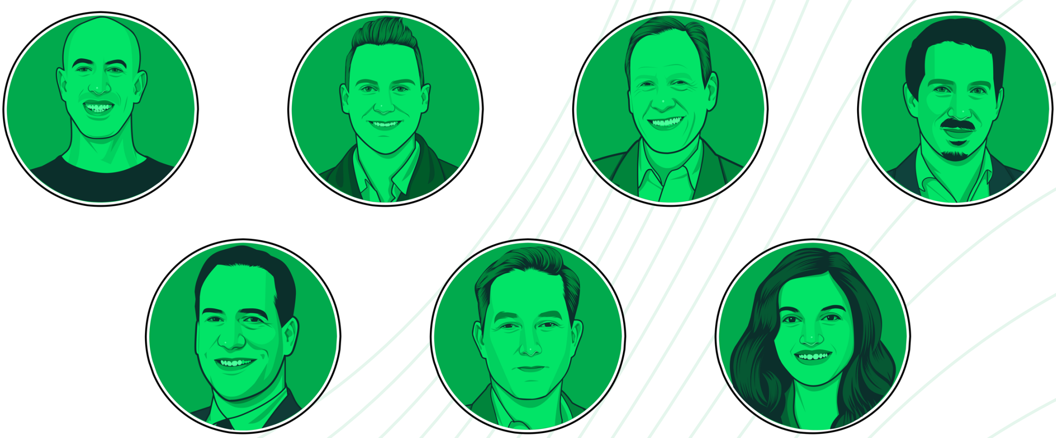
MEDSIDER

VOLUME III

MEDSIDER MENTORS

LEARN FROM THE FOUNDERS AND CEOs OF HINGE HEALTH, ACCESS VASCULAR, BRIGHT URO, REFLEXION MEDICAL & MANY MORE



SCOTT NELSON

For more information, address Medsider, PO Box 780637, San Antonio, TX 78278.

For information about special discounts for bulk purchases, please contact Medsider at hello@medsider.com.

This book is brought to you in part through sponsorship by Big Sky Biomedical.

TABLE OF CONTENTS

INTRODUCTION

Over the past few months, I've had the privilege of talking to some of the brightest minds in the health technology and medical device arenas. Many of you have joined in by listening to those conversations on our Medsider podcast.

To add even more value, we've distilled the key insights from these founders and CEOs into this volume of Medsider Mentors. Feel free to use these learnings as a reference guide to the podcasts you've already enjoyed. Or, if you're a premium member, you can use them as a sampler to decide which episodes you're most excited to download and re-listen to.

For those who have read and enjoyed our first two volumes of Medsider Mentors, this edition offers fresh perspectives and expands on some of the ideas we started exploring there. If you missed it, consider going back to get the most out of both volumes.

In this collection, you'll find insights from entrepreneurial trailblazers on embracing risk, navigating regulatory complexities, and pushing the boundaries of innovation. We talk about the importance of pursuing the right market, overcoming personal and professional challenges, and building strong teams to thrive in a competitive space.

Here's a taste of what's to come:

Scott Nelson on Embracing Risk and Taking Shots

Welcoming risk and pursuing opportunities beyond your job description can lead to some pretty remarkable things. As the founder of Medsider, I can attest to this through my own journey from corporate life to building a startup that generated $20 million in revenue within just a few years. I open the volume discussing the essential values for medical device founders drawing from my experiences and the importance of weighing a corporate career versus entrepreneurial endeavors.

Jim Pursley on Pursuing the Right Market

Patient-centric solutions are revolutionizing healthcare. Hinge Health CEO, Jim Pursley, reveals his company's approach to improving the lives of millions and shares valuable insights on identifying the right market, cultivating self-critique, and ensuring that healthcare solutions deliver both clinical improvements and cost efficiency.

INTRODUCTION

Ziv Peremen on Creatively Navigating the Regulatory Landscape

Ziv Peremen, CEO of X-trodes, has successfully leveraged creative commercialization strategies for their cutting-edge Smart Skin technology, while navigating the regulatory landscape. Ziv shares valuable industry lessons on building a solid company infrastructure and seizing commercial opportunities in a complex regulatory environment.

Marc Zemel on Making Lasting Impressions

Marc Zemel, CEO of Retia Medical, discusses the critical nature of first impressions in the medtech space and the intricacies of navigating third-party diligence processes. With extensive experience in both successful startups and Fortune 500 companies, Marc shares insights on how to get the right stakeholders on board early on and how to protect your company with safety mechanisms during business negotiations.

Torrey Smith on Innovative Networking Strategies

Discover how Torrey Smith's innovative networking strategies linked him with venture capitalists and influential physicians. Learn about his company's ambitious journey toward FDA clearance for the PillBot and how social media, creative experimentation, and compelling storytelling can empower a medtech startup to overcome challenges and establish strong industry relationships.

Derek Herrera on Aligning Collaboration and Decision-Making

Derek Herrera faced a number of medical challenges after sustaining war-related injuries in Afghanistan, which led him to recognize the potential for innovation in several areas, including the urological space. As the founder of Bright Uro, his company is revolutionizing bladder diagnostics with a more comfortable, efficient, and accurate device. Learn how alignment, collaboration, and decision-making contribute to a successful medtech startup in this compelling interview.

INTRODUCTION

Mark Carbone on Turning Ideas into Thriving Businesses

Mark Carbone, CEO of PN Medical, turned a respiratory therapy idea into a thriving business, and shares his insights on product development, commercialization, and distribution. Discover the importance of finding champions who can move the needle for your business, protecting your products with the right intellectual property, and identifying trustworthy distributors.

Dan Zavorotny on Building a Thriving Consumer Health Startup

Dan Zavorotny co-founded Nutrisense, a successful direct-to-consumer healthtech company that uses personalized nutrition data to improve people's health and wellness. He shares insights on building a thriving consumer health startup and talks about the importance of customer feedback and creative hiring strategies, as well as the necessity to drive diverse teams to drive healthcare innovation

Osman Khawar on Early-Stage Technical Risk Reduction

Nephrologist and entrepreneur Osman Khawar, CEO of Diality, emphasizes the need for early-stage technical risk reduction in medical device startups. Dr. Khawar highlights the significance of collaborative relationships, assembling the right regulatory team, and building a mission-driven culture. Learn from the experiences of a physician turned entrepreneur passionate about transforming dialysis care.

Meesha Dogan on Transforming Scientific Breakthroughs into Marketable Products

Meesha Dogan, CEO and co-founder of Cardio Diagnostics, channeled her passion for biomedical engineering into a company focused on early heart disease detection through her co-invented, patent-pending cardiac diagnostics. Meesha shares how to transform scientific breakthroughs into marketable products, make them accessible, and choosing the right approach to raising capital.

INTRODUCTION

Ohad Arazi on Understanding User Needs

Ohad Arazi, CEO of Clarius, has an extensive background in the technology industry that led him to his role in developing high-definition wireless ultrasound systems. Ohad discusses how to create products that meet the needs of the target market, understanding regulatory and reimbursement pathways, and the importance of having a strong channel strategy.

Sam Mazin on Maximizing Value Creation in Your Startup

Sam Mazin, a physicist turned entrepreneur, shares the secrets behind his successful medtech startup journey. Focusing on risk retirement, strategic clinical trial designs, and persuasive investor pitching, Mazin explains how to maximize value generation and capital efficiency in the medical device space.

Lloyd Mencinger on the Importance of Resilience and Persistence

Lloyd Mencinger, CEO of Aqua Medical, has firsthand experience adapting to the ever-changing medtech landscape. Delve into key strategies for resilience, including capital management, swift product iterations, and the power of perseverance to overcome obstacles and build a thriving medical device company.

Steve Dimmer on Balancing Focus and Flexibility

Steve Dimmer, a seasoned veteran in the medical device industry with over 30 years of experience, including a variety of medtech startups, took on the CEO role at CurvaFix to revolutionize pelvic fracture treatments. Discover how he identified a large market opportunity, secured the right investors, and developed a tailored regulatory strategy that led to quick market clearance.

INTRODUCTION

Carol Burns on What it Takes to Win as a Medtech Startup

From critical care nurse to medtech powerhouse, Carol Burns has a stellar track record as a serial entrepreneur. As the CEO of Cagent Vascular, she's leading the company's efforts in bringing the innovative Serenator angioplasty balloon to market. Carol shares vital insights into navigating the challenging startup landscape, highlighting the significance of assembling a strong team, establishing a solid foundation for product development, and honing fundraising strategies.

It's no surprise that I eagerly anticipate every single one of these discussions, as I can learn from and apply practical gems of wisdom when leading my team at FastWave Medical. Therefore, I hope this volume proves to be as beneficial for you as it has been for me.

Thank you for being a dedicated reader, and as always, feel free to share your suggestions on who you'd like to see featured in the next edition of Medsider Mentors.

Best wishes,

Founder of Medsider

Founding Partner and Managing Director of Big Sky Biomedical

Co-Founder and CEO of FastWave Medical

LESSONS LEARNED BOOTSTRAPPING A STARTUP FROM $0 TO $20 MILLION

Interview with Medsider Founder Scott Nelson

Scott Nelson

Summary

Scott Nelson, founder of Medsider and numerous medtech startups, tells how each of his career transitions brought invaluable lessons, the risk and reward of leaving corporate life, the essential values for any medical device founder, and how to find opportunities that are rooted in your experiences.

About Scott

Scott Nelson has spent the last two decades in the medtech space, starting in medical device sales roles that ultimately led to startup leadership positions. During that time, he followed his curiosity through several career transitions while engaging in side projects along the way. He's the founder of Medsider, Joovv, Crossfire Medical, and FastWave Medical. The latter two are spinouts with his partners at Big Sky Biomedical.

Key Learnings

- When in a full-time role, dedicate 10-20% of your time to exploring opportunities outside your job description — the insights you gain will benefit you and your company.
- Acknowledge the risk inherent in any career change, understanding the potential for reward and growth on the other side.
- Founders need to be willing to dabble and experiment in the early days of a project, make space to pivot as the work evolves, and ensure they're working with the right team as early as possible to optimize decision-making and results.
- Never stop networking — stay close to your connections and allow space for future projects you can't anticipate. Look for opportunities that align with your experiences and expertise.

Taking Risks in Each Transition

Following his first position out of college at a small commercial finance company, Scott began his medical device journey with Conmed, which later launched him into the cardiovascular space.

Nearly a decade later, Scott was a senior sales manager at Covidien through their acquisition of Bacchus Vascular, a thrombectomy start-up. He took a major leap — and pay cut — by participating in a two-year program with the company that brought sales leaders in-house to marketing positions. Scott saw the move as a valuable opportunity to learn about all sides of the business and planned to move back into sales leadership when the time was right.

However, he faced a significant shake-up when Medtronic acquired Covidien. Major leadership changes meant that Scott's plan to leverage the role into something bigger was no longer an option.

This led to a period of uncertainty: Would he take an internal lateral move, keep climbing the ladder, or pursue something else? The first two options didn't compel Scott, and he soon got a first taste of the start-up space with his move to head up partnerships at Touch Surgery, a London-based digital health company that was later acquired by Medtronic.

The common denominator in each of Scott's early career transitions was risk: shifting away from the path he was on to pursue something else in hopes of gaining new knowledge and experiences.

He says this is inevitable: "The moral of the story is that every career pivot is going to come with some risk. You've got to be willing to take some swings."

Going Beyond the Job Description

Looking back, Scott wouldn't trade any of his early experiences, particularly the lessons he gained in a corporate environment. His in-house marketing role offered priceless exposure to many departments and aspects of the business that he wouldn't have obtained on a strictly-sales trajectory.

Anyone in a corporate role greatly benefits from spending 10-20% of their time exploring and discovering different parts of the business. This process offers major advantages for both the individual as well as the company itself.

Regardless of your current role, go beyond your job description by volunteering for unique opportunities and raising your hand for any project that comes up that takes you somewhere new.

To guide this exploration, Scott also recommends curating a network of mentors. When new projects or opportunities come along, it's invaluable to have individuals in your corner — even if you only talk once a year — who can provide wisdom based on their previous experiences.

Taking the Leap From Corporate Life

Many entrepreneurial-minded people are prone to having side hustles alongside their full-time roles — and Scott was no exception. However, he's not quick to advise someone making hundreds of thousands of dollars per year to simply take the leap to a side hustle they find interesting, either.

"There are few and far opportunities where you're going to basically be able to turn a side hustle into something that completely displaces that gig," he says.

Abruptly taking the leap from a high-paying position to going all in on something you find interesting results in a considerable amount of pressure. What you once loved will become painfully high-stress.

Scott further explains that the career leaps he's taken haven't been dependent on immediate success. It's important to have the financial flexibility and runway to pursue passion projects before depending on them to pay the bills.

After spending just over a year at Touch Surgery, Scott felt that the product-market fit wasn't right, and the risk of staying seemed greater than the risk of leaving. He moved to a marketing agency that was growing its medtech practice, where he learned an immense amount in a year's time.

During that same time, Scott had been working on a significant side hustle: Joovv, a red light therapy company inspired by his wife's success with spa-based treatments and his interest in exploring at-home options.

Once again, he followed his natural curiosity, this time to commercialize a product in the red light therapy space. But the early exploration and prototyping work took place while he was still working full-time.

A full year into what he calls "dabbling" with Joovv, the product started to take off. He had a specific monthly revenue target in mind that would compel him to leave his full-time role — and once Joovv became a million-dollar business, he took the leap to run the company full-time.

The leap was worth it. Scott profitably bootstrapped Joovv from $0 to $20 million in revenue over the course of three years.

Key Values for Founders

Ultimately, there will be risk involved with any move from a stable position to starting something new. Some projects won't come to fruition. Others, like Joovv, will be the win you've been looking for.

Scott points to several startup essentials for the success of various endeavors he's been a part of.

1 Willingness to explore

Scott and a few engineers worked on another medtech startup during the early days of Joovv. They spent several years exploring prototypes, collecting voice of customer research, and pitching the company to various investors before ultimately pausing it.

Some projects will be a swing and a miss; others won't. "You've got to be willing to dabble a bit," Scott says. Exploring and experimenting — including trying things that don't work — are going to be the best ways for founders to discover which projects will ultimately be a success.

2 Being ready to pivot

With Crossfire Medical, another of Scott's co-founded startups, the original team circled back around in mid-2020, bringing new life and ideas to the company, and ultimately closed on a seed round of financing about a year later.

Scott says that flexibility is key for founders, who need to be willing to allow projects to evolve and change over time. If stepping away is the right move — either temporarily or for good — entrepreneurs need to be open to either shutting something down or pushing through the challenges.

3 Aligning as early as possible

One of Scott's key lessons has been to be sure to work with the right people on a project as early as possible. As soon as a side project starts to show promise, assess the team you have and make adjustments sooner rather than later.

Down the road, even if you have the right contracts or legal elements in place, if you disagree with the people around you about capital-raising or major business decisions, the end result likely won't turn out well.

Finding Opportunities Rooted in Your Experiences

Now at Big Sky Biomedical, Scott works on early seed-stage medtech startups to help them avoid what he calls the “medical device valley of death.”

Scott and his partners at Big Sky assess three key factors when engaging in new projects: the clinical need, the regulatory pathway, and the reimbursement outlook. Big Sky works within a narrow window of projects that check each of these boxes.

When considering opportunities to invest or start a project from the ground up, explore from that same place of natural curiosity grounded in your prior experiences.

For Scott, this means staying close to the consumer health space. He found the fast pace and tangible impact incredibly exciting. Using this domain expertise, Scott now looks for ways to apply direct-to-consumer best practices to traditional medtech projects.

Even if you’ve transitioned out of one area, there are likely principles you can pull into your new space. Stay tuned into your former industry niches — you never know what future opportunities you might encounter.

Perhaps most important, don’t lose touch with industry contacts, especially those with whom you connect and share your fundamental beliefs. Scott has found the well-known cliche to be true: your network is your net worth. It’s one of the most valuable tools for opening up new opportunities.

Interview with Hinge Health President Jim Pursley

Jim Pursley

Summary

Hinge Health President and former Chief Commercial Officer for Livongo Health, Jim Pursley discusses finding the right market, being your own biggest critic, and marrying clinical improvements with cost savings.

About Jim

Jim Pursely has spent the last decade tackling some of the biggest problems in healthcare. He was part of the founding executive team as the Chief Commercial Officer of Livongo Health and took the company public, culminating in an $18.5B acquisition by Teladoc Health. Since March 2021, Jim has been Hinge Health's President. The company is ranked #2 on Crunchbase's Diversity Spotlight Report

Key Learnings

- Go big when picking a market. It's much easier to convince providers to spend money on a more cost-effective solution to a problem they're already paying for than to convince them of a different problem they don't believe exists.
- Put evidence of cost savings above potential ROI numbers when positioning your offering. You have to be honest with yourself about the degree of economic savings your product creates. If you focus too much on immaterial numbers, you may end up making poorly calibrated decisions.
- Focus on both cost savings and clinical efficacy. Both are critical to building a profitable technology that improves people's lives. Focusing on either one to the exclusion of the other means building a business on a poor foundation.

MARRYING CLINICAL OUTCOMES WITH COST SAVINGS

Picking the Right Market

Hinge's success comes from not shying away from the big problems. Roughly half of all Americans suffer from muscular skeletal issues. The overall cost to the US healthcare system is around $600 billion a year and these muscular skeletal issues are mostly overlooked compared to cancer, obesity, and heart disease.

Focusing on muscular skeletal therapies was a master stroke not only because the market is so massive but also because they are delivered so inefficiently. That meant prospective customers were well aware of the problem Hinge was trying to solve and were desperate for alternatives.

Getting physical therapy is difficult, which is why so many people opt for expensive and potentially dangerous alternatives like surgery or opioids. It's cost prohibitive for most patients, with most having to pay out of pocket for some or all of the cost.

For a lot of injuries, like pelvic injuries for women, there's a real shortage of staffing. Pelvic health physical therapists are in short supply, and all the money in the world may still not secure you the sessions you need.

Under Jim's leadership, Hinge Health is pioneering remote alternatives that promise to make routine physical therapy more accessible. Using its technology, caregivers and physical therapists can evaluate patients remotely.

When we spoke, Jim explained the logic of this approach.

"There's one thing to try to convince a whole bunch of people to see a problem that they didn't fully appreciate or recognize versus saying, you're already spending time and money and energy here. You're just doing it in an unpleasant, maybe inefficient way. And there's a better way to think about product market fit," Jim says.

Address a problem where money is already being spent, allocated, and budgeted. And focus on solving an issue that hasn't been addressed yet.

Factoring in Cost

Jim says one of the big mistakes health technology companies make is focusing exclusively on clinical outcomes when designing a trial or study. For him, it's important to consider both clinical outcomes and cost savings when gathering data on your product.

In Jim's words, "I think a lot of healthcare entrepreneurs miss out maybe on the latter part. They'll maybe design a trial or a study that's highly, highly focused on clinical outcomes, which is great, but won't look for maybe some quantifiable cost improvements as a part of that study."

Factoring in Cost (Cont’d)

For example, to determine economic impact, Hinge examined 136 employers ranging from Fortune 500 companies to smaller firms. They were able to create $2,400 a year per patient in savings. This is much more reliable than self-reported ROI.

Focusing on cost savings can be an effective way to get crucial third parties on board. For Hinge, employers and corporate healthcare plans have opened up completely new markets. These kinds of providers are motivated by finding cost-effective solutions to widespread problems.

That’s why targeting employers is a core part of Hinge's strategy. Jim describes them as "the innovation engine of the nation's healthcare system."

For Hinge, focusing on healthcare plans was an effective way to reach small-scale employers who might otherwise not be a realistic target.

Jim says, “Health plans have been wonderful partners to us in helping to expand our reach.” Taking advantage of employer-provided plans relies on finding a good fit between your product and the services those plans already provide. In Jim’s words, “How do we integrate our offering with their offering so that one plus one equals three?”

Getting the Right Investors on Board

You should think carefully about who you raise money from. You should consider whether the investor you choose shares your vision and has the patience to persevere through multiple stages of your project.

Jim embraces a more competitive investment environment. He says you need to be wary of investors willing to pour money into projects they don’t understand. When the market turns, you want capital partners who know what you're offering and can effectively evaluate the success in your industry.

"Are your investors going to continue to support you if I raise a Series A or B?" Jim asks. “Is this an investor who will come in my C or D round? Because they intend to be a long-term partner, they will invest in public markets. Will they be a buyer on the day of the IPO if I am fortunate enough to take the company public?"

CREATIVE WAYS TO MARKET YOUR TECHNOLOGY WHILE NAVIGATING THE REGULATORY LANDSCAPE

Interview with X-trodes CEO
Ziv Peremen

Ziv Peremen

Summary

X-trodes CEO Ziv Peremen discusses the company's Smart Skin technology and reveals that by making it commercially accessible in a creative way, he's gained invaluable data, discovered new commercial uses for the product, and established key relationships as they await regulatory approval.

About Ziv

After completing his PhD in neurocognitive science with a specialization in understanding consciousness, Ziv Peremen has spent the past 12 years focused on the intersection of data and physiology. Together with Professor Yael Hanein, an expert in the field of human-machine interface learning and inventor of innovative sensor technology, they founded X-trodes.

Key Learnings

- When developing your technology, think about creative ways to potentially commercialize in advance of regulatory approval. For X-trodes, that meant selling their product as part of a research kit, leading to critical learnings for the company.
- Focus on building a solid company infrastructure from the start. Don't skimp during this period, as it's critical for discovering the kinks in your technology, receiving key feedback from end users, and partnering with impactful players.
- Avoid manufacturing custom products that are not critical to your core technology stack. Invest more resources in finding off-the-shelf solutions rather than depleting your budget trying to recreate the wheel.

CREATIVE WAYS TO MARKET YOUR TECHNOLOGY WHILE NAVIGATING THE REGULATORY LANDSCAPE

How is Smart Skin Different From Other Wearable Devices?

It goes without saying that consumer-wearable technology like Oura rings and Whoop smart bands offer a compelling user experience, but the data collected by these products is not designed for medical use, which can limit their utility.

Smart Skin, which is manufactured by X-trodes, is engineered with clinical-grade technology meant for sophisticated sleep monitoring as well as the collection of a vast amount of data for other medical uses.

Be Open to Discovering More Than One Way to Commercialize Your Product

Early on, Ziv and his team had a choice between manufacturing a device for consumers or medical providers and settled on the latter. But as Yael, his co-founder, was presenting the technology at conferences, based on feedback from peers, they discovered a demand from researchers to access the technology.

Based on this demand, X-trodes partnered with Emotiv, a well-known bioinformatics company, to distribute commercial research kits for electroencephalography (EEG) applications.

Through this collaboration, customers have access to the X-trodes sensors and can use Emotiv's data platform for neuroscience research to process their user-generated data.

These research kits don't represent the primary business model for X-trodes, but the company seized the opportunity to commercialize before regulatory approval, which allowed them to introduce their product to the market, gain critical insights, and establish key partnerships.

Avoid Manufacturing Custom Components That Are Not Part of Your Core Technology

The sensors that attach to the skin are the core component of the X-trodes technology and are manufactured by their company. Early in their journey, the R&D team couldn't find the electronic components necessary to work with their sensors.

After sampling various off-the-shelf parts, Ziv and his team decided to develop their own custom electronics. The end result worked out very well.

But in hindsight, Ziv encourages other founders to strongly consider the ramifications before going down the custom manufacturing path.

CREATIVE WAYS TO MARKET YOUR TECHNOLOGY WHILE NAVIGATING THE REGULATORY LANDSCAPE

Avoid Manufacturing Custom Components That Are Not Part of Your Core Technology (Cont'd)

Ziv stated, "We started to recruit more and more experienced technicians and increased our R&D...budget in order to afford this solution. In the end, it took us a year and a half and several millions in order to get the result that we have today. [Looking back] I would [have] invested more resources to find something off the shelf."

Design the Optimal Fundraising Environment for Your Startup

X-trodes has successfully raised two rounds of capital, one of which was $4.5 million. Ziv credits this to opportune timing by creating the right environment for fundraising.

Rather than waiting for the perfect opportunity to fundraise, a startup founder or CEO should be building the right thought leadership processes from the start. This includes strategic PR, speaking at conferences, consistent communications with your network, etc., all in an effort to create a conducive fundraising environment to attract the right type of investors.

FIRST IMPRESSIONS ARE CRUCIAL IN MEDTECH

Interview with Retia Medical CEO Marc Zemel

Marc Zemel

Summary

Retia Medical CEO Marc Zemel talks about his experience bringing game-changing software to the medtech industry, why first impressions are critical, and how to ensure you have built-in safety mechanisms during third-party diligence processes.

About Marc

Marc has extensive experience in fundraising for successful startups and is an experienced leader of Fortune 500 companies. Prior to founding Retia Medical, Marc earned an MS in Mechanical Engineering from MIT and an MBA in Sales and Marketing from Yale. He's also held key leadership roles at Becton Dickinson as well as a capital equipment start-up.

Key Learnings

- **First impressions are vital:** In the medtech industry, there are very few second chances. Unlike the software space, you can't really build a minimum viable product (MVP) in healthcare. It's critical to hit the market with a product that does what it's supposed to do. Yes, there is always room for innovation and improvements, but the baseline product needs to be as advanced as possible before it's commercially used on patients.

- **Always have a backout clause:** In any business transaction, it's useful to have an out clause. Long-running diligence processes such as acquisitions require heavy resource allocation, costing both time and money. A backout clause offers protection so that should things fall apart, the efforts are not all in vain.

- **Get the right stakeholders on board early:** Domain experts are vital for product development. Whether you're making hardware or software, it's crucial to coalesce a group of stakeholders that are genuinely interested in your technology. Ideally, this group consists of people with connections to help generate commercial revenue or to get your devices in front of the right audience.

FIRST IMPRESSIONS ARE CRUCIAL IN MEDTECH

Innovating in a High-Risk Industry

Marc became attracted to the medtech space while studying for an MBA at Yale. Shortly after, he founded Retia Medical and was one of the early adopters of software for medical analysis. Marc saw huge potential in the market for medical software and set about designing the Argos system with a software-first perspective.

“We started Retia before the term ‘digital health’ existed. I was excited about algorithms because they are pretty hard to create, and so pretty-well protectable.”

The concept for the Argos system came directly from medical professionals, who complained that the software they were using was out-of-date and inaccurate. When dealing with high-risk patients, data inaccuracies can cost both money and lives.

The Argos Cardiac Output Monitor uses real-time data to monitor high-risk patients thanks to its Multi-Beat Analysis algorithm, which allows clinicians to provide accurate care based on the needs of the individual patient rather than focusing primarily on the case-specific median.

As an example, Marc explains a real-life scenario below when Argos was trialed on an ICU patient and immediately identified a problem that clinicians had not been able to detect.

“About a month ago, we brought our monitor out to a trauma ICU, and they were rounding with it to check on some patients. The patient's blood pressure and heart rate were fine. All the clinical data appeared to be normal. [But after hooking up the Argos], they noticed the patient's parameters were very abnormal, and it turned out that we detected an acute bleed. This patient was bleeding internally, and nobody knew it.”

Focus on First Impressions

The amalgamation of software and medical technology is not one without its pitfalls. The traditional software development process often involves producing a rudimentary product, more akin to a barely-functioning prototype. Sort of like a minimum viable product – or MVP.

But early on at Retia, Marc realized the software MVP framework was not feasible for most medical companies. Instead, clinicians want to see a product that actually functions versus discussing development sprints and iterative deliverables.

“There's no minimum viable product in medtech. Your first impression should be the best.”

FIRST IMPRESSIONS ARE CRUCIAL IN MEDTECH

Focus on First Impressions (Cont'd)

Medical professionals demand a certain level of quality in their tools, and if you show them a concept that's too early, you may lose their interest. Additionally, there is no room for error or software bugs in medical devices since the real-world implications are too significant.

However, Marc understood that many clinical professionals have a vested interest in upcoming technology. As a result, they are eager to get involved in discussions and offer feedback.

Networking events and focus groups are a great way to gather valuable information that can directly impact the development process. Just make sure your idea is far enough along in order to glean useful insights.

“Clinicians love to help because they want to see what's coming. And there are some really awesome people that will readily give up their time because they want to see improvements.” Marc advised.

Never Underestimate the Cost of Due Diligence

During Retia Medical's Series B funding process, Marc learned a lesson he only needed to experience once. The time and effort required during any diligence effort should never be underestimated. And it's critical for startups to protect themselves from the possible fallout.

Marc explained that he racked up significant fees and legal expenses during a long M&A diligence process. But when their potential acquirer pulled out at the last minute, Retia was left with the bill because they didn't have any breakup clauses in place.

“If I had to do that all over again, I would have insisted on a breakup fee. Whether it's a fundraise or an acquisition, you need to have some kind of backup plan,” Marc commented.

Diligence processes not only cost a lot of money but take up considerable employee time and attention, which can prevent the company from making meaningful development progress.

Marc recalled, “They had 90 people on their diligence team and we answered something like 450 questions. But 14 Zoom meetings later, all [your] employees will start asking for status updates. You can pretend to run diligence in parallel to your development, but you're not big enough to do those things at the same time.”

THE POWER OF STORYTELLING IN A MEDICAL DEVICE STARTUP

Interview with Endiatx CEO
Torrey Smith

Torrey Smith

Summary

Torrey Smith, CEO of Endiatx, breaks down the unique online networking strategies that helped him connect with venture capitalist investors and influential physicians, plus his company's plans to achieve FDA clearance for the PillBot through a fast-tracked regulatory process.

About Torrey

Torrey Smith co-founded Endiatx alongside fellow Silicon Valley technology experts Dan Moyer, James Erd, and Alex Luebke. After leaving a different medical device company to scratch his entrepreneurial itch, Torrey and his co-founders are developing a new technology that aims to lower the barrier for patients to get diagnosed and treated for gastrointestinal diseases

Key Learnings

- Don't be afraid to experiment with existing concepts when developing a product. Some of the most incredible inventions are built upon the adaptation, modification, and combination of technologies, data, and mechanics that already exist.
- Leverage social media platforms to reach doctors, investors, stakeholders, and your targeted users. You'll never know when a single post, video, or email can help you connect with someone who can support your product's regulatory process or expedite its adoption in real-life clinical settings.
- Never underestimate the power of sharing your product development progress from the very start. This helps you establish connections with people who will be eager to invest in your vision, even in the early stages.

Leverage Existing Technologies, Concepts, and Data

A common misconception is that you'll need a completely new and revolutionary idea to disrupt the healthcare landscape. But the PillBot attests to the power of innovating and adapting existing technologies to create a product with even more capabilities that can address important healthcare issues.

For instance, the PillBot isn't the first device built upon the concept of microrobotics for diagnostic or interventional medicine.

NaviCam and PillCam are other medical devices that have ushered in monumental breakthroughs and advancements in the utilization of microrobotics in healthcare. The PillBot combines existing mechanics that help devices move through water bodies with elements that remote-controlled drones employ.

Through the strategic adaptation of these available technologies, the PillBot was designed to be the "eyeball in the stomach." This device will enable doctors to receive visual inputs of a patient's gastrointestinal tract through a pill-sized robot, reducing multiple hospital visits and endoscopies into a convenient, at-home Zoom call.

"You look at their journey and ask them what their experience is like, and usually, they'll tell you they went to the hospital a bunch of times before a doctor spent five to ten minutes looking around with an endoscope and then told them they had gastritis," Torrey says.

Essentially, the PillBot was designed to lower the barrier for patients to get diagnosed and treated for gastrointestinal conditions. Yet, this groundbreaking invention did not require never-heard-of mechanics or novel technologies to shift the healthcare landscape in a tangible manner.

Furthermore, the company is now looking to attain FDA clearance through the 510(k) or De Novo pathways, both heavily reliant on existing predicates.

In other words, currently-approved products using similar technologies can pave the way for you to get your device into the market quicker through a fast-tracked clearance process.

THE POWER OF STORYTELLING IN A MEDICAL DEVICE STARTUP

Don’t Underappreciate Social Media as a Valuable Networking Tool

Torrey uses social media platforms such as LinkedIn and YouTube to share the progress and development of the PillBot. According to him, LinkedIn has played a significant role in amplifying the company's reach and success. But this came about with an intentional commitment and initiative to network and build genuine connections with doctors and prospective investors.

"I am so grateful to the LinkedIn platform because it allowed me, as literally someone kind of starting from scratch, to just start sharing the journey and start making friends. And if your title on LinkedIn said Gastroenterologist, there's a good chance you had an invite in your inbox from me," Torrey notes.

Networking has helped Endiatx garner the interest and support of experienced, renowned, and highly-respected gastroenterologists, some of whom have joined the company’s medical advisory board.

Torrey's team also frequently uploads YouTube videos about the PillBot to increase product awareness and bring more people on board with their vision.

Of course, this doesn't discount the importance of physical networking and attending in-person events. But with the exponential growth of social media, it's wise to utilize these platforms to network with people in your field and even worldwide.

Share Your Product Development Process in Real-Time

Getting investment dollars is one of the biggest challenges a medtech startup like Endiatx often faces. For example, Torrey mentions that the company has eyes on a market launch sometime in 2026, which equates to roughly seven years of research, validation, and product iteration before any commercialization (and revenue) can take place.

According to Torrey, storytelling was the simple yet powerful strategy he took to get venture capitalists, doctors, and investors to fund and support his company's growth. That said, you don't have to wait until you have a finished, perfected end-product before telling your story.

Torrey leveraged the power of storytelling from the get-go by sharing the PillBot development process with just about anyone happy to listen.

"It's a story that you tell your team and when you're trying to bring people on board. This story helps you make it real to your investors and to stakeholders like doctors. And then, eventually, it goes all the way to patients when you're finally saying, hey, we're trying to change your life substantially for the better. The storytelling never ends, and there's something kind of beautiful and sacred to it," Torrey says.

Torrey also emphasizes the importance of being vulnerable and open with your journey. This gives your company a unique heartbeat and fosters a personal and genuine connection with those following along.

Through his email updates, Torrey shares the achievements he's proud of, as well as the struggles, challenges, regrets, and fears he encounters, showcasing his grit to make the PillBot a reality.

"Share your ideas, share your dream, but make yourself dangerous. If you're unwilling to give up on something and you can find a way to take punches and stand up after failure, you start to build a founder's persona that, over time, starts to look pretty investable," he says.

Interview With Bright Uro CEO
Derek Herrera

Derek Herrera

Summary

Bright Uro Founder and CEO Derek Herrera shares how his personal experience pushed him to champion innovation in the urology space and how he's optimizing his latest medtech venture for efficiency and success.

About Derek

Derek served as an elite Marine officer in the U.S. military before suffering debilitating injuries while in the line of duty. Using his personal experience, he founded UroDev Medical, Habit Camera, and Bright Uro. His latest venture aims to develop and launch an innovative urology device that's meant to replace an invasive bladder diagnostic test that hasn't changed in decades.

Key Learnings

- Leverage your personal experience, or close connection, to the problem you're trying to solve. When developing medical devices, an intimate knowledge of patient or clinician challenges can be a powerful motivator and provide valuable insights into your target market.
- To set your medtech startup up for success, you must carefully tread the line between efficiency and maximizing opportunities for success. From top to bottom, it's imperative that each person on your team clearly understands their role and its impact on the company's goals.
- Be ruthless with your decision-making during product development. Incorporating only the most necessary features and having a clear picture of how you will navigate the regulatory landscape is crucial if you want to successfully launch your device in a cost-efficient way.

Using Personal Experience as a Catalyst for Innovation

Derek didn’t end up in the world of medical devices following a eureka moment. His personal experience and challenges have pushed him to truly understand the needs of clinicians and patients.

After sustaining debilitating injuries in Afghanistan, mobility wasn’t his only challenge. Derek also grappled with bladder management issues daily and became obsessed with trying to solve the problem. This led him to start UroDev, makers of a fully internal, in-dwelling urinary catheter designed for adult males with urinary retention.

His new company, Bright Uro, aims to replace an outdated and invasive way to assess bladder function. The current diagnostic, which has been used for over 50 years, involves sticking a catheter into a patient’s bladder, which is then hooked up to a laptop and an infusion pump. The test collects medical data using a method that’s not physiologic and a machine that’s cumbersome and expensive.

“Urodynamic monitoring today is like halter monitoring was ten years ago. And so we want to be like iRhythm, which is a wearable ECG monitoring company, the company that kind of revolutionized wearable ECG monitoring,” Derek says. “We're going to be like iRhythm for Urology and make all the same changes that they've made for the types of patients that we can serve.”

While not the original inventor of the technology, Derek demonstrates the importance of adaptability and resilience in one’s personal and professional life. He leveraged his experience as a patient to develop a medical device that could help others in similar situations.

Likewise, he tapped into strong ecosystems and networks to access valuable resources and expertise. This was demonstrated when he re-domiciled his first company in Minneapolis, considered the hub of urology device innovation.

“There's just a center of gravity of talent and experience there that if you haven't tapped into and you're in urology, you should start to do that because they know a lot more than me. I've been in the industry for almost ten years, but these people have been here way longer than I have. We're fortunate to have access to that network,” Derek says.

The Importance of Alignment in Executing Meaningful Work

Derek and his team are working on a low-cost miniature sensor for the bladder that will allow clinicians to collect more physiologic data to diagnose and determine the proper treatment. The flexible sensor is designed to stay in a patient's bladder for a certain period, and after it's removed, clinicians can download the data wirelessly.

Bright Uro is using in-depth patient feedback to drive innovation. Its technology is more user-friendly and can provide more useful information to clinicians.

"It's going to create a significant enhancement in the diagnostic yield from the data that we can provide. And as a diagnostic company, that's how we can create value", Derek says. "Specifically, things like informing the treatment pathway and potentially improving outcomes from those therapies. Getting the right patients the right treatment at the right time. That's where we want to go with this technology."

While citing the large potential impact of developing medical devices, Derek points to the challenges and uncertainties in the medtech industry, resulting in exciting, challenging, and rewarding moments for entrepreneurs.

"You have to be really ruthless and judicious with how you deploy capital, drawing the line on every single thing that you spend a minute or a dime on," Derek says.

Derek also believes it's critical to establish alignment and collaboration within a startup medical device or health technology company. Employees at all levels need to understand their specific role in helping the company achieve its mission and vision.

He advocates for medtech startups to find a good balance between efficiency and maximizing the opportunities for success and using the company's long-term goals as a compass for actions that can make a positive difference.

Why Efficient Product Development is Critical for Medical Device Startups

Rapid iteration is always one of the primary goals of an early-stage medical device company, but there is always a constant pull on how much time and effort are spent on perfecting a solution or determining what's acceptable.

To optimize decision-making, Derek emphasizes the importance of understanding and navigating regulatory and reimbursement processes.

"There should be a plan for how it's going to get approved, what the regulatory path is, and what the market opportunity is," Derek says. "Before you invest time in building something, make sure you know what to build. Make sure it solves a real problem for patients and clinicians. Ask them. They'll tell you if they think it sounds great or not."

Derek has spent a lot of time understanding the regulatory and reimbursement landscapes because he knows that getting clearance in a timely fashion is paramount. Also, ensuring your device will be reimbursed by insurers is critical to understanding the commercial potential.

To efficiently bring a product to market, Derek reminds entrepreneurs to minimize feature complexity. Be ruthless in deciding which features are necessary and which can be left out. At Bright Uro, this framework has been crucial to Derek and his team.

To fire on all cylinders, Derek believes hiring the right people is probably the most important ingredient for startup success. As a founder or CEO, you need to be overzealous about finding the right employees, tapping into the best consultants, and seeking the help of the right investors. A company will not achieve its goals and objectives without the right people.

"Begin with the end in mind and be ready to go the distance because you can't control when or if someone's going to want to acquire you," Derek says.

Startups must have a long-term vision. Entrepreneurs must be ready to go the distance. Be persistent in the face of challenges and setbacks. Amid adversity, be resilient.

"Innovate or die, right? Rapidly iterate. That's the only way to survive as a startup. And so that's the biggest lesson I've learned and continue to try to push forward with every day," Derek adds.

Interview with PN Medical CEO
Mark Carbone

Mark Carbone

Summary

PN Medical CEO Mark Carbone shares valuable lessons on product development, commercialization, and distribution. Mark reinforces the notion that it's harder than you think and opens up on the insights he's learned pressing through various challenges.

About Mark

Mark is the CEO of PN Medical, makers of medical devices that help improve the pulmonary performance of patients, vocal artists, and professional athletes. Mark used his technology background and entrepreneurial experience to turn PN Medical into a frontrunner in the pulmonary space.

Key Learnings

- Finding champions is crucial. People who can truly move the needle for your business. Look for individuals who not only have domain expertise but are driven to leave a legacy.
- Protect your products at all costs. You need to partner with the right IP counsel, allocate enough legal budget, and secure as many trademarks and patents as possible.
- Identify distributors that not only can execute but are trustworthy as well. Ensure they have an actual salesforce on the ground that can deliver real results for your brand.

Find Champions Who Can Get Things Done

When Mark became the CEO of PN Medical, the founder requested that the company continue to put patients and clinicians first. With that as his compass, Mark pushed the brand into its next phase using his technology background, starting with the development of PN's own hardware and software.

Mark shared the challenges of getting the company to where it is now and what formula worked for him in leading PN Medical into the future.

"HR is my biggest issue. It's the biggest investment. The most important thing you can do as a CEO, I think, is to form the best team. It's pretty much half of my job to find great people who are just really good at what they do," Mark says.

Building the team at PN Medical involved tapping into his trusted circle of family and friends. Mark also revealed that he specifically looked for professionals on gig economy platforms such as Upwork, where he found his chief scientist and nearly half of PN's current team.

Along the way, Mark also learned that deep research is crucial if you want to drive awareness and experience any type of commercial success. Using PN Medical's solid reputation and semi-limited budget, Mark aimed to find a balance between publishing clinical evidence and promoting the brand. That meant persuading potential champions willing to devote their time to building their legacy of helping move healthcare forward.

"I always found a really excited champion, somebody who had a little budget in their department. They're into new stuff and they want to move up the ladder at their organization and they'll do anything to get a study published," Mark says.

However, he reminded fellow medical device entrepreneurs and leaders to know when to walk away and move on when partnerships or collaborations are stuck.

Like most medtech companies, Mark needed help navigating the various regulatory complexities, including commercializing through Amazon. Mark advises finding regulatory and legal professionals with proven domain expertise and demonstrated track records.

Find Champions Who Can Get Things Done (Cont'd)

"You really have to find someone who knows somebody. Not so much for approvals, but for coaching, so that when you do go through the approval process, you don't get crushed with endless denials. The more you do your homework upfront and don't try to make too many claims, it should push you through faster," he says.

Mark also put the spotlight on the significance of striving to improve one's self as a business leader. When asked about things that keep him up at night, he had this reflective thought, "It's me. It's me as a leader. I need to work on being a better leader every day. I was great as a startup leader, but it's different now."

He said you might be good when the company is small, but as the business grows, you need to find ways to become a better leader. Mark is an avid reader and relies on leadership coaches to help him figure out what works and what doesn't.

Make a Concerted Effort Early On to Protect Your IP and Build Relationships With the Right Investors

Aside from finding the right champions, Mark believes medical device and health technology CEOs should focus on ways to protect your brand and its products. This involves working with the right IP attorneys, allocating the right legal budget, and making sure you pursue the proper trademarks and patents.

Mark reveals that one of the biggest steps in protecting your business is choosing the right investors. It can mean success or eventual death. Not only do you need to find investment partners that understand the medical space, but it's equally important to work with investors aligned with your brand's values.

"The investor really [should] be equally yoked. You have to have similar beliefs. And if there is an exit strategy, it can't be like a two-year window; it has to be longer. They have to give you some room," Mark says. "You shouldn't take money just because they're giving it."

Mark holds a firm belief that it is imperative for businesses to have a plan when their medical device, for example, finally has a good share of the market. He recalled a story when the company had to hire lawyers after realizing their products were at the crosshairs of competitors and counterfeiters.

"You need to have a legal budget once you have a good market share. There has to be a set line item every month," Mark says.

Make a Concerted Effort Early On to Protect Your IP and Build Relationships With the Right Investors (Cont'd)

Once you make significant inroads and start taking share, you'll get the attention of competitors and regulatory bodies, too.

Based on this experience, Mark reminds business leaders to have corresponding plans as their forecasted growth becomes a reality to avoid potential disasters. Today, PN Medical works with a top legal firm that helps them go after counterfeiters and other bad actors across the globe.

Aside from having enough legal budget to protect your business from intellectual property infringements, Mark said one of the wisest moves medtech companies can make is to get as many trademarks and patents as possible. This is crucial if you want to protect all the things that you have worked hard for.

Work With Powerhouse Distributors That Will Keep the Cash Register Ringing

As a startup, finding a trustworthy distributor that can truly drive results can be a major reason why you succeed or fail.

But how do you find a good distributor to partner with? Here's Mark's advice: "First, I need to know that they have a real sales force, that they really do have salespeople on the ground."

He also warns of exclusive relationships with distributors, something he did not have to deal with when he started at PN Medical. If that's your only option, Mark recommends having the right hooks in place – product volume, timeframe, or sales revenue – so you remain in control.

Distributors can get you very far, but the wrong partners might abuse your relationship and undercut you by commercializing products through non-approved channels or selling at lower prices.

Mark reinforced the idea that the road to success in the medical device and health technology industry is difficult.

"It's harder than you think. You're going to want to give up a lot. And it's going to affect your family, it's going to affect your marriage, it's going to affect your kids, it's going to affect your health. You'll want to give up, but just keep pressing through."

Interview with Nutrisense Co-Founder Dan Zavorotny

Dan Zavorotny

Summary

COO and co-founder of Nutrisense, Dan Zavorotny, discusses the reason he opted for a DTC business model in the healthtech space, as well as hiring strategies to get the right team members on board. He also shares how early-stage customer feedback shaped the foundation of his metabolic wellness company.

About Dan

Before co-founding Nutrisense, Dan worked as a healthcare management consultant at KPMG, where he advised Fortune 500 companies and three of the top five hospitals in the US. His company, Nutrisense, combines continuous glucose monitoring with personalized dietitian coaching to help people optimize their metabolic health based on real-time data.

Key Learnings

- Going direct-to-consumer (DTC) brings unique challenges but is critical to disrupting the healthcare industry. A DTC model gets you valuable input on real-life, everyday problems, so you can make meaningful improvements to existing infrastructures in a way that drives the space forward.
- Get your product into the hands of your customers as early as possible and be open to receiving feedback that can be used to guide the improvement process. Contrary to popular belief, you may not need high-powered clinical studies backing your product before entering the market.
- The people you work with can make or break your company, and there are creative ways to get top talent on board with your mission. And it's important to coalesce a diverse team—having the exact same mindset and skillset as someone else does not guarantee that a particular candidate is going to be the best addition to your tribe.

Why You Need a Direct-to-Consumer Model to Disrupt Healthcare

According to Dan, the challenging thing about a DTC business model is the need to constantly convince target consumers to invest in the value the product delivers. Customers may choose to cancel their subscriptions or request a refund if their perceived benefits ever go away. Success requires constant reinventing, innovating, marketing, and delivering value month after month after month.

Besides the need to market efficiently, establish a compelling brand, and offer consistent value to customers, DTC companies also face other challenges. For instance, a recession can make it more difficult to remain competitive and relevant, especially when going up against already-established leaders in the space.

While there are many challenges with a DTC model, Dan states that it's the best way to disrupt the healthtech industry and bring forth innovation that truly makes a difference in the lives of consumers.

He isn't looking to create products that are just a fraction better than existing brands on the market. Instead, his company's value proposition is to develop a first-of-its-kind offering that will meet real needs, solve everyday problems, and drive the industry forward.

"If you want to disrupt an industry, you have to go directly to the consumer, specifically in healthcare. If you want marginal improvements, you should go B2B," Dan says.

And though Dan understands the inherent difficulties with a DTC approach to healthcare, he still stands by the reason that led him to quit his corporate job in the first place — his eagerness to see meaningful innovation in the broader healthcare ecosystem.

"Because if 100,000 people try a product and they love it, and then some B2B company wins because they have more connections even when their product is subpar, they'll always come back and say, hey, I want a product like that one. And we're pushing a B2B company now to upgrade their skills. And that's what we're trying to force — we're trying to force the industry forward," Dan notes.

Nutrisense aims to demystify metabolic and nutritional health for the general population and serve as the "healthcare professional in your pocket." The company was one of the first to leverage CGM devices already on the market and pair them with personalized advice from dietitians who review the data collected in real-time.

Customer Feedback is Critical During the Early Stages of Your Startup

In November 2019, Dan's team launched the Nutrisense platform on the very day it was technologically possible to do so. At that time, Apple had just made the NFC scan functionality available to all companies, and that was the moment Nutrisense's mobile app hit the market.

Considering they were very early with their technology, the Nutrisense team ran into unforeseen challenges, but Dan saw this as a valuable opportunity to gather crucial feedback. Most customers had to learn how to apply their CGM sensor in the right way, and a large proportion struggled to install the app correctly. Through this process, Dan's team set up video calls to demonstrate the right method of putting the device on for each of their first 100 customers, which allowed them to collect a lot of useful insights.

Despite these hurdles, Dan leveraged all forms of feedback—both positive and negative—to improve and redesign the platform in a way that delivered what customers needed.

They initially started with just one dietitian. But Nutrisense strategically turned nutritional coaching into a core part of the platform when the team realized that many customers wanted personalized advice on glucose management, sleep, exercise, and diet.

"We actually only brought in one person in the beginning, who's our co-founder, to be a dietitian. She'd answer some questions people had here and there. And then we started getting bombarded," Dan explains.

"We started to change things where the dietitian became the focal point, and the glucose became an input for the dietitian to interpret—then the glucose, plus the workouts, plus the sleep, plus your annual physicals became a combination of inputs. And that's the focus you could only get by just going ahead and letting people try it."

Dan further pointed out that, at times, innovation may have to happen before clinical research can occur. He mentioned that with some products, it shouldn't be necessary to wait for years of scientific studies before creating and launching a product. If you can commercialize with a compelling proposition, despite lightweight medical data, you may be able to pick up on key learnings that you otherwise wouldn't have.

Why the Right People Will Make or Break Your Company

As Nutrisense experienced exponential growth, Dan had to find the right talent to hire. And convincing them of his mission was one of the keys to bringing the right people on board.

According to Dan, podcasts became part of the company’s recruitment strategy. Whenever they were on health and wellness podcasts, they took the opportunity to let people know Nutrisense was hiring.

Most startup founders understand that it’s challenging to get in front of the best talent if they don’t even know your company exists. So if you have the opportunity to raise awareness around your value proposition, mission, and future plans with an engaged audience that has similar ambitions, it’s a win-win-win.

Instead of having to convince job seekers to make a move, this flips the script and gets them excited to apply and get on board with your vision.

Another mistake entrepreneurs tend to make when building a team is bringing on people with operational frameworks that are too similar. This could bottleneck the company's progress due to the lack of diverse skills, opinions, and experiences to draw from.

"So, it's always about looking for someone as extremely opposite from you as possible. Yes, this will create a lot of conflicts and a lot of tension during your company's growth. But that's a positive tension, not a negative one because you do not want to be in agreement all the time," Dan noted.

And as your company continues to grow, Dan warns that one of the hardest pills to swallow will be the fact that different people are better suited for different parts of your startup journey.

"So when you're at five people, [you might need] someone who is a generalist, who's amazing at ten things. And all of a sudden, you're at 100, and that person may not always be the right person. And now you need specialized people for unique things," Dan explained.

Your company's workforce needs will also likely change as it advances. And though this may sound like more effort than it's worth, learning to pinpoint your hiring needs and recruit the right talent is key to scaling your company's growth.

"You eventually realize that when you have the right people, it just exacerbates your success," Dan says.

WHY EARLY-STAGE TECHNICAL RISK REDUCTION IS CRUCIAL FOR MEDICAL DEVICE STARTUPS

Interview with Diality CEO
Osman Khawar

Osman Khawar

Summary

Diality CEO Osman Khawar discusses why early-stage technical risk reduction matters and how to navigate regulatory clearance through collaborative relationships. He also shares valuable tips on building and leading a mission-driven team.

About Osman

After obtaining an MD from the University of Glasgow and an MPH from Johns Hopkins, Osman went on to become a board-certified nephrologist with a passion for serving dialysis patients. He is currently the CEO of Diality, a medtech company in the midst of creating a hemodialysis system that's versatile, mobile, intuitive, and cost-effective

Key Learnings

- One of the most common shortcomings of medtech companies is the lack of early-stage technical risk reduction. Reducing uncertainties during the initial phases of development can save you a ton of trouble down the road and give investors the confidence they need to support your venture.
- The effort needed to build collaborative relationships with the right stakeholders is sometimes underappreciated. For example, one of the best ways to ensure a smooth regulatory clearance process and efficient clinical adoption of your product is to prioritize building alignment with the right people and organizations.
- The team members and investors you bring on board can make or break your company's success, especially in its earlier stages. A great way to build a mission-driven, patient-centric group of people is to connect them with real-life patients and consumers.

WHY EARLY-STAGE TECHNICAL RISK REDUCTION IS CRUCIAL FOR MEDICAL DEVICE STARTUPS

Start Technical Risk Reduction as Early On as Possible

Osman believes that a lack of early-stage technical risk reduction is one of the most common mistakes companies make in the medical device space. He emphasized the importance of undertaking technical risk reduction as early as possible.

By delaying this process, you risk having a product that doesn't meet your requirements. In most cases, projects only get more complex, intricate, and expensive over time. And it will be much harder for significant adjustments and shifts to be made during the later stages of development.

Osman explained that any innovation or invention, no matter how brilliant, inherently comes with its own set of risks. And the best way to minimize the impact of these risks is to go through a series of prototypes and carry out consistent product iteration and improvement at each stage of the process.

Feasibility prototyping enables you to collect early evidence that can prove or disprove your technology's validity and sets the stage for grounded, realistic targets during your development process. Such prototypes can typically be designed with minimum resources and time and can significantly reduce development risks in the future.

"You answer a lot of fundamental questions about technology that you can't get with design and analysis. And the first indication of where they will hit your desired performance targets is really from there," Osman said as he expounded on the benefits of feasibility prototyping.

Reducing such uncertainties also gives you the upper edge in convincing investors to come along on your journey.

Another core part of early-stage product optimization is finding the right balance between features and functionality. An over-the-top product with too many features can lead to more technical risks.

According to Osman, domain expertise is crucial in achieving this delicate balance, as it helps you pinpoint what the market requires and optimize the development process to meet those needs.

Build Collaborative Relationships to Facilitate Regulatory Clearance and Clinical Adoption

One of the best ways to increase your odds of successful regulatory clearance is to build collaborative relationships with the relevant agency.

Gaining full-fledged access to what other medtech companies have done in the past can be challenging, and at times, the most current requirements may not be reflected in available guidelines.

Thus, Osman's advice is to create a space for two-way interaction and feedback, which can provide insight into what's front and center in the FDA's mind. Keeping the dialogue open and communicative will massively de-risk your regulatory submission.

"I would just encourage as much collaboration as possible. That sort of environment is responded to well on both sides of the table, and I think it really keeps everyone focused on what we're trying to do, which is improve the quality of care in the United States." Osman elaborated.

But the benefits of collaborative relationships aren't only confined to seeking regulatory clearance. Osman explained that aligning with care providers can help you understand what's essential in clinical settings and develop products that fit different healthcare models.

According to Osman, value-based care is becoming increasingly prominent in dialysis care. Understanding how Diality's hemodialysis system fits into that model came through his personal experience in nephrology and conversations with other care providers in the space.

"Eventually, you want to start talking to real people who are going to buy your device and pilot it. And I think the earlier you have those conversations and relationships, the better." Osman said.

Your Team Members and Investors Will Shape Your Company's Direction

Being thoughtful of who you take on board is critical at every stage. Investors, partners, and team members can significantly influence the direction of your product development process.

Osman explained that having the wrong people involved can lead to a clunky, impractical product with excessive features and high technical risks.

"Sometimes that happens because the wrong partner is chosen, you've got the wrong investor, and you've got the wrong team around you. Your product iteration needs to be understood by your investors. And if you don't tell that story well, you get yourself in a bind."

Osman also advised entrepreneurs to build a supportive investor base by encouraging their potential stakeholders to be thoughtful of the investment and commitment they're making. He explained that alignment is important going into any funding rounds.

Apart from getting the right investors on board, building a solid core team is also crucial for success. And since his company has taken on a patient-centric approach, Osman ensures his team is informed and engaged with the company's mission by connecting team members to real-life patients.

"And so for employees, pre-COVID in particular, we used to go to dialysis units and take them there, so they can understand and meet with patients. We bring patients into the office at all our team meetings just to discuss it. It used to be really key to our culture. I think it's important that your team is mission-driven and enthusiastic about what you're doing. The only way you can do that is to connect them to the problem in the market."

Osman also added that a great way to lead a team is to identify its core competencies and ensure the company stays in the lane it excels in.

Osman plans to rope in external help for specific areas his team may not be experienced in—for instance, enlisting the help of a contract research organization (CRO) to aid with designing and executing clinical trials. This allows his team to effectively focus on their true expertise, which is product development.

"I think it's important that you define your core competency and what you're good at as a company. And you continue to leverage that. You may add on other pieces to it, but you can't lose sight of what you're good at," Osman elaborated.

HOW TO ALIGN GOALS IN AN INTERCONNECTED HEALTHCARE ECOSYSTEM

Interview with CEO and Co-Founder of Cardio Diagnostics Meesha Dogan

Meesha Dogan

Summary

CEO and co-founder of Cardio Diagnostics, Dr. Meesha Dogan shares how her company was founded upon the grounds of compelling scientific research. She also talks about the different methods to improve the clinical adoption of a device and explains the possible benefits of going public.

About Meesha

Dr. Meesha Dogan is a well-respected leader in the epigenetic space. After completing her Ph.D. in biomedical engineering, she co-founded Cardio Diagnostics and co-invented its patent-pending cardiac technologies, which seek to improve the early detection, diagnosis, and prevention of heart disease through objective risk assessment testing.

Key Learnings

- Reverse-engineering a solution to an existing need in healthcare isn't the only way to build a viable product. Another approach involves transforming compelling scientific breakthroughs into a marketable product designed to fulfill an unmet clinical need.
- Accessibility plays a vital role in determining the fluidity of your product's transition from lab to market. Getting your product into the hands of consumers is just as important as getting it in front of healthcare providers, organizations, employer groups, and other key stakeholders.
- The best approach to raising capital might look different from one company to another. But whether your company chooses to go public or raise funds from angel investors and venture capitalists, onboarding the right people during this process can make all the difference.

You Don't Have to Start With an Unmet Market Need

For Meesha and her team, science spoke the loudest. Their core principle was, and still is, to create and release products they could back through scientific and clinical evidence. Because of this, some of the earliest days of Cardio Diagnostics were heavily rooted in science, technology, lab work, and research.

The compelling research and data birthed from these early stages laid the foundation for the creation, validation, and commercialization of the Epi+Gen CHD. In this case, scientific breakthroughs and research preceded any form of market research that pointed to an existing need.

Instead of taking the standard approach to reverse-engineer a solution based on an existing pain point in healthcare, Meesha's team thought of a solution to transform their data into a practical and accessible product that would help solve an overlooked need in cardiovascular healthcare.

The early research-driven stages were followed by consistent efforts to validate their product and educate physicians and stakeholders about the emerging field of epigenetics.

"And so, in our case, I think we did that next step right in working with Intermountain Healthcare to validate it externally and make sure that it's showing us what we saw in the proof of concept. And then I would say the next iteration of the company was to say, how do we now take something that works so well on the bench and turn it into something that works in the commercial real world," Meesha explained.

Part of the process from lab to market will likely involve collaborations with other parties. So Meesha also emphasized the importance of devoting a reasonable amount of time and resources to finding the right partners.

"I think not taking any shortcuts in finding that partner, a reliable partner, a well-known partner, someone who is truly in it for their patients, for the science, was very critical," she said.

HOW TO ALIGN GOALS IN AN INTERCONNECTED HEALTHCARE ECOSYSTEM

Accessibility Should Be Front and Center

Cardio Diagnostics aims to pioneer the adoption of a more comprehensive and patient-tailored approach through the combination of epigenetics, machine learning, and high-performance computing.

Meesha's team believes everyone should have access to the best possible diagnostics they can get their hands on. And this meant that accessibility was paramount to consider throughout the research, development, and commercialization process of Epi+Gen CHD.

Improving accessibility may be in the form of providing remote options. Or, it could mean setting up an online portal for customers to opt into a service or product.

For instance, the Epi+Gen CHD test may be completed through a traditional provider setting or via the telehealth route, where the consumer retrieves their sample wherever they want and schedules a telemedicine consultation with the prescribing physician.

Apart from consumers, getting your product into the hands of key stakeholders will also tilt the scale in your favor and improve accessibility.

"It won't lead to mass adoption if we're not bringing all the stakeholders in healthcare together. It just cannot be a consumer play when you are a clinical company. So for us, one of the key things that we've spent a lot of time, resources, and energy on has been to bring together providers, provider organizations, payers, patients, as well as groups like employers," Meesha mentioned.

Educating different parties on the value of your product can help you align your goals with theirs. Take, for example, how employer groups may utilize Cardio Diagnostic's risk assessment test to improve their employees' wellness and productivity through preventative care.

"The reason is it's an interconnected ecosystem, and whether we like it or not, everyone has to come together and understand what's the win-win for them," Meesha noted.

"It's an ability for us to bring together the stakeholders and say we're all working toward the same thing. We may not be working on it the same way, but there's an opportunity for us to come together and align."

The Traditional Fundraising Route Isn't for Everyone

In October of 2022, Cardio Diagnostics officially announced its business combination with Mana Capital Acquisition Corp to create a publicly listed company.

Though not the conventional way of raising funds, going public may bring about various advantages to a company. For example, an IPO may provide more efficient access to capital, propelling the product development process forward, continued investment in research, attracting better talent, and generating publicity.

According to Meesha, Cardio Diagnostics had two main reasons for going public rather than raising capital via angel investors and venture capitalists.

"One was access to the capital markets, and the second is we wanted to have a public currency, whether it's to make better hires or whether it's to have more tangible ways to compensate people."

The special purpose acquisition company (SPAC) became an efficient vehicle for them to achieve this, and the decision paid off. That said, Meesha advised that it would be wise to first check your company's motivation for going public.

"I know a lot of people who went through the SPAC process because they wanted to trust money, and they were very disappointed at the back end. So truly check your motivation for wanting to go public, whichever way that is."

And throughout the entire process, it's also crucial to have the right talent onboard, whether you've chosen to go public or raise capital through seed and series funding.

For instance, having the proper legal counsel to walk you through the process and protect your company with proper representation can make all the difference when going public. It's a complex journey, and hiring the right people to improve that process is definitely not an investment you'd want to skimp on.

"You can get overwhelmed really quickly between the financial side of things that you have to do, and getting the right people on your team is absolutely crucial. It's not the time to get an intern or a discount on an attorney or a financial person," Meesha explained.

Interview With Clarius CEO

Ohad Arazi

Ohad Arazi

Summary

Ohad Arazi, the CEO of Clarius, shares the inspiring story of Clarius and its innovative handheld ultrasound device. From navigating regulatory hurdles to training audiences on new technology, Ohad explains how Clarius has achieved impressive growth year after year and provides valuable insights relevant to any medtech startup.

About Ohad

Ohad is the CEO and President of Clarius, a leading provider of high-definition wireless ultrasound systems. With his extensive experience in the technology industry, ranging from the Israeli military to industry leaders like McKesson, Telus, and Zebra Medical, Ohad's impact on Clarius' persistent growth is undeniable.

Key Learnings

- To build a product that truly meets the needs of your target market, it’s critical that you understand its must-have features from a functional, clinical, and financial perspective.
- Have a clear understanding of the regulatory and reimbursement pathways and be able to effectively communicate them when pitching to investors. Also, understand the surrounding tools and infrastructure that make it easy for your target audience to adopt your product.
- Your channel strategy is crucial and needs to be approached soberly and with intellectual honesty. As a startup, you sometimes need to leave the beaten path and disrupt the legacy market to generate revenue quicker.

Cracking the Code: Creating a Product Your Market Can't Live Without

Product-market fit is key to the success of any startup, but it's a challenge with a lot of nuance. You need to understand how your product is necessary in terms of clinical function, but also whether it makes sense for users financially. Only then can you come up with a must-have solution with an opportunity to disrupt the legacy market and change it for the better.

Since Ohad didn't have a background in medical imaging when he started his career in the medical device space at McKesson, he spent two years immersing himself in radiology-dark rooms and cardiology labs, observing and asking questions to understand their workflows and pain points.

"To convince them to make a replacement decision or to buy into a new technology [and] change their workflow, which is a very difficult thing to do in a medical setting at the point of care, we had to really understand how they work," recalled Arazi.

So, when developing Clarius' technology, the first goal was to generate image quality that was on par with what specialists were already using. But, as Arazi notes, that wasn't enough.

"By observing them, we saw that what they really need is voice controls. They need to be able to say increase zoom, increase gain, take a snapshot. Our AI automatically detects the optimal image as the key image that they use for reimbursement because if they're billing for an image-guided code, they need to retain the record to show the needle in an ultrasound view, because if CMS then audits them for their reimbursement, you have to be able to provide that evidence. So things like that all stem from really observing the workflow and understanding where you can add value."

According to Ohad, getting to know the problems users face is, ultimately, how a company can ensure that its product is not just generally aligned with user needs but also very specific in addressing the unique challenges they face in a particular setting.

The Role of Regulatory and Reimbursement Strategies in Medtech

Getting regulatory clearance in the medical industry can be a huge challenge. Clarius serves as an excellent illustration of a company that has been successful in acquiring regulatory clearances in 74 countries from the EUMDR, TGA, and FDA.

To achieve such global milestones, it's important to identify clinical gaps that have not yet been addressed. "Sometimes you walk into an environment where you've identified a clinical gap that isn't yet supported by reimbursement, and that's okay as well. There are pathways to do that."

The Role of Regulatory and Reimbursement Strategies in Medtech (Cont'd)

Ohad advises entrepreneurs not to get hamstrung if there is no pathway for reimbursement and to create one instead by being clear on the clinical value of their product.

Ohad adds: "Once we identified things that were not being addressed, we didn't try to replace or disintermediate radiologists, but actually complement them by offering things they weren't doing today. We leveraged AI to stratify risk for a variety of conditions and we found out there's clinical value, but there's no reimbursement yet. We created a reimbursement case, and we ultimately got two category 3 CPT codes for imaging."

Apart from understanding reimbursement globally, Ohad emphasizes the importance of having a business-oriented regulatory team that facilitates the entire compliance process.

"First of all, it underscores that in the life of a medical device company, the regulatory team is so important, and it's incredibly important that they're also business-minded. They should understand the drivers behind [business decisions]. Generally, as you build out your company, I've always been very cautious to make sure that the regulatory team is not the gatekeeper. Actually, they should be the facilitator."

Breaking the Mold: Clarius' Disruptive Channel Strategy for Global Success

Ohad explains that a successful commercial strategy requires not only having the right product but also innovation in the channel and go-to-market strategy.

At a high level, Ohad advised to ask yourself, "[W]hat is my channel, and how will that channel be successful relative to the challenges of the buyer base I'm selling into?"

For Clarius, their strategy focuses on specialists who work in a private office setting, which accounts for 75% of their sales. Instead of going after enterprises, they've channeled their marketing strategy towards users, that is, the medical practitioners themselves. The company created a virtual experience for end users to show them how Clarius' ultrasound device can change their workflow for the better and improve the patient's overall satisfaction.

Ohad cautioned against selling into an enterprise, as the sales cycle might take between 12 to 18 months, and the cost of customer acquisition could be high.

Breaking the Mold: Clarius' Disruptive Channel Strategy for Global Success (Cont'd)

Instead, Clarius' sales process is largely executed digitally, with 25% of sales occurring online and 83% of all sales happening within 30 days of acquiring a lead. They don't send trial devices; instead, they educate potential customers remotely, just like someone would research before buying a new MacBook Pro. Even though Clarius is selling to a highly sophisticated audience who's used to purchasing products the traditional way, their strategy appears to be working extremely well, as evidenced by the company's exceptional growth.

In summary, it comes down to really believing in your product's value and convincing investors you know how to drive execution in the market. Ohad advises to try and find innovative ways to pitch your product to the right audience, which often requires disrupting legacy incumbents: "As a startup company, you're always disrupting. You have to be blind, deaf, and dumb because if you listen to anyone and if you saw everything, you would never do what you're doing because the odds are impossible."

WHY EARLY RISK RETIREMENT IS THE BEST INVESTMENT YOU CAN MAKE

Interview With Co-founder and CTO of RefleXion Medical Sam Mazin

Sam Mazin

Summary

Sam discusses why a startup medtech company should focus on retiring risk and pitching investors as early as possible. He also talks about the most important aspects every entrepreneur should consider when designing clinical trials to meet various goals.

About Sam

Dr. Sam Mazin received a Bachelor of Applied Science in Computer Engineering from the University of Waterloo, Canada, and holds a Ph.D. in Electrical Engineering from Stanford University. He co-founded RefleXion Medical in 2009 and is the inventor of the company's core technology, which aims to improve treatment outcomes in patients with tumors in the lung or bone resulting from primary and metastatic cancer.

Key Learnings

- Test and tackle the highest-risk concepts of your product in the early stages. This is one of the most efficient ways to put your initial, and often limited, capital to use.
- Talk directly to the appropriate audience when determining the type of clinical studies to run. You should design your clinical programs around what a single consumer wants to see from your research instead of trying to meet the needs of different user groups through a single study.
- It's never too early to start raising capital. Instead of waiting until you've perfected your product, start reaching out and pitching to potential stakeholders as soon as you can. And don't be afraid to re-approach investor groups that previously said "no."

Tackle the Biggest Uncertainties First and Foremost

In its early days, one of the biggest challenges that RefleXion Medical faced was convincing stakeholders and early-stage venture capitalists to invest in the development of SCINTIX. And when they finally found a group of investors willing to give their vision a go, Sam had to put his very limited capital to good use.

Thankfully, Sam's company had made the strategic decision to bring on a highly experienced engineering leader, David Larkin, who introduced a life-changing philosophy to the RefleXion Medical team. He recommended they use its limited resources to tackle the most significant risks and uncertainties before anything else.

David's philosophy, "follow your fear," encouraged the team to think about the key risks involved in advancing the company to its next inflection point. Sam and his team then worked on retiring any major risks, even in the company's earliest stages, before they even moved on to address the lower-hanging fruits and more straightforward tasks.

"At the end of the day, you're trying to retire risk. Retiring risk translates directly to value creation. Your stock is worth so little at the beginning because the risk before you is so high. And so the more you can chip away at that risk, whether that's a technical risk, clinical risk, market risk, or regulatory risk, the more you're creating value in the company," Sam explained.

Because of this strategy, the bulk of RefleXion Medical's initial capital was delegated to answering critical questions about the product's viability and functionality.

Productivity in an entrepreneurial sense should revolve around risk retirement and seeking answers to critical dealbreaker questions rather than the number of tasks you've managed to check off your to-do list.

"At least to just answer the question, can this be done? I thought that was probably the most important set of early decisions the company made. And that was to efficiently invest capital to turn over those cards, the critical cards, and to answer the question of whether it's worth continuing," Sam elaborated.

Reverse-Engineer Your Clinical Studies Based on Your Audience's Needs

When designing a clinical study, all medtech entrepreneurs should first ask themselves what the end goal of the study is or how it can reduce a specific risk.

More often than not, the clinical work required to acquire regulatory clearance from the FDA differs from the research needed to drive market adoption or prove a product's economic viability.

Thus, it's best to only run clinical trials after speaking to your end audience to ensure your resources are utilized effectively.

If you intend to conduct a clinical program that will facilitate regulatory clearance from the FDA, make it a point to first converse with the FDA and get well-acquainted with their requirements for approval.

But if you're looking to run a clinical trial that will help boost your product's clinical adoption, it's crucial that you speak to target users and potential stakeholders to get a sense of what they expect to see from your research.

In any circumstance, Sam's advice is to think about the specific audience of a certain study and design the study around that particular group of consumers.

"You don't want to make a study that's for everybody because you're going to dilute it for everybody. The FDA will be looking for something in particular. Users will be looking for something in particular. Payers will be looking for something in particular. And so ideally, you're tailoring whatever you're trying to do to that specific stakeholder," Sam said.

You Don't Need a Perfect Product to Start Pitching

One crucial concept every medtech entrepreneur must grasp is this: investors like to invest in lines, not dots.

You don't need to wait for a perfected end product before approaching potential capital partners. Investors are captivated by stories that demonstrate progress. Even if your focus isn't to raise funds from the get-go, pitching early on helps you to build your company's story and nurture relationships with investors.

"You may go in for a pitch, and it may not be enough to get you to that next meeting. But you now have a data point for the investor, and the investor has a data point for you. And a quarter later or two quarters later, you go in for another pitch, and now they see what has happened in that time," Sam explained.

You Don't Need a Perfect Product to Start Pitching (Cont'd)

"It also helps you track the investor, too; how reliable are they in terms of the types of questions that they need answered? It's a relationship that you're developing. It's not a 'one-time cash comes in the bank,' and then you're not going to see each other again."

Another key concept to keep in mind when fundraising is that "no" is, in fact, a "maybe." Rejection is one of the toughest pills to swallow in entrepreneurship. But being on the receiving end of a "no" doesn't mean you'd have to cross that particular investor group off your list for good.

Because you'll be making constant progress along the way, plus the requirements and interests of potential investors are ever-evolving, don't be afraid to approach the same group when your business gains more ground and achieves new milestones.

And when you first start pitching, Sam recommends casting a wide net in terms of the type of investor you're going for. Staying fixated on what you might think is the perfect investor profile could lead to wasted resources if things don't pan out.

Once you do find a group of investors who are truly compelled by your company's value proposition and mission, that's when you can lower all your nets and devote the bulk of your time and energy to building a relationship with them.

"And then finally, the ones that I think latch on to what you're doing, they may not invest right away, but they become "believers." You can tell there's a different feeling about them because they almost never question your value proposition. They get that if you could do this, this would be big. Those are the ones to spend more time and energy on. Because once you get one of those really revved up, they can amplify your reach considerably," Sam said.

Based on his experience, these people become much more than just initial investors. When they align with your vision, they will help highlight important points that should be communicated and work with you to drive your company forward. Essentially, they will become some of your most valuable marketers and communicators.

Interview With Aqua Medical CEO
Lloyd Mencinger

Lloyd Mencinger

Summary

Lloyd Mencinger, CEO of Aqua Medical, highlights the critical role of capital efficiency and rapid iteration in the early-stage development of medtech startups. He also discusses the importance of driving value for the company versus solely focusing on an acquisition. Lloyd emphasizes the challenges of capital fundraising and that perseverance is key to prevailing in the face of adversity.

About Lloyd

Lloyd Mencinger is a high-energy CEO with decades of international experience in medical device sales, marketing, and business development. He has a strong track record of delivering results in both blue-chip and early-stage companies, including Boston Scientific, Edwards Lifesciences, and Baxter Healthcare. Currently, Lloyd is the CEO of Aqua Medical, a company on the verge of developing groundbreaking technology for type II diabetes and other GI conditions.

Key Learnings

- Embrace capital efficiency and rapid iteration in your startup journey. Keep your organization lean and focus on quickly cycling through prototypes. This will help you reach proof of concept faster, considering your resources are extremely limited.
- Focus on driving value in your company rather than solely aiming for an acquisition. Work towards achieving milestones that increase the company's worth and provide a sustainable path forward.
- Persevere through the fundraising process. If you encounter low success rates for pitches, don’t get discouraged right away, but keep reaching out to potential investors. Remember that the journey can be lonely, so lean on your support network, faith, or other sources of encouragement to help you navigate the challenges of raising capital.

Embracing Capital Efficiency and Rapid Iteration

When you're in the early-stage development of a medtech startup, you are bound to make beginner mistakes. However, to avoid these errors from wiping out your company, Lloyd stresses the importance of embracing capital efficiency and rapid iteration to reach an effective proof of concept. This means that during the early alpha and beta builds, it's essential to cycle through iterations quickly and use resources wisely.

One critical aspect of this approach is to keep the organization lean. As Lloyd notes, "Do not build out a big organization. Do not scale up and think you need all these things. I mean, keep it super lean because runway oxygen is your life... Try to do as many prototypes [and] try to do it as cheaply as you can to get to proof of concept."

Of course, he acknowledges, you won't necessarily get it right the first time, but mistakes are part of the process. "Disappointments and mistakes are requirements. They're the only thing that will propel you to success for the next phase. You have to make mistakes. You have to learn from them. That's the only way it's going to keep you going up and to the right," concludes Lloyd. The idea here is to fail forward and bounce back.

Another crucial factor for success is to have the right team on board. Lloyd emphasizes the importance of searching for the right connections and partners, especially in regulatory matters.

He cautions that some big consulting firms can make the regulatory journey harder by making illogical requests, such as requiring in-human clinical studies without properly considering other creative approaches that require fewer costs and resources. Instead, he advises startups to find practical, knowledgeable partners with relationships at the FDA who can help them navigate the regulatory process.

With the right team and strategy, startups can efficiently navigate the challenges and move forward toward their milestones.

How to Drive Company Valuation: The Importance of Milestones

A startup journey is like a cross-country trip, where each milestone is like a stop on the way to a final destination. Lloyd stressed the importance of reaching value inflection points at each milestone of your startup journey instead of blindly aiming for an acquisition.

How to Drive Company Valuation: The Importance of Milestones (Cont'd)

His view is that while it's of utmost importance to be cognizant of who your natural acquirers are, operating with tunnel vision can distract you from the opportunities that'll bring value to the company. "You might get acquired in Arizona. You might get acquired in Dallas, but don't count on it. If you're building for acquisition, you may miss the window," Lloyd adds.

In his view, if building clinical value is the primary focus of a medtech startup company, the rest will follow.

Lloyd also shared a story from his experience at Boston Scientific, where he had a potential acquisition lined up, but an unforeseen event outside of his control prevented the deal from going through. "It's not until the wire is in the bank, that you have the deal closed," he says, emphasizing the unpredictability of this process.

Overall, what a startup needs is a sustainable path forward. You should be able to adapt to changing circumstances to reach your target milestones. While an acquisition might happen along the way, it should not be the sole objective, as it may lead to missed opportunities and an inability to adapt to changing circumstances.

Navigating Rejections, Angel Groups, and Other Parties in the Fundraising Process

Raising capital is a numbers game where you might only have a 1% success rate. The other 99% of the time, it just might be you getting rejected when pitching to a potential investor.

As CEO of a successful startup, Lloyd acknowledges that the journey can be lonely, especially in the medtech space. He advises potential startup founders to stay determined throughout the fundraising process and not let discouragement hold them back.

The key is to rely on your support system, Lloyd says, and "Fight through the discouragement. Now, I'm a guy of faith, so that's where I go with that. But you just have to plod through."

Lloyd emphasizes that fundraising is an exercise in persistency. It's all about pounding the pavement and connecting with a string of investors. While angel groups can be hit or miss, he recommends attending meetings like WSGR and LSI to hone your networking skills.

Navigating Rejections, Angel Groups, and Other Parties in the Fundraising Process (Cont’d)

According to Lloyd, fundraising is a visceral, emotional challenge and a lonely job. That’s why he holds the view of collaboration over competition, especially in an industry where you’re trying to disrupt and create new markets. The reality is that there's always the risk that the opportunity may not materialize, making it crucial to team up with other innovators in the industry.

To overcome the difficulty of raising money, Lloyd also recommends finding a better purpose than simply making money. “We're in medtech. We are in the business of saving people's lives. We're not selling potato chips. So this is a big deal. What you are doing, you need to believe in it. And if you truly believe in it, it will shine through.” Passion and integrity are key drivers of success in any startup, but especially in the medtech industry. And investors can easily tell whether a founder genuinely believes in their company's mission or not.

Interview With Curvafix CEO
Steve Dimmer

Steve Dimmer

Summary

Steve Dimmer, CEO of CurvaFix, shares his insights on the importance of mitigating risk and pitching to investors early in the development process. He also provides valuable advice on designing clinical trials that meet specific goals based on his own experiences at CurvaFix.

About Steve

Steve Dimmer holds a Bachelor of Science in Electrical Engineering from San Diego State University and a Master's in Business Administration from the University of Washington. He has over 30 years of experience building medtech companies, including multiple start-ups and stints at several large multinationals. Currently, Steve is the CEO of CurvaFix, a medical device company focused on developing innovative solutions for orthopedic procedures.

Key Learnings

- Stay focused on your mission, but don't put on blinders – be open to exploring new opportunities and pivoting when necessary.
- Don't be afraid to ask questions and listen to feedback from potential investors. Use this feedback to improve your pitch and strengthen your narrative.
- Develop a tailored regulatory strategy for your specific therapeutic area and assemble a team of domain experts to help you successfully navigate the often-complex regulatory landscape.

HOW TO LISTEN TO WHAT THE MARKET IS SAYING

Ensure You Have a Market Fit and Keep an Open Mind

Before diving into the development of a medical device or health technology platform, Steve suggests that founders and CEOs should ensure they're addressing a significant problem recognized by their target audience.

They should validate the problem with potential customers, ask questions, and confirm they're headed in the right direction. Market fit is a buzzword, but it's also necessary for a successful journey. In Steve's words: "It's important to evaluate the market and find a product that fits into it. Then you need to present your product in clear terms because there's a lot of noise out there, especially in the medtech industry. So, you gotta make sure your product stands out...".

It's crucial to make sure that the problem you're solving has a large enough market to justify the investment and effort you will put into it. Tackling these issues early on can save you time and resources down the line and help your start-up stand out in a crowded market. In short, Steve's strategy is to go for the Achilles heel early on before investing too much time and resources in a product.

Steve encourages medtech entrepreneurs to maintain focus while developing their products, but at the same time, keep an open mind. While it's essential to validate the problem with customers and the market early on, it's also crucial not to overlook bigger and better opportunities. "Is that really the problem you should be solving, or do you have a bigger opportunity that you didn't know about because your blinders were on?" Steve asks.

In Steve's case, he saw the opportunity in fragility fractures when he was working as a consultant for a local VC on high-impact trauma applications, which does make a difference in people's lives but is not a huge market. When Steve moved his focus to fragility fractures, he knew that he was not only solving a fundamental problem, but a problem that serves a large market.

Mastering the Art of Fundraising

When it comes to raising capital, Steve advises entrepreneurs to take a strategic approach by setting clear milestones to track progress and considering alternative funding options if initial capital is hard to secure. Understanding the financial expectations of investors and tailoring your pitch to appeal to their desire to make a profit is also key.

Mastering the Art of Fundraising (Cont'd)

According to Steve, entrepreneurs should view their pitch to potential investors as a train that needs to be loud and clear when it arrives. The goal is to make investors think they'll lose out on a big opportunity unless they invest.

If you get rejected, which is not that uncommon, it's important to ask VCs for feedback and identify areas that need improvement. By actively listening and addressing these issues, entrepreneurs can increase their chances of securing investment in the future. Steve suggests putting together a deck, getting feedback from a group of people who aren't afraid to offer critiques, and asking them to identify the things that aren't clear enough or don't make sense.

Entrepreneurs should also ask themselves whether they'd be curious to know more about the proposal if they were in the investors' shoes. "I think the best entrepreneurs are really self-critical and critical of what they're doing. I think you need to be good at it. If you're just drinking your own Kool-Aid, you may end up finding out later that you weren't right," explains Steve.

Again, even if you get rejected, the ultimate goal is to receive an invitation to come back and present an improved proposal down the road.

Crafting a Tailored Regulatory Strategy

When navigating the regulatory landscape, it's crucial for medical device startups to develop a well-informed and flexible strategy. Consider whether to engage in pre-submissions (Q-subs) or go straight to the actual submission, taking into account the nature of your device and the available guidance. Remember that regulatory strategy is not one-size-fits-all and should be tailored to the specific needs of your medical device and company.

Another crucial thing to consider is to assemble a team of domain experts, including regulatory specialists and medical advisory board members, to provide advice and validation for your approach. Keep in mind that the FDA's primary concern is patient safety, so be prepared to educate them on your technology and its benefits.

Crafting a Tailored Regulatory Strategy (Cont’d)

In terms of building a strong team, Steve stresses the importance of starting with a well-rounded Board of Directors. He suggests selecting members with complementary skills and experience, including venture capitalists (VCs) who can provide strategic insights and attract investors. In addition, he recommends reaching out to physicians to join the advisory board, as they can help establish credibility. When building out your advisory team, Steve emphasizes that you shouldn’t be afraid to say no to certain individuals. If you run the process with the right diligence, the best partners for your company will surface

BRIDGING THE GAPS AS A STARTUP MEDTECH CEO

Interview With Cagent Vascular CEO

Carol Burns

Carol Burns

Summary

Carol delves into the importance of establishing the right team to lay the proper foundation for your medtech startup. We further discuss how to prioritize essential product features and their clinical applications for future growth, as well as overcoming fundraising challenges through effective networking. She also highlights the importance of listening to investigators and designing strategic clinical trials to generate valuable data and drive success.

About Carol

Carol Burns is a seasoned CEO and serial entrepreneur with a passion for cardiovascular devices. Her tireless energy and proven track record have enabled Carol to accel in all phases of medical device development, from early-stage proof of concept to eventual commercialization. Carol thrives in the fast-paced startup world, leveraging her industry relationships and clinical knowledge to identify technologies with the highest potential for success.

Key Learnings

- A strong, diverse team is the foundation of any successful medtech startup. Having a group of passionate professionals who are committed to the company's vision and ready to contribute their skills and expertise fosters innovation and quick wins.
- In the early stages of a medtech startup, it’s crucial to focus on the core aspects of the product and its clinical applications, establishing a solid footing for future development.
- Persistence and strategic thinking are vital during the fundraising process. Nurturing relationships with potential investors and consistently providing them with updates on the company's progress can ultimately yield fruitful connections and secure the necessary funding.

Why You Need to Assemble the Right Team From the Beginning

Founders and CEOs of medtech startups need to be adept at making prompt decisions and adapting rapidly to reach the next milestone or inflection point for their company. This is especially true when it comes to assembling the right team. A diverse, capable group of people forms the bedrock of any successful venture. Carol emphasizes the importance of bringing together passionate professionals committed to the company's vision and using their varied skills and backgrounds to drive innovation.

Carol's experience has taught her the importance of constant evaluation and iteration in tackling the various challenges startups face. The team's ability to act swiftly to achieve the next milestone is crucial to a company's likelihood of success within the medtech ecosystem.

Building the right team for your medtech startup requires a strategic approach, an understanding of when to delegate tasks, and a willingness to change direction when faced with obstacles. Selecting team members who can support and empower one another will help propel the company forward. Carol also highlights the importance of being proactive and making quick decisions when the team isn't functioning as desired. "Pivot quickly rather than keep trying to give it a little more time... Eventually, you have to say, stop, we need to move on to a different group... In our case, most of the time we have a core team, and then we outsource to another group to actually build the prototypes".

If you work with a team of professionals with deep domain expertise in your target therapeutic area, it will also be easier to overcome regulatory hurdles. For example, Carol's company obtained CE Mark approval in 2017 and FDA clearance in 2020, following the traditional path for US-based medtech startups. However, the recent changes in the European regulatory environment, particularly in the Medical Device Regulation (MDR) certification process, have added some complexity and made it more expensive.

Fortunately, Carol was able to successfully navigate the MDR certification process with the help of her knowledgeable and experienced team. In addition to working with the right experts, Carol also believes it's critical to develop a good working relationship with your notified body.

Ensure a Strong Foundation for Future Development

Carol emphasizes the initial importance of establishing that your product is ready for clinical work. This involves conducting thorough bench and animal testing to ensure the device is safe and ready for human trials. The primary goal of your early clinical initiatives should be to understand the technical success, i.e., verifying whether the product works as intended, whether it's safe, and whether it offers efficacy endpoints valuable to physicians.

She explains, "Just do a small trial and make sure that what you have works. Because from there, undoubtedly, you will iterate on the device. Just find out first whether your device does work as intended."

Another crucial aspect Carol highlights is the selection of trial sites. To optimize enrollment, it is essential to choose sites that are technically equipped, have a sufficient procedure volume, and a track record of proper patient follow-up. Partnering with investigators who consistently deliver quality clinical trial data can significantly impact the trial's success.

Carol shares her experience, "We've worked with Andrew Holden in New Zealand and Michael Lichtenberg in Germany, Christian Wissgott, Marianne Brodmann, etc. These are several of the names we've worked with, but they deliver consistently, and provide excellent clinical trial data."

Carol also underscores the importance of engaging with regulatory bodies, such as the FDA, throughout the clinical trial process. By maintaining open communication, medtech startups can ensure they meet necessary requirements and avoid potential roadblocks in the product development journey.

How to Hone Your Fundraising Approach

Another valuable lesson Carol's experience has taught her is the importance of listening to investors and craft effective fundraising narratives. Engaging with the right capital partners and understanding their perspectives can provide valuable insights into the best path forward for your company.

In the competitive world of medtech, securing the necessary funding is crucial to a startup's success. Carol stresses the need to pay attention to investor feedback and tailor your fundraising approach accordingly.

How to Hone Your Fundraising Approach (Cont'd)

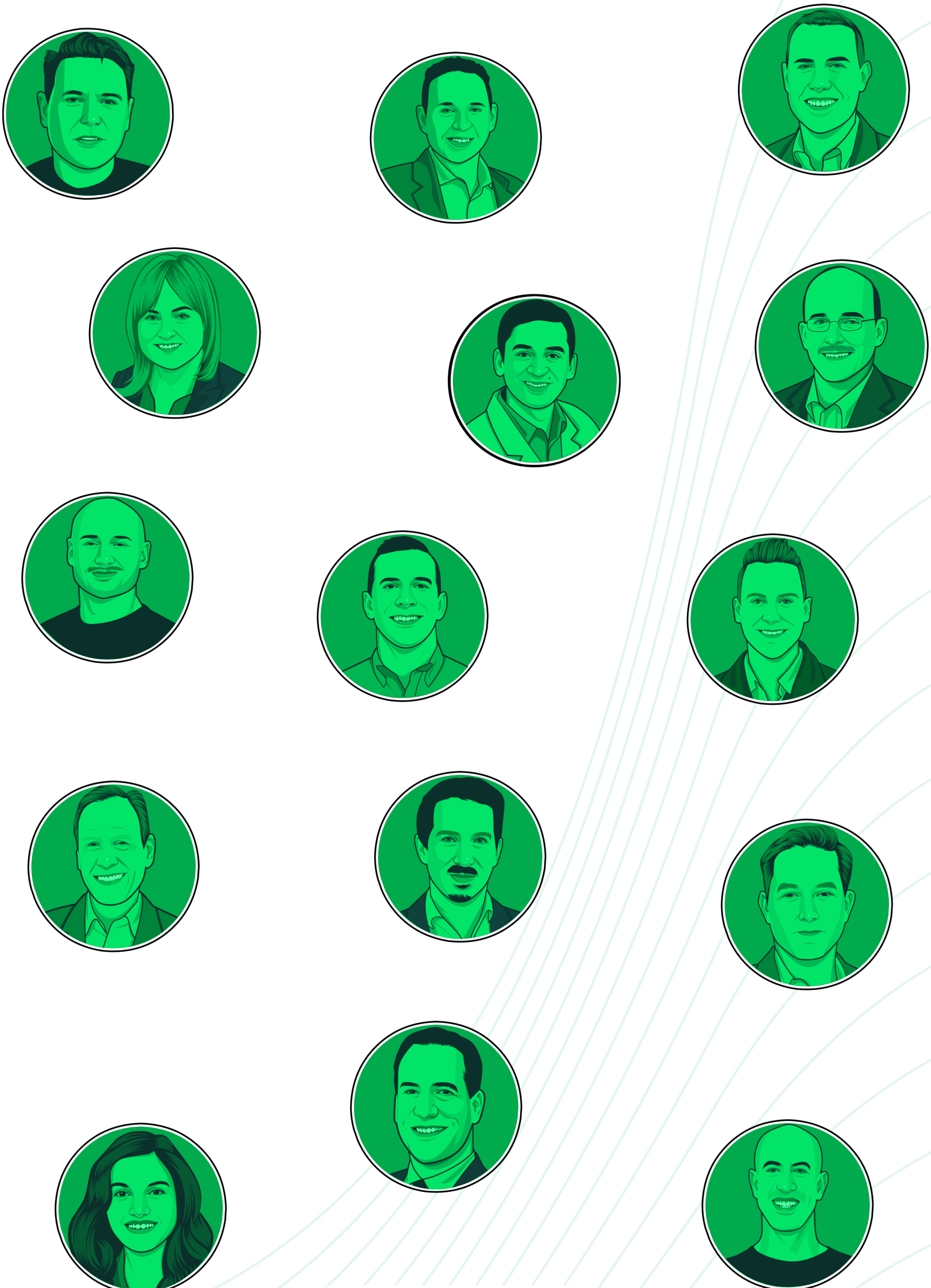
By proactively engaging with potential investors, startups can identify areas of improvement in their business plan, technology, or clinical trial design. This iterative process can help your company become more attractive and increase the likelihood of securing funding.

Carol also advises startups to be persistent and strategic. Building relationships with capital allocators and providing regular updates on the company's progress can eventually lead to fruitful connections.

While it's essential to consider feedback from industry stakeholders, Carol believes you need to strike a balance between investor expectations and the company's long-term goals. While they often bring a wealth of knowledge, experience, and connections to the table, startup leaders must maintain their vision and mission.

VOLUME III

MEDSIDER MENTORS



SCOTT NELSON