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Winning the game: Public funds for biotech companies

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Abstract

This is a transcript from a session held at the Biotechnology Industry Organization 2005 Annual International Convention held in Philadelphia from 19th to 22nd June, 2005, where the authors discussed their experiences and answered questions from the floor. All biotechnology companies can benefit from public funding – small, mid-size and large corporations and non-profits. Examples include funding for applied health research; the BioShield homeland security initiative; and sales to federal, state and local government customers. The panel discussed the basics: (1) where to find money (for example, at NIH, FDA, DOD, DHS, DOE, EPA, via ATP, SBIR and DARPA grants, or from philanthropies such as the Gates Foundation); (2) pros and cons of various approaches to obtaining public funds (via earmarked appropriations, grants, cooperative research agreements, procurement contracts or philanthropy); (3) structuring the deal (allocating liability, intellectual property ownership, deliverables, sharing and commercialising results); and (4) managing the relationship (reporting requirements, follow-on funding).

Michael Gollin: We have entered a new era of biotechnology funding. One characteristic is that it remains very difficult for biotechnology companies to find private funding. Second, there has been an increase in public philanthropic funding, from organisations like the Gates Foundation, pouring hundreds of millions of dollars into public/private partnerships for neglected diseases like malaria.¹ Third, NIH funding has flattened in the last couple of years, which increases the competition for scarce research dollars. Fourth, federal research funding for biotechnology is an increasingly political issue on Capitol Hill, judging for example by limitations on stem cell research. And, finally, the new Department of Homeland Security and its Project BioShield are reshaping research agendas with billions of dollars of funding relating to chemical and biological threats.² In 2004, a contract valued at nearly \$1bn awarded by the Department of Homeland Security for an anthrax vaccine, while NIH is awarding \$500–600m per year for vaccines for smallpox, bird flu, plague and other diseases.³

There is very little guidance for biotech companies on how to find and evaluate such new sources of public funding. We assembled a distinguished group of panelists to share their perspectives and experiences with public funding for biotechnology research.

FUNDING SOURCES AND TYPES OF PUBLIC FUNDING

Eva Jack: MedImmune is a large biotech company located in Gaithersburg, Maryland with 2,000 employees, and is fully integrated, which means we do research all the way to sales and marketing. So, for example, we are not going to go after a small business grant for obvious reasons besides the fact that we just don't qualify. We look at Requests for Proposals (RFPs) from the Department of Health and Human Services (NIH), and we do collaborative research agreements with NIH such as Cooperative Research and Development Agreements (CRADAs), where there are actually no resources or dollars exchanged. Intellectual property is shared

Funding sources

under a CRADA and we take an exclusive license for the IP that comes out of that research collaboration. The RFPs we pursue are fairly large, typically in the \$50–100 million dollar range.

Terry Chase: Chesapeake PERL is a small company with 20 people, and we're happy to be staying in the game. We have gained extensive experience in bioprocess manufacturing and scale-up through financing, merger, intellectual property development, factory commissioning, and first revenue. Our sources of public funding have been quite diverse. They include donations from organizations to universities that our company then had access to. We've received public funds from the state of Maryland through many different programs, everything from seed money, to money for specific projects, to tech transfer funds for biotech companies. And they're not \$50 million, but anything from \$20,000 to \$500,000. We've also worked with 11 different universities. Sources of funds from universities are few and far between, of course, but they are available. We were able to have a university pay people to work at our company, with any intellectual property split between the university and the company. We've also gotten funding from federal sources – SBIR, Phase I and Phase II and a grant from the Advanced Technology Program of the National Institute of Standards and Technology. The amount of public funding that we have has far exceeded our funding from venture sources and angel investors.

Jesus Soriano: The ATCC is an 80-year-old not-for-profit Bioresource Center in Virginia. We have the biggest and most diversified collection of biological materials in the world, including cell lines, microorganisms and DNA. We are not an agency of the government. We are independent, do not receive any government subsidies, and do compete with academic and commercial organizations for government grants and contracts that fit our mission. ATCC has developed processes that allow us to identify and apply for grants and contracts

efficiently. Classically, ATCC was awarded grants and contracts from agencies such as the National Center for Research Resources or the National Science Foundation to support the core functions of our mission: the acquisition, authentication, preservation, production and distribution of biological materials. During the last decade, our expertise led us to successfully bid for and develop government-funded programs providing quality controlled reagents to specific fields such as malaria (MR4, funded by NIAID), Biodefense (BEI Resources, funded by NIAID), or the National Stem Cell Resource (funded by the National Institute of Aging). In keeping with our mission, we were awarded contracts that should benefit the public, such as using our reference microbial strains, preserved during decades, to study the development of anti-microbial resistance (funded by the Food and Drug Administration).

Robert Smith: I'm a lobbyist. I go to Capitol Hill with my clients. We identify sources of money through the appropriations process. If we don't find money in appropriations, we go to the different agencies and we use relationships with members of Congress who represent the places where you come from.

Michael Gollin: Our panelists' organizations have found a remarkably wide variety of different types of public funding. We are not able to give a list of all the funding sources that are available because there is no such list. It is very difficult to identify sources of funding and it requires a lot of ingenuity and networking and creativity.

Questioner: Can you give a rule of thumb for a foreign-headquartered company with a wholly owned subsidiary in the US, as to eligibility for various forms of federal funding?

Michael Gollin: As a general rule, it doesn't matter whether a US corporation's shares are owned by a foreign company or domestic investors, but intellectual property rights may be impacted.

Eva Jack: There are rules about

manufacturing in America and things like that, and you just have to disclose that you're a foreign entity, but it goes through the exact same process.

Robert Smith: For the type of funding that I do, we would look at wherever your wholly owned US subsidiary is located and try to identify funding that way.

Questioner: I work for a state economic development agency. Do you have any anecdotes on the usefulness of economic development, state or federal?

Terry Chase: In Maryland, there's definitely a lot of value added. It's not only funding which, of course, is very important. There are also contacts, introductions to investors and, most importantly, introductions to customers and now, also a corporate alliance. Our next step of funding will come out of that alliance. So that was beyond what we could hope for. Also, helping us with leveraging state funding with other sources of funding, 50–50 matches.

Questioner: What percentage of your budgets come from public dollars?

Terry Chase: Very little.

Jesus Soriano: Significant.

Eva Jack: Somewhere around 30 per cent. Because of our investors and revenue, over time our public funding is decreasing as we grow.

HOW TO IDENTIFY AND OBTAIN PUBLIC FUNDING

Michael Gollin: Rob, how do you identify and pursue appropriations and earmarks and funding on Capitol Hill? How does the process work, and what can an individual company do to begin the process of working with their Congressional representatives?

Robert Smith: How many people can name their member of Congress and their two senators? Members of Congress are there to serve you. You provide jobs and raise the quality of life in their district, so they're there to help. You may be unlucky and have a representative that actually doesn't go after federal funding (or pork, as it's called), but you can

usually find someone who's willing to help, either through your associations or through consulting services. We also identify targets, pots of money for example in Homeland Security, the Labor/HHS bill, Department of Defense, Agriculture, BioShield II. In this post-9/11 era, if you can relate what you do to homeland security in some way, your chances for funding are increased a couple fold up on the Hill.

There are many ways to engage representatives at the local level. They all have a district office. Reach out to that office. Explain who you are, what you're doing in their district employing people, and have them come out to the facility, walk them through it and show it. Then follow-up, identify a pot of money or a project that you want to do, or partner with the military, or partner with a university. And go to Washington at the beginning of the year, in January or February, when the fiscal year cycle is about to start up and start working with your member of Congress. Tell them a) how this is going to benefit mankind in general and b) how this is going to benefit their district. Also, you may find another champion among the 535 members of Congress. They've all got different stories, different healthcare issues, different things that have affected their families in different ways.

Most funding projects we deal with range from \$500,000 to \$10 million. The best project doesn't always win. It has a lot to do with your member of Congress and their willingness to push for you. Here's an example from last year's 2004 omnibus appropriations bill: '\$900,000 shall be available for grant to [a small Midwestern university] to examine and assess advancements in biotechnologies.' What does that mean? No one knows. But it's in there and it's going to that university, almost a million bucks.

Michael Gollin: It seems like many biotechnology appropriations go to universities and non-profits. And to companies which are fortunate enough to be working with that university.

Identifying and obtaining public funding

Robert Smith: There is almost always a company, a partner behind it, especially on the military side. Through the year-long process, it may look like the appropriation is being requested by a university or the Department of the Army. But all along, the member of Congress, staff, and the agencies themselves, are aware of who's footing the bill for lobbying.

Michael Gollin: There are also, of course, the larger lobbying initiatives which create the pots of money at NIST and HHS, which are at the more collective level. Jesus, how have you identified funding sources that have already been appropriated or already exist?

Jesus Soriano: ATCC has a longstanding experience in grants and contracts. Many of our employees, not only the scientists, try to identify new requests for proposal (RFP). The critical action step part is deciding whether we should bid or not for a particular grant or contract.

Although our scientists generally lead this process, all pertinent departments of ATCC give input, and the decision is ultimately made by management.

Terry Chase: Maryland has about 13 different incubators and the funding sources essentially parade through and give seminars. That's how we found out about most of our public funds. Now we've graduated from the incubator, and we have an alliance with Battelle – a large, non-profit research organization – and they have many people that help look through the different RFPs for the government and help find ones that match with our capabilities. So we manage the ability to sift through all of the funding sources by working with a company who has the resources to do that, knows where to go, knows the game well. With RFPs, there are indicators that they are really sole sources and that, even if you put together just a great proposal, you may not get it, because it may be written in a way that only one company can really get it.

Michael Gollin: How did you identify

the partner and what considerations did you have in forming that partnership?

Terry Chase: Battelle had a large presence within the state, knew what they were doing and saw a match and pretty much made the introduction. Battelle was looking to expand in protein manufacturing and we were looking to manufacture protein. A local economic development official said, 'Hey, you guys should be working together'. And so that's how it worked.

Battelle has more people looking for RFPs than we have in our company. They also have a complete office in DC doing lobbying.

Eva Jack: The underlying theme is to be as proactive as you possibly can. The web provides a good source. In our therapeutic area, since we're not going after a lot of government contracts, I have agencies that I know and that I stay in regular contact with. But there are resources, on the NIH website, and the Federal Register. And as Terry said, if you see something that looks interesting to you, call the contract administrator. They can be a great resource and they're always willing to answer your questions. As to our staffing, depending upon what the project is, we'll pull a team together both from the business development side, from the science side, legal, finance, and sometimes even from clinical.

Questioner: I'm at a community college and we have our own grant writer, we have our own lobbyist. Small companies, I think, might be at an advantage if they could partner with maybe a smaller entity like that. We were just given a grant that was pretty substantial and I'm trying to find a partner to help me with it. Smaller companies might look at partnering with community colleges. They have trained students that can do entry-level work inexpensively. They get experience, the company gets some help without training, community colleges offer safety training, ideas, things that smaller companies might not be able to have.

Jesus Soriano: We collaborate with many academic institutions in the area of

Be as proactive as possible

research and development. Most often our scientists identify external collaborators for specific projects in their areas of expertise. Based on the scope of the project, ATCC may decide either to directly fund the project as sponsored research, or to partner with the external collaborator in the application for grants.

Terry Chase: Sometimes, a university's schedule is a little bit different than what a company might be used to. For instance, you'll be collaborating with someone and then they're gone for spring break. So to overcome that different mentality about the project schedule, we have put a full-time employee of the company at the university. They don't have spring break unless that's part of their annual leave. We have two universities that like that deal because they don't have to worry about covering salary, as well as far as overhead; some universities are 40 per cent overhead on everything, and then there's fringe on top of that.

Questioner: A lot of the time you have 30 days to respond to a \$10 million RFP which basically is a sole source because nobody can pull together that fast, especially a small business. How aggressive are you guys in sending an unsolicited RFP to these people, and what kind of success rate do you normally get out of that?

Jesus Soriano: ATCC develops multifunctional project teams that pursue any valid grant or contract opportunity very diligently. In addition, we do try to raise the awareness of private and public funding agencies in areas where public science, health and safety may benefit from the controlled use of ATCC's reference standards and expertise.

PROS AND CONS OF DIFFERENT APPROACHES

Michael Gollin: Based on your experience, what are the pros and cons of the various approaches you've taken? Which types of funding are you happiest with, and which ones are you least happy with – earmarked appropriations, grants, cooperative research agreements,

procurement contracts, philanthropy, state funds, and so forth?

Eva Jack: Working with government agencies allows you to explore new regions and things that are very risky for a company to take on, on their own. So that's really a strong pro. It also gives you access to facilities, for example, for a company like mine that deals with making biological materials and particularly in the flu area where you need a BL3 facility. Also, on the pro side, the contract administrators are great. They're always there to answer your questions and tend to be very, very helpful as you go through the process.

One of the cons of dealing with the government is it can take a really, really long time to finalize a contract. There are intricacies in the contract negotiations, in part because there's a standard government contract, regardless of topic, that they try to apply across multiple industries and that can get difficult when trying to negotiate and markup the document. With regard to FluMist, the government decides which virus strains will be distributed, and they are, of course, the largest purchaser. We're still working through these issues.

Terry Chase: There is a downside to getting a significant SBIR grant or other federal dollars when you're trying to raise additional money from the private community as well, because if you're getting a lot of grants and the revenue isn't going up at the same time, the perception will be more that you are a grant-generating firm, instead of a revenue-generating firm. So we've tried to focus on not going after every RFP that looks like we might be able to get it, but only going after specific opportunities that are advancing what's already in our business plan. We're not going to go and make a certain reagent that hasn't much to do with what we're about as a company, even though we might win it, because that will distract us from what we're doing and make it more difficult to raise investor dollars.

Jesus Soriano: I agree. If you are an

Pros and cons

early-stage company and you wish to move your technology beyond proof-of-concept, obtaining an award such as a SBIR grant (which has been peer-reviewed) will increase your credibility. However, trying to fill your books with taxpayers' monies through indiscriminate bidding for grants and contracts indicates that your corporate strategic plan is deficient or non-existent. It is the government and private foundations who decide which areas should be funded. To a certain extent, under a government contract, the ultimate power rests not with the CEO, but with the contract officers and contract managers of the funding agency, an organization with a totally different culture than yours. As a government contractor, you must be flexible and understanding, and remain aware of your duties and rights under the contract, and the specific regulations pertinent to both the scope and interpretation of the contract.

Robert Smith: When we can get money, it's good. When we don't, it's bad, but the good thing is, there's always next year's appropriations process. If you're close to getting in one year, but you just don't quite make it when the staff is writing the final version of the bill, you can come back next year, and you have a better chance.

Questioner: Do funding agencies view earmarked appropriations as a reduction of funds that they could have applied elsewhere? Or do they view it positively as extra funds that they can use, even if they are targeted to a particular company or technology?

Robert Smith: In general, they're not fans of earmarks. They feel like they should just get the pots of money. They expect to decide where this money goes. So they're sometimes a little bit hostile. But Congress has the power of the purse. The agency may try to reprogram the funds. Or they say 'This is just too big a contract to sole source. We're not going to sole source' when we have written language so that it specifically could fit only one company. And you get epic

battles with bureaucrats who do not like to be told by legislators where to put the money or that they have to sole source. I think they see that as money that they would have anyway, but Congress tells them that that's not the case: 'We sent you this money to spend on this. If you're not going to spend it on this, next year you just won't get the money.' All politics is local. And this company is from the representative's district. He or she got them the money. That money is going to go for jobs and resources in their district, so they can get pretty passionate about it. Usually all it takes is a letter and a phone call.

STRUCTURING THE DEAL

Michael Gollin: Most of us are familiar with the general restrictions under the Bayh-Dole Act and other federal funding: an obligation to notify the government about any inventions that come from the research; a royalty-free government license to practice such inventions; march-in rights by the federal government; and a preference for US industry, meaning that commercialization needs to be substantially in the United States. There are many other strings attached to public funding. Have these restrictions affected the structuring of federal or public funding that your organizations have obtained?

Jesus Soriano: At the time of bid preparation, you must begin considering the granting agency as any other future corporate partner, and foresee which terms you must try to negotiate, although always within the boundaries of the scope of the contract, or according to applicable regulations.

If you seek a partner, whether academic or corporate, to apply for a grant or contract, you must reach a clear understanding with your prospective partner on those issues that you consider critical for the success of the venture, or your corporate strategy. For instance, if you must award a subcontract under a government contract, the subcontractor will have the right to claim title on any

Structuring of federal or public funding

Managing the relationship

invention actually conceived or reduced to practice with the money that you paid. Think of a subcontract as any other deal with any other company, even if you are the party managing the government's money under the prime contract.

Terry Chase: We're still learning how to structure deals. It is straightforward with the SBIR and the ATP program. We know that there are march-in rights, but we don't expect anyone to march in and start rearing caterpillars to extract proteins. They would need a lot of other pieces of intellectual property and know-how. And a patent that is developed under the federal funding would not really leak our technology into use by a federal lab because it's a patchwork of different pieces of intellectual property.

Eva Jack: You should understand your major issues in the contract itself and the deal structure and get them out on the table as soon as possible. Make sure that you're discussing them regularly, bring it to the government's attention so that they know what your concerns are. Sometimes they can be flexible and sometimes they can't. But if they understand your issues they can try and work through them as soon as possible.

Michael Gollin: Sometimes they can't be flexible, and sometimes they don't want to, and it's important to know the difference. We negotiated a research arrangement involving the Veterans' Administration, and under the statute supporting cooperative agreements, they're not allowed to pre-assign or pre-license any inventions. In that case our client would have to bid for the rights to the invention that they were researching. The only way to pre-assign or pre-license rights is through a CRADA, a cooperative research and development agreement.⁴ We got stuck because the VA is in the middle of a long internal debate about whether they will or will not give CRADAs. You could wait years for them to sort that out. But we found a workaround because the VA has a partnership with a university which had the right to decide licensing issues. So the

university is able to pre-license the technology. Our contact at the VA had willingness and a strong desire to pre-license, and eventually we found a way to do it.

MANAGING THE RELATIONSHIP

Michael Gollin: How do you make sure that the relationship goes smoothly as it goes forward?

Eva Jack: Typically, there's a research plan. The scientists meet regularly, so there's ongoing communication, at least on that side. The other thing that we have found very helpful as part of Sarbanes-Oxley compliance is to institute an internal database on contracts. A lot of companies are doing that now. I get an internal e-mail reminder 30 days before there are certain provisions in the contract that are due, such as a potential payment.

Michael Gollin: As to notification of inventions, do you use the federal iEdison program?⁵

Eva Jack: We're not using iEdison. We've come up with our own. There are also software programs you can buy.

Terry Chase: We've found that as a small company, there are many compliance issues that are required that we're not in a position to do. So without our alliances we simply would not have the people or the system to be able to manage a \$50m federal contract as prime contractor, even though we have significant work.

Jesus Soriano: If you have a grant, you must perform. You may have a scientific advisory committee to whom you have to report once or twice a year. If you have a contract, you have a contract manager and officer that should hold you accountable for your deliverables.

Michael Gollin: Can you expand on the idea of doing the project that's funded versus doing your own mission for the organization?

Jesus Soriano: Yes. The government decides which areas will be funded. And if your company needs no grants and contracts to succeed, you must clearly

determine whether bidding on a contract or a grant fits your corporate strategic plan. If you do not have a strategic plan, you must first develop it, and then stick to it. Once you create a strategic plan, be ready not to pursue certain opportunities, as you may accept unnecessary risk by trying to implement a contract that is unrelated to your corporate goals and objectives.

Michael Gollin: This is a disadvantage of public funding: if you are spending your internal resources, your people, your energy, and your focus on a contract project, it could mean that you're not spending them on something which would bring more benefit to the organization.

Questioner: I'm with an economic development agency in Canada. When a business receives funding from a federal or state institution or government, are the terms usually on a repayable basis or non-repayable basis? Are they tied to the commercializable success of the work? And will the funding extend into areas such as building facilities and financing capital equipment?

Terry Chase: I've found that the first funding – for example, the first \$50,000 that our firm received – was from an economic development agency and was repayable. But it was also convertible, after a sophisticated investor came in and valued the company. Until that happened, it was personally guaranteed by me. The second \$50,000 was unrestricted, we could use that for anything, practically, and it would be repaid based on a royalty stream if the specific work that that grant paid for was commercialized. It was around 2 per cent of revenue.

When you get into the equity, it was just the deal terms, investors had liquidation preferences, and the first round sets the stage on the valuation to how much percentage are they taking in the first round. We've had some other deals where the funding was convertible or repayable, and the repayment was always, at least from the state, was always capped at a certain revenue. That was a

term that we really liked, actually, because if you're not making a lot of money, you didn't immediately have a debt built up on your balance sheet where you don't want to have a lot of debt, especially when you're small and you're personally guaranteeing things.

LESSONS LEARNED

Robert Smith: For any companies starting to think about learning and playing the appropriations game, you have to be serious about it. You can't go into it halfway. You've got to have buy-in from your board and CEO level. You need someone who's dedicated, who understands the technology. You can hire a lobbyist, and a lobbyist can go up and have relationships on the Hill and earmark your money, but there's always got to be somebody from the company sitting there, and somebody's got to be able to explain what this technology is, what it's going to do, how it's going to make the world better, why it's better than what someone else is proposing. So if you're thinking about going this route, you've got to go all-in. Otherwise, you're wasting money, you're wasting your time, a lobbyist's time, and most importantly, a member of Congress's or staff's time.

Jesus Soriano: Think twice how the grant or contract fits within your strategic plan and, once you are awarded money, be prepared to execute. If you happen to be in a niche market and you excel, you may be the sole source when that contract is renewed.

Terry Chase: A small company needs to be as creative as possible, and not only looking at ways to bring money into your company, but ways not to spend money. Not just saving money, but getting third parties or partners or collaborators to pay for things that move your company forward. Collaborating with universities is a great way to do that. Also, with strategic partners for instance, we're able to do a P and L most of our major expenses. We've also been able to do animal trials, without paying, through a collaboration. We would have had to raise millions of

Lessons learned

dollars, tens of millions of dollars, to get to the point where these collaborations have moved us forward. We had millions of dollars in facilities donated to non-profit organizations where we give a small amount of equity for access to these facilities, which we then own. So there are ways of reducing your expenses through public funding, not just bringing money into the company which is, of course, very important.

Eva Jack: Be proactive and know what you want. Understand the kinds of contracts that you're looking for, and what are the pros and cons of the end results of those.

Michael Gollin: Thanks to our panel for sharing their experiences with us. Their insights should help others find ways to obtain new public funds.

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