VOLUME VI

MEDSIDER MENTORS

LEARN FROM THE FOUNDERS AND CEOs OF LIMFLOW, FIELD MEDICAL, SINAPTICA, SPARK BIOMEDICAL, INTERSHUNT, AND MORE.

SCOTT NELSON

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INTRODUCTION

In the world of medtech, there's seldom a teacher better than direct experience. That's why I founded Medsider, to foster a community where we share knowledge and hard-earned insights. And thanks to the numerous interviews I've had with accomplished entrepreneurs in the space, I've gained invaluable lessons into the strategies and frameworks that drive innovation.

In Volume VI of Medsider Mentors, I'm thrilled to present another collection of candid interviews with medtech pioneers. They share the highs and lows of their journeys and the strategies across core functions such as early-stage ideation, fundraising, clinical and regulatory approaches, mergers and acquisitions, and more. If you're seeking inspiration, tactical advice, or simply a glimpse into the minds driving medtech forward, this is for you.

Ken Mariash, CEO of Sinaptica on Breaking Down the Startup Journey

Decades of experience leading healthcare giants like Boston Scientific – where he was instrumental in commercialization and strategy development in the company's $1B neuromodulation division – brought Ken Mariash to his startup, Sinaptica. Instead of developing pharmaceuticals, Sinaptica Therapeutics is tackling Alzheimer's with a device, a personalized brain stimulation therapy that's shown remarkable promise in slowing the disease's progression. Ken shares insights on how to break down the startup processes into baby steps, how to identify and bridge a company's gaps for M&A, the vitals for achieving successful commercialization, and the importance of communicating your mission in a simple and comprehensible manner so that your investors will champion it at dinner parties.

Daniel Powell, CEO of Spark Biomedical on Avoiding Unnecessary FDA Red Tape

Daniel Powell found his true passion in neurostimulation in 2006 and has since launched multiple products in the space for companies like St. Jude Medical, LivaNova, and Getinge. Since co-founding Spark Biomedical in 2018, he has been spearheading the development of the Sparrow Ascent, a wearable neurostimulation device designed to alleviate the devastating symptoms of opioid withdrawal. They have secured FDA clearance for multiple iterations of the technology and are expanding their applications to Neonatal Opioid Withdrawal Syndrome. Daniel talks about the value of early testing when validating product-market fit, diversifying funding sources, and working effectively with FDA.

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Carla Spina, CEO of Noa Therapeutics
on Cross-Pollinating in Medtech

Thanks to her expertise spanning chemistry, biochemistry, and pharmaceuticals, Carla Spina is equipped to tackle complex medical problems from multiple angles. As the founder of Noa Therapeutics, she's working to develop singular, non-steroidal, small-molecule therapies to wholly address the complexity of immune diseases. Carla shares her unique approach to drug development, how engaging with diverse stakeholders helps identify key milestones required for growth, and the importance of collaboration and fostering strong networks within the startup community.

Tess Cosad, CEO of Béa Fertility
on Iterating With the End-User in Mind

Tess Cosad, CEO of Béa Fertility, is a femtech expert with a fresh look at innovation. Driven by the difficult experiences of her loved ones, Tess is determined to transform the fertility landscape by offering clinical-grade, at-home treatments as an alternative to the often arduous traditional IVF route. Tess reminds us how innovation doesn't necessarily require scientific breakthroughs. Sometimes, simply enhancing the design and user experience of existing methods can give birth to successful products that offer compelling value. She shares her experiences building consumer-facing products, the key drivers of product design, how to optimize adoption through market positioning, and how to make decisions with imperfect information.

Patrick Anquetil, CEO of Portal Instruments
on Aligning Your Business with Potential Partners

With a PhD from MIT, an MBA from Harvard, and advanced degrees from other prestigious institutions, Patrick Anquetil's academic credentials alone command respect. But what sets him apart is his track record in taking medtech startups from concept to commercialization. Today, as the CEO of Portal Instruments, he's working on a needle-free drug delivery system with the potential to transform how medications are administered. Patrick shares how he navigated Portal's business model, the importance of rapid prototyping and accelerated timelines, and how to find and retain a diverse set of partners for your startup.

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Harlee Sorkin, CEO of InterShunt
on Ruthless Prioritization For Capital Efficiency

Harlee Sorkin co-founded a venture studio that has spun out eight medtech startups including InterShunt Technologies, led a successful company exit, and serves as an assistant professor focused on translating research into real-world solutions. Today, as the CEO of InterShunt, he's spearheading the development of a treatment for heart failure. The company's minimally invasive catheter system creates a shunt within the heart that improves blood flow and reduces cardiac workload. Harlee discusses his ruthless prioritization framework, why you should be raising friends instead of funds, and why you should be outspoken about your mission to different stakeholders.

Dr. Ananth Ravi, CEO of MOLLI Surgical
on Being Driven by Purpose

Ananth Ravi had to witness the difficulties of cancer treatment growing up in Zambia due to the loss of his best friend to treatable brain cancer. Years later, he found his calling for developing patient-centric solutions when he was working at Sunnybrook Hospital during a Patient Family Advisory Committee meeting where he listened to treatment stories from breast cancer patients. Today, as the CEO of MOLLI Surgical, Ananth is developing wire-free localization technology that dramatically improves precision and patient comfort during breast cancer surgery. Ananth shares his journey from physicist to medtech entrepreneur, why intuitive design trumps everything, and the funding sources you need to tap into as your company evolves.

Anish Kaushal, CEO Amplitude Ventures
on Career Transitions and Insider VC Perspectives

Anish Kaushal originally planned to be a physician but instead ended up an investor and writer. When he finished medical school, he went on a detour to find his true calling. After hundreds of cold emails, he discovered the world of venture capital and now plays a pivotal role at Amplitude Ventures, a leading Canadian healthcare VC firm. He's full of insights on fundraising, networking, navigating career transitions, and the power of persistence. We talk about how to craft the best pitch deck, how and why you should be proactive in fundraising, and the art of building strong networks.

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Dr. Steven Mickelsen, CEO of Field Medical on Being Creative in the Face of Scarcity

A professional musician turned electrophysiologist and entrepreneur at the forefront of cardiac innovation, Dr. Steven Mickelsen holds a unique edge. He has made some very important contributions to pulse field ablation (PFA) technology, notably through his previous company Farapulse (acquired by Boston Scientific). Now, as CEO of Field Medical, Steven aims to address the critical unmet needs of ventricular arrhythmias with the next generation of PFA technology. We discuss how to build creative but capital-efficient prototypes,the value of targeted expertise in both the clinical and regulatory domains, and approaches to fundraising that prioritize long-term value creation and win-win partnerships..

Benjamin Sexson, CEO of Monogram on Crowdfunding and IPOs in Medtech

First mechanical engineer, then business developer, and now robotics innovator, the CEO of Monogram Orthopedics, Benjamin Sexson, is dedicated to developing the first fully-autonomous robot for knee replacement surgeries. Benjamin talks about why entrepreneurs are particularly vulnerable to the cognitive bias known as the “sunk cost fallacy” and how to avoid it, his tested strategies for confident pivoting, his experience with alternative funding sources like crowdfunding and IPOs, and his approach to building an A-team and maintaining a feracious company culture.

Bill Snyder, CEO of Vivante Health on Finding Your Place in the Healthcare Ecosystem

Bill Snyder has tackled demanding leadership positions at major health companies like Humana. Yet, his dedication to innovation with a personal project on the side led him beyond a traditional corporate career. Recognizing untapped potential and a massive need in the digestive health space, Bill founded Vivante Health. Today, he leads the company’s efforts with their GIThrive digital platform, offering coordinated care for those who suffer from chronic digestive conditions. Bill shares insights on how to find your company's place in the healthcare ecosystem, how proving potential cost savings and positive clinical outcomes are a must to expand adoption, and advice on securing funding for your startup.

Ahmed Zobi, CEO of Syntr Health on Getting Even Leaner

Ahmed Zobi's background in biomedical engineering, microfluidics, and tissue engineering are all assets, but it was his ability to translate that expertise into action that truly sets him apart. As the founder and CEO of Syntr Health Technologies, he successfully turned a concept into a market-ready technology in an impressively short amount of time. Syntr's FDA-cleared SyntrFuge is the world's first automated microfat processing system, with initial applications in aesthetics and plastic surgery. We talk about how to embrace a leaner startup approach, how to build an MVP with an emphasis on functional minimalism, and funding sources like grants, accelerators, and other niche programs that might be helpful during the early days.

Dan Rose, CEO of LimFlow on Positioning for an Acquisition

Dan Rose successfully led his company, LimFlow, to a lucrative exit with Inari Medical as its CEO. LimFlow addressed a critical need in Chronic Limb-Threatening Ischemia (CLTI) treatment by developing an innovative rerouting system for blocked arteries. Dan's expertise, cultivated over 25 years in medical devices, offers a unique perspective on the entire lifecycle of a medtech company—from early-stage innovation to successful exit. We discuss the intricacies of managing the needs of multiple investors, why you have to design with the average user in mind, and the importance of understanding the reimbursement landscape early on.

INTRODUCTION

Marissa Fayer, CEO of DeepLook Medical
on Building What's Needed

Marissa Fayer, a medtech executive, entrepreneur, public speaker, and philanthropist, leads DeepLook Medical with a personal drive. A passionate advocate for women's health, Marissa brings decades of medtech experience to her role as CEO. DeepLook specializes in AI-powered diagnostic tools that specifically address challenges in detecting cancerous lesions within dense tissue. Marissa shares her insights on addressing a real problem and leveraging predicates, talking to stakeholders in an accessible fashion, her experience with accelerators, and the importance of seeking capital beyond a narrow niche.

Trent Reutiman, CEO of Mercator
on Readjusting Your Focus

Trent Reutiman, a medtech veteran with 25 years of leadership experience across various small and large companies, intimately understands the journey from concept to commercialization. At Mercator MedSystems, he champions the Bullfrog microinfusion system focusing on precise drug delivery for peripheral vascular disease with broader therapeutic possibilities. We delve into the balancing act between clinical and commercial efforts, explore how CEOs can reassess and shift their focus, and discuss strategies for protecting the integrity of a startup's technology.

Thank you for your continued support as a reader. I'm always open to your ideas and suggestions for future Medsider Mentors features, so don't hesitate to share who you'd like to learn from next.

Best wishes,

Scott Nelson

Founder of Medsider
Co-Founder and CEO of FastWave Medical

Shaping the Future of Alzheimer’s Care

Interview with Sinaptica CEO
Ken Mariash

Ken Mariash

Preview

Ken Mariash is a leading figure in the neuromodulation space and the CEO of Sinaptica Therapeutics, where his team is developing groundbreaking treatments for Alzheimer's disease. Their device delivers non-invasive neuromodulation therapy to key networks of the brain, and has shown unprecedented improvement in treating this disease. Ken shares his time-tested wisdom, covering a range of topics from kick-starting a venture and how to approach M&A transactions, to mastering commercialization and best practices for engaging with investors.

About Ken

With over two decades of experience in leading sophisticated organizations, Ken Mariash brings a wealth of knowledge and expertise to the table. His journey has taken him from management consulting at Charles River Associates to significant roles at CSL, Baxter, and Boston Scientific. During his time at Boston, Ken was instrumental in commercialization and strategy development in the company’s $1B neuromodulation division. Today, he’s serving as the CEO of Sinaptica, a startup making significant strides in Alzheimer's treatment.

Key Takeaways From Ken’s Experience

- Incremental, manageable steps toward your goals are a safer and saner approach. Consider which variables will add more value to your company’s current position and be maniacally focused on achieving those efficiently.
- An early-stage company will inevitably have some gaps, and it’s not easy to make a compelling M&A case when you have a lot of white space. If you’re aiming for an exit, be targeted. Identify a champion who will actively align your company’s unique value propositions against your target buyer’s needs.
- For successful commercialization, you need reimbursement, a flawless value proposition, a pitch that clearly shows the superiority of your data, and thorough market research.
- When raising funds, be simple enough so that your investors understand and can articulate your plan after you leave the room.

Shaping the Future of Alzheimer's Care: Interview with Sinaptica CEO Ken Mariash

Incremental Value Creation

Ken will tell you that unless you're Elon Musk, you likely have limited capital to work with when you first start a company. However, while some entrepreneurs like doing it all at once, Ken is all for creating incremental value in a sequential fashion.

In Ken's view, overreaching with limited people and resources or attempting to secure a massive round of Series A funding and trying to do too much with it is overly ambitious. Instead, he recommends being "maniacally focused on what's going to move the ball forward in the most productive way."

While successful capital raising is undeniably useful, money doesn't solve everything. Ken says, "I try to get a 10x return on every dollar I spend." The real challenge lies in identifying incremental steps that enable significant achievements with relatively modest investments, whether it's a proof-of-concept study, securing intellectual property rights, partnering up with hardware manufacturers, or recruiting key team members. Focusing on small, well-thought-out steps often leads to success without overwhelming the mission.

Clinical studies are the perfect field to apply this mindset. Medtech startups often grapple with designing clinical studies that maximize returns on multiple fronts. Ken likens this to solving a multivariate algebra equation, balancing regulatory requirements, reimbursement strategies, physician marketing, health economics, patient needs, along with other factors.

"It's all about balancing what's achievable versus what would be nice to have," Ken says. Ticking off multiple boxes with one study is lucrative, but it's unrealistic to expect to cover all bases in a single stride. Moreover, trying to do so — unless you have real leverage that works across multiple fields — almost certainly makes the study very complex and too expensive.

Ken's strategy redefines success not as a grand, singular achievement but as stepping stones leading to smaller victories. He prioritizes achievable, realistic goals over grand ambitions, focusing on generating substantial value with each step. This proven strategy is as realistic as it is pragmatic.

Conversations with Strategics

Ken has experienced firsthand on what makes a transaction succeed and what causes it to falter.

In the early stages, it’s natural to have some gaps in your operation. However, “Selling a concept that has a lot of white space is challenging,” shares Ken. To navigate this, it's crucial to align with your target acquirer's needs, leveraging your strengths accordingly.

For that, Ken recommends finding an internal champion who can effectively leverage your unique value proposition, whether it's commercial call points, specialized expertise in a therapeutic area, or technical product knowledge. The key is to focus on something that complements the existing strategy of your target company and aligns well with your existing strengths.

Surprisingly, the best champion for this often doesn’t come from the business development (BD) department. The BD team may assess and negotiate the deal, but you need someone within the strategic's division whose job will be actively selling it. This could be a marketing professional or even a product manager, someone who believes in your product's fit with their existing portfolio and is convinced they can commercialize it. Ken reiterates, “Obviously, you have to have a great story and a great pitch, but having an internal champion is what a lot of people miss.”

Ken also offers practical advice on the timing of M&A deals. Convincing a healthcare giant to invest R&D dollars into your project is quite a challenge. These companies generally aim to steer clear of ventures that might dilute their profit and loss (P&L) statements. If your company is too early in its development and requires heavy R&D investment, making a compelling case for it can be difficult. Ken suggests that the most strategic time to approach is when you're on the brink of pivotal data, thereby minimizing the burden of R&D.

And lastly, Ken recommends engaging with multiple potential buyers at once to create a competitive environment or a "bake-off".

While Ken's insights are invaluable for navigating the complexities of M&A transactions, finding a champion for your venture, and striking at the right time, it's also important to remain flexible and open to other avenues. As Ken points out, certain scenarios require a reassessment of your end goal. In some situations, companies grow too quickly and become too expensive for acquisition. So, if a company is growing exceptionally fast and has the potential for an IPO (Initial Public Offering), an exit via M&A might not be the best decision.

Shaping the Future of Alzheimer's Care: Interview with Sinaptica CEO Ken Mariash

The Four Pillars of Effective Commercialization

When it comes to commercializing a product, Ken breaks it down into four actionable steps.

First, reimbursement is crucial. Understand who will pay for your product and map out the route to secure coding, coverage, and payment. "Being able to do finger-painting exercises for investors to show the pathway to coding coverage and payment is absolutely critical," says Ken.

Secondly, you need a flawless value proposition. You should be able to explain why someone should buy your product in one compelling sentence. "If you can't answer that question in one line succinctly and powerfully, it's not a good value proposition," Ken warns.

The third piece of advice is about how you position data. Medical devices are developed in relation to data — whether it's from clinical studies, patient information from an implantable device or a wearable, or other patient reports. Ken says, "The data is always the enamoring thing about these new products, and yet if the insights aren't actionable, it's actually more of a distraction." Therefore, it's essential to not only collect data but also clearly define how the data supports your go-forward plans.

Fourthly, and perhaps less obviously, relates to the role of market research. While traditional market research has its place, Ken suggests a more direct approach: talking to sales reps. Engage with salespeople who have sold to your customer and patient segment and learn how they would position your product, how they would market it to physicians and staff, and ultimately, how it would be presented to patients. This real-world feedback is often more valuable than extensive market research. "Instead of spending hundreds of thousands of dollars on a research project, you can just talk to five really good sales reps and probably get more value out of that deliverable," Ken adds.

Shaping the Future of Alzheimer’s Care: Interview with Sinaptica CEO Ken Mariash

Simplifying Fundraising

When it comes to fundraising, Ken emphasizes the need for a plan that's not only great but is also simple enough to be easily understood and remembered, even over a casual dinner conversation. "Investors should be able to articulate your plan effortlessly to their partners at home. It's all about making it simple and digestible," he explains.

Ken also underlines the importance of answering the question: why now? In the world of investment, there's often a tendency to wait and see. To counter this, you must create a sense of urgency and movement. Ken recalls a lesson from a mentor, "We chase what moves." It's about convincing investors that the ground is shifting beneath their feet, that a megatrend is passing by and they have to decide right now whether to join or miss out. "That's crucial for gaining traction with your fundraising efforts," he advises.

While it's important to delve deep into data, especially in healthcare, Ken emphasizes the necessity of bringing investors back to the core, intuitive idea. After analyzing the data, remind your investors of the simple, key concept of why you're doing this. This is about hot cognition, where a straightforward idea resonates and draws people in, as opposed to cold cognition, which is getting lost in the data. “Coming back to that, it will stick in their mind, like a key that opens a lock,” says Ken.

In essence, if you can strike the right balance between detailed data and a compelling, simple narrative that sticks in the mind — while creating a sense of urgency and movement that compels action — you’ll set yourself up for a lot of interested investors.

Balancing Innovation with Practical Outsourcing

Interview with Spark Biomedical CEO Daniel Powell

Daniel Powell

Preview

Daniel Powell is the CEO of Spark Biomedical, developers of the Sparrow Ascent, a drug-free wearable device to combat opioid withdrawal symptoms. Daniel shares key insights from his journey: the importance of testing ideas and creating a MVP, diversifying funding sources, and how to make informed regulatory decisions.

About Daniel

Daniel Powell found his true passion in medical devices, specifically neurostimulation, in 2006 and has since launched multiple products in the space for companies like St. Jude Medical, LivaNova, and Getinge. Daniel co-founded Spark Biomedical in 2018, and he's since been serving as the CEO. Spark has developed the FDA-cleared Sparrow Ascent, a novel wearable device for treating opioid addiction, and is also advancing neurostimulation technology to address Neonatal Opioid Withdrawal Syndrome.

Key Takeaways From Daniel's Experience

- Let go of your ego and rigorously test whether you have product-market fit. Focus on creating a minimum viable product (MVP) and explore efficient ways to outsource design and development. In the earliest stages, keep your team lean and mean by relying on a few trusted consultants.
- There are many ways to fund a venture, and relying on only one of them is a risky strategy. Diversify your plan with grants, venture capital, family offices, and angel investors. And make sure to approach each potential partner in a tailored fashion.
- Navigating FDA involves jumping through numerous hoops, some of which you can avoid if you know how. Do thorough research, enlist top-notch consultants, and be ready to guide the regulatory reviewers whenever needed.

Balancing Innovation with Practical Outsourcing: Interview with Spark Biomedical CEO Daniel Powell

Optimize for Viability

In the early stages of a startup, objectively assessing the viability of your idea is key. “We were trying to kill the idea, but the doors just kept opening, and everything just kept working,” Daniel explains. “We were trying to reduce risk each step of the way and not spend money that we didn't have to,” he continues, summing up the keys to early momentum in a startup: being realistic, de-risking the venture at every phase, and managing capital wisely.

The first thing on your agenda should be determining what your minimum viable product (MVP) looks like, with a focus on the ‘minimum.’ While it's tempting to dream big and incorporate every impressive feature into your product, it often leads to unnecessary risks. For instance, “Sparrow not being an implantable product but a wearable, that made life so much easier,” Daniel emphasizes.

In Sparrow’s case, the initial idea included Bluetooth functionality for data collection and analysis as well as other user experience features. However, the Bluetooth feature brought with it regulatory complexities related to HIPAA and cybersecurity. The team made a decision to omit it entirely, at least during the early stages. “Incorporating these aspects would have put massive risk on the project on the FDA clearance front,” Daniel explains. “It wasn’t an absolute necessity. It could be in phase two.” If you get a Sparrow Ascent now, it will come with wireless diagnostics via Bluetooth connectivity, but this feature wasn’t part of the early versions by intention.

Daniel's second piece of advice, in line with his lean startup methodology, is to put all your pride aside. It’s tempting to build an operation where you have complete control over every aspect, but it’s not always the most efficient way. Owning the entire manufacturing chain, a warehouse, all the infrastructure, and employing a large staff can quickly deplete resources.

Outsourcing, even in critical areas like R&D, can prove to be the smarter choice. The only key asset Daniel holds dear is his collaboration with Spark’s CTO, Alejandro, a tenured senior neuro engineer who was critical in leading the development processes.

With this efficient model, Daniel was able to pursue quick hits, which led to early wins. “What I was looking for each step of the way is checking the necessary boxes to proceed to the next level — the next level of valuation, the next level of capital,” Daniel shares. Demonstrating the ability to execute quickly was particularly useful in raising future capital.

Balancing Innovation with Practical Outsourcing: Interview with Spark Biomedical CEO Daniel Powell

Go Broad with Grants, VCs, Family Offices, and Angels

Despite their demonstrated efficiency and experienced team, Daniel admits Spark Biomedical did hit a major roadblock — they almost ran out of money. Luckily, it didn't sink the ship, but turned out to be a great lesson in the end. Daniel shares, "I'd been very successful at raising money and just got complacent." Then, several large potential investors fell through. But being a CEO means you have to keep steering the ship toward the light. He recounts, "I sat there and said to myself: 'I am going to give myself permission to panic today, and then tomorrow, I'm going to work on the problem.'"

Daniel's takeaway for fellow entrepreneurs is straightforward yet rings true: "The one thing I can guarantee every entrepreneur listening to this is everything will take longer, and everything will cost more than you planned, period. Just operate on that as a truism."

With that in mind, there are a few ways to fund a venture, such as grants. They do bring along a few benefits, like non-dilution and added credibility. However, Daniel doesn't see them as the primary financial lifeline for his venture but as a complementary strategy.

"If you're building your business off grants, timelines are going to be horrific. You're rolling the dice, and even if you win, you're going to have to wait for the grant to be awarded and then for the cash draw. It's a nine-month waiting period before you can effectively start," he explains. Yet this doesn't mean Daniel and his team completely deprioritize grants: "We've been very successful at grants and DoD contracts and have been awarded about $17.5 million in non-dilutive funding in the first five years. Navid and his team are grant-writing machines," Daniel adds.

Despite Spark's success in raising a substantial amount of non-dilutive funding, Daniel admits his initial lack of understanding of the difference between investor types like angels, high net-worth individuals, family offices, and venture capitalists was a hurdle he needed to cross. You can't pitch them in the same way, because VCs, for example, are a completely different species in the ecosystem. Instead, Daniel recommends, "Don't let one of your first pitches be the critical one you need to land." Allow yourself the space to learn and adapt.

Daniel offers a golden nugget of advice for dealing with professional investors: "In hindsight, I should have introduced myself to every VC possible over the course of a year, put them on a mailing list, given them regular updates every quarter, become familiar, become an everyday brand that they're watching, and then say: 'Hey, everybody, I'm going to open a Series A, who wants in?'" It won't work with every investor, but when it does, it's an excellent approach for drumming up competition and interest.

Balancing Innovation with Practical Outsourcing: Interview with Spark Biomedical CEO Daniel Powell

Understanding FDA: It's Not Black and White

Daniel's journey with FDA was far from straightforward. He puts it candidly, “They're not bad, they're not good. They're just people.” This human element means facing inconsistencies and personalities in your engagement with the agency, which means they might not always follow the procedures you expect.

“They operate in a massive bureaucratic world where it’s often safer to say ‘no’ than ‘yes,’” Daniel explains. Given that FDA's primary role is to safeguard public safety, its risk-averse nature contrasts with the typical entrepreneur's mindset. To navigate this, Daniel emphasizes you have to prepare thoroughly and sometimes even guide them in the right direction. This means being ready to prove that any minor issue they find is not a societal risk.

Daniel is candid about ensuring that you don’t underestimate the regulatory process. The path to compliance can be muddled, and the benchmarks are not always clear. For instance, Spark faced a unique challenge in passing a biocompatibility test, which wasn't a requirement for other class II wearable manufacturers. Daniel’s takeaway is straightforward: When it comes to regulatory approval, you can’t just wing it. You have to have experienced consultants and knowledgeable people on your side, but even then, you should brace for challenges.

Another insightful piece of advice from Daniel is about the importance of clarity in pre-submission meetings with FDA, which you’ll likely have several of. It’s crucial to make every detail crystal clear to avoid any minor misunderstandings, which can potentially ripple into bigger problems later on.

When it comes to ensuring his cross-functional team is fully aligned, Daniel is proud of his group. “I've really got this fun journey of observing a first-class clinical team go through the planning phase and include the business folks too,” he shares. In the past, as Daniel humorously notes, “Marketing was part of the dirty, nasty people who made money selling stuff and shouldn't come anywhere near the purity of science.” But for a medtech entrepreneur, merging these spheres is essential. Your clinical and business strategies should work hand in hand so that you can insert certain claims in clinical trials to “help sell the story.” This also means that you need to be cognizant of who you’re getting advice from when setting up your clinical trials, about which Daniel warns, “If you get a bunch of academics running your clinical show, your company values will likely be misaligned.”

Building a Startup in a Collaborative Ecosystem

Interview with Noa Therapeutics CEO
Carla Spina

Carla Spina

Preview

Carla Spina is the pioneering force behind Noa Therapeutics, where they are developing treatments for inflammatory skin diseases with their innovative multimodal small-molecule therapies. Carla shares her invaluable experiences on the importance of engaging actively with the startup ecosystem and staying connected with those who are shaping the field. We talk about how building a company is a collaborative venture that requires a strong network of entrepreneurs, investors, and industry experts, and the significance of authentic interaction when reaching out to a variety of potential stakeholders.

About Carla

Carla Spina, CEO of Noa Therapeutics, began her academic journey at the University of Calgary in the fields of inorganic and analytical chemistry, and continued with a Ph.D. in Bioinorganic Chemistry at McGill University. After going to BASF in Germany to develop pharmaceutical formulations, Carla returned to Canada and led the development and global commercialization of antimicrobial wound care devices. Currently, she spearheads Noa Therapeutics, a Canadian biotech firm that is transforming how immune diseases are treated.

Key Learnings From Carla's Experience

- Being capital efficient during the early stages is both about where you spend the money and where you secure it. Engage with your ecosystem to validate your idea and to get as close as possible to those who are already in the field and looking to collaborate, such as startup incubators, academics, and accelerators.
- Building a company is not a solitary endeavor. The key is to actively seek help, share ideas, and learn from others. This approach not only helps to validate and refine your ideas but also expands your network, which is crucial for long-term success.
- Reach out to a wide range of potential investors and stakeholders as you never know where funding opportunities may arise. Build strong relationships and seek advocates in your space by being authentic and genuine in your interactions. At the end of the day, talking to as many people as possible is crucial.

Building a Startup in a Collaborative Ecosystem: Interview with Noa Therapeutics CEO Carla Spina

Engage With Your Ecosystem for a Capital-Efficient Start

In the early stages of a startup, aligning your vision with the needs of key stakeholders, such as patients and healthcare providers, is not just about meeting market demand but also about efficient capital use.

It's easy to fall into tunnel vision when you're passionate about an idea, but you need to ensure that your vision resonates with the wider community. "The month I opened up the company last summer, I spoke with four patient advocacy groups to validate that the need I saw was real and widespread," Carla explains. She approached sophisticated investors and industry partners, not only to validate the value of Noa's work but also to understand the key milestones required for sustained financing and growth.

Another cornerstone of capital efficiency is to engage with a diverse array of funding sources. Carla is vocal about the invaluable support she received from various ecosystem partners. She highlights organizations in her region, Ontario, like the Ontario Biosciences Organization, Life Sciences Ontario, Ontario Centers of Innovation, Canadian Entrepreneurs in Life Science and incubators like the Biomedical Zone. “These are all really excellent programs that have been ideated by founders and operators or ecosystem partners who have supported us along the way,” Carla shares.

When you’re operating on limited cash, even the smallest grants count, such as the $25,000 from the Business Skills Development Program Carla had secured. Though modest, it was pivotal in improving the skills of her team and herself. “Not only did it enable me to identify mentors in this space and connect with the greater ecosystem, but it also gave me the skills that I needed to start Noa,” she shares.

Building a Startup in a Collaborative Ecosystem: Interview with Noa Therapeutics CEO Carla Spina

Your Startup Will Take a Village

When Carla got invited as a keynote speaker at McGill to give a speech on funding a company, she had another plan in her mind: show, not tell, how to build a company. Rather than delivering a traditional speech, she turned the event into a collaborative forum, inviting an incubator program, early and late-stage investors, and even an IP strategist from her law firm.

The purpose of this was to illustrate that founding a company is just the start of a long journey. Her presentation also connected students with those who can help them thrive in the ecosystem. “I wanted the students to understand that this isn't something that you do alone — it takes a village,” Carla shares.

“You will meet amazing people in your life, and those amazing people will extend their network to include you,” she shares. “And when you ask who you should meet and who you should be connected with, who can help you along your way, they'll connect you with other amazing people,” Carla shares. In her philosophy, no one should ever develop ideas in isolation. It limits your perspective. “If you have an idea, discuss it with 20 people. Not only will you validate its novelty and utility, but you'll also be building a network for the future.”

Seeking assistance is a vital part of the journey. "If you ask for help, you generally receive it," she shares. You need to step out of your comfort zone to solicit advice and guidance. Carla, an introvert by nature, understands this challenge. "I didn't talk much for the first 17 years of my life. Learning to reach out and ask is a skill that anyone can develop,” she emphasizes.

It’s not only external support, too. Carla also speaks passionately about the power of peer networks, especially as a female founder. “Our board is 67% women, 100% female-founded and led. We have an incredible peer support network,” she shares. She credits the Women in Health Initiative led by the Ontario Innovation Organization for not only providing early funding but also for creating a strong network of female founders and executives. Carla candidly admits, "beyond the financial aspect, this network has been a pillar of mental support throughout our journey."

But Carla’s philosophy isn’t just about asking. Noa is actively planning to open its doors for mentorships and internships, particularly focusing on young women in STEM. "We want to pay it forward," she says. "Sharing our knowledge to help cultivate the next generation of scientists and innovative leaders is really important."

Building a Startup in a Collaborative Ecosystem: Interview with Noa Therapeutics CEO Carla Spina

Conversations as Currency: Fundraising and Market Insights

At the end of each fundraise, Carla and the team go through a postmortem to see what they learned in retrospect. After closing they oversubscribed their first round, Carla shared confidently that the key lesson learned is simple: **talk to everyone!**

There's a balance between operating in stealth mode and vocally seeking assistance. "You never know where money is going to come from, so don't wait to reach out," Carla advises. Noa was bootstrapped for the first six months, relying quite heavily on non-dilutive funding. The company filed its first provisional patent before the team made a move on fundraising, ensuring they were in a strong position to engage investors.

Still, Carla's advice is to begin the process of raising funds as soon as you can. Be in constant communication with your potential investors. "If an investor doesn't have any funds available, if they are dry or if they just aren't deploying capital at the moment, ask them, 'If you're not the right person, then who is?'" advises Carla.

Raising capital is a numbers game, but it's also about relationships. For example, Carla's friend of 20 years, and an investor in the company, played an important role leading them through Noa's first six months. "It was very much relationship building and getting people to know you as a person," Carla shares.

In her experience, having champions who'll put in a good word to other investors in the ecosystem, was absolutely beneficial. However, a good relationship is not something you can fake, or something you can simply check off a list. It takes being authentically honest, open, cooperative, and proving yourself as a reliable partner in the industry.

By maintaining open communication channels with all stakeholders, the team at Noa gained insights into competitors' products, challenges, and failures. They cast a wide net and gained insight into the development pathway as well as where they should stand to have an advantage in the market.

However, she advises, "Don't take everyone's opinion as written in stone." You need to be able to weave together different perspectives to create a more robust and resilient business strategy.

Carla's parting advice on fundraising is succinct yet powerful: Don't be afraid to set ambitious goals. "Regardless of whether you're fundraising for a million dollars or 100 million, it's the same amount of work. So aim high."

Taking the Stress Out of Conception

Interview with Béa Fertility CEO

Tess Cosad

Tess Cosad

Preview

Tess Cosad is a femtech enthusiast and the CEO of Béa Fertility. Founded in 2020, Béa offers innovative, hormone-free, accessible, at-home fertility treatments and ovulation tracking as an alternative to traditional clinic-based offerings. Their flagship product simplifies the fertility journey thanks to its user-friendly design. Tess delves into the challenges and triumphs of launching a consumer-facing product, the importance of a solid design team, how to be comfortable making decisions with imperfect information, and the lessons she learned about being a CEO while raising funds.

About Tess

Tess Cosad is the co-founder and CEO of Béa Fertility, a startup specializing in at-home fertility treatments and ovulation tracking with the goal of providing an effective and affordable alternative to IVF. Prior to Béa, Tess founded Emberson Ventures, a B2B marketing agency, and Hers By Design, a femtech company. She was also the first woman to lead a digital marketing-focused accelerator program in Saudi Arabia.

Key Takeaways From Tess's Experience

- Prioritize design, especially if you are targeting the consumer market. Be as simple as possible. Don't leave room for your audience to infer or make assumptions about your product. Position and frame it strategically to your target audience.
- Keeping your initial team lean and agile is a great advantage. However, it's crucial not to overlook instrumental roles. Missing key players in pivotal functions can lead to various delays across the entire business.
- Fundraising is a numbers game, and it doesn't get easier as you progress to larger rounds. But repeating and refining your pitch countless times allows you to clarify your company's mission and clearly communicate the opportunities ahead.

Taking the Stress Out of Conception: Interview with Béa Fertility CEO Tess Cosad

Designing With the User in Mind

Innovation doesn't necessarily mean creating new technology from scratch. For Béa, it meant reviving an old clinical method and making it accessible to consumers with a focus on improved design and user experience.

Tess reveals, "Our first hire was a UX researcher and designer. So right from day one, we prioritized user experience." While there's a technological aspect to Béa's device, the focus isn't solely on the engineering. "Once the mechanical aspects were set, our attention shifted to continually enhancing the user experience — a process that doesn't stop even after the design freeze and the start of manufacturing," Tess shares.

The journey of perfecting Béa's device involved extensive user research. In the earliest stages, Béa's UX researcher conducted human factor (HF) studies to assess how people interpreted instructions. This was just the beginning of a journey through 16 HF studies, involving 90 different print prototypes of the device. The goal was to achieve a design that was ergonomically easy to use, both individually and with a partner. Tess shares, "There isn't an iteration of the product that's been shipped out the door to a user that I haven't personally tested or where we haven't obsessed over the instructions for use first."

When you're introducing a medical device, especially for at-home use, simplicity and intuitiveness are key. Tess explains, "There's a human on that side of the experience and they're treating themselves. So they're probably a little nervous. You need to make it as simple as possible for them to understand what it is that you're selling."

Secondly, when you're going straight to the consumer, you need to position your product in the market in a way that properly communicates its value. Figuring out where it fits in the market was a crucial part of Béa Fertility's strategy. Tess had two options: placing Béa alongside at-home insemination kits, or having it stand as an alternative to the traditional fertility clinics. This decision would not only define Béa's market segment; it would also establish how people would perceive and value Béa's offering. Tess opted for positioning the product as an alternative to the professional fertility clinics, because otherwise, they would have to compete against bottom-dollar syringes on Amazon, while Béa is deeply devoted to the user experience and customer support.

In summary, when developing a consumer-facing product, try to keep it simple. Don't leave room for your audience to infer or make assumptions. Show them exactly what your product is and what to compare it with. Ask yourself: what is the context you're framing your product within? Who are your competitors, and how do you stand apart? By clearly guiding your audience's understanding, you can shape all subsequent decisions — like what marketing channels and methods to employ as well as which pricing strategies work best.

Making Decisions With Imperfect Information

Since the early days, Béa has operated with a small, yet focused team. “Having a really core, tight team for the first few months that was ruthlessly focused on design, user experience, and validation was a really good strategy,” says Tess.

When looking back at the company’s journey, Tess acknowledges that quicker decision-making would have been beneficial. “We often had a tendency to want to absorb the data and to sit on it. We were a little bit slow sometimes to really move on some of the key insights that we learned,” she shares. This was partly due to the team's initial lack of medical device expertise, leading them to rely on external consultants. “To have that expertise a little closer to the team, maybe even on the team, probably would have helped us move quicker,” Tess shares.

Another thing Tess reflects on is the timing of their engagement with the FDA, which resulted in unnecessary complications and delays. She thinks they should have approached the FDA with a clearer path in mind with specific questions, rather than seeking guidance on the path itself. Looking back, Tess shares that if she were to do it all again, she would have brought on a regulatory advisor as soon as possible. Having someone who’s familiar with regulations but also deeply familiar with your product is crucial to ensuring a smooth regulatory path.

Today, Béa still has a small, but better-rounded team. “We have one regulatory person and one quality assurance person. But we have a network of consultants who know us well, who we leverage when needed,“ Tess shares.

However, there’s a more nuanced lesson to learn here. As a CEO, your job is making swift decisions with imperfect information each and every day. Tess reflects, “Sometimes, I absolutely wish we trusted our intuition and moved quicker because as a team, our gut instinct is pretty good. And in some instances, I have no regrets for taking the time we took, because we ended up getting to a better place.”

You can’t obsess over each decision — you are bound to make some incorrect choices. “The point of making decisions is to move forward, to course-correct, and to learn. And if you can do those three things over the long arc, you will get to where you want to go,” she says.

Taking the Stress Out of Conception: Interview with Béa Fertility CEO Tess Cosad

Fundraising Never Gets Easy

A venture capital-backed startup, Béa recently achieved a significant milestone by raising around $3 million.

Leading up to this point, the pre-seed round was a journey of persistence and resilience. Tess recalls, "It took me 284 conversations to raise that 475k." If you follow mainstream media outlets, you often hear about founders securing multiple term sheets in days. However, fundraising, especially in the pre-product stage for a consumer-facing medical device, is incredibly challenging.

As a first-time entrepreneur, Tess lacked both a network and experience in raising capital. Starting from scratch, her approach was as low-tech as it gets: a Google search on where to find angel investors in London.

Fundraising, Tess explains, is more than just securing capital, "90% of the time, you're presenting to investors that are forcing you to crystallize your vision, understand your target audience, and recognize the opportunity that lies ahead." It can be arduous, but fundraising is invaluable for shaping a compelling narrative and gaining a deeper understanding of the business.

For their seed round, Tess had to network extensively again because the contacts she made during the previous round weren't in a position to invest. She found that fundraising doesn't get easier with time. As the company progresses, you need to raise for a different stage. In Tess's words, "The goalposts are moving as you do."

Amid these challenges, Tess emphasizes the importance of being selective with investors, especially for a VC-backed company. "The biggest lesson between the pre-seed and seed rounds is the realization that where the money comes from matters. It's crucial to be discerning," she advises. You need partners who truly believe in your product and support the vision of the company.

Why Learning Fast Beats Failing Fast

Interview with Portal Instruments CEO
Patrick Anquetil

Patrick Anquetil

Preview

Patrick Anquetil, CEO of Portal Instruments, has extensive experience in guiding bioengineering companies from their nascent stages to market success. At Portal, they are developing a novel needle-free drug delivery system. This cutting-edge technology promises to revolutionize how medications are administered, making the process less invasive, more precise, and more comfortable for patients. Patrick talks about how he landed on Portal's business model, how his team condenses timelines across key company functions, and why their diverse set of partners is a golden asset to the company.

About Patrick

Patrick Anquetil, CEO of Portal Instruments, brings over 20 years of experience leading bioengineering companies from concept to commercial success. Prior to Portal, he co-founded two medtech startups, SynapDx and Aretais. Patrick holds a doctorate in Mechanical Engineering from MIT, and advanced degrees from Harvard Business School, ETH Zurich, and the University of Tokyo. His scientific achievements have been featured in top journals and media outlets such as MIT Technology Review, Wired Magazine, PBS, and CNBC.

Key Learnings From Patrick's Experiences

- Your business model might take time to develop. Until you find the best route, follow the incentives, seek partnerships with those who have both the resources and a tangible need, stay adaptable, ready to pivot when necessary, and network extensively.
- Focus on condensing timelines and being practical in every aspect of your startup. Adapt rapid learning and iterative development. Invest in resources that allow your team to quickly turn ideas into prototypes, fostering a culture of nimbleness and risk-taking.
- In medtech, the right collaborations are golden. They bring more than money; they offer insights, resources, and access to new markets. Mix it up with your partners — think big corporations, venture capitalists, and other relevant players. Every collaborator has their own agenda, so stay flexible and find a sweet spot where your goals align with theirs.

Why Learning Fast Beats Failing Fast: Interview with Portal Instruments CEO Patrick Anquetil

Follow the Incentives

Portal's business model revolves around partnering with pharmaceutical companies. Patrick explains the thought process behind it, "Who's got the money? It's not the patient. Even if they have it, they typically don't want to pay for it. On the other hand, in our case, pharma companies not only have money but also have drugs that need to be injected."

Partnering up with pharma, although it looks obvious, wasn't a decision Patrick made in a snap. As Steve Jobs once said, "You can only connect the dots looking backwards." He explains, "You've got a platform technology; you could do anything. How do you actually select the right application?" The possibility of the pharma route was a realization that dawned on Patrick gradually over the course of 2 years. He shares, "It typically takes two years to figure out what the business model is. That was also the case with my previous company, SynapDX."

Yet, this time frame doesn't mean you passively wait for clarity. Patrick emphasizes the importance of being part of a greater whole, "Make sure you're part of an ecosystem where you contribute value as well. And if that value is significant, then you can actually capture some of it back."

Two key realizations played a big part in the team's decision-making process. First, they realized that the financial structure with pharma could include royalties, upfront payments, and milestone payments — similar to the financial structure for formulations. Second, they recognized the value of injections, especially expensive ones. This provided them with an opportunity to recapture some of that value, whereas with commodity injections, the chances of recapturing the upside would have been slim due to the smaller margins.

However, working with the pharmaceutical industry has its ups and downs. While pharma companies have substantial funding, their processes can be incredibly slow, as the franchise companies are extremely risk-averse. Still, despite the slow pace, Portal has several development programs with pharma companies with a product launch on the horizon.

Patrick's advice to budding entrepreneurs is grounded in his experiences, "Talk to as many people as you can." The process of establishing a business model is iterative. Early and frequent conversations are vital in understanding the true value proposition. "It's not obvious and it never is," he concludes.

Why Learning Fast Beats Failing Fast: Interview with Portal Instruments CEO Patrick Anquetil

Condense Timelines, But Be Practical

Medtech startups face a multitude of challenges: unproven technology, uncertain markets, lean resources, and well-funded competitors. "Everything is stacked against a startup," says Patrick. That's why effectively using time through rapid learning and iterative development is crucial.

Portal has structured its development cycles to be as efficient as possible. Patrick explains, "To really know if your design works, you need to build it, test it, and then proceed to the next phase of development." This approach requires an environment where engineers can quickly turn their ideas into prototypes. By investing early in comprehensive in-house capabilities, including a full machine shop with 3D printing and laser cutting, Portal ensures that its engineers can swiftly iterate their designs and best leverage their capabilities.

Some entrepreneurs swear by a completely outsourced model. Although that approach can work, Patrick points out the hidden costs of outsourcing, even when it's relatively fast. "If you're going to take a week to get your part back, you're going to be more conservative," he emphasizes. Having the capacity to create and test parts within hours fosters a culture of nimbleness and risk-taking within Portal.

The mindset of condensing the timelines is not only applicable to engineering but also to finance, marketing, and commercialization. Patrick advocates for a 'learn-fast' over a 'fail-fast' approach. "If you know the answers are at the end of the book, why read the whole book? We don't have time for that," he explains. Simplicity and common sense, he believes, are key in decision-making as a CEO.

Why Learning Fast Beats Failing Fast: Interview with Portal Instruments CEO Patrick Anquetil

Partners Can Carry You Forward

Patrick is a veteran in raising funds. However, when he first joined Portal, he admits being too optimistic about raising $20 million in two months — he soon found that it takes over a year. Securing venture capital, especially in high-stakes sectors like medtech, is an unpredictable plunge.

"Without partners, the company would not exist," Patrick puts bluntly. Portal's beginnings were deeply intertwined with its first partner, Sanofi, whose investment in MIT research laid the foundation for the company.

Then, the decision to bring on more strategic collaborators was a critical move. Patrick views partnerships as essential, not just for practical reasons, but as a fundamental aspect of building a successful company. "Having partners forces you to recognize that you cannot do it alone. You need partners to actually go in, which I think is true for every possible thing about the human experience. No one's ever done anything alone. It's the same thing with companies," Patrick says. Having partners also forces you to be mindful of their priorities and see the value in interests beyond your periphery, and that, in Patrick's words, "creates opportunity."

Portal's array of partners and investors is diverse, ranging from large corporations like Sanofi to the venture capital firm 5AM Ventures, an industry conglomerate like 3M, and other companies like Takeda and Gerresheimer. The integration of each of these organizations was strategic to Portal's specific needs at particular times.

Having a diverse array of collaborators is not easy. You have to understand what each of them wants, be it technology access or solving a particular problem, as well as how much they are willing to invest. It requires some room for adaptability. However, it was this diversity that allowed Portal to secure significant capital, vital for continuing its journey and achieving the company's goals.

Think Big, Start Small, and Prioritize Ruthlessly

Interview with InterShunt CEO
Harlee Sorkin

Harlee Sorkin

Preview

Harlee Sorkin's company, InterShunt Technologies, is leading the development of a groundbreaking minimally invasive catheter designed to treat heart failure. The technique they use focuses on creating a shunt within the heart. By improving blood flow and lessening the heart's workload, it holds promise of easing heart failure symptoms, potentially setting a new standard in patient care. Harlee delves into the nuances of leading an early-stage medtech company and covers essential topics such as development prioritization and capital fundraising. He also shares what it's like to navigate clinical and regulatory challenges as a first-time medtech entrepreneur and how to effectively engage with stakeholders across the healthcare ecosystem.

About Harlee

Harlee Sorkin, is a co-founder of Common Place Holdings, a venture studio that has spun out eight medtech startups, including InterShunt Technologies, the startup Harlee is leading today. Before Common Place, Harlee led Traco Labs, a health and nutrition ingredient manufacturer, to a successful exit. He also serves as a Clinical Assistant Professor at the University of Illinois at Urbana-Champaign, where he focuses on translating research ideas into commercially viable applications.

Key Learnings From Harlee's Experience

- You have to prioritize ruthlessly during the capital-scarce initial phases of your startup. It's a cycle of setting and achieving milestones that prove potential and help you secure further capital so you can move on with your next goals.
- Reframe fundraising as friend-raising. Begin cultivating these relationships well before you need the capital, as this process can be time-consuming. Align your funding requests with clear, achievable milestones and choose the right investors for each stage of your company.
- Engage openly and frequently with a diverse range of stakeholders. Don't be afraid of people stealing your idea; it doesn't happen as often as one might think. Treat every conversation as an opportunity to learn and refine your ideas and you'll end up with a wealth of perspectives and insights.

Think Big, Start Small, and Prioritize Ruthlessly: Interview with InterShunt CEO Harlee Sorkin

Prioritize Ruthlessly

In the world of startups, especially in medtech, the early stages are a balancing act of ambition and practicality. Harlee shares, “Capital is precious very early on. What do you need to do? The answer is everything. We all know that's not possible. So you have to prioritize, and sometimes you have to prioritize pretty ruthlessly.”

One thing that sets medical device entrepreneurship apart from other sectors is the extended timeframe required for development. In verticals like SaaS, success often comes quickly if your product finds a paying market. In contrast, medtech demands a more iterative approach. Before a medical device can even reach its users, its efficacy and safety must be thoroughly proven. It’s a cycle of ideation, securing initial capital, implementation, gathering feedback, and then seeking more capital. Harlee refers to this as 'permission-based capital' where you earn further investment by demonstrating your ability to fulfill your promises.

When you have a sharp focus on fundable milestones, some other aspects may need to be temporarily sidelined, even if they’re significant. You need to identify and hit goals that not only push the venture forward but also help you create a narrative of potential, showing what's been accomplished and what could be done with additional resources.

Harlee emphasizes three focus areas that are pivotal in the early stages. First is the team. You might not have the complete team during the first days, but securing one or two key members with unique skills and an edge in achieving set milestones is imperative. The second is intellectual property, i.e., understanding the competitive landscape and ensuring freedom to operate without legal liabilities. And lastly, proof of concept. You have to demonstrate that your solution works, no matter how rudimentary your initial models or experiments are.

Think Big, Start Small, and Prioritize Ruthlessly: Interview with InterShunt CEO Harlee Sorkin

Friendraising Versus Fundraising

Harlee likens the role of a CEO to the narrow waist of an hourglass. On one end are the investors and shareholders, represented by the board, and on the other, the broader organization. The CEO's job, standing at the junction, is to communicate the company's needs and goals upward while effectively allocating resources downstream. That requires a lot of strategic communication and efficient resource management.

In Harlee's experience, fundraising goes hand-in-hand with building relationships, or in his words, 'friend-raising,' and it's by no means a short route. The time you start raising funds definitely shouldn't be when you need them, as it can take months if not years.

Harlee's experience with raising capital is full of moments of both triumph and frustration. The key, he believes, lies in right-sizing the ask — aligning the funding request with appropriate milestones and ensuring engagement with the right investors for each stage. "There are progressive stages to medical device development," Harlee shares, "First you create a device that functions well in a lab setting. Then you ensure it's effective in a live animal model. Following this, you adapt it for human use." In InterShunt's case, Commonplace Holdings provided the initial seed capital, but as the venture progressed, the approach to fundraising had to evolve.

Engaging with angel investors and institutional investors alike, Harlee shot two birds with one stone. Not only did he secure some immediate financial support but he also laid the groundwork for future investments. By fostering awareness and interest among potential institutional investors, he positioned InterShunt favorably, which made all the difference when the time came to showcase achieved milestones and seek larger amounts of capital.

Think Big, Start Small, and Prioritize Ruthlessly: Interview with InterShunt CEO Harlee Sorkin

Your Network is Your Trump Card

Harlee readily acknowledges that when he stepped into the interventional device field, it was uncharted territory for him. He candidly shares, “The first thing I did was go find a regulatory consultant to help us understand what this universe looks like”.

Engaging with domain experts helped the InterShunt team understand their operational leeway and identify the most viable regulatory pathway. This groundwork informed their strategic decisions, allowing the team to cost-effectively balance risk during the product development phase.

A key strategic move for InterShunt was conducting their initial human studies in the Republic of Georgia in early '22. It was a calculated trade-off, taking into account factors like cost, quality of care, and follow-up. While first-in-human opportunities in the US existed, they found that the cost and outcomes in Georgia were more favorable, even if it meant potentially slowing down subsequent steps.

Identifying the right teammates was another crucial step Harlee took. Making sure he was always on the lookout, he didn’t simply search for engineering expertise; he also knew he needed talent with clinical and regulatory knowledge. A key figure in this process was Maggie Wallner, whose rich experience with the Watchman device at Atritech made her an invaluable asset to the team. She transitioned to InterShunt, initially as a consultant and then as a team leader.

Harlee also emphasizes the significance of having experienced clinical individuals involved early in your project, as their expertise directly influences the device's design and usability. However, when it comes to regulatory matters, Harlee believes that while specific domain expertise is important, having strong relationships with key personnel in the specific center at FDA where you intend to move your product forward can’t be understated.

In summary, Harlee's varying approaches often intersect at relationships and collaboration. Whether it's through consultants with specific expertise or connections with experienced personnel within FDA, the value of building and maintaining strong professional relationships is vital for any medtech startup. In the world of medtech, who you know can be just as important as what you know.

Empathy-Driven Innovation

Interview with MOLLI Surgical CEO
Dr. Ananth Ravi

Dr. Ananth Ravi

Preview

Under the guidance of Ananth Ravi, MOLLI Surgical has developed an award-winning, wire-free soft tissue localization technology for breast cancer surgery. Their device, MOLLI, precisely marks the location of lesions for removal during surgery and is setting a new standard for patient comfort compared to traditional methods. Ananth unpacks his story, touching upon the benefits of being in close contact with a medical ecosystem, the importance of intuitive design, the ideal role of regulatory consultants, and the funding strategies he employs for MOLLI.

About Ananth

Growing up in Zambia, Ananth Ravi lost his best friend to treatable brain cancer, which ignited his passion for creating equitable and innovative cancer care solutions. Before founding MOLLI Surgical, he served as a medical physicist at Sunnybrook Odette Cancer Center and as clinical operations lead in brachytherapy. He is a co-inventor on numerous patents and holds several grants for medical devices. Today, Ananth is leading MOLLI, a medtech startup that has made significant strides in simplifying procedures in breast cancer surgery while dramatically improving patient comfort.

Key Learnings From Ananth's Experience

- Immerse yourself in the environment where your product will be used. Ensure that your innovation is driven by a real, identifiable problem. Then build products that minimize risk, maximize patient benefit, have a low learning curve, and are user-friendly and clinically effective. Continue to stay engaged with your stakeholders even after building your MVP.
- Be purposeful from the start. Actively work on expanding your network, raising awareness of your vision, and understanding the market. As you build and leverage consultants, be sure your core team isn't overly reliant on any particular individuals or firms.
- Having a variety of funding sources is imperative for sustainable growth, especially as your company evolves through various stages. That said, it's important that you consistently communicate the impact, value, and significance of your company's work to your investors. This is key for appealing to both existing and potential capital partners.

Engage First-Hand and Solve a Real Problem

Innovation must be purpose-driven. You need to solve a real problem and do it exceptionally well. Ananth emphasizes the importance of building something so intuitive and effective that it becomes an immediate asset to its users. Expounding further, he says, “It's just like your phone, you don't have to have an IFU to teach you how to use it. I think that's what we want with all of our medical devices. It should be so intuitive and risk-reduced that anybody can just plug it in and be able to do high-quality care with them.”

Creating medical devices requires solving problems with minimal risk and maximum patient benefit. As a former practitioner, Ananth understands the challenges associated with treatment errors.

“We were deeply involved in patient care, which really helped us focus on what's important. I've been involved in delivering care and using technologies that sometimes led to treatment errors. Having to discuss these with patients and their families was tough. Now, when creating our own devices, it's crucial to prioritize design and always consider risk mitigation, because these devices are our responsibility,” Ananth shares.

Ananth's role at Sunnybrook placed him at the heart of the clinical ecosystem. This proximity to the patients and medical teams was a strong factor in MOLLI’s success. One lesson Ananth learned from his experience working in a high-pressure clinical environment is that the robustness and ease-of-use of a medical device are absolutely vital. In a world where medical staff are often stretched thin, technology must be straightforward and reliable to be appealing and effectively adopted.

Even as MOLLI began to take shape, Ananth remained at Sunnybrook to ensure that the device was perfectly aligned with patient needs and the realities of clinical applications. He shares, “There's something about seeing things for yourself, with your own eyes. You have a different lens than others, and bringing that lens to what you see rather than just hearing about it, is much more insightful.”

However, all this doesn’t mean that being a physician is a prerequisite for innovating in medtech. It’s just crucial that you maintain a close connection with physicians. They can support clinical trials, offer real-world feedback, and help with early soft launches. It’s a key strategy to prove your technology's effectiveness before broadening its reach.

Though Ananth is no longer a practicing medical professional, he still stays in touch with the medical ecosystem. "I'm working to replicate that experience,” he reports. “Now, out of that clinical environment, the challenge is maintaining that level of engagement to ensure our devices meet clinical needs precisely."

The Business of Saving Lives

Initially, Ananth and John pursued their project in an academic fashion, focused primarily on aiding patients at Sunnybrook. However, when external interest began to surface, they realized their work had the potential to reach beyond the academic sphere.

The realization that bigger opportunities await came organically to Ananth, but there are certain advantages to being purposeful right from the start, like expanding your network and raising awareness about your vision, as well as understanding the market and shaping an effective commercial launch strategy.

But before you can even think about a commercial launch, there stands a significant milestone: regulatory approval. For Ananth, the journey to FDA clearance for MOLLI was a learning curve. The initial approval was quite time-consuming. However, the subsequent products, MOLLI 2 and re.markable, were approved much faster – within just a month and a half. Ananth credits this efficiency to the insights they gained from earlier challenges, which he refers to as "well-earned scars."

Ananth’s approach to navigating the regulatory landscape is twofold: balancing an ambitious, aggressive pathway with a more conservative, realistic plan. He understands the unpredictability of regulatory processes and values flexibility in their approach.

He suggests starting with the minimal viable testing early on, immediately after building a prototype. He emphasizes, "Test early, as it's bound to fail initially, then iterate until it succeeds." This method is capital-efficient and instrumental in gaining insights into potential improvements, paving the way for more thorough testing later.

Regarding the role of consultants, Ananth stresses the importance of hands-on involvement during the early stages. Although consultants offer valuable guidance, you’ll experience delays if you over-rely on them, particularly when onboarding new consultants. Ananth experienced this first-hand with MOLLI. They initially depended heavily on consultants for regulatory, and, by implication, clinical affairs as well. However, once their contract was through, the gap in in-house expertise they left behind became glaringly obvious. However, this doesn’t mean you should abstain from using consultants. You just need to ensure that the core team builds and maintains the necessary expertise. Ananth’s advice is to view them more as auditors to identify gaps, rather than having consultants own an entire function.

Empathy-Driven Innovation: Interview with MOLLI Surgical CEO Ananth Ravi

Storytelling for Sustainable Growth

Ananth believes diversity in funding sources is imperative for sustainable growth. In the early days, when capital was a major constraint, non-dilutive funding proved to be MOLLI's lifeline—partially thanks to their academic background.

As the company progressed and gained more momentum, the opportunities to explore different funding avenues also expanded. This sort of growth places a company in a position where it has to make tough choices, something no one likes to do.

Ananth acknowledges the strengths and challenges of both non-dilutive and equity fundraising. He points out that while non-dilutive funding can be demanding, especially in terms of time spent on grant writing, it's crucial to weigh this against the trade-off of potential business growth. When a company starts to commercialize rapidly, shifting focus towards activities that directly enhance the business often makes dilutive funding more suitable.

A pivotal moment for a startup is when it starts generating revenue. At this stage, the nature of capital shifts towards potential revenue. However, Ananth advocates that, despite this shift, the core narrative of the company should remain constant. You have to address the significant questions, highlight the impact your company makes, and the value it adds, both at present and in the future. Whether communicating with grant agencies or investors, successfully conveying this message makes your business appealing to both types of funders.

A significant part of MOLLI's messaging revolves around its mission to democratize high-quality care. This includes educating patients about the treatment options available to them. Driving public awareness and advocating for high-quality care is an important part of MOLLI's message. One such initiative is their H.O.P.E. (Help-Optimism-Positivity-Empowerment) Program, a collection of resources, interviews, support, and services recommended by patients, clinicians, and advocates. This holistic approach to market development has organically benefited the company, amplifying its initiatives well beyond what it initially expected.

Grit and the Power of Showing Up

Interview with Venture Capitalist
Anish Kaushal

Anish Kaushal

Preview

Anish Kaushal, a former physician turned healthcare investor and author, shares his unconventional career journey from medicine to VC at Amplitude Ventures. He reveals vital fundraising strategies from an investor's perspective, offers practical tips for crafting pitch decks that capture attention, discusses why always being in the mode of seeking funds is so important, expands on the value of building extensive networks, and talks about the cumulative effect of small improvements. He also provides guidance on staying open and ready for career shifts in today’s fast-paced professional environment as outlined in his latest book.

About Anish

Anish Kaushal is an ex-physician turned healthcare investor at Amplitude Ventures, one of Canada's leading healthcare VC firms. His engagement with venture capital began at M Ventures in Amsterdam, a corporate VC fund of Merck KGaA, where he quickly developed a passion for the field. Outside of his professional pursuits, Anish is an avid reader and writer who has published over 900 articles and summarized 250 books across 50 categories. He has also authored two books, the latest of which is From Here To There: A Niche Guide to Navigating Career Transitions.

Key Learnings From Anish's Experiences

- Get to the bottom of the problem you’re solving. Clearly define the gap, the solution, the regulatory process, and how it’s going to be reimbursed. Show VCs that you're not improvising and that you have a well-considered roadmap with clear, achievable milestones.
- To make a memorable pitch deck, keep it short and clean. Know your audience, personalize your pitch, include hard evidence, invest in design and readability, and deliver all these in a story that resonates.
- Always be in fundraising mode. You won't always get an intro so be proactive in approaching people and telling your story. Find them online and send them emails. And don’t be afraid to approach other players in the industry as they often know about the best opportunities.

Grit and the Power of Showing Up: Interview with Venture Capitalist Anish Kaushal

Do Your Fundraising Homework

You have a killer idea and a great team—all that's missing now is the fuel to power your engine and take flight. It's really important to be committed to your mission, as it's exactly what a capital holder is looking for. But to ignite their belief, you first need to do your homework.

Anish says that "money is out there, and people are definitely looking for opportunities." Your job is to reach out and convince them that your idea merits investment. And that's why you need a sleek pitch deck.

Before reaching out, you need to thoroughly understand the problem you're solving, where it stands in the greater ecosystem of healthcare, and why it is plausible. Anish warns, "You can tell someone who knows the problem inside out from someone who doesn't." This isn't something you can feign—you have to proactively and genuinely engage with the ecosystem so that you see the problem from every angle. This will not only strengthen your hand in securing funding, but also boost your confidence when talking to investors or strategics.

You have to clearly define the problem in your pitch deck, as well as what your product or service aims to solve. This clarity sets the foundation for the rest of your presentation. Following this, provide a detailed description of your product, whether it's a device, a service, or a diagnostic. It's essential to elaborate on how you plan to manufacture your product and whether the logistics are feasible and practical. Equally important is delineating the regulatory pathway and highlighting where your product currently stands in terms of approvals. While having already made significant regulatory progress is not mandatory, demonstrating engagement with entities like FDA can significantly bolster your case.

Next, address the concerns and interests of various stakeholders in the healthcare industry. Your pitch should articulate why your product matters to each group, be it investors, end-users (patients or healthcare providers), or insurance companies. Try to paint a picture of a solution that creates value for all parties involved—the more stakeholders that win, the better your case gets.

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Grit and the Power of Showing Up: Interview with Venture Capitalist Anish Kaushal

Do Your Fundraising Homework

“The best entrepreneurs that I've seen are the ones who really know the problem inside out,” Anish shares. Ideally, this is a problem you've experienced firsthand. However, if that's not the case, learn from those who have. That’s why engaging with every stakeholder, including doctors, nurses, patients, payers, and advocacy groups, is vital.

A critical but often overlooked stakeholder is the payer. Make sure you understand the economics before approaching a VC. Anish advises, “As an investor, in order for us to make money, it's all about commercialization, which is all about reimbursement.” While you don’t need to have secured their buy-in yet, it’s essential to explain why your solution makes economic sense from the payer’s perspective. In Anish’s words, “If you understand people's incentives at every stake, like patients versus doctors versus payers versus hospital admins, and you know how your product is going to help solve their problem, then you have a winning idea.”

In summary, you need to understand the position of each stakeholder and clearly communicate that you have a well-thought-out roadmap with tangible milestones for the path ahead.

Grit and the Power of Showing Up: Interview with Venture Capitalist Anish Kaushal

How to Create a Memorable Pitch Deck

For startups, capital is scarce, but for VCs, time is even scarcer. That's why your pitch deck needs to be as direct and concise as possible.

When sending out a pitch deck, your goal isn't to close a deal on the spot; it's just to get a reply or a follow-up meeting where you can delve into the details of your idea. So, don't overwhelm your audience with too much information. Anish advises, "Limit your pitch deck to 10 to 15 slides, and keep text to a minimum."

However, these slides shouldn't be disconnected anecdotes; rather, they should come together to tell a story.

You should also research the people you're approaching. No one likes to read a generic pitch or a mass marketing email that's been sent to a thousand people. Tailor your pitch to the interests of your audience. One way to get attention that Anish suggests to entrepreneurs is to use the principle of similarity. It's a very simple but surprisingly effective attention grabber. "Find one thing that makes us the same," he says. This can be as simple as a shared interest or background.

One practical approach is having different versions of your pitch deck based on who you're pitching. Anish offers a quick tip: Have a master version with around 40 slides. Then, filter and personalize your deck based on who you need to send it to. To do that efficiently, knowing who you're pitching to is really important.

Another critical component you should include in your pitch is data. "Telling a story is not enough. At the end of the day, it always comes down to data," Anish notes. You need to prove you're following up your promises with hard evidence. Anish emphasizes that you need to not only communicate what you're going to do but demonstrate how you're doing it as well.

Transparency is also crucial. Any sophisticated investor is going to expect challenges. Including your slow-downs and how you're addressing them in your pitch is a better idea than keeping those in the dark until the end. "Experienced investors appreciate such honesty," Anish shares.

Finally, the design of the pitch is important. You have to keep people engaged with your story, and that comes through your delivery. "Just a small, subtle change in design really makes a difference," Anish notes. A well-designed presentation can make a compelling first impression. For that, find a freelancer on a budget, or even use software like beautiful.ai to make the presentation pleasant to look at.

Grit and the Power of Showing Up: Interview with Venture Capitalist Anish Kaushal

An Entrepreneur is Always Fundraising, Even When They're Not

“It's really a relationship game at the end of the day," Anish notes regarding capital raising. Building these relationships takes time, effort, and patience. Getting an introduction is best, but it's completely fine if that doesn't happen.

Anish’s strategy to break into the VC world was as simple as it gets. He began by cold-emailing the top 75 healthcare VC firms globally. Most didn’t bother, but the few did get on the phone with him or sent him nice, long, informative replies. That’s how he landed an internship in M Ventures, a corporate VC fund of Merck—or EMD Serono as it’s known in the US. When the internship was over, he repeated the same strategy, cold emailing around 100 VCs in the span of just a few months, with which he ended up locking in final interviews with three different firms.

Anish’s take-home message for reaching out to people is simple: show up again and again and again. However, there’s one caveat: no one likes to read cold emails sent to a thousand people. You need to personalize your message to your target audience’s strengths, weaknesses, and opportunities.

“A common feature of a successful CEO or a startup executive is that they have conversation channels open with investors and keep them updated. Once you open a dialogue with an investor, make sure to keep them in the loop,” Anish advises. Coming out only when you need money is not a good look from a VC’s perspective. Anish’s advice is to send out a newsletter or a quarterly update to an email list where you can share your challenges and triumphs. Anish shares, “If we haven't built a relationship over a long time and you have no traction, and I haven't seen you progress, it's really hard for me to judge if your case is differentiated.” Remember, if you’re an entrepreneur, even when you're not fundraising, you are fundraising.

Apart from building and actively engaging a network, capital raising also requires you to be attentive to timelines, even when things are moving in your favor.

Let’s say you closed a meeting with an investor. From the initial meeting to due diligence, term agreements, and finally, signing a contract, the process of receiving funds will be lengthy. "It will take at least three months," Anish estimates, with syndication potentially adding another three to six months to the timeframe. The amount being raised also changes this timeline; raising $2 million versus $100 million involves different processes and timescales.

In summary, you have to always be in fundraising mode, even when not actively seeking capital. Build and maintain relationships with investors, be prepared for lengthy processes, and adjust your expectations based on the amount you’re seeking.

Grit and the Power of Showing Up: Interview with Venture Capitalist Anish Kaushal

How to Successfully Make a Career Transition

Today, industries morph at breakneck speed and the traditional, singular, linear career path is becoming more and more antiquated. As stressful as it is, it is perfectly normal for a person to change their mind, change their perspectives, and change their careers.

"The world where you'd stay with one company for 30-40 years is over," Anish notes. "Everything is advancing exponentially and massively shifting all the time." As changing careers becomes more normalized, stepping out of your comfort zone to try your hand in a completely different industry isn't always easy.

Staying in one job if you love what you're doing is perfectly okay. But if you don't, there are many things out there waiting to be explored. Even though the options are particularly hard to gauge early in your career, it's not impossible. Anish shares,"The overarching genesis of why I wrote the book is to show people how to get themselves from 'I have no idea what I'm doing' to 'here's a couple of steps in between that can get you there.'"

Anish stresses that conventional schooling alone doesn't go very far. You need to be actively involved and build something to truly learn. Hands-on experience is the best way to develop the skills you need. Internships in various industries are invaluable for this. But that doesn't mean you can't change paths if you don't have the time and luxury to be an intern. It's still possible even for people who are in mid-career.

First of all, figuring out what you want to do takes time and shouldn't be rushed. This is why experimenting with lots of different things is a great idea. Also, basic Googling skills and using resources like YouTube, Reddit, and online forums for guidance can get you places you couldn't imagine. But beyond that, Anish encourages reaching out to industry professionals for advice. "People are genuinely generous, especially with young people seeking advice," he says.

In addition to this, finding your next dream job won't happen overnight. Anish stresses the importance of two things: patience and resilience. As cliché as these words may sound, there's a hard logic behind Anish's approach to navigating his career, with the key being constant outreach to people.

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Grit and the Power of Showing Up: Interview with Venture Capitalist Anish Kaushal

How to Successfully Make a Career Transition

“Start with who you know, whether it's within your own company or an adjacent company, or even people that are just in random industries that you didn't even know about,” says Anish. Having made the shift himself, Anish understands that people are always looking for talent and might be aware of opportunities that aren’t on your radar. Therefore, engaging in conversations opens many doors. Anish adds, “The best ideas and jobs often aren't advertised.”

Once you are comfortable with approaching people, you need to learn how to carry the conversation with these people on the fly. “Show them that you care about them first,” Anish advises. Then, figure out how to ask for what you need. He explains how to format and structure these conversations in his book in further detail. But here's a key takeaway: a lot of it depends on who you're talking to.

Just as Anish advises always being in fund-raising mode, he also suggests continually nurturing relationships. “Don’t go to people only when you need something, go to them with updates as you go,” he advises. Spend a little time on research, putting together who you want to reach out to, and talking to them, every day. If you send just 10 emails every day, that adds up to 300 after a month. And that’s how you get momentum.

You will have some conversations that lead to nowhere and hear a lot of hard no’s. Those are the ones you need to dissect to learn what went wrong. And at the same time, just one affirmative response is all you need to make a transition.

“Life happens in the grind, not at the top. Keep going at it. If you’re resilient you will get there. Anybody who keeps showing up is going to, eventually.” But you can’t do the same things and expect different results. Improving even just 1% each day accumulates over time. In Anish’s case, he started writing a blog in 2021, posting daily. “Most of them haven't been seen, but that's how I reached the point where I could actually write the book,” he says.

For those intrigued by Anish’s journey and seeking more in-depth guidance, his book From Here To There: A Niche Guide to Navigating Career Transitions and his website www.anichexperience.com which he regularly updates with new blog posts are a treasure trove of insights.

How to Innovate in Medtech with Limited Means

Interview with Field Medical CEO
Dr. Steven Mickelsen

Dr. Steven Mickelsen

Preview

Dr. Steven Mickelsen is a practicing electrophysiologist who is leveraging his clinical expertise and entrepreneurial spirit to revolutionize cardiac care. He made significant strides ushering in pulse field ablation (PFA) technology into the field through one of his previous companies Farapulse, which sold to Boston Scientific. Today, as CEO of Field Medical, he continues to contribute to the space by developing the next generation of PFA for ventricular arrhythmia management. Dr. Mickelsen shares his hard-earned wisdom on how limited means can breed resourcefulness, how to build a modest yet effective prototype, why having real expertise in clinical and regulatory spheres is a necessity, and how to raise funds with a win-win mindset.

About Steven

Starting out his career as a professional musician, Dr. Steven Mickelsen made a pivotal shift in his late twenties and ventured into the world of medicine. As a practicing electrophysiology (EP) physician, he has combined his medical expertise with an entrepreneurial spirit to revolutionize cardiac care. Steven made significant strides in the development of pulse field ablation (PFA) treatment with one of his previous companies, Farapulse, which sold to Boston Scientific. A serial entrepreneur, Steven is working on his next startup, Field Medical, which is developing the next generation of PFA technology to address ventricular arrhythmias.

Key Learnings From Dr. Mickelsen's Experiences

- Money is always tight at the beginning of any startup. But scarcity can breed creativity, so use that to your advantage. Build prototypes with readily available parts and focus on nailing your narrative to convince investors.
- Finding real expertise in the clinical and regulatory arenas can be challenging due to the specific requirements unique to each startup. Find a good consultant early and keep them close – their expertise will save time and boost your startup's chances for success.
- When raising capital, be honest about costs and timelines, both to yourself and investors. Be clear and concise in your communication and tailor your pitch to the specific type of investor you are targeting. Don't stress over retaining a large equity position and aim to develop technology that meets the needs of physicians and patients.

How to Innovate in Medtech with Limited Means: Interview with Field Medical CEO Dr. Steven Mickelsen

Limited Capital Can Breed Resourcefulness

“Despite the fact that there was a lot of innovation in the early Farapulse days, the reality is that the technical leaps that we make now are just so much bigger because we have a foundation to jump off of,” Steven reflects on his journey. Field Medical’s device marks the third human-ready pulse generator that Steven has been involved in designing. By now, he knows what it takes to get it done, but he gained this wisdom at a high price.

During the early days of a startup, money is always tight. However, Steven underscores a fundamental: limited resources foster creativity. "It's surprising how far you can get with nothing, and it's surprising how little progress you can make with all the money in the world,” he says. With Farapulse, Steven and his team had to navigate through the alpha stage on a modest budget of $40,000, which pushed him to acquire new skills. He recalls “I couldn't afford to outsource it to anybody. I literally learned how to build electronics, bought components, put them together, crossed my fingers that I was not going to kill myself, and asked for help from people at the university.”

Steven’s advice is clear: make a prototype as soon as possible and make it as simple as possible. Use off-the-shelf components and don’t be afraid if your first prototype is ugly. What’s important is to have something tangible, functional, and with a potential for scalable development. For example, Steven repurposed a laser pulsar for the insides of the original Farapulse generator. Learn to leverage a practical approach like this to test and refine your idea without a substantial initial investment. “A mock-up is so cheap to build. Build it, show it to people,” says Steven.

In fact, it doesn't even have to be a physical prototype to get your point across. You can model a photorealistic version, for example, to demonstrate where you’re headed.

While prototyping is important, keep in mind that there’s one thing you must have to get to the next level: a good business model. "Nothing moves forward without a model for making money at the end," says Steven. Having a clear path to profitability not only makes it easier to raise funds but also provides a framework for sustainable growth.

Find Real Expertise Until You Develop Your Own

The regulatory and clinical landscape can be a huge black box for anybody who doesn't have direct experience in bringing a device to market. Steven acknowledges the difficulty in finding industry expertise, as navigating field-specific regulations is complex. "It's hard to Google-search the requirements for a pilot study or the cost of a large phase three clinical trial," he notes.

There are clinical research organizations (CROs), but their cost can be prohibitive for a startup. This is why it's imperative to have someone on your team who understands the nuances of regulatory and clinical requirements. "You're going to need one person who really understands how to submit papers to FDA, what the regulatory environment in Europe right now is, and what European Medical Device Regulation (MDR) entails," Steven points out.

Steven's strategy with Farapulse was to conduct initial clinical trials in Europe. While this strategy made sense for Farapulse, the regulations were different a decade ago, and things have changed a lot with MDR. Now, the 510(k) path in the US is preferred by most startups. However, the recipe is never one-size-fits-all in medtech.

In the US, one of the constraints is the challenge of enrolling patients in a significant clinical trial in an economical fashion. "In the US, hospitals charge so much more and the enrollment speeds are so much slower. For a startup that's burning money every day, that's not good. Instead, you can go to Europe, you can fly everyone there, and you can enroll 10 patients in one week," he explains. For a startup where every dollar counts, the faster patient enrollment in Europe is a significant advantage. He further adds, "It's really important to get that experience and be able to iterate on it. If you have to wait too long to get your data, it can be very painful."

Knowing the ropes of these processes can define whether you succeed or fail. In Steven's case, he learned to navigate these challenges through hard work and direct experience. He says, "Good consultants exist; they're out there. Once you find one that's really good, never let them go. Then it's not as daunting as you think."

How to Innovate in Medtech with Limited Means: Interview with Field Medical CEO Dr. Steven Mickelsen

Master a Clear and Compelling Story

A CEO's main job is to raise money and keep the company on track. Now that he has the experience, Steven is quite confident with finding the right resources and developing a plan for eventual commercialization. "We've had a year to put together good practice, budgets, and marketing planning. Because, when you go out to raise money, it is important to get your finances in order to understand how the money works and to be able to present that side of the business proposition confidently," he emphasizes.

To raise funds successfully, Steven emphasizes that, "There has to be a good idea, there has to be a market opportunity, and there has to be the right team. It's crucial that you, as a CEO, can provide realistic estimates about costs and timelines, and this is easier if you've done it before."

The business side of a startup, particularly when dealing with institutional money, is not easy. That's why Steven chose to exit with Farapulse. He shares, "I just didn't think I had the experience to be able to pull off that leadership role. I needed more experience before I could do that. I spent the last decade getting that experience. I feel pretty confident now."

The most important things when trying to secure funding are storytelling and clarity when you present to investors. "The reality is—it probably depends much more on the storytelling and clarifying what it is you're doing in a way that gets investors interested," he says. Diverse types of investors, whether they are angels, high-net-worth individuals, or institutional investors, have varying requirements, and your pitch must be tailored accordingly.

One nugget of wisdom that Steven shares on this topic is that due diligence and negotiations will often favor the investor. "It takes months to close a round," he warns. That means the more homework you can get done, the better. Preparation can significantly shorten the time-consuming process of closing a round.

Finally, Steven advises having realistic expectations regarding fundraising. In medtech, unlike in some other industries, it's okay to not hold on to a large percentage of your company. "The real goal is to have a successful technology that's needed by physicians and deserved by patients. If we can bring that forward and our investors can come out on top, then it's a win-win."

He wraps up his take on developing in medtech by saying, "You have to have a personal stake in why you are working in this area. There is investment here because it's an opportunity, but there's also an interest in making the future better. And by making it better, if you can get some return on your investment, then great." According to Steven, even investors are usually proud of their contribution, as they know they were instrumental in getting technology that benefits patients into the hands of physicians.

Crowdfunding and IPOs for Medtech Startups

Interview with Monogram Orthopedics CEO Benjamin Sexson

Benjamin Sexson

Preview

Benjamin Sexson is the President and CEO of Monogram Orthopedics. He is a mechanical engineer from Caltech and a CFA charterholder. At Monogram, Ben and his team are developing a fully autonomous robotic system for knee replacement surgery. Ben talks about the importance of a good team and a liberating company culture as well as the importance of believing in what you're doing and openly reassessing its validity regularly. He also elaborates on Monogram's daring strategies for validating its technology and walks us through the pros and cons of crowdfunding and going public.

About Benjamin

As co-founder and CEO of Monogram Orthopedics, Benjamin Sexson is leading the company's advancements in robotic orthopedic surgery. His tenure at Pro-Dex, one of the world's top manufacturers of orthopedic robotic components, eventually brought Ben to lead the development and launch of Monogram's flagship product mBôs. Ben has authored multiple patents and previously founded Brides & Hairpins, a successful B2B retail brand. He holds a bachelor's degree in mechanical engineering with honors from Caltech and is a CFA charterholder.

Key Learnings From Benjamin's Experiences

- Avoid the sunk cost fallacy. Don't let past investments cloud your judgment about a project's present viability. Regularly reassess the viability of your idea based on current conditions, not past investment. Be willing to pivot towards a better solution, even if it's difficult. Maintaining a steadfast belief in your work is crucial; without it, your ability to overcome challenges and effectively communicate your vision will be compromised.
- Finding the right funding source is tricky, especially for early-stage startups. Consider alternative routes like crowdfunding or IPOs. Be aware that both options have their challenges: crowdfunding requires a strong marketing push and IPOs can create administrative headaches. Thoroughly evaluate your specific needs but don't be afraid to iterate as you move forward.
- Medtech is a team sport. A strong support system and an A-plus team are a must. Find talented people who are willing to shoulder responsibility with you through the tough times and can set aside their egos. Maintain a company culture where everyone is heard and there's no punishment for raising one's opinion, even if it proves to be wrong.

Crowdfunding and IPOs for Medtech Startups: Interview with Monogram Orthopedics CEO Benjamin Sexson

Don't Champion Something You Don't Believe In

One of Benjamin's core philosophies is to never back something you've lost faith in. This aligns with a significant risk for any startup: the sunk cost fallacy.

The sunk cost fallacy, or trap, is a cognitive bias where you justify continued investment in a project based on how much you've already invested in it rather than its future potential. Let's say you own a stock and its value dropped to half even though the overall market has risen in value. At this point, it's essential to reassess the investment based on its current value, not on the initial conditions. As Benjamin puts it, "Don't think about what you had. Right now, today, what you have is changed." If you hold on to the stock that keeps dropping in value instead of selling it and putting the money into a different stock that is likely to rise in value, you would be subject to the sunk cost fallacy.

This is where startups must be wary. After investing time and money, it's tempting to keep pushing a product that in fact has proven to be suboptimal. Benjamin urges leaders to remove previous spending from the equation and ask, "How much capital do we have and what are the decisions with the information we have right now?"

When Monogram arrived at a crossroads with their rotary tool system, it was time for Benjamin to put this philosophy into practice. "You can start going down rabbit holes by changing different aspects, but at the end of the day you have to answer this question: What is the optimized end case for this product? Is it a good product?" And if the answer is no, then you know what to do. Instead of pushing something that's not good enough, you pivot towards something that could be much better.

Having spent time invested in a dead-end idea is never optimal. But the ability to change course is a startup superpower. Big companies, Benjamin points out, often struggle to admit mistakes due to money spent and internal politics. "It takes a very special manager to say the decision was wrong. A lot of companies are trying to make everybody believe it's great."

At the end of the day, Benjamin's advice comes down to a simple, yet powerful, mantra: "Always do what you believe in. Be true to yourself." If you lose faith in your product, the lack of conviction will show. He emphasizes, "I fundamentally believe in it and our team believes in it. If you lose that, it's very hard to be a good salesperson."

Belief doesn't mean ignoring limitations. At times, depending on the capital you have left, the right decision is to move on to the next phase of development, but the key is believing in what you are doing. "If you're not on the edge of your seat a little bit at a startup," Benjamin quips, "you're taking up too much space."

Crowdfunding and IPOs for Medtech Startups: Interview with Monogram Orthopedics CEO Benjamin Sexson

What Funding Suits You Best?

"God, nobody wanted to give us money," Benjamin laughs, recalling Monogram's early days. Like many young companies, Monogram had to find a way to bridge the gap between a great idea and paying the bills.

Rather than contacting VCs, Ben chose to follow two unorthodox routes for an early startup: crowdfunding and IPOs.

There's a reason why IPOs are an unusual choice for a startup. Ben explains: "How do you attract the best people when your stock options are, at the moment, worthless? You can't buy groceries with potential."

Next, Benjamin turned to crowdfunding. However, counterintuitively, this method is seldom free. Ben partnered up with a marketing firm hoping to bring their message to a wider audience.

Monograms's team needed to raise awareness for what they were building, so they tried a bold move: realtime surgical demonstrations on YouTube. There was no high production, no editing, just the team doing what they do best. "People want to be on a bit of an adventure with you," Benjamin shares. Although risky, Monogram's transparency and authenticity won them an audience willing to overlook the rough edges. One memorable occasion proved Monogram's success in outreach: a podcaster, initially a harsh critic, was won over by a stellar live stream. Benjamin recalls, "We just absolutely crushed it. He became an investor."

"Crowdfunding was a blessing," Benjamin explains, "but it had become a little bit of a one-trick pony." When the company reached a point of maturity, Ben decided to go public in order to access strategic capital.

At first, Monogram worked with brokers, only to find out that the 'packaged deals' with preferred share classes were too restrictive for Monogram's startup nature. The brokers put each investor into a preferred class, and gave them voting rights. But Monogram had thousands of people on their list, with big and small contributions. This made the administrative tasks a bit tricky. "You need the investors to vote on some resolution, but you end up in their spam folders," Ben explains, as being one part of the problem.

The reason for going public was to access the right type of investors, but coupled with crowdfunding, IPOs made Monogram's cap table practically uninvestable by parties who ultimately had big-time capital.

Luckily, Ben figured out how to best serve Monogram's funding needs: to convert all the preferred share classes into common classes. After that, going public solved a big portion of the problems and opened the door to the kind of capital a medtech startup needs. But it was easier said than done. Ben says, "There's not a good, clean way to take a crowdfunded company public." The process is still rough around the edges. This is what he advises those who want to go public: make sure you know the reasons, make sure you can handle a lot of administrative work, and be aware that, as a startup, you'll be under the spotlight much more than you were before.

Crowdfunding and IPOs for Medtech Startups: Interview with Monogram Orthopedics CEO Benjamin Sexson

Be a Team Player and Expect the Same From Others

Monogram's success is clear. But Benjamin is quick to acknowledge that this journey wouldn't have been possible without his support net. "My wife has been an important part of this. Without her help, Monogram wouldn't have existed," he shares. For two years, his wife financially supported their family while he dove headfirst into the company. "Anyone trying to build something – find the people who believe in you, in life and in work," Benjamin emphasizes.

"Almost every entrepreneur I've met has had some help, whether they recognize it or not," says Benjamin. Entrepreneurship, especially in medtech, is a team sport. Dr. Douglas Unis, orthopedic surgeon and early collaborator, was another key figure in Monogram's story. Today, the company has grown to 24 dedicated employees. "We have some of the world's most talented engineers," Benjamin shares. And he knows that a big ego will get you nowhere. It's about the work, not who's the smartest. "If you think you're the most amazing engineer in the world and you want to talk down to other people on the team, you're not welcome here. That's our culture," he says unequivocally.

"I can't take all the credit," Benjamin admits. "My strength is keeping the mission front-and-center, building the right product, and bringing together a team with a 'let's fix this' attitude, not a 'who's to blame?' mentality." As humble as he is, this is the exact job description of a CEO and it's not easy to pull it off, especially if you're building a fully autonomous robotic arm to perform knee replacement surgeries.

So even with a great team, there were some stressful moments throughout the company's R&D efforts. For example, initially, they used a rotary tool and effector in their system. But there was an issue that became apparent as they moved forward. "The bur spins so fast it heats the bone. You have only limited time before you start cooking the bone – which is disastrous for the patient," Benjamin explains. Even though the team has already made significant investments into the rotary, Ben decided to pivot to an agile saw – with the encouragement he received from their CTO.

Things turned out great, but even if they hadn't, Ben explains, he wouldn't have thrown the CTO under the bus. A startup is where you make a decision together and you win or lose together. The point is to solve the problem, not to find a scapegoat. "We're now actively cutting without external fixation in phenomenal cut times that can be even further optimized. We actually have something that we all believe is the best robot in the world," Ben shares, rightfully proud.

Finding Your Place in the Healthcare Ecosystem

Interview with Vivante Health CEO
Bill Snyder

Bill Snyder

Preview

Bill Snyder, CEO of Vivante Health, and his team are commercializing an all-in-one digital platform for digestive health conditions. GIThrive is a platform that combines data-driven technology with a team of physicians, registered dietitians, and health coaches to deliver personalized care. Bill talks about the importance of finding where your company stands in the overall healthcare ecosystem, why clinical outcomes and sorting out reimbursement are critical to survival, and his experiences raising capital for Vivante.

About Bill

Bill Snyder is the CEO of Vivante Health, a leading digital digestive health company. With over 15 years of experience in healthcare technology, his background includes building and leading national sales efforts at Virta Health and overseeing their health plan practice. Previously, Bill spent 11 years at Humana in various leadership roles, including Vice President of the company's greater Chicago region.

Key Learnings From Bill's Experiences

- As a digital health company, you have to know where your product or service fits in the overall healthcare ecosystem. That way, you know how to interact with other providers and consumers, and in turn, you can connect the dots for your end-users about the precise role you play in the care they receive.
- Ensure your product is financially accessible for adoption. That requires you to understand different plans and regulations and demonstrate your product's clinical efficacy and potential for cost savings. Target customers that you can create a clear win-win situation for.
- Show your progress to build trust with potential investors. Network and communicate with them on a regular basis. Focus on sustainable growth and understand your business's unit economics in detail so you can articulate and justify your decisions.

Finding Your Place in the Healthcare Ecosystem: Interview with Vivante Health CEO Bill Snyder

Healthcare Startups are a Contact Sport

A digital health solution must either enhance or replace existing care delivery and payment models. Reinventing everything from scratch is rarely a winning strategy. However, each of these scenarios position you in a different place in the ecosystem, and each of them requires a different go-to-market strategy. Sometimes, great ideas might not fit well in the current healthcare workflow. It's important to understand where your product fits and continuously engage with your customers.

First and foremost, you need to understand the problem you're solving and where it fits in the broader healthcare landscape. “If it's not a big problem, if you're not impacting a lot of people and improving something significantly that you can point to, it's really difficult to break in,” Bill states.

Secondly, you need to step back and determine where your solution stands within the existing, established healthcare workflow. “You have to think about how you interact with the plan and with other providers,” while also focusing on the member and the patient, Bill explains.

To answer these questions, deep clinical expertise is non-negotiable. "If you're not a clinical founder, you have to have a really strong clinical team," Bill advises. The same thing applies to coverage and reimbursement, too. Partnering up with functional experts helps you navigate the complexities and ensure that your solution is properly positioned to deliver maximum benefits.

On that note, consistently engaging with different parties is another pillar of success. According to Bill, operating in the healthcare space is a contact sport. Being in the field and understanding customers' needs as well as their purchasing journey is crucial for business growth. Vivante, for example, works with large-scale employers who cover healthcare for their employees (B2B2C model). In this context, it’s important to make integration incredibly easy for employers. That’s why Bill is in regular contact with the platform’s members. He collects information continuously to improve their offering and the overall patient experience. “We're always talking to our members and trying to gain information in terms of what more we could be doing for them and what we are not thinking about,” he shares.

Finding Your Place in the Healthcare Ecosystem: Interview with Vivante Health CEO Bill Snyder

Prove Clinical Outcomes and Economic Impact

While regulatory approval is a major milestone, the journey to widespread adoption doesn't end there. Figuring out coverage and reimbursement is a huge box to check, because when you get approval from FDA, you need to know who is going to pay for your product. Getting a device or solution approved is one step, but ensuring it's financially accessible for adoption is another step that's just as important.

The healthcare reimbursement landscape is complex, with different types of coverage such as fully-insured, self-funded, Medicare Advantage, Medicaid, and others – each with its own regulations and requirements. For now, Vivante works with large employers to distribute the GIThrive platform. And for that, they need to convince them, cater to their needs, and essentially, make the platform alluring.

These types of customers are more receptive to innovative solutions like Vivante's, which have the potential to lower costs and improve employee health outcomes, Bill reports. He sees a future where working directly with employers will become more common in the industry, as innovative employers increasingly prioritize benefits that enhance their employees' well-being while also being cost-effective.

It's crucial to help employers make decisions easily. To do that, Bill champions providing compelling **clinical outcomes** and **cost savings**, and ensuring **ease of integration**. For that, you need to demonstrate clinical efficacy, not just once, but continuously.

The clinical outcomes don't have to be revolutionary studies or groundbreaking outcomes. For example, Bill's first move was to compare pre and post-analysis of the company's customers. Starting off, individual patient anecdotes were important to establish trust. However, it doesn't end there. "Clinical rigor should always be part of the company's DNA, and you should always be thinking about what more you can do," shares Bill. He intentionally started off with lower acuity members on the platform to gather some vital data and establish efficacy. As they amassed information and refined their platform, GIThrive became equipped to support higher acuity populations. Currently, the Vivante team has a few publications underway, which will help to further promote GIThrive. Bill summarizes, "We started with the clinical measurements that we know we can stand behind when we're talking to other providers or clinical governing bodies."

Beyond the context of clinical efficacy, Vivante also has to prove the safety of personal data of their platform's users. That's why they have certifications like HITRUST and SOC 2 Type II, to show that the patients won't suffer from data breaches on sensitive personal health information.

"Go out and show them how you're going to take the cost out of the system for them and make their members feel better," Bill concludes.

Finding Your Place in the Healthcare Ecosystem: Interview with Vivante Health CEO Bill Snyder

Know Your Numbers Inside and Out

Vivante successfully raised an impressive $31 million in 2023. However, Bill is quick to remind us that it's not about a one-time win, but a matter of sustainable growth. Success in fundraising depends on solid business fundamentals. As Bill puts it, "It comes down to the unit economics of the business".

Growth is alluring, but Bill reminds other leaders to keep an eye on profitability while scaling the business. That's what's most attractive to potential investors.

GI health is a massive market with a potential for a huge impact. But potential is not what Vivante solely capitalizes on. As Bill explains, they have "top-line revenue growth with really healthy gross margins, as well as a path to profitability." His advice? "Know your numbers in and out." Track your key performance indicators (KPIs), understand your customer acquisition costs (CAC), and calculate your lifetime value (LTV) ratios. "Know where you're going and how you're going to get there," Bill says. The ability to clearly articulate and justify your decisions builds trust, ultimately helping you secure capital.

Bill also emphasizes the importance of viewing capital raising as a strategic process. You can't just scattergun your approach and respond to every opportunity. Instead, leverage your network, carefully curate a list of potential contacts, and initiate fundraising efforts with existing capital. "For anyone who's raising capital, the best time to raise is after you've just raised," Bill suggests.

Maintaining ongoing communication with potential investors is key. The point is to keep them in the loop, develop relationships, and build trust rather than just interest. Bill advises to send regular updates, even when you're not actively fundraising. This way, as he puts it, you can show them that you not only met your promises, but exceeded them.

Lastly, Bill underscores the importance of being selective with partnerships. Having support from your board makes a huge difference. Take it from him, "Sometimes it can feel so desperate and you'll take money from wherever you get it. But that's a detrimental mistake. Taking capital from misaligned investors disrupts progress and creates a problematic cap table."

Interview with Syntr Health CEO Ahmed Zobi

Ahmed Zobi

Preview

Ahmed Zobi, founder and CEO of Syntr Health Technologies, and his team have developed an automated microfat processing system for use in aesthetics and plastic surgery. The FDA-cleared SyntrFuge device allows clinicians to harvest patients' adipose tissue and then reinject it as processed microfat within minutes into the desired area, eliminating the use of fillers. SynterFuge has the potential to be applied in other fields like wound care, orthopedics, podiatry, dermatology, and many more. Ahmed shares his ideas on the risks and rewards of entrepreneurship, how to operate in a lean fashion, why he puts regulatory clearance above all, and how he managed to be the youngest candidate to ever receive a phase 1 SBIR grant.

About Ahmed

Ahmed Zobi, founder and CEO of Syntr Health Technologies, has a decade of experience in the medical device industry. He advises and mentors many startups, has been recognized as a Forbes Next 1000 Honoree, and is a guest lecturer at the USC Keck School of Medicine. Ahmed also serves as a board member at various organizations, including the Wound Healing Society and the UCI Center for Innovation and Entrepreneurship.

Key Learnings From Ahmed's Experiences

- Embrace a lean mentality, move forward with your available resources, and challenge every expense. Don't let the pursuit of perfection paralyze you and don't waste time and money over-engineering early versions. Prototype rapidly to seek real-world feedback to guide your next steps and be prepared to pivot if necessary.
- Focus on meeting FDA's core requirements first. Don't get bogged down trying to add extra bells and whistles to early prototypes and submit as soon as you can to kickstart a productive dialogue with the agency. Even if you don't get immediate approval, the prescriptive feedback will guide your path forward.
- VC funding might not be an option during the early days of your startup. Explore all opportunities like grants, accelerators, and any niche programs that fit your technology. Don't be afraid to cast a wide net across relevant NIH departments. When approaching VCs, research their portfolios and track their records. Show them how investing in you fits their specific goals and strategies.

How to Run Your Medtech Startup on a Budget: Interview with Syntr Health CEO Ahmed Zobi

Build Something Imperfect on a Budget

As someone who started innovating during his undergrad years, Ahmed knows firsthand the challenges of building a medtech startup on limited resources and the importance of maximizing every dollar.

Startups demand a mindset of decisive action. Don’t let the pursuit of perfection paralyze you. Practicality and forward momentum are what keeps your venture viable.

In the early days of Syntr, Ahmed reports, it was all about getting things done quickly, validating them rapidly, and being prepared to fail and learn from it. He shares, “You often see CEOs and startup founders get married to their idea of a product that it has to be perfect. They spend five years working on an app or a medtech device that ultimately goes nowhere because they can’t let go of perfectionism.”

Case in point: the first functional prototype cost the Syntr team around $30 in materials. It was quite rudimentary. In an attempt to build a functional model, they used a simple spin chuck motor encased in thick aluminum pieces, hoping that if any part broke, it would be contained by the aluminum. The goal wasn’t to skimp on safety, but their main priority was to get to proof-of-concept versus designing a polished product. They developed five or six prototypes within a month and a half and reached something they could call their alpha.

Ahmed stresses the value of using early prototypes to generate data for FDA submissions. “If your FDA pathway requires clinical trial data, you can get the data off your prototype, even if it’s an early prototype. As long as the design, the underlying workings and mechanism of the product are the same.” Don’t chase perfection early on. Remember, even a somewhat ‘janky’ prototype can yield valuable data if the underlying technology works. Ahmed says, ”I personally like real-world data versus the expense of clinical trials because the real-world data is what doctors are going to talk about at conferences.”

To move efficiency during the early development phases, you have to understand who’ll actually use your device. While surgeons are critical, Ahmed emphasizes getting input from the full spectrum of potential users. There are some aspects that the surgeon doesn't think about, but the nurses or other staff do. “If the nurse or the scrub tech doesn't like your product, it isn't going to be used in the OR no matter how much the surgeon loves it,“ Ahmed shares.

Prioritize Regulatory Approval and the Rest Will Follow

Balancing regulatory requirements and clinical trials is one of the central challenges for medtech startups.

During the initial days, Syntr's situation was complicated by COVID-19 where the EUA authorizations slowed down nearly all other FDA clearance timelines. Based on a predicate, the SyntrFuge system was subjected to a 510(k) class II pathway, which didn't require clinical data. Ahmed had to manage his budget between clinical trials, regulatory affairs, and internal payroll; ultimately, regulatory approval took priority. Today, Ahmed's bias is to prioritize fulfilling the FDA requirements first. Once you have clearance, you can gather real-world data and possibly pursue clinical studies if needed. This, of course, applies to companies with faster regulatory pathways such as 510(k).

While pre-submission meetings with FDA can be helpful to start a dialogue, Ahmed cautions that they don't guarantee smooth sailing. "There will never be a perfect path forward, because the FDA can tell you something in the pre-sub, and they could still ask for more things after you've submitted," Ahmed reflects.

"If you have a quick regulatory pathway, my advice is to just put whatever you have forward, and avoid anything extra," Ahmed explains. "Once submitted, you lock FDA into a bona fide agreement, a time frame for a response." If your application doesn't get rejected, a submission creates a dialogue that guides your path forward—and it's best to start the conversations as soon as possible.

FDA clearance offers significant benefits beyond market entry, opening the door to partnerships and commercialization opportunities. Ahmed says, "Your product could be the secret sauce to another product in the same field." Distributors can bundle your product with others, boosting sales and reach. "You don't see that happening if you just have clinical data." Ahmed explains. "But if you have the regulatory approval, you're out there, you're working, you're hustling in the market, and you're expanding your network to distribution partners." For example, since Syntr's clearance, the company has been approached by several companies that were interested in bundling the SyntrFuge with other products.

Exhaust All Funding Avenues

Securing funding is a make-or-break challenge for medtech startups. Ahmed emphasizes the importance of exploring all potential avenues and being resilient.

VCs and potential acquirers are typically looking for commercial-ready startups. Showing that your company is on a fast-track to potential revenue is a motivation for capital holders – and it should be your number-one priority.

On the other hand, non-dilutive funding sources like SBIR grants can be pivotal for early-stage innovation. Ahmed was the youngest candidate to ever receive a phase 1 SBIR grant back in 2017. For those pursuing similar kind of funding, Ahmed's advice is action-oriented: "Apply early, apply often." Again, don't let perfectionism stall your progress. He elaborates, "You can only guess what they potentially want to see. Put in your application early. When I say early, I mean as soon as you possibly can." Remember, the funding cycles do take some time, between 9-12 months depending on the deal.

Grant writing is undeniably an overwhelming process. While outsourcing to specialized firms can be useful, they can never guarantee funding. In Ahmed's words, "They are only as good as the information that you give them. And if you don't have any good information, they can't pull things out of thin air." It's really important that you understand what goes into the process and build your grant-writing muscle before you hire help. You can use programs that help applicants learn how to submit SBIRs like the NIH SEED, and tools like NIH Matchmaker that match your product summary with institutions that your technology potentially falls under. If you do hire outside help, seek writers who understand your field and, ideally, have a success-based fee structure, which is around 4% to 7%, according to Ahmed.

When it comes to other sources of funding like venture capital, Ahmed points out that they are your customers, too. You need to know what they're looking for and tailor your pitch accordingly. Not all VCs are the same – some might prioritize societal benefits and just want their initial investment back, while others might seek a 5x return. The key is to know your audience. Just like you understand your users, the regulatory pathway, and your grant funding process, you should also understand your investors. If you focus solely on the product, or the idea, you miss the VC's perspective. You have to break it down like you would your regulatory strategy, or your user research. If you want investors to buy into your vision, you need to understand their needs first.

Interview with LimFlow CEO
Dan Rose

Dan Rose

Preview

Dan Rose's career in medtech features pivotal roles at Direct Flow, Sequana Medical, and Medtronic, culminating in his position as CEO of LimFlow, which recently exited to Inari Medical. Dan shares his extensive wisdom on M&A transactions, engaging with investors while maintaining business autonomy, the importance of developing with the 'average user' in mind, and the significance of early dialogue with regulatory bodies.

About Dan

Dan Rose, a leader with 25 years of experience in the medical device space, has worked in both multinational corporations and startup ventures throughout his career. He holds a BA and an MA from the University of Virginia, and an MBA from the Darden Business School. Most recently, he led LimFlow's exit to Inari Medical as the company's CEO and has held pivotal positions at Direct Flow Medical, Sequana Medical, Medtronic, and other medtech companies.

Key Learnings From Dan's Experiences

- Vet your potential investors carefully and consider how their involvement will impact your business operations, especially if there are multiple parties involved. Limit their influence on decision-making to maintain flexibility and control over your company's direction.
- In the early development phases, design for the average user to maximize adoption rates. Always iterate towards simplicity and be prepared to pivot accordingly. Don't focus solely on cutting-edge features or only cater to experts. And don't hold onto complex elements or features simply because they were part of the original plan.
- Understanding the reimbursement landscape and how your technology fits into that is crucial to progress your conversations with VCs. Research potential investors to ensure that they have the capacity to invest and that their interests match your company's focus. Pursue those who can infuse substantial capital, streamlining your fundraising process.

Managing to a Successful Acquisition: Interview with LimFlow CEO Dan Rose

How Involved Should Strategics Be?

Navigating investor relationships is a big part of being the CEO of a startup. Dan's experience taught him the complexities of working with strategics, especially when multiple parties are involved.

LimFlow had a device that was quite innovative and unique in many ways with its intricate IP and clinical data. The team was granted expedited access by FDA from the beginning, which later turned into a breakthrough device designation. This position demanded clear and consistent communication in order to convince investors that this was a ship that would float, and that's exactly what Dan prioritized from day one. Consequently, LimFlow's fruitful collaboration with Inari was built organically, over time, and through clear and open communication.

Transparent dialogue forms the backbone of building trust with investors. That means communicating successes and roadblocks with your board is essential. Delays and cost overruns are commonplace in medtech startups, and any experienced VC expects this. Dan shares, "Everybody's late and everybody spends more money than they said they would. It's very rare not to. The VCs are used to that." As long as you deliver on your promises in a thoughtful, strategic way, there's no need to try and hide the challenges in your business. He continues, "How you work through it is the testament that you can solve the next set of problems that are always going to come."

On that note, Dan is quick to express mixed feelings on involving strategics in business operations. He knows this firsthand – at Direct Flow, having three or four different strategics invested in the company eventually led to challenging dynamics. He points out that investors may be monitoring each other's moves, for example, which takes transparency and openness out of the picture.

Managing these dynamics effectively hinges on conducting efficient, goal-oriented board meetings. With multiple strategics' interests at play, the meetings can feel more like "a roadshow", Dan shares.

That's why Dan is cautious about involving multinationals in business operations, even if the relationship looks promising. During his time at LimFlow, while constantly cultivating interest in a potential acquisition, Dan was wary of taking investments that could limit future opportunities. When Inari showed interest during their Series D round, Dan decided to involve the Inari team based on their good relationship and shared culture, but he didn't grant them any special rights, however.

Managing to a Successful Acquisition: Interview with LimFlow CEO Dan Rose

Optimizing for Simplicity

The success of a medtech startup often hinges on the delicate balance between innovation and practicality. There are many variables at play here, such as the inherent tension between financial resources, development timelines, and the pursuit of a perfect product. In that vein, Dan stresses the importance of simplicity and user-centric design. And that means you have to be ready and able to pivot when necessary. “A great outcome through a super complex fashion is not good enough,” Dan cautions. Rather, what should guide your path are practicality and usability.

The system you start with is rarely the system you end up using. Dan admits that it took a lot of refinement and stripping down to reach LimFlow’s final product. Redirecting blood flow from arteries to veins in the opposite direction was inherently complex. Naturally, the initial design wasn’t as elegant as the last. But the team managed to work on the product until it was far less complex and more user-friendly.

One thing to keep in mind during the early development phases is that you’re not designing for yourself or even for the cutting-edge surgeons that you might involve in early testing. Dan’s strategy is to aim for the average user with the basic skill set right in the “middle of the curve,” because ultimately, that’s what drives demand. To hone your product to this demographic, you need to build iteratively until you achieve a level of ease-of-use that’s acceptable for the broader medical community.

Such commitment to user-centricity can involve tough decisions. For instance, Dan speaks of how they pivoted away from ultrasound features, which were unique to the company. And by doing this, not only did the team eliminate complexities in the device but ultimately arrived at a product that reduced crossing times by an hour. Such pivots take courage, especially when you've exhausted a lot of resources and acquired intellectual property around an idea. Yet, these aren’t good reasons to keep a feature that doesn’t align with the end goal: user-centric design and widespread adoptability.

To maintain such flexibility, it’s absolutely crucial to build the right team of people with whom you can effectively debate, refine ideas, and iterate. On top of that, once again, transparent communication with your board is essential. Dan highlights, “There should be zero surprises in the board meeting. Board members should be aware of what's going on before they get in. The conversations are more fruitful when everybody's had time to marinate.” In this sense, as the CEO, you must serve as the bridge between the team and the financial realities, i.e., the board, and make sure everyone understands the nuances of your development as well as your position in the market.

Win Over Investors with Your Expertise

As you progress through the different funding stages from Series A to E, Dan reassures that fundraising gets slightly more manageable, but it's never easy. This is because investor expectations evolve just as your company evolves.

One significant issue you should solve before looking for investors is reimbursement. The companies that have been successful in securing funding are those that found the sweet spot between clinical value and economic viability.

Dan shares, "In the Series E, at least 35 to 40% of all our discussions with VCs were about reimbursement." So, having a robust strategy in this area can be the defining factor. Hospitals and doctors need to get paid, and if your product doesn't align with the reimbursement landscape, it might never see the light of day. Dan recommends learning how the system works and understanding the basic vocabulary before starting these conversations with investors.

In the story of LimFlow, Dan admits to having started with an undefined reimbursement pathway that evolved over time as the company worked to pioneer new territory. He explains, "We worked the system inside and out. We covered every angle – clinical trials, reimbursement, and learned every facet. We nailed down the coding and became experts. That way, when talking to VCs, we could speak confidently about how it would work, what the expected pricing would be, and the long-term potential."

To manage your time and efforts efficiently, it's essential to target investors who actually have the capital to invest in your domain. Dan advises, "Know who you're talking to, what investments they make, and what they are looking for, as well as the successes that they've had in the past. Compare yourself to those successes and find the parallels." To know all these things, you need to do your homework: understand what the investors are looking for and whether their interests align with your venture's goals. While being polite is important, you shouldn't spend time on those who can't invest.

Instead, you should identify those who can infuse substantial capital. Dan explains, "One person can solve your round by writing a $30 million check. That's a lot different than trying to piece together six different investors for a few million each, even though it's the same amount of work."

Don’t Build A Unicorn, Build A Useful Zebra

Interview with DeepLook Medical CEO Marissa Fayer

Marissa Fayer

Preview

Marissa Fayer, with over two decades of experience in the medtech sector, is the CEO of DeepLook Medical, developers of AI-powered diagnostic tools that help radiologists detect cancerous lesions in dense tissue. Marissa talks about the basics of product development, how to build iteratively, tips on identifying ideal regulatory pathways, and how she picks her advisors and board members.

About Marissa

Marissa Fayer, CEO of DeepLook Medical, has over two decades of experience as a medtech executive, entrepreneur, investor, and philanthropist, spanning companies like Hologic and Olympus. She’s the founder of HERhealthEQ, a non-profit focused on advancing global women's health, and an entrepreneur-in-residence at Graybella Capital and Goddess Gaia Ventures. She’s a TEDx Speaker, a UCSC Miller Center Social Entrepreneur Fellow, and winner of the 2022 First in FemTech award.

Key Learnings From Marissa’s Experiences

- Make sure that you’re solving a real problem rather than creating solutions in search of a gap. Identify a genuine need and develop a product that enhances efficiency and outcomes while fitting seamlessly into existing workflows.
- When engaging with FDA, explain your technology in layman's terms. Leverage predicates if they’re available. Design trials primarily for regulatory purposes, but ensure they’re equitable for broader credibility.
- Accelerators are valuable for startups at any stage. They can offer networks, new perspectives, publicity, and even potential funding opportunities. However, they are also time-consuming, so assess the benefits and choose wisely.

Don’t Build A Unicorn, Build A Useful Zebra: Interview with DeepLook Medical CEO Marissa Fayer

Don’t Build a Unicorn, Build a Useful Zebra

Marissa joined DeepLook as an advisor in 2020 and became its CEO in 2022 when the company was past product development and on the precipice of commercialization. This wasn’t Marissa’s first rodeo; she’s been involved with a number of launches before.

When it comes to product development, Marissa emphasizes the importance of focusing on real, existing problems rather than conjuring up solutions for problems that don’t exist. “Don't just create something that has actually no value to anybody, and try to figure out how it fits,” she advises bluntly. You need to identify genuine needs and address them effectively. Ask physicians, hospital administrators, anybody actively involved in healthcare, “How can you make their day better?”

One critical aspect, especially in healthcare, is fitting into existing workflows. “Physicians, nurses, and anybody in healthcare has limited time. You have to either drastically change outcomes or reduce the amount of time spent on something,” Marissa observes. According to her, this approach – focusing on making their lives easier rather than overwhelming them with solutions that don’t fit into their daily practice – is absolutely essential.

Your goal should be to find a painful problem, understand it thoroughly, and then figure out how to integrate the solution into an existing workflow. Following this formula, Marissa’s approach is to start small and build iteratively. “You can't start at the endpoint,” she notes. “You have to start where people can understand it and where you can work.” In DeepLook’s case, they started with deterministic software without learning capabilities – thereby avoiding HIPAA complications. Gradually, over time, the team built the AI and ML algorithms into it.

Marissa’s overarching advice is to stay humble. Not every product needs to be a ‘unicorn’ – a rare, highly sought-after revolutionary piece of tech. Instead, she says, “99% of companies are not unicorns, but they're the ones that are propping up the economy. They're profitable and offer consistent returns to their investors. They're improving patients' lives and physicians' day-to-day workflow. Not everything is this pie-in-the-sky outcome.”

Start Simple and Explain It Clearly

Based on Marissa’s extensive cross-functional experience, she champions two key strategies when it comes to navigating the regulatory landscape: maintain simplicity and leverage existing predicate devices.

"The way we obtained regulatory clearance was by using very understandable code," she explains. The fact that they started with deterministic software, as opposed to AI – which is often less familiar to regulators – was an advantage in the beginning. In other words, start with simple concepts that non-experts can understand.

Marissa notes that the easiest regulatory path in most cases is a 510(k). “That was the route that we were lucky to have taken. That is the route we will probably continue to take.” If there’s a predicate in your domain, don’t miss the chance to capitalize on it. She also highlights the importance of demonstrating to regulators how your technology is “better, different, and how it can be utilized in the real world.”

Marissa also advises not to overcomplicate clinical studies. Design trials primarily for regulatory purposes at the start, and then you can run more complex studies later to demonstrate differentiation to end users. However, maintaining equitability is of utmost importance to her. Marissa illustrates, “You could be using a 20-year-old predicate. I guarantee you it’s not tested on women, people of color, etc.” Even if it's not required by FDA, testing your product on a diverse range of participants adds credibility to your clinical work.

Don’t Build A Unicorn, Build A Useful Zebra: Interview with DeepLook Medical CEO Marissa Fayer

Accelerators Are for Every Stage

Having participated in well-known accelerators like Massmedic Ignite and AARP Age-Tech Collective, Marissa is well-versed in their benefits and how to leverage them effectively.

She emphasizes that accelerators are not just for early-stage companies – they can also be pivotal for more mature startups. Being part of an accelerator helps you expand your network and brings different perspectives and viewpoints. As she calls out, “You don’t have to follow their process rigidly.” In Marissa’s case, the accelerators specifically gave her publicity and networking opportunities – which are essential if you’re about to go commercial – and opened up potential funding opportunities.

While the benefits are obvious, it’s important to pick the accelerator carefully. It has to align with your stage and needs. For instance, while Y Combinator might be ideal for early-stage tech startups, it may not offer much for companies approaching commercialization.

Seek Funds Outside of Your Niche

As an entrepreneur in residence (EIR) at Graybella Capital and Goddess Gaia Ventures, Marissa has a lot of experience on the other side of the table. Yet she quips, “Fundraising is the bane of my existence. I wish I never had to do it again.” The irony is, that she's both experienced and successful at it.

According to Marissa, it’s important to broaden your radar beyond your specific niche, while not straying too far either. For example, if your company is focused on women’s health, like DeepLook, you don’t have to limit your outreach to femtech investors. Marissa notes that only 2% of venture capital dollars go to women's health, even though females represent 51% of the population. This might apply to other industries too. “Building a diverse investor base gives you visibility, which is crucial, especially when planning an exit strategy,” Marissa explains.

During the actual fundraising process, you need to demonstrate well-thought-out plans and real progress. “Investors want to see tangible progress and potential, not just impressive presentations with no substantial work behind the surface,” Marissa shares. You need to set realistic expectations and stage-gated plans, and communicate both to potential investors.

Balancing the Clinical-Commercial Tightrope

Interview with Mercator MedSystems CEO Trent Reutiman

Trent Reutiman

Preview

Trent Reutiman has 25 years of leadership experience in medtech with a particular focus on minimally invasive interventional therapies. As the CEO of Mercator, Trent and his team have developed microinfusion devices with the unique ability to locally and directly deliver targeted therapeutics during catheter-based interventions where mechanical therapy isn't sufficient. Trent talks about the importance of generating data, how to balance commercial efforts with clinical initiatives, and why meticulous management is critical for successful commercialization.

About Trent

Trent Reutiman, CEO of Mercator MedSystems, has 25 years of leadership experience in medtech, including roles in sales, marketing, and business management with a focus on minimally invasive interventional products for companies like IDEV, ROX Medical, RITA Medical Systems, Guidant, and Cordis.

Key Learnings From Trent's Experiences

- Clinical and commercial efforts are a balancing act. You need to demonstrate your technology's efficacy by gathering solid data for regulatory approval and reimbursement. However, you also need to consistently improve upon the design and usability of your device. Embrace the fact that the initial product may not be perfect, but if it achieves the right outcomes, you can refine it over time.
- Be willing to reassess and shift your focus, especially when facing challenging scenarios or strong competition. Don't hesitate to reposition your product to meet emerging needs or enter less-crowded markets. Embrace change as an opportunity to prove the versatility of your technology.
- Treat your product and market with care. Be selective about who you sell to – especially if your technology requires a learning curve – in order to preserve its efficacy. Know your position in the market and articulate it clearly. Remember, a quick 'no' is better than a slow 'maybe.'

Balancing the Clinical-Commercial Tightrope: Interview with Mercator MedSystems CEO Trent Reutiman

Balance Commercial Efforts With Clinical Initiatives

Medical device development and commercialization require various types of data. In a lot of cases, you need solid clinical data to support your device's regulatory pathway and/or to make a strong case for why it should be covered by insurance.

The level and type of data required depend on your specific context, like market dynamics and reimbursement scenarios. For example, if you're in a fast-moving market and your product already has some level of reimbursement, you might be able to rely on registry data, which is less costly and easier to manage.

However, in more challenging scenarios, like getting FDA approval for a novel device or establishing a new treatment method – drug delivery for venous treatments in Mercator's case – you might need more robust, randomized, and controlled data. In other words, you need to balance the development of the device itself versus the clinical outcomes that you aim to demonstrate. When it comes to that, there's a decision to be made: do you focus on showcasing the most compelling clinical outcomes with the device in its current form, or do you dedicate your energy to improving it instead?

Having said that, clinical studies and product development aren't mutually exclusive. For instance, Mercator's published early work on dexamethasone in arterial applications, though it never reached commercial markets, laid the groundwork for Bullfrog's application for venous treatments.

Trent shares his take-home message, "You might not have the end-all-be-all product, particularly in the initial clinical stages, but if you're aiming for the right outcome, you'll always be able to come back and continue to refine the device." The goal of an MVP is to show that it does what it's supposed to do; that it fills a gap in healthcare. After you've proven this key concept, you can start to focus on things like ergonomics and ease of use, but not any sooner. You have to be clear about your priorities and sometimes accept imperfections to move forward.

Having said that, Trent also acknowledges that it's hard to know, in the heat of the battle, when to step on the gas and when to pull back. While obtaining 510(k) clearance or CE Mark are important milestones, they come with their own sets of challenges. For example, there's a financial burden maintaining regulatory approvals, especially when the product is still in clinical development and not yet commercially viable. Trent shares, "It almost sounds blasphemous since everybody wants a 510(k) or aCE mark. Just be aware, pre-commercially, they're expensive to maintain."

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Tough Times Require Sharp Pivots

“The initial reaction of most people when they see Bullfrog is: ‘That's a very clever device.’ But it was initially conceived as a coronary drug delivery device,” shares Trent. Although Bullfrog was designed for something that's different from what it is now, thanks to Mercator’s flexibility and agility, the company has pivoted and evolved significantly to find its place in the workflow of physicians and, consequently, a place in the market.

The story goes like this: Mercator’s focus was initially on securing an indication for arterial applications. The team conducted studies and published data sets with that goal in mind. However, there were a few other companies – medtech giants – who were already ahead in the development of drug-coated balloons (DCBs). As a small company, Mercator wasn’t able to take on such tough competition from leading companies like Bard and Medtronic. A shift was needed.

Trent and the team decided to pivot to below-the-knee (BTK) applications with a new drug version, following an initial study using dexamethasone – a medication that yielded comparable results to DCBs.

Things were looking bright and Mercator was planning for a phase-3 study with 400 people. But everything came to a halt by COVID-19 and the challenges of enrolling patients and securing financing.

However, these challenges turned into an opportunity to highlight the versatility of the platform. At the time, Mercator had a lot of users who worked on both the arterial and the venous sides, and physicians were really interested in the potential of anti-inflammatory steroids for venous interventions. Shifting focus to that area, Mercator gained significant traction. Trent shares, “If there is an upside to COVID, and there aren't many, for us, it’s that it unlocked the real platform capability of Bullfrog.”

Leaning on early work with their anti-inflammatory steroid, Mercator developed a larger device that is more suited for venous applications. They then extended their 510(k) to cover this new application, placing Mercator as a front-runner in bringing drug delivery to the venous space. “We're far out in front of the others now,” Trent shares.

Having said all that, Mercator’s previous efforts weren't in vain (pun intended). Trent says the company is still open to exploring arterial applications, particularly below the knee, where their phase-3 study awaits more resources or potential partnerships.

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You May Not Want to Sell to Everybody

Mercator's commercialization strategy might seem counterintuitive to some, but the delicate balance between benefit and risk has made it a necessity. Although seemingly easy to use, Bullfrog is a device that requires a degree of sophistication, and as the saying goes, *the dose makes the poison*.

Despite increased demand from distributors, Mercator doesn't just sell to everyone. Their target customers are those who are deeply involved in clinical work and who understand where the Bullfrog device can be properly utilized – such as patients who don't fit standard study profiles. Trent shares, "It might sound funny, but we literally have distributors chasing us down."

Ensuring your device is used in optimal conditions for the intended outcomes is often underappreciated. Otherwise, it might get sidelined or unfairly be deemed inefficient.

Trent also warns against rushing to market without a meaningful reimbursement strategy. This might lead to inefficient use of the product – or even potentially harm the product's reputation in the long run.

In addition to being astute about your customer base, it's also crucial to be selective about where your investment comes from. You need to clearly express who you are as a company and who your potential investors are. Trent says, "Know your own model, know your own milestones, and don't take any more money than you have to because you'll raise in the future again."

Different investors focus on different stages of a company's development, from early-stage Series A to later-stage growth capital. It's important to tailor your funding efforts to the right type of investor for your stage. In medtech, involving investors who have a medical background or understanding, such as family offices with a physician who's part of the team, can be more productive. And a fast 'no' is often better than a slow 'maybe'.

About the Author

A self-described medical device and health technology enthusiast, Scott is the co-founder and CEO of FastWave Medical, a venture-backed cardiovascular startup developing differentiated intravascular lithotripsy (IVL) systems for calcific artery disease, a market valued at over $9B.

Scott is the founder of Medsider and was named one of MD+DI's most influential medtech voices to follow in 2024. His work with Medsider has been featured in publications like Forbes, Mass Device, MedCity News, and MD+DI.

Scott is also the founder of Joovv, one of the leading photobiomodulation brands in the world, and has participated in highly popular podcasts with Dave Asprey, Skinny Confidential, Ben Greenfield, Aubrey Marcus, and many others. He's also been featured in media outlets like the New York Times, ESPN, and Men's Journal.

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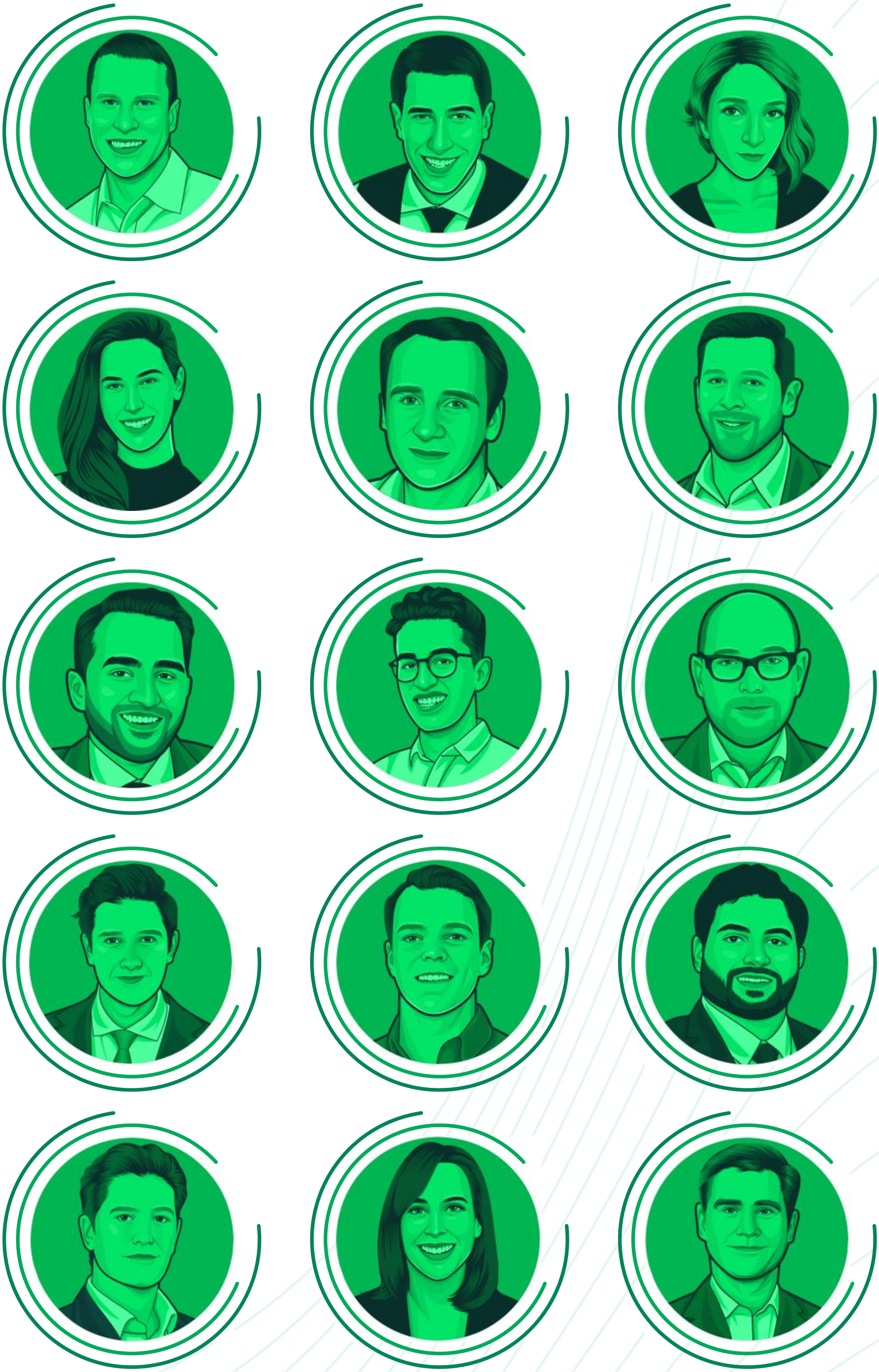

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