BIOWORLD™ TODAY
THE DAILY BIOPHARMACEUTICAL NEWS SOURCE
BIOTECH'S MOST RESPECTED NEWS SOURCE FOR MORE THAN 20 YEARS
APRIL 30, 2015
VOLUME 26, NO. 83
SPECIAL REPRINT

ALLICENSE 2015

Not-for-profits seeking stronger partnerships in return for early dollars

By Marie Powers, News Editor

In the heady days when venture capital (VC) was flowing like a waterfall, not-for-profit support of biotech endeavors was considered – by both parties – as a type of gravy, sometimes with the end goal of producing a scientific paper but rarely with a clinical milestone in mind.

But as VC dollars moved further downstream to programs already in human trials, funding from foundations and other not-for-profits became an indispensable source of early stage financing. That change wasn't lost on the funding organizations. Increasingly, they're applying the lens of business discipline rather than of charitable giving and seeking comprehensive partnerships with biotechs rather than one-shot gifts.

A panel at next week's Allicense 2015 conference will explore in greater detail the phenomenon of strategic partnering between biotechs and not-for-profits in a session alluding to return on investment from "unusual places."

When VCs stepped back, "a big hole" developed in early stage company formation, according to Chris Ehrlich, managing director of the advisory firm Locust Walk Partners and senior advisor to the Peter Michael Foundation (PMF), which aims to improve the diagnosis, treatment and management of prostate cancer.

"For a while, the strategic arms of pharmaceutical companies got involved and made some investments, but that's really not their job," Ehrlich told *BioWorld Today*.

Instead, foundations quickly spotted an opportunity to help accelerate promising therapies that fit within their research missions. For example, the PMF, established by the British technology entrepreneur, had a longstanding tradition of inviting donors to an annual dinner at the celebrated Northern California winery his family established and managed. But after many years of funding academic research that produced an ever higher stack of papers but no treatments, the PMF began to question the value of its donations.

"It wasn't a very efficient model," Ehrlich recalled. "When people give money, they want accountability."

Ehrlich worked with the PMF to establish Cancer Solutions LLC, which is operated under the jurisdiction and governance of the PMF, a 501(C)(3). However, Cancer Solutions allows high net worth individuals to invest in specific prostate cancer projects that have both scientific and commercial potential. Although the PMF remains committed to improving the diagnosis and treatment of prostate cancer, "by putting a commercial lens on the project, we believe we can make a greater impact further and faster and, in the process, provide the opportunity for an investor return, albeit not at historic venture capital levels," Ehrlich explained.

A second company, Prostate Management Diagnostics Inc. (PMDI), emerged from a collaboration between the PMF and the Genome Institute at Washington University School of Medicine, according to Doug Fisher, an executive in residence at Interwest Partners who serves as president of PMDI.

"This is a very unique concept," Fisher said. "For years, Peter Michael had given money away to academics who would publish their findings, but that didn't really change the practice of medicine for prostate cancer patients."

PMDI also is seeking to achieve that goal.

"We had an opportunity to leverage the resources of the Peter Michael Foundation to create a company along with Washington St. Louis," Fisher said, noting the medical school created a sponsored research agreement to cement the program in place. To date, the start-up, formed in October 2014, has raised approximately $1.2 million.

'THIS IS MORE THAN A SURFACE SCRATCHER'

The PMF isn't alone. The venerable Leukemia & Lymphoma Society (LLS), established 65 years ago, continues to look for new funding strategies despite surpassing $1 billion in funding across its history.

"Until seven years ago, the funding went exclusively to research projects in academic settings at research institutions all around the world," said Louis DeGennaro, president and CEO of the LLS. "At that time, we were deploying $50 million a year and funding a portfolio of 300 academic projects. When I looked at that portfolio, what I saw was that, every year, about 10 percent moved out of discovery into development. They were moving toward

a therapy for patients, but they were floundering because you can't really develop drugs in an academic setting."

The LLS created the Therapy Acceleration Program to harvest promising projects from the grant program and accelerate their development with the goal of "getting them into the hands of biotech or pharma to deliver products to patients," DeGennaro told *BioWorld Today*. To date, two spinouts have emerged from the program and more are on the way.

The LLS also began to partner directly with biotechs, looking for companies with late preclinical assets that might have applications in lymphoma or leukemia but were insufficiently funded to advance into human studies. With 10 drug development professionals on its staff, all with advanced degrees in medicine or pharmacology, and with input from key opinion leaders around the world who serve as its medical advisors, the LLS was ideally equipped to vet potential assets.

So far, the organization has deployed from $1 million to $12 million for individual programs ranging from late preclinical or investigational new drug-enabling studies to pivotal trials.

"We don't have deep enough pockets to fully fund a drug development program," DeGennaro admitted. "We're in it for a short period of time, a couple of years. Our dollars are designed to help companies get over a particular development hurdle. Our hope is that, when they do that, they'll be able to go back to the capital markets and raise more money or they will get a big pharma partner."

To date, the LLS has been involved in five such projects that attracted major pharma deals.

Laura Shawver, founder and director of Cleave Biosciences and, prior to that, the Clearity Foundation, said the mission of not-for-profits continues to change and grow alongside that of the biotech industry. Clearity was initially formed to improve the outcomes of women with ovarian cancer by helping them, for starters, to gain access to tumor profiling, but that process "is starting to become a commodity," Shawver said.

The next step for the foundation is to operationalize treatment by marshaling its database and helping to improve the collection of follow-up data – still a major issue for ovarian cancer and, indeed, oncology treatment, in general.

Shawver's interest in interacting with biotechs and medical professionals is to improve the efficiency and effectiveness of clinical trials – a process that also would save money for biotechs and, potentially, prolong and improve the lives of more patients.

"We, as an oncology community – oncologists and scientists and drug developers – need to find a way to help people get on clinical trials earlier who potentially match to an alteration because they may have a better chance to respond," she said. "We have to shift the paradigm for how we think about clinical trials. We have to place people in trials that make sense for them, wherever those trials happen to be running. Ultimately, insurance companies then will be reimbursing drugs that work instead of reimbursing drugs that don't work."

Medical not-for-profits and patient advocacy foundations aren't blind to the risks inherent in helping to bankroll early stage companies, said Mark Fischer-Colbrie, a board member of the Juvenile Diabetes Research Foundation (JDRF), which is the single largest funding source for diabetes research. But in addition to funding, they also offer an array of resources that can help young biotechs to lower their business risks.

"Given our network of contacts, we can ask an expert from anywhere in the world to talk with a small company that's looking to move an asset forward," Fischer-Colbrie pointed out. That advice might range from clinical trial design to regulatory strategy to an appropriate reimbursement structure.

JDRF also keeps an eye on the global diabetes landscape to identify technology gaps and tries to plug those by supporting compelling drug candidates and technologies. Currently, the foundation is funding nearly four dozen clinical trials.

"We're highly proactive," Fischer-Colbrie said. "We know there are some gaps that will not be filled unless JDRF steps in, whether that involves moving something from an academic setting to an early stage drug discovery company or seeking to persuade a biopharma company to redirect or expand research with a promising therapeutic into type 1 diabetes."

With deep interest and resources in a given therapeutic space, applying a business lens to the grant-making process is a natural follow on.

"We're still learning," Fisher conceded. "This is an experiment, and we'll see if it works. But we know already that we can leverage a built-in base of investors who support the foundation as well as the connections the foundation has with researchers and industry. That's an incredible value-add."

An underlying theme of this year's Allicense conference is a focus on shaking up traditional models of biotech financing and partnering and exploring new options. In Ehrlich's view, the new paradigm of foundation funding for scientific research and biotech discovery fits squarely into that mold.

"This is more than a surface scratcher," Ehrlich maintained. "Science continues to advance. Venture capital backed away early because it was a poor economic model relative to limited partners. Pharma wasn't really the right group to get involved early because they like to bring things in when they're better cooked. This is a cool model to move the science to a point where it's de-risked and people will be more interested."