

## Amneal Pharmaceuticals LLC

HAUPPAUGE, N.Y. — Referred to in some circles as “Generic’s New Generation,” Amneal Pharmaceuticals, LLC develops, manufactures and distributes prescription and over-the-counter generic pharmaceuticals regulated and approved by the Food and Drug Administration.

Only eight years after its inception, Amneal is on track to become a top-five U.S. generic drug maker.

The company, which is headquartered here and employs almost 900 people in its operations worldwide, has fueled its fast-paced growth by diversifying its portfolio with sophisticated products to serve a broad range of customers, according to executives. Ongoing expansion of research and development and manufacturing resources has generated a robust product pipeline.

Amneal now ranks as the ninth-largest U.S. generics manufacturer in number of prescriptions dispensed, according to June 2010 IMS Health data, moving up from 12th position in just one year.

Amneal executives say several factors account for the company’s exceptional growth: expedited abbreviated new drug application (ANDA) approvals, a relentless drive for both product and operational quality, reliability of supply, award-winning customer service, solid partnerships throughout the delivery chain, deep industry knowledge, and flexibility in meeting customer and supplier needs.

Product diversification is a cornerstone of Amneal’s aggressive expansion strategy. The firm is proactively focusing on such high-growth areas as acute care and integrated delivery networks (IDNs).

To maximize its opportunity within acute care, Amneal is building expertise in the injectables market, developing unit-dose packaging and creating other targeted offerings. The company is pursuing strategic acquisitions of products, facilities and intellectual property, and it is forming partnerships to enter new markets.

Amneal is also hiring top talent for executive leadership roles. Shankar Hariharan, a veteran of both the branded and generics pharmaceutical sectors, joined the organization in May as chief scientific officer and executive vice president of specialty pharmaceuticals.

“Our strategic plan emphasizes not just aggressive growth, but smart growth,” notes Jim Luce, executive vice president of sales and marketing. “Amneal is fiscally responsible in conducting its operations with a goal of delivering outstanding customer value while maintaining profitability.”

The company’s catalog features 250 products in 32 product families across 20 therapeutic categories.

Plans are to introduce 16 offerings this year, including several Paragraph IV and 505(b)2 filings. Amneal’s goal is diversity of dosage form, product size, therapeutic category, volume and complexity, ensuring the supplier a strong, balanced performance in the marketplace.

Current therapeutic categories addressed include cardiovascular, anxi-

ety, seizures, central nervous system, gastroenterology, endocrinology, rheumatology, respiratory, hematology, ophthalmology, dermatology, allergies and pain management.

Under its own label since 2007, the generics maker’s highly developed product mix now includes oral solids as tablets, capsules and soft gels in immediate and modified-release forms; liquid suspensions and solutions; controlled substances; and hormonal and high-potency pharmaceuticals.

Products launched in the past nine months include Nizatidine oral solution, Amneal’s first exclusive or first-to-file generic; Tramadol/APAP tablets and Lorazepam oral concentrate, both controlled substances; Spironolactone HCl tablets; and Benzonatate soft gel capsules. Nasal sprays, topicals, injectables and biosimilars are planned for the near future.

Obtaining ANDA approvals quickly from the FDA is critical to converting a robust pipeline into commercially successful products, the executives note. To date, Amneal has received 47 approved ANDAs in multiple dosage forms, with a target of 30-plus filings annually.

One of the company’s core passions is building superior customer relationships that maximize value for both organizations through direct, open and objective interaction; customer innovation; and service excellence.

Amneal develops an in-depth understanding of the needs of both its customer — the pharmacy buyer, pharmacist, wholesaler or distributor — and the customer’s customer — patients of chain or independent pharmacies served by wholesalers and distributors — and collaborates across the supply chain to simplify operations, reduce costs and increase profits.

Executives say that Amneal’s dedication to customer service has paid off immensely.

In the past 18 months the company won five major awards — the DIANA (Distribution Industry Award for Notable Achievements in Healthcare) from the Healthcare Distribution Management Association in June, plus top generics supplier honors from McKesson Corp. in May, Smith Drug in April, AmerisourceBergen last year and Cardinal Health in 2008 and 2009.

The wholesaler/distributor industry awards recognize excellence across the generics maker’s organization — quality, supply, pricing, account management, customer service, leadership, innovation and collaboration — which Amneal executives say is their core focus in managing accounts.

More important than the actual awards, they note, is customer affirmation of the company’s guiding principles and business strategy.

Amneal manufactures all of its generic drugs in the United States. Four current good manufacturing practice-compliant, state-of-the-art plants in Hauppauge and Brookhaven, N.Y., and Branchburg and Paterson, N.J., can produce 16 billion oral solid and 10 million liquid units annually.

In addition, the company is evalu-

ating several facilities for acquisition and increasing capacity at current sites. Amneal also maintains a research and development center in Ahmadabad, Gujarat, India.

Boosting production volume and streamlining distribution ensures customers of a reliable product supply and fast response, according to Amneal executives.

In May the firm announced a significant expansion of its Glasgow, Ky., distribution and sales operations, tripling the size of the warehouse and more than doubling head count.

Executives say the huge opportunity before Amneal and the industry is to validate the real benefits of pharmaceutical treatment in improving outcomes and reducing the need for other procedures, thus significantly reducing total health care costs.

In addition, the generic pharmaceutical segment of the industry has become even more critical to controlling health care expenditures, as it provides the most cost-effective solution for pharmaceutical treatments.

Looking at the near term, Amneal executives note that generic drugs are a fairly recession-proof product even in the current troubled economy. They represent affordable treatment options for consumers who are trying to reduce expenses and yet require medications to maintain or improve their health.

With ongoing advances in quality, greater choice of dosage forms and efficient large-scale manufacturing in an industry with consistently expanding demand, Amneal is very well positioned to increase both mind-share and market share in the generic pharmaceutical industry through 2010 and beyond, they assert.

Amneal has worked tenaciously to develop strong, open relationships with stakeholders in the chain drug industry, the executives say, and clearly understands the need to consistently provide the key deliverables required together with exceptional value beyond what is expected. The professional, high-integrity, yet comfortable approach to account relationships has built strong trust and confidence with chain drug customers, they add.



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