Can the Gupta siblings solve Lupin’s US puzzle?

The US has been a sore point in the pharma company’s business. A turnaround is in the works

- **Lupin’s US revenue has shrunk while its margins are the worst among pharma companies. A series of setbacks—regulatory troubles, price erosion and impairments—have impacted the company.**

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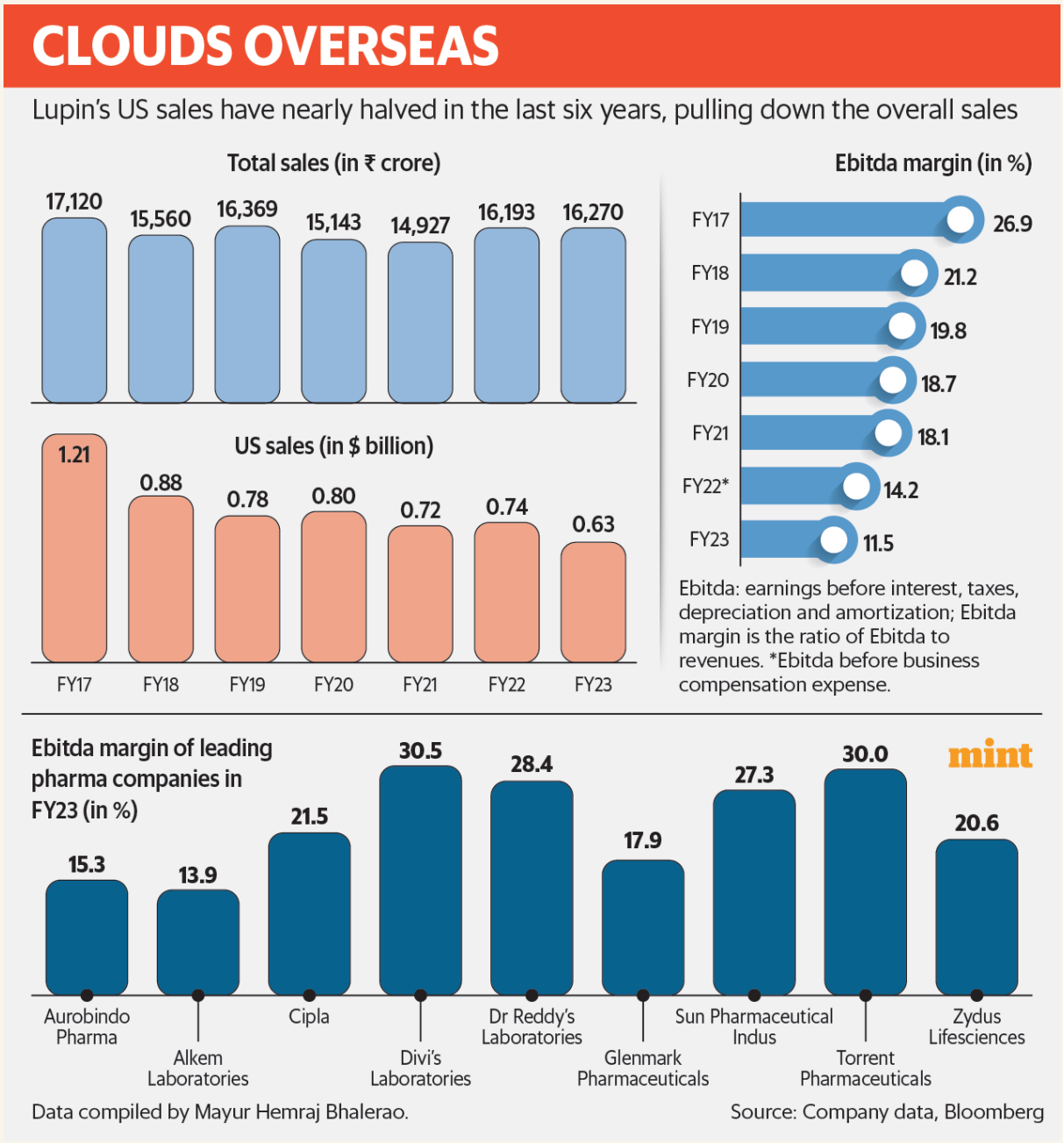
Desh Bandu Gupta, the founder of pharma company Lupin Ltd, liked to relax with his family every evening. But the dinner table conversations were mostly around the pharmaceutical business. And mostly, it was a two-way conversation—between Desh Bandhu and his eldest daughter, Vinita. Desh Bandhu’s wife, Manju, son Nilesh and other children dined quietly. Manju did try to ban business chatter at the dinner table but it worked only for a while.

All this changed with the death of Desh Bandu in June 2017, at the age of 79. Manju took over as the chairperson of the company. With the matriarch at the helm, the business hard talk may have moved seamlessly, from the boardroom to the dinner table.



Graphic: Mint

In the last few years, these conversations would have centered on the US market, where Lupin is heavily invested. Things weren't going well.

In 2016-17, the US business crossed $1 billion (₹8,263 crore), while the India business was comparatively smaller at ₹3,816 crore. An

investor presentation from the year stated that Lupin was “uniquely positioned to become a leading global pharma" and that it has “maintained an impeccable quality and compliance record". By 2022-23, the US revenue halved to $632 million. The India revenue, however, jumped to over ₹6,000 crore.

What happened?

For long, the US generics market has been the holy grail for Indian pharmaceuticals businesses. Generics drugs are copies of ‘innovator’ drugs that companies can launch after the original patents expire.

But this market has become harder to crack than ever because of growing competition. Then, Lupin faced a series of setbacks around price erosion, legal settlements, impairments and slow product launches, which links back to its regulatory troubles.

The US Food and Drug Administration (FDA), a federal agency responsible for public health, has made frequent observations around Lupin’s manufacturing practices. For instance, a ‘warning letter’ from the FDA, in November 2017, summarized “significant violations of current good manufacturing practice (CGMP) regulations for finished pharmaceuticals" in Lupin’s Goa drug manufacturing plant. The letter also observed “repeated failures at multiple sites".

And then, in another warning letter, issued last year in September, the FDA observed similar deviations from CGMP for active pharmaceutical ingredients (API) produced at the company’s Palghar facility in Maharashtra.

Besides identifying the violation, warning letters from the FDA make it clear that the company must correct the problem. The letters further provide directions and a timeframe for the company to inform FDA of its plans for correction.

For Lupin, such warnings slowed down product launches to a crawl. And this shows up in its US sales.

But that’s not all. Lupin, in 2015, acquired US-based Gavis Pharmaceuticals LLC and Novel Laboratories Inc. for $880 million. This didn’t go well, either, resulting in impairments. Add to this the inflation in raw materials and price erosion because of higher

competition, and the company faced a perfect storm—its margins tanked.

The company's earnings before interest, taxes, depreciation, and amortization (Ebitda), in 2022-23, came in at 11.5%, compared to 14.2% the year before. In 2016-17, Ebitda was reported at 26.9%.

"Lupin's margins are the worst among the pharma companies," a fund manager said, asking to remain anonymous to avoid breaching his firm's internal compliance norms.

The question is where does the company go from here?

Manju Gupta, whose initial contribution of ₹5,000 to Desh Bandu helped Lupin start in 1968, wouldn't be too pleased at this state of affairs. Neither are her children. Vinita, 54, is currently the chief executive officer (CEO) while Nilesh, who is six years younger, is the company's managing director.

Can the sister-brother duo pull Lupin out of the quagmire it finds itself in?

Fixing margins

As the eldest sibling, Vinita had informally started working at Lupin when she was 14; Nilesh joined at 22.

Vinita, over the years, expanded the business globally and is now based in the US. Nilesh continues to be in India.

The siblings have chalked out a turnaround plan but that road must begin with better coordination between them—which is why they have made a pact to collaborate more closely. For the next six months, the plan is to meet at least once a month, along with their teams, the duo said in a rare interview together.

The siblings are aware of the challenge the US business poses. "We went down all the way to $600 million (from over $1 billion), and we are emerging out of that hole," said Nilesh.

Lupin has now dropped several low value products from its portfolio—such as oral solid medicines—and is shifting more towards the high-

value respiratory segment, which adds up to over 25% of its US revenues.

“In the US, we continue to focus on differentiated platforms. We are trying to focus on platforms like nasal sprays and diazepam gel or suspensions, or liquid products," Vinita said.

Alongside its focus on high-value products, Lupin is slashing expenses on products or acquisitions that haven’t panned out well. The siblings blame some of this on ‘bad timing’.

Yet, the fund manager cited above wondered if Lupin is right in placing as much reliance on its US business to boost margins, when the past experience has proven to be contrary. He cited the example of Lupin’s approach to its Japanese business in 2019, where the company was facing similar challenges—Lupin chose to divest that business. Similarly, Lupin should consider spinning out its US business, the fund manager suggested. He noted that in the US, the delays in drug approval tend to escalate costs because of intense competition.

Spinning out the US business, may, however, go against Lupin’s strategy of geographical diversification.

In recent years, the company has tried to reduce its burn in the US business and allocate more capital to India, but it needs to do more, the fund manager added.

At the start of 2022-23, Lupin stated it anticipated cutting back costs by about ₹550 crore. It managed to reduce costs by ₹330 crore, chief financial officer Ramesh Swaminathan said in the company’s earnings call in May. Lupin expects further inventory write-offs to reduce costs.

Fixing Gavis

In 2017, Lupin acquired US-based Symbiomix Therapeutics, LLC for $150 million, hoping it would expand its US women’s health specialty business. Symbiomix’s primary product is Solosec, used to treat bacterial vaginosis as well as a sexually transmitted infection, Trichomoniasis. Solosec received FDA approval in 2017. But in 2021-22, Lupin took a ₹707 crore impairment on Solosec, citing “adverse market conditions".

“We took a bet. It did not work out, especially in the covid-19 period, when the physician office visits were highly disrupted. This was a major challenge for the Solosec product," Vinita said.

Lupin, in January 2022, decided to curtail investment in Solosec and partnered with another company, Exeltis, to market it instead.

A far more expensive bet was the acquisition of Gavis Pharmaceuticals. Gavis specialized in high-value opioid drugs, widely prescribed in the US at that time.

According to the World Health Organization, opioids “includes compounds that are extracted from the poppy seed as well as semisynthetic and synthetic compounds with similar properties that can interact with opioid receptors in the brain. Opioids have analgesic and sedative effects, and are commonly used for the management of pain". However, misuse and use without medical supervision can lead to opioid dependence.

Soon after the acquisition, the US government started a crackdown on opioid use. Lupin ended up taking three impairments on the acquisition— ₹1,464 crore in 2018; ₹1,580 crore in 2020; ₹126.7 crore in 2022. Thereafter, it dropped several products from the Gavis plant to cut back on costs.

The family believes Gavis is now back on track and the company’s plant in Somerset, US, has been repurposed. “Gavis is contributing nicely to margin improvement," Vinita said.

Lupin received a big product approval last year to be manufactured at this facility—Suprep, which is used before a colonoscopy. More recently, on 1 June, Lupin announced it had received FDA approval for Diazepam rectal gel, an epilepsy related medicine, again from the same facility.

Separately, Lupin is expecting a boost to its US business from the generic equivalent of Spiriva, the blockbuster inhaler drug of biopharmaceutical company Boehringer Ingelheim. FDA approved the drug this month, after endless delays. It is expected to be launched soon and Lupin sees the drug generating $100 million in US sales.

Fixing the plants

The turnaround plan, therefore, appears to have gained some momentum. Encouragingly, the company said it is fixing the compliance issues at its manufacturing facilities.

Between July 2022 and March 2023, the company received FDA-related approvals for five of its plants, including the Somerset facility—in 2020, the FDA had made 13 observations around the facility and issued a warning letter in June 2021. That letter pointed out that cleaning procedures for certain equipment, including tablet presses, were inadequate. FDA investigators observed drug residue from previously manufactured drug products in these presses, which were further used to manufacture several potent and non-potent drug products.

There is work left to be done in at least three plants located in India—Tarapur (Maharashtra), Mandideep and Pithampur (both in Madhya Pradesh).

“We have done substantial remediation at each of these sites. We have submitted a final update for Pithampur Unit-2 and are done with 80-90% of our work for the other two sites. We would expect these three sites to move in a satisfactory state of compliance within the next 18 months," Nilesh said.

The company is strengthening controls on cross-contamination and investigations, in addition to building a strong governance framework. “We now have a cadence starting from weekly reviews at site, all the way up to an apex governing committee that monitors quality and compliance across all our sites. We are committed to ensuring the purity and safety of the products manufactured," he reiterated.

Rethink on buys

Meanwhile, Lupin’s Gavis experience has triggered a shift in its acquisition strategy, which has played out over the last 12-18 months. The company is now opting for bite-sized acquisitions to build its complex generics portfolio in select therapies rather than big bang ones.

For instance, Lupin acquired two inhalation drugs last year for ₹622 crore from Sunovion to boost its respiratory segment in the US. It purchased nine brands from Bausch Medical Companies Inc in Brazil to build on central nervous systems therapies. The company also

acquired Southern Cross Pharmaceuticals to build scale in the Australian generics market. Last month, it bought French pharma company Medisol for ₹160 crore to access the hospital segment in France.

Going ahead, Lupin may explore more acquisitions in Europe, where it is under-indexed currently.

“We’ve gone from the simple generics to the complex platforms, whether it is inhalation products, or Telmexx (medicine for high blood pressure) or complex injectables and biologics," Vinita said. “In the future, we see opportunity for gene and cell therapy...it is going to be a game changer for the industry," she added.

Desh Bandhu named his company as Lupin, inspired by a flower that can grow under harsh conditions. The siblings have seen Lupin weather harsh storms but now seem confident of changing the game, carrying forward their father’s legacy.

“We have to leave it in much better, safer hands than what we got," Nilesh said.