

## Amneal Pharmaceuticals LLC



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PATERSON, N.J. — Privately owned and operated since 2002, Amneal Pharmaceuticals LLC is a growth-oriented company dedicated to developing, manufacturing and distributing superior quality generic pharmacy products while ensuring exceptional service levels.

"From the inception of Amneal five years ago we have been committed to outstanding quality and unwavering integrity in all our operations and actions, beginning with creating a team of R&D experts with vast experience at the biggest name pharma companies, both branded and generic," states Jim Luce, Amneal's executive vice president, sales and marketing.

"In July 2005 with an infusion of capital from a private investment group we dramatically expanded our R&D efforts and laid the groundwork to launch our own label."

With outstanding R&D and manufacturing in place, Amneal only needed a sales and distribution component to enable their brand launch.

One of its partners, Akyma Pharmaceuticals, had an established market presence, an existing and experienced sales team, and a high-tech, state-of-the-art distribution and warehouse system to rival the largest pharma companies, yet needed a pipeline of products.

Amneal acquired Akyma to complete the supply chain and provide instant sales and distribution capabilities. "To further build on our strong foundation of superb R&D, we are now developing several complex, challenging and niche products to significantly expand our pipeline," says Chintu Patel, Amneal's chief executive officer. "We are currently building a 48,000-square-foot R&D center in India that will give us the ability to submit 20 to 30 ANDAs per year and expand our dosage forms beyond oral solids. Our total campus is 25 acres, which will allow us to ex-

pand aggressively as we grow our business."

Patel notes that vertical, preferred API partnerships and relationships are critical to ensuring superior service levels and competitive pricing while maintaining fair margins to grow the business and that the company has a superb and open relationship with the FDA and outstanding cGMP/FDA evaluations.

Amneal was one of the first companies to file ANDAs via the FDA's evolutionary cCTD/QBR/QOS process and was the first company to secure FDA approval using the Bin-to-Hopper manufacturing process.

Amneal currently has nine approved ANDAs plus five more to come by year-end 2007, 12 projected in 2008 and more than 20 annually after that.

"The value of a generics company is really about the portfolio," claims Luce. "Early on we focused on easier products such as immediate release that weren't too complex. The past few years our drive has been on controlled release, extended release, niche API and very challenging formulas, and our approval success rate has been 100% so far."

Amneal recently signed a joint venture to develop 10 products in the ophthalmic category that will be to market between late 2008 and 2013 based on patent expiration dates and FDA approval.

Its partner, Indoco Remedies, was the first India-based ophthalmic plant to receive U.S. FDA approval.

Indoco's role in the partnership is to complete the R&D and manufacturing of these products, while Amneal's is to compile all data, complete and file the ANDAs with the U.S. FDA and maintain the regulatory approvals as well as market, sell and distribute these products to the U.S. market, notes Luce.

"Amneal has and always will be focused on manufacturing innovation

while maintaining a very aggressive yet strategic growth plan," states Patel. "We are proactively pursuing tech transfers, ANDA acquisitions, site transfers and joint ventures to expand our pipeline and portfolio."

In the hyper-competitive market of generic pharmaceuticals, Amneal is committed to building deep relationships with its customers.

"We ask our customers 'What's keeping you up at night?', and the answers we get are quite diverse yet insightful," adds Luce. "At that point, it is our job to seek to understand what value we can provide — in addition to high-quality products, competitively priced with outstanding service levels — that will help generate solutions to their challenges. The goal is to bring value and knowledge to our customers with every interaction."

In addition, Amneal believes the best way to build a strong business is not just through sales relationships but through building organizational relationships. "We need our finance person talking with our customer's finance person, our distribution warehouse manager communicating with our customer's distribution center's management, etc., to find any opportunity to make the process and product flow more effectively and efficiently," points out Luce.

With multiple levels of contacts all focused on supply chain excellence and efficiency, if there are any questions or concerns along the way, everyone will focus on addressing it for the benefit of value creation for both companies, he notes.

"Amneal is clearly positioned to cause its own success, have market significance and achieve its aggressive growth pattern and expectations while bringing a unique, highly professional, customer-focused approach to the industry," adds Luce. "Our marketing tag line says it all: Generic's New Generation."