March 2014 Webinar on Direct–to–Phase II Pilot and SBIR Phase IIB Bridge Award

Christie Canaria: Hello everyone and thank you for joining us today. My name is Christie Canaria and I'll be moderating today's webinar. I have here with me Patti Weber and Andy Kurtz, Program Directors at the NCI SBIR Development Center along with Jennifer Shieh. We'll be speaking about the latest provisions in the SBIR programs and specifically the Direct to Phase II Pilot and NCI Bridge program. But before we get started I'd like to point out some housekeeping rules. All attendees are on mute, but we still welcome your questions and feedback. So please use the question/answer tool in your WebEx window for sending your questions. Additionally if you want to, you can e-mail us at NCISBIR@mail.nih.gov. And towards the end of the webinar we will answer your questions so please send them to us throughout the presentation. We will also have a poll, which we hope you'll fill out as it helps us produce better events, such as this webinar. In addition I want you to know that we are recording this event, and afterward, we will be sending out information that you need to access it. And Without further ado, I'll pass it over to Patti Weber.

Patti Weber: Good afternoon everyone. Thank you for joining us. Hopefully our presentation today will help you understand the view Direct to Phase II Pilot programs. I'm just going to give you an overview of the recent update in eligibility along with the NIH, NCI and SBIR programs and I'll talk about this new Direct to Phase II Pilot program. And I'll go over the structure of the NCI SBIR development center and our rules here at the NCI.

So just to remind you the SBIR and CTR programs are congressionally mandated. And as many of you are aware the senate side has been increasing and currently we're in fiscal year 2014 and set aside for the SBIR program is 2.8%. This is applied to all federal agencies that have an extramural R&D budget over $100 million. Next year, fiscal year 15 has set aside for SBIR will be 2.9%. And for the STTR program that is currently at 0.4% and will stay the same next year but will continue to go up.

Currently the budget at the NIH is about a $700 million and at the NCI $116 billion for the combined program. So as I mentioned these study sites are continuing to go up so next year the set aside for SBIR will be at 2.9% and remain the same for STTR. But will go up in 2016 and 2017 for STTR to .45% and to 2.9% in 2015 and up to finally 3.2% for the SBIR program in 2017. The program has been approved and authorized through 2017.

So what are some of the reasons to keep SBIR and STTR funding? Basically this program provides you with seed funding to develop your innovative technology. This is not a loan. You don't require—the government does not require repayment and it will not impact your stock or shares in any way. Funding is completely non-diluted. The small business also retains intellectual property rights. And we feel very strongly at the NIH and NCI that receiving an SBIR or STTR award provides recognition and verification and visibility for your company because many of our companies over the years tell us that without this award they would not have been able to attract a business partner to further commercialize their technology or investment from either venture capital or other non-profit investment, for example. But the award really does provide the recognition that they need to get that funding. And this is a website that you can go to, the NIH has a reauthorization website where you can find answers to any other questions you might have that we didn't touch on today. This is a website for the main NIH SBIR program.

So there are some provisions in the current omnibus grant solicitation that I'm going to go over. So first of all, I think everyone is aware that SBIR and STTR applicants must register with the small business administration and this can be done at SBIR.gov. And so one of the new provisions that currently active at the NIH only and only for SBIR is that VC backed companies can apply. These include companies that are VC owned companies, companies that are funded by hedge funds and private equity firms. These companies can now apply, again only through the NIH SBIR program. There is another new provision that's currently in place, applicants can request $5,000 in technical assistance beyond an award cap. Keep in mind if you do request this, technical assistance, you cannot participate in any of the NIH technical assistance programs. One example of requesting technical assistance is you could use the funds to pay for a regulatory consultant if your technology requires a FDA submission.

And so the newest provisions are now implemented, so we do have increased cap so we've received per-approved labor topics from the small business administration and all of these topics are listed in the funding opportunity announcement so they'll be in the Omnibus. So if your project is not listed you should speak with a program director because it's possible that we can look at waivers from some of the other NIH institutes and currently at the NCI we have topics in place with a phase 1 application of up to $300,000 and phase two at two million. Otherwise top of 225 and 1.5 million are observed. You currently can switch between the SBIR and the STTR mechanisms, so an applicant can apply for a phase two SBIR based on a phase one STTR and vice versa.

You can also apply for phase two B SBIR funding, the phase two B refers to our Bridge award. This can be now based on a Phase 2 STTR award. So you can also be, the direct to phase 2 pilot program is now active. I'm going to go into that a little bit in more detail and Dr. Kurtz will cover the Bridge award later.

So as you are aware many of you the SBIR and STTR programs are a 3 phase program with phase one meant to fund a feasibility study. Phase two is to fund development work and then phase three is commercialization which is conducted without federal dollars. So typically your phase one proof of concept study is about $150,000 but it can go up to 25 or 300 for the waivered topics and is usually a six month project for an SBIR and one year for an STTR; however you can request a longer time period for an SBIR with justification.

As I mentioned the phase two is really to fund research and development and the proposal does require commercialization plan and typically the budget is $1 million over two years. And again, phase three is conducted without federal dollars.

We also have—or you also have the opportunity to submit a fast track application in which you would combine a phase one and a phase two proposal. So just keep in mind with a fast track application, the quantitative milestone is very important in order to be considered competitive in this type of application. So with the new reauthorization you have the opportunity to go direct to phase two and skip the phase one.

This slide shows you that the time line at NIH and how the applications are submitted in the review sites of the review and followed by the three submission deadlines continue to be in place, April 5, August 5 and December 5. With the review taking place two to three months later and council review and award about nine months after submission.

I'm going to go through some of the SBIR eligibility requirements so the first group is pretty much the standard requirements the applicant has to be a small business or organized for profit, 500 or fewer employees and that the PI's primary employment must be more than 50% at the time of the award and during the award period.

And if you're going to change something, the company can be more than 50% owned by individuals or independently operated or it can be 50% owned and controlled by other business concerns that are more than 50% owned or controlled by individuals and the regulations that are is what allows the companies to be more than 50% owned by multiple venture capital operating companies as part of a private equity firm or any combinations of these so this is the new rule. Again as I mentioned, this is a rule that's only in place within the NIH SBIR program. It's not in the STTR program.

So this slide shows you the SBIR and STTR eligibility requirements. Again the applicant is always the small business concern or organized for profit. And with the STTR there's a little bit of difference in terms of how much effort can be contracted out. For an STTR a minimum of 40% must be conducted by the small business or at least a minimum of 30% by the U.S. research institution. A research institution can be a college or university, a non-profit research organization and it can also be a federally funded R&D center for example the Frederick National Labs in Maryland could potentially be part of an STTR application. So again, in principle, the principal investigators primary employment in the case of an STTR can be either with the small business concern or the research institution. And this is something that if you're debating whether you fit best with the STTR or the SBIR regulations, you should probably speak with a Program Director before submitting.

In terms of an STTR, the small business concern must have an agreement in place with the university to have the right to carry out follow-up research and development that will allow full commercialization of that technology. So this chart shows you some of the differences between an SBIR and an STTR. To help you decide which is a better fit. In terms of the principal investigator, as I said, the PI must be employed by a small business 50% time at the time of the award and throughout the duration of the award. With the STTR the PI can be employed either by the small business or the academic research institution but must commit a minimum of 10% of their time to the project. With the SBIR, the small business in phase one must do 67% of the work, and that can move up to 50% when you get to Phase Two. And again the STTR requires partnering with the research institution and small business and must have a minimum of 40% of the work in phase one and the research institution is 30%. The small business concern is always the applicant and is always the awardee. In the case of an STTR the award does not go to the academic center.

The funding rates vary annually with these programs based primarily on application numbers and the best choice is to propose your budget and leadership structure. Again, this is something that is always a good idea to talk to the Program Director prior to submitting.

In regards to whether a fast track or a Direct to Phase Two is best for you, let's take a look at the fast track first. So with the fast track you would really need to have strong and promising preliminary data and if you still have studies that need to be conducted, perhaps you don't have quite enough data to go right to a Direct To Phase Two and you might consider a fast track. You've got to have very good quantitative milestones with your Phase One so a no/go decision will be made at the end of a Phase One and if there are reasonable and logical aims that you can include and fit into the timeline for this Phase One the fast track might be better and also for you additional dollars to do the full project because you can get up to $300,000 for your Phase One and up to $3 million for your Phase Two. So if a Direct To Phase Two is the best fit for you, you would want to consider, do you have enough preliminary data that's equivalent to what NIH would expect at the end of a Phase One award. For example, with a therapeutic

product you would really want to have *in vivo* proof of concept data before even considering to apply for a Direct To Phase Two.

So you would really not want to have any additional proof of concept studies remaining if you are considering a Direct To Phase Two. If you are already doing clinical trials for a therapeutic, you would definitely be a good candidate for a Direct To Phase Two.

There are plenty of other examples and if we can help you decide whether or not your project is appropriate for a Direct To Phase Two award. It's really best to contact your Program Director if you're considering applying to this new pilot funding opportunity announcement. So this is a pilot program that's currently available. The program analysis number is PAR-14-088 and you should check the funding announcement to make sure that your technology area fits with the participating NIH Institutes or Centers. NCI is participating in this Direct To Phase Two pilot and it does apply to SBIR only, not STTR. Again I have to emphasize this, it's designed for small business concerns that have completed phase one milestones using non-SBIR funds.

So if you have received a previous Phase One award from the NIH or any other agency, you need to apply through the Omnibus for your Phase Two not to use in Direct to Phase Two mechanism.

And it does have the standard receipt dates of April 5, August 5 and December 5. And this next receipt date does happen to fall on a Monday because the 5th is on a weekend so the deadline will be Monday, April 7 and the pilot program is effective until 2017. So you will have several receipt dates coming up to take advantage of this opportunity.

The standard eligibility rules still apply for this funding opportunity announcement. And there is a transition benchmark to small businesses, so if you've been awarded more than twenty Phase Ones in the last five years, you need to have a 25% conversion rate, so you have to have received at least 25% of your Phase Ones have been converted to a Phase Two. So that's really something that you want to check and you will have to verify that transition rate at SBIR.gov.

Well, I'll talk a little bit about the SBIR Development Center here at NCI and what we do. This chart shows you all of the institutes and Centers at the NIH with NCI being one of them. There are four institutes and centers that do not have funding authority for SBIR and STTR, The Fogarty Center, the Clinical Center, the Center for Information Technology and obviously the Center for Scientific Review.

At NCI we have a pipeline of over 400 vetted projects and this pie chart gives you a breakdown of the areas that we are currently funding and the percentage so you can see we're primarily funding therapeutics at 33% of our portfolio. And followed by *in vitro* diagnostics and imaging agents and devices, so we have a fair number of projects in the digital health IT software tool area, as well as devices for cancer therapy and also tools for basic cancer research.

This slide shows you all of the folks I work with here in the office. We work with Michael Weingarten who's our Director and we've got nine Program Directors now and certainly AAAS fellow Christie who introduced this webinar today. So we're all here to help you. We all have specific technology areas that we can cover. So you can look us up on our website at SBIR.cancer.gov. You can find out areas of specialties and you can find our contact information. So if you need to speak with one of us about your idea for the Omnibus or the Direct To Phase Two, please look us up and get in touch with us before you submit.

So what we do here at the center, we really focus entirely on managing SBIR's and STTR's. And part of what we do is we conduct regular outreach events and the goal of that is to try to recruit more focused mutually minded SBIR applicants. We conduct these events throughout the year in various parts of the country. And we also as I mentioned coach applicants

on developing a stronger application. So if you need help, that's what we're here to do is to help you.

We provide oversight and we actively manage our projects and our portfolio. And we guide our companies throughout the process. We also try to facilitate match making through existential third party investors and strategic partners and we do this by attending various events involving investors to let you build a contact database so once we know somebody is interested in a particular technology, we can make that arrangement and introduction and hopefully help you get the follow-up funding that you need to fully commercialize your technology.

So here we are. If you have any questions about what's been presented so far, please submit them. And if you don't see the Q&A box you can expand it. So I'm going to turn the next part of the presentation over to my colleague Andy Kurtz and he's going to cover the Bridge program.

Andy Kurtz: Thanks, Patti. So as Patti mentioned, please feel free to submit your questions. We're going to collect those and we'll be addressing as many as we can at the end of the presentation today. So we're now moving into the second part that's focused on the new newly published RFA for our Phase Two Bridge program.

Before I start, I'm just going to give you a couple of pieces of information about how to find general information about funding opportunities and then we'll get into the Bridge award program. As most of you probably know already, the majority of our regular SBIR grants come in under the Omnibus Solicitation that's published every year in January and receipt dates on April 5, august 5 and December 5. There are other special announcements, SBIR announcements throughout the year, not only here at the NCI but at other Institutes and Centers. Those are published on a weekly basis. The receipt dates can either follow the standard timeline above or they can sometimes have special dates. You need to read the specific announcement carefully. The Bridge award is one of these special announcements. We just published this RFA in February and applications are going to be due coming up on April 21.

If you'd like to sign up to get regular updates for NCI funding opportunities you can go through our website and click on the sign up for updates link and provide us with your contact information. You can also find information underneath funding opportunities drop down menu on the website. There is also an NIH main SBIR page where you can find NIH funding information and if you would like you can specifically search the NIH guide for RFA and program announcements related to SBIR and you can search by keyword if you're looking for a particular program or for a particular area of science.

So before I get into the nuts and bolts of what I have to tell you today. I want to say that this is intended to provide some general information about the Bridge program. If you are planning to apply, I would strongly recommend that you contact either me or your current NCI Program Director that works with you on your Phase Two award to talk about the specific details of what you're planning. The Bridge program, in particular, I think every project and business partnership is very unique and could really benefit from a specific discussion with your Program Director about your application.

What I'm going to try to do today is update you on some recent administrative updates to the program. There have been some changes this year that expand eligibility, I'll also try to get into a few of the frequently asked questions when folks call and ask us about this program. Again, I do want to emphasize that you need to carefully read the RFA so you're familiar with all the requirements in order to submit your application.

The last thing I'll say before I get into the specific information is that much of this is the same as the information that we provide to the review panel that will be looking at the applications and scoring them. In order for you to submit the strongest application that you can, definitely take notes today and as I said feel free to contact us for more specific information.

So the Bridge program is designed for our more promising phase two projects and includes the end of the phase two awards and ultimate commercialization. So as we look at the portfolios we have a number of very promising Phase Two projects and many of which are hitting their milestones that they planned for in their Phase Two but the reality for many of these projects is that the capital environment to move something either into the clinic or through clinical development en route to commercialization really requires much more funding than a typical Phase Two award can provide.

At my level, the whole Phase Two Bridge award is to extend that Phase Two project hopefully to a somewhat later stage where either a strategic partner or other outside investors will be willing to come in and fund the project fully for commercialization.

The way that this is set up is as a competing renewal program or SBIR Phase Two award and the goal is to provide additional NIH funding for extending the project. Because it is competing it does involve in other peer review cycle and that's really focused on evaluating the progress during the Phase Two project period and whether the future plans and possible goals as they move closer to commercialization. One of the major goals is to accelerate the development of the project by incentive partnerships and other third party investors and strategic partners earlier in the development process. How do we accomplish that goal? When we are making funding selections, we give competitive preference and funding priority to those applicants that can raise third party funds to match the amount of the bridge award funding that they're requesting. And so our expectation and that match of third party investors would be a minimum one for one match although some of our previous awardees have actually exceeded that by a fair amount, so that the general idea is that as an applicant that you can leverage a previous SBIR support and all of the risk that you have mitigated by that previous government funding as well as this opportunity to compete for some additional NCI dollars, in order to negotiate and attract some third party financing that may be somewhat earlier in the process than those investors might otherwise be comfortable with if NCI were not a partner.

So we view the benefits of this program to be mutually beneficial to the NCI and to other outside investors in the private sector. From our perspective here, at the NCI, this provides the opportunity to leverage quite a bit of support on the part of outside investors and external resources and help advance projects that have been seeded with NIH funding. They also provide valuable input from some of the third party investors by way of their own commercialization, due diligence that they will do on the project before they invest. Many of these investors provide commercialization guidance throughout the project period, so they provide expertise that may or may not reside in the company in order to help move that project forward. In many cases, those investors, if things go well, we'll provide additional financing beyond the Bridge award to be able to take that product or service to full commercialization.

On the side of the third party investors, the folks that would be providing their own funding, I give them the opportunity to partner with small businesses developing commercial technology that have been imbedded by the NIH peer review system, that many of you can appreciate, I hope, is quite rigorous and again also to partner on projects that are already a substantial amount of proof of concept data for hopefully have mitigated the risk of the project somewhat, although many of these projects still do carry a fair amount of technical risk.

Ultimately the benefit of the third party investors is that they can share in some of the early stage investment risk with NCI at a very critical stage of development.

We have made sixteen awards with this program over the last five years, this bar graph just shows you relative to the amount of funding that the company received from the NCI how much each of those companies was able to raise from outside investors. You can see in a couple of cases that outside financing substantially exceeded what they requested from the NCI. In terms of where that money comes from, about a third of it comes from traditional venture capital. About a third come from other strategic partners, so in the case of Bridge development projects often a large pharma company. And then the remaining third comes from investors that wouldn't fall into those other two categories, many of whom may be angel investors or other investment firms that don't fall into those other two buckets.

So again as I go through today, what I want to do is try to give you some updates and some general information on questions that come up routinely. Some changes for the current year that are now in the RFA involve eligibility for the program. So currently in order to be eligible you may have received a Phase Two grant or contract award for your either SBIR or STTR either from the NIH or from any other federal agency. So this is a big change. Up until recently you could only predicate a Bridge award on an NIH funded Phase Two. Now that's become some, for example the NSF, or you could also have an STTR funded phase two under the SBIR program.

I do want to emphasize thought that if your grant, your Phase Two award is coming from another federal agency or if it is a contract, you must contact us here at the NCI so that we can arrange for your application to be accepted by the Center for Scientific Review. The reason for that is that there will not be a grant record of an SBIR Phase Two grant here at the NIH and so we will need to alert the Center for Scientific Review that your application is coming so that they won't not accept that.

The other important thing is that even though we will accept applications from other agencies or other institutes at the NIH, other than the NCI, the goals of the project must fall within the technical scope of the RFA, which are published in section one of the RFA. Just to let you know what the general categories are. So we are accepting projects that cover what we call cancer therapeutics which include the things that are on this bulleted list of what we draw with them. They're also contained in the RFA, projects focused on the cancer innovative technology such as interventional devices or other *in vivo* diagnostic technologies and we will also consider either *in vitro* or *in vivo* cancer diagnostic and prognostic technology.

As you'll see all of these technologies are things that generally will require some form of FDA approval, but either the RFA is focused on projects for which they are very capital intensive and going to require regulatory approval.

The other thing to mention is that in order to be responsive to the RFA the activities under the previous Phase Two awards must provide the appropriate technical foundation to justify the continued development of the technology for a cancer relevant indication for use. Again, in addition to falling within the technical scope that I just described, if you are working on a platform technology that was initially developed for a non-cancer indication and again, that could have been a project that might have been funded by another agency or a different institute than the Cancer Institute, the project will still only be responsive if those earlier data demonstrate that the technical proof of concept that are going to be scientifically relevant for a cancer indication. So there have been cases where folks have a platform technology. They put a pivot in order to come in under the Bridge program for additional funding but all of that prior work really

needs to lay the technical foundation for that cancer product. And again this is something we can talk more about with applicants on a one-on-one basis to make sure they know that.

Very important thing to note because there is a lot of information right now about various funding levels and budget caps for the different SBIR announcements, that are available right now under the Bridge program. There is a hard cap on the budget which is $1 million in total costs per year and project periods that are up to three years. So up to $3 million in total funding not to exceed $1 million in any given year. You may not exceed these limits. Under the responsiveness criteria listed in the RFA, it specifically states that applications may be rejected on the basis of amount. So please pay careful attention to the budget when you're submitting the application.

So in addition to the standard information that's required in any phase two application we list a number of items that should be included as supplemental information so if you're looking at the RFA either included under section 4.2, there's a subheading of SBIR & STTR information. One of the things that we need to include within your commercialization plan, is what we call a statement of need. In that statement of need we expect you to answer several questions related to your project and what you perceive to be what I sometimes call the valley of death or in other words, why is government funding needed at this stage of the development of the product and why can't you—why are you not able to raise outside funding to complete commercialization on your own. So again we ask you to define that valley of death for your particular product or technology so that we could understand why government funding is critically needed to accelerate the development of the product for commercialization and that should include as much detail as you can provide on the specific activities that you will do with the NCI funding that would not otherwise be possible with independent third party investments or things that would be significantly delayed without additional NIH support.

And then a corollary explanation to that, to what extent could a possible award under this program advance your product or technology far enough so that you would be able to then attract sufficient outside investment to carry out full commercialization.

Again it's the other key piece to the Bridge program is this expectation that you would demonstrate the ability to raise third party funds to supplement the NIH award at a minimum per dollar for dollar match. And we ask you to include again, in the commercialization plan, what we call a fundraising plan and that would include a detailed and specific plan for securing substantial independent third party investor funds. For the purposes of this program, we generally will count any investment that you have been able to close up to one year before the receipt date of the application towards the total amount that you're including in your fundraising plan. So applications are due on April 21 of 2014 and anything after April 21 of 2013 would be counted towards the total, could be counted towards the total for applications that would be coming in in this next cycle.

Within the fundraising plan we ask you to include the type of third party investor funds that you're going to be raising. In general that should include, cash, convertible debt, or other liquid funds. It can be applied for the advancement of the project and we ask you to tell us the source of that investor funding whether it's coming from venture capital, other biotechnology funds or any other source that you're going to be tapping into, especially the total amount of third party investor funds that you're going to count towards the total whether that's happened before you submitted the application or is going to be raised during the course of the project and please tell us what that anticipated schedule is for receiving those funds including any relevant

terms and conditions that those investors might have tied to those future amounts they are going to invest, particularly if it's going to be drawn, say over a three year period.

We also ask that you provide us with some sort of description for how those third party investor funds are going to be used to help advance the project. It's important to mention that the funding that is received from the NCI should only be used to advance the research related elements of the project whereas what you do with any amount of funds that you raise from third party can be used at your own discretion in consultation with those investors. What we ask is you provide some information or to demonstrate the substantial value added contributions for the commercialization of the product and as part of that we would like to know what are the specific activities that the third party investor funds will support and have those investors pass any restrictions or triggers or milestones to future payments, and if so, what are those restrictions or milestones and are those things that tie back directly to the goal advancing the project towards commercialization.

Another important section of supplemental information for the Bridge award and again this goes above and beyond the usual requirements for reporting on your SBIR commercialization history. We would like to know about your complete SBIR & STTR history that is to say information on all SBIR or STTR awards that you have received from any federal agency. We ask for specific information about that and we'd like to know if the company has gone through any name changes within the last few years so that we can track whether or not your company whether currently or under a previous name has had SBIR funding and what you've done with that. We'd like to understand that the company is a subsidiary or a spinoff of another company and then let us know the name of the parent company. We'd like to know what percentage of your company's revenue was derived from SBIR or STTR funding during each of the previous five years and again we would like to know that information both for Phase One and Phase Two. Again, total number of SBIR or STTR awards received from the government and then for each award, please provide the grant or contract number, the amount of the reward and the name of the awarding agency and then the total amount of revenue that the company has generated as a result of commercializing anything that was funded under the SBIR or STTR projects within the last five years.

The goal here is really to understand what is the company's history with the federal SBIR program and what's the company's track record and to provide us with some confidence that additional SBIR funding would lead towards taking the product closer to commercialization with the understanding that there is still a fair amount of technical and commercial fit just to understand what the company has been able to do previously helps us to evaluate the overall capability of the company.

And the other very important thing to include particularly for the Bridge application involves letters of support, so in addition to all the standard letters of support that would come in under any SBIR application that would speak to things like collaborations and access to expertise and resources. We need to see letters of support that document your commitment from the third party investors. Again, those letters should indicate any actual or planned commitments as well as conditional commitments and more specific you can be in these letters, the better. So we would really like to see a specific dollar figure or at least a dollar range and all of that should be consistent with the other instructions under the fundraising plan. The documentation again could include a conditional letter of support that states that the third party funding is contingent upon NIH selecting the application for award, but in all cases, everything that you provide should corroborate the plan that you've provided yourself in the fundraising plan which goes into the

commercialization plan section of the application. So in essence the investors should be backing up everything that you're telling us in terms of the financing that you're proposing to close for the Bridge. There is an option to provide additional supplemental information and these could be things that are not letters of support but may be other documents related to your third party investor funding. You should include documentation should be things like term sheets and include things like redacted statements or any other appropriate documents that support your fundraising plan. You should collect all of those documents in a single file and you should save those under the file name third party investors. So under the supplemental information section of the application, that file name, that file becomes a bookmark in the application under that file name and that will be another piece of the application that the reviewers will have access to as they're going through your application.

One very common question that comes up is, do I need to have raised all of my third party financing before I apply. Do I need to show the NCI that I have three million dollars in the bank in order to be competitive? So the answer is that no, you do not need to have raised all of the matching dollars up front, but the expectation is that competitive applicants will have closed at least as much third party financing as they will be requesting for the coming year of the Bridge award. So in order to be competitive for year one of a Bridge award funding, before we would issue that year one award, we would expect to see that the company had an equivalent or great amount of third party investor funds already closed and in the bank.

Again, we would expect the same thing prior to initiating year two and year three of the award. We would like to see a plan presented in the application for when that money is going to come in and what's the overall timeline, but again we would only check to see that the funding had actually closed for the coming year.

There is language in the application that if the financing strategy or plan changes at some point, that is something that we can re-review and approve if it's considered to be equivalent or better than the original plan. For example, if one of your investors pulled out of the deal, but you're able to raise funding from another set of investors or the second or third year of the award, that's something that we could review as the project moves forward. If the company fails to meet its obligation or fails to meet the plan that they presented in the initial application then the NIH reserves the right to take action which could include discontinuing the award for future years.

The last thing that I want to talk about and I'm not going to get into the details, but I want to bring to your attention that there are a number of specific review criteria that have been added to the standard NIH criteria for this program, so in particular the significance of the project that speaks to unmet need and commercial potential of the technology or the product that you're developing. Other specific criteria related to the approach and then there are specific items in there that ask the reviewers to evaluate the viability of your fundraising plan and other information about the company and the overall commercialization strategy.

I do want to just emphasize that the reviewers will be instructed to evaluate your application based on all of those collected review criteria so please pay close attention to those things and again please set up a time with the Program Director if you plan to apply.

So the last couple of things I will say, again, please read the entire RFA very carefully and please plan to submit your application at least a couple of days early. I would strongly recommend more than a few days early. There are a number of different components to the application. The Center for Scientific Review has been very strict of late as far as not accepting applications beyond the deadline. We do appreciate how much work goes in to putting these applications together and it's really unfortunate when applications are rejected for somewhat

trivial administrative reasons and there is usually nothing that we can do on the program side to fix that problem. The best thing to do is get things in early. That will give you a few days to resolve any errors that may arise during the submission.

I'm going to end there and I'm going to turn it back over to Christie to moderate the Q&A session.

Christie Canaria: Thank you for those of you who have stuck with us throughout the presentation. Again, we invite you to submit your questions using the Q&A box here. Of course you can also send your comments and questions at our e-mail NCISBIR@mail.nih.gov. Again, remember that we won't be answering specific questions at our webinar, but if you do have those, specific questions, please email us and we will connect you to a Program Director here in our office.

At this point we will also be opening up a poll and we ask that you please share your feedback with us. It's very important for us to know what you as applicants need in order to put together the application. So programs like this that we've put on, we do for you. Please give us your feedback and we'll begin to answer some of the questions and please continue to send them in.

Jennifer Shieh: A couple of quick questions, is the SBIR phase one 50% employment requirement for the PI the same for phase two? Answer is yes. Would a small business that is less than 50% owned by a venture capital organization be eligible? The answer to that is also yes. Another quick question,iIf I request the $5,000 technical assistance, am I still eligible for the Phase Two B Bridge award. Yes. The $5,000 technical assistance is per each award each grant application you can request $5,000 of technical assistance. The Phase Two B Bridge award is not a technical assistance program. It's a separate grant and requesting the $5,000 would just make you ineligible for participating in the needs assessment program in Phase One or the commercialization program in Phase Two.

Another question that's come in if proof of concept was obtained by university collaborators rather than a company, could you still be eligible for a Direct to Phase Two project? I'll let Patty take that?

Patti Weber: I—honestly I don't see why not. As long as the funds to generate the proof of concept didn't come from an SBIR award. That's a good question. Could it come from an R01?

Andy Kurtz: I think the answer is that that would be fine, but probably the critical thing to answer with the Program Director would be what are the typical deliverables for a Phase One SBIR that might have been accomplished and just make sure that academic work is aligned with what might be considered proof of concept under an SBIR award and again the best thing to do would be to track down a Program Director who works in that area and they can advise you on that.

Jennifer Shieh: The next question is on waivers. What is the process to get a waiver so that a phase two application can be submitted with a $2 million budget and what topics at NCI are included for the waivers?

Patti Weber: For this, the company just needs to include the justification in their budget. The waivers have already been approved by the small business administration; the NIH went through kind of a long process working with the small business administration to get these waivers, so the NIH would have flexibility on this issue because they assumed that people would want to spend over the cap. So the approved waiver topics are listed as an appendix in that topic document that's associated with the Omnibus and NCI has listed a number of topics and they include therapeutics which includes small molecules, biologic, radiomodulators, cell based therapies, *in vitro* and *in vivo* diagnostics including companion diagnostics and prognostic technology, imaging technologies including agents, devices and image guided interventions, devices for cancer therapy, agents for cancer prevention but not technology for cancer prevention, development of low cost technology for global health, development of companion diagnostics, vaccine development for cancer prevention and novel technologies to address undruggable targets. If your technology is not on the NCI list, you should contact a Program Director because the NIH basically has waivers for virtually every technology area. If it's an area that we would like to support, the waiver is there. Please do contact a Program Director if your topic or your technology area is not on NCI's list.

Jennifer Shieh: Back to the Direct to Phase Two question. How many Direct to Phase Two applications are you projecting to receive and what is going to be the budget allocated for Direct to Phase Two?

Patti Weber: We really don't have an expectation. It might be similar to a number of fast tracks we receive which is definitely smaller than the number of Phase One applications that we receive and the number of Phase Two. There's not a set aside budget for the Direct to Phase Two. You're just going to be reviewed as everyone else is reviewed and funding decisions are based on the priorities score as well as other factors. We don't have set aside budget for Direct to Phase Two.

I just might throw it out there that I probably received six or so inquiries from companies with requesting whether or not their idea would be appropriate for a Direct to Phase Two and I'm assuming that's probably about average for my colleges and they'll probably get more popular as time goes on.

Jennifer Shieh: And in general can these programs, especially Direct to Phase Two be used in addition to NExT which is the NCI Experimental Therapeutics? So the situation that is being asked about is that they'd like to use SBIR funding to develop the technology to the point where C-tuff trials are warranted. And so how does I believe the question might be is how does SBIR program funding relate to the other kinds of NCI contract resource programs that are available?

Andy Kurtz: We certainly have situations where companies are utilizing resources from different programs including NExT with collaborations with the SBIR programs. It's of course is requested that you disclose anything in your application about your plans to pursue resources under those other programs or certainly any projects you have ongoing under those other programs. We—before we would fund an award, we would look to see that we weren't duplicating efforts with resources coming from different programs, so the best thing to do would be to schedule time to speak with someone about your specific project and the different activities that need to get accomplished because very often discussing that with a Program Director can really help inform what you might propose within the SBIR versus what you may try to propose

working with NExT as an example. But there are opportunities to leverage resources from multiple programs.

Jennifer Shieh: There was a question about finding a list of NCI topics that qualify for funding via the Direct to Phase Two program. And as a point of clarification the topic, the list of waiver topics is a separate situation from the Direct to Phase Two program. With Direct to Phase Two, NCI will consider funding any projects that are within the mission of NCI as with any of the Omnibus topics.

Andy Kurtz: The Direct to Phase Two is intended to be very open along with the Omnibus announcement is. There are no restrictions on the technical scope so long as it falls within the broader mission of the NCI.

Jennifer Shieh: And so now moving on to some more questions specific to the Bridge award, if you're working off an NIH SBIR Phase Two that is not with NCI but with another institute, do you still have to contact the SBIR Development Center to ensure the proper receipt?

Andy Kurtz: From an administrative standpoint, if you are predicating your bridge award on a previous NIH funded Phase Two grant, it's not necessary to contact us again. I would encourage anyone considering submission to contact us to talk about their projects in general and anything they may want to consider to be more competitive. But if you have a previous Phase Two grant there will already be a record of that in the system so we should not need to take any special actions to make sure that your application is received.

Jennifer Shieh: And a somewhat similar—in a similar vein we were discussing platform technology from funded by another Institute but being used for cancer specific purpose, may be funded may apply for a Bridge award. Can you provide a definition of platform technology?

Andy Kurtz: Well, I guess maybe I'll give an example. A platform technology in the area of drug development could include, for example, a nanoparticle delivery system that might be capable of delivering a variety of therapeutic payloads and so as one example perhaps someone has done a great deal of development work around the delivery vehicle but unless they have used that to specifically show the encapsulation and delivery of an anti-cancer agent that would be pursued under the Bridge program, then that would not be considered an appropriate project because you wouldn't have established the appropriate foundation. By platform technology what we're talking about, is technologies that could be applied for a number of different indications or uses whether there's a diagnostic or interventional and again, that would be fine but it needs to be cancer focused and there needs to be preliminary data that lays the foundation for the activities that would be proposed under the Bridge.

Jennifer Shieh: So there was a question about time limits and the timeline. Is there a time limit for finishing Phase Two to apply for Phase Two B and what's the timeline for completing Phase Two and applying for the Bridge award?

Andy Kurtz: The first question in general we expect that applications would be submitted no longer than twenty four months so two years after the end of the Phase Two. We do have the

ability to evaluate things on a case by case basis if the Phase Two expired further back than two years, but some of the things that we look for is whether or not there's still a compelling unmet need that's addressed by the technology and in particular whether there's investor interest in the technology and if that could be substantiated within the proposal. Again, if you have a project that's more than two years old and are considering applying, please do contact us and we can talk more. Second part of the question was?

Jennifer Shieh: The general time line so I think when should you start thinking about applying for a Bridge award?

Andy Kurtz: So in any given fiscal year, so the applications are typically reviewed in late spring or summer with the goal of making all of those awards by the end of the fiscal year which is the end of September. If you're applying in the current year, your Phase Two award needs to have ended no later than August 31st of this year and so in general, you can be considering a Bridge award very early on in your Phase Two, but you should not be submitting a Bridge award application until you're generally within the last year of your Phase Two award.

Jennifer Shieh: Do early commercial sales that leverage Phase Two activity results count towards a funding match?

Andy Kurtz: Sometimes. So it's sort of depends on, I'm going to be very general here, it depends on the technology and sort of the specific product that's being sold and how that relates to the product that's being developed for ultimate commercialization under the Bridge, so we have a very few number of instances where we consider that and discuss it and I actually don't believe we have any funded awards where that type of arrangement has counted towards their matching requirement, but that's something that we can talk about with respect to your specific project.

Jennifer Shieh: And should third party funding be equity based?

Andy Kurtz: I'll answer that by saying that we generally will not count in kind reports, so in general yes. Most of the investments are equity based. We would count funding in general from other outside organizations, for example, a state technology fund that may be providing dollars, could be grant dollars, that were awarded on a competitive basis. Those are things that we would consider, but in general most of the competitive applications that we see come in are from investor funds that are equity deals.

Jennifer Shieh: And I'm going to have one more question about investment and what counts but if an investor group has guaranteed a line of credit for the company, does this count towards the raise funds requirement for the company?

Andy Kurtz: Possibly. Please call us so we can talk more. Again, I can't emphasize enough that every Bridge application is very unique and typically whenever an applicant asks a question that raises six or seven more from our side and it's easiest to have these discussions by phone.

Jennifer Shieh: Maybe some potentially more general questions, actually. Can we talk a bit about the study section composition? And they didn't specify whether this was for the Bridge award or

for Direct to Phase Two, but perhaps you can speak to study section compositions and what the differences might be.

Patti Weber: I'd say for the standard SBIR and STTR study sections, I know the SRO's do try and include in reviewers with industry background, but I would say for the most part maybe there are two or three reviewers, out of a dozen, that are from industry and the remaining are from academic, but you can always go to the website for the Center for Scientific Review and look at the descriptions of each of the study sections and go back three review sessions and look at the roster and see for yourself who these people are who are reviewing for each of the technology areas and we always recommend that people do that. I'll let Andy speak for the Bridge review.

Andy Kurtz: So for the Bridge, this is a special RFA that we actually review here at our own Institute. We with our own review staff and external reviewers, is something that we do at the NCI. We definitely place a greater emphasis on recruiting industry reviewers both that either work in companies like big pharma companies and folks that are investors themselves and sometimes from the venture side and other times folks that do business development perhaps within large companies. These are folks that tend to see a lot of deals and then as well as the usual academic reviewers, we certainly try to recruit as many physicians as we can to evaluate some of the technologies from an end user perspective. So the Bridge program really is focused on a very integrated consideration of all of the technical regulatory, commercial sort of business considerations that would go into a successful project.

Jennifer Shieh: And maybe two more questions. So one, getting back to Direct to Phase Two and the eligibility there, if we had an old SBIR Phase One but the Phase Two was not funded and we're not eligible to resubmit the Phase Two proposal, can we apply to the Direct to Phase Two now?

Patti Weber: That's a good question. The language in the announcement says that the work needed to be done without federal dollars, but it perhaps if you have continued to work on that technology and generated additional data without federal dollars then you could submit. It's possible that you could be eligible to submit a Direct to Phase Two, but I would think it couldn't just be submitting the results of your old SBIR Phase One as your preliminary data and proof of concept for the Direct to Phase Two. It would have required additional work, an additional proof that you've continued to develop it and work on the commercialization aspect as well. Remember the Direct to Phase Two is going to have a commercialization plan associated with it.

Jennifer Shieh: And just to follow on with that, if you did want to apply for a Phase Two based on the old Phase One work, you may be able to do that and you should contract your Program Officer or our office if it was an NCI—

Patti Weber: I would recommend that definitely in this situation, contact a Program Director.

Jennifer Shieh: And there's a couple of questions, though this will be the last question, about foreign collaborations and what is allowed there. Are we able to work with Institutions outside of the U.S.? And if so, how much?

Patti Weber: Generally it is not allowed. And if it's a situation arises where perhaps you can only get a reagent outside of the country, you can talk to a Program Director and we'll give you advice, if it truly is the only source then we have to go through a process to get that approved by the Fogarty International Center to allow any funds in the SBIR or STTR program to go out of the country. So these are looked at on a case by case basis.

Andy Kurtz: I would just follow up by saying that it is not considered a valid justification to go outside the U.S. because it's cheaper to conduct clinical trials in India than it is domestically, so the things that sort of rise to the level of being justified reasons to go outside the U.S. are nearly always scientific reasons. So as Patty mentioned resources and things that could not otherwise be obtained within the U.S. And again, as Patty mentioned, to be able to do that does require some additional administrative steps which sometimes can really delay the funding action, so those are things that you want to consider carefully and talk through those with a Program Director.

Christie Canaria: Thank you everyone for joining us today. If after this event you have additional questions please feel free to e-mail us. In addition, we will be posting this material online so all our registered attendees you will be sent that link to you by e-mail. Again, thank you very much. Our e-mail is NCISBIR@mail.nih.gov and you can visit us online at SBIR.cancer.gov. Thank you very much.

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