Multitasking epilepsy

Steve Edelson, Executive Editor

The translational space for epilepsy presents an arid landscape. The **Epilepsy Therapy Project** is trying to reverse the status quo and thinks it can help bridge the translational gap with a combination of grants, investments, guidance and matchmaking for companies and academics working on epilepsy.

According to ETP president Joyce Cramer, the reason for the lack of new drugs and devices for epilepsy is the perception “that it’s all taken care of—it’s an understandable misconception given there are 14 medications available.”

However, the list of unmet needs in the indication is long. “For 30%–40% of the epilepsy population, seizures are uncontrolled, and that hasn’t changed over the last decades,” said ETP chairman and cofounder Warren Lammert, who has a daughter with severe epilepsy. “Furthermore, one-third of patients who gain some control from existing medicines suffer side effects such as cognitive issues and fatigue.”

Lammert was taking his daughter to Orrin Devinsky, VP for translational programs and a professor of neurology, neurosurgery and psychiatry at **New York University** and director of the NYU Comprehensive Epilepsy Center. Through Devinsky, he met other fathers of severely epileptic children, and the group started brainstorming ways to contribute to advancing compounds into development.

According to Lammert, the result was ETP, whose mission “is to accelerate the development of epilepsy therapies in a venture philanthropy framework.” Lammert added, “We’re trying to act as an incubator for the best ideas in epilepsy. There are many exciting ideas in universities and companies, but there’s a valley of death in getting those ideas into commercial processes.”

To achieve this goal, ETP’s main approach consists of providing \$50,000–\$500,000 grants to academic or company-based research groups. ETP created two advisory boards to identify the most promising ideas—one scientific, the other business-oriented. The former includes academics and crossover clinicians. The latter includes VCs and industry scientists.

Cramer said the organization wanted two boards with distinct mindsets. “The scientific advisors often don’t think of entrepreneurial aspects—they’re really scrutinizing the basic science concepts and the experiments. The business advisory people are generally serial entrepreneurs or VCs. Most are skilled scientists, but they also review

IP and commercial landscapes. Those are the things the science advisory people can miss.”

Both boards play roles in awarding grants. After ETP makes an initial cut based on two- to three-page letters of intent, the boards independently review detailed grant proposals from academia and industry. Afterward, ETP looks at both sets of scores to cull the field of applicants.

Although ETP’s grants are relatively small, Lammert thinks the organization’s focus on the preclinical space should help get good mileage out of the dollars. “Often at the preclinical level our money can help a company do a tox test,” in which favorable results could attract a venture firm. “We also work in partnership with other epilepsy organizations like the **Epilepsy Foundation** to make the most out of our small dollars. We also encourage companies to come to us with other partners in hand so that we might join with another source of funding in paying for a particular trial or lab experiment.”

Cramer told *SciBX* that ETP differs from many other epilepsy organizations, many of which concentrate on patient advocacy, because it is focused on getting ideas to commercialization. “Our goal isn’t to help individuals but to get projects commercialized. That’s the only way ideas get to patients. You can be exploring your entire career, but it won’t get to patients without IP and funding.”

Thus, she noted that the types of grants funded by ETP “have changed over time as our purview matured, moving further away from basic science. In our recent rounds, we’re funding more late-stage preclinical development. Often we help complete the animal studies that would provide

proof of principle.”

Last month, for example, ETP and the Epilepsy Foundation awarded two grants totaling \$200,000 under a joint venture called the New Therapy Grants Program. The first grant was for preclinical studies of a galanin gene therapy for mesial temporal lobe epilepsy that is uncontrolled after surgical tissue removal or treatment with drugs.

The therapy was developed by a group at **Asklepios BioPharmaceutical Inc.** and **Emory University**. The goal is to deliver galanin, an anticonvulsant protein, directly to the temporal lobe using an adeno-associated virus (AAV) vector in hopes of locally regulating activity rather than using surgery to destroy tissue.

The second grant went to a team at **Columbia University** that is developing an intracranial EEG recording system designed to better define the epileptogenic region of the brain.

On Sept. 10, ETP completed its review of 43 letters of intent for its next round of grant awards. There were 11 that survived the first cut: 2 for new molecules, 5 for seizure detection devices, 3 drug-device combinations and 1 device.

Cramer expects a final decision on the grants in early December.

One size does not fit all

In addition to its formal grant programs, ETP makes one-off investments

“We’re trying to act as an incubator for the best ideas in epilepsy. There are many exciting ideas in universities and companies, but there’s a valley of death in getting those ideas into commercial processes.”

**—Warren Lammert,
Epilepsy Therapy Project**

in companies and also tries to push projects through the translational gap by providing feedback to academics and small companies on how to move their discoveries forward and by acting as a conduit for matchmaking between those two parties and larger companies.

The decision to take an equity stake “really depends on the circumstances. Sometimes a company will have an interesting project but won’t fit well into the grant approach’s six-month time frame” for generating a data event, noted Lammert. “In that case, we may do a seed-stage investment.”

“From a standpoint of building a sustained philanthropic endeavor, we think that taking some equity along the way can allow us to be self-sustaining and invest more in future projects,” added Lammert.

Regardless of whether ETP issues a grant or makes an investment, the foundation thinks the feedback its boards provide to applicants is an important component of epilepsy drug and device development.

“With our awards processes, we can go back to companies with suggestions about how they should execute and carry out studies that provide useful information that would build confidence for further investment,” Lammert said. “One recurring issue can be trying to run a study that’s of

too small a scale to provide actionable results, so we sometimes need to encourage people to grow the scale of a study.”

ETP also runs an annual Epilepsy Pipeline Update conference, which this year included pipeline updates from 43 companies. “We invite everyone who has a new therapy that is in or close to entering the clinic,” Lammert said. “It might be the single most important thing we do. It’s really an important networking event for small companies and university scientists looking for partnerships with larger companies that can provide the significant funding needed to move ideas forward. Acting as a matchmaker is an important function for us in addition to the financing of ideas.”

Edelson, S. *SciBX* 3(36); doi:10.1038/scibx.2010.1081
Published online Sept. 16, 2010

COMPANIES AND INSTITUTIONS MENTIONED

Asklepios BioPharmaceutical Inc., Chapel Hill, N.C.
Columbia University, New York, N.Y.
Emory University, Atlanta, Ga.
Epilepsy Foundation, Landover, Md.
Epilepsy Therapy Project, Middleburg, Va.
New York University, New York, N.Y.