



# Stanford eCorner

## Leadership and Disruptive Technologies (Entire Talk)

Thomas Prescott, *Align Technology*

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Thomas Prescott, CEO of medical device manufacturer Align Technology, discusses disruptive product innovation and leadership in the medical device industry. Prescott shares the company's story, including insights on the launch of their signature product, the Invisalign orthodontic system. He also discusses operational trends and the need for sound analysis of financing, product execution, and business development tactics.



### Transcript

I'd like to introduce Thomas Prescott. Thomas? Thanks, Steve. First, Tom, thank you. Boy, it's great to be here today. I'm thrilled. A lot of IQ and energy and interest. And whenever I get the chance to interact with whether kids are in grade school or junior high or high school, college, talking about science and entrepreneurship in the future, it reminds me why we work so hard, because the point where you are in... It's Darth Vader. I'm assimilating you. You're now corporate America.

It reminds me that everything is still possible. And that's the wonderful plate you've got in front of you for the rest of your life. So, it's really my honor to be here today. One quick survey while we're here. We have a range of students and faculty. How many of you ever had braces? Raise your hands. All right, scientific survey, more than 50%. How many of you loved it? Someone loved it. Why did you love it? I felt like I was in the club because of it. You got in the club.

You officially got your team colors on. It was great until you went home and all you could eat is soup. I will tell you, Align Technology, we're here to do a couple of things with you today with your forbearance. My agenda is just to organize, to keep me on track. And you've got a lot of things to do. I'm going to give you snapshots of a great Silicon Valley success story, a Stanford success story and an innovation and entrepreneurship success story. I'm also going to give you a few observations. I'm not qualified to teach leadership or to tell you the right way to do it. I'll just share with you a few observations, what I'll call a few tenets of leadership and management. And then, finally I want to share with you a little of my thinking about the headwinds in the medical device industry that I think are critical.

med tech and biotech, a very critical part of our future for all humanity as well as certainly one of the bulwarks of American entrepreneurship and innovation that we've exported globally. So, with that, how many of you have heard about this line before? The clear braces company? You may know many things about it and you probably think of it as a piece of plastic but it's many things. But mostly Align Technology is an engineering marvel. And the little piece of plastic that represents the aligners, in fact, I should ask anybody here a patient in treatment? Boy, not much market penetration, one person. You see the opportunity we have here. So, when the venture guys ask you how big your market is, we're maybe 80 people, we're in a quarter percent penetration. But Align Technology came into being as an impossible idea, like many of the things you play around with. I love the contest. And today, you're looking at an environment where everything is still possible but many things are harder. So, go back to what you think about what was going on in 1997 at Stanford, at the Graduate Business School.

What would be a couple of differences in your minds just jump out different today from 1997? One thing. Sorry, never mind. No, never mind. That doesn't count. Next, somebody jumped in. What's different today, one thing? Yes? Social networking. Social networking? Think about what, even think what that meant. It was maybe classmates.com or something like that, right?

What else is going on? The dotcom bubble. I'm sorry? Over there? The dotcom bubble hasn't happened yet. The dotcom bubble.

Yes? iPhones. iPhones and all of these iApps, everything. So, I'm going to jump on this for a minute. The bubble was still a bubble, it hadn't popped. So, before that bubble popped, what was going on, say, in the financing community? Was there more or less funding than today? Way more. Way more, you got it. So, think about two graduate students at Stanford, and I take my hat off to them. Zia Chishti and Kelsey Wirth, they had this idea. And they went up and down Sand Hill Road, not far from here. And everybody said, "No, you're crazy." Two wild-eyed Stanford students with an idea that you can somehow get away from braces and brackets and wires.

And Kleiner-Perkins, here's an ad for them, said, "You know, this is a crazy idea. But I'll give you a little bit of money if you can solve these, answer these three or four questions." They did that and they came back and got them connected with a few medical schools and orthodontic departments. And they answered a few more questions. That ultimately led to a pretty fast-paced cycle of financing and tackling big technological problems because, you know what? People could use pieces of plastic to move teeth or retain teeth. But no one had ever imagined how you might use technology to make this more systematic using computers and 20 to 32 3-D objects in the mouth with no reference frame and then the manufacturing technology to enable this and so on, five or six or seven fronts. It was basically impossible. And there were no technologies out there in the world that anybody could find that could actually do that even if you re-purpose best-in-class technology. So, this became quickly a financing and race-to-solve technology problem. So, you could actually develop a product and bring it to market. At the core of Align Technology is technology and innovation.

And while you may think of us as a consumer company today, we've certainly pioneered in the dental industry the ability for a smaller company to create brand awareness and mobilize consumers and ask for a product by name, which is a new dynamic. But the bigger innovation in the company was underscoring the technology we innovated. Much of this was done before I came in early 2002. But they innovated new processes and technology to personalize each patient treatment with a class 2 medical device. Those of you that hang around the medical school or biomedical engineering understand that's not trivial certainly today; it wasn't back then. We've become the global leader in mass customization. Imagine how personal this is. It fits in you. And if it doesn't fit perfectly, it doesn't do the job. You're going to take it out.

The only way compliance happens is if you want to wear it and you see progress. And every one of these aligners, every one of these treatments, has to fit you perfectly or it doesn't work. We don't make any standard parts. Every part we make in a demand flow manufacturing system is completely unique with no standards. We've got microns of fit and conformance and yet every one is unique because everybody's mouth is different. Everybody's anatomy, physiology and treatment is different. And we have to accommodate how the orthodontist or dentist wants to pursue that treatment within some clinical standards. So, the company basically did this. This is not an advertisement but I'm probably proud of our team that has done this. And since you're talking about entrepreneurship and innovation, we're sitting here in one of the best engineering schools in the country.

You guys can appreciate what that meant and what it took, 16 million completely unique class 2 medical devices. And now over now over 1 million or 3 patients in treatment are finished. And we continue to have 90% plus of vary or extremely satisfied remarks from the patients. So, we're just getting started. You see a minute ago a really small share, at least a slice. And again, you've come across, you see how amazing the technology we've created to do it. And so, at the core of it is intellectual property and novel innovation. But you're looking now at something that looks very easy. I'd like to take you back a little bit. And we're going to come back and talk about this, I guess.

And before I do that and I'm on video, I realize there's a risk that this is being preserved for all. But I need to do a full disclosure. Two things, when I look at the flyer, that's an older photo, clearly there's truth in advertising here. That's probably a four- or five-year-old video, more gray hair, et cetera. The second thing is I'm a failed entrepreneur. The only company I've ever started up failed. And remember, they always fire the sales and marketing guy first. That was me. So, we did a company back in 1985, '86, for early optical disc storage and applications on a factory floor. I had to come out of factory automation.

And it was a great idea until we had one customer doing a pilot project. They were called GM. And if you ever do your history, that was the end of Roger Smith. So, GM got a cold. Auto suppliers got pneumonia or died. And you? Yes, the answer is yes, we died. We didn't go. So, as I looked around at potential entrepreneurs and tipped my hat to entrepreneurs, many of them failed in many things. And so, I don't know whether you read Thomas Edison or somebody else, whether it's experiments or anything else, there is more failure than there is success. But failure is an outcome and you learn a lot from it.

So, with that kind of full disclosure about me personally, I've had the pleasure of coming in and working with, coming in behind and working alongside multiple founders. And in most every case I've had enduring great relationships with founders. And Steve and I were talking briefly, what's the difference between an operating hack like me and a true entrepreneur. And the answer is a few things. One, it's life experience and skills. And then, two, I might pursue a big bet as an operating type. And I would have plans and a rationale for doing that. But I'm not as likely to go after a wild, crazy idea that's totally disruptive. And

so, once somebody does that, maybe they can't scale that business or it's not growing fast enough or there is some other problems. And somebody like me can be a good complement to that.

It's not often that a great entrepreneur can be a great operating personnel. There are exceptions. But I have the greatest admiration for the true entrepreneurs that have figured out a way to create something truly disruptive. The challenges, how many of those companies that have created this new thing, this new segment, whether it's in social media, how many of you early movers there really got to gain it? Facebook certainly won. But in looking at any new space where somebody has come up with a disruptive new idea or new technology, how many of those early movers really got a chance to capture most of the profit from that new space? So, how many had MP3 players before you had your iPhones or iTunes or things like that? What happened to all those guys? See, Apple thought of something completely better, bigger, more complete. We never knew we needed that until they did. We never knew we needed the iPhone and all the apps ecosystem before we did that. But the original players in many spaces don't get to capture all of the profit. And so, young companies that go through startups have great opportunities to go, not only innovate but then you got to race to try and continue that innovation cycle and start to scale your business. So you have a chance of actually creating business success.

So, Align Technology, I'm going to step you through a couple of stages. I'll say the startup through real-growing pains and early in '97 Zia and Kelsey were at Stanford Business School, getting their master's, their MBAs. And they thought there had to be a better way. They came up with this idea. They actually got a little bit of seed money. The company was formed in April of 1997. It was followed by a pretty good-sized A round of financing in the summer. And they went ripping off on solving problems, imagining technologies and starting to think about how they could actually bring a product like this to market. The product actually came to market. And the first product was shipped in August of '99.

There was a lot that happened between then, including several financings. All in before we made a profit, the company raised \$280 million. Now, do you think that's likely today? They're shaking, "No way." There is much more pressure on companies with very big ideas that require a lot of capital to enable them. And so, virtual models, you've had some great speakers in here talking about virtual models and different ways to do this. Very few companies are going to have the capability to raise those kinds of dollars. I don't know if you could have done what these guys did in today's environment with the axis to capital that was back then versus what it is today. But that said, they did a fabulous job at that. They had a first-class group of folks here, many from Stanford computational labs, some of the same DNA that went into some of these great companies in the Valley. And they were solving enormously difficult 3-D geometry problems and manufacturing technology problems and with all the dog years of work that you can imagine went into that. I'll take this out to 2002, when I came in.

The company was shipping product but we were not what I'll call successful. Operationally we were not capable. The right case wasn't going to the right office. The product didn't always fit perfectly. Our customer service wasn't very good. And we had a new dynamic emerged. To scale, finding scarce computer kind of 3-D CAD cam skills, Zia who had deep Pakistani roots, had gone to Pakistan and set up an operation there, where we could scale on a cost-effective way. And then, what happened in September of 2001, 9/11? It became very difficult for us to continue to scale that facility, bring Westerners over there, drive process improvement and everything else. The company was struggling to continue to grow and scale, running out of money. What happens when that goes on in startup companies? What do the boards start saying? Stop.

What do we do? Should we think about a new CEO with more experience and everything else? I wasn't there for those discussions. And I was really coming out of, well, I'll say more clinically intense med tech, interventional cardiology, respiratory, patient safety monitoring. I loved health care and I loved the mission-directed nature of the health care businesses and med tech businesses had. "Do you want to go see this dental company?" I thought, "Dentistry? Gosh, it didn't seem like it was clinically intense." When I came down to Align, I saw amazing people, great technology and a wonderful opportunity but some significant problems. I came aboard in March. We looked at the whole business, decided we had to be more focused with our choices and what we were doing. We cut our burn rate. We raised a little bit of money and we actually turned cash flow positive in 2003. Along the way we made the decision that we had to exit Pakistan. We moved some of that operation to Costa Rica.

Zia ultimately left the board. And we basically started doing fewer things that pissed off customers. It's a long list of things that when you're not operating well, you can go right down that list and fix those. So, what's the old story when you're in a hole? Don't keep digging. So, step out of the hole. We basically just started running the business more sensibly and taking care of the basic stuff. So, that was the startup, the scramble, the financing and the first commercialization and growth of the company. By the end of 2004, we were about \$140-150 million in revenue and growing nicely, again 30, 40% a year. What happens when everything starts going well in a company? Everybody gets sick? No. What happens when everything is going well? What about your personal life? Everything is going perfect.

You assume it's going to be great forever, right? So, maybe relax. And companies are like any organization. When people don't keep pressing into something, keeping your eyes on the horizon for the bigger thing, you start to relax. And guess what? You got an inflection point. And you start getting less focused. Your execution isn't as good. And the time you should press the most is when you're doing the best, right? That's when you can press advantage, whether it's technology, market, your

organization. And so, we ran into a few execution challenges. And then, lo and behold, one of our founders showed up again. I'll just say we have a rich history.

And we wound up in lots of litigation for a couple of years. You know what? Nietzsche was right; what doesn't destroy you or kill you makes you stronger. Ultimately, adversity is a good thing in nature, in the marketplace, in competition for innovation. And we went through a couple of cycles. But through that process, we went through some very challenging times. And I have included this to bring it out through 2008 because we all know what happened in the meltdown. Just when we were getting our act back together, after competitive threats were mostly dissipated, the whole world went crazy. And consumers ran into a shell and our customers were freaked out. We were all collectively saying, "What happens next?" So, what happens when everything else goes wrong? You step back and take a very sober look at your prospects and your opportunities. And we did that and we put a turnaround plan together and took some costs off the business, got refocused.

And through that period, we've really been scaling the business and came through the downturn. We actually grew. We took \$25 million costs off the business. We made some hard choices to focus and fewer priorities and had existed that cycle doing pretty well. I'd say right now it's a pretty choppy economy and you work through the time you're in. But the phase we're in right now is basically scaling to make sure we stayed. We created this new space. We innovated and pioneered clear orthodontics. Our goal now is to be the leader. And we really only have about 3% share of the existing starts just in North America alone.

Those starts were the orthodontists. So, we got very a small share. We got an opportunity to switch over the whole world to clear aligners. Who would want braces? We'll help you feel like you're in a club, give you something else. But at every stage of a company, there are very different challenges and you could learn much from what we've been through hopefully vicariously so you don't have to repeat it. I'll stop there. I have given you a speed review of our history. And I'm happy to take questions in real time here. I have a few other ideas I'll throw on the table. What questions do you guys have about stages? Yes? Steve: Let me pick questions from the 178 Class.

I asked a couple and I'll keep them instead of the typical three we normally ask in the MS&E178. It is wrapped around this class and you've been kind enough to volunteer, to come into it. I won't use up our magic three. I'll just use one. And I think the most interesting questions boil down to, what is the interface between the founder and the new operating guy who comes in? Are there expectations that are unsaid or not said? What do you wish would happen to make that better? Implicitly, that's a load of questions on purpose. Thanks. Again, with the exception of one founder, I've got great relationships with many founders. I've worked alongside three or four. What I'd say first of all is you need a mature relationship. And you need to recognize there's different life experiences, skills, orientation.

And if you can do it right, they ought to complement and not compete. Now, that requires emotional maturity on the operating person that says, "Well, everything here is bad. You need to fix it," versus saying, "Boy, this is amazing. I can see a lot of ways it can be better." Are there sacred cows? Are there some other things that are very important to you as a founder. Oftentimes, founders remain in the board that still maintains an important relationship. On the case of the founder, many founders, it's your child. You can't imagine seeing it other than how you see it. So, it requires some emotional maturity from the founder to develop that working relationship with the operator. In the best case, you have a board that is having open dialogue about this. You have a founder that really cares most about the company being successful.

You have an operator that is able to leverage their skills but is respectful and appreciative of the fact they would've never given birth to this wonderful thing called this new company, creating jobs and opportunities for a lot of other people. One of the presentations that I know the few individuals that have characterized this is Shakespeare in Hamlet and others. There is plenty of drama in Silicon Valley about startups and founders being moved out and all that stuff. I would assert that it doesn't have to be that difficult. And if you're thinking about starting up a company, think about what it involves and imagine success. I do that personally. I visualize the outcome I want, whether it's three years, five years. And then, I imagine where my skills won't fit anymore. I personally don't want to run a \$5-billion company. It's too far away from customers and employees and the magic of innovation for me to get really excited about that.

So, for me to think about this business, if I'm here five more years and we're billions in revenue, it's less interesting for me and I wouldn't be as passionate. So, I have to start thinking about, either that or the board does it for me, when would be the right time for me to be thinking about somebody else that loves running a \$2-billion company, taking it to 5 because the work you do is different. I think it's the same thing for each of you that are starting companies. And if they are virtual, it may be different. You may not have a successor, an operator. You may be able to rely on the ecosystem around you instead of so many other people that in virtual space can complement what your skills and experiences are. But I believe life is too short and you ought to have open, honest discussions. And if the operators come into a situation where the founder doesn't agree and the board doesn't agree, then I'd say that's not a situation the operating type would say, "I'm not sure this is the right thing for me." I personally don't like to drop in to situations like that. Let's open it up to the questions. Sure, any other questions? Yes? I'm interested in knowing how the market penetration process was because you weren't competing with some other businesses

and then your products was a new type.

So, how easy or hard was it to convince the doctors to employ this? And then, what kind of resources was necessary to do that? Sure. I'm going to try very hard to play back the question. And if I don't get it right, you're going to help me. I think there was a three-part here. The first is interested in market penetration. How hard was it to get doctors to believe in and start to adopt and then, three, what kinds of resources went into that? Was that pretty close? All right. It's hard. In the medical device industry, whether it's a dentist or a doctor or in a specialty, they are looking for proof, clinical evidence, white papers, clinical studies in some cases. In the early days, Align did not have that. One of the reasons they went out quickly to consumers was they said, "Boy, who would really want braces?" They had a great value proposition but the problem was, especially orthodontists, it was almost dogmatic.

Everything they did was brackets and wires. So, the job they had to do was explain to them, give them the clinical reasons, the economic reasons and all the other reasons why they would say, "You should trust us with part of your practice to at least start trying this." And the company wasn't really set to do that. They didn't have a lot of people in the early days that understood clinical development and innovation inside med tech and why doctors make choices. So, they went to the consumer and it was exciting for a young private company to run a \$30-million ad campaign. There was a lot of buzz but very little of that translated into case starts for Align. It turned into a lot of a case starts for the bracket manufacturers. They should have at least sent us Christmas cards. So, the company basically had to retrench a bit, provide the reasons to believe, clinical evidence and a lot of science. And we're still doing that. The consumer has a far greater demand for this product than the channel, our GP dentists and orthodontists.

There's our group of committed champions here, maybe a third of the orthodontists out there. But many of them are more comfortable using the traditional approach itself. You got to invest in clinical studies, trade shows, a lot of clinical education. We have an award-winning website where we have a lot of CE content. Bring them along. Give them reason to change. The other thing that happens in dentistry is, how many of you are in the biomedical or med tech or other areas of engineering? What's one thing to say cardiac surgery or interventional cardiology versus dentistry? What would be one big difference? The payer. The payer, yes. Private pay, that's a big difference. How about morbidity/mortality? Anybody here heard of somebody dying from a dental procedure? If it happens, you probably got very bad care.

But the very low morbidity/mortality in dentistry and orthodontic specialty and the very fragmented nature and private pay mean they are slower to change. If a big change occurs in the interventional cardiology, let's use stents, changes within a quarter or two, you would see most people using what's now considered as standard of care based on very clear clinical evidence. It would almost be irresponsible to stay with old technology if it was proven that there is greater morbidity/mortality. Now, we might test that when the government is the payer and say, "We don't care so much about that." So, back to your original reason, this is why it has taken a longer time. We're still working on it. The company spends a lot of money on clinical research, on sales and marketing and all of those things. And I'd say we're still in the first or second inning of that adoption and market shares are still very small. Other questions? Yes? What is it like running a company that has a very physical product in a place like Silicon Valley where there's computer startups coming in at 10,000 miles an hour? I mean, do you guys have to physically go out and meet the people that you're going to be working with? The question is, what it's like we're living in Silicon Valley, where things move at breakneck pace and it's an electronic world. And you can reach the customers in a virtual space, in a parallel universe, and a real economy without ever seeing them. And yet we've got a real physical product, we have to deliver on it? For me, it's a great thing personally because, again, I am passionate about medical devices and health care and having a purpose-based company, very mission focused were we can do well and yet see how people are so excited.

We don't save lives in this part of our med tech. But we really change lives. A beautiful smile for somebody that never could smile or feel good about themselves is a really a big deal. And I frankly underestimated that when I came here. I was used to lifesaving technology. This is life changing. So, for me, I would probably have a harder time in a virtual world because I get renewed by all the stories and seeing patients and doctors out there with people that we've touched. So, for me, medical device health care is a passion more than it is a job. It pays pretty well, too. Yes? Do you have a Facebook fan page, by any chance? We do.

If you're not a teen, I would also point you to [invisalignteen.com](http://invisalignteen.com). That feels creepy but we do. In fact, on the question on social networking, we have a very viral kind of product path. When you have a very honest offering, it resonates with your consumer. And the value proposition, when you knock it out of the park all the time, we've got some very passionate fans that love to talk. And one of the things we see today with frankly your generation and those younger than you is your own self-produce content. You don't rely on somebody else's content and you're telling your own story. So, we're trying to enable that with all the digital social media environment and ecosystem. And we're doing a pretty good job. Yes? How would you say the culture changed when you came into your company and now? What's the fundamental change in the culture and the people? So, the question was, what has changed with the culture since I came in.

It's not just me, it's bringing in another team and bringing in people that commit to the core values. I would say the core

values of this company haven't changed. The DNA of the founders will always be in a company. And I think that's a good thing and you shouldn't dodge that. You see the base of the technology we created and that's a wonderful blessing. But also the passion for our customers and their patients is there as well, being the right kind of place to work. Now, we don't quite have the campus of a Google or whatever. But our employees are there in their weekends. And they're doing it because they believe in it and they want to take it to the next level. And I think now you can layer on, when employees run out of gas because you work really hard and you don't get things done.

So, now if you can add the basic stuff to consistently execute well, that progress, that winning re-energizes the team. I do think, though, in any company you have a stated culture. You can find it on a wall or a card. And then, you see the invisible culture. And a lot of times, the things we don't like about where we are or where we work are that invisible side. And I think it's really important to be honest about that, "Here's what we say but here's what we really do." And a lot of times those norms are more powerful in the company, "Gee, we like an open discussion," yet you never have arguments, right? It always happens in the hallway or whatever. So, I think when you guys are out, if you're talking to companies in getting jobs, are there any jobs available? Go figure out what the real culture is; otherwise, what they say. There is always the intended culture and the unintentional culture that's out there in the business. I hope we've made it a bit better and it's built on what they had. Other questions? Yes? How is your difficulty to gain an approval from the Food and Drug Administration in order to launch a new medical device into the market? I'm going to cover that in a minute.

The question is, how difficult is it working with the Food and Drug Administration and other bodies outside the US to get approval to launch and commercialize a new medical device. It's really hard right now. You guys have had Josh Makower in here not too long ago. He has been here a few times. He is a great entrepreneur and serial founder. I just spent some time with him last weekend at a meeting. It is very hard right now and what's more difficult is it's moving. And so, what happens when there's uncertainty, when what appears to be political policy is both being played out through heightened regulatory action? That can appear to be arbitrary sometimes. And then, when new rules are coming in, how they'll be implemented is not clear. That's all the way from CMS, where they're determining reimbursement and payment, all the way through FDA and clinical trials and all that.

So, for a founder, for a VC firm and for the other actors in a young company, this is very destabilizing. Most VCs I know have backed away from big idea opportunities because the capital isn't available for it and the risks are too high right now. And that's a huge problem but I believe we're going to work through it. There needs to be certainty about what the process is and then you can figure out what you're going to do with it. A couple of other questions maybe on this? Yes? In the back. So, you're in orthodontia. Which field of medical device technology do you foresee will be prominent in the upcoming decades? The question was, we're playing in dentistry right now, in orthodontics, what do I think is going to be really prominent. There are some obvious technology gaps. The traditional way medical devices have come about is a clinician that's really smart saying there has got to be a better way to this. This is an unmet patient need.

People are dying or they certainly aren't getting well or you have chronic diseases that just linger. And you have engineers that are thinking of the same thing. And they get together and figure out a way. So, there is going to be convergence in the next 5, 10, 15 years. I believe today's medical device technology with an original clinical focus, patient problem, unmet need. And my hope is that just as convergences happen in some other areas of the technology world, multiple technologies getting together and shifting the curve, I think there is a great opportunity in medical devices. Sitting here today, the obvious places where innovation is rewarded are for the big disease states, interventional cardiology, and there is a whole class of problems from atrial fibrillation to still sudden cardiac death and things like that. There are huge problems with what's called COPD, chronic obstructive pulmonary disease, which is just a terrible way to waste away, emphysema and all that. Sixty percent of the population is going to wind up with type 2 diabetes. So, what I'd say, there are enormous problems and enormous opportunities.

But my hope is that traditional strength of medical devices will continue and we will bring a whole new way to get them to be more cost effective and be able to prove that the system can afford that intervention because it will eliminate the need for a long-term chronic disease state. I would say go figure out what the most expensive problems are. Diabetes is clearly going to be one of them. Heart failure is going to be one of them. Sudden cardiac death and certainly cancers of all types have been around. We're still not smart enough about how to apply even the best in class drugs today. And I think there are a handful of really amazing companies in this valley working on very targeted therapeutics. Why should one class of the best class of treatments for breast cancer only work on 20% of the women? And they endure all the side effects and yet they don't really work. And six months later you've got bigger problems. We should know what will work, what therapeutic regimen will work on individual patients.

It's actually a hard time but I'm very optimistic about the long term if we don't kill the golden goose. I didn't answer your question, sorry. But there is a lot of big problems out there, sorry. One more question there or not? I'll move on. Yes? Just kind of a follow-up to that. Did you see this kind of innovation in the pharmaceutical industry? The question is, do I see innovation in

pharmaceutical industry. When I moved in to medical technology out of factory automation, it was after I had a startup that failed. I was kind of answering her question for myself. What's going to be hot for the next 20 or 30 years? I need to learn more about being a better leader and a manager. And I want to find a segment in the economy that does not go through the business cycles the same that I had seen in broad-based industry.

In fact, then we didn't exactly have Google. The Internet wasn't around. And so, you go to the library and spend time with microfiche and SMP reports and all that stuff. What took weeks, you probably can do in 30 minutes today. But the upshot was I looked at health care and medical technology and I decided not to go after pharma. It's a long way of me saying, I don't think I'm qualified to answer about pharma. What I do see happening is they're moving over from classic pharma into biotech. And they're moving in the generics and they're finding ways to find low-cost environments where they can bring a therapeutic regimen. One of our board members was a number 2 guy in Amgen and they work very hard but it's very expensive what they do for biologics. I don't know what's going on in pharma as well as others but there are great people you could bring in.

I do believe that integrating pharmaceutical regimen is a big opportunity with informatics and the genetic profile, how can you make certain therapeutics work for a certain class of patients and know they won't work for others because a lot of the therapeutics don't have the effect they want but you can probably get somebody better than me to answer the pharma question. Way in the back, yes? How are our FDA regulations different in international markets? How are FDA-type regulations different in the international markets? Five years ago, the FDA had the most organized process with the most straightforward milestones and what I'll call stability and understanding, the reason why we have more clinical trials and innovation. And that was really the case for about 15 years. And that's why most of the clinical trials and invention was going on here. About five years ago, that started to change. Now, most people go do clinical studies first in human trials and work like that. That's moving out to the European countries, Latin America and others not because they are lower costs necessary but because there is a more straightforward process to move through to get the clinical understanding done. That informs how you come back to the FDA then with a pivotal trial, design or something else although typically the FDA won't accept those. They need to be in the United States. So, it's just flip the reverse.

The USA used to be the gold standard and the place you'd start. And then, with that in hand you could go out to the rest of the world. Now, it's just the reverse. My fear is our regulators are trying to say to others, "Slow down. You're making us look bad." And it really can crush innovation. Safety is critical and important. You can't do without that. And if you're not doing it right, there need to be repercussions. But the innovators I know are passionate about curing diseases and improving patient life. And it's getting slower and tougher.

But it's right now easier outside the US than in. I'll try to move on. We're keeping track of time here. We've got a great market in here. I can give you all referrals for great orthodontists in the area if you're interested. But it's fun for me to talk about this business. We could do this for three or four more hours. You have a lot more to do. So, what I'd like to do is shift to this idea and then go into management-leadership ideas. We have been working very hard on evolving and scaling this business.

But we wouldn't have had the opportunity to do that if it wasn't for that crazy idea that most every venture capital-type up and down Sand Hill Road said no to. Kleiner-Perkins wound up funding it. But if they hadn't said, "Yes, we're willing to bet on this crazy idea," we never would have had the opportunity to evolve and create this great story and would have been one more idea never acted on. So, you're sitting here in the absolute cradle of entrepreneurship and innovation. I'd say go do something, go create that revolution in your own minds. Before you do that though, think about, even as you start, you can plan ahead to make sure that when you pioneer that space, when you create that opportunity, how are you going to figure out with your friends, your partners, your employees to be able to capture the opportunity that means. Or are you going to be the first blip that somebody else owns the space on? So, think not just about how you're going to create the revolution but how you're going to build a real business to capture that profit. And one organizing principle today, and I'm a fan of Clayton Christiansen, you see it in reality today. He says, "Be patient for growth. Don't be patient for profitability." That's a really interesting idea.

And that has flipped on its head from what we've talked about in 1997, '98, when funding was available. In fact, then it was, "Go for eyeballs, pour money on it and run hard and get your turf like the Great Land Rush back in the 1800." Today, I think you have the opportunity to say, "How do I create a real business? Is there a real business model here or is it just an idea that I have to pour cash into?" So, have the end in mind. Think about how you would scale this business and turn it into a real company. And sometimes it wouldn't be a real company. Maybe it's just an interesting product, all right? I'm going to shift gears. And I'm just going to put all this up here and talk through it. I mean, you can ask a few questions about it. I'll just call this hard-won experience. Every one of these that I speak about I've usually violated. So, if I just start with what I used to think about for strategic planning and the ideas, I used to think, "I will come up with a brilliant idea or the strategy."

And then, I will hire the right people to help me execute it." The answer is, it's just the opposite. Everything starts with having the right people around the table, having the right team. And along the way, that team has to evolve. The people you started with may not be the people you can go to the middle with and may not be the people you can scale with because they have different skills and temperaments. They may have different things in mind. But at any point ask yourself, "Are these the

right people with me? And by the way, have I changed? Am I working at the right place?" if you're in somebody else's company. But everything starts with the right team, whether it's a startup or it's an operating business or anything else. You can tell I don't like this stuff at all, right? I don't know how you go through your life without being alive and feeling passion and having a purpose. And so, part of this great thing about having a startup is, it weeds itself out. It's got to fit itself into your life.

It might disrupt your degree. Of course, your parents or whoever is paying for your college would really have some ideas and say, "You're doing what?" But the idea is, if you're passionate about it and you can't sleep because you have to do it and it's completely unreasonable, then it's going to sort itself out pretty quickly, whether you're really serious about it or not. And whether that's how you bring your passion to bear or something else, I'm just telling you life is short. If you're sleepwalking, fix it, change it. If you're in a company you're not passionate about, get out of there. Find another job. Find a place you can make a difference. Have some fun. Work with people you believe in. Look, it's not perfect.

You're always going to have bosses or people to work for you or co-workers that are jerks. And you can always find reasons to feel like a victim. But I'm telling you right now, if you're not feeling alive, even when you've got a lot of work to do at Stanford in a great engineering school and you got a homework to do tonight and labs, I'm just telling you, change it. Life is all about passion. When it comes to turning that personal passion into a company, you have to have a vision. And you have to have this compelling idea about what you're going to accomplish and how you're going to go about it so you can get people to opt in or opt out and they can say, "That isn't for me." They can't read your mind as a manager, as a founder. And they're not going to figure out how to do that. It's hard to mobilize an entire organization, whether it's 3 people or 3,000, without compelling vision, mission and passion. And it better be genuine, the thing on the card. What are you really about as a company? What matters to the people there? How many of you find yourself in life focusing on a journey? How many of us do that? Boy, it's really hard right now.

I loved the slug. You're dragging. You're fighting a cold. You've got a lot of work to do. You haven't got much money. I'm not feeling the love right now for the journey. The point is though, you're always looking ahead. If you can't find some energy out of the journey, no matter where you are in your life situation, whether you're in school or you're working, especially if you got a group of people around you that you love to be on a journey with, if that journey becomes as important, the good days and bad, as the destination, you're going to be successful. If you find that the only thing keeping you in there is focusing in the future, whether it's, "My stock options someday might be worth money," whether it's, "If I just do this for a couple of years, I'll get a better job," that is just the means. And so, the point is, find a way even in the hard times, not just work but in life, to say, "Am I doing what I want to be doing? How can I extract a little bit of joy from the journey even at the hardest times?" And that's a challenge and we all go through that.

But that's the thing that renews you in spirit. Now, we get down to the real stuff, this question earlier about financing. If you don't make money over some period of time, you cease to exist. There are amazingly great companies here in the Valley that three or four years ago had great futures. And they're getting crushed in financing. Those are the ones that are getting financed or they're going away. Now, the good news is, it's kind of Darwinian. The companies that are getting financed are the best in class companies but it's a hard thing. So, the point is, at some point with any company, you have to not to be a nonprofit anymore. You have to figure out a way to make money or you're going to cease to exist.

Even if you're a wealthy operating company just making a lot of money, you're only a few turns around the corner from disaster, a disruptive new entrant, a prophecy. You always have to be thinking about what happens if this happens? If growth slows, how will we adjust? Do we have plan A, B, C? So, it goes back to if you're not making money, you're not in control of your own life with the company, whether you're an entrepreneur. And if you can't see how you'll finance it, then you got to figure out how to bootstrap it yourself and make enough to at least cover your cost. Execution is most of the game. I have friends at McKinsey and other great consulting firms and their great strategy presentations. At the end of the day, that strategy realizes an execution. And an execution realized, whether it's three of you in a room and you've got a little company or whether it's 3000 people, everybody understanding what the play is, knowing what they're supposed to do and then making that happen again and again and again. Great companies sometimes don't make it not because they didn't have great ideas or a compelling strategy and vision, it's because they just couldn't execute and get it done. And if you can build that systematic capability in the company, by the way you hire and the systems you build to support that, then it doesn't seem like an everyday thing where you're propping it up. You'll know it's wrong and your execution is not working when if anybody takes their hand off it, it falls down.

So, what you want to think about is, how do you build a company where it just happens because you're doing the right things and you're doing it in concert. And so, you're going to get rewarded for finishing stuff in life, whether at school, whether it's your business, building something. And so, the strategy is really about the beginning often. The execution is about ensuring you can finish that. Makes sense? I know it sounds boring. I'm just an operating guy. What do I know? I'm not so boring as you think. Going too fast is far better than going too slow. And so, most of the mistakes, when you don't make a decision, guess what? What is that? That's making a decision, right, especially if it's hard or it's going to upset somebody or whatever? How

many times have you done something where you said, "Boy, I should have done that a long time ago"? Any of you have that experience? You know it. It just takes time.

So, in an organization, imagine that magnified by the number of employees you've got. And if you drop in that reflex delay for what everybody knows is the right thing to do, even if it's hard, you just burn time and that's the thing you can't get back. So, going too fast creates problems. But if you're good about it, you can undo those and adjust. But at least if you're headed in the right direction, going fast, making decisions quickly and then adjusting is usually a far better problem than going too slow and considering it forever. And that leads to the next one, which is procrastination is the mother of all ineptitude. You can always find a reason not to do it now. A boss of mine a long time ago who was really hard on me, you could tell him now I admire him, he used to make me do the thing I hated the most on my list of to-dos. I'd have a whole list of stuff I had to get done. And he'd say, "I got to see that by noon." I'd go, "Oh, I thought I could put that off until next week." And the point was, get after the hardest thing.

And you guys have learned this. You're all smart. You're in a great school. When you're freshest, you go after your hardest subject, your toughest lab. You get at it when you're fresh. And even if it's not what you want to do, there is something you have greater interest in, but you know you got to do that. You've learned by experience. So, the point is, if you put off this thing that's hard or it's ugly or it isn't defined, it's just going to get worse and it goes back to the point above that, right? Now, you're going slow. This idea about winning and momentum and confidence, it's you. When you start getting successful, somebody is going, "Wow, it went pretty well." You feel like you can take more risks.

You feel like you can move faster. You trust your instincts better. It's like that magnified in the company. Once a team starts to have success, it just further primes the pump. This idea of momentum and confidence and ability to take risk just gets magnified. And by the way, you can lose that and then it's a great question. Do we go back to being risk averse or do we continue to press advantage? And the answer is, all right, what do we learn from that. How do you fix that? What went wrong? What would we have done better? Have an after-action review and say, "Boy, that may have screwed up and it may be painful. But what do we take out of that? How do we reapply that quickly?" It doesn't mean everything else we did wasn't right. It just means we stubbed our toe on this one.

Now, go back and reapply that. And then, gaining confidence in yourself and your team to go along, that's a really big deal. When you haven't had that win, now you got to get a few wins on your belt and the organization takes off from there. So, here we are. Most of our competitors out there are huge companies and we're competing with divisions of theirs. They have vastly greater resources, huge organizations. They can put almost unlimited capabilities to work against us. Guess what? You saw the slide. We have enormous intellectual property in this area. And we keep inventing new things and extending our intellectual property and imagining how one of you brilliant people would come up with an idea now after I've given you this lousy little speech how you can get Align Technology as a competitor.

If you're paranoid, someone is behind you, right? You're only paranoid if there really is somebody behind you? I guess this is the definition from a psychologist friend of mine. The point is, you always stay humble and hungry and be paranoid that somebody could get at your business. And if you do that and you always imagine, whether it's a big company or a startup, what would they have to invent to turn us upside down. What would a big company have to do to upset our business model and do better than we can? What if somebody could satisfy the customer dramatically better with a better value proposition than we could? And so, you maintain that healthy paranoia and that helps keep you humble and hungry. Again, if you're goal is not only to innovate but to capture a lot of the advantage in the space, then it takes naturally. This last question about culture when we're talking over here, any leader, whether a manager of a small department or a group of three and you're the CEO, you cast a shadow. And those are good habits and personal styles as well as bad. And you usually have blind spots. So, have the presence of mind to understand that how you're being perceived is necessarily how you believe you're being perceived. And to recognize that there are great things about you and also there are things that aren't great about you that either rub other people or create challenges or some people don't understand you.

So, I would say be open to 360. Accept that's part of your opportunity for growth and recognize that any leader cast a shadow, good and bad. We're all humans. None of us are perfect. Any thoughts or questions about these? Yes? Is your IP council in-house or outsourcing? Why? The question is, is our IP council in-house or outsourced? The answer is in. We have a pretty significant IP staff for a company of our size. And we use a lot of external litigators. We've been in lots of IP tussles. We've never lost an IP battle about our IP. We have protected it and defended it and extended it very well.

But one of the things the company did very, very well, I give them enormous credit, they recognized how novel this was. And along with the financing sources, the VC said, "Let's invest real resources into writing quality disclosures and thinking how we'd practice this art and creating a very good patent. We have an amazing patent in state. So, that's important to us. We spend real resources on it. Most of that is inside. Other questions? I'm almost running to the end of your attention span and forbearance. We've talked about a couple of things when you were asking questions about health care and opportunity. I'm going to say that one of my concerns is this regulatory environment that is set up as a bill that shouldn't be, having to put them all

up here and we can just touch on them. Thank you.

So, we talked about this. There is a sea change going on from a policy perspective as we're trying to figure out the new health care system if it is yet a system indeed. And that means regulators and policymakers and others are all in motion. For a young company trying to get funding and for existing companies trying to bring new product and innovation, that's paralyzing. The problem is, on the bottom everybody is becoming more risk averse. And I was railing against a friend of mine who runs a lot of life science venture deals. He said, "We believe in some of these young companies. If we fund a big A round right now about something we really believe in, when it comes to the B round, we're going to get crushed anyway and our whole investment wiped out. So, we're just waiting for somebody else to do that. And then we'll do the B-round and crush them." Now, you know what? That means the company never gets off the ground because everybody is waiting for that.

The second thing is, nobody wants to take any risk. Everybody is pulling back. That's everybody in the system. At the end of the day, what this means is, I think we're going to have a very big problem. In the next five to seven years, we're going to have a bit of a gap in technology and innovation flow that's going to propagate through the system. My hope is, this all settles down, the rules get established and promulgated and we all adjust and we continue to move biotech and med tech forward. With that, I'll just basically say, to the question up here by the young lady, there are still incredible opportunities in life sciences, in med tech and biotech. And there is so much need. I saw a statistic that only 8% of the world's population even has basic access to a doctor, only 8%. So, imagine what's possible for us to think about helping the rest of population.

You got some big trends, urbanization, affluence increasing and disease states going from acute to chronic. Imagine the scale for the world over the next 50 years of what that translates to. These are enormous societal problems. There will be opportunities to make a huge impact in people's lives and to build great companies. And so with that, I'll stop. I think I'm out of time. And I thank you for your attention.