Early Commercialization Resources Panel Discussion

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Session Transcript:

>>Matt McMahon: Hi folks, I'd like to welcome everybody back if the panelists could turn on their videos please yeah thanks for sticking with us everybody we've got some really exciting and interesting conversations today we're going to round out the day with a topic that has come up a few times from some of the innovators but it's related to the early commercialization resources that our innovators have taken advantage of that have really strengthened their projects and these are not the usual types of things you might find in the academic world. We're talking about things like regulatory and reimbursement advice as well as business development guidance all the types of things that are a little bit unusual in the academic world and so the perfect moderator for this panel is Steve Flame. Steve's our entrepreneur-in-residence at NHLBI a longtime friend of the Proof Of Concept network program and has deep experience himself in the in the business and investing world so I'll hand it over to Steve to take it away for this panel.

>>Steve Flaim: Well thanks Matt it's a pleasure to be here, and so one of the themes that has been running through the program today and it's been really an interesting program is the fact that it takes a completely different set of resources to discover a technology than compared to what it takes to take it towards commercialization. And so what I had with me today is a panel of three people who are academic investigators each funded through one of the REACH hubs and what we're going to do is ask them to give us some thoughts on the benefits of the SEED program, the REACH Hub and the resources that they accessed through those programs and how those resources helped accelerate, benefited their project accelerated potentially accelerated their project towards commercialization and maybe also benefited them as individuals. So let me introduce the panel first, we have Dr Cem Altunbas he is associate professor at the University of Colorado and Anschutz medical campus and funded as part of the SPARK|REACH program secondly, we have Dr Fateme Fayyazbakhsh and she is an assistant research professor at Missouri University of science and technology and funded through the MBArC REACH Hub and finally, we have N Sanjeeva Murthy who is an associate research professor at Rutgers University and funded through the ROI REACH hub. So, I'm going to start with Jim let him give us his synopsis then we'll go to Fateme and we'll end with Sanjiva but for each of you before you start tell us a little bit about your technology what the product is that you have in mind the target product if you will and where you are in the commercialization process before telling us about the resources so start with Cem.

>>Cem Altunbas: Okay, so I'm a medical physicist my research area is in extra imaging physics the technology that we are developing is a compact CT scanner for a variety of clinical applications. So sorry I forgot which else I should mention at this yeah so just tell us quickly what product your you're anticipating and then where you are in the commercialization path. Yeah so the product is a medical device a compact CT scanner, and at this point we are at the proof of concept stage we have a bachelor prototype that we have some funding in addition to the REACH program a STTR phase one funding that we got, and that is where we are at now okay on the proof of concept.

>>Steve Flaim: Okay, and then so my question is you know the resources that are that were made available to you through your REACH Hub and through the SEED office. How what did those resources that that were important to you, how they changed the way you were thinking about the product accelerate the product just give us some background some real live experience with those resources what kind of resources etc.

>>Cem Altunbas: Yeah, so as part of the REACH program I had two advisors they are entrepreneurs and business executives themselves as a living. I had routine meetings with them during my enrollment with the REACH program, so what is important is that of course I get the feedback from them from a business perspective and one key part that is hard to access if you are alone is their network, because when you interact with entrepreneurs themselves they have their own large network and that network can be helpful to you in variety of ways, for example what funding sources are available we might be aware of NIH funding which is great but there are other funding sources out there and they can point you to the right direction and some of them may not be suited for your technology at the level that for example I'm at the proof of concept level. The other is that again through their colleagues I met and an administrator who worked in medical in healthcare industry we did market research, so we talked with other stakeholders who assessed the value of compact CT scanner in variety of clinical applications. That was great because doing it by myself or with students is quite challenging talking with say other health care administrators right, how do you even access them? How do you talk with surgeons? So with the right person making that connection with the right person helped me greatly to get feedback from people who will be the end users of my device if you realize it. And as a result of that we made certain changes to our technology market alignments for example I have for several applications I thought it would be a great hit my proposed product but after the market research we thought that sure it might be good but there are maybe other areas that we should look at maybe it is not that that's not the perfect fit that I was thinking, and especially as a scientist we have a certain way of looking at our projects and that's kind of our baby, by getting this feedback from business people you ground your project in a different way you think that that's the best thing after sliced bread but maybe that is not the case. But that is good so you realize and you take action to address that so I think those were the those were the big benefits of me getting involved with REACH program also the funding that I got I managed to in spend some of that for these market research market alignment studies that I cannot do that with an RO1 funding and I cannot even do that with my STTR fund because those are strictly R&D grants so the NIH REACH program along with some state of Colorado funding we managed to do that.

>>Steve Flaim: Fantastic that's excellent and there's a lot of the important things that are needed in early steps towards commercialization are not available from research grants, so you must find additional funds from other sources and the REACH program provides that that's excellent Fateme can you give us your view of this?

>>Fateme Fayyazbakhsh: Sure, after receiving my PhD in biomaterials I started my postdoc appointment here in major University of Science and Technology in 2019. Our research focuses on bio fabrication and especially 3D printing of tissue engineering scaffolds and bio-engineered tissues for regenerative medicine approaches. We developed a 3D printed wound dressing with a novel by active formulation and after we got promising results in our first animal test, we decided to move forward our research toward commercialization parallel with our basic research, we filed our first patent then our research was funded by MBArC NIH REACH program through the Midwest Bio-medical Accelerated Consortium or MBArC that was a great learning opportunity for me from different aspects such as market analysis. I had no idea about all those market analysis and reimbursement strategies and other related concepts before that MBArC boot camp in the MBArC boot camp which focus on biomedical or product commercialization. I had an experience with like to enable access to different experts in like insurance companies, regulatory pathways experts or people from different organizations like FDA or NIH so then we encouraged to talk to different stakeholder groups. I had interviews with people from industry especially specifically ATS wound care, which is a local wound care company, so they had great experience with product development and really which was related to our project, so they introduced us to the related clinicians and surgeons and nurses so then to have a better understanding of burn wound as an unmet clinical need. I sent an online questioner to those clinicians to get their comments on the current products the shortcomings that and what they are looking for and what kind of features they like to see in the new product, so that helped us to solidify the pivotal value propositions and our competitive landscape for our product. Then we have done a market analysis for burn wound product so Jaya Gosh the program director she helped us with like finding she showed us what we should look for and different aspect of that project. Before we had no idea about them but she helped us to have a comprehensive look at all those different aspects, to for example reimbursement strategies for per voluntary treatment which is very complicated so I had to talk to different nurses and talk to insurance companies to see what are what strategies we can envision for our product and so as you as you said Cem, it was totally different in the beginning after that was something very simple then after that by moving forward our research, we had to add different features to that and it was not only from the scientific point of view from like for example with our stakeholder interviews we found that all those patients and nurses they really care about like how easy that dressing can be removed from the food so before that we didn't notice. So, then Jaya helped us to meet with a regulatory expert at SEED office they helped us to figure out the right regulatory pathway and require documentation for further reference of our product.

>>Steve Flaim: Fantastic, that's really an excellent description of the kind of resources that are available and I think highlights one of the things that's really important about the REACH hubs and that is that they bring a network of people together who can work with you and look at all

these different issues on early stage commercialization steps fantastic thank you Fateme so Sanjiva can you give us your synopsis from your perspective?

>>N Sanjeeva Murthy: Okay, thank you Steve, I have been working on the neural guidance conduits for almost 10 years. And the idea is to repair injured or disease nerves with a degradable polymer conduit that facilitates the growth of the nerve across the gap. I have been working on the fundamental aspects of material and biology, but about 18 months ago two MD students from Rutgers Medical School approached me and floated idea of whether I can commercialize this this device. Soon after a team organically formed on this idea and the team consists of these two MD students, a molecular biology PhD student, I a material scientist and Dr Pang who's an MD PhD who is an expert on cell-differentiation in this short 18-month period we made significant progress. We obtained a small tech express award from Rutgers and then we got a slightly bigger award from the New Jersey health foundation, and finally this the work we did based on these two small awards led us to the larger grant from the NIH REACH which Rutgers called Health Advance. The Health Advanced grant was key not only in pushing the science forward but making aware of the things that we had to pay attention to in commercializing our device. We had three mentors at various stages, these people made us aware of the unmet need and the stakeholders we got in touch with. The hospital administrators, patients, surgeons, insurance companies, salespeople, scientific offices at various companies as well as regulators. In total the three students the MD student and the PhD biology student they interviewed 25 people. They got an idea of what we need to do in order to differentiate our technology from what is in the market and what is the pathway to marketing over device, the health advance which is the local NIH REACH office has been instrumental in providing these industrial advisors one is who is the head of the new ventures group at Rutgers, other John Keel who has been a CEO of other companies and also our consultant recently we are working with Pete Golikov who is also an industrial expert. These three people make sure that we keep our eye on the ball. They know that our science is good but they help us make sure that our goal is not just to do good science but also to take this product to the market. Just last month they made us connect with a company who came and spent at day with us and reviewed our progress under confidential agreement and we're also thinking of whether to approach new venture capital on our own or to license our device to these other companies.

>>Steve Flaim: Fantastic, and so have you considered starting your own company to commercialize the product?

>>N Sanjeeva Murthy: Yeah, those are the two ideas we've been thinking of Steve we are thinking whether we should approach investors and get some enter capital and one of our students who is going to finish his PhD in another six months or so he wants to run the company but Rutgers is also pushing us to consider licensing that technology to another company so we haven't decided which way to go.

>>Steve Flaim: Right okay very good y'all that's always a kind of a dilemma for the for the founder or the academic investigator discover the technology do you create a company and

develop it yourself or bring in people or do you license it to somebody that's already sort of in the process of doing that kind of work. It's a tough decision it requires a lot of thought for sure.

>>N Sanjeeva Murthy: What we felt was that the company we spoke to we thought we know more than about our technology than they are so we explained that we handed over our technology to them they may not be able to run it as good as we think it should be run right run it to the ground and it may not fly.

>>Steve Flaim: Yeah, and sometimes the company that wants to license the technology actually what they want to do is take it off the market so it doesn't compete with something that they're developing so you really got to do some diligence behind that kind of work to be sure that that you know if you if you really want your technology to be developed you got to be sure that you work with people that want to develop your technology. One of the other things that I think Fateme mentioned is the importance of having a healthcare economic plan I mean how does the product the product that you've envisioned how does that benefit health care and what's the value to the health care system? And so a lot of a lot of investigators don't really understand the healthcare economics, and the importance of thinking about that early on you don't you don't want to develop a product that nobody's going to use because it doesn't really add any value. So, you really must sort of spend some time ahead of way ahead of commercialization to really understand that there is a value to that product. So, and then I guess the other thing that we frequently don't see early stage technologies looking at is the reimbursement story, you obviously need you need to be able to ultimately show to investors that your technology will be reimbursed by insurance companies and that's just that's an early stage requirement and I think a lot of early stage investigators don't really think about where about those kinds of features so I think Fateme mentioned both of those things I think that's true for all of these projects if I'm not mistaken.

>>Fateme Fayyazbakhsh: Yes, exactly and without regarding the economic health care, so it's very important like it should be cost effective not for a single use so for example in wound care context, so it's not only about the final price of the product it's like how many times they need to buy it? So maybe there are some products the patients need to renew them like twice a day so and there's another one with the removal time of seven days or one week. So, it can shift the paradigms significantly so from the economical point of view and it's not in in terms of those products it's because they are not too expensive so the patient more care about like how much it is it could be painful. So, the very first complaint of all those patients in according to our online survey was pain so, they were complaining of pain, and they all asked like can you reduce the pains we will pay for that maybe 10 times more, but we want to something like tail the painless removal and soothing during the application time.

>>Steve Flaim: Right and so Jim on your project one of the things that I was thinking about as you were speaking is the whole concept of how it how would your product change the practice of medicine? How would it fit into the workflow? Is have you know accessed any resources from the REACH Hub to address those issues and understand how that would fit into the workflow?

>>Cem Altunbas: Yes, so through REACH projects our researcher through the interviews and based on our expertise we did exactly that and see what the competing products are there and how it fits into the existing imaging product portfolio available in a hospital for example just to give a simple example a portable CT scan or a compact CT scanner can be used in ICUs. But how do you precisely use it in IC unit ICU is a busy environment even if you make a compact device can nurses and other technicians who work in the ICU can they easily operate that and do they want to operate it in an ICU because there might be a CT scanner two doors down. So, what value are we are bringing on to the table so those interviews that we have done over a period of a year with different stakeholders were crucial and not only to understand how it is going to be used but also understanding the features of the device. You have to make it very light is the weight important or portability is that the most important detail and you are making it compact but how compact is compact or if it is too compact too small so it is not usable, because it's an if you have seen a CT scanner it's a donut shape device where the head or the human body goes in how tight you should do that to make it compact. So, NIH REACH projects and the information that we gathered during that time was vital.

>>Steve Flaim: Okay, so that's very good so we do have a question from Tonya what she says can each of the presenters speak briefly about their innovation or what or how would someone get into the REACH program to get this early-stage funding and the supportive advisory team does anybody want to take a crack at that question?

>>N Sanjeeva Murthy: Yeah, I will start first we have to differentiate our technology from what exists out there, and we have we have been working in this area for almost 10 years. So, I knew what the market has made available to the surgeons. But our distinguishing feature was that we can provide a conduit that is filled with growth factors and other things that are that can be implanted and can do better than the inert devices that are that are currently available. So Cellularized nerve conduit is our hallmark there is no Cellularized no conduits currently available in the market. Regarding how we got to Health Advance or is we had we had to undergo a boot camp first, if you don't go through a boot camp, we are not eligible to apply for this what you call a Health Advance grant which is the local NIH REACH program. And in the boot camp there were presentations by faculty of industrial experts as well as university administrators as how we can apply for the Health Advance grant. That is simply beginning then we had to go we underwent about five weeks of training through Watertown Innovation core I-Core where we were taught not me, my students were taught how to prepare a good proposal. And for every Saturday for almost six weeks, I really started in the morning we used to spend about three hours going through how to write a good proposal and writing and also where advisor he told us how to present our case, how to how to present the views of the various stakeholders, the market need and the pathway to the market and spending enough time to prepare a good proposal was a key to winning the award.

>>Steve Flaim: Yes, so I know that each of the REACH hubs does this process a little differently Fatima can you give us a summary of how it worked for you.

>>Fateme Fayyazbakhsh: Yes, so our project got funded by MBArC in our second attempt. So, the first time we didn't have a file our technology file, so that our patents so the intellectual property is very important for this kind of research. So, I think the first step is filing your provisional patent and then you can apply for commercialization so I wanted to add this, and then you need to make sure if your research is in early stage or it can be like it gets closer to like transitional research. So, for example in our case if you're still thinking about the formulation and how it can be modified, or we think we already optimized that and we need to think about the functionality so these are it's different case by case, but you need to make sure you are not in the basic research step.

>>Steve Flaim: Okay, very good and uh Jim how about you can you give us a synopsis of the process at your place.

>>Cem Altunbas: Yeah, so we are lucky enough that we have a REACH Hub here at University of Colorado and every year they have a call for proposals, and I believe about 10 or so people are selected, or groups are selected inventors are selected. And you are part of the program for two years where you get support from the program and that is offered through an infrastructure available in our tech transfer office to support this Proof Of Concept commercialization projects, they also bring other funding sources through the state of Colorado as well so yeah so that's how that works for me and I think I applied for I didn't get funded in the first time. But that process was good because I got feedback every time that I applied from the people who review my grant, and most of them are again seasoned executives familiar with the commercialization domain and then I finally got funded.

>>Steve Flaim: Excellent, so you know I have to say that when I finished my graduate degree I got into academic research and it's it seemed to me over the years as an academic researcher that the goal of my work was to get publications and more grants. And I got to this point where I where I thought to myself you know there's got to be more to it than just that and really I'm interested in developing a product and we you know we need to figure out how to do that and so I I've really spent most of my career sort of banging along this commercialization pathway, you know going to work for big companies and small companies and being a CEO and learning things the hard way and uh you know it's really gratifying for me to see how all of you have been able to access these resources very quickly, to consolidate all of the what you need to do in order to understand how to develop a product based on your technology I think that this is a wonderful outcome. I'm know it's taken a lot of years for each of you to do what you do and it's taken a lot of years for the SEED program and the REACH Hubs to put themselves together, but to me this is a this is a wonderful turn of events where we I think we all realize the importance of basic research, also the importance of converting technology to healthcare products so I guess my last question to all of you in in general is there do you feel like there's any important issue that we've missed here in in explaining to the audience the tech the resources that are available through the through the SEED office and the REACH hubs that we haven't touched on that people should really be aware of and that you've been able to take advantage of?

>>Fateme Fayyazbakhsh: In our project we propose to work with large animals in large animals for science study so it's it wasn't available in our campus, so I had to contact so many CROs to find out which one can do that part for us and it's kind of complicated. So, part of that was done by us the other part was done by that CRO and there's lots of complication to finding the CRO and then signing the contract with them, so it's totally different when at the time we wanted to start this research and the outcome the outcome came good but it was totally different so everybody should be ready for any kind of change and all kind of change and also I think it would be a good idea to have a database of all those CROs for different approaches like for animal testing for sterilization packaging or all kind of product development or some companies like NIH Partners or something like that.

>>Steve Flaim: Yeah, just for the sake of definitions, a CRO is a Contract Research Organization, and these are companies that they do specific kind of work for to help develop products for example if you are developing a product and you need to do the FDA is going to require you to do some safety studies on the product. You probably don't have the resources at your institution to do the right kind of safety studies that the FDA will require, and so what you would do would be to go to a contract research organization that could that have the resources to do that kind of study. And so, Fatima the MBArC program give you the network and the connections to the cross that that you were able to.

>>Fateme Fayyazbakhsh: Yes, and it wasn't their only help they helped us to like how to negotiate for getting a better price or how to solidify our research and how to make it clearer what should be done here what should be done there and yes uh they did they were helpful.

>>Steve Flaim: Were there MBArC mentors that literally participated in those conversations, or did they were they giving you background guidance?

>>Fateme Fayyazbakhsh: It started with their background contacts comments but like I can give you an example yeah currently we started our small business, and we are applying for SBIR STTR around so for that one which is the like continue the next part of us MBArC research so in that one we want to go for product development, and we like to go under contracts with cross for serialization so they Jaya and another colleagues of hers so they were in our meeting with that CRO and they really helped us and they helped us to go for more for in the commercialization direction rather than the like academic direction. Fantastic that's excellent you're not in your head there.

>>Cem Altunbas: I think when we applied to the NIH REACH projects to get funding and support, one part is that I think the small print there it doesn't say that, or you will apply to a STTR grant or you will get help for applying for STTR SBIR grants. But I think to me that was a big side benefit although that was not a direct aim of the REACH project, but once you get into that environment you meet other people right these side benefits right they are they may not be obvious at the beginning when you apply to the program, but you get all the benefits because once you are there you have access to that network and you see what others are doing to commercialize their projects. What kind of a STTR do they go to phase two or phase one so and

people who have experience on how to write an STTR and SBIR or you talk with them. So, I think that also increases your chances of writing an STTR and SBIR grants even though I have a phase one funding but when I first started looking at STTR funding mechanisms I didn't even know where to start. So, in that sense it is important to be in an environment that supports your goals. If those goals are a STTR SBIR funding I think NIH REACH would be ideal even though it is not as strictly a SBIR or a STTR funding, but that helps for applying to such events.

>>Steve Flaim: so, it sparked it did you literally have meetings where the innovators got together and were able to communicate amongst each other? Or work how did that interaction work?

>>Cem Altunbas: That's a good question so in addition to the business advisors or spark advisors that I had we had these periodic meetings with a group of a bunch of other advisors and other SPARK fellows like me and I would see, and they were they grouped it in such a way that I was in the medical devices group.