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Article Reprint • Page 1 of 6

Finance

Wanted: Less dilution

By Erin McCallister Senior Writer

The \$1 billion in therapeutic tax credit money doled out by the U.S. Treasury last week was spread so thinly among 3,000 companies that biotech CEOs are already looking at ways to make a hoped-for second round more meaningful.

In addition to spurring investment in smaller biotechs that have struggled to gain access to capital since the economy melted down, the funds were intended to give them the capital to hire more staff and accelerate the development of programs that address an unmet medical need, reduce the costs of healthcare or cure cancer in 30 years.

While companies are not going to turn down \$244,479 — the

amount individual projects ended up receiving — and the sums can provide runway for the very smallest startups, there was general disappointment with the size of the awards, particularly for more advanced companies.

It also would be hard to argue that merit was an important consideration in handing out the awards. Indeed, some were given for compounds that have failed multiple clinical trials or even been turned down by **FDA**.

As a result, CEOs and tax experts who spoke with BioCentury recommend that if the credit is extended, the review process should reflect characteristics of other successful grant programs. Their suggestions include a focus on fewer, more substantive awards, and a process that allows projects to get bigger awards based on progress made with smaller initial grants.

Getting to a Version 2.0 of the program is not a foregone conclusion, however, given the current deficit-cutting climate in Washington. To make the industry's case for continuing and perhaps expanding the program, the **Biotechnology Industry Organization** will have to document the benefits to patients, to American competitiveness and to job creation.

Initial expectations

The therapeutic discovery project program (TDPP) was designed to provide tax credits or cash grants to companies with fewer than 250 employees to cover up to 50% of eligible R&D expenditures incurred in tax years 2009 or 2010. It was designed by BIO and approved as part of the Patient Protection and

Affordable Care Act (PPACA).

IRS initially estimated that 1,200 companies would submit applications, which, if split evenly, would have resulted in an average award of about \$833,000. However, the actual number of companies was more than double the estimate and the requests totaled \$10 billion.

Faced with far more project applications than expected — more than 5,600 — IRS decided to split the pot equally among all qualified projects, giving out 4,606 awards to 2,923 companies. The result was a maximum of \$244,479 per project, well short of the expected \$1-\$5 million.

Because companies could submit an unlimited number of applications, some biotechs received \$2-\$3 million. Indeed, the

companies that did best were the ones that submitted the most projects.

The largest amount of money — about \$3.5 million— went to the **Wellstat Group**. The group of companies includes Wellstat Therapeutics, which received awards for its programs in gout, Type I diabetes, cancer, multiple sclerosis (MS) and inflammatory disease. Wellstat's Wellstat Diagnostics LLC received awards for its RNA detection technology for cancer and pathogens, nonalcoholic fatty liver

disease and lyme disease (see "Stacking Up Awards").

Right behind Wellstat was **Immunomedics Inc.**, which received awards for 12 projects for a total of \$2.9 million.

The company's strategy was to throw the kitchen sink at the program, including projects from almost all of its clinical and preclinical pipeline.

According to Chau Cheng, director of investor relations and grant management, Immunomedics received awards for all the applications it submitted. He told BioCentury the biotech submitted multiple applications which totaled more than the \$5 million cap "because you never know which projects may be certified and which will not."

At Sept. 30, Immunomedics had \$23.2 million in cash and a three-month operating loss of \$6.7 million. At June 30, the company reported an annual operating profit of \$33.9 million.

Inovio Pharmaceuticals Inc. President and CEO Joseph Kim told BioCentury the company would have put in additional applications had he realized the awards were going to be capped at \$244,479. The biotech submitted three, for which it received

See next page

"They got the money out quickly under this program, and that was an important part of the process."

Christopher Ohmes, Ernst & Young

from previous page

the maximum.

"We could have easily put in half a dozen additional applications if I knew there was a \$244,000 per project cap. I am thankful that we didn't just put in one, but we could have put in more than three," he said.

Spread thin

For companies with programs in Phase I or beyond, this first round of grants will only nibble at the margin of a project.

For example, Marcadia Biotech Inc. received a single award for its Phase I diabetes candidate MAR701. The injectable dual agonist of incretin hormone receptors for gluclagon-like peptide-I and glucose-dependent insulinotropic polypeptide is complet-

"We're not talking about a \$100 billion infusion; we're talking about a few billion, which is truly an investment in the future of the country.

This is not a bailout."

Ron Cohen, Acorda Therapeutics

ing a multi-dose Phase I study. The biotech expects to start Phase II testing in 2011.

"We could have used a lot more, but we're happy with what we got," CEO Fritz French told BioCentury. "\$244,000 is a fraction of our monthly burn, but it is something that can help fund toxicology testing or a portion of our work on MAR701."

According to French, the company's application included qualified expenses in the millions.

While other companies submitted multiple applications, which helped to bolster their final awards, French said Marcadia chose to focus on the one application.

"We could have picked some backup programs for MAR701, but we didn't think it was worth the effort," and MAR701 is the company's primary focus, French said.

Like Marcadia, Marina Biotech Inc. got less than it expected.

The company received \$733,000 covering all three of the programs submitted: CEQ508 to treat familial adenomatous polyposis (FAP), CEQ626 to treat inflammatory bowel disease (IBD) and the biotech's RNAi therapeutics platform.

The company's lead program, CEQ508, is an oral RNAi targeting beta-catenin (CTNNBI) in Phase I testing for FAP.

While President and CEO J. Michael French welcomed the capital infusion, he doesn't think it will have a significant impact.

"This \$733,000 is roughly half our monthly burn rate. Half of a month isn't going to have a significant impact on what we've done or what we plan to do," he said.

GlycoMimetics Inc. and **Xoma Ltd.** also received much less than requested.

According to GlycoMimetics CEO Rachel King, the company applied for \$5 million to support its program for sickle cell disease. The company received the maximum \$244,000.

GlycoMimetics "will focus on fewer key areas of the sickle cell program than we had hoped," King told BioCentury This Week, BioCentury's public affairs television program (see www.biocenturytv.com).

GlycoMimetics' GMI-1070 is in Phase II testing to prevent or attenuate painful vaso-occlusive crisis and early death in sickle cell patients. GMI-1070 is a glycomimetic inhibitor of E selectin (SELE; CD62E); P selectin (SELP; CD62P), and L selectin.

Xoma got four awards totaling \$978,000, including one for its lead program, Xoma 052. The humanized IgG2 mAb against IL-I beta is in a Phase IIa trial to treat Type II diabetes.

CEO Steven Engle told BioCentury that while the funds will do little to defray the costs of the company's Phase IIa trial, they could help support research into additional indications for the mAb, including cancer.

"We are spending tens of millions on Xoma 052, so this is a drop in the bucket, but we're glad to have it," he said.

Little goes a long way

Engle acknowledged smaller biotechs or preclinical programs could be helped significantly with such an amount. "Animal experiments can be in the tens of thousands, so such an award could allow a company to do multiple experiments, depending on the animal," he said.

Engle added that for companies searching compound or antibody libraries, the funds could help provide additional screening opportunities, which could yield additional leads.

Marcadia's French agreed that the funds could help earlier-stage companies.

"If this money helps to advance a startup six months, that is a big deal," he said.

French added that the capital could help these early-stage companies attract more investors because it will give the startup time to improve and/or add to its science.

One startup that received an award was **SKS Ocular LLC**. The ophthalmic company was founded this year and received a single \$244,479 award to develop an animal model for dry agerelated macular degeneration (AMD). The company submitted a

See next page

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from previous page

single application requesting \$450,000.

President and CEO Jason Slakter noted one of the biggest challenges of developing treatments for dry AMD is the lack of animal models that accurately reflect the disease process in humans.

According to Slakter, current models have focused on creating severe artificial damage to the back of the eye that looks similar to dry AMD using different noxious stimuli.

As a result, researchers are "essentially testing the therapeutic on the toxin, not the process that results in dry AMD in humans," he said. "Our model is based on certain biomarkers

that are elevated in humans with AMD, and the changes the biomarkers produce in animals truly recapitulate the human pathologic condition."

SKS is developing a mouse model based on the elevation of carboxyethylpyrrole (CEP), which researchers at the **Cleveland Clinic** found to be associated with dry AMD.

The company plans to use the money to develop the model in higher species and to begin in-house discovery work for therapeutics to treat dry AMD — which it will now do "in parallel rather than sequentially," Slakter said.

CBO Jeanmarie Guenot added that the company will be able to do key experiments to attract and support partnerships for the dry AMD model.

Both said the award puts the company "at least six months

ahead of schedule."

Another small company that said the money will help move it forward is **Inviragen Inc.** The infectious disease company got two grants totaling \$488,959 for its preclinical recombinant attenuated Chikungunya vaccine and its Phase I recombinant trivalent dengue fever vaccine.

According to co-founder and CEO Dan Stinchcomb, the funds will accelerate by one or two months the company's Phase I follow-up trials looking at dose alterations and dosing schedules for the dengue fever vaccine.

"Even a month or two could give you a competitive advantage," he said.

The biotech expects to start those studies once it sees data from the current Phase I trial. Safety information from the Phase I dosing study is expected in IQII, with data on the secondary measure of immune response expected in 2QII.

As for the Chikungunya program, Inviragen expects to enter Phase I in late 2011.

The biotech also expects to add to its 30 employees with the award, another goal of TDPP.

Stacking up awards

BioCentury estimates the \$1 billion in grants and credits under the Qualifying Therapeutic Discovery Project program went to about 2,914 companies, after consolidating subsidiaries and related parties under one entity. For the most part, the awards are a small fraction of the money raised by these companies since inception. Twenty-two companies garnered more than \$1.5 million for multiple projects, with the highest total of \$3.5 million going to five companies that fall under the Wellstat Group.

(A) The Wellstat companies are not subsidiaries of Wellstat Management Co. LLC or any other parent company, but all are all owned by Nadine and Samuel Wohlstadter. Samuel Wohlstadter was a founder of Amgen Inc. (NASDAQ:AMGN). In total, Wellstat companies have about 170 employees. Includes Wellstat Biologics Corp., Wellstat Diagnostics LLC, Wellstat Immuno Therapeutics LLC, Wellstat Ophthalmics Corp. and Wellstat Vaccines LLC; (B) Includes Neurogen Corp. and Metabasis Therapeutics Inc., both acquired by Ligand Pharmaceuticals Inc..; (C) Includes High Point Pharmaceuticals LLC spinout; (D) Includes ImQuest BioSciences Inc.; \$M; Sources: BCIQ: BioCentury Online Intelligence; IRS

Total

of

Raised

Company	awards	grants	at least
Wellstat Group (A)	\$3.5	16	ND
Immunomedics Inc. (NASDAQ:IMMU)	\$2.9	12	\$171.5
Arisaph Pharmaceuticals Inc.	\$2.8	12	\$20.0
Theravance Inc. (NASDAQ:THRX)	\$2.7	11	\$501.2
PTC Therapeutics Inc.	\$2.5	12	\$181.6
Merrimack Pharmaceuticals Inc.	\$2.4	10	\$181.3
Rigel Pharmaceuticals Inc. (NASDAQ:RIGL)	\$2.4	10	\$559.9
Synageva BioPharma Corp.	\$2.3	12	\$69.0
Pain Therapeutics Inc. (NASDAQ:PTIE)	\$2.1	10	\$195.2
Ligand Pharmaceuticals Inc. (NASDAQ:LGND) (B)	\$2.0	8	\$403.6
Achillion Pharmaceuticals Inc. (NASDAQ:ACHN)	\$2.0	8	\$240.7
Transtech Pharma Inc. (C)	\$2.0	8	ND
ChemoCentryx Inc.	\$2.0	8	\$163.5
Alnylam Pharmaceuticals Inc. (NASDAQ:ALNY)	\$2.0	8	\$246.0
SomaLogic Inc.	\$1.9	8	\$53.5
Metabolex Inc.	\$1.8	8	\$185.4
Xcelience Holdings LLC	\$1.8	14	ND
Omeros Corp. (NASDAQ:OMER)	\$1.7	8	\$131.2
ImQuest Pharmaceuticals Inc. (D)	\$1.7	7	ND
MacroGenics Inc.	\$1.7	7	\$126.6
Celldex Therapeutics Inc. (NASDAQ:CLDX)	\$1.7	7	\$95.8
Microbiotix Inc.	\$1.6	8	ND

Qualifying qualifiers

While TDPP was administered by IRS, NIH convened experts to review the applications.

IRS specified three types of projects as eligible: One type was to "treat or prevent diseases or conditions by conducting preclinical activities, clinical trials, and clinical studies, or carrying out research protocols for the purpose of securing approval of a product" under an NDA or BLA.

Alternatively, a project could be intended to "diagnose diseases or conditions or to determine the molecular factors related to diseases or conditions by developing molecular diagnostics to guide

See next page

from previous page

therapeutic decisions."

The third option was a project to "develop a product, process, or technology to further the delivery or administration of therapeutics."

To determine if projects met the criteria, HHS used a peerreview process that included 74 first level reviewers who conducted the initial scientific review. The legislation dictated that this preliminary review ended on Sept. 30. With applications due on July 21, this gave the reviewers just over 50 calendar days to conduct the initial scientific review.

With over 5,600 applications, the level of selectivity applied by the reviewers was limited and is reflected in the review process outline.

Of the II areas of review, only three included more than a

yes/no evaluation. These last three questions asked the reviewer to evaluate the scientific basis of the project, the likelihood it will be successful and the capacity of the applicant to complete the work (see "R&D Reviewer's Checklist").

The oversight and approval panel was chaired by Antonio Scarpa, director of the Center for Scientific Review (CSR) at NIH, and included six additional CSR scientists. The panel made the final recommendation on approval for the applications.

Upon completion of the preliminary review, the IRS was required to approve or deny any application within 30 days of Oct. I.

According to Christopher Ohmes, co-leader of the Research Credit Practice at **Ernst & Young LLP**, the review process had to be accelerated because one of the goals of TDPP was to make money available to capital-strapped companies.

"They got the money out quickly under this program, and See next page

R&D reviewer's checklist

For an applicant to have received a tax credit or grant, the reviewer must have concluded the project passed three hurdles. First, it must have met at least one of the criteria that define a qualifying project (questions 1-4). The project next must have met at least one set of selection criteria (questions 6-8). Finally, it must have shown the potential to achieve the stated goals in a reasonable time frame (questions 9-11). If the first reviewer concludes an application passes all three hurdles, a recommendation for funding is supported. Applications were given a second chance if the first reviewer determined it fell short on any one of the three hurdles. But if the second reviewer recommended the project for funding, a third reviewer needed to come to the same conclusion for the project to get funding. Source: HHS

Pass	Fail	Questions
"Yes" to at least one of questions 1-4	"No" to all four questions	(1) Is the project designed to develop a product to treat or prevent a disease or condition by conducting preclinical activities, clinical trials, or clinical studies, or by carrying out research protocols for the purpose of securing approval of a product under section 505(b) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act?
		(2) Is the project designed to diagnose a disease or condition?
		(3) Is the project designed to determine molecular factors related to diseases or conditions by developing molecular diagnostics to guide therapeutic decisions?
		(4) Is the project designed to develop a product, process, or technology to further the delivery or administration of therapeutics?
"Yes" to Q5 and either part of Q6	"No" to all	(5) Is this project likely to result in one or more new therapies? (6a) If the answer to question 5 is yes, will the new therapy(ies) treat areas of unmet medical need?
OR "Yes" to Q7		(6b) If the answer to question 5 is yes, will the new therapy(ies) prevent, detect, or treat chronic or acute diseases or conditions?
		(7) Is the project likely to reduce long-term health care costs in the U.S.?
OR "Yes" to Q8		(8) Is the project likely to significantly advance the goal of curing cancer within the next 30 years?
Score of 4 or better for Q9 and an average score of 2.5 or better	Score of 5 for Q9	(9) Has the applicant demonstrated a credible scientific basis to establish that the project has a reasonable potential to achieve its stated goals? Score 1 through 5, with 1 indicating success is highly likely and 5 indicating success is unlikely.
on Q10 and Q11 OR Score of 3 or better on Q9 and an average score better than 4.5		(10) Considering the stage of development of the project, progress described, and the planned research and development strategy, is there a reasonable potential that the project will achieve its stated goals? Score 1 through 5, with 1 indicating the project is very likely to be completed within a reasonable time frame, and 5 indicating information provided was not sufficient to make an assessment.
on Q10 and Q11		(11) Will the resources, management experience, and organizational capacity of the applicant support successful completion of the project? Score 1 through 5 with 1 indicating the resources are likely to support successful completion and 5 indicating insufficient information has been provided to support completion or work on the project has been abandoned for reasons other than lack of financial resources.

from previous page

that was an important part of the process," he told BioCentury.

However, the filter allowed awards to projects that have failed clinical trials along with others that have received complete response letters from FDA.

Perhaps most notable was Genasense oblimersen from **Genta Inc.** The company received two awards totaling \$488,958, including one for Genasense, an antisense agent targeting Bcl-2 mRNA.

FDA has issued multiple complete response letters to the company since a 2006 Oncologic Drugs Advisory Committee

voted 7-3 that the company had not demonstrated efficacy in chronic lymphocytic leukemia (CLL).

The TDPP award was for Genasense to treat advanced melanoma. The Phase III AGENDA trial in the indication is ongoing. In 2009, the trial missed the co-primary endpoint of progression-free survival (PFS), but data on the other primary endpoint of OS are expected in 2011.

Genta has appealed each FDA response, and the agency has responded

each time that an additional trial would be required. In a statement to BioCentury, Genta spokesperson Janet Pignio said allocations among the Genasense indications will not be done until after the OS data are available.

Other projects that received funding that have failed in the clinic include Dimebon latrepiridine from **Medivation Inc.** and pimavanserin tartrate from **Acadia Pharmaceuticals Inc.**

In March, Dimebon missed the co-primary endpoints in the Phase III CONNECTION trial for AD. In May, the company stopped a pair of ongoing Phase III trials in severe AD. The Phase III CONCERT trial in patients with mild to moderate AD is ongoing, as is a trial in Huntington's disease (HD). Medivation is co-developing Dimebon with **Pfizer Inc.**

Medivation received additional awards for other programs.

In 2009, pimavanserin missed the primary endpoint in the Phase III ACP-103-012 trial to treat Parkinson's disease psychosis (PDP). Another Phase III trial in PDP is ongoing.

While the guidance stipulated that projects that had been denied FDA approval would not be eligible, the exact language on the application was less strict: the application stated the project is not eligible if it is "terminated or suspended" due to failure of a clinical trial, failure of a preclinical research milestone or failure to secure FDA licensure.

Certain devices also were eligible, including medical devices designed to diagnose diseases or conditions or those designed to "further the delivery or administration of therapeutics," where therapeutics are defined as drugs or medical devices.

But the awards included devices that do not seem to meet these criteria.

For example, **Piezo Resonance Innovations Inc.** received a \$222,566 award for a medical device to clean feeding tubes *in situ*.

Similarly, **Protec Maternity Wear LLC** received a \$100,200 award for garments to prevent fetal electromagnetic field (EMF) exposure.

One application that was not accepted came from **Cellular Dynamics International Inc.** The company received four awards for the maximum amount; however, the biotech submitted five applications.

According to CEO Robert Palay, the fifth application was for its iCell cardiomyocytes, which are marketed for drug research. The technology uses human induced pluripotent stem (iPS) cells.

Palay said the company was not told why the iCell application was denied; however, the awards were designed to support programs in development, not marketed.

Cellular Dynamics is working on improvements to the iCell technology to include a panel of cells from multiple patients, which it plans to launch in 2011. The current technology uses

cells from a single individual.

Credit swapping

TDPP is modeled after the 48C advanced energy manufacturing tax credit, but Ohmes told BioCentury the 48C process "was much more robust in terms of the money that went to the top applicants."

Applicants were asked to submit detailed applications, which ran to hundreds of pages. The applications were then

ranked based on likelihood of success, with the largest sums going to those that were ranked highest.

Ohmes attributed this difference in the review process to the needs addressed by the two credits.

"48C was an alternative energy credit focused on energy conservation and looking to advance technologies that were perhaps considerably less developed and took more time to develop," he said. The therapeutic credit was designed to fill a short-term niche.

Ohmes also suggested the variety of biotech projects and multiple goals of the therapeutic discovery program did not make the projects amenable to ranking.

"Reviewers had to first look at whether the project was a pharmaceutical, biologic, diagnostic or some type of device for delivering a therapeutic. Then the legislation looked at tying those research endeavors to an unmet need, a chronic or acute disease, reducing healthcare costs or curing cancer in 30 years. On top of this, it added the layer of creating higher paying jobs," Ohmes said.

John Gimigliano, principal in the Washington National Tax practice of **KPMG LLC**, agreed that the 48C process "was done that way to make sure that the most relevant technologies were fully funded."

On the other hand, the TDPP was "very democratic," he

The result, Gimigliano said, was that "it spread the money around further, but it didn't deliver the real bang because for some of these drugs \$244,000 isn't a big number relative to the total spend."

Version 2.0

"We could have easily put

in half a dozen additional

applications if I knew

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per project cap."

Joseph Kim, Inovio Pharmaceuticals

Despite its flaws, companies hope TDPP will be extended, although it's not clear that will happen.

Gimigliano thinks extending the credit could be a hard sell, See next page

from previous page

not only due to the aversion of the incoming Congress to new spending, but because of how TDPP was enacted in the first place.

The program had its origins in discussions BIO had with members of Congress in December 2008 when the lawmakers were crafting the emergency economic stimulus legislation.

At the time, BIO failed to persuade congressional Democrats

to include a provision similar to the advanced energy credit.

Subsequently, BIO spent time talking with senators and staff about the effects of the capital crisis on biotech. The result was an amendment to the healthcare bill that was drafted by Sen. Robert Menendez (D-N.J.) and co-sponsored by Sen. Maria Cantwell (D-Wash.).

The credit was approved by the Senate Finance Committee in a late-night session with no discussion, and the provision made it into the final Senate bill because its sponsors kept it under the radar.

"Normally on a provision there are sponsors and supporters who introduce it into law, shepherd it through committee, fight for it on the floor," said Gimigliano. "But we really don't have that here, so it is hard to say what members might say 'this is mine and I want to fight for it."

But Ron Cohen, president and CEO of **Acorda Therapeutics Inc.** and chairman of the Emerging Company Section at BIO, doesn't think it will be as much of a challenge.

"We're not talking about a \$100 billion infusion; we're talking about a few billion, which is truly an investment in the future of the country. This is not a bailout," he said.

If the program is extended, most CEOs agree that changes to the vetting and or disbursement process would be a step in the right direction.

"In the future it would be better to provide smaller numbers of grants that are more substantive because these larger grants or credits can have a larger impact," Inviragen's Stinchcomb

Cohen also would like to see a bigger pot and larger grants. "It would be great if it were \$5 billion, with a \$10 million or \$20 million limit per company so that biotechs could do Phase III or later stage trials," he said.

Marcadia's French believes a more competitive review process should be considered.

"If there is a way to make it more competitive without adding bureaucracy, it would be helpful to have some criteria to help sort the wheat from the chaff," he said.

In addition, the program could borrow a page or two from small business innovation research (SBIR) grants.

For example, a Phase I six-month feasibility award is \$150,000 and is to be used to determine the scientific or technical feasibility and commercial merit of the proposed research.

Phase II SBIR awards are valued at \$1 million over two years, with funding based on the results of Phase I.

GlycoMimetics' King told BioCentury This Week that staging

the awards like SBIRs might be a good approach.

"It would be nice [for the next version] to be similar to SBIR where smaller grants are awarded initially, and larger awards follow those," she said.

Stinchcomb liked the idea that companies showing progress in Phase I would be eligible for additional funds. However, he wouldn't want the entire SBIR process to be replicated because the **Small Business Administration** limits access to the grants based on the amount of VC ownership.

In building their case for renewal, companies and BIO may

have to document benefits to patients, jobs and increasing American competitiveness.

"Our hope is that once the companies use the grants and move them forward, we will be able to point to progress when we go back to Congress next year to talk about how the program will be expanded or optimized," Cohen said.

This could include "people running experiments that they wouldn't have run otherwise," Xoma's Engel said.

It also could include hiring.

"If this money helps to

advance a startup six

months, that is a big deal."

Fritz French, Marcadia Biotech

AVI BioPharma Inc., which received five awards totaling \$1.2 million, expects that a portion of the money will support hiring in both Washington and Oregon, CEO David Boyle told BioCentury.

As for keeping the U.S. biotech industry competitive, Alan Eisenberg, EVP for emerging companies and business development at BIO, told *BioCentury This Week* that a recent survey conducted by the organization showed that 54% of emerging biotech companies have been approached to move some or all of their operations outside the U.S.

COMPANIES AND INSTITUTIONS MENTIONED

Acadia Pharmaceuticals Inc. (NASDAQ:ACAD), San Diego, Calif. Acorda Therapeutics Inc. (NASDAQ:ACOR), Hawthorne, N.Y.

AVI BioPharma Inc. (NASDAQ:AVII), Bothell, Wash.

Biotechnology Industry Organization (BIO), Washington, D.C.

Cellular Dynamics International Inc., Madison, Wisc.

Cleveland Clinic, Cleveland, Ohio

Ernst & Young LLP, New York, N.Y.

 $\textbf{Genta Inc.} \ (\texttt{OTCBB:GNTA}), \ \texttt{Berkley Heights}, \ \texttt{N.J.}$

GlycoMimetics Inc., Gaithersburg, Md.

 $\label{eq:local_local_local_local} \textbf{Immunomedics Inc.} \ \, (\text{NASDAQ:IMMU}), \ \, \text{Morris Plains}, \ \, \text{N.J.}$

Inovio Pharmaceuticals Inc. (NYSE-A:INO), San Diego, Calif.

Inviragen Inc., Fort Collins, Colo.

KPMG LLC, New York, N.Y.

Marcadia Biotech Inc., Carmel, Ind.

Marina Biotech Inc. (NASDAQ:MRNA), Bothell, Wash.

Medivation Inc. (NASDAQ:MDVN), San Francisco, Calif.

Pfizer Inc. (NYSE:PFE), New York, N.Y.

Piezo Resonance Innovations Inc., Bellefonte, Pa.

Protec Maternity Wear LLC, Galveston, Texas

SKS Optical LLC, New York, N.Y.

Small Business Administration (SBA), Washington, D.C.

Wellstat Group, Gaithersburg, Md.

Xoma Ltd. (NASDAQ:XOMA), Berkeley, Calif.

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