Karen Jagoda: Welcome to the Empowered Patient Podcast.com Show. I'm Karen Jagoda, and my guest today is Venkat Nelabhotla. He's the president and CEO of Vyome, that’s V-Y-O-M-E-T-X.com, and I want to welcome you to the show today, Venkat. I appreciate you taking a few minutes to talk to us.

Venkat N.: Thank you. Thank you very much. I look forward to the conversation.

Karen Jagoda: Thank you. Let's just start with a brief synopsis of the mission of Vyome, and the kinds of therapies you are focused on, because it's a really interesting challenge you've taken on.

Venkat N.: Yes. We are very uniquely focused on dermatology, skin pathogens, in terms of the antimicrobial resistance that they have developed over a period of time. We're offering very unique platform technologies and therapies to address this big and a common problem in relation to skin infections. This is our overall mission, of course our lead asset, lead program, is about acne. Addressing the antibiotic-resistant acne, the disease.

Karen Jagoda: We hear a lot about the microbiome inside of our guts, but you all are looking at the skin microbiome, which I think is really a new area of interest and something that I don't think very many people even know about. Can you tell us a little bit about what the skin microbiome is composed of?

Venkat N.: Yes. Skin microbiome is composed of multiple bacteria. That includes gram-positives and very rarely you have some gram-negative. Gram-positive acne is a very common, commensal organism and that can get pathogenic when you have this disease, acne vulgaris. Then, you have your staph aureus-based infections that are caused by staph aureus which is, again, part of skin microbiome, that can become pathogenic in certain conditions, causing certain diseases.

Venkat N.: So within the skin microbiome, we try to understand why this otherwise commensal, harmless organism such as P. acnes, now they call it as C. acnes, become pathogenic. Then, understand the genomic behavior of these bacterial strains and develop products. So, that's how we actually went about, by fundamentally understanding this microbiome and microbes, and developing treatments.

Karen Jagoda: How has the knowledge about the skin microbiome changed the approach to skin conditions like acne? What's different now?

Venkat N.: I think the biggest difference that we’re looking at is understanding why an inflammatory acne where, the biggest cause of acne is colonization of this bacteria, becoming pathogenic and causing inflammation. So we tried to understand why, otherwise, this P. acne bacteria, which is commensal, become
very pathogenic. One of the things that we understood is the resistance pathways to the existing topical and oral antibiotics. We figured out the mutations, some of them are well-published, some of them we figured out, and then try to offer a new treatment.

Venkat N.: If you see, in this acne, this antibiotic resistance of P. acnes is advancing to roughly 10 million-odd patients, which is almost close to a New York City population. So, a lot went behind in understanding the resistance to clindamycin, which is an existing topical antibiotic, and to minocyclin, which is an existing oral antibiotic, in developing and offering a completely novel antibiotic that can address that problem.

Karen Jagoda: So the work that you're doing could help those who are currently resistant to available antibiotics, but could they also help people who are taking these antibiotics? Would it perhaps be more effective?

Venkat N.: Yes. It addresses what you just said, the first one, that it actually cures, kills, the bacteria that has become resistant to existing topical and oral antibiotics. Then, it also doesn't easily build resistance, given the mechanism of the drug and the selection of the drug that we have intentionally selected. We've done extensive work around the emergence of resistance and we've figured out it's very difficult to develop resistance for our product.

Karen Jagoda: That's pretty exciting. The world of acne, I think, is... there's a lot of myths and misunderstanding. Do you find that the patient's diet makes a big difference in how they react to certain drugs, or is it more of a genetic basis that would determine whether they're going to be resistant to current treatments?

Venkat N.: Essentially, the current treatments, most of them, actually, there are only a couple of antibiotics that are in use. They've become very old. One of the reasons why it has developed resistance is, since they have been in existence, there has been no innovation in offering completely new class of antibiotics. That's one of the reasons why the resistance developed. Second thing is the current topical antibiotic, as well an oral antibiotics, are bacteriostatic in nature, which means they don't effectively clear the bacteria, they only inhibit the growth of bacteria. Versus our product, which is a bactericidal, which means it effectively kills the bacteria.

Venkat N.: There's also a couple of reasons why the current, existing topical antibiotics have developed significant resistance. It's both in terms of time that they've existed for and also the kind of mechanism of action that's actually helped them to develop resistance.
Karen Jagoda: Are you looking at acne in teenagers or acne in people of different ages? How would you characterize the people who are most resistant to current therapies?

Venkat N.: Yeah, it’s largely the teenage, let’s say up to mid-20s, that is the big target population. That’s where it happens. There is some adult acne, but we’re largely focused on that teenage-to-mid-20s age group.

Karen Jagoda: So, this drug is VB-1953, is that the clinical trial name?

Venkat N.: Yeah. This is our program name, currently. It is in clinics now. We are in a large phase 2, dose-ranging study in the US.

Karen Jagoda: Are you able to find enough people to participate in your trials? It seems like this would be a pretty common problem, so is it a challenge to find people?

Venkat N.: No, not at all. I think with right CRO, the right sites in the US, we’re able to get these patients. The size of the study is 480 patients, and we’re demonstrating that study pretty smoothly at this stage, in terms of enrollment.

Karen Jagoda: What’s next for VB-1953? Is there another development that’s on the near horizon?

Venkat N.: Yeah, we’re actually looking at many other skin infections. We’re looking at a disease called gram-negative folliculitis, which is not as big as acne but this is a very significant, and a morbid, skin bacterial infection. We’re looking at every purposed drug out there, and the beauty is that you don’t have an approved drug, so there’s a big unmet need in offering a topical antibiotic. Perhaps looking at replacing the use of oral antibiotics, which is the current standard of care.

Karen Jagoda: VB-1953 is a topical antibiotic, and that means it can be used in small doses, just in places where it’s necessarily, rather than taking a pill, which might have more side effects? Is that one of the reasons for a topical?

Venkat N.: In the first place, VB-1953 itself is a topical gel, it is not an oral product. Just to clarify that bit. For acne, it has to be used religiously and rigorously over a three month time to have a comprehensive effect. So it’s not something that should be used less frequently or for less treatment time. It has to be used for three months, and that’s the standard of care.

Karen Jagoda: Got you. Tell me a little bit about your own background, in your past, to getting to this place with Vyome. Can you give us a little background?
Venkat N.: I come with the background of having an MBA degree and having grown small-to-medium-sized companies to billion-dollar valuation companies, both in biotech, pharma, and also in cosmeceutical products. I was a CEO of a listed company from India, which had global operations, where I scaled the scale to a couple of billion dollars value. I was also part of a big vaccine company, which got, eventually, sold to Sanofi.

Venkat N.: So, this phase started in 2010, I partnered with a Harvard scientist who's a brilliant strategist. We felt that, in dermatology and skin infections, the innovation has been very, very less, and we found a big niche area in terms of scientifically focusing on antimicrobial resistance. That's where we got all these breakthroughs.

Karen Jagoda: Was that also where the skin microbiome basic information is coming from, or has come from?

Venkat N.: Skin microbiome has been, particularly from a genomics point of view, has been sequenced, and that information is there, from a basic science point of view. But what we did is actually exploiting that information in understanding the pathways of resistance to current treatments and designing new drugs.

Karen Jagoda: Before we run out of time today, I just wanted to ask you a little bit about this skin microbiome question, and that is; if my skin has been affected by some bacteria, and your skin has been affected by the same bacteria, is our reaction to that bacteria going to be determined by our own genetic predisposition? Or is it a really complicated question of who's going to be more likely to develop acne, for example?

Venkat N.: Yeah, I think a combination of multiple things. More than genetic, I think it’s got something to do with the immunity of two different individuals, number one. Number two, in the case of acne, P. acnes bacteria attacks, particularly in teenage, because of excess sebum production. Which is, again, actually, a triggering point due to hormonal disturbances during the age of puberty.

Venkat N.: So, of course, yes. Let's say, if you see most of the adults do to have acne for the same reason. Their hormones are well stabilized, and you don't see and excessive sebum production under the skin. Sebum is nothing but an oily kind of stuff.

Venkat N.: So, yes, it is. How skin microbiome becomes pathogenic, some of this bacteria is actually linked to individual to individual.
Karen Jagoda: I have to assume, then, that also the environment, and the sort of lifestyle, how often they wash their hands or wash their face, is that also part of the story here, of how this develops?

Venkat N.: No, it's not specifically part of the story, but it has linkage to that. I think the real story is understanding these bacteria, these microbes, their genetic sequencing and the resistance pathways to existing treatments.

Karen Jagoda: Are you optimistic? Are we at the beginning of a new understanding of the skin and the way it reacts to the outside world as well as to what's going on inside our bodies?

Venkat N.: Yes, of course.

Karen Jagoda: What's the thing that's most exciting for Vyome in the pipeline, that you see? Maybe not in the near term, but in the longer term, is there some goal that you all are striving towards?

Venkat N.: Yeah. Essentially, we want to realize this vision of somebody who are experts, scientifically, in understanding the skin microbiome and the antimicrobial resistance, and have a few drugs approved in US and being commercialized, and become a respected specialty pharma company.

Karen Jagoda: Thanks to my guest today, Venkat Nelabhotla, president and CEO of Vyome. That's V-Y-O-M-E-T-X.com. Follow them on Twitter @VyomeTx.

Karen Jagoda: I'm Karen Jagoda, and you've been listening to the Empowered Patient Podcast.com Show. Follow me on Twitter at @KarenJagoda. Like us on Facebook at Empowered Patient Radio.

Karen Jagoda: Thanks for listening, and we'll see you next time.