BY DENISE MYSHKO

Seeding Early-Stage RESEARCH

Business incubators have been around for some time as a way to provide funding and business expertise to start-up biotech companies. **Now, large biopharmaceutical companies are getting in on the act as a way to fill their pipelines**.

Future success in the pharmaceutical industry will hinge on the ability of companies to deliver novel products that meet patient needs. To do that, pharma companies are teaming up with biotech companies, launching their own biotech divisions, investing in genetics, and acquiring other companies, all in an attempt to leverage innovation.

Now, a few companies are trying one more, albeit still uncommon, way to fill their pipelines: they are launching their own business incubators as a way to fund early discovery research.

Certainly, business incubation isn't a new concept. Business incubators, acceleration programs, and economic development programs have existed for years. States and regional organizations established research parks and labs and have provided grants and operational support services to start-up companies as a way to foster business development and job growth in their regions. Universities and academic institutions have also sponsored such programs.

Corporate involvement, however, adds a whole new dimension to the incubator concept with different objectives. So far, a couple of biopharmaceutical companies have implemented such initiatives. The goals of two such companies, Pfizer and Biogen Idec, are to feed their pipelines and access new technologies.

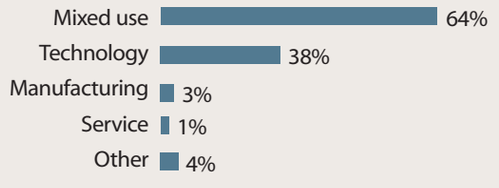
"From Biogen Idec's perspective, it's all about helping to keep the pipeline filled," says Rainer Fuchs, Ph.D., VP of Biogen Idec and executive director of Biogen Idec Innovation Incubator (BI3). "It's not a financial incentive. We don't expect to make money from our initial investment into these companies. The measure of success is when these companies can deliver products that feed the Biogen Idec pipeline. We have the option to acquire the company upon successful completion of the program and that means that it will have input to our discovery pipeline."

BI3 is designed to put scientific founders in the best position to successfully demonstrate the therapeutic potential of a drug candidate and realize significant economic benefits within timelines as short as two to three years.

THE NEED FOR CORPORATE INCUBATION

Pharmaceutical research and development productivity in the United States is in a state of decline. According to the Tufts Center for the Study of Drug Development (CSDD), although U.S. approvals of new molecular entities increased 29% from 2001 to 2004, large pharma's share of these products dropped by more than half — from 67% of total approvals to 29%.

NORTH AMERICAN BUSINESS INCUBATORS BY PROGRAM 2006



Source: National Business Incubation Association, Athens, Ohio. For more information, visit nbia.org.

Hybrid incubators provide funding for early-stage companies so they CAN GET IT TO THE POINT WHERE AN INSTITUTIONAL INVESTOR WILL BE INTERESTED.

Tufts researchers found that the number of new drugs entering clinical testing from the top 10 firms increased by 52% in the first part of this decade. New product development at small- and mid-tier pharma and biotechnology companies is increasingly filling the product gap that large pharmaceutical firms have been experiencing.

America's pharmaceutical and biotechnology research companies invested a record $58.8 billion last year in the research and development of new life-changing medicines and vaccines, an increase of almost $3 billion from 2006, according to analyses by the Pharmaceutical Research and Manufacturers of America (PhRMA) and Burrill & Company.

PhRMA-member companies alone spent an estimated $44.5 billion on pharmaceutical R&D last year, up from $43.4 billion in 2006, according to the PhRMA survey. The Burrill & Company analysis shows that non-PhRMA pharmaceutical research companies in the United States spent an estimated $14.3 billion on R&D last year, compared with $12.7 billion in 2006.

Sometimes funding through an incubator is the only way to move a technology or product forward, says Susan Shows, VP of Georgia Research Alliance (GRA).

"We come in when the discovery is too mature for the federal agencies to fund, but not mature enough to gain interest from investors," she says. "True venture capital and even institutional investors are looking at later and later stage companies. In early stages, it's grueling for companies to get funding."

"We fill the gaps of early-stage funding and then the market takes over," says Steve Clark, VP of business incubation services at TechColumbus, an incubator in Columbus, Ohio. "Either they find a strategic partner or more sophisticated dollars. To us, a success is attracting customers, new smart investments, or a new strategic partner. We are not the end all to many of the bioscience companies. Ultimately, their success will most likely be through license agreements with bigger players that have salesforces to distribute their products."

THE BENEFITS OF INCUBATION

Business incubation is a support process that provides entrepreneurs with services through its network of contacts. Incubators vary in the way they deliver their services, in their organizational structure, and in the types of clients they serve.

The incubators are not just research parks, which often promote community economic development and technology transfer. Incubators provide grants and loans, as well as consultation around business operations, human resources, other funding sources, and offer assistance with equipment.

As of October 2006, there were more than 1,400 incubators in North America, compared with only 12 in 1980, according to the National Business Incubation Association (NBIA). Of those, 1,115 were in the United States, 191 were in Mexico, and 120 were in Canada. NBIA estimates that there are about 5,000 business incubators worldwide. Most North American business incubators (about 94%) are nonprofit organizations focused on economic development. The remaining North American incubators are for-profit entities that are usually set up to obtain returns on shareholders' investments. Among all incubators, 54% are "mixed-use," assisting a range of early-stage companies; 39% focus on technology businesses; 4% focus on service businesses, serve niche markets, or assist other types of businesses; and 3% serve manufacturing firms.

Experts say one of the biggest benefits of funding through an incubator is the access to business expertise.

"These start-up companies have limited management," says Barbara Schilberg, CEO and managing director of BioAdvance, The Biotechnology Greenhouse Corporation of Southeastern Pennsylvania. "They may have one or two people early on. Often, they don't have research space or even an office. They don't know which contract research groups to use. We help them get started and we help them find board members. We help them find employees. It's not just about writing a check."

TechColumbus provides coaching and mentoring to help companies becomes sustainable commercial entities.

"We have a business consultant on staff who helps each company understand its value proposition, its target market, its growth path, what resources it needs, and where it might find them," Mr. Clark says. "He is consulting with all the companies to streamline their commercialization path. Many of these companies have entrepreneurs who are very technically focused and who are

Dr. Rainer Fuchs
Biogen Idec

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BUSINESS INCUBATION

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very good on the technical side but may need help when it comes to the business."

TechColumbus is home to more than 25 incubating companies, and in the last five years companies in the incubator have created more than 265 jobs, raised $53.4 million, and generated $87.4 million in revenue.

TechColumbus evaluates about 400 opportunities a year and engages in about 20% of them. About 60% of the bioscience projects that are provided funds are in the device arena, between 20% and 30% involve diagnostics, and the rest focus on therapeutics, Mr. Clark says.

TechColumbus provides grants between $20,000 and $90,000 to produce a prototype and to conduct market studies. It also offers convertible notes of between $200,000 and $500,000.

The money, $22 million in total, that is used to support the programs comes from the state and private sources, Mr. Clark says.

"We are just the operators of the funds," he says. "This is a rigorous process, and we have a lot of people from the venture capital world who sit on our advisory boards to evaluate the various projects."

One of TechColumbus' incubated companies is InVasc Therapeutics. InVasc has a vast pipeline and is currently focusing on two compounds that treat hypertension, diabetes, and atherosclerosis. Company officials say they expect to file an IND in the next 15 months, thereby allowing clinical trials to begin.

One advantage of being at an incubator is that InVasc Therapeutics is surrounded by other emerging companies, thereby facilitating an exchange of ideas, says Nadya Merchant, Ph.D., chief commercialization officer, InVasc Therapeutics.

"For InVasc scientists, there is the opportunity to be in a lively work environment with like-minded neighbors instead of in a solitary lab," she says. "In my mind, this is an incredible morale booster for our employees. InVasc has received significant mentoring from the TechColumbus team. This includes services such as providing feedback on the business plan, and introductions to industry consultants and investor groups."

Dr. Merchant says InVasc has been fortunate to have had some great networking opportunities, which are essential for the growth of any early-stage company.

At the Georgia Research Alliance, Ms. Shows says her group works to team up the technology and product inventors with seasoned entrepreneurs.

"We know enough entrepreneurs who know how to raise that first million dollars," she says. "We're starting to find ways to link those people to specific projects. We find people who are just coming off a project or their company has just been acquired. We have even given entrepreneurs an office and administrative support and have provided them with access to various projects to see if there is a fit."

GRA has provided research grants — as well as noncollateralized loans of up to $250,000 — for more than 100 projects and has helped to create 70 companies through the pre-incubator services part of the program, called VentureLab. Combined, those companies have 430 employees. Twenty-seven of the companies have graduated from VentureLab, which means they are either in an incubator or, in some cases, have moved beyond incubator status: eight of them stand on their own. Combined, the 70 companies assisted by GRA have attracted $275 million in private equity investment.

Ms. Shows says her group also works to team up technology and product inventors with seasoned entrepreneurs.

"We find entrepreneurs who know how to raise that first million-dollar amount," she says. "We're starting to find ways to link those people to specific projects. We identify people who are just coming off another project or their company has just been acquired, we give them an office and administrative support — if needed — and provide them with access to various projects to see if there is a fit."

The alliance's corporate operations are funded 100% by private resources; the group also receives $40 million from the state, which is used for grants, as well as for investments in infrastructure at the six universities that are part of the organizational network.

One of GRA's incubated companies is MedShape Solutions, which develops devices for use in minimally invasive surgery. The company has three products in the pipeline that company officials expect to be cleared late in 2009.

"We've been lucky enough to receive a phase-one and two phase-two grants from the GRA of $25,000 and $100,000," says Kurt Jacobus, Ph.D., president and CEO of MedShape Solutions. "That may not sound like a lot, but for us, especially in our early days, it equated to several months of burn rate — and it's nondilutive financing. We also received a $100,000 match from GRA when we secured external funding. GRA also has helped us with equipment support grants."

Dr. Jacobus says GRA has provided intangible benefits as well.

"In our earliest days, GRA provided access to a seasoned early-stage company executive — what they call a 'venture catalyst' — to advise the company," Dr. Jacobus says. "He provided excellent guidance on business planning, fundraising, general management of an early-stage

INCUBATOR FAST FACTS

BUSINESS INCUBATOR SPONSORS

INCUBATOR SPONSORS — ORGANIZATIONS OR INDIVIDUALS WHO SUPPORT AN INCUBATION PROGRAM FINANCIALLY — MAY SERVE AS AN INCUBATOR'S PARENT OR HOST ORGANIZATION OR MAY SIMPLY MAKE FINANCIAL CONTRIBUTIONS TO THE INCUBATOR.

- About **31%** of North American business incubators are sponsored by economic development organizations
- **21%** are sponsored by government entities
- **20%** are sponsored by academic institutions
- **8%** are sponsored by other types of organizations
- **8%** of business incubators are "hybrids" with more than one sponsor
- **8%** of incubators have no sponsor or host organization
- **4%** are sponsored by for-profit entities

TYPES OF BUSINESS INCUBATORS

INCUBATION PROGRAMS COME IN MANY SHAPES AND SIZES AND SERVE A VARIETY OF COMMUNITIES AND MARKETS:

- Most North American business incubators (**about 94%**) are nonprofit organizations focused on economic development
- **54%** are "mixed-use," assisting a range of early-stage companies
- **39%** focus on technology businesses
- About **6%** of North American incubators are for-profit entities, usually set up to obtain returns on shareholders investments.
- About **4%** focus on service businesses, serve niche markets, or assist other types of businesses
- **3%** serve manufacturing firms
- About **53%** of business incubators operate in urban areas, **28%** operate in rural areas, and about 19% operate in suburban areas

Source: National Business Incubation Association, Athens, Ohio.
For more information, visit nbia.org.

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Susan Shows
GEORGIA RESEARCH ALLIANCE

SOMETIMES FUNDING THROUGH AN INCUBATOR IS THE ONLY WAY TO MOVE A TECHNOLOGY OR PRODUCT FORWARD.
We come in when the discovery is too mature for the federal agencies to fund, but not mature enough to gain interest from investors.

company, key introductions, and the like. He was so helpful to the development of MedShape that he now serves on our board. A big benefit of working with the GRA is having access to smart minds: people who challenged our thinking, tweaked our business, and helped us think about ways to better position the company for success. The cash grants are a great benefit, but getting great advice from someone who has been in the game many times before is incredibly valuable."

Another incubator start-up is BioAdvance, which received $33 million five years ago from Pennsylvania's settlement with the tobacco companies. The organization has invested $11.5 million, and those companies have gone on and raised another $215 million in capital. One company was sold for about $200 million.

BioAdvance has provided 21 companies with as much as $1 million in funding, money that is then converted to equity when another institutional investor comes in.

"We have another nine companies that have received preseed money that have not yet graduated to the seed level," Ms. Schilberg says. "Two-thirds of our portfolio of companies have produced a gain either on paper or provided cash back to us."

THE CORPORATE INCUBATORS

Biogen Idec's incubator provides founders with the financial resources necessary to convert drug prototypes into development candidates that can quickly enter the clinic.

"Our model has resonated with people whose primary interest is getting drugs to patients, not necessarily with people whose goal is to build the next fully integrated pharmaceutical company," Dr. Fuchs says. "Our intent is to find new products. In many cases, it's about goal alignment. Most people have not had a positive experience with the venture capital model.

"In our model, the path to liquidity is only two to three years, at which time we would buy out the company," Dr. Fuchs says. "The financial return to the founders could still be very significant and there is less risk involved and a higher likelihood that the program will actually continue along the original research plan, as opposed to being turned into something very different."

BI3 offers state-of-the-art laboratory space, office space, and shared equipment in an access-controlled environment adjacent to Biogen Idec's headquarters in Cambridge, Mass. BI3 also offers access to Biogen Idec's drug discovery expertise, scientific services, and technology, as well as all the business and administrative support required to manage day-to-day company operations.

Dr. Fuchs says what makes BI3 unique is that these services are offered in one bundle.

"In my view, one of the most important aspects is access to the scientific expertise of Biogen Idec," he says. "This expertise takes two forms. One is in the form of consulting. We provide our experts as consultants to the incubated company. If the need is to humanize an

Steve Clark and Dr. Stephen Molnar
TECHCOLUMBUS

Steve Clark of TechColumbus and Stephen Molnar, Ph.D., Director of Research for DIRAmed, stand in the company's laboratory at the TechColumbus incubator. **DIRAMED IS DEVELOPING A NONINVASIVE GLUCOSE MONITORING SYSTEM FOR DIABETICS.**

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antibody, for example, we can put them in touch with the right folks at Biogen Idec, who can provide insights on what works and what doesn't."

One BI3 incubated company is Escoublac, which was formed based on the discovery of a new link between bone biology and metabolism by Gerard Karsenty, M.D., Ph.D., professor and chair of Genetics and Development at Columbia University Medical Center (CUMC). Escoublac's goal is to explore whether the discovery can be translated into new treatments for metabolic diseases, including Type 2 diabetes and obesity. Escoublac's research focus will build upon Dr. Karsenty's discoveries that the hormone osteocalcin is involved in regulating insulin and fat storage in the body.

Unlike Biogen Idec, The Pfizer Incubator is focused more on new technologies rather than specific products for its pipeline. The company is looking for innovative ideas that, if developed, could solve tough scientific and technological challenges facing the industry.

The Pfizer Incubator (TPI) offers scientist-entrepreneurs an opportunity to bring their medical innovations to patients. In TPI, scientist-entrepreneurs contribute innovative ideas and the ability to solve complex scientific and technical challenges. TPI provides all necessary resources to move ideas forward into practice. The company is interested in technologies and products rather than solely a financial return.

Pfizer plans to invest on average about $2 million a year in each incubated company; funding will typically be granted for two years.

Pfizer provides laboratory space that can accommodate both chemistry and biology projects. TPI also will provide basic laboratory equipment and scientific services, such as IT support, glass wash services, and waste collection and disposal. Depending on the project or technology, companies may also have access to other Pfizer services, such as the ability to screen at the company's chemical library.

The Pfizer Incubator's first laboratories are on the company's campus in La Jolla, Calif. The labs reside in a modern building built in 2004 and consist of five separate dedicated labs, which can be expanded to eight, and 23 offices in 28,000 square feet of flexible space. The labs can be configured for either chemistry or biology.

So far, Pfizer has incubated three companies. Fabrus is the first company to enter The Pfizer Incubator and was founded by Vaughn Smider, Ph.D., an assistant professor at The Scripps Research Institute. Fabrus is developing a novel technology platform to enable the identification of unique therapeutic antibodies that might lead to new therapies. During the two-year incubation period, Fabrus is working to develop novel antibody libraries, and ways to screen them against biological targets. The technology will be tested on targets in some of Pfizer's 11 disease areas.

Another company is Wintherix, which was founded by a team led by Dennis Carson, M.D., director of the Moores Cancer Center and Professor of Medicine at UCSD School of Medicine. The new company is using its proprietary biological knowledge and Pfizer's compound library to search for molecules that inhibit Wnt-related signaling pathways in cancer cells. Wnt-signaling is thought to play a role in the development of cancer in humans and represents a potential new way to treat the disease.

The third company is RGo Bioscience, which was cofounded by Alexander Chucholowski, Ph.D., previously president of ChemBridge Research Laboratories (CRL), and Dr. Thomas Hermann, an assistant professor at the University of California, San Diego (UCSD), where he researches the potential of small molecules to act on ribonucleic acid (RNA). RNA plays a key role in many disease mechanisms and the new company aims to develop novel ways to deliver RNAs into the human body.

Pfizer's partnership model gives innovators a faster way to see their ideas turned into technologies and products for patients. Financial rewards for the innovator could also come earlier — when the technology is validated. Longer term, the potential exists for substantial financial return, if the incubated company's products reach the market.

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

Experts on this topic

STEVE CLARK. VP of Business Incubation Services, TechColumbus, Columbus, Ohio; TechColumbus' mission is to accelerate the growth of the innovation economy by providing vital resources and assistance to people and enterprises that depend on technology to achieve their business goals. For more information, visit techcolumbus.org.

RAINER FUCHS, PH.D. VP of Biogen Idec and Executive Director of Biogen Idec Innovation Incubator (BI3), Cambridge, Mass.; BI3 offers the opportunity for entrepreneurial scientists to convert novel biological insights into life-saving and life-changing therapeutics. For more information, visit biogenidec.com/bi3.

KURT JACOBUS, PH.D. President and CEO, MedShape Solutions Inc., Atlanta; MedShape Solutions develops medical devices primarily for use in minimally invasive surgery; the company combines expertise in materials science, medicine, and engineering to provide innovative solutions to challenging medical needs. For more information, visit medshapesolutions.com.

NADYA MERCHANT, PH.D. Chief Commercialization Officer, InVasc Therapeutics Inc., Atlanta; InVasc is a drug development company working toward the discovery and development of novel therapies for the treatment of hypertension, diabetes, and vascular diseases. For more information, visit invasc.net.

BARBARA S. SCHILBERG. CEO and Managing Director, BioAdvance, The Biotechnology Greenhouse Corporation of Southeastern Pennsylvania, Philadelphia; BioAdvance identifies and invests in promising research and technologies that could lead to important advances in medicine and human health. For more information, visit bioadvance.com.

SUSAN SHOWS. VP, Georgia Research Alliance (GRA), Atlanta; Georgia Research Alliance is a private, nonprofit corporation that aims to capitalize on innovative university research to build a vibrant, technology-rich economy. For more information, visit gra.org.