Punit Patel – President and CEO, Zydus Americas

Our next phase of evolution is moving from pure-play generics to something more complex across branded products, biosimilars, and NCEs

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Punit Patel, President and CEO, of Zydus Americas, speaks about leading the company's pivot from a pure-play generics business into complex generics, biosimilars and new chemical entities. Anchored by its partnership with Formycon to launch a biosimilar to pembrolizumab, Patel goes on to outline Zydus' broader business ambitions, expanding into oncology, rare disease, and even local manufacturing. As Vice Chairman of the Association for Accessible Medicines, he also shares his perspective on the policy hurdles facing generics and biosimilars in the US. From tariff exposure to PBM reimbursement practices, Patel offers his perspective into what durable, long-term growth looks like for Zydus, and the non-branded segment, in the American market.

Your career spans pharmacy practice, big pharma, and procurement with eight years as President of Red Oak Sourcing. What is the red thread that connects those experiences, and what made Zydus the right next chapter?

I started my journey as a cashier at CVS many years ago. Eventually I became a pharmacy intern and then a pharmacist. I take a lot of pride in the fact that I was a retail pharmacist. I got my PharmD from Massachusetts College of Pharmacy in Boston, worked in retail pharmacy for many years, and then moved to CVS Corporate. That's where I'd say I cut my teeth in the corporate world, understanding how large pharmaceutical and pharmacy organizations work.

Throughout my career, I've been purposeful about understanding the full supply chain of the healthcare ecosystem. And I've always looked at any opportunity, business-related or otherwise, with the patient in mind. I spent years being 2 feet from the patient as a pharmacist, and I believe that if you do what's best for the patient, the rest will work itself out.

Regardless of the role I was in, I've always wanted to understand how drug discovery and manufacturing actually works. What brought me to Zydus was that I knew the promoters of Zydus Lifesciences Limited for about 15 years and I respect their philosophy and approach to the healthcare business. The leaders have a strong educational background in science, and the founders are scientists and pharmacists. For example, Sharvil Patel, our managing director, holds a PhD and MD. One of the things I've always admired about Sharvil and Pankaj Patel, our chairman, is that every decision comes down to what the science says and what's good for the patient. That's the foundation they've built a global pharmaceutical company on, and that's what brought me here.

How would you characterize Zydus's position in the US market today, and what does the next phase of the strategy look like?

Zydus is focused on discovery and development. As a science-based company, we are entering our eighth decade in this space globally, however Zydus USA has only been around for about 21 years after we commercialized our first product here in 2005. Even though we're 75-plus years old globally, the US business is still fairly young. We're moving from infancy and getting into the next phase of the business.

Zydus USA is a predominantly a generics-based company, focused on small molecule manufacturing and drug discovery, and we've done relatively well in that space. Today we're the fourth or fifth largest generic company in the country by volume and value according to IQVIA. Getting to that top position in the country has built a solid reputation with our customers and partners who know us as good people running an established business. We take pride in our supply resilience in the US, which has been a major topic of conversation over the last six years since COVID.

One of the reasons I joined was to help pivot the organization over the next five years. Our next phase of evolution is moving from pure-play generics to something more complex across branded products, biosimilars, and New Chemical Entities (NCEs). We have recently gotten into the 505(b)(2) space and we are working with our partner, Formycon AG, who we are planning to launch

a number of products. This includes a biosimilar to Keytruda (pembrolizumab) which we are very excited about. Our first NCE product, if approved, is targeted to launch in 2027 by Zydus Therapeutics.

As we evolve our business, the question is how do we build a sustainable, durable, long-term healthcare company? We're doing that at a pretty rapid pace right now and it's an exciting growth opportunity for Zydus.

Can you walk us through the Formycon partnership to develop a pembrolizumab biosimilar? What drove the decision to enter both the biosimilar and specialty space with such a key therapy?

Our relationship with Formycon is a deep one and pembrolizumab will be a pivotal product for us. We've made a bit of a splash by partnering together to launch what will be one of the largest biosimilars in the country, if not the world. Pembrolizumab is one of the best-selling biologics in the marketplace which says a lot about its importance to patient care.

Our promoters have always been purposeful about which businesses we get into, and they have high conviction in oncology. Through a patient lens, strategic therapeutic areas like oncology will make such a real difference in patients' lives, and that's what we want to be part of today. Alongside pembrolizumab, we're adding a number of bolt-on assets around it. Our partnership with Formycon; this isn't just a one-product deal. We are taking a multi-pronged approach to build a sustainable platform in the oncology space.

When it comes to this kind of transformation, I think a real advantage for Zydus is that we don't play the quarter-to-quarter game of worrying about what's next. We're thinking about a long-term trajectory that will make us a successful company delivering life-changing products for our patients. That's a significant differentiator compared to some other companies. Taking a long-term view helps you make the right bet that will pay off as they mature.

Moving into the specialty space, where can Zydus USA transfer its existing commercial expertise from generics, and where will you need to build new capabilities to compete?

Zydus has a deep internal research driven pipeline of products. For instance, we're looking to build a full pipeline and platform in oncology, from manufacturing through to commercialization. Over

the last 24 months, we've moved from our portfolio being close to 95 percent pure-play generics into the oncology space through 505(b)(2) products. Our acquisition of the Agenus manufacturing facilities in California in mid-2025 [now known as Zylidac Bio] was very strategic in getting us into the colorectal cancer space with a product we're bullish about and that we hope will make a real difference for patients.

When it comes to succeeding in this venture, the first thing to note is that we already have a baseline knowledge of various therapeutic areas. Even though we're a newer player in the US oncology market, this area isn't new to us. Zydus has nearly 75 years of legacy in India and is the leading oncology player in the market. Zydus also holds the largest biosimilars portfolio among the peer group. That expertise in biologics, biosimilars, and immune therapy already exists within the company. What we're focused on now is transferring it into the US. We're moving into these modalities locally, and we're building on a strong, institutional knowledge base already in place.

The second is making sure we recruit and retain the right talent. For me, it always comes down to people and patients. Having a team with real experience in oncology and the US specialty market is critical if you want to accelerate your knowledge and thinking quickly. I believe we have an industry-leading team across these therapeutic areas.

Between the Zylidac acquisition, the business development deals we're doing with our strong partners and making sure we have the right commercial team in place, we are building access to important medicines so that the patients can benefit from them.

From your perspective, how much education and reputation building needs to happen to achieve a strong position for biosimilars in the US environment?

I sit on the Board of Directors of the Association for Accessible Medicines (AAM) as Vice Chairman, and we talk about this a lot. If we look at biosimilars globally, we know that the science behind these products is validated because the rest of the world already uses biosimilars actively today and the US has been steadily catching up on biosimilar approvals and patient use. A separate interchangeability designation after approval is a uniquely American construct. Therefore, with the right policy and regulatory pathway, I believe we can get to a point where biosimilars become more accessible in the US.

Last week, U.S. policymakers took an important step by passing legislation establishing an expedited pathway that removes the routine expectation for comparative Phase III clinical efficacy

studies for many biosimilars. This reflects a growing global scientific consensus that these large, expensive trials rarely provide meaningful additional evidence once a biosimilar has already demonstrated a high degree of analytical similarity. This change doesn't reduce FDA's approval standards, what it does is modernize the evidence package by focusing on the tests that are most scientifically sensitive for detecting clinically meaningful differences. Comparative Phase III studies alone can add approximately USD 50-60 million to development costs and several years to development timelines, while contributing little additional information in most cases. Even with these reforms, developing a biosimilar remains a significant investment, typically exceeding USD 100 million.

Catching up with international markets is going to take many parties working together across the value chain. Manufacturers bringing products to market, policymakers and regulators getting the right systems in place, and our customers, from specialty distributors to retail pharmacies, partnering to make sure we're bringing more access to medicines for patients. While we still have a lot of work to do, I'm genuinely optimistic about the industry's biosimilar path in the US over the next five to ten years.

After passing Section 232 earlier this year, which exempted generics and biosimilars from tariffs, President Trump announced that a 100 percent tariff could apply to these products from 2027. What implications would that have for the space?

I'm cautiously optimistic about this as well. When tariffs were first announced in 2025, it was a bit of a shock, but it also gave us the opportunity to educate. Through AAM and other industry platforms, we were able to get in front of the administration and talk about the intricacies of generics.

About 50 percent of US generics come from India, and the companies associated with generics work on very thin margins which don't come close to big brand pharma margins. Imposing a tariff of any percentage would be a direct hit to the bottom line. It's just not sustainable. So when you think through tariffs and the regulation the administration has proposed, it gave the generic industry the chance to make our case. We're different from branded pharma. We provide savings and access to taxpayers and patients in this country, and taxing us creates consequences nobody wants, including drug shortages.

In 2012, the generics market was about USD 75 billion, and it's still about US 75 billion today. The market hasn't grown at all. One might ask why any company would want to stay in a market that

isn’t growing. For Zydus, this is a purpose-driven business. We also want to build a sustainable, long-term market with real growth where we can reinvest in the business and bring new medicine to patients.

When you think through tariffs or any economic headwind like this, you have to assess the real purpose of the business in this market. It’s a complex, fragmented space with more than 200 suppliers and only a few buyers. It’s been deflationary for years, and we need to figure out how we change that going forward. I know that Zydus and our customers take pride in what we do and remain committed to supplying American patients with the medications they need; that is a common priority.

What is the strategic importance of the Agenus facility acquisition, and what does it signal about the company’s long-term commitment to manufacturing in the US?

In the case of biologics, the investment in Zylidac gives us a foothold to bring our large biosimilars portfolio from India, manufacture the products domestically, and make them readily available to American patients. Economically, this decision makes sense because these are value-driven products that can bear the cost of local manufacturing, even with higher costs of goods and labor in the US.

As I said before, small molecule generics are a different story. Bringing generic manufacturing to the US is a tough bet. Production costs are far higher here than elsewhere in the world, and the demand signal from the market aren’t here to support that kind of investment. It’s simply not sustainable. Neither Medicare nor commercial payers want to pay more for generics, so it’s hard to justify manufacturing these products domestically when costs run close to ten times higher while pricing stays the same.

We’re committed to bringing manufacturing into the US. and Zylidac Bio gives us more conviction to continue building US-made manufacturing in biosimilars and other complex therapeutic areas.

What changes would you like to see happen in the ecosystem to better support the generic and biosimilars space overall?

If you look at this market a decade ago, when a branded product lost its patent and a generic came to market, you’d typically see 90 percent conversion to generics within 90 to 120 days which

quickly gave patients access to lower-cost options. Fast forward to today, we have examples of branded products losing patent protection and generics only being able to capture 50 percent of the market with the rest remaining branded. There’s no real conversion anymore, and the reasons come down to patent gaming, pharmacy benefit managers (PBMs) not covering generics, and economic headwinds driven by a consolidated marketplace. We have to ask what that means for patients and for savings to the health system overall.

To get back to how conversion worked ten years ago, I believe the solution should be that any generic available in the marketplace should be covered under tier one by every PBM. Right now, brand companies may provide rebates to PBMs even when a generic is available, and if this rebate is not passed through to the patient, it may discourage the filling of the prescription . Patient premiums have risen over the last several years, more patients are on high-deductible plans and paying up to USD 2,000 before a patient utilizes their deductible, and cash-pay costs keep climbing while access keeps shrinking.

When you think through the full continuum of healthcare, this is one of the key challenges we should be actively fixing. As a sector, we are working on it through AAM and other platforms, but the principle is simple. If a generic is available, it should be covered for patients, on both the commercial and Medicare side. Right now, that’s not the case.

From a biosimilars perspective, there are still many different hurdles we need to overcome in this space. We’re moving in the right direction with the new bill removing the Phase 3 trial requirement, but there’s more challenges to address. For example, interchangeability with the branded biologic, determining whether the FDA’s approval pathway should be accelerated, and evaluating where the demand signals are within our customer base are still points of tension that we need to be mindful of. Lowering the clinical trial barrier was just the first step. Interchangeability, pricing, and reimbursement are all still on the docket, and all of these pieces need to be addressed in parallel.

Every business has headwinds, but I remain optimistic. Whether it is about the regulators , pharma manufacturers here in the US or in India and Europe, or our customer base, we all have one thing in common; we all work to serve the patient. If we all keep in mind what’s best for patients, I’m confident this will move in the right direction.

Beyond biosimilars and oncology, what other development ventures are on the horizon for Zydus?

There are a few other businesses I'll touch on that are important to our growth. The first is Sentynl Therapeutics, which we acquired in 2017. Sentynl is focused providing access to medications for patients with rare and orphan diseases where prevalence is very low. I'm proud to say Sentynl now has three commercial products in that space with an industry-leading team running the business. Sentynl is a major growth lever for us, and I see real potential to expand our US rare business significantly.

The other piece that sets us apart in the generics industry is Zydus Therapeutics, our branded NCE arm. We recently submitted our new drug application to the FDA for our first, entirely self-funded, investigational molecule in the primary biliary cholangitis (PBC) space and are hoping for potential approval and launch sometime in 2027. We are very excited as we've invested significantly in our internal capabilities to develop and bring this asset to market without external investors.

PBC sits in the orphan therapeutic category, which further shows our ambitions in the rare disease space where the patient need is extremely high. Like Sentynl, Zydus Therapeutics and saroglitazar will be another major growth engine for us in the US.

We also have a companion animal health business called ZyVet Animal Health. It's a purposeful business for us and we even have our own R&D center in India where we run clinical trials with companion pets instead of working through a third party. 2025 was our first commercial year for ZyVet, so we're just getting up and running. While it's a small business today, we have high aspirations for this space as well.

Looking ahead, what are your top priorities for the next three to five years, and what does the long-term vision of success for Zydus in the US look like?

Over the next three to five years, I want to see Zydus continue its development as an innovation-led, sustainable lifesciences company that's rooted in science and discovery. This way we can keep bringing critical, life-saving medications to our patients.

We've already started that pivot and will keep investing in it. Today, we have generics, biosimilars, 505(b)(2) products, an animal health business, a rare disease business, and a soon-to-be NCE business. Having a healthy balance across these strategic areas signals that we're here to stay for the long run while protecting us from the external pressures we can't control.

Beyond that strategy, what will make us successful is having the right people in place doing the right work. Our chairman coined the internal saying, "we build people, and people build the

business," which is something I've taken on in my day-to-day. At Zydus we are all big on team and people. This starts by making sure everyone thinks about anything we do through the lens of the patient. If we keep the patient in mind, our businesses will be successful. I can say that's held true.

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