NEW YORK (GBI Research), 24 April 2012 - **Generic drugs** are evolving and, at the same time, being outshone by their predecessors – super-powered pharmaceuticals developed through simplified development pathways – according to a new report by healthcare intelligence company **GBI Research** .

The new report* indicates that the development of "supergenerics" is creating significant opportunities for companies by enabling them to enhance efficacy, reduce side effects and increase the convenience of approved brands.

The term "supergeneric" has been given to the development process for small molecule drugs which offer a therapeutic advantage or differ from me-too generic products. While generic drugs represent a copycat version of the parent drug, supergenerics represent new therapeutic entities that demonstrate improvements in product delivery, design or the manufacturing process.

Supergenerics may be able to offer a low-risk, low-cost alternative to the traditional pharmaceutical development of new medicines, due to their shorter development timeline. New Chemical Entities (NCEs) take a long time to develop, often at a cost of over $1billion. Conversely, the development of a supergeneric is more comparable to that of a generic compound, as it has a known mechanism of action and an established safety and efficacy profile.

The supergeneric approval pathway also offers products a less complex clinical development process. Paper NDA or 505(b)(2) is the drug development pathway that companies are required to file under in the US for the development of novel formulations and new combinations, such as supergeneric products. Importantly, this route allows companies to incorporate pre-existing data, including late-phase clinical data, into its NDA by reference, which can lead to substantial savings in comparison to pursuing a NDA 505(b)(1). In addition, temporary market exclusivity is guaranteed in the US, as the NDA 505(b)(2) pathway attracts a three-year period of market exclusivity, providing some degree of product protection.

Since 2004, over 245 drugs have been approved via this pathway, of which 70% were novel formulations and 18% were new combinations. There are currently more than 60 novel supergeneric formulations of approved oncology, CNS, pain and respiratory products undergoing development.

Many products are in development by specialty pharma or drug delivery specialists, which have limited commercialization expertise and are seeking developmental partners. This highlights the significant commercial opportunities available to companies wishing to develop supergenerics to enhance their portfolios and leverage their expertise in drug development.