

PowerStent® Drug Eluting System

-----A Case Study for SBIR Fast-Track Grant Application

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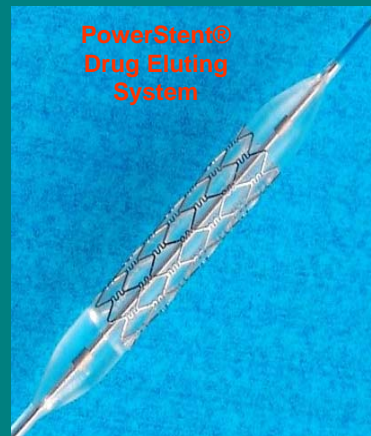
Part 1: VasoTech and Its Technologies

Brief Introduction to VasoTech, Inc.

- Mission:
Dedicated into R&D and manufacturing of implantable devices, particularly in the area of cardiovascular diseases, tumors, and bone fixation etc.
- Technologies:
 - BioDe® Biocompatible and Biodegradable Material.
 - ComBo® Anti-restenosis Drug Formulation.
 - SmartGel® Biodegradable implant for Tumor Therapies.
- Products:
 - PowerStent® drug-eluting stent----Preclinical investigation.
 - SmartGel® anti-tumor implant-----Preliminary Investigation.

PowerStent Technologies

- Late Stage Thrombosis and In-stent Restenosis are the two major problems in current stent technologies. PowerStent is a new generation DES designed to overcome those two problems. It consists of three broke through technologies:
 - An inflammatory-free biodegradable polymer.
 - A potent anti-restenosis drug formulation
 - And a featuring designed drug delivery platform.



BioDe® Biodegradable Polymer

- Fully biodegradable with adjustable degradation time from 3 to 12 months
- Highly biocompatible: inflammatory-free to surround tissue.
- Larger drug-loading capacity due to its multiple nano-porous structure.
- Can be applied in wide areas such as DES, Bone screw, Anti-adhesive membrane etc.

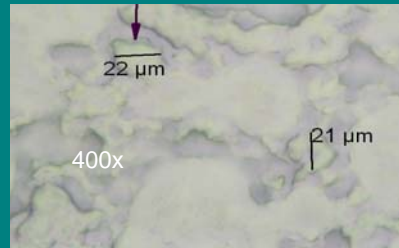
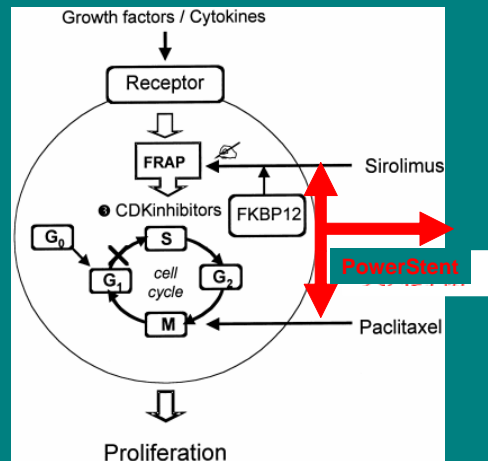


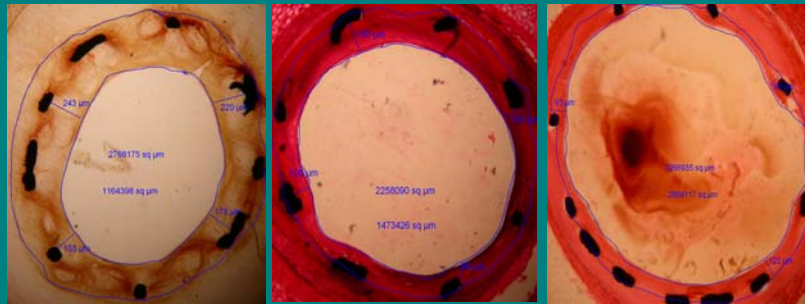
Fig. Microscopic observation of nano-porous structure of BioDe™ Polymer

ComBo® Anti-Restenosis Drug Formulation

- Target both signal transduction ways of Rapamycin and Paclitaxol does.
- Strong anti-restenosis effect than either Rapamycin or Paclitaxol DES has.
- All drugs in the formulation are commercially available.



PowerStent: Histopathological Observation at 28 Days After Pig Coronary Arteries Implantation



A: PLGA Polymer

B: BioDe® Polymer

C: Combo® Drug

Figure 13: Plastic sections of stented pig coronary arteries at 28 days post implantation A: PLGA only, B: BioDe® and C: BioDe® polymer +Combo® drug (PowerStent). The blue numbers stamped in each image are our original measuring data for residual area (RA) (lower number in central), Internal Elastic area (IEA) (upper number in central) and neointimal thickness. The percent of restenosis was calculated by using the formula: % restenosis = $(IEA-RA)/IEA \times 100$ as described at D.1-Histopathological Analysis.

Part II: The Strategies/Tips for SBIR Applications

Strategy 1: Do the best to go with the most efficiency program

SBIR/STTR Three Phase Program

- **Phase I: Feasibility**
 - ~ \$100,000
 - ~ 6 Months (SBIR)
 - ~ 1 Year (STTR)
- **Phase II: Full R&D Effort**
 - ~ \$750,000 (SBIR/STTR)
 - ~ 2 Years (Submit within 2 years at end of Phase 1)
- **PHASE III: Commercialization**
 - No SBIR/STTR Funds (other federal or non federal funds)
- **Fast-Track (Phase I + Phase II)**
 - The most cost-efficiency program to go with.

The Facts of Fast-Track Applications

- The most cost-efficiency program to go with.
- The most complex proposal to write.
- NIH review fast-track proposal separately before (Phase I or Phase II), but now review it as one proposal---Yes or No.

Strategy 2: Do the best to satisfy reviewer and funding agency's need

The Facts of Reviewing (Reasons for Strategy 2)

- Application are reviewed prior to the meeting at reviewer's spare time—only those well received proposals will be reviewed carefully.
- Reviewer are never wrong, but never right either. They simply provide an assessment of you application.
- NIH policy does NOT allow Rebuttal of Peer Review outcome. No appeal for difference scientific opinion (except for procedural or factual errors)
- Study Sections don't fund! Institutes fund,---you must satisfy the funding agency's need either.

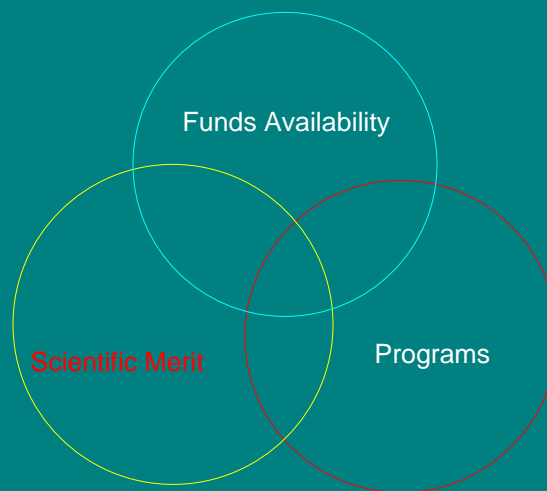
Review of Applications

- The meeting is for discussion and negotiation of priority score
- Strong Application get brief discussion
- Weak application get brief discussion
- Marginal application get longer discussion to ensure fairness to the applicant

Review Criteria for Applications:

- Significance
- Approach
- Innovation
- Investigator
- Environment
- Commercial Opportunity
- Commercialization plan (for Phase II)
- Other factors: Human subject, Animal welfare, Women and minorities issues, and Hazardous conditions.
- **Budget does not affect your score.**

Determinants of Grant Award



Strategy 3: Do the best to collaborate and collaborate with the best partners

The Facts of Collaborating

- There are no competitor in science, there are only potential collaborators.
- Any single PI can't provide project needed knowledge and experience. You must do secure collaborators for area of research in which you lack experience and training.
- Only collaboration can provide win-win situation for everyone involved in the grant application---reviewers and institutes like this.

VasoTech's Collaborators:

- Dr. Stephen McCarthy from M2D2 and UMASS at Lowell.
- Dr. Roger Laham from Beth Israel Hospital of Harvard Medical Scholl.

Others

- Budget does not effect your score, but it do hurt you application if it is over inflated.
- Phase I application does not require any preliminary data, but without preliminary data, it is hard to win.
- Before you submit to NIH, send the proposal to at least two lay-professionals for reviewing/advising.

Thanks! And Good Luck
to Everyone