Following the news (25 February 2019) that Roche has entered into a definitive merger agreement to fully acquire Spark Therapeutics for $4.3bn, Tajekesa Chapman, Pharma Analyst at GlobalData, a leading data and analytics company, offers her view on the acquisition:

"The hemophilia market is currently undergoing major changes in its treatment landscape due to advances in recombinant protein engineering, novel strategies to target the coagulation cascade and the introduction of gene therapies. Roche's decision to acquire Spark Therapeutics is a highly strategic move to stay ahead of these developments.

"The company will acquire Spark Therapeutics' unique hemophilia A gene therapy portfolio, which includes the leading clinical assets, SPK-9001 for hemophilia B in Phase 3 (clinical development program by Pfizer, under a licensing agreement), SPK-8011 for hemophilia A entering Phase 3 development this year, and SPK-8016 for hemophilia A with inhibitors which is currently at Phase 1/2 trials.

"Roche's recent entrant, the bispecific antibody Hemlibra, has been instrumental in the disruption of the hemophilia A market. Hemlibra is addressing the main unmet needs in hemophilia, as an effective treatment for patients with inhibitors and for all hemophilia A patients, alleviating some of the treatment burden associated with route and frequency of administration through its convenient subcutaneous self-administration up to every four weeks. Gene therapies promise to further address the unmet needs in hemophilia treatment through a one-time administration to eradicate, or at least improve, the severity of the disease. Their potential as a long-term treatment poses a threat to current hemophilia therapies, including Hemlibra. By adding SPK-9001, SPK-8011 and SPK-8016 to the portfolio, Roche will therefore ensure it remains a major player in the hemophilia market.

"SPK-9001, a partnership with Pfizer, will be Roche's first entrant into a budding hemophilia B gene therapy market, in close competition with uniQure's AMT-061 and Freeline Therapeutics' FLT-180a, also in Phase 3 trials. To remain a contender, Roche will have to take advantage of Spark Therapeutics' proven expertise in the development and commercialization of gene therapies, having been the first company to receive FDA approval for a gene therapy, with Luxturna to treat a rare inherited retinal disease.

"Upon launch, SPK-8011 and SPK-8016 will enter a hemophilia A market with potential competition from BioMarin's Valrox, Ultragenyx Pharmaceutical's DTX-201, Sangamo Therapeutics' SB-525 and Shire's – now Takeda – SHP-654. Hemlibra is expected to have garnered substantial uptake and brand familiarity among hemophilia A patients to act as a launching platform for Roche's gene therapies.

"Spark Therapeutics' portfolio also includes further candidates and gene therapies for other inherited retinal diseases, lysosomal storage disorders and neurodegenerative diseases. Ultimately, this deal will help Roche grow its hemophilia A and B portfolio and differentiate it from the current standard-of-care, which faces increasing market competition and an impending market disruption."