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A Spotlight on Disruptors and Innovators

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Guest: Dr. Amogha Tadimety is co-founder and CEO at Nanopath, in Cambridge, MA, whose novel nanosensing technology won the AACC 2022 Disruptive Technology Award.

Bob Barrett: This is a podcast from the journal *Clinical Chemistry*, a production of the American Association for Clinical Chemistry. I'm Bob Barrett. In all fields, new inventions periodically hit the market that dramatically change the status quo. Termed disruptive technologies, they're initially met with skepticism but eventually prove themselves to be a viable alternative to the "old" way of doing things and quickly become the new standard. Laboratory medicine is no exception, with several recent innovations ranging from laboratory automation to PCR to mass spectrometry that have dramatically changed clinical laboratory operations and our approach to diagnosing disease. Who invents these technologies and how do they come to market? What challenges do the inventors encounter along the way and how are they overcome? What will be the next technology to disrupt the field of laboratory medicine and what types of changes can we expect?

A Q&A session in the March 2023 issue of *Clinical Chemistry* explored new technologies that may prove to be the next big innovation in laboratory medicine. A company founder with extensive industry experience and life science consulting and venture capital describes the process of starting a new diagnostics company, shares lessons learned along the way, and describes the potential impact of her company's disruptive technology. In this podcast, we are pleased to be joined by one of the panelists in this Q&A session. Dr. Amogha Tadimety is co-founder and CEO of Nanopath, a molecular diagnostics company headquartered in Cambridge, Massachusetts, whose novel nanosensing technology won the AACC 2022 Disruptive Technology Award. So to start off, Dr. Tadimety, could you tell us the story of Nanopath's founding? What made two first time founders decide to take this leap?

Amogha Tadimety: Sure, yeah. So, my co-founder Alison Burklund and I had met at Dartmouth during our PhDs. We are both chemical engineers by training and we were drawn to the program there because it's extremely translational. So, rather than kind of a traditional academic PhD where you're wedded to your advisor's grants and you're focused on developing new theory, a lot of the emphasis in our program was focused on translating a company out of that work. So, we had access

to classes at the Tuck School of Business. We were on a fellowship that was separate from grants, with the real focus of spending the time during our PhDs developing something that could be translated out to patients.

And so, we both had a lot of ideas, but met and became friends and realized that we'd landed on a fundamentally new core technology that could enable a totally different paradigm of molecular diagnostics. So detection of RNAs and DNAs from patient samples. Rather than requiring the lengthy centralized lab workflows, our technology has the ability to directly detect DNAs and RNAs in patient samples without any sort of amplification, so that allows us pragmatically to be much faster than anything else that exists. So, we spun out the company at the end of our PhDs, right at the start of the pandemic actually, with the goal of bringing more advanced point-of-care technologies to patients, especially patients who are underserved by traditional workflows.

Since then, since our founding in early 2020, we've gone on to raise just over $11 million and just closed our series A last summer, but I think it was a core belief in the fundamental technology and a desire to translate it for patients that spurred us to spin out the company.

Bob Barrett: And how about Nanopath's technology and development timeline? What are some of the key activities the team is working through right now?

Amogha Tadimety: Sure. So yeah, right now, we are in kind of the feasibility stage. So, we have really strong pilot data in two different indications. So let me take a step back really quick. So I talked about how we have a novel molecular diagnostic test and we spent a lot of time trying to figure out where to apply this first and we saw just an immense amount of unmet need in the outpatient women's health space. So think about a patient presents to their either annual well woman exam or a primary care doctor and they know something's wrong but they don't know exactly what's causing their symptoms. So the world of urinary tract infections, STIs, HPV, bacterial vaginosis, and there aren't very many good tests right now in the outpatient setting. So the vision is to develop a test that can be operated in the 20-minute office window that allows the patient and provider to come to a treatment plan together.

So, we're in the feasibility stage now, as I mentioned. We are working through development of the platform for multiple different clinical indications. We are probably three to four years away from kicking off FDA studies. So we're doing panel development, we're doing clinical sample testing, assay optimization, product development. We are currently based in Cambridge, Mass with 10 full-time employees as of this

morning, and super excited to kind of take the technology forward.

Bob Barrett: And as a first-time founder, what are some key lessons you learned from the entrepreneurial journey?

Amogha Tadimety: Sure. Yeah. I think what's been the, like, so interesting about this journey is that diagnostics just as a fielder incredibly multifaceted, right? There is true fundamental engineering and science. There's biology, there's chemistry, there's a lot of commercial work that needs to be done quite early. There's regulatory. So I think it's been super exciting to learn about a whole bunch of different fields. I think it's really pointed to the importance of the team that we're building. I think our primary kind of task over the last six months was, how do we bring on people who are experts in their respective field, who are excited to take this pretty nascent technology and kind of build the product of their dreams. So key learning is just the importance of the team.

Another thing that we found is we're definitely taking a hard path. There's a lot of regulatory work. There's a lot of kind of different activities that need to time well together, but it's just been incredibly worthwhile to think about the impact that this may have on patients to build collaborations and to grow the company.

Bob Barrett: It certainly looks like innovative technology. How do you anticipate it being used? And does it have the potential to address clinical needs in rural and underserved areas?

Amogha Tadimety: Yeah. So the way that we're thinking about, kind of productizing this technology is in two components. So a disposable test cartridge that contains the sensor that we're talking about, coupled to a small piece of benchtop readout instrumentation. The idea is the reader will sit in the doctor's office. If the patient presents for symptoms, the medical assistant can do a single sample transfer step into the cartridge and run that on the reader. That's the vision. We want it to be really simple and really plug and play, and we realize that it will need to be CLIA-waved and FDA approved, but that's the path that we're taking.

One of the things that's most exciting is that we think this technology can have just a really substantial impact in settings that don't have access to centralized labs. Right? So the patient comes in. They only have that one kind of hour blocked for all of their questions that they have about their health. And is there a way we can give them a really comprehensive picture of what is going on so that they can make a plan their provider and then go about their day. So that's very exciting. We are thinking about, kind of diligently, about how we can develop a product that is useful across a

range of settings, across a range of different clinics. So we're always looking for partners who are in rural America, who are in global health settings. We're thinking about how to scale down the cost of both the disposable and the instrument, can we make a handheld instrument that you could use kind of four brigade style test and treat applications? So I think it's very top of mind to make sure we're developing something that is relevant across a range of settings. I think we will feel like we failed if the technology is the only working to serve patients who would have been fine otherwise. And there's also a range of applications we can go after. I've kind of been telling the story from the outpatient women's health world, but you can imagine acute hospital infections. You can imagine at-home monitoring over time. So, I think our dream is to try to apply and implement this technology in a range of different settings anywhere that you would want molecular information at the point of care.

Bob Barrett: Well, Dr. Tadimety, I'm curious about your experience with a AACC's Disruptive Technology Award competition. How has this propelled your company's growth?

Amogha Tadimety: Yeah, so that the competition was an incredibly fantastic opportunity. I think Alison gave just a really compelling presentation and it was really helpful and exciting to get that kind of validation from the scientific community, right? It's the largest kind of really well-respected group of laboratory medicine experts. And so, having, kind of feeling their excitement for our approach, for the quality of our data, building our network, has just been instrumental. In the time that we, since we've done the competition, we've grown the team from four to ten. We have a lot of really kind of budding new partnerships with people that we've met there. So, it's just been totally instrumental to our growth. And I think very, very helpful for broadening our network in this community.

Bob Barrett: That was Dr. Amogha Tadimety from Nanopath, winner of the AACC 2022 Disruptive Technology award. She and her team have developed the novel biosensing platform that has the potential to revolutionize molecular diagnostic testing. She participated in a Q&A session that was published in the March 2023 issue of *Clinical Chemistry* and she has been our guest for this podcast on that topic. I'm Bob Barrett. Thanks for listening.