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# Amneal Aims To Bolster Generics Margins

*As Company Aims To Deliver Six To Seven High-Value Products Annually*

by **Akriti Seth**

Amneal says it is taking initiatives to improve its generics margins by improving its manufacturing and supply chain, after its generics segment sales dropped by 11% in the first quarter. Amneal is aiming to deliver six to seven high-value products annually, while the company is also looking to launch three biosimilars in the next couple of years.

Amneal has announced taking several steps to improve its manufacturing and supply chain as part of efforts to boost its generics profit margins. While the company manufactures most of its generics in-house, it has transferred several products from external manufacturing partners to its facilities, “to reduce cost and improve supply chain.”

Talking about the key initiatives taken across the company to improve efficiencies, Chintu Patel, co-CEO of Amneal, said “many of these types of initiatives will help improve our gross margins in a sustainable way.”

Commenting on the company’s new goals of “optimizing global operations, reducing excess overheads and cost, improving margins in generics and increasing profitability,” Chirag Patel, president, co-CEO of Amneal, said “we are executing well towards these goals as generics gross margin in the first quarter grew to 45%.”

Talking about the company’s overall growth trajectory, Anastasios Konidaris, chief financial officer of Amneal, said this “reflects our strategy and solid execution in transitioning to more complex generics as well as the efforts of our team to drive supply chain efficiencies and favorable pricing on certain manufacturing materials.”

However, Amneal’s generics segment saw a drop of 11% in its net revenue to \$313m for the first quarter of 2021. Commenting on the decline, Konidaris said, “this decline was not surprising and was primarily driven by an almost non-existent flu and cold season, which adversely impacted

products like generic Tamiflu (oseltamivir), as well as higher purchases last year at the onset of the COVID-19 pandemic.”

From new products launched since January 2020, the company reported revenue of over \$36m, offsetting price deflation as well as the lingering negative impact of the pandemic. Amneal attributed the revenue to the performance of epinephrine, azathioprine, levothyroxine and sucralfate. Amneal’s recently launched Zafemy (norelgestromin and ethinyl estradiol transdermal system) also performed well. (Also see "[Amneal Ready To Go Head-To-Head With Mylan’s Xulane In US](#)" - Generics Bulletin, 1 Mar, 2021.)

Chirag Patel said, “I am extremely pleased with our first quarter results and how the full year is shaping up” as the company reported an adjusted gross margin of 44.6% for generics, 250 basis points higher than Q1 2020 and 630 basis points ahead of full year 2020.

“Of the 80 generics approved with Competitive Generic Therapy designation industry-wide, Amneal has launched 10, by far the highest number in our industry,” stated Chintu Patel. “Over 80% of our pipeline is non-oral, solid products and an increasing share of that is drug-device combinations.”

Furthermore, calling R&D “the growth engine for the industry,” Chirag Patel said, “While our base business faces competition, our R&D team is constantly moving us up the value chain with high barrier to entry products that have longer tails of revenues and profits.”

## **Company Aims To Deliver Six To Seven High-Value Products Annually**

Chintu Patel said, “We believe that we are at an exciting time for ‘Amneal 2.0’ as we begin to see the benefits of the transition of our development activities towards complex dosage forms, drug-device combinations and other high-value programs.” (Also see "[Patels Working To Build ‘Amneal 2.0’](#)" - Generics Bulletin, 10 Mar, 2020.)

Looking forward, Amneal said that it aims to continue refreshing its pipeline and deliver at least six to seven high-value products on an annual basis.

“We are actively looking to expand our high-value complex generic portfolio into select international markets via external partners,” added Chintu Patel.

Amneal’s existing partnership with Fosun Pharmaceuticals has already yielded four product filings in China. (Also see "[Amneal’s Generics Business Reinvigorated By New Launches](#)" - Generics Bulletin, 4 Mar, 2021.) Amneal said that it is expecting to file another five by the end of the year.

Furthermore, Amneal revealed that it had gained several near-term new drug application programs across neurology and endocrinology. The company expects to begin to launch as early as 2023.

“Looking ahead,” Konidaris said, “we expect a step-change increase in generic net revenue due to continued new product growth, strong commercial execution, and the fact that the seasonal nature of the flu and high purchases last year due to the pandemic are behind us.”

“In generics, we have established a well-oiled engine to replenish our development portfolio and drive increasingly complex product launches,” said Chirag Patel. “Amneal continues to invest in product development in both generics and specialty.”

Amneal sees durability in both complex generics and biosimilars. “The complex generics may be shorter, biosimilars will be longer,” said Chirag Patel.

### **Company Expects To Launch Three Biosimilars In Next Couple Of Years**

After filing for three biosimilar products – bevacizumab, filgrastim and pegfilgrastim – Amneal said that it expects to launch the biosimilars over the next couple of years, with filgrastim anticipated this year, pegfilgrastim in 2022 and bevacizumab in 2023. “Beyond that,” said Chintu Patel, “we are actively evaluating additional opportunities via partnership models where we can be first or second to market.”

“Just like in small molecule 505(b)(2), biosimilars may end up into biobetters or follow-on branded biologics, which could be brought earlier in the market,” said Chirag Patel. “So, we’ve been very diligently working over last couple of years to identify great partners.”

Talking about “the cost-effective partnership model,” Chirag Patel said, “we waited, and we wanted to see how it develops because we did not want to spend or invest \$150m or \$200m per biologic.”

Furthermore, Amneal plans to aim for a few more oncology assets and autoimmune assets, on the eye side as well, to establish a long-term biosimilar or follow-on biologics platform. Chirag Patel added, “it takes time to really launch the biosimilars unlike Europe. There is excess capacity in manufacturing sitting out there, especially in Europe and South Korea and China. So, we are tapping on to those.”

“Biosimilars will be an increasingly meaningful component of our pipeline going forward Chintu Patel added, “we believe biosimilars will be a key strategic opportunity for us over the next five to ten years.”

### **Company Sees 9% Growth In Specialty Segment**

Amneal’s specialty segment, that centers around neurology and endocrinology, saw a 9% jump in revenues to \$96m in the current quarter.

“In specialty, we are acutely focused on executing the development plans for IPX203 and Kashiv

specialty pharmaceuticals programs we acquired earlier this year,” stated Chirag Patel. (Also see [\*"Amneal Takes Control Of Kashiv Specialty In \\$100m+ Deal"\*](#) - Generics Bulletin, 12 Jan, 2021.)

Chintu Patel pointed out that IPX203, the next-generation product for Parkinson's disease, is the company's most advanced of its four specialty pipeline programs and is currently in Phase III clinical trials with an estimated launch in 2023.

Talking about the pipeline, Amneal said, “we have K127 for myasthenia gravis; K128, a modified trihexyphenidyl for the treatment of sialorrhea; and K114, a modified T3 product for the treatment of hypothyroidism.”

### **An Uptick Expected For AvKARE Next Year**

As Amneal is growing its unit dose business by launching eight to ten liquid products out of its New Jersey site, Chirag Patel sees the expected launches as “a nice uptick for AvKARE next year.”

As the company continues to grow its AvKARE distribution business, it reported net revenue of \$84.7m in Q1 2021, up \$26.7m million or 46% compared to prior year period. As the acquisition was closed on 31 January 2020, the current quarter reflects three months of sales versus two months last year.

“While the top line was slightly lower than our expectations due to lingering effects of the pandemic, the business was able to overcome it by leveraging a more profitable product mix as well as operating expense efficiencies,” said Chirag Patel.

For Amneal, AvKARE continues to represent a strategic long-term opportunity as the company focuses on the federal government channel. “This business is buoyed by favorable tailwinds, including the continued stream of branded pharmaceuticals going generic every year,” said Chirag Patel.

### **Company's Pandemic Lessons**

Referring to the lessons learned from the COVID-19 pandemic and the current crisis in India, Chirag Patel warned, “This latest COVID outbreak is a reminder of the dependency of the US generics pharmaceutical industry on foreign manufacturing,” He continued, “We believe it remains critically important to make more products in America for America.”

According to the company, its significant domestic manufacturing base, quality record and the US domicile enabled it “to work closely with federal and state legislators and public policymakers to provide meaningful solutions.” Chirag Patel added, “we look forward to sharing updates as we make progress.”

“We are also ensuring the continuous supply of medicines for patients and customers in the US,”

added Chirag Patel.

Furthermore, acknowledging the “very challenging situation” in India, Chirag Patel said, “we are working diligently with Indian government officials, charitable foundations and other pharmaceutical leaders to utilize our expertise, resources to secure critical care medications and equipment.”

Talking about the situation in India, Chintu Patel said, “We expect the situation to improve, hopefully, after one month.” He added, “we’re doing everything we can to help the situation with oxygen concentrators or with working on supplying or donating remdesivir and steroid products.”

Though Amneal never sold anything to the local market from its US Food and Drug Administration-approved plant in India, the company said that it has now received Indian government license to sell its products.

Chintu Patel added, “From the beginning of the pandemic, we focused on building an even more resilient global supply chain, which has led to strong inventory levels across all locations.”

### **Confident In The Company’s Momentum**

Referring to the company’s product portfolio, successful new product launches and focus on execution and driving of efficiencies, Konidaris pointed out that in the first quarter of current year, Amneal reported net revenue of \$493m overall, with adjusted earnings before interest, tax, depreciation and amortization of \$126m and \$148m of operating cash flow.

Chirag Patel said, “we remain confident that our momentum, the strength of our commercialized and pipeline assets, solid execution will deliver another year of strong top and bottom line performance, consistent with our guidance.”