

Health Care Beat: Episode 55 - Building the Future of Health Care: Innovation, Investment, and Impact

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Amanda Genovese

Welcome to Health Care Beat, a health law podcast brought to you by Seyfarth Shaw's cross disciplinary Health Care group.

Chris DeMeo

Each Health Care Beat episode focuses on key industry trends and legal developments while identifying practical takeaways for those dealing with these issues every day.

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I'm Amanda Genovese, a Seyfarth attorney in New York.

Chris DeMeo

I'm Chris DeMeo, a Seyfarth attorney in Houston. Let's get started.

On this episode of Health Care Beat, we'll focus on the realities of investing in early-stage Health Care companies and the key legal and strategic considerations that can set them up for success. And before we get started, we have a program note, our usual co-host, Amanda, is on assignment, as they say. So we have a very special co-host sitting in today, and that is Arnold Brown. He is a partner in our San Francisco office and a member of the firm's corporate group. Arnold, thank you so much for agreeing to co-host. And it is also Arnold who introduced the firm to Pier 70. So our guest today is Shaun Hawkins, Managing Partner at Pier 70 Ventures. Arnold and Shaun, welcome to Health Care Beat.

Shaun Hawkins

Well, Chris, thanks for having me. Arnold, good to see you again.

Arnold E. Brown, II

Yeah, thanks, Chris. And it's great to be on the podcast.

Chris DeMeo

So Shaun, can you tell us about Pier 70 Ventures and how long the company has been making investments in the Health Care space?

Shaun Hawkins

Sure, Chris. So Pier 70 has been around since roughly 2021. We started our fundraise for our first fund early that year. We had our first close mid 2022, and we started making investments fourth quarter of 2022. So currently we have 17 portfolio companies all within the Health Care space. And just to back up a bit, I love to brag about my team because we have a phenomenal team, three managing partners. We have a number of advisors. One of my managing partners who's based in Seattle on peer number 70, Miller Adams. I used to be the head of Phantomworks for Boeing and was investing in medtech for an aerospace company. And then my other partner, Dr. Preetha Ram, a PhD in biophysics from Yale, used to be the dean of sciences at Emory, is out there in Silicon Valley. And I'll give a little bit on my background, but I'm based here in Indianapolis. So we actually have the country covered from these three locations. We have advisors in the northeast and the southeast, and we invest across the country. But in terms of my background, I spent 15 years at Eli Lilly and Company doing licensing and M&A. And then eventually I started one of our fund to fund platforms, had the pleasure of being Lilly's Global Chief Diversity Officer. And then I became the head of life science private equity globally for Lilly. And so grew that platform to \$1.4 billion. We invested in funds, we invested directly in biotech companies, we spun assets out. And that was one of the coolest jobs I could ever have. And so we all bring our experiences to bear here at Pier 70, in which we like to invest at the intersection of innovation, execution, and impact. And we have built a firm that can deliver what we feel like are market rate returns while investing in founders who may be overlooked or in markets that have significant unmet need, but they're not necessarily part of traditional investment by traditional firms.

Arnold E. Brown, II

Shaun, having spent time inside a large strategic like Eli Lilly, the well-known pharmaceutical company, and now as a venture investor, what do you think early stage founders consistently misunderstand about engaging with big pharma or strategics?

Shaun Hawkins

So typically what I see, especially in Health Care with early stage biotechs and medtech in particular, is not only misunderstandings, but a bit of mistrust. They think these big pharma partners are potentially going to steal their IP, that they just want to get their insight and then, you know, figure out how to iterate around them. And at least my experience at Eli Lilly and Company, and for those that don't know Eli Lilly, you know, Eli Lilly and Company is one of the largest pharmaceutical companies in the world, a rich portfolio that includes oncology, diabetes, obesity, immunology, a rich neuroscience history. Most people know Lilly based on insulin. there if they have family members that had suffered from diabetes, if they have family members who've had depression and they know Lilly from Prozac, but Lilly's phenomenal company in firms like Eli Lilly, they understand the large development chain and supply chain and what's required to get an innovation and idea from idea all the way to the market. And so inside one of these large firms, right, a deal has to kind of maneuver through a handful of filters. scientific validity, there has to be portfolio fit, there has to be, and we're gonna talk about this

hopefully, but really good IP protection, which is the lifeblood of most of these companies. And you also have to understand that you need internal champions. A lot of founders believe, hey, if I just have a great technology, I'll publish on it and then they'll find me. But as you engage, you really need to understand who are the stakeholders, do those stakeholders have controls over budget, and do those stakeholders, or can those stakeholders be your champions? And I think once founders understand that, they actually can learn how to maneuver through the walls of a large firm like an Eli Lilly and company. I think the other thing is founders have to understand is once you engage, you have to deliver, right? Once you create a development plan or a go-to-market plan without, you know, extraordinary data that should cause you to deviate, you need to execute on your plan. You also need to make sure that you engage frequently, and engage honestly with your pharma partners. And then lastly, those partners bring tons of capabilities, right? They can clean up some of the errors if it's a therapeutic or a med tech. And let's say that though that innovation is not terribly optimized, they can clean up some of those inefficiencies. They can also help you develop an FDA appropriate data package and a commercially relevant data package. So make sure you leverage all of their capabilities. And then if your secret sauce and what your capabilities are are really mostly the research in the early parts of development, but you don't really have much in the way of commercialization experience, leverage big pharma or big medtechs commercial organizations. Try to learn from them. You may build your own shadow sales force, but leverage those commercial organizations. They're already in the accounts you're trying to see, they already have access. They've already done a lot of the hard work to build those relationships within that go-to-market approach. So make sure you leverage that and then ideally learn it if you're gonna build a going concern.

Arnold E. Brown, II

Let me go ahead and ask a follow-up question. Aside from the obvious things such as product development and revenue growth, what can startup companies do to improve their chances of getting funded?

Shaun Hawkins

Yeah, so, you know, I would say most of the time, Founders, and rightfully so, default to, hey, what's the product? And sometimes they think about traction. But in many cases, founders think, if I have a product or a potentially superior product, that that's all they need, right? And that's actually not, we've seen too many examples of superior products not actually making it to the market and inferior products being the market leader. The other thing, sometimes a founder knows so much about their own product. that they think it is significantly different than a lot of competitors. And at the end of the day, the end consumer just looks at, you know, the entire universe of those competitors as roughly the same and doesn't really understand the nuance. And so what we'd like to see in our founders is for them to have clarity on the uniqueness of the product, especially if we are investing in a medtech or biotech. Digital health, not so much, but in medtech and biotech, we need to see IP protection and we need to see IP that goes out for a decent amount of time based on whatever market that we're going in. And then that founder needs to be able to explain clearly, like 60 seconds. People always talk

about the elevator speech, right? And that's clear. You really need to be able to understand or be able to communicate what problem you're solving, why it matters, and why you're the team to do it. And if you can clearly do that, now you have our attention and you have the attention of a lot of venture capitalists. And I think the next thing you need to do is really clearly articulate that unmet need, especially in the medical space, right? As you can imagine, there's hundreds of assets being developed for cancer right now, hundreds of assets being developed in the endocrine space. So what need are you addressing that maybe others aren't? What are you bringing to the table? And then when we ask about your competitors, we better not know more about your competitors than you do. You need to be encyclopedic about everyone in the space and don't say that we have no competitors. There's nothing else like that. There is someone else out there doing something similar. The number of people who pitched some sort of variant of AI, whether it's voice or whether it's kind of a scribe and saying no one else is out there and I can do a quick Google search and find four or five other people doing it. Like that just never helps you. And so make sure you understand your competitors and then understand how you differentiate versus those. And then lastly, the team matters, right? Even if you're just an in of one, talk to us about the team you're going to build. And then we need to see if you also are going to be coachable or can we have this partnership where we talk about your potential growth together. We have to be able to integrate as a team on day one, because there's gonna be ups and downs as investors and as founders. They're gonna be tough times, and if we can't get along when times are good. Then we know when times get tough, we're going to end up losing value. And we're always looking for market asymmetry and we're always looking for ways to get alpha. And I think we have a great product that is addressing great need with great leadership. We're going to get that alpha.

Chris DeMeo

That's fantastic insight, Shaun. And I feel like I'm on an episode of Shark Tank. That's great. And I get the sense, and hearing your story that this is clearly not your first rodeo, as we like to say in Houston. So when you're dealing with early stage companies, given the significant risks that exist in the Health Care space, which may not exist in other industries, how do you not only navigate those risks, but potentially use those to your advantage?

Shaun Hawkins

You know, it's interesting, when it comes to risk, right, especially in early stage Health Care, it's not something you can avoid. It's something you try to sequence. You try to time your investment, whether it's tranching or whether you wait until you make your initial investment so that you can price it and so that you can get a return for that risk that you're taking because it doesn't go away and you either understand it or you pay for it. And so that's just, it's just part of the business, which is why a lot of people generally stay away from investing in Health Care. And if they do invest in Health Care, a lot of folks do not play in the space we do as it relates to biotech. And so as an investor, you need to understand your risk. And we break our risks down or we break risk down into a couple of categories. So it's our scientific or technical risk. It's the regulatory risk. It's

generally clinical. And then you follow on with reimbursement, manufacturing, and then agency or legal risk. But these are the areas in which we're looking. And they're balloons. So as we push and modify or manage risk in certain areas, we're probably giving risk in other areas, especially the earlier we invest. But we also know what we're doing. So just as an example, and my data are a little bit dated, but as you look at, let's say, therapeutic development, if I go from an idea to a drug that makes it to a market, I have a one in 10,000 probability. But if I focus roughly about a year or so to first human testing and look for an exit, which is, so we call that either candidate selection or IMD enabling tox. And if I go to phase 1A, 1B, which is human proof of concept, I generally have a one in four or one in five likelihood of at least having an exit. And so I'll take those probabilities all day, right? And as I'm investing, I'm investing in a portfolio. And in biotech in particular, You have one that hits, you actually return, you can potentially return your fund, but you definitely return all the capital that you invested in that basket of biotech. And so as an investor, I have to understand my risk. As a founder, you need to understand the risk and you need to understand what lens or lenses your investors are using to evaluate the risk that you're bringing to the table. And so, you know, we lean into complexity, but we like to understand it as much as possible. If something is knowable, we try to reduce our knowledge gaps and stay disciplined, right? And so we stay disciplined and when we come into a company. So if you're a digital health company, you need to be generating revenue. We need to understand who your customers are and your pipeline, and we will do our diligence to validate each of those. If you're a medtech company, we would prefer you to have your 510 or some sort of regulatory clearance already. So again, we manage some of that regulatory risk, that technical risk. But if not, roughly about six to nine months from filing, again, we reduce our regulatory risk and technical risk, and then we focus on commercial risk. And in biotech, as I alluded to, we focus on that area where we have about a 25% likelihood of success versus a one in 10,000 likelihood of success. And then we invest in four to five companies in that sleeve so that we can, you know, have portfolio style risk.

Chris DeMeo

That's very helpful insight. And it leads us to my next question is that we know, as you hinted at in your answer, there can be a steep learning curve unless you're in it. Like if you just are dipping your toe into the biotech, medtech waters, it can be much more difficult. And so. Can you tell us a little bit about how important it is that founders have a good understanding and experience with these regulatory frameworks and legal requirements that you were telling us about?

Shaun Hawkins

Sure. You know, it's absolutely critical, but not necessarily in the way that most people think, right? I do not need every founder to be a regulatory expert. You need to understand the regulatory environment. You need to understand what pathway you're on. Are you filing a BLA? Are you filing IND, 510K, PMA? Are you filing going to eventually have an NDA, like what are you filing, right? So you need to understand your regulatory pathway and be able to interact with the agency such that you increase your likelihood of having successful outcomes, right? So, and this is not a nice to have. So

we sit, we talk with our potential companies. If they've had interactions with the agency, we review those notes or those meeting minutes. So that's absolutely critical. But the great thing is there are a number of high quality consultants that are out there that can help an early stage company build a development program and a development pathway to increase their likelihood of success with the agency. And just like with IP investment, IP counsel, investing in that type of regulatory expertise can't be overstated. And so if you don't bring that knowledge, if you can't afford to hire someone full time, which most of our early stage companies, right, because we're investing in generally seed extension, series A type companies, they're generally not going to have a regulatory expert on staff full time. So you have to work with some of these consulting groups, right? And because the regulatory, in Health Care at least, affects your time to market. It affects how efficient our capital is being used. It affects the valuation inflection points that benefit both the founders, benefit us as investors, and then ultimately exit opportunities, whether that's through an IPO, whether that's through strategic M&A or licensing. And so, you know, what we describe as we evaluate founders is we grade them on their regulatory maturity, right? So we want to understand and they need to understand where the friction is. We want them to engage early. We will engage early with them. And we want to understand how they're building the right team to manage that level of risk.

Arnold E. Brown, II

Well, shifting gears a little bit to talk about something that you, Shaun, and myself, we've talked about many times from the standpoint of your portfolio companies. What role does legal due diligence play in your investment process? And specifically, does it come into play early as a core part of your evaluation or later once other factors are kind of laid out and established.

Shaun Hawkins

So for us, legal due diligence starts early, significantly early, because in Health Care, you know, we can't afford to deal with cleanup and it's core to our underwriting. And so we will engage on the IP due diligence side, we'll engage with our law firm. on the corporate due diligence side, but again, they're looking through a legal lens. And then also when there are licensing agreements. And that's where I think we as a firm also have secret sauce because we help companies, early stage companies renegotiate their licensing agreements with universities all the time and get them commercially viable. And I'll come back to that and explain why it's important. The other thing that I would tell your listeners is look at Safer Shaw because they're a great firm and we've enjoyed our experiences working with them. But when we're looking early for legal due diligence, IP ownership in that chain of title, again, is key because this is going to be the lifeblood of every biotech company, at least that we invest in, and the majority of medtech companies. But from a licensing standpoint, Many times we will see in a university originated licensing agreement that is very one-sided, right? Because you have a scientific founder that's just happy they got a couple hundred thousand dollars to actualize their life's work and to try to prove out some sort of scientific hypothesis. So now they're off to the races and they generally are not investing money in a lawyer, right? And going through and saying, is this licensing agreement the right thing for us? The other thing that gets in the way is, do you have the ability, whoever sub-licenses,

right, especially if you're a big pharma, big biotech, do I have the ability to freely sub-license, to freely subcontract? Because some of that is part of my know-how, and I don't want a university or someone else to necessarily know what I'm doing within my supplier development chain. And additionally, I am not gonna ask them for permission to do any of that, right? And so usually those things are in the agreements and again, they get in the way. The other thing that people don't understand is with big pharma and any multinational company, they're gonna have multiple affiliates and they're gonna move assets around and assign rights to those affiliates for tax reasons, for business reasons, for manufacturing reasons. And again, they need the ability to move those assets around freely without having to ask someone's approval. And so when something is coming out of academia, there's a license, usually between the tech transfer office and the scientific founder. They're not thinking about that, right? They're just saying, can I get this thing to the clinic? Can I get this thing ideally to patients? And they're not thinking about some of these other areas that will impact the value of their technology because it gets in the way of some of these big firms acquiring or licensing that technology.

Arnold E. Brown, II

Yeah, that's really good insight. And I think important for people to understand how important it is to actually look at the terms and be very comfortable with what the terms are for those university licensing programs. So that's phenomenal. And I have a follow up question, maybe looking at another part of the IP chain here, how important early stage companies' IP strategy for protecting their IP. How important is that to be in place when you're making your investment? I know you talked a bit about helping companies that don't already have that in place, but how do you see that as a key element of your investment decision?

Shaun Hawkins

Sure. From an IP strategy standpoint, I think a well-developed strategy is key. So at the beginning is, do you know what you own, right? And we're looking for founders who, you know, have intentionality, right? So what do you own? What are you trying to protect? And then being honest about where you have, let's say, vulnerabilities. And then let's think about this in the context of your overall asset development or your overall product development. So what new IP can be created, right? So if you're developing, let's say, a therapeutic, and your patent expires five years or three years after you are expected to get approval, you're not going to get much value for that. And you're probably are not going to get pharma interest unless it's a rare disease or there's just very limited competition. And so we need to think about, you know, do you have an IP strategy that includes composition of matter if it's a therapeutic, that is really your strongest IP protection in the therapeutic space. And that is something that most larger firms will require. But then we want to make sure you have, what's your strategy for creating new IP? What's your process patent strategy? What are your methods strategy? And are you developing a robust package so that you can create some patent or exclusivity extensions, right? And so that's where you add more value. Because just think about it, if you have one of these multi-billion dollar drugs, right? You have one of these drugs that are generating \$20 billion a year. Every year's worth of extension that you can add is a material impact to that larger company that is going to likely acquire licenses to their

bottom line. And so having that robust strategy, even though it's going to cost you some money upfront, it's going to add a lot of value and should create a nice financial exit for the founders and for the investors.

Chris DeMeo

Well, sadly, that is all the time we have for today. This has been great, Shaun. I really appreciate you joining us today and sharing with us your experiences and your insight on this process. It's been a pleasure having you here, and we'd like to thank you for joining the podcast. And to my co-host, Arnold, thank you for showing up and helping out on the podcast. We really appreciate both of you being here, and hope you have a great rest of the week.

Chris DeMeo

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