Whether, When, and How do I Start a New Life Science Company?

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LUIS GUTIERREZ: Good afternoon. My name is Luis Gutierrez, and I am an Entrepreneur in Residence (EIR) in the Small business, Education and Entrepreneurial Development (SEED) office that oversees the REACH program. My co-presenter is Dr. Steve Wolpe, another one of our EIRs. Between us, we have founded, co-founded, invested in and evaluated lots of startup companies, and we'll try to share some of the lessons learned in that regard to the topic of "Whether, When, and How do I Start a New Life Science Company?"

I don't see more people piling in, so in the interest of time, we'll just go ahead and get started. Go to the next slide please, Katie.

A couple disclaimers and housekeeping points. The following is obviously informational content, hopefully for educational purposes. But if you want to start a company, there is no substitute for engaging a good corporate attorney. We're not here to dispense legal advice either at large or at an individual situation. The current presentation is aimed to provide background and hopefully to spark more dialogue over time so that you can properly engage council, it is counsel with an SEL. Apologies for the typo. There is a couple other housekeeping arrangements. This presentation will be recorded and the slides also made available in a week or so. Also, no needs to take furious notes and or if you have colleagues in your institutions or areas that couldn't make this particular hour, they will be able to see this recording and we will take questions at the end for sure. We have an hour blocked. We're aiming to present for 30-35 minutes or so and then leave ample time for questions. Up at the top of the screen, on my screen the 4th icon from the left is the Q&A button and that's how we'll be submitting questions. They'll be moderate and screened, and in some cases grouped because sometimes you have 2-3 people with a similar question grouped for presentation to us. If there's something that we're just unclear on, we'll get interruptions. But by and large, we're going to try to present first and do Q&A later. So, with that I think we're ready to start the meet of the presentation. Katie.

What are we going to talk about today? Why, Whether, When and How to start new life science companies, we're going to start with the why? Why start a company at all? There's lots of ways of doing research. There's lots of ways of contributing to medical progress so why start a company? And what's the difference between starting a company and licensing a technology? Whether it is you know that trigger point of the world needs this. The research you need to do on the market needs to include the scope, mission and name of the company. When this is very important, securing access, presumably exclusively to core IP, to me this is a necessary prerogative. You don't have a company in the Biosciences space if you don't have exclusive IP.

But there's also the when and what to trigger and where to incorporate and then delineating the founders their roles. Including the ability to fully dedicate their professional effort for many people, starting a company should represent a fork in the road, I will do A or B. You can't have it all. I hope we'll discuss that a little bit too. And then the how what type of company to form. There are lots of different legal structures. What are the pros and cons? How do you allocate equity among the founders? How do you set aside equity for the people you're going to need to recruit along the way, both as workers and as investors, and then the sources of capital. You'll know what FFF means by the end of this presentation and grants accelerators and other sources of funding as well. Go to the next slide, Katie. Thank you.

Reality check, once you start a company, you're no longer in science, you're now in sales. I credit my colleague Steve for that quote. And it is one of those forks in the roads of “AM I, primarily a scientist, or am I now a commercial person?” And if you're starting companies because it's a commercial enterprise, you are still a trained as a scientist. You have the knowledge of a scientist. You may still be doing science, but your overarching goal is getting a commercial product on the market that can be used clinically and hopefully get to millions of patients. So, I said market- that is critical for starting a company. What's the customer analysis? Who's going to buy this product? How big is that market? How many of such people are there? The competitive side- what's the available set of solutions that are out there today? And why are they going to buy yours instead of somebody else's? These are critical market driven questions rather than scientifically driven questions that are critical to the viability of a company. You're going to have a company. There is yet to be a model where you give everything away for free. Somebody has to pay, or somebody has to monetize in some way even so-called free apps are really driven by data capture and/or advertising. There's always some economic exchange going on. What's the risk benefit analysis? Will your product be safe? Will it be affordable? Pharma economic analysis will your products save money for patients? Providers? And/or payers? Some audience has to come out ahead. Who is essential to the economic exchange for a product to be viable in today's analysis? And then protection, IP analysis and/or other exclusivity? Can you protect yourself against competition? Lots of people have other clever ideas and pretty much any good idea can be knocked off. How are you going to ensure that they're buying your product rather than somebody else's? Next slide please, Katie.

What I've laid out here on a left to right continuum is sort of, you know, from the beginning to what's the end in mind. So, at the beginning you need to define your scope of your company. What is and what just as importantly, what is not within the research and commercial scope of the intended company and to the extent you're working with co-founders, which is probably the norm actually in life sciences. Getting a commonality of purpose about the things that are going to exist within the company that we are going to do together and by definition, what is not in that set that we won't be spending time on or won't be spending the company's time and effort on. It is critical to have some boundaries because otherwise you can quickly kind of lose focus and get nothing done rather than getting one thing done. Once you figure out the scope, we are going to be the company that does X and not doing Y or Z name. One of the earliest decisions you're going to have to make, even if it's just as a placeholder you is to give the company a name. It's like a baby, once they're born, you can't get a birth certificate until you come up with a name. They won't let you out of the hospital without one.

Checking the availability of trademarks, web domains, etc. are critical. Are you going to get it right the first time? Hopefully, but not always, and it can and often does, change later. But you got to start with the name. It will save yourself a lot of heartache if you do some preliminary trademark searches, naming conventions in multiple languages, kind of search and domain searching upfront. Because these days without that, you don't really exist if you don't exist in cyberspace. Third, is the mission. Are we a pharmaceutical development company? A device company? A diagnostic company? which isn't listed, or a services company? Are we making a tangible product or are we providing effort towards some activity that has solitary effect on health? These all have implications for what kind of company you form, how you make your money, and the capital intensity of the development effort. These also have some implications for from the early stage of what kind of filing documents do you have? And we'll be talking about that a little bit more later in the presentation. The model, here it's a fork in the road. Are we a product development company or a services company? Investors hate the mixed model. There's a certain elegance of, well, we'll do some services as a way of paying the bills while we work on our product. The problem with that is that you're a on the service side. Competing with service providers who are 100% focused on service. Chances are you're going to be losing service business if you're not fully dedicated to it and also your product development business doesn't get your full attention if in fact you're spending your time on services. So early advice and I know that a lot of scientific enterprises look at it you're not going to get to the next one, which is exit. How do you plan to grow and expand the company as an independent entity so that it can eventually be either acquired or go public?

Ultimately, any company has to reach one of three endpoints. It gets acquired, in which case the founders and the investors get paid out. Goes public, which is an opportunity for those who want to liquidate can and the others can stay. I guess it can also stay a private company, but then only the founders ever make money, like a family business, etc. It's very tough to recruit outside talent and impossible to recruit outside investment because they're never going to get a return. I guess the 4th outcome, sadly, is bankruptcy. So next slide.

And that's not the one you want to have in mind. I talked a lot about a key kind of decision point about whether to start a company is have you secured IP. Basically, the lack of exclusivity eviscerates commercial value. If you're not the only game in town for being able to provide this product then it's almost impossible to invest in because the minute you're successful, others will come in. There's not much in the way of a first move for advantage there. That said, there are many different ways of protecting intellectual property. You can file patents, or you can go the trade secret route. I only recently learned that the lubricant WD40 is not protected by any patents. They took the path like Coca-Cola and it's the formula is a trade secret and it's good enough and sufficiently superior to other lubricants that people still buy WD40, even though it's strictly a secret formula and not patented. It's not common to go the trade secret route in biotech and Med tech, so most people do go the patent route. Then of course, our copyrights and trademarks this has to do with name, logo, verbiage etc. And then the geographic scope is huge. I'm talking to an NIH oriented audience. Everyone on this call is living and working in the US, and the US is the largest single market for most of biotech and Med tech products. But you need to have at least Western Europe, Japan, and the developed world covered in your IP as well. At some point over time and you are well advised your value of your company goes up

with the geographic scope with which you've protected your IP. With that, I'm going to hand over to my colleague Dr. Wolpe to take it from here.

STEPHEN WOLPE: Yes, so thanks Lewis. So let me just back up one minute. Luis is throwing a lot of stuff at you. I'm going to throw some more stuff at you, and I don't want you to get intimidated by everything. It's a very different process starting a business than what you're used to in academics. I went through that as I started out as a postdoc; I had some discoveries that were relevant for industry and I was recruited to industry and it's a real mind change. As Lewis said at the beginning that it would be helpful to have a good lawyer to help you. It also would be helpful to have a good business person. Your tech transfer office at your university can help, but having an experienced business person that you can call on and really ask these questions. Maybe that person is at the Business School at your university. City or just someone you know? But there's a lot of angles, as Luis just mentioned, and setting up the company and someone who's been there and done that, it is really helpful in getting you acclimated to what's the business climate as opposed to an academic one. So, in terms of at what point does it make sense to set up a company? There are multiple answers to that. A large part of that is driven by a personal interest. If your interest really is just doing research and producing publications and working on academic questions and don't start a company, it's you know let your post doc or let somebody else start the company, but if you're interested in going beyond publications in actually developing a product that ultimately could be used in the clinic and help patients then and I think at that point it makes sense to start a company in, in the current environment. It also helps to have a company because it acts gives you access to additional funding beyond academics.

Luis mentioned that we're in the SEED, they coordinate the NIH SBIR/STTR program which gives grants specifically for companies. If you as an academic and spin out a company, that company can do sponsored research in your lab. You can set up an SBIR/STTR and have another source of money for your research. You also, if the company gets investors, then that company can again set up sponsored research agreements with your lab and that's another source of funding for the work that's done in the lab. And then finally to what Luis had mentioned earlier it doesn't make sense to set up a company unless you have a competitive advantage. So, if any of you who watch Shark Tank and see Mr. Wonderful talk about people who don't have a patent getting crushed like a bug by the big companies. That's exactly the same in biotech. If you don't have a strong patent position, then investors won't invest in and you're not going to be able to keep off competition. So, all of those really need to come together before you decide to start a company. And then the question is what type of company it is a brick-and-mortar company, meaning it has a building, it has offices, it has real estate or virtual. Currently, most start up biotech startup is virtual because you don't have any money, and you don't need the overhead of brick and mortar or labs. It's only really necessary to have that and a lot of the research can be done by contract manufacturers. Contract research organizations CROs and contract manufacturers, or CDMs. And generally, for a start-up biotech, it doesn't make sense to put a lot of money into a building when there's already existing infrastructure that you can access in terms of site of incorporation versus operations.

We need to explain what incorporation means so when you start a company, you have to incorporate it so it's a legal entity and there's a process you go through. If it's as we'll talk about, if it's a simple

partnership or LLC, you can do that yourself in a day in your state. Every state has a website you go to. You say I want to start a company where it's going to be a simple partnership, and you fill out the form and boom you're a company as we'll talk about in a minute. If you're going to start a biotech that requires investment or that's going to develop a product, then you want to form what's called C-Corp and then the site of where you incorporate becomes an issue. This was the standard until very recently, has always been for a startup company that's looking for investment. Yeah, we'll explain the difference between LLC's and C-Corps in a minute. More recently, spurred on by Elon Musk, who got fed up with some of the Delaware specifications people have started to incorporate in Nevada, Wyoming, South Dakota. And other things to take into account and there's different tax advantages for each. The Delaware system was renowned because it has a specific court system for companies called the Chancery Court and almost every major company you've heard of GE, Coca-Cola, lots of international companies or Delaware C-Corps primarily because of the transfer system and also the tax advantages. And we're located in Maryland. Maryland has some of the counties will match if you get an SBIR so that adds additional revenue, and they do that to try and spur company formation in their state in order to eventually grow companies and have employees and increase their tax base. There's states that are starting to do that and the choice of the state really depends on where you're located and you know the relative tax advantages.

The other question is, have you set up who's going to run the company? A lot of academics start out as CEO's and that becomes problematic, we know you know your technology best. You may have one of your postdocs be an employee, but it becomes a bit problematic when you start to raise funding because you're not 100% devoted to the company. You're mostly running your lab in the university. That's your primary affiliation and investors want somebody who's fully dedicated to the company. So at some point, even if you start a company, you should try and hire a business person who can lead the company and attract investors. And most often that somebody who has a track record, investors look for someone who's been there and done that. In addition to the management of the company, who is the CEO, do you want a CFO who can help raise funds and look after the finances and the COO or Chief Operating Officer who can make sure that things get done on time? You also need a Board of directors, then the Board of directors has the fiduciary responsibility of overseeing the company and making sure that everything is done legally and making the ultimate decisions for the company. And you'll also want a scientific Advisory Board, and often what you try to get people who are what are called KOLs or key opinion leaders, people who are known in the field, that investors will recognize their names and want to invest in the company. And who can give you good scientific advice?

So, in the next slide, I touched on this a little bit earlier. When you talk about a company, there's multiple legal entities that you can form one or just simple partnerships called LLC's or LLP's or Sole Proprietorship. If, if you're the owner and if you have a service company, these are perfectly fine. You're going to be selling a service. These are what are called pass through corporations where it just goes on your personal taxes, it's not very complicated, but these aren't entities that you would set up if you want investors. If you want investors, most likely what you want to do is set up a C-Corp. That's what all investors are use to and they know how to deal with that. They know the tax advantages and from your point, which a lot of people aren't aware of, there's the 1202 tax exemption. But the 1202 tax exemption it was set up by IRS in order to spur the formation of corporations, and if you start a

company and you hold the stock in that company for five years, or if you're an early investor in that company and you hold the stock for five years and then you sell the company for a $100 million, the first $10 million of that is tax free. It doesn't have to be $100 million, whatever you sell it for varies by year by year, but generally it's around $10 million you and the other founders and investors get that first $10 million tax free, but that only applies to C-Corps. So you'll hear a lot of people, especially on the East Coast, argue about whether you should start as an LLC and switch to C-Corps when you're ready to invest, but that really doesn't make sense to do that. You should just start as a C-Corps because why spend two or three years as an LLC and not have that account towards your five years for a 12O2 exemption. It's better just to start as a C-Corps from the beginning, even if it's a little more complicated and have that time accrue to the 1202 tax exemption. And again, these are all things that you know we're throwing at you, talk to a tax attorney or a business person who can really explain it.

All right. On the next slide. For services it's simple. Pass through Corporation is fine. That's if you just plan on selling your services. Let's say you're an AI company and you have software. You're just going to license out your software and you don't really need investment it's perfectly fine to do it as an LLC or sole proprietorship. S-Corp is sort of in between the two. It's fine to do it as an S-Corp. Just talk to it, tax attorney for your particular situation. See which of these is best.

And then as I mentioned. On the next slide, if you are developing a product, a device, something that you're going to need to bring in investors and by investors, I mean professional investors, not just friends and family but a VC, an institutional investor or if you want to partner with a large pharmaceutical company or large business C-Corps are what everybody's used to. They understand them. If you go to them as an LLC, their attorneys are not going to be very happy setting up collaborations with LLC's. They want to see C-Corps. And as we mentioned, Delaware C-Corp is really currently the standard.

So that's okay. Go ahead to the next slide. So then once you set up your company. What percentage of the company do you own? Usually, if you're in academic and you're spinning out a company started his sole proprietorship. So you'll start to see core and you'll own 100% of the stock. And then what you want to do is you'll license the technology from your university and university will say, well, we want a part of the company. So they'll often take a percentage of your company. So now you're no longer and 100%. Let's say you're at 95% and then you may want to hire employees, and so you start what's called a stock option agreement and you set aside maybe 10% of your stock. For employees and they get stock options in your company. When you do that, when you first incorporate the company, it's not worth anything it's just a company on paper and so usually what you'll see is that every share in the company. And when you start the company, they'll start with, let's say 10 million shares. They just take an arbitrary number and say here's how many shares you're going to have, and each of those shares will be like .0001% in value. Once you license in the patent, then the valuation of the company goes up. And once you bring in money, the valuation goes up. But what also happens is your percent of the company goes down and that's called dilution. So let's say you have a company it's worth, on paper $10 million and you bring in an investor and they put in $10 million into your company. The pre-money value of that company is 10 million. The post value is 20 million. So that investor who put in 10 gets 50% of your company, right? 10 million out of the 20 million. And you get deluded by 50%, so you no

longer own 100%. You now own 50%. But you own 50% of a company worth 20 million as opposed to 100% of a company worth 10 million. So you need to understand dilution. That's where grants are really important and what are called non-dilutive funding. So NIH, when it gives you a grant. It doesn't ask for equity in your company. And that's called non diluted funding if you bring in money from investors, they want a piece of your company and that's when you get diluted. So understanding dilution and non dilution is very important in terms of your company. The other thing that I skipped is when your company is worth only .0001 percent 1 penny per share, you want to do what's called an 83b declaration and your lawyer can explain that. Basically you just tell the IRS, you know, here's the evaluation of a company. Then you don't have to pay tax when all of a sudden your valuation goes up to 10 million or 20 million. Until that's until you actually sell your stock. So talk to a lawyer about 83b declaration when you when you first form your company. All right next.

LUIS GUTIERREZ: One other point, Steve, before we move on.

STEPHEN WOLPE: Yeah, sure.

LUIS GUTIERREZ: Go back Katie. Steve ran through the example of the single founder. And that's very true. You often have a multi-founder situation from the get go and those first bullet points are of how to divide and often we get called in as the IRS to at least provide some advice. How do you divide up the initial equity when there are multiple co-founders? And I think a key guidance is sort of who had the idea or the ideas and that's certainly worth some allocation. Who's going to actually work to turn those into a business, including coming to that fork in the road and saying I'm going be doing this full time and you guys keep your academic day jobs. That gets the major allocation and so it is a related topic to dilution and then that at the beginning those who are opting in to do the work for will continually be a 5-to-10-year slog before. They get the bulk of it because it's really the allocations about the value that's going to get it created. Steve just noted at the beginning, as of the incorporation date, the shares are worth some tiny fraction of a penny. They're worthless, which is why you want to do the 83b election, because then you're getting taxed on income of essentially 0. But it's really about the future and you think about the founder shares in terms of what are you signing up for in terms of the proportional effort on the go forward basis? So that was the point I wanted to make there.

STEPHEN WOLPE: Yeah, yeah. Now that's a good point. And to follow up on that, the other side of it is if you do hire a CEO and they do get a good chunk of your company, you don't want them to say thank you very much and then walk away. So usually those shares are vested, which means let's say you give them 10% of your company, you don't just give them 10% right at the beginning. You offer them 10% the best over time. Let's say they've asked over five years, that means they get 2% every year, and that's an incentive for them to stay with the company and build it rather than just take the shares and go somewhere else. Again, these are all things that you'll learn as you start the company. It's not, you know, it's a lot to take in, in a one-hour seminar, but just find people who can work with you and explain these things as you as you go along. All right.

The next slide, we talked about this a little bit earlier. There's nondilutive, where the grant or the funders. It could be a nonprofit it doesn't have to be NIH. There are foundations that will give grants,

but those are all really attractive because you don't get dilution of your stock. On the other hand, as you all know, because you're all used to writing grants, you don't always get grants the first time or the second time, and sometimes not the third time. You have to keep after it, and even if you get the grant, it can take a year before the money reaches the bank and so. To get the company going, you usually need to raise capital from investors. And there are different ways of doing that. We won't get into details, except there's a website, there's an incubator called Y Combinator. On the West Coast that's famous for having developed a lot of this in the early days. Look up Y Combinator. They developed what's called a safe note, which is basically. An agreement between you and the investor and they've worked out all the terms so that what they found was that investors sometimes would slip in terms into their agreements that founders didn't understand and ended up really taking a large portion of the company, which wasn't quite fair. They've come up with safe notes in order to make sure that it's the agreement is fair to both the investor and the founder. But usually what you start off, we call friends, family, fools, people who share your dream people you know, and are willing to invest. You know, $20-30, $50, maybe if they're wealthy $100,000 just to get the company going. And then you bring in Angel investors which are people usually wealthy individuals who want to get back or who are interested in the space? If you're doing a diabetes company, maybe they have a family member who has diabetes, and they want to invest in your idea. And then you go for the larger money and there's what are called family offices, which are set up by wealthy families. To do their investments, there's venture capital, VCs and there's strategic partnerships which can be dilutive or sometimes they're not dilutive. If you can license your technology to pharma, they'll pay you and you're not getting diluted. So these are all things that as you go along to think about. This is where sales comes in, right, so your users decide. Many of you are scientists, be really careful about your claims and not trying to say everything is evidence based and putting lots of caveats. That will kill you if you go to an investor where you say yeah, this is really good, but it might not work. It's, you know, we have some data, but we don't have this and that. An investor will just turn around and walk away. You have to actually sell them on your vision. You have to completely change your academic mindset. Training to that of a salesman. That what you have is the best in the world and you have to exude confidence and you're going to make this succeed where nobody else can. And it's completely, diametrically opposed to everything you've ever been trained as an academic. So that's where the idea that you no longer in academics, you're now in sales. So I think we can skip this this is just lots of different ways of raising money. And if you have questions about any of these, we can do it during the Q&A. And then we have additional resources, the Y Combinator that I mentioned, NIH SEED website. We have lots of training modules that you can look at and other websites where you can find out more about what we discussed.

LUIS GUTIERREZ: We will move into the Q&A portion. We're right about on the time we expected. We've got a healthy amount of time for questions and would love to take some.

CHRISTY SASIELA: And we have some questions.

LUIS GUTIERREZ: All right.

CHRISTY SASIELA: So the anonymous voice from the Internet says “When universities take equity in a company, do they invest or is that just something they take you for launching from their university?”

LUIS GUTIERREZ: Good question, I'll start. In, in my experience, do they invest? They've invested in the fact that IP that they paid for through the lab, they paid for with staff they paid for, now has value. Are they giving you a check? No, more often than not. To the contrary, they're going be asking in the license that you cover their IP costs going forward.

STEPHEN WOLPE: Yeah I agree. And generally, it's when you license from a university and want equity. They also want milestone payments and the most important thing for the Tech Transfer Office is that they get paid back for all of the costs of their patents. They've probably filed patents for you and they want to recoup those costs from the company, that's kind of a sticky question. Would you want to make sure when you start the company, Luis talked about US versus worldwide coverage, generally universities only do US because the tech transfer office gets lots of inventions. They don't know which ones are going to succeed. And the real cost of patents goes up when you start filing internationally, because you have to do translation. So your patent has to be translated into French, German, Korean, Chinese and that's a very expensive proposition. And the patent can end up costing couple $1,000,000 to file everywhere and maintain. But from a company point of view you want it to be covered everywhere. You want worldwide coverage. So going back to the question of when to start a company, if you think you have something really hot. And the university has filed a PCT. You may want to start a company, and PCT is an international filing that then goes to what are called. Well, after PCT you then go through a national stage where you identify which countries you want to file in and you may want to start the company as soon as you follow PCT so that the company can raise money and have you file internationally and really have your invention covered worldwide, so that fits into the whole strategy as well.

CHRISTY SASIELA: Excellent. Our next question is “how do scientists typically find a CEO? I see most people having a former postdoc or grad student, but with clinical medicine we're mostly working with MD's whose post grad salary expectations are higher than most startups will tolerate and have earlier career practice and medical license needs.”

LUIS GUTIERREZ: Yep. So I'll, again start. The finding a CEO sometimes it could be one of your Angel investors. Having a post-doc is fine early on, but ultimately when you get to the investment stage asking for professional money you've gone through the Friends Family and Fools, and you've gone through the Angel groups. Now you're getting into professional investors. They often talk about, you know, betting on the jockey betting on the horse in this analogy, the horse is the technology.
The jockey is the CEO and the management team. And they're not looking for great scientists. They're looking for people who've done it before, which by definition, is not a first time CEO. It is the CEO who is as a person who's had leadership roles in pharma and biopharma firms in the past. Leading to at least CEO level role if not CEO. And knows intimately the business components of launching this product, whether the company is going to launch it themselves or is going to partner you, need to be able to really ascertain what's the business case. So that's the kind of person they're looking for. And

given that medical technologies tend to have a relatively short market life, right? You launch and you're whether it's your patent expires and or something better comes along, that's a five to seven-year ride. Which but humans have 35-40 year careers. You have a supply out there of experienced people who are now let's say in their 40s. Sometimes 40s, more likely 50s and 60s who are not yet retired, who are looking for the next technology. They're candidly going back to and looking for the next horse to ride. And so how do you find these people? Industry events. They sometimes find you because they're in search mode. You sometimes find them abiding their time, doing things like serving as an entrepreneur in residence, whether it was a university, a local biotech or a group like SEED.

STEPHEN WOLPE: Yes, I'll just add to that a couple things. First, if I understood the question, it the premise is wrong. You don't need an MD or a clinician to be CEO of a company that's developing a clinical product. In fact, you probably don't want that necessarily what you want is a really good business person. As, as Lewis said, you can have a chief medical officer who has all of those credentials.

LUIS GUTIERREZ: And it's probably part-time.

STEPHEN WOLPE: But that doesn't need to be the CEO. The purpose of the CEO is really to get out there and raise money. I mean, they'll also direct the course of the company, but that's in response to the Board of Directors. But you want a CEO who can raise funds and the other type of person you can look for are people who've not just been there and done that, but made a lot of money doing it. And many of them are people who you know are ex pharma or ex biotech. Who now want to get back and will serve as a fractional CEO or part time CEO or even full time, but just aren't expecting a big salary because they've already made their money, but they really like developing new drugs or they just want the experience their board of retirement and you don't want to start something new. A lot of them, a lot of them, a lot of them will be big pharma people.

LUIS GUTIERREZ: Or they do want big money. They don't want enough salary. No, you said they don't want big money. I would argue it's actually they might, but they know the salary isn't the way to get there.

STEPHEN WOLPE: Yeah, yeah.

LUIS GUTIERREZ: They want 5%, 10% of the equity on a billion dollar exit. The math works.

STEPHEN WOLPE: And the other thing that people don't think about that you really need to consider, especially if you're going to have a post doc or something is you're used to being in a university where you have benefits and you have healthcare and you have healthcare for your family. And once you're in the startup company, if you're full time in the startup, you don't have that anymore. You have to go on Obamacare. You know you have to pay for all the benefits that you're used to getting from your university. So that's something when you hire CEO, they need to be aware of, especially if you're a postdoc that not only aren't they getting a great salary, but they're also losing benefits that they may be used to in their previous position.

CHRISTY SASIELA: You just make that sounds so exciting. Like everyone should want to jump into that boat.

STEPHEN WOLPE: That's right. Yeah. So, it's the kind of thing actually that's serious. 90% of or greater of startup biotechs fail, and you know a lot of times the ones who succeed have failed three or four times before, and they learn from their failures. But it's not an easy road to start a biotech. And it's, you know you've got exciting technology and you believe in it and you want to develop it then. Start a company, but be aware that it's not going to be easy so that would be my advice is consider it carefully from both sides.

CHRISTY SASIELA: Very wise advice. Sound advice, indeed. We have a couple more questions. I'm hoping we can kind of run through them a little more quickly so we can get to most of them. The first question I'd like to just get one of you to respond to is "Can you file a PCT internationally if you have already filed in the US or will it be considered prior art?"

STEPHEN WOLPE: So prior art is something that's published. First of all, you never want to give a public talk an abstract, a paper before you follow your patent. So anything that's out there, I know you want this to be quick, but let me just explain what a patent is. So patent is a contract between an inventor and the government, and the inventor says I know something nobody else in the world knows. And the government says, well, we want you to make that public in order to spur additional innovations. And we'll give you 20 years exclusivity, if you're willing to make it public. But once it's public, the government has no need to do that. So, so anything that's published. Will be prior art if you file in the US it's not prior art, but if it's published then it is prior art. But generally, what you do is you file a PCT first. If you follow us. That's a good question. Whether you can, you can still follow internationally if it hasn't been, whether you can follow PCT. I'm not sure if you've already filed in in the US. You could abandoned that that file and follow PCT if it hasn't published. But it's not clear to me how that works. You'd have to check with a good patent lawyer. But the main thing is to make sure if you want to file a PCT that you don't have any public disclosure and if your patent hasn't filed.

CHRISTY SASIELA: So, Steve, you just mentioned that you should definitely not publish if you think you or even put an abstract out there or give a public talk. We have a question. "I have a molecule which has strong effect in in in vitro studies. But I don't have enough money to do in vivo studies unless I publish. What are my options?"

STEPHEN WOLPE: Again, patents. When I first started with patents, it blew my mind because it's the opposite of everything that you've ever been taught as a researcher. If you have one example, put it in a patent. You don't need to repeat it. You can do what's called hypothetical examples. So, you can actually write an example in your patent of how you would use it in vivo. You don't need data. What a patent does is it codifies your ideas. And so get a good patent lawyer, you don't need to have in vivo data to follow patent. You just need to have the idea and you need to describe it well. The other thing a lot of academics do is not understand the whole idea of a provisional application. A provisional application should be written almost as completely as a patent. So I've seen people just throw in a manuscript and call it a provisional. A provisional locks down the date of invention and it needs to be

properly done so talk to a patent lawyer. If you're going to file a provisional, or if you want to file something and then publish, the main thing is to get your idea submitted to the Patent Office before you publicly disclose it. If you have in vitro data and you know how to use it in vivo, you can file a patent and then you can go publish, do whatever you want, but just get it filed first.

CHRISTY SASIELA: Excellent. Luis, maybe you can help us with this next question. “What's the give and take of an early board member? Do they invest? Do they offer advice in their networks to grow the company? How does that differ from a scientific Advisory Board?”

LUIS GUTIERREZ: Yep, great question. Your early board is typically driven actually by investment. They are investors and they're almost expected to help you find other investors or a board of directors because it's a governance. It's governance over the company versus a scientific Advisory Board they're the ones giving technical advice. Your board members are there to give business advice, but the biggest business advice is where can I find money? And so your early boards of directors tend to be overwhelmingly tied to fundraising and the ability to do more.

CHRISTY SASIELA: And our next question, “I understand that investors do not like a case where two founders have 5-050 ownership as this complicates decision making. Is this true?”

STEPHEN WOLPE: Well, you have to distinguish ownership and decision making, right? So it depends on how it's set up. You can own 50-50 stock, but the way your company set up one of them can control, but aside from that, you know if an investor is going to invest, once they invest, it's no longer 50-50.

LUIS GUTIERREZ: Right. It's no longer 50/50. That's where I was.

STEPHEN WOLPE: I don't think it's a big issue, but you know it always depends on the investor.

LUIS GUTIERREZ: Yeah, equal shares, I don't think is necessarily a bad thing unless the investor looking at it says I can tell that's unfair and one of them's going to get pissed off. Because I can tell by looking, they're not actually doing 50-50. That's what might upset an investor, by the time the investor invests, it's by definition not 50-50 anymore.

STEPHEN WOLPE: Yeah.

LUIS GUTIERREZ: And in fact, even a small investor is the controlling vote.

STEPHEN WOLPE: Alright.

LUIS GUTIERREZ: Right, if they don't agree.

STEPHEN WOLPE: Yeah, yeah, it said. It actually puts an investor in a powerful position because even if they get 10% of the company and the other two end up with 45-45.

LUIS GUTIERREZ: In a very powerful position.

STEPHEN WOLPE: They're now, the swing vote as Luis said. So it's probably not to your advantage to be equal, but I don't think the investors should care very much.

CHRISTY SASIELA: There's a follow up question to that,"Can you invest in your own company beyond Founders stock or equity?"

LUIS GUTIERREZ: Yes. So, a founder can also make cash investments. Typically, the founder's equity is done as common stock. And most investors are going to want preferred stock once you actually get to stock. Once you're beyond safes and convertible notes. And the founder, like any other individual, can invest cash in the company additionally. They do it largely to signal just how committed they are.

STEPHEN WOLPE: Yep.

LUIS GUTIERREZ: Because they've already got the upside via the common. So it's really more of a, you know, I'm digging in my pocket too.

STEPHEN WOLPE: And actually, investors really like that if you have what they call skin in the game that you believe in your company and your invention enough that you're willing to put your own money in before you ask some investor for their money.

LUIS GUTIERREZ: Yep.

STEPHEN WOLPE: That's something investors really, really find attractive.

CHRISTY SASIELA: Excellent. "Are there any suggestions on how to negotiate with tech transfer to prevent dilution or some dilution of a company that you're founding?"

STEPHN WOLPE: You can try. I am doubtful that the university is going to agree to that. As Luis, said, the university has already invested in you, right? So, they paid you a salary, they've supported your lab. They've done all these things. And if you start a company, they expect to get some percentage. That's always negotiable. You know, as I said, there's the, the main thing, the tech transfer offices want in my experience, is to get their patent expenses recouped and everything else is sort of gravy to them because they know that most companies aren't going to succeed.

LUIS GUTIERREZ: Yep.

STEPHEN WOLPE: So it's all in negotiation like everything else. But generally, universities will want some percentage of the of the company.

LUIS GUTIERREZ: And typically it's a small percentage that's not terribly suffocating, because otherwise

you're literally, you know, you're drowning your own babies. And that doesn't make sense to them as long as they get their cash out of pockets covered and they've got some sliver on the upside.

STEPHEN WOLPE: Yeah.

LUIS GUTIERREZ: It doesn't. I've not seen greediness on the equity be the issue with universities.

STEPHEN WOLPE: Yes. Yeah, it's. It's usually substantially less than 10%.

LUIS GUTIERREZ: Yep.

STEPHEN WOLPE: But it just it it's all negotiation.

CHRISTY SASIELA: For our final question today, “Can you elaborate more on how founding scientists split equity into proportions considering past efforts? Is this time involved? What part of the science they created specifically, anything before the company was formed, or should it be focused on work commitments to grow the company?”

LUIS GUTIERREZ: Exactly. So where I was I was rejecting the premise of the question until you got to the last phrase because the work that led to it, it's important. It needs to be memorialized. It's the little part of the iceberg that's above the water. The hard work's the part below the water. To the 9/10. It's really about the going forward. So and that's not a bad analogy, 90% of the it's about who's doing it going forward. And certainly the person quitting their academic job to lead this thing gets the lion's share. And if the others don't like it, they're welcome to quit too. Right you want to do the work? Come on over. Oh, you want to keep your endowed chair and your benefits great. Those are two very different approaches. So, it's not about the past contribution, it's about the go forward contribution and responsibility and kind of on us to get it done. Because otherwise it's just a good idea. That was that was unmonetized.

CHRISTY SASIELA: Excellent. So we have just have just two minutes left and are there any final pearls of wisdom that you would offer our attendees to consider when or whether or not to form a company.

LUIS GUTIERREZ: Sure, I think we'll circle back to Steve's point about are you leaving signs to go in sales? Are you so committed that this meets a market need? That and you've done the research necessary to understand that this is superior to the current standard of care, superior to other approaches. It’s about market analysis. It's not about, oh, this is a nice, you know. It's a novel receptor target. Well, So what? What does that mean in terms of market adoption.

STEPHEN WOLPE: I mean, I would agree with that and just do your competitive analysis. Talk to who your end users are. You know, NIH has the I-CORP program (for NIH SBIR/STTR recipients). I've talked to clinicians with my brilliant idea and they just tell me why it would never work in the clinic. Get that kind of perspective, you know, really pressure test your idea before you start a company and know that

there's really a need for it and that it's going to pass a reality test. I think is probably the best advice I could give.

CHRISTY SASIELA: Thank you both so much, Luis Gutierrez and Steve Wolpe. You have been tremendous. You have shared so much with the audience today. Really appreciate the time and audience we participants. We appreciate your being here and the lively Q&A that we had going on. Have a wonderful remainder of your day.

LUIS GUTIERREZ: Thanks.

STEPHEN WOLPE: Thanks. Bye everyone.