

# Sound Pharmaceuticals, Inc.

**JONATHAN KIL, MD**, is President, CEO & Director of Sound Pharmaceuticals, Inc. Dr. Kil has an extensive background in auditory and cell cycle biology, which translates directly into the scientific platforms of SPI. He has served as the principal investigator on several NIH grants including an SBIR phase II award for auditory hair cell regeneration. In 1998, Dr. Kil co-founded Otogene, the first inner ear biopharmaceutical company, using anti p27Kip1 technology that he developed with investigators at the Fred Hutchinson Cancer Research Center. As President, CEO, and CSO he transitioned its basic R&D technology into a pre-clinical drug development platform. He left in February of 2001 and co-founded SPI in July of 2001. Dr. Kil earned his BA from the University of California, Irvine, his MD from the University of Virginia and completed his post-doctoral training at the University of Washington.

## **SECTOR- BIOTECHNOLOGY**

**(TAT103) TWST: Would you begin with a brief historical sketch of Sound Pharmaceuticals and a picture of things as they are now?**

**Dr. Kil:** Sound Pharmaceuticals is an early-stage biopharm company, that began operations a year and a half ago in 2002. We are focused on developing drug treatments for sensori-neural hearing loss. We have three product pipelines that we are developing and look to start our first clinical study at the end of 2003. We are extremely novel in our approach to sensori-neural hearing loss. There are no drugs in our space and no ongoing clinical trials. Our technologies are revolutionary in that they aim to not only protect sensory hair cells in the cochlea or inner ear, but also aim to regenerate them. We have some novel technology that we licensed from leading research institutions including the Fred Hutchinson Cancer Center in Seattle, WA and the Memorial Sloan Kettering in New York. We were also just granted our first issued patent in Europe covering claims for inner ear disease, and these claims are very broad. Our com-

pany has raised approximately \$2 million in a seed round and is looking to close \$10 million in a first round to initiate clinical trials and further our R&D. That's where we are in a snapshot.

**TWST: How similar or dissimilar are you to the competing companies?**

**Dr. Kil:** There are a very few companies actually in this space. We are very unique, no one else including academic/university scientists has the technology to regenerate auditory hair cells in mammals. We have this technology and we are looking to develop that into a therapeutic.

**TWST: Where will this lead you over the next couple of years?**

**Dr. Kil:** Ultimately, we see this novel protective and regenerative strategy being employed in other neurodegenerative diseases. Companies that are attempting to improve function in neurodegenerative diseases like Parkinson's or Alzheimer's, rely mostly on growth factors and/or stem cells. We have a very unique approach where we are trying to stimulate the regeneration of the remaining cells by inhibiting an inhibitor of cell

cycle progression. That's a very complicated way of saying, we found proteins that inhibit cell regeneration and when we antagonize those proteins, we can stimulate cell regeneration. We look to apply this technology in other disease states involving the retina and central nervous system.

**TWST: Can you tell us about the two or three main projects that you are working on now?**

**Dr. Kil:** Specifically, otoprotection is protection against noise-induced hearing loss. According to OSHA, noise is the leading occupational disease. Over \$2b is spent on disability compensation for noise-induced hearing loss on the job. Whether you're in the military or in manufacturing, it's a significant problem. Our first goal is to prevent or reduce noise-induced hearing loss. We anticipate working with the Army on this. We have a letter of support from Madigan Army Medical Center, in Tacoma, Washington, which services Fort Lewis, a major Army center. Our second program is aimed at preventing chemotherapy-induced hearing loss. We have excellent data in live animal models where we can not only prevent the hearing loss, but also extend the animals' life and improve their other bodily functions as well. We look at starting that clinical trial at the end of 2004. And with regeneration, we anticipate starting that at the end of 2005. That therapy is rather unique in that it will be applied directly to the inner ear. This approach will limit the possibility of systemic side effects and will allow us to build up a greater concentration of our drug in that local space.

**TWST: Which do you think holds the greatest opportunity for you?**

**Dr. Kil:** Regeneration is obviously our potential blockbuster. Right now, the hearing aid market is in excess of \$6 billion. Yet, only one out of six people who qualify for a hearing aid will actually

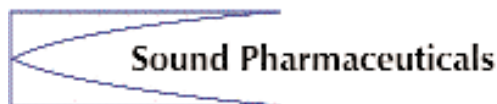
buy one. A fraction of them, much less than one out of two will actually wear them routinely. There is a lot of unmet medical need in that device space, and if we can regenerate hearing using a therapeutic approach, we could take a significant part of that market. The other great opportunity, maybe, one that is more readily approachable is going after the age-related hearing loss market. Our otoprotective strategy is very well defined, meaning we are going to reduce noise-induced hearing loss in a well-defined population, i.e. the Army. No one really knows what causes age-related hearing loss, but we know it is highly associated with previous exposure to noise. We want to extend those results to chronic daily therapy for age-related hearing loss. If we can keep people on a daily regimen of therapy starting at the age of forty and reduce their decline in hearing, we could preserve hearing through the later decades of life when you are in your sixties, seventies, and eighties. Twenty million people in the US have age-related hearing loss. It's the most common neurosensory disease. Many people believe it's blindness, but it isn't. Those are our two big opportunities.

**TWST: You based your career on studying and exploring auditory and cell cycle biology. With regard to these important discoveries regarding hearing damage, what's your rough time table for their development over the next few years?**

**Dr. Kil:** We will have products on market for otoprotection starting in 2007/8, and for chemoprotection in 2009. For our regenerative strategy, we are looking at 2010 and other markets in the retina and CNS, probably by 2012 and 2015. So, we have both near-term and long-term strategies for our drug development.

**TWST: What obstacles and problems, if any, can present themselves to you in the next three or five years?**

# Investors Brief



## Corporate Headquarters

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## RECENT MILESTONES

### Sound Pharmaceuticals Validates Oral Compound to Prevent Noise Induced Hearing Loss.

September 17, 2003 - Sound Pharmaceuticals, Inc. (SPI) announced today it has made significant pre-clinical progress on its drug development platform for the prevention of noise induced hearing loss. Results of their studies will be published later this year in the peer-reviewed journal "Laryngoscope".

"The prevention of occupational noise induced hearing loss is the first step to improve hearing in the millions of individuals at high risk of acquiring permanent and disabling hearing loss. We are very excited to announce the advancement of SPI1005 as a pre-IND candidate," stated Eric Lynch, PhD, Vice President and Director of Research. "Our goal is to file an Investigational New Drug application with the FDA for initiation of clinical studies on the prevention of hearing loss in high risk environments such as the military."

SPI1005 is a potent small molecule mimic of the enzyme Glutathione Peroxidase (GPx). GPx is a key enzyme in the neutralization of reactive oxygen species formed in the cochlea during and after loud noise exposure. GPx deficient mice exhibit increased susceptibility to noise induced hearing loss. By mimicking the activity of GPx with orally delivered SPI1005, researchers at SPI have been able to protect the hearing of animals exposed to intense levels of sound, both physiologically and anatomically.

SPI1005 shows no obvious toxic side effects at four times the effective dose. Recently studies by an independent academic group in Japan have validated the active pharmaceutical ingredient in SPI1005 using another animal model of noise induced hearing loss. "The fact that two groups have come to similar conclusions with the same molecule in the same dose range, is very exciting to our scientists and further validates this molecule as a candidate for the prevention of noise induced hearing loss" said Lynch.

### European Patent Office issues patent on novel hearing loss treatment

September 26, 2003 - Sound Pharmaceuticals, Inc. (SPI) announced that its patent "Method for the treatment of diseases or disorders of the inner ear" has issued in Europe, effective Oct. 1, 2003.

SPI has developed a novel strategy to stimulate auditory hair cell regeneration using proprietary cell cycle inhibition technology. Typically, auditory hair cells in mammals are not replaced when injured or lost. This results in permanent and often progressive sensorineural hearing a disease that affects over 30 million in the US. In non-mammals like birds, hair cell regeneration occurs through the spontaneous proliferation of the adjacent supporting cell. These newly proliferating supporting cells can go on to become replacement hair cells. However in mammals, auditory supporting cells do not proliferate or regenerate into hair cells even in the presence of growth factors.

SPI identified that p27Kip1, a cyclin dependent kinase inhibitor, prevents supporting cells from proliferating after embryogenesis. Compounds developed by SPI to inhibit p27Kip1 have been shown to stimulate supporting cell proliferation after drug or noise induced hair cell loss. "We are the only group that has demonstrated the ability to stimulate proliferative regeneration in the cochlea of mammals" says Dr. Jonathan Kil, President & CEO. "It is anticipated that this revolutionary technology will be critical in developing treatments to restore hearing in humans."

## Corporate Business Description

Sound Pharmaceuticals (SPI) is a privately held biopharmaceutical company in Seattle, WA. Our goal is to develop prescription drugs that will enable doctors and patients to prevent and treat hearing loss, a disease that affects over 30 to 40 million Americans. Estimates from the NIH and the CDC place the total annual costs of hearing loss at approximately \$50 billion per year in the U.S. alone.

Currently, there are no FDA approved drugs that protect or restore your hearing from noise damage, ototoxic drugs or aging.

## TECHNOLOGY

SPI will focus on the development of three pre-clinical product pipelines that have lead candidate products in pre-clinical testing using live animal models.

### Otoprotection

Otoprotection studies in animals indicates that the inner ear can be protected from the irreversible effects of noise damage by the systemic administration of pharmacologic agents or drugs. We have already demonstrated efficacy in live animal models of hearing loss. In addition, two of our current drug leads are already approved for human use in other diseases and are considered to be well tolerated or exhibit adequate safety.

SPI expects to develop its proprietary formulations (patents pending) into oral drugs that will prevent noise and age induced hearing loss.

### Chemoprotection

Chemoprotection from platinum based anti-tumor agents such as cisplatin will be our first goal. Unlike "rescue" agents (e.g. growth factors) that are administered after chemotherapy toxicities have occurred, chemoprotectants are given prior to or concurrent with chemotherapy. Chemoprotectants have the added potential benefit of preventing irreversible side effects such as hearing loss. SPI expects to develop its proprietary formulations (patents pending) into oral and injectable drugs to protect against drug induced hearing loss.

### Regeneration

For those patients who already have substantial hearing loss, SPI is developing drugs aimed to restore hearing. SPI is currently optimizing compounds that antagonize specific cell cycle proteins resulting in new cell division or proliferation. In mice deficient in p27Kip1, a growth inhibitory protein, normally non-dividing epithelial cells within the inner ear are now able to divide. More importantly, these newly dividing cells have the capacity to become replacement auditory hair cells.

**Dr. Kil:** One would be an unacceptable level of toxicity in our regeneration strategy. We already know, in our otoprotection and chemoprotection that these compounds do no harm. With our regeneration platform, there may be some unforeseen toxicity that we have not observed or predicted. That would be our potential greatest pitfall.

**TWST: Have you given any thoughts to future partnerships and alliances?**

**Dr. Kil:** Yes, we are talking with several groups now about co-developing compounds for innerear indications worldwide.

**TWST: Can you expand on that?**

**Dr. Kil:** Right now, they are pretty sensitive negotiations. So, I wouldn't want to state any names.

**TWST: Do you see any other opportunity to enhance your capital structure?**

**Dr. Kil:** We are always looking to enhance our capital structure. That's why we are trying to close this first round of financing for \$10 million. That would give us enough runway for the next two full years of development and will allow us to get our otoprotection compound into phase III, our chemoprotection compound, provided we have a partner, into phase II, and initiate our regenerative therapeutics into phase I. So, I think very rapidly in the next two to three years, we will evolve from a pre-clinical company into a mid to late stage clinical company. At that time, we would position the company for an IPO or major acquisition, which I think is a very rapid time line for a return on investment.

**TWST: Could you tell us about the background and expertise of a couple of key members of your team?**

**Dr. Kil:** In addition to myself, our Director of Research, Eric Lynch is a well-known hearing biologist. His background is in molecular genetics and he identified one of the first deafness genes as well as the first breast cancer gene. He's been

working on deafness for almost two decades and he lends incredible support to the development of our molecular strategies. One of the other scientists that we have is a leader in surgical approaches to the inner ear and his name is Dr. Rende Gu. He has significant experience in the auditory system and his approaches to the inner ear allow us to deliver some of these drugs. Our company is quite small right now with only eight fulltime people.

**TWST: What type of culture have you tried to develop within Sound Pharmaceuticals?**

**Dr. Kil:** We are a combination of scientific excellence and commercial know-how. One thing that I'm very proud of is that we not only have journal clubs every week where we discuss the latest breaking discoveries in other labs, but we can move on them very quickly. Within a couple of days, we can start a new line of experimentation to analyze potential benefits to the auditory system. Having been in several academic labs that were auditory focused, I have not seen that ability to act on new data in such a timely manner. We try to convey a corporate culture of not only scientific know-how, but expediency, the ability to move very quickly on projects as well as to stop projects that aren't working.

**TWST: As Chief Executive Officer of Sound Pharmaceuticals, what do you focus on most on a day-to-day basis?**

**Dr. Kil:** Technology development, fund raising, intellectual property, and then partnership opportunities.

**TWST: Where do you recently expect the company look like three to five years from now? You mentioned some milestones, can you expand on that for us?**

**Dr. Kil:** I anticipate us being a public company having our first product come to market and our next two products being in late stage clinical development, having significant corporate partnership

and really being rewarded by The Street for being a very novel company upon many levels. One, we would be the first and potentially only company focused on developing drug treatments for inner ear disease. Number two, seeing our technology being exploited in other disease systems such as neurodegenerative and neuroretinal disease. That's where I see us being in 3 to 5 years.

**TWST: What do you do to bring your message out to potential investors, Dr. Kil?**

**Dr. Kil:** I attend and present at investor conferences throughout the year, typically two to three. We have a website that lists some of our most up-to-date discoveries and news. And it's quite interactive, we have links to other centers of excellence, which further validates not only our strategies but the way the field is moving and developing. We also attend and present at scientific conferences to encourage collaboration with academic scientists and disseminate our results.

**TWST: Can you give us two or three best reasons why long-term investors should take a serious look at Sound Pharmaceuticals?**

**Dr. Kil:** Novelty and excellent broad reaching technology are important considerations. In addition, we have developed business strategies that will generate product and partnership revenue in the near term, and yet still have ample opportunity to generate blockbusters in the long-term. We have also thought carefully about who will pay for our products and when, and how they can save the system money buy reducing the cost burden of hearing loss. That's why I would invest.

**TWST: Is there anything you want to add?**

**Dr. Kil:** No, not at this time but just thanks for the opportunity.

**TWST: Thank you.**

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