Disclosure

- Founder /Stock holder– Banyan Biomarkers, Inc.
- DOD funding
- NIH funding
- Founder - Gryphon American Consulting
Kevin K.W. Wang, PhD

Education
- B Sc. Biochemistry / Biomedical Sci. (Guelph, Ont, Canada)
- PhD Pharmaceutical Sci. (University of British Columbia (Canada)
- Postdoc. Pathology (Wayne State Univ., Detroit, MI, USA)

11 year Sr. management and scientific experience in US big Pharm.
- Pfizer
- Parke-Davis

Director of multiple Million $ research center program in Academia
- Center of Neuroproteomics and Biomarkers Research (University of Florida)

Founded and On Executive Team of biotechnology company
- Banyan Biomarkers, Inc. (2003 -11)
  - Chief Operations / Scientific Officer
  - 60 million DOD, NIH funding
    - Over 15 grants, contracts

Demonstrated productivity and innovations
- Published more than 210 peer-reviewed papers, reviews and book chapters
- co-edited four books
- Holder of 11 US and international issued patents, >6 more pending

Current Academic affiliations
- Taipei Medical University - Chair Professor
- Chinese Univ. of Hong Kong (Medicine)
- University of Florida
- University of Michigan
- National Neurotrauma Society – Past President / Council Member (2011-13)
Build on your Unique Strengths

- I am internationally recognized for my unique expertise and track-record in drug discovery/development, proteomics and neuro-disease biomarker discovery.

- Multi-years experience in big **Pharmaceutical company, Academia** and **start-up Biotech. Co.** allow me to integrate scientific innovation, managed science and seamless translation into product development.
Early stage – formative years

- Unique advances, discovery
- Unmet (medical) needs
- IP, IP, IP
- Product Vision
- Timing / Climate
Virtual company – Early Start-up Stage
Decisions- Decisions- Decisions!

- To license out or to start own company
- Timing
- Forming a company, LLC or Partnership, s-corp. (legal entity)
- “Virtual company”
- Immediate funding (The “FFF” model)
- Fed. Grants (SBIR, STTR, others)
- Company vision / Mission statement
- Product articulation, time line
- Strategic planning
- SWOT analysis
- Networking with like-minded
Brick and Mortar company – Stage
Details, Focus, Money

- When clear product-developed oriented activities are identified and ready
- When non-academic funding is secured
  - e.g. awarded an SBIR
- Executive/administration/ Operations
  - (at least part time CEO needed)
- BOD (Board of Directors)
- Financial (book-keeping and budgeting, tax returns/audit)
- Lab, office space rental
- Staffing (getting and keeping the best people is key)
- HR policy (employment agreement)
- Avoid “Nice-to-have studies”
- Avoid overstaffing or growing too rapidly
- Consider Outsourcing
- Recruit experts/consultants who supplement your strengths
- Scientific Advisory Board (SAB)
  - Provide objectivity
- Annual Strategy Meeting
  - Review SWOT analysis
  - Invite Expert Consultant
SBIR / STTR Program Descriptions

**SBIR:** Set-aside program for small business concerns to engage in federal R&D -- with potential for commercialization.

**STTR:** Set-aside program to facilitate cooperative R&D between small business concerns and U.S. research institutions -- with potential for commercialization.

**SBIR:** PI Primary (>50%) employment must be with small business

**STTR:** PI Primary employment not stipulated
   [PI can be from research institution and/or from small business]
SBIR/STTR

- **PHASE I**
  - Feasibility study
  - $175K and 6-12 months (SBIR)
    or 12 months (STTR)

- **PHASE II**
  - Full R/R&D
  - 2-Year Award and $1M (SBIR)
    or $750K (STTR)

- **PHASE III**
  - Commercialization Stage
  - Use of non-SBIR Funds
SBIR PROGRAM
ELIGIBILITY at time of award

- Organized for-profit U.S. business
- At least 51% U.S.-owned and independently operated
- Small Business located in the U.S.
- P.I.’s primary employment with small business during project
- 500 or fewer employees
Funding

- Federal & other grants
  - SBIR, STTR, others

- Private
  - FFF;
  - Angel Investors
  - “Smart money”

- Venture capital
  - Series A, B
  - Raise only amount of money you need
  - Beware of Ownership Dilution
  - Beware of Losing control of company or co. directions

- IPO
  - Need professional
  - Can access additional capital needed for commercialization
  - For Co. with products that have clear path to market
SBIR and STTR Programs

Critical Differences

Principal Investigator

**SBIR:** PI Primary (>50%) employment must be with small business concern

**STTR:** PI Primary employment not stipulated

[PI can be from research institution and/or from small business concerned]
**SBIR – STTR PROGRAM**

- Program re-authorized through FY 2012
- 10 agencies with R&D budgets greater than $100 million participate
- Amounts to be set-aside of R&D budget: (currently 2.5 %)
- Total $1.3 B FY12

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Leveraging academic collaboration to create win-win R&D situation

**Academic Lab**
- **BIG R, small D**
- Rich research lab infrastructure
  - Your own Lab
- Accustomed to sponsored research activities
- Tap into Univ./institutional resources
- More IP might be generated as future product pipeline
- Attract other related companies or technologies
- Synergistic funding

**Start-up Company**
- **Small R, BIG D**
- Ability to get SBIR grant
- Focus on product advancement
- Creating cutting edge technology
  - Including new science-to-engineering interface
  - Or science/software interface
- Synergistic funding
Case Study
In 2010, about 2.5 million emergency department (ED) visits, hospitalizations, or deaths were associated with TBI—either alone or in combination with other injuries—in the United States.
More than 1.6 million American warriors returning from Iraq and Afghanistan

From 2000-2013, there are >294,000 cases of identified TBI in US military

Improvised explosive device (IED) blast exposures a leading cause (80%) of mild TBI for active duty military personnel in war

Rigg, JL and SR Mooney (2011)
Unmet Medical Needs
(Why Do We need Biomarkers for TBI)

• **Existing diagnostics or assessment methods for TBI are not perfect**
  • Severity (GCS- Glasgow coma scale), LOC, PTA
  • Brain imaging: CT, MRI,
  • Outcome measures Neuropsy. batteries, Glasgow Outcome Scale (GOS, GOS-E); Disability Rating Score (DRS) etc.
• **Not very sensitive to mild injury**
• **Significant subjectivity**
• **Excessive radiation risk**
• **TBI Protein Biomarkers-based Diagnostic**
  • Organic and quantitative, objective, repeatable, rapid POC measurement
  • *Complementary* to existing diagnostic / assessment methods

Head Trauma → Detect Biomarkers in CSF or Blood →

- Injury Severity
- Detect mild TBI
- Track disease progression
- Predict Outcome
- Identify Mechanisms
- Guide Therapy Development
- Monitor Recovery
- Personalized medicine
Banyan Biomarkers, Inc. is creating the first objective test to diagnose brain injury in less than 30 minutes by a simple blood test. The company was founded in 2002 with the vision to commercialize in vitro diagnostic tests for the detection of brain injury and neurological diseases. Initially inspired by research conducted at the University of Florida and The Evelyn F. and William McKnight Brain Institute, Banyan Biomarkers has made significant progress in developing and clinically validating novel enzyme linked immunosorbent assays (ELISAs) for traumatic brain injury (TBI). Banyan scientists have created an extensive pipeline of potential biomarkers and the company has a robust intellectual property portfolio. Banyan has an experienced team of medical technology executives and has secured over $70mm in grants and private investment of $8mm in Series A funding. The company recently completed enrollment of 2,000 patients in the ALERT-TBI pivotal trial and results are expected in Q3 of 2014.
Naurotrauma Imaging: From Bench to Bedside & Point-of-Care

Civilian
- Clinical /Medical lab, Major Hospitals
- Emergency Medicine
- Doctor’s office; Out patient Clinics
- Sport –related use

Research
- Animal studies
- Human studies
- FDA – Clinical studies
  - As new Diagnostic device (IED)
  - As companion Diagnostics / Theranostic

Neuroimaging
- PET / SPECT
- MRI / DTI
- FMRI
- CT
- Others (MRS; combined PET-MRI, PET-CT)
The Banyan Story

- **2002** Initial DOD grant awarded to UF investigators for TBI biomarker discovery
- UF filed IP protection on 4 independent patent applications
- **2003** Banyan Biomarker Inc. founded (virtual)
- UF signed exclusive IP licensing agreement to Co.
- Co. Received first SBIR; then STTR
- **2005** Co. lab moved into BDI (Biotech Dev. Incub.) Alachua, FL
- Co. awarded over 55 million DOD and NIH funding for product development and clinical trials
- Co. outsource/subcontract to Founder’s UF lab for certain research work (both animal and clinical studies)
- Co. received additional innovative research and clinical utility grant funding (~15 million) – over 10 grants
- **2011** Co. began to make milestone payments to UF – [Dept-Center – Inventors] (3 yr).
- Co. raised $8 million private investment funding (series A) for final product development
- **2014** Co. just completed 2,000 patient enrollment for the ALEERT-TBI pivotal trial. Results expected in 3Q14.
Entrepreneurism - Why do this?

- Fun / Exhilarating
- High Satisfying to see your research translating into the real world
- Learn a lot different skills
- Can help your academic lab funding and shape future focuses
- USA / UF is the best environment to do this

Negatives

- Like have two jobs
- Mindful of COI (Conflict of Interest) - UF compliance issues
- $$$ worries
- Not for everyone
Thank you

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