

## Time for a change in how the tissue engineering industry does business

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After an aggregate expenditure in excess \$6.5 Billion dollars, and over 30,000 person-years of work, the annual sales of tissue engineering products are less than that of a single modestly successful pharmaceutical drug. And the impact of medical practice and healthcare is nil. Going forward, the field needs to change its business practices in at least four significant ways: **(1)** The “blockbuster:” model, introduced by the venture capitalists who midwived the field in the nineties, must be abandoned. No tissue engineering firm is likely to produce a product fiscally equivalent to Genentech’s recombinant insulin or Amgen’s EPO. Instead Tissue Engineering should adopt the business model of the early medical-device and biomedical-implant business: low going-in costs, early profitability, and consistent growth from relatively small starting base. **(2)** Investment decisions must be made on the basis of the healthcare benefit to the patient and cost/benefit to the provider, rather than on assumed a-priori benefits of cell based medicine **(3)**. The inability of tissue engineering firms to move ostensibly successful products into the clinic is a failure of translational research which must be addressed. Moreover, one-off “proof of principle” clinical demonstrations, however impressive, must not be confused with translational research **(4)** Firms must develop FDA approval pathways, within the current regulatory framework, which can be executed for less than \$50-\$100 million. The window-of-opportunity for tissue engineering is not indefinite, especially vis-à-vis pure-play stem cell therapy, so these initiatives must be implemented promptly.