Biomaterials as a Business: Moving Up the Food Chain

Robert Ward, ExThera Medical Corporation, Berkeley, CA 94710

Polymeric biomaterials represent enabling technology in many pioneering medical devices and prostheses. Examples include cardiac assist devices, orthopedic implants, leads, and (glucose) sensors, in decreasing order of the mass of polymer required per device. The infrastructure required to develop and manufacture new polymers is expensive to build and maintain, and the qualification of new polymers by risk-averse device manufacturers can take many years. However, the sales volume available to the biomaterials manufacturer is often two or three orders of magnitude less than the sales realized by the device manufacturer, despite the considerable technical skills required in materials R&D/Manufacturing.

At The Polymer Technology Group (PTG) silicone-hydrogel contact lens materials proved to be a notable exception, and a good example for would-be biomaterials entrepreneurs: they require sophisticated synthesis, purification and characterization expertise, an established quality system, patented compositions of matter, and a substantial investment in capital equipment, all of which represent barriers to entry for competitors. More importantly, the volume *and* the profit margins of the 'monomer mixes' we sold were high. Although one liter produced >10,000 disposable lenses, the worldwide market is huge, relative to any conceivable implantable application.

Despite our success with contact lenses, some stock deals, and licenses in the orthopedic and sensor fields, we began to think that we should move up the value chain toward finished devices. First we added value to the materials by fabricating components, sub-assemblies and a few complete devices. This helped our clients get through clinical trials and added to our revenue. Later we decided that the infrastructure we had built could be used by *us* to create new device *companies*. We formed E*mer*gence, an incubator for new companies with polymer-intensive products. At almost the same time we were approached by Royal DSM of the Netherlands. They wanted to buy the biomaterials business but were not interested in the recently-formed incubator. Because we were not in the market to sell PTG we negotiated a high price and ultimately got it. We had bootstrapped the company at start up raising little equity, making the multiple on invested cash >550. As a result investor's return on the sale was >130X their original investment. (VCs are happy with 10X). Although the sale of PTG deprived Emergence of PTG's infrastructure, we dealt with that by becoming customers of 'DSM Biomedical' for development and pilot manufacturing.

Today we are running ExThera Medical, one of the three incubated companies within Emergence. ExThera has developed the **Seraph® Microbind® Affinity Blood Filter**, a broad spectrum sorption hemoperfusion device that safely removes (drug-resistant) pathogens, toxins and pro-inflammatory cytokines from whole blood. It can be used therapeutically to treat bacteremia in the prevention of sepsis and septic shock, or it can be used as a pathogen reduction device in blood banking. Because of our long experience in the development of novel device/material combinations and surface modification, our main issues in building Exthera have not been technical. Instead they have been related to the dearth of early stage venture capital available for device start-ups. Most US-based VCs have become very risk averse and want clinical results before they will invest. Our device has a huge clinical need and can significantly reduce the cost of healthcare, but to date only Angel Investors have stepped up. This situation is one that the biomaterials entrepreneur must also deal with, especially if they integrate forward into the expensive process of developing a device that uses their novel materials.