Commercializing Academic Research Using NIH SBIR Funding

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Introduction

Pinnacle Technology has developed successful university collaborations to bring new preclinical research systems to the marketplace. Primary funding for these collaborations has been through the NIH Small Business Innovation Research (SBIR) program. To date, Pinnacle has collaborations with three Universities; the University of Kansas, Northwestern University and the University of Pennsylvania.

The products have been developed primarily for mice and rat neuroscience research but are being used in a wide range of applications.

Products on the market include biosensors for measuring glutamate and glucose in the brain (KU collaboration), an EEG/EMG system for sleep and seizure research (NWU collaboration), and a combination system to simultaneously measure EEG/EMG/Biosensor (KU, NWU collaboration).

Products under development include a wireless fast scan system for dopamine measurements (KU collaboration), a lab-on-chip system (KU collaboration) and a sleep measurement and deprivation system for fruit flies (UPenn collaboration).

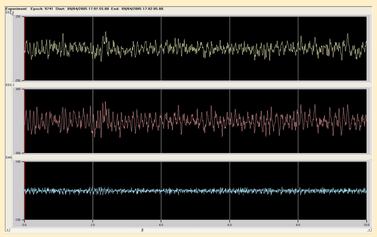
Product ideas and collaborations are developed in many different ways. A few examples of how Pinnacle has built collaborations follow.

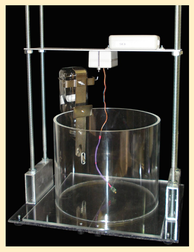
Company Driven

In company driven collaborations, Pinnacle sees an interesting SBIR topic and finds a leading academic researcher in that field for collaboration.

EEG/EMG – Northwestern University – Dr. Fred Turek
NIH 5R44MH076318

The EEG/EMG system is a tethered, low-cost turnkey system. Use of this system offers several advantages over currently available systems in that surgery time is reduced by 50%, 2 EEG channels are available, and cable noise is eliminated. The extra EEG channel provides the capability of autoscoring sleep data. The system was developed for sleep research, but it quickly became obvious that it filled a need for those that require the recording of EEG in awake, moving animals such as Parkinson's and epilepsy. It was modified to have different filters and within the year a third version was offered with 3 EEG channels to serve this new market.

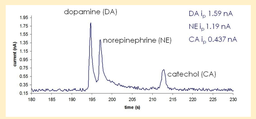




The figure on the left is a screen shot of REM sleep data from the 8200 system. The figure on the right shows the complete set-up for an experiment.

Lab-on-Chip – University of Kansas – Dr. Susan Lunte
NIH 1R43NS064664

The Lab-On-Chip project's ultimate goal is to place a wireless microdialysis system on the head of a rat. This is a "special" SBIR with a 2 year Phase I and a 3 year Phase II. During Year 1, the team is building a system for large animals, in this case sheep. In Year 2, the system will be prototyped for mid-sized animals. Phase II will focus on miniaturizing the entire system for a rat. This SBIR was written to specifically move R01 research funded by NIH to the marketplace.

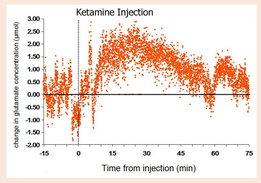


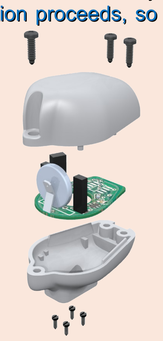
The figure above is wirelessly transmitted data using the prototype large animal system. The photo to the right shows the first round prototype system.

Researcher Driven

In researcher driven collaborations, a researcher approaches Pinnacle usually to design some electronics and software. As the collaboration proceeds, so does the company involvement.

Biosensors – University of Kansas – Dr. George Wilson
NIH 5R44NS037608, 5R44NS047955





Pinnacle initially began this collaboration by building electronics for Dr. Wilson's laboratory to use with his sensors. Now, Pinnacle licenses the sensor technology from the University of Kansas and sells turn-key wireless and tethered biosensor systems. These enzyme-based electrochemical biosensors allow researchers the ability to monitor real-time, *in vivo* changes in glutamate or glucose concentration anywhere in the brain. When used in conjunction with Pinnacle's unique head or back-mounted wireless potentiostats, researchers are able to perform untethered measurements in conscious, freely-moving rats or tethered mice. The figure above shows the effect on brain glutamate after a ketamine injection in a freely moving rat. Samples are collected every second. The current standard to measure glutamate is microdialysis which give you a sample approximately every 5 minutes.

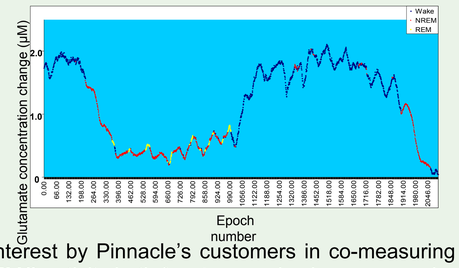
Sleep System Fruit Flies – University of Pennsylvania – Dr. Allan Pack
NIH 1R43HL092682

The overall goal of this project is to develop an automated system capable of high throughput sleep analysis and sleep deprivation. *Drosophila* engage in sleep like behavior, respond similarly to sleep altering drugs and show a marked period of rebound following a period of sleep deprivation. Furthermore, *Drosophila's* genome contains approximately 13,600 genes; all of which have been sequenced and annotated.

Customer Driven

In customer driven collaborations, Pinnacle's customers will request a new tool they would like to see for their research. After determining the product's market value, discussions are held with NIH Program Managers to see if this fits their scope of interest. Then academic researchers are found to bring in expertise.

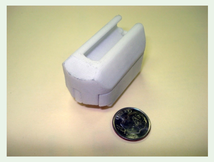
EEG/EMG/Biosensors - University of Kansas — **Dr. George Wilson, Dr. Michael Johnson**
Northwestern University — **Dr. Fred Turek**
NIH 5R44MH076318

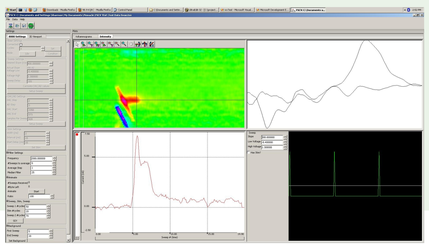


There was a great deal of interest by Pinnacle's customers in co-measuring neurotransmitters and EEG/EMG activity both for sleep and seizure research. Pinnacle put both development teams together and submitted a proposal. Currently we have a turn-key system that can measure a neurotransmitter simultaneously with EEG activity for a period of approximately 24 hours.

Wireless Fast Scan – University of Kansas – Dr. Michael Johnson
NIH 5R44NS050935

For years Pinnacle's customers have been requesting a wireless system to measure dopamine and other catecholamines. This required a different type of measurement system, fast scan cyclic voltammetry. Pinnacle took what they knew about wireless systems and found a research specialist with whom to collaborate.





SBIR Process

SBIR grants are in two Phases, feasibility and development. The average Phase I grant is about $120, 000 for 6 months and the average Phase II grant is about $850,000 for two years (highly variable by Institute – 2.5% set aside of extramural budget). These awards are company driven, 33% of the funds can go to the academic partner in Phase I and 50% in Phase II. There is another program called the Small Technology Transfer Program (STTR) in which academia can be the lead (0.3% set aside of extramural budget). In 2006, $640 M was available for these 2 small business programs from NIH. A Phase I grant must be awarded before a Phase II grant can be applied, however, there is a fast track proposal where both grants can be submitted simultaneously.

The NIH solicitation for SBIRs has 3 due dates each year, April 5, August 5 and December 5. They go through a similar review process as an R01, with a scientific review and an advisory panel review. They are submitted via Commons. Approximately 50% are not scored. If a submission is not accepted for funding, one resubmission is allowed under the current rules. One major difference from standard NIH proposals is that the commercialization potential is a major review criteria, especially for Phase II.

Kansas may provide a 50% match of the SBIR via the Kansas Bioscience Authority. The funding can be used to enhance the research, or in Pinnacle's case, is being used to increase marketing and sales efforts and outreach. Pinnacle has received a match on two Phase II SBIRs from the Bioscience Authority and has used that funding to increase sales almost 300% over the past two years. Other states have different types of support, ranging from assistance with writing the proposal to bridge funding between awards.