Europe, Japan, and the U.S. have staked out different development pathways for RM products, the focus across the three regions is on expediting development. Whereas RM market opportunities are generally positive, developers face substantial challenges, not least of which is uncertain reimbursement prospects. In the U.S. and elsewhere, payers increasingly are applying strict cost-benefit analyses to a growing array of medicines to guide reimbursement policy, and developers will need to demonstrate that their RM products pass the test.