URL: https://stvp.stanford.edu/blog/videos/a-needs-based-innovation-framework-entire-talk

As a Stanford Biodesign Innovation Fellow, Kate Rosenbluth was captivated by the unmet need to treat hand tremors. She discovered that the site of deep brain stimulation was accessible through the peripheral nerves in the wrist, and teamed up with Scott Delp, director of the Stanford Neuromuscular Biomechanics Lab, to found Cala Health, where she is now the chief scientific officer. The company's wearable neuromodulation therapies merge neuroscience research with cutting-edge technology to deliver individualized peripheral nerve stimulation. Here, she presents a framework for "needs-based innovation," and explores how she emphasized a needs-based approach in the context of Cala Health.

Transcript

- [Woman] Who you are defines how you build.. (audience clapping) - Well, it's so great to be here today and I decided to focus my talk on a topic of needs-based innovation because when I think back to when I was an undergrad sitting in audiences like this, one of my more I'd say fundamental misconceptions was that I saw startups and laying the groundwork for success as being fundamentally about that moment of, you know, flash of genius as being primarily about the invention and about the solution.. And over time and experience, I think I've really come to learn that a lot of the groundwork for success is really laid in taking a deep understanding of the needs.. Of really building your company, of building your team, of raising capital, and ultimately of selling your products.. Is really in many ways grounded in understanding your why and then building that sort of through the course of a framework behind the company.. So what I'm gonna talk through today is really grounding a number of stories from building Cala Health, which is as Emily mentioned is a company I spun out of Stanford Biodesign about five years ago.. And I'm gonna use that really as the framework to walk through needs-based innovation.. So I think of this as the why, the what, and the how of breakthrough innovation.. So we are gonna talk about breakthrough innovation, about revolution versus evolution, and do that through a series of stories from the company.. Goes without saying please put your hand up any time, I'll make sure that we leave room for Q and A at the end..

But likewise, happy to pause any moment if any thoughts come to mind and we'll take some time to talk through those.. So, I chose this picture for the cover because this picture, in many ways to me, captures both the past and the present and the future of Cala Health.. So, as Emily mentioned, at Cala we're focused on a condition called the essential tremor.. So this is a hand tremor condition that makes it difficult for people to do tasks that most of us take for granted.. Things like writing, eating soup with a spoon, putting a key in a lock, and when I was early on in my needs journey, these were some of the stories that really sort of captured my heart, that really ignited my passion as well as mapped on to my background.. I'm a neuro-scientist and engineer by training.. I'll bring in some stories from Biodesign.. I was also an alumni of the Mayfield Fellows Program here.. And when I think about a woman like this, I remember a woman just like this who specifically what she wanted to do was to be able to make lunch for her granddaughter.. She couldn't hold a knife, put it in a peanut butter jar and spread a sandwich..

You can see here she's wearing a device.. This is Cala Trio.. We're now a commercial stage company, we have our first product out on the market.. Just from sort of rough staging we raised about 80 million of venture capital.. We're five years in, first product out on the market and a pretty exciting pipeline behind that.. So you can see here she's wearing this wristwatch-like neuromodulation device and I'll show you a video in a moment about how that's controlling her tremor.. So before I jump into this framework what I wanted to do was actually just pause and show you a quick video that is a video showing you what this condition looks like and introducing our product.. And then I'll use that to walk through a number of examples of our story of building this company.. So we're really focused on restoring people's joy through helping them deal with the symptoms of hand tremor.. With people who live with hand tremor it makes tasks from, you know, cutting, drinking et cetera incredibly challenging..

So you can see here essential tremor is a chronic nervous system disorder.. You can see for this man here how challenging it is to do something like spread cream cheese.. This woman is a pianist.. You can imagine, you know, how devastating this is for her from a career lens to try and play the piano with a tremor like that.. So this is our first product, Cala Trio.. It's a wrist worn device.. We have clearance from the food and drug administration.. It's used by patients on demand, essentially when

they desire to have hand tremor relief.. They simply put it on as this gentleman is doing here.. They use a dose of therapy is about 40 minutes and that offers them relief from hand tremor..

I'll walk a little bit through our business model.. Again through a needs-driven innovation model we realized that today's healthcare system we had to reinvent putting the patient at the center of care.. So we've actually set up the company to be both a manufacturer and a distributor so we can drop ship product right into people's homes with a prescription from their physician.. In the science that we really built this technology from was a realization that the nerves at the wrist, in this case the median and radial nerve, connect up into a location in the brain called the ventral intermediate nucleus and that is the site where implants are positioned in the brain.. So I did a PostDoc in neuro surgery, I've seen many of the implantations.. You put an electrode at this location and it's like magic watching the effect on the hand tremor.. So we really re-imagined that to take for example someone who is not able to write and to stimulate on the wrist non-noninvasively and restore their ability to write.. And really to get people, you know, doing, back to doing the tasks that they love which for me, you know, very much of what drives me is seeing how we take sort of that technology and that science and how we deliver it all the way through, you know, really changing people's lives.. Let me just pause there.. Any question on there before I jump into some of the learnings? Okay, so when I think about, you know, what is entrepreneurship and everyone has their favorite definition..

My favorite definition is this one.. A team of people, this is about people, achieving transformational impact in the face of limitless uncertainty and limited resources.. So if you really think about what you're doing on, you know, every day it's how do you see your, how do you see your way through that limitless uncertainty and limited resources? Whether it's in a startup or a large organization, in a for-profit or non-profit this is really about small groups of people achieving that impact.. And so you'll see when we start to think through this why, what, how framework it's really about figuring out, you know, at the end of the day one of your most valuable assets is your time.. Because you have passion and you have skills and you have to figure out what you spend your time on and that's why it really makes sense to take the time to figure out what is the need you're trying to solve so that you know that you are putting, you know, your time into things that will meet your definition of transformational impact.. I would say, you know, just by way of background, I sat down to actually kind of write out the various programs that I've had the, you know, great privilege to participate in through my own education and I wanted to put this in here really to emphasize that this content, you know, can be learned.. You are all tremendously lucky to be, you know, in this audience today and when you really think back to, you know, how can we teach, how can we scale, how can we grow sort of entrepreneurial thinking and innovation it really comes to some of these frameworks that we can then apply sort of very broadly across everything from, you know, startups, like I say startups to non-profit, it's, and academic initiatives.. So as I mentioned I'm a Mayfield alumn.. Then when I was at Berkley for, I did a PhD in bioengineering.. I participated there in a management of technology..

UNIDO is the United Nations Industrial Development Organization.. So I spent some time down in Swaziland, down in southern Africa, working on medical device development for, in that case Swaziland has the unfortunate notoriety of having the highest rate of HIV in the world.. During my PostDoc, I did a PostDoc in neurosurgery at UCSF.. During that time I had the good fortune to work with Andy Grove one of the real sort of giants of management theory.. On launching a program at Berkley called the masters of translational medicine program that's still, you know, very active today.. I came back to Stanford as a Biodesign fellow.. I'll walk you through a good amount of that thinking today.. And then worked on helping start the Accel Innovation Scholars program and also did a good amount of work with the Clinical Excellence Research Center which is really around cost-driven, value-driven innovation in the health care space.. So this just goes to say a lot of what I'm pulling on today, you know, this can be taught, this can be learned and I really encourage all of you to learn what you can, train and teach whenever you have the opportunity.. So I wanted to introduce first the framework..

I'll take a pause, see if we have any questions and then start to jump into two learnings on each of these topics.. So when I think about needs-driven innovation to me it really comes down to why, what and how.. And you can think of that as being what is the need that we're solving? What is the solution to that need? And then what is the plan? What is the tactics? And I'm basically gonna walk you through two specific examples of those.. Let me just ask before I jump into those, now that you know a little bit about Cala and a little a bit about where we're heading is there any topic you're just dying to, you wanna make sure that I cover while walking through this? Anything? Okay, perfect, I'll just jump in, then we can take this where it goes.. - [Man] I had one.. - Yeah.. - [Man] What are the problems you've faced? - Okay.. - [Man] Do you-- - We'll have lots of those don't worry.. - [Man] I mean, is this potentially a problem for your company? - Great, yep, anything else? - [Man] Erm? - Yeah.. - FDA clearance..

- Oh perfect, okay, great, regulation, anything else? - [Man] How did you find your team? - Great, we'll cover that, yeah.. - [Man] You mentioned the shift towards the patient-centered approach for your particular application so I'd love to hear more about that.. - Perfect, four good ones.. Okay, well feel free to pipe up if there's other ones we should add to that list.. I'll make sure we cover those four.. So if we start with the why just to start on an entirely negative note.. The reason to focus on why up front is because most startups fail.. So if you look at the data, you know, at the end of the day most startups don't make it.. Maybe one in ten or so has a really outsize return and when you look all the way to let's say unicorns it's, you know, maybe 1% of companies that ever go on to achieve unicorn status.. So when you're early in your own entrepreneurial journey how do you beat the odds? And I believe that really that focused on needs-driven innovation is one of the key ways that you can beat the odds, that you can set yourself up for success, that you can give yourself kind of a right to win in not only a competitive market but building startups is really, really hard..

So how I think about this is really through, you'll see in each of these stages, in the why, what and how, going through basically a time of idea generation and then going through screening.. So for example let's say you're at the start of an entrepreneurial journey.. When I was in Stanford Biodesign I spent several months just literally observing, following around any back office billing practitioner, nurse, surgeon, you know, patient and their family going through the health care system and just taking detailed notes on every unmet need that they experienced during the course of their hours.. The beautiful thing about generating leads in that way is that everything that you saw that was a problem was a real problem for a real person at a real moment in time.. You know you have an unmet need if you saw it.. Then you can go on to actually take those kind of observations and frame them up for example into need statements which takes the form of saying a way to do something for some population in order to and define your outcome.. So for Cala Health for example our need statement was a way to reduce hand tremors in patients with essential tremor who could not have brain surgery in order to restore their ability to eat, write and drink.. You can imagine when you're then stacking, going back to how do you spend your time, you can generate, you know, we generated hundreds of these leads.. You can then basically stack rank them by taking, you know, your screen.. Maybe it's, you know, impacted size of the population times the revenue potential per user or something like that..

You can then screen these needs against each other.. So for example in essential tremor after meeting these patients, after being, you know, really taken with how overlooked their condition was.. Between, they basically can choose between brain surgery and then no drug has ever been developed to treat this condition and it's experienced by about seven million people in the US.. It's a big unmet need.. It's about eight times more common than Parkinson's which is much better known.. And within even a need like that if you have already an area, you know, that you're interested in you can even take that and say well is the need we're solving the need for safer brain surgery? Is it the need for people who can't have brain surgery to have an alternative? You know, is it, and you can start to compare basically and contrast, you know, what is the fundamental unmet need that you're solving? And so that's basically how you go through needs generation and needs screening.. In our case that specific need came from the story of a man who, I still remember this like it was yesterday, he was in seeing a neurosurgeon, he had just learned that he was not a candidate for brain surgery and he was just absolutely in tears.. He was saying how, you know, he couldn't write a note to his wife, he couldn't have a coffee with a friend.. He had tried all the drugs, none of them worked for him because of some other medical conditions, you know, he couldn't undergo the surgery and something about that really just stuck with me.. It's someone, you know, begging for brain surgery and realizing that, you know, truly there was an unmet need there that we could address..

So we took that observation of, you know, his single experience, converted that into the needs statement and when I spun the company out of Stanford, you know, we largely fundraised on recognizing a need and having a great team of people around being able to solve that need.. I pulled in this quote from Thomas Edison.. If you look at the history of a lot of great inventors they truly did focus on needs.. I love this quote saying, you know, "I find out what the world needs.. "Then I go ahead and invent it." Thomas Edison is the inventor of the light bulb and the founder of general electric.. So the second why is, the second reason to spend your time thinking about why is really to ignite your passion.. And that's because startups are really hard.. Like if any of you have read Ben Horowitz's "The Hard Thing About Hard Things" it is really, really hard.. And so you need to ignite your passion.. You need to understand your why because that is what will fuel, you know, your marathon..

These aren't sprints these are marathons.. And if you know what need you're trying to solve that not only fuels you that also finds the right team 'cause you need to find the people from very diverse backgrounds but who resonate with your why and likewise down the road to sell your product.. So there's a great YouTube video and book "Start With Why" by Simon Sinek and that's actually walking through for example some of the history of, you know, companies like Apple and pointing out that there's a big difference between saying, from a marketing lens, between saying, you know, "We sell computers.. "They are sleek and modern and elegant," you know, "Do you wanna buy one?" And saying, "We challenge the status quo." You know, "We believe that you have potential.. "Oh and by the way we make computers, wanna buy one?" And so it's really that idea of saying, you know, how do you actually start with why and use that to, you know, build everything from your own passion, to your team, to selling your product? One other thing I just want to highlight here I pulled in a quote from Henry Ford with the Model T, you know, so he really created mass product manufacturing of automobiles, and he said, you know, "If I had asked people what they wanted, "they would have said faster horses." And what I love about this quote is it kind of highlights the inherent tension between the first two points that we just went through under why.. Which is on the one hand we're saying to some extent observe the market, right, observe what the unmet needs are, take a very objective, analytic approach to screening these and at the same time there's also just something about passion and about the fact that oftentimes people don't know what they need.. You know, there's very dichotomous views on user groups for, customer feedback groups for really breakthrough innovation 'cause arguably people don't know what they need until you've given them what they need and then they can't live without it.. And so I just wanted to highlight that here of to me finding your why really needs to have both that, you know, market validation, sizing the valuation of an unmet need and just being really true to kind of your instinct and your gut and your passion and recognize that both of those belong in where you spend your time.. Okay so now we're gonna move on from the why, from the needs finding portion of this, into the what.. And I like to call this follow your no'es and the idea here is basically, so you can see here you do needs generation, needs screening..

Then you do solution generation and solution screening.. And the reason I like to think about following your no'es is that when you're doing something really new, when you're doing something radical you will hear no all the time.. Especially when you move into the solution phase.. So at a level of needs at the end of the day most unmet needs are unmet need.. There is a

question of how big an unmet need is but it's almost like they're all good, which one is better? When you get into solutions you will hear every reason why your idea is a horrible idea.. And I think that one of, you know, when I think about our team, when I think about sort of what we've built and who has really excelled in a sort of fast paced startup environment to me that's one of the really key things is how can you listen to all of those no's and find who gives the most insightful no.. Who is really willing to sit down with you where you can just say honestly, "I hear your no, I hear your no "and I'm trying to see my way through this.. "Can you take the time to explain to me in detail why "this is a no?" And then have them detail it out and poke holes in the theory and that's where so much of innovation comes from.. So if you look at, you know, our product Cala Trio, and to the question about business model I'll touch on that here as well.. When we were delivering our first solution, the product solution, we heard no all the time..

Right, the site of essential tremor is in the brain.. It is the, you know, ventral intermediate nucleus in the thalamus.. Therefore, to treat that site, you either have to put an implant in the brain or you have to take a drug that crosses the blood brain barrier.. You know, no, it's not possible to do that without drugs or without surgery.. And then when we started to dig in on it we started to realize, you know what, actually it's a circuit.. It's not a single site in the brain.. And by definition that circuit goes out to the wrist, it goes out to the arm because why on earth can you treat the brain and have it reduce hand tremor? These have to be connected.. And so then we started to think through well based on that can't you reverse engineer the circuit? So if you can stimulate in the brain in order to calm the hand can't you stimulate at the hand to send a signal to the brain to actually interrupt the circuit in the brain to reduce the hand tremor? And that's how our product works.. So you know now some years down the road we have beautiful mechanistic data showing the effect of our therapy in the brain.. So it's basically a stimulation we're treating here in order to treat the brain in order to reduce the hand tremor..

But I think that's a great example of it was only by finding the people who could give us the most articulate reasons why what we were trying to do was a little bit crazy that those ended up being our scientific advisory board members, our clinical advisory board members.. They're the people who got sort of intellectually engaged and saw that through with us.. Likewise on the patient-centered care model that someone asked about.. When we got to a point of having a therapy that we know worked for this unmet need, worked for these patients, we stepped back and said well now we have to figure out how to get this into patient's hands.. From our clearance from the FDA, this is a prescription therapy, we spent time with neurologists starting to understand, you know, how neurologists primarily write scripts.. So, for example, prescriptions for drugs.. So we said we need to fit into their workflow, we need to have a prescription-like experience.. On the other hand our users, our customers, they expect an experience that's very much like, you know, your Fitbit or your Apple Watch.. They expect product to be drop shipped to their house.. That they can, you know, go online to check information about the data coming off of their devices..

They expect to be able to call customer service.. And then when you put those together we really said, you know, there is not a current model that works for that.. You know, you typically can't call a drug company to ask questions about the medications that you're taking.. In a world of devices typically people use distributors and we really started digging into that and saying, you know, but why would we wanna give our product to a distributor who then gives it to the patient? That means that we've just lost touch with being able to help people through the journey, with being able to, you know, bring them joy through that end-to-end product solution.. And so we realized that we needed to be a distributor.. So we created a very new model that basically said we'll be a manufacturer and a distributor.. What that uniquely lets us do is we can inform, we educate the patients about how their body moves.. I would say we educate many more people than actually have essential tremor about how their body moves.. We then assist them with getting the prescription either by giving them the information they need to carry to their own doctor or by in-servicing docs or, in some states, offering telemedicine.. We then directly receive the prescription..

We actually manufacture at the company as well.. We drop ship product directly to their doorstep and that, and then we assist them with coming up on therapy and really learning again how their therapy, how the therapy works for them as well as their own unique physiology.. I should mention also the product actually measures using motion sensors it measures every person's tremor and then it tunes the stimulation to interrupt the neural circuit for that specific patient.. So we already had built into the product a lot of the motion sensors, cloud connectivity through the base station et cetera that let us set up sort of a digital model like this.. Yeah? - [Man] Before you got FDA approval was there any thing that you did to convince yourself and convince your investors that your solution actually had merit and actually worked? - Yeah, so the question so everyone can hear it was was there anything before the FDA approval that we had to convince ourselves and our investors whether the therapy worked? The answer is yes.. We have always invested heavily in clinical science and research.. So for example, the first work that we did that was a study run here at Stanford we showed that we could stimulate peripheral nerves in order to effect someone's tremor, in order to reduce their tremor.. At the time we didn't know would this be a wearable? Would this be an implant? You know, sort of I would say we hadn't gone down the product innovation side of it but we had a good sense both of the unmet need as well as of the science that sits behind that.. You know likewise we really believe in accessibility to therapy.. One of the things that accessibility requires is reimbursement and so we've been fortunate to have investors who are really sort of alongside us in building the longer case for clinical evidence, value-based evidence for example, to really show sort of where we sit in the healthcare system..

Actually on the topic of investors, I'll come to the sort of diversity and pluralism in a few slides here, but I would mention Cala has a very interesting set of investors.. It's largely strategic investors and they actually span across pharma, in

GlaxoSmithKline and Novartis, tech with Qualcomm and Google Ventures and then medical device in Johnson & Johnson medical corporation.. And I do really believe in bringing together kind of a diversity of experience and viewpoint in order to be able to sort of sit around the table and, you know, knock down walls when it comes to both sort of best practices as well as the big pitfalls of the various industries.. Great, yes? - [Man] So, I was wondering if you could speak a little bit about the strategy to go direct to the patients? Did you experience any problems or hurdles that you needed to overcome to eliminate like the physician in that pipeline to say, "Okay, your prescribed it, "now you have to put it on, you have to wear it properly, "you have to make sure it's working right." From an FDA perspective or just from a device efficacy standpoint what were like major things that you needed to address there? - Good, really, really great question.. So the question was basically in going to a home use therapy that we among other things, you know, ship directly to the patient and bring them up on and sort of what that means from a lens of the healthcare landscape from the physician, you know, prescriber and regulators? So one of the, going back to the idea of kind of needs-based innovation, on day one of Cala we did two things.. We set up our quality system and we opened a clinic.. And that was really came from recognizing that the way to test and refine and see our way through the newness of what we were considering doing was to have patients and physicians as our partners, you know, onsite every day.. Such that for example the people who are designing products could have real sort of interaction with the clinicians.. The sites are run like that as this clinical site is run like any other clinical site, you know, all IRB approved studies et cetera, but having it physically co-located with the company really opened sort of people's eyes I think to testing and refining different business models.. So what we discovered over time is, first of all to the question of the physician in that loop, we work, we are 100% embracing of the physicians..

You know a lot of our prescriptions come through physicians who are key opinion leaders at the major, for example, movement disorder centers.. We just ran a study that was the largest study ever run in essential tremor.. It was 263 patients, three months of twice daily use.. We measure the efficacy of every dose by every patient so we have almost 22,000 data points to really mine and that, for example, to develop all of the predictive analytics.. We do a lot of machine learning work around, you know, how do we identify and treat these patients? From a physician lens it's what the healthcare system needs.. Right, we are able to actually measure how patients are doing.. We are able to engage both the physicians, the patients, you know, their care givers and I think that that's one of the beauties of digital is it is actually a great democratizer.. So when I think about our product portfolio it's really been about how do we have few sort of hardware products, you know, hardwares also hard.. So when having a few, you know, hardware products, few skews, but actually recognize that some people would prefer to get their prescription by being in their car and jumping on their phone and doing a quick telemedicine appointment and other people would rather to go in and see a movement disorder neurologist.. And so we basically said, you know, both of those let's serve both of these patient populations..

And I actually believe from a value-based healthcare lens, you know to me it's unforgivable that you look at all of the cost curves of the US spends more per citizen on healthcare, almost double any other developed country, and yet we drive some of the worst health outcomes in basic metrics like maternal mortality and to me, you know, we can't spend 20% of our GDP on healthcare, it's continuing to scale and yet not deliver those outcomes and so to me it's also sort of a moral imperative to tackle some of these issues of how do we sit within the current reimbursement system, you know, how do we engage with the physicians and how do we build these very scalable models of care that can reach beyond the current system as well.. Great, so the second what is to embrace ethics and to embrace it early and often.. And I love this cartoon.. So you can see here someone sitting in a car saying, "If these idiots would just take the bus "I could be home by now." But every single person is saying that so everyone sits in traffic.. Clearly the best solution here would be to put everyone on a bus and it might mean that they don't each get to be in their own private car but they would all get where they're going.. And when you look at, you know, questions like this kind of refers back to the moral philosophy of what people call the tragedy of the commons, which is the idea of the commons being a furnished pasture with you have got cows and if everyone has their cow, if everyone's cows go and eat the grass there is no more grass and no one can have cows.. And so there's a ton of, you know, different ethical theory built around the economics of this, the politics of this, the regulation of this and it's really the idea of, for example, when you have conflict through conflicting needs of different stakeholders how do you address that? And why I encourage, you know, as you're thinking about your solutions to embrace all of the ethical quandaries early on is that the more time that you have to kind of see your way through that you can do things like balance sort of ethical conflict, conflicting needs.. So as an example for us, sort of the modern day pasture for us, is digital health data and data around patients.. And a great example I think just of, you know, the type of ethical topics that we have always focused on from very early on in the company, long before we were commercial, was things like how do you balance the rights of the individual against the rights of the group? So let's say as an individual person we're collecting, cloud data on usage on efficacy that really empowers a beautiful experience for the patients, cost-effectiveness for the healthcare system et cetera but it also raises a lot of questions.. Because arguably as an individual you should own your data, you should have, you know, it be protected privacy wise, no one should be able to sell your data and at the same time let's say that you are, you know, a citizen who has a rare genetic disease..

And if everyone else was required to share their data then you would be able to discover the solution to your rare genetic disease.. If all of the treatment data, genetics data, you know, of everyone around you were pooled together then, you know, you would be able to discover that.. And I think that that's a good example of where, you know, we recognized early on that we had to be very careful about how we thought about things like an individual's right to their data and the right of another person to actually learn what therapy works best for them.. So then we could do things like actually taking the technology solutions, you know talking about another unmet need, to then get very proactive about how do we build out the technologies

that actually let us sort of have our cake and eat it to? That let us, you know, provide an incredibly data secure environment for patients and set up the infrastructure that allows us to learn, you know, one patient's type of tremor, what works for them and then actually provide that as advice to another patient to help them, you know, get the most benefit from therapy.. So I would just say as you're going through thinking of solutions always, you know, think about what are some of the ethical questions that will come up around this.. You know, dig in on them and learn about them and I sometimes think that this is an area that almost gets a little bit overlooked.. So, embrace ethics.. So just a couple of last pieces and I'll open it up for questions.. So moving from the why to the what to the how.. When I think about some of the areas that, you know, there's a lot that we have not done well..

When I think about some of the areas that we have done well I'm gonna highlight two that really come up there.. One is the idea of celebrating diversity.. And I think that there's a lot of talk about diversity when it comes, for example, to race and to gender.. It goes without saying to me that you wanna have diverse viewpoints particularly in the execution, in the implementation, not only the design in your products but the execution of your company because the more diverse viewpoints you have then arguably the broader the market you serve.. To put it in sort of raw, you know, financial perspective.. There's also a lot of subtler kinds of, sort of pluralism in diversity that when I think back on some of our biggest challenges as well as our biggest successes include things like Cala sits at the intersection of three very different industries.. So kind of the neuro, pharma, biotech world and a lot of what we're doing on the neuro side.. We're also a hardware wearables company.. We also are very deep in sort of data science and cloud.. And if you think about it when I look at for example our senior management team we have people who come everywhere from, you know, metronomic to Apple to you know it's a very diverse team and that's actually one of the things that makes it incredibly strong..

It also means that people come in with very different expectations, very different backgrounds.. I pulled out this figure from a recent book I've really been enjoying is Frederic Laloux's "Reinventing Organization" and he basically frames the leadership styles through sort of a social evolutionary perspective.. Going all the way back from, you know, impulsive red organizations from sort of a, you know, tribes and militias and points out that, you know, in a moment of anarchy you probably want to be led by a red leader, by someone who is, you know, leading from a place of fear for example.. Then he traces the leadership styles through conformism, through this is sort of the command and the control mentality.. You still see it in certain organizations, you know, perhaps like the military, the Catholic church.. There is a, you know, a conformism.. You see this in things like school uniforms for kids.. As that then moved on into the dominant theory of today's sort of Fortune 500 companies, which is achievement orange, which is the idea of command but don't control.. You see this in things like bonus incentives.. You know, set what the goals are but then let people act in their own way, let them solve the problem and then reward them when they, you know, when they do that..

More recently moving into pluralism, green, which is the example from that book is comparing United Airlines and Southwest and pointing out that they're very different in their manuals for flight attendants.. Where United will actually define here are how you handle these various situations whereas Southwest took a bit of a different, looser around the edges but basically said make your customers happy and then put more of the control kind of at the edge of the organization in terms of how to do that.. Evolutionary teal is kind of letting go of your ego and if anyone can, you know, figure out how to really be an evolutionary teal organization, would love to talk with you about that.. So, I would just say when you look at a leadership style as a founder it's really easy to kind of look at yourself and say well what is my organization gonna be? Are we going to be an achievement orange organization or a pluralistic organization? But at the end of the day your organization is gonna have people who come from all of these backgrounds.. Especially when you bridge, you know, industries and generations and, you know, cultural backgrounds.. So you really need to build a culture of respect that actually welcomes, celebrates and builds on, you know, people bringing their best selves in order to work together.. I'm also a big believer in strengths based leadership.. So the idea, and I can't tell you how many times I've had, you know, two employees who when you actually sit down and really talk with them about where is there Venn diagram of what they love doing, what they're passionate about, where their skills are and what the company needs you realize they just kinda need to swap jobs.. So you'll realize that you know one person is not loving what they're doing and really wants to do something else and there's another person who's exactly the opposite.. So from a management lens, from a how you get things done, I often think, you know, I often find myself kinda thinking about how can we raise people to be their best by focusing on strengths and then looking at that pluralism and diversity of sort of what builds a team and what builds an organization..

A last thought on this and then I'll take some more questions is this idea of self-fulness and what this really is is when you're building a company it's really hard.. One of the things you need to protect is actually yourself.. Is how do you, you know, how do you keep pushing through this? How do you bring your best self every day? How do you keep going through those cycles of here's the needs, here's the solutions, how do we act on this? Now we have a new solution idea, how can we take that back to validate the needs? You know, there's a lot behind doing that.. And the idea of self-fulness is basically if you drew two circles and you said one is what makes me happy and another is what makes the people who I feel connected to happy and you look at that overlap.. Then that means you can spend your time basically in three zones.. Selfishness is what makes you happy but hurts other people.. Helpfulness is where, or selflessness to take it to the more extreme, is where you're doing things that don't make you happy but do, you know, help or serve people who you care about.. And arguably when you're in either of those areas you can think of it as you can be a maximum of 100%.. You can either get joy for sort of yourself or out of serving people.. Self-fulness is the idea of selfishness plus helpfulness so you can be self-full..

And if you think about it when you spend time there you can be 200%.. 'Cause you can get double the joy.. You can get the joy out of doing what you love and serve other people and just kind of going back to this idea of, you know, really understanding your why, building your team, celebrating diversity.. It's sort of one of the things I keep coming back to of how do you design your life, design your company, design your work in a way that you spend as much of your time as you can in the, you know, self-fulness alignment.. So just to wrap up here.. We talked through needs-based innovation.. The why, the what and the how with the need, the solution and the plan.. How do you beat the odds? You know, how do you beat the odds through really objective analysis of needs? How do you ignite your passion which is also find your team, you know, sell your product, raise capital.. For the solution, really thinking about following your no'es seeing your way through all of those nos to find the yes.. Embracing ethics and then down on the plan, you know, celebrating diversity and discovering sort of your place of self-fulness..

So that's what I put together in the slides and I'd love to take any questions and I'm gonna check the list to see if I addressed those four topics.. (audience applauding) So let's see.. We covered some of the patient-centered care.. Regulatory, let me know if there's any further questions on that.. How do you build and find your team? And what were some of the problems we faced? I hope we covered a number of those problems.. Any other questions, yeah.. - [Man] I was wondering if you could speak a little bit about having a quality of life centric sort of outcome? - Yeah.. - [Man] Like especially in medicine you want to, you really have a value proposition that's in to reducing costs or doing something else.. When you go out to try to convince people that this is something that you are going to want having a product that's like I'm going to go out and buy this new thing might be a little bit difficult.. I was wondering if you could speak a little bit about like having that type or wondering about how you propositioned, wondering how you got started? - Yeah, great question..

So the question is basically about our value proposition and sort of how we think about this in essential tremor's thought of as a quality of life condition.. I think at the end of the day there is a ton of business opportunities in these quality of life conditions and yet historically they've been more challenging from a reimbursement lens for example.. So, you know, if you really fundamentally start with, you know, what is sort of the value of a product, right.. We are having a tremendously positive impact on not only people's lives but also on their experience in the healthcare system.. So if you look at the two ends of our product you can see there's clearly good health economics when it comes to how do you not undergo a 50 to $80,000 brain surgery.. And then on the far other end we are actually a solution that can take patients very early in their journey.. So for example who are just presenting with hand tremor, get them on therapy and provide actionable information back to both the patient and the medical system.. And so when you look at today's highly fractured system in the fee-for-service world of healthcare typically it takes patients, you know, many different appointments with specialists before they get all the way through sort of diagnosis and onto therapy.. So I'd say on those two extremes we really believe in kind of accessible access to affordable healthcare that saves the system money and it also, as you look at some of the things like accountable care organizations, it's also sort of a big draw from how do you have competitive draw into these systems where systems want to be associated with, you know, at the end of the day what patient's love.. And so really sort of when we look at that model, you know, we don't have high cost drugs to compare against for example because no drugs have been developed for this condition..

But we believe that we actually have a pretty nice case on that and we're actively working with Medicare on.. Initially with Medicare moving into the private payers on securing, you know, favorable and accessible coverage.. Yes, yeah.. - [Woman] So I have a question for you about your need generation and need screening process.. So, obviously you have this incredible background in neuroscience and I'm sure that impacted the things that you were thinking about and the observations you were able to make when you went through this process.. And so I was wondering if you could speak a little bit more about that and also about, you know, how much of a technical background do you think an entrepreneur needs to have in a certain field in order to be able to pursue a meaningful idea like you did? And what if we are someone who notices a real need but we don't have expertise in that area? Is it still possible to pursue? - Great, so the question is around how do you account for the fact that often, for example I have a neuroscience background so somewhat not surprising I looked at some needs and solutions that sat in the neuroscience and engineering background.. And then I'm sorry the second part was, oh, and if you don't have a technical background kind of where do you dig in there? I would say I laid them out in order today of saying needs, solutions and then the tactics, the how, but it's really much more of a continuum.. So, for example, sometimes when I'm working with the large companies or presenting sort of on the entrepreneurial needs-driven innovation type thinking I get asked the question of well we already have a portfolio, we have expertise in the following areas, we're not gonna go out and do primary observation in a hospital and stack rank the ideas and decide where we go 'cause we need to look at it relative to our business, right.. And I think the thing is there is wherever you start on that continuum you need to do the full circle.. So if you're starting at a place of you don't have a company you can go through the needs and into that..

If you start with a, for example, what is your technical skill set or what is your company's product line you can also start there.. You can come up with a solution before the need but what is absolutely critical if you do that is that you come up with your own, your initial solution, you're flexible about what it is, you then go back into the needs screening and you force yourself to go through what is the need statement.. You take 100 different variants of that need statement.. You go through a robust ranking and a checking around that and you give yourself the space to slightly modify your solutions.. And so oftentimes people, you know, are not starting.. I mean for example the fact that I came up with a number of solutions that mapped to my technical background, that's great.. At the same time we were very rigorous about continuing to assess our needs so that we didn't bias that too much.. And I'd say on the not, the question of none technical founders, at the end of the

day I mean innovation is a team sport.. So you need a team that has diversity and that background.. And so, you know, I certainly there are, you know, there are technical founders, there are none-technical founders..

I actually just recently moved from our CEO role to our CSO, our chief scientific officer role when we went commercial.. To me that is a perfect fit for me in doing that and I think that that's just a great example of it takes a team and the team changes over time and that's sort of the beauty of it is you can learn and you can, you know, emancipate yourself from certain responsibilities and then move into other sort of areas of growth.. So I'd really just think about that needs into solutions as much more of a circle than you know a starting point and an end.. We certainly haven't reached the end.. We're back, you know, in intense R and D again on the next generation products.. Yeah? - [Man] So you found a solution to deliver drugs, (speaker drowned out by man coughing) the problem (mumbling).. Drugs already existing.. So where's the revenue stream, from the drugs or the device? - So I think of electricity as our medicine.. So it's just electrical therapy, there's no pharmaceuticals in it, but we deliver it on a prescription like model that for the prescribing physicians feels a lot like a prescription.. Oh sorry, the question was on drugs and devices and sort of where that sits..

So I'd say, you know, I think this is a very good entrepreneurial practice also is we basically stepped back and looked at the best practices of all of the industries that we touch.. So we looked at, you know, wearables and that product experience.. We looked at, you know, pharma, as I've mentioned of opening the clinic.. We spent a lot of time just observing.. You know, a physician's appointment with a patient, their follow up and that's how we really kind of invented that business model as well as that product.. (man mumbling) So the question is how is it different from a TENS unit which is a different type of neural stimulation.. So we're a fundamentally different type of therapy.. We actually had to go through the De Novo pathway at the FDA which is for you have no predicate devices.. So I'd just say different from a mechanism of action.. The only similarity being their non-invasive stimulation..

But there's a lot of other, you know, transcranial magnetic stimulation et cetera, yeah.. - [Man] Can I ask one more quick question? - Sure, one last question, yeah.. - [Man] So what's next in your pipeline? - So we have a ton, I'm really excited about the pipeline.. So we're working in a couple of areas.. So indication expansion we're particularly working right now in deeper in neurology as well as in psychiatry and cardiology.. So we recently announced a collaboration with MGH and Brigham and Women and are doing sort of work out in Boston as well.. We also are pushing much farther on the connected care experience.. So now that we have, you know, connected devices in the field we're really kind of building out that full ecosystem around how to do affordable, accessible sort of transparent medical care.. (audience applauding) (upbeat music)..