Stock Note

Gufic BioSciences Ltd.

Oct 21,2024

Gufic BioSciences Ltd.

Industry	LTP	Recommendation	Base Case Fair Value	Bull Case Fair Value	Time Horizon
Pharmaceuticals	Rs 435	Buy in the band of Rs 432-441 and add more on dips to Rs 392	Rs 475	Rs 505	2-3 quarters

HDFC Scrip Code	GUFBIOEQNR
BSE Code	509079
NSE Code	GUFICBIO
Bloomberg	CF: IN
CMP Oct 18, 2024	435
Equity Capital (Rs Cr)	10.03
Face Value (Rs)	1
Equity Share O/S (Cr)	10.03
Market Cap (Rs Cr)	4363
Book Value (Rs)	53
Avg. 52 Wk Volumes	277390
52 Week High	448
52 Week Low	237.5

Share holding Pattern % (Sep, 2024)	
Promoters	72.5
Institutions	6.1
Non Institutions	21.4
Total	100

* Refer at the end for explanation on Risk Ratings

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Our Take:

Gufic BioSciences is engaged into the production and marketing of pharmaceutical, nutraceutical, and natural products. It is one of the largest manufacturer of lyophilised injections, with facilities in Navsari (pharmaceuticals) and Belgaum (natural products). About 58% of its revenue came from the domestic branded business, with about 50% of this from sales of critical care products to mainly tertiary hospitals. Critical care brands like Guficap, Micafung, Polyfic, Ticofic, Tigefic, Doxific and Merofic, continue to dominate the market. Polyfic secured the No.1 position in the Polymyxin-B Injection market and Micafung emerged as the market leader in Micafungin. Gufic has a history of forming partnerships with innovators, having licensed technology from firms like Technoflex (dual chamber bags), Prime Bio (Botulinum Toxin strain), Bright Gene (APIs for re-combinative products and anti-infective), CinnaGen, and Lucasmeyer. The share of lyophilised injectable is on the rise, with nearly 25% of new injectable products approved in the past 5 years being lyophilised. Lyophilisation enhances both stability and shelf life. Overall debt has increased to Rs 320cr in the last two years, on the back of large capex initiated by the company. It would taper-off from FY26 onwards gradually.

Gufic is likely to commission new facility at Indore with an investment of around Rs 350 crore, anticipated to generate revenue of Rs 900-1000 crore at peak capacity. Management plans to validate the plant for exports to the US and Europe but will initially focus on domestic market until validations are secured. Capacity utilisation is projected to be ~20% in the first year, and would increase to ~40% in FY26. As the unit scales up, operating margin and profitability would improve substantially. Management targets revenue of around Rs 1500 crore along with better operating margin in the next four years.

Valuation & Recommendation:

Gufic reported strong revenue growth on the back of robust growth from domestic business in FY24. Operating margin witnessed a fall of 140bps YoY at 18.1%. Company has guided for 15-20% CAGR in revenue over the next 4 years as the new facility would see gradual ramp up.

Company has implemented capex at Dhar, Indore for increasing its capacity which should start commercialization in H2FY25. We estimate 17.8% CAGR in sales led by 15% growth from domestic formulation business over FY24-27E. We expect operating margin to witness 200bps expansion on the back of better gross margin and cost efficiencies. Net profit is likely to see 26% CAGR over the same period.
We feel that investors' can buy the stock in the band of Rs 432-441 and add more on dips to Rs 392 (26x Sep-26E EPS) for base case target price of Rs 475 (31.5x Sep-26E EPS) and bull case target price of Rs 505 (33.5x Sep-26E EPS) over the next 2-3 quarters.

Financial Summary

Particulars (Rs cr)	Q1FY25	Q1FY24	YoY (%)	Q4FY24	QoQ (%)	FY21	FY22	FY23	FY24	FY25E	FY26E	FY27E
Total Revenues	203	195	4.0	195	4.0	488	779	691	807	920	1,094	1,319
EBITDA	36	35	0.8	34	4.5	84	148	135	146	162	215	266
Depreciation	4	4	1.7	4	-1.1	16	19	22	17	20	25	29
Other Income	1	1	42.0	1	40.4	4	3	3	2	3	3	5
Interest Cost	5	4	12.7	4	26.0	14	5	8	15	20	17	13
Tax	7	7	-2.4	7	2.1	14	31	27	30	32	45	58
PAT	21	21	1.2	20	4.3	44	96	80	86	93	131	171
EPS (Rs)						4.6	9.9	8.2	8.6	9.3	13.1	17.1
RoE (%)						29.2	43.3	25.9	19.6	16.1	19.2	20.7
P/E (x)						95.4	44.0	52.8	50.6	46.9	33.2	25.5
EV/EBITDA (x)						56.1	31.8	34.9	32.3	29.0	21.9	17.7

(Source: Company, HDFC sec)

Q1FY25 Result Update

Revenue for the quarter grew 4% YoY at Rs 203cr. EBITDA margin contracted 60bps YoY at 17.6%. Gross margin improved 300bps YoY at 53.3%. Net profit was up 1.2% YoY at Rs 20.85cr.

Company launched Dydrogesterone 20mg & 30mg SR Tablets in the quarter. This is expected to revolutionize patient compliance by reducing the dosing frequency, thereby enhancing the treatment experience and outcomes.
Specialty Task Force Division - Fertimax: To further enhance market reach, the company launched a super-specialty task force, Fertimax, consisting of 40 well trained and experienced field personnel. This strategic move would boost field efficiency and drive deeper market penetration.

Gufic retained market share with leading products like Puregraf, Dydrofic, and Puretrig. These brands continue to perform strongly, benefiting from strategic focus on maintaining leadership in niche markets.

In Q1FY25, the company launched Tiecoplanin DCB, Biapenem DCB, and S Pantoprazole. These products are to meet growing demand for advanced therapeutics in hospitals, enhancing product portfolio. Company announced the upcoming launch of Contrast Media. This introduction will be a significant breakthrough, addressing the demand for quality products in major corporate hospitals.

For FY24, total revenue increased 16.8% YoY at Rs 807cr led by strong traction in domestic formulation business. Domestic sales grew 23%

YoY at Rs 719cr. EBITDA margin contracted 140bps YoY at 18.1%. Gross margin was down 30bps YoY at 51.7%. Finance cost increased 87% YoY at Rs 15.4cr. Net profit was up 8% YoY at Rs 86cr.

EPS for the quarter stood at Rs 2.08 and it stood at Rs 8.6 for FY24.

Key Takeaways from Conference Call

- Company has made significant strides with a new product development, including the introduction of a potassium channel inhibitor in the proton pump inhibitor market. This is almost Rs 3000 crore market. It was launched in Jul-2024.
- Infertility market size is around Rs 4000 crore. There are few players having strong presence which includes Merck, Intas Pharma, BSV and Gufic.
- Cost efficiency, change in product mix and operating leverage would be key drivers for margin expansion.
- Company has made substantial progress with manufacturing facility in Indore. The media fill validation studies underway. This validation is crucial for minimizing product batch rejections and streamlining the approval processes.
- Critical Care division has sustained growth through enhanced market penetration and leadership in niche anti-bacterial and anti-fungal products. Gufic has penetrated over 2,000 hospitals now with brands like Guficap, Micafungin, Micafung, Polyfic, Ticofic and Merofic becoming preferred choices among medical professions.
- Company launched Dalbavan, which is a second-generation lipoglycopeptide antibiotic during FY24. It is used for serious bacterial infections.
- Neurocare division has successfully launched Zarbot, the first Indian botulinum toxin of international category. Zarbot has gained confidence of leading neurologists with acceptance and prescriptions by over 100 leading neurologists in India within a year of launch.
- Company has over 200 products registered in regulated and semi-regulated markets like UK, Australia, Philippines, Thailand, Sri Lanka and Nepal etc. Moreover, Gufic has a strong pipeline of 150 products, thus the company is well positioned to leverage existing combinations and target new market opportunities.
- Management guided for revenue of Rs 950-1000cr for FY25.

- Company derived ~58% of revenue from domestic formulations, 22% from Contract Manufacturing (CMO), 15% from International formulations and 5% from API in FY24.

- Gufic got an in-licensing approval from an innovator, which manufactures pain management molecules. It's a company based in Taiwan and they have already got approval in Southeast Asian markets like Taiwan, Singapore, Malaysia, Japan.

- In the US market, they are looking for a partner for Phase III. Company has taken exclusive rights for India. This will be manufactured in Taiwan and will be imported here. After the company reaches a particular milestone in sales in India, then it will be manufactured by the Indore factory in the long term.

- Indore is almost 1.5x size of Navsari. Once Indore starts commercial production then overall capacity will increase substantially. Company has invested around Rs 350cr for capital expenditure at Indore and there are four lines for manufacturing. The line one and line two are lyophilization drugs, line-3 is for liquid vials, and line-4 is ampule machine.

- Management said that capacity utilization could be around 15-20% in the first year of operation. It should scale up to ~40% in FY26 and further improve to about 60% in the third year.

- Company expects CAGR of 15-20% in revenue over the next 4 years.

- Company has completed the validations of three manufacturing lines at the Indore facility. These validations are critical to ensure that production processes adhere to the highest standards of quality and efficiency.

- In Indore, the company has total four lines, line one and line two are lyophilization drugs, Line-3 is actually liquid vials, and line 4 is ampule machine. Commercial production is expected to start by Oct-2024.

- With commercialization of new 4 lines at Indore, we expect strong growth post FY25. Company would see gradual ramp up at its new facility.

- Management targets revenue of around Rs 1500 crore in the next four years.

Key Triggers

A play on the growing share of lyophilisation

Gufic BioSciences is engaged into the production and marketing of pharmaceutical, nutraceutical, and natural products, along with APIs. Company is one of the largest manufacturer of lyophilised injections, with facilities in Navsari (pharmaceuticals) and Belgaum (natural products). In the past, Gufic has strong history of forming partnerships with innovators, having licensed technology from players like Technoflex (dual chamber bags), Prime Bio (Botulinum Toxin strain), Bright Gene (APIs for re-combinative products and anti-infective), CinnaGen, and Lucasmeyer.

The share of lyophilised injectable is on the rise, with nearly 25-30% of new injectable products approved in the past 5-7 years being lyophilised. Lyophilised injectable constitute ~45% of the global injectables market. Biopharmaceuticals are outpacing traditional compounds, heightening the significance of lyophilised products. Lyophilisation enhances both stability and shelf life. Gufic is set to commission about Rs 350 crore plant in Indore, anticipated to generate revenue of Rs 900-1000 crore at peak capacity. Management plans to validate the plant for exports to the US and Europe but will initially focus on domestic sales until validations are secured. Capacity utilisation is projected to be ~20% in the first year, increasing to ~40% in the second year.

Gufic had benefitted from the sales of Remdesivir and Liposomal Amphotericin B in FY22 due to COVID-19. As the things got normalised in FY23, the company had reported decline in overall business and profitability, however the company registered robust growth in domestic business during FY24 driven by new product launches and registrations in the export market. Gufic has started submitting dossiers for all countries that it intends to exports. However, until these approvals are received, the unit will primarily cater to the domestic market (both front end + contract manufacturing). This will help free up some capacities from the EU GMP certified Navsari unit. It has identified 15 molecules that it intends to manufacture at scale from the Indore facility.

Established market position in the pharmaceutical industry

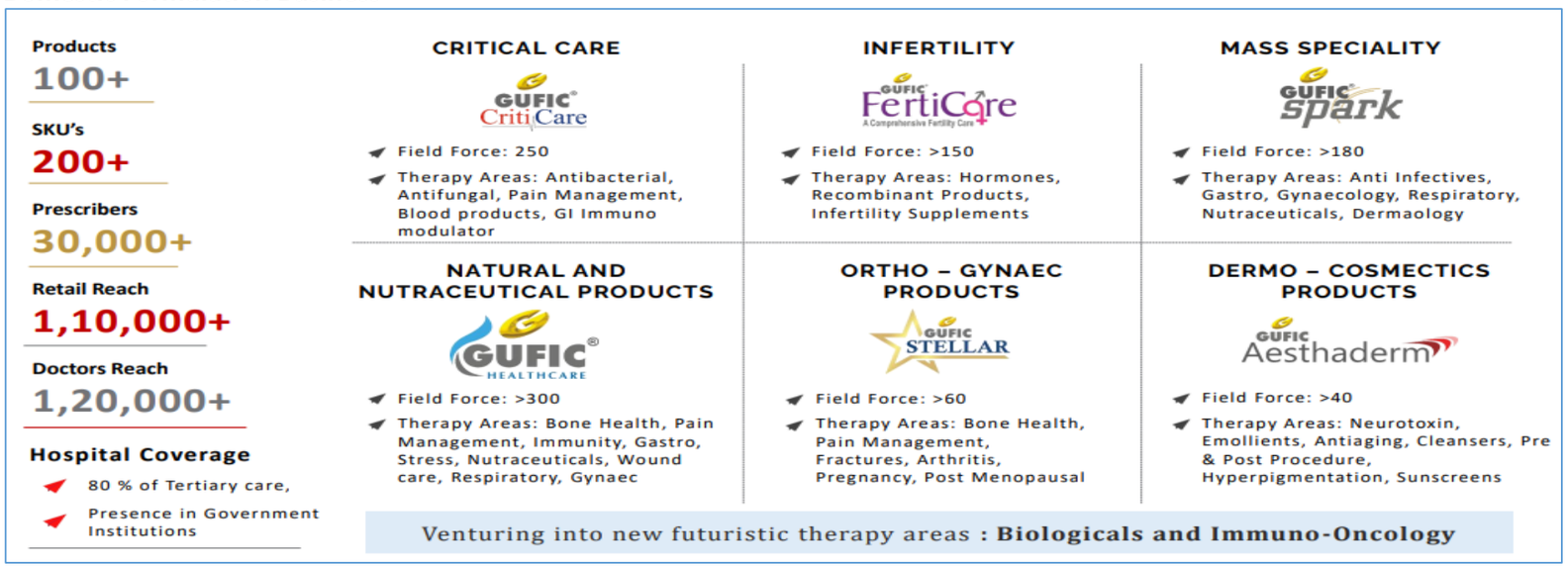
The promoters have over five decades of experience in the pharmaceutical industry. Their strong understanding of market dynamics and healthy relationships with customers and suppliers should continue to support the business. Gufic obtained various certifications and approvals for its manufacturing facilities and diversified its product portfolio through continuous R&D. The product portfolio is diversified, with the top-10 products contributing to ~15% of revenue in FY24. Revenue grew and stood at Rs 807 crore in FY24 from Rs 690 crore in FY23 and is expected to increase further, backed by healthy demand, continuous R&D and diversified product portfolio. Furthermore, steady ramp up of the newly established Indore unit, which is expected to commence commercial production from Oct-2024, should contribute to incremental growth. Established market position in the pharmaceutical industry should continue to support the business risk profile over the medium term.

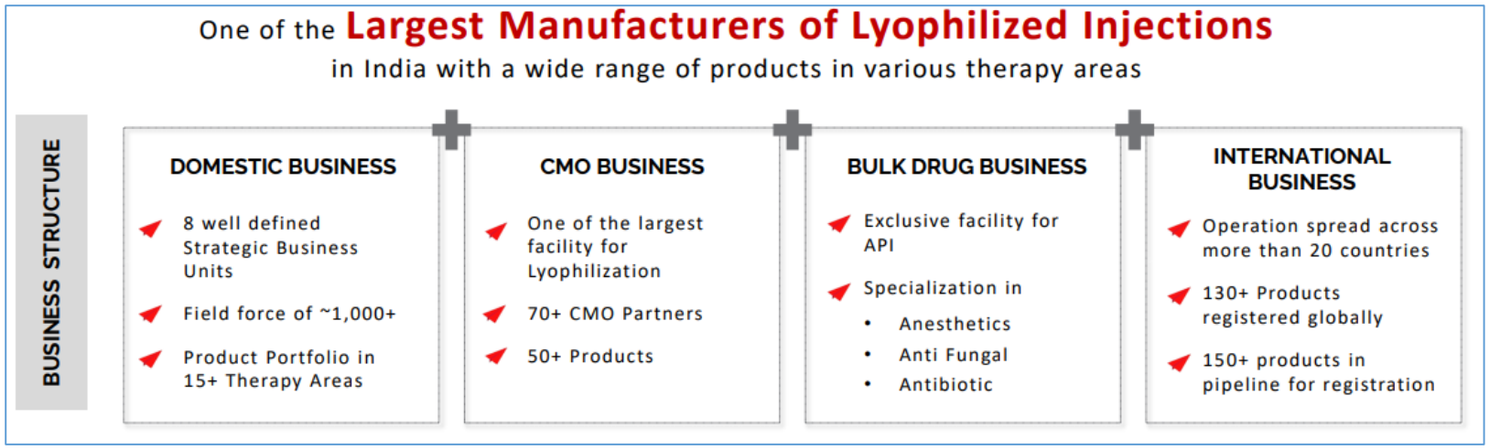
Company is in the final stages of commercialising capex to increase its existing formulation capacity with a new unit in Indore (Madhya Pradesh) to meet additional demand. The company is in the process of applying for approval from various regulatory bodies, including US, UK for the new unit. Until then, the company plans to serve the domestic market from this unit. Going forward, the company's ability to scale up capacity utilisation levels to remain driver for the medium term.

Critical Care division holds more than 25% market share in the domestic market for Caspofungin, Micafungin, and Polymaxin B. Newly launched brand in the ceftazidime + avibactam market has rapidly gained traction, now representing 15% of the market and ranks at no.2 in this category. Renowned brands such as Guficap, Micafung, Polyfic, Ticofic, Tigefic, Doxific, and Merofic are highly favored by both doctors and hospitals.

The clientele includes large players such as Glenmark Pharmaceuticals, Cipla, Intas Pharma, Alkem, Lupin, Abbott Healthcare Pvt Ltd and Hetero etc. Healthy relationships with reputed pharmaceutical players led to repeat orders, contributing to steady revenue growth over the years. Besides, it has a network of 25 carrying and forwarding agents and more than 500 stockists across India, through which it has access to over 1 lakh retailers. Top-5 customers contributed 24% of revenue in FY24. Benefits from longstanding relationships with the well-established customer base will persist.

Domestic Formulation Business





(Source: Company, HDFC sec)

Large capex to be key growth driver

The Indore facility is expected to be commissioned in Q3FY25. While the facility was initially slated to be commissioned by the end of FY23, the management decided to increase capacities of the project, and that led to late commissioning of the project. Company is expected to spend Rs 350 crore on the project (including land procurement). The peak revenue potential from the facility is expected to be around Rs 900 crore. The new facility is expected to break-even by the end of FY25. At peak capacity utilization, the asset turnover to increase to ~2.5-2.8x (compared to the current levels of ~1.5-1.6x.

Gufic has started submitting dossiers for all countries that it intends to exports. However, until these approvals are received, the unit will primarily cater to the domestic market (both front end + contract manufacturing). This will help free up some capacities from the EU GMP certified Navsari unit. It has identified 15 molecules that it intends to manufacture at scale from the Indore facility. The company is spending Rs 8-10 crore on trials at Indore for trials and validations. This could keep near term margin trajectory muted but could trigger a margin expansion in FY26 once these costs go away and capacity ramps up.

Initially the company would serve to the domestic market, until the unit receives approvals from foreign regulatory bodies, including the US FDA. Further, this is expected to allow the Navsari plant to focus on more on export markets, as it holds approvals from various regulatory bodies, including WHO GMP, EU GMP, and countries in Africa and Latin America. Over the medium term, with plans to export to the USA from the Indore plant, overall revenue and profitability are expected to scale up significantly.

Sparsh - Domestic business vertical

Under the Sparsh vertical, Gufic operates a direct-to-hospital distribution model, having mapped approximately 8,000 hospitals nationwide and established business channels with around 1,400 of them. The vertical offers 90-100 SKUs and sells an average of ~30 SKUs per hospital

through a field force of ~66 employees. A key reason for establishing the vertical was to directly map products consumed by hospitals. This allows Gufic's field representatives to sell targeted products based on the specific needs of hospitals in each area. Company has achieved ~100% visibility on tertiary sales – a significant challenge within the industry. Its strategy going forward is to capitalize on the hospital network and launch value added products to improve realisations and margin profile.

Diversified product portfolio across segments including pharmaceutical formulations, bulk drugs and herbal formulations

Gufic manufactures pharmaceutical and herbal formulations, APIs/bulk drugs as well as consumer/personal care products such as sanitary napkins and anti-stretch mark creams. The product portfolio remains diversified across therapeutic segments such as anti-fungal, anti-infective, antibiotic, anaesthetic, and fertility. Within the formulation segment, the company caters to various dosage forms such as tablets, capsules, ointments, syrups, lyophilised and liquid injections. However, injectable (liquid and lyophilised) remain its key revenue contributor, forming 75-80% of the company's revenue, followed by APIs (5-10%), the consumer care division and others. Within the injectable segment, the company also carries out contract manufacturing for leading brands in the domestic and international markets, in addition to direct sales to hospitals/physicians.

Botulinum Toxin has huge potential

Gufic has partnered with Prime Bio, USA for manufacturing Botulinum Toxin API and formulations. While the market is in its nascent stage in India, there is tremendous opportunity to scale up this product in the country. Prime Bio is headed by Dr. Bal Ram Singh (also founding director of the National Botulinum Research Centre at Umass Dartmouth).

Gufic has purchased the cell line from Prime Bio and has set up a manufacturing unit at Navsari to manufacture the product. The agreement with Prime Bio mandates Gufic to share a portion of its profits with Prime Bio. It markets its aesthetics product under the brand name of Stunnox. Gufic can ramp up revenue from this division in a similar manner to the ferticare division, which was launched in 2016. Within eight years, Gufic has managed to penetrate 50-60% of all IVF clinics in India and its brands are go to products for ~50% of the gynecologists in the country. It has a dedicated field force of 100 sales representatives trying to leverage its lyophilisation capabilities. For therapeutic use, Gufic has launched Zarbot under its critical care vertical. This product will target the neurology segment and has been prescribed by ~100 neurologist so far. It is also working on launching the Topical form of Botulinum Toxin to cater to patients afraid of taking injections.

Botulinum Toxin is a neurotoxic protein produced by the bacterium Clostridium botulinum. It is a neurotoxin that blocks nerve signals to muscles. However, in controlled doses, Botulinum Toxin is used medically to treat muscle spasms, migraines and wrinkles. Besides Gufic, the compound is manufactured by a handful of manufacturers in the world including: 1. Abbvie (formerly Allergan) 2. Ipsen 3. Merz Pharmaceuticals (Germany) 4. Medytox 5. Daewoong Pharmceuticals (South Korea) 6. Revance Therapeutics.

Allotment of 33.33 lakh equity shares at Rs 300 per share

In Sep-2023, Board had approved issuance of 33.33 lakh equity shares (3.32% stake) to Motilal Oswal Financial Services at Rs 300 per share. Company raised Rs 99.99 crore through preferential allotment.

Annual Report FY24 Update

Domestic Branded Business

Super Specialty Business

This is the major part of Gufic's Domestic Business which include the Critical Care and Infertility portfolio. The focus of Critical Care Division remains to retain the leadership position in Anti-Fungal and Anti-bacterial products. It aims to consolidate the acute therapy business in the Anti-Infective category and also introduce newer molecules in the segment through its major SBU in Secondary and Tertiary care hospitals and institutions. More than 8000 hospitals were surveyed and supplies in few of these hospitals were initiated. The division will focus to increase the penetration and coverage.

Critical Care

Critical Care Division remains a cornerstone of Gufic. In FY24, Gufic announced strategic product launches, market penetration and the application of advanced technology.

Gufic became the first company in India to secure DCGI approval for the manufacturing and marketing of Dalbavancin, a second-generation lipoglycopeptide antibiotic. Dalbavancin is a game-changer for Outpatient Parenteral Antibiotic Therapy (OPAT) in India, enabling early discharge and reducing the burden on healthcare facilities.

Recognition for Cavim (Ceftazidime + Avibactam): The brand Cavim, continues to receive accolades as one of the top 20 new launches according to IQVIA. It is the only anti-bacterial injectable on the list, further strengthened Gufic's position as a leader in the critical care space.

Pioneering Advancements in Immunotherapy: Immunocin-Alpha, innovative therapy for sepsis, has completed successful trials. Based on the clinical data the company is likely to get DCGI approval soon, which will further enhance critical care portfolio.

Critical care brands, including Guficap, Micafung, Polyfic, Ticofic, Tigefic, Doxific and Merofic, continue to dominate the market. Polyfic secured the No.1 position in the Polymyxin-B Injection market and Micafung emerged as the market leader in Micafungin.

Novel Pain Management Product: Gufic has in-licensed a ground breaking pain management solution, marking its debut in India. This synthetic analgesic offers a unique mechanism of action that differentiates it from traditional opioids, providing effective pain relief without the severe side effects commonly associated with opioid use. This novel analgesic positions Gufic at the forefront of pain management in India, offering a safer, more effective alternative to traditional opioids while addressing the growing concerns of opioid misuse and addiction.

Ferticare

Company continues to advance product offerings and expand market reach, the Ferticare Division continues to strengthen in the ART space. The innovation and developing differentiated and complex fertility treatments, positions the company in the Assisted Reproductive Technologies space. With ongoing investments in R&D and strategic initiatives aimed at enhancing hormonal independence, Gufic is well-equipped to meet the evolving needs of patients and healthcare providers alike.

With its continuous efforts, Gufic ensured to regain the business loss in infertility segment during COVID-19 Pandemic, as Infertility business had seen a major decline in the pandemic due to dramatic decrease in the number of IVF / IUI cycles. The business was completely opened up and the division focuses on building brands within the Hormonal category and offer newer drugs and newer drug delivery systems with PFS (Pre-filled Syringes) and DCS (Dual Chamber Syringes). The leadership position of Gufic Infertility in the hormonal product range like Human menopausal gonadotropin (HMG) and Human chorionic gonadotropin (HCG) is maintained, and to further strengthen its presence Gufic has planned to launch the most potent form of HMG which reduces the chances of failures in IVF cycles.

Spark Healthcare Division

Company has expanded presence in both mass markets and specialized niches. The introduction of Polmacoxib in Stellar Division and subsequent expansion into the Healthcare Division has fortified orthopedic specialty offerings. This launch also paves the way for a stronger presence in the nutraceutical business.

Extended-Release Dydrogesterone: The extended-release dydrogesterone formulation offers significant benefits over regular dydrogesterone, including improved dosing convenience, consistent therapeutic effects and enhanced patient compliance. With the current dydrogesterone market valued at approximately Rs 1,000 crore, there would be a shift towards extended-release formulations.

Topical Cannabis 3% Formulation: Gufican/Gufibis, India's first topical cannabis 3% formulation, represents a novel solution for pain management. It is effective for various conditions such as arthritis, muscle soreness and neuropathic pain, this product is poised to capture a unique segment of the pain management market. As the demand for alternative pain relief solutions grows, Gufican/Gufibis is well-positioned for substantial market adoption. Aestherderm & Neurocare Division Built on the foundations of expertise in injectables, this division plays a crucial role in strengthening Gufic's presence in the niche categories of aesthetic dermatology and neurology.

Strengthening Market Position through Splitface Trial Success: A landmark splitface trial comparing to botulinum toxin product, Stunnox, against a market leader has yielded remarkable results. The success of this trial has not only enhanced awareness but also instilled confidence in offerings within the aesthetic community. Stunnox is now tried and accepted by over 1,100 cosmetologists, positioning it as a credible and preferred choice in the market. leverage these findings to further drive market development efforts.

Specialized Neurology Team for Targeted Approach: In the Neurocare segment, the company has assembled a specialized team equipped with extensive domain knowledge. This team strategically targets the neurology market, ensuring a focused approach that has already yielded significant results. Zarbot, botulinum toxin for neurology applications gained the confidence of leading neurologists within one year of its launch. With over 100 neurologists prescribing Zarbot, the product is poised for further growth.

Sparsh

The division has established itself as a pioneering force in the Indian healthcare market through its unique direct-to-hospital distribution model. This innovative approach, allows Gufic to build stronger, more transparent relationships with hospitals while offering them competitive pricing and a comprehensive range of injectable products.

In a short span, SPARSH has made significant inroads across the healthcare landscape, establishing business channels with over 1,400 hospitals by the end of FY24. It has already established presence in over 1,000 hospitals with the launch of 92 molecules. This broad-based penetration demonstrates the strength of field force and the effectiveness of strategy. SPARSH is not just a wholesale supplier; but a one-stop-shop solution provider for all types of parenteral needs.

Introduction of SeraSeal: A key product in the portfolio is SeraSeal, an innovative hemostatic agent designed to stop bleeding on contact, even in arterial hemorrhages. This patented, single-component system has the potential to save lives and has already been accepted and successfully tested in leading hospitals across India.

Gufic Aesthaderm

The sub-chronic therapy of Aesthetic Dermatology continues to show its growth for Gufic after its launch last year. Gufic was the 1st Indian company to manufacture and launch a brand of Botulinum Toxin Type-A Injection in India through its international tie-up with Prime-Bio Inc., a US based company. The division had also launched a range of high class Aesthetic products in segments like Moisturizing agents, Anti-aging, Hyperpigmentation, Sunscreen agents during its launch phase. The products continue to show a steady growth in the target market with more and more practitioners now confidently using the same. Within a short span of time, Stunnox - Gufic's brand of Botulinum toxin gained momentum to reach amongst the top-2 brands in the space. Gufic also initiated the process of registration for a range of Hyaluronic Acid based Dermal fillers to complement and augment the basket of products in the category. Gufic has successfully completed a split face clinical trial between Stunnox (Gufic's brand of Botulinum Toxin Injection) and Botox (the innovator brand of Botulinum Toxin Injection).

International Business

International Business Division focuses on owning product registrations to enhance market access and control over global supply chain. This strategy allows to capitalize on the growing demand for cost-effective, high-quality pharmaceuticals, particularly in regulated markets. Company aims to expand product portfolio, coupled with strategic focus on key regions, positions for sustained growth in the international

markets. By maintaining a strong pipeline and continuously exploring new markets, the company will penetrate more globally and contribute to the accessibility of essential medicines worldwide.

FY24 saw significant progress in product approvals across diverse markets. Company secured new product registrations in Sri Lanka, Chile, Myanmar, and Malaysia, and notably received approval for an injectable product in Australia, UK & Brazil.
Strategic Focus on Regulated Markets: Gufic remains focused on Europe and LatAm (Latin America) regions. Company is leveraging on existing formulations in countries where it has already established a presence and also continues to explore new opportunities by identifying market gaps in untapped regions.

Expanding Product Portfolio: As of FY24, Gufic has registered a total of 210 products across regulated and semi regulated markets like UK, Australia, Mexico, South Africa, Philippines and Thailand. Furthermore, it has a pipeline of 150+ products for registration in over 30 countries.

Research & Development (R&D)
Gufic's focuses on growing market offering in complex injectables and expanding product portfolio across four primary pillars: Critical Care, Assisted Reproductive Technology Therapies, Toxins and Science-based Nutraceuticals. R&D team is backed-up by a strong Clinical team which includes, Medical and Regulatory teams, with an expertise to take Synthetic and Biological products across Phase-II and Phase III clinical trials.
Gufic's R&D is committed to maintain its leadership in lyophilized injectables, particularly in the critical care segment. It continuously explores new formulations, delivery systems and process improvements to ensure products set industry benchmarks for safety, efficacy and cost-effectiveness.
Its R&D pipeline is rich with over 50+ products in various stages of development, targeting both regulated and semi regulated markets. This includes next-generation antibiotics, antifungals and other critical care drugs that address unmet medical needs and enhance patient outcomes.
Company recognizes the importance of hormonal independence; its R&D is dedicated to developing recombinant alternatives to critical hormones used in infertility treatments.

IPM reported 8% growth for FY24 led by Chronic therapies
As per IQVIA IMS, the Indian Pharmaceutical Market (IPM) had reported an ~8% YoY growth for FY24, primarily led by price increases. Acute therapies underperformed broader market growing at just 6% despite a high single digit price increase. Chronic therapies remained a key driver for the IPM, ~10% value growth supported by healthy high single-digit growth across most therapies.

Q2FY25 IPM update

Indian Pharma Market (IPM) grew 5.1% YoY in Sep-24 (vs. 7.6% in Aug'24 and 8.9% in Sep'23).

Cardiac/Derma/Anti-diabetic therapies grew at 9.7%/8.3%/7.7%, while slower growth was experienced by Respiratory/Anti-Infective, which declined 1.1%/0.3% YoY.

Barring the quarterly seasonal variations, growth in the domestic Pharma market continues to remain resilient and we expect India formulations revenue for to clock 9-10% CAGR over FY24-27E.

In Q2FY25, IPM reported ~8% YoY growth driven by ~10% growth from Chronic area while Acute grew at ~7%.

We note that Gufic has a differentiated portfolio in the domestic market. It has presence across 15 therapeutic areas with major being Ferticare, Anti-Infective, Gyanecology, Respiratory and Nutraceutical segments.

Pricing Pressure

The pharmaceutical industry continues to face growing pressure to reduce drug costs due to concerns about healthcare affordability, rising healthcare expenditures, and public demand for more accessible and cost-effective treatments. Several key factors drive this pressure, prompting the industry to explore various strategies for addressing the challenge of lowering drug prices. One major factor is the increasing demand for transparency in drug pricing. Patients, healthcare providers and payers are seeking greater clarity on the components that influence drug prices, including research and development costs, manufacturing expenses and profit margins. The expiration of patents for branded drugs also introduces competition from generics and biosimilars. Generic drugs, which are bioequivalent to their branded counterparts, typically enter the market at lower prices, resulting in significant cost savings. Biosimilars, which are similar-but not identical-to biologic drugs, are introducing competition in the biopharmaceutical sector as well. Another emerging trend is the shift towards value-based pricing models, where the cost of a drug is linked to its proven clinical outcomes and therapeutic value. This approach ensures that drug prices are aligned with their efficacy and the benefits they provide to patients. In addition, payers such as insurance companies, national health services, and pharmacy benefit managers (PBMs) increasingly negotiate discounts, rebates and favorable pricing arrangements for large patient populations, further driving down drug costs.

Outsource Drug development and manufacturing

Pharmaceutical companies will continue to outsource drug development and manufacturing, leveraging external expertise and resources to enhance efficiency, reduce costs and accelerate the overall drug development process. Outsourcing allows pharmaceutical companies to tap into the specialised expertise of Contract Research Organisations (CROs) and Contract Manufacturing Organisations (CMOs) that focus on specific aspects of drug development. These specialised partners often have deep knowledge and experience in preclinical and clinical research, formulation development and manufacturing. Outsourcing can be a cost-effective strategy, especially for smaller or emerging pharmaceutical companies that may not have the infrastructure or resources to handle all aspects of drug development internally. By outsourcing to CROs and CMOs, companies can avoid significant upfront investments in facilities, equipment and personnel. Outsourcing also provides pharmaceutical companies with flexibility in adapting to fluctuating workloads. They can scale their operations up or down

based on project requirements without the fixed costs of maintaining an in-house infrastructure. Collaboration with specialised service providers can accelerate the drug development timeline. Outsourcing allows companies to leverage the established capabilities of CROs and CMOs, potentially reducing development times and enabling quicker entry into the market. Drug development is inherently risky, with uncertainties at various stages. Outsourcing enables companies to share some of these risks with their partners. For example, a CRO might take on the risks of conducting clinical trials, and a CMO might assume risks related to manufacturing processes. It also means that pharmaceutical companies can concentrate on their core competencies, such as research, strategic planning and commercialisation, allowing them to allocate resources more efficiently and strategically. Furthermore, reputable CROs and CMOs adhere to strict quality and regulatory standards. Partnering with organisations with a strong compliance track record helps pharmaceutical companies ensure that their products meet regulatory requirements and quality standards.

Challenges

Regulatory Compliance

Indian pharmaceutical companies face significant challenges in meeting international regulations and quality standards. Regular inspections, voluntary actions, official actions, warning alerts and import alerts are now a days common. Navigating the changing laws of different countries while conducting extensive research to produce new drugs can be daunting.

Price Controls and Market Dynamics

The Indian government regulates the prices of essential and commonly used medicines to ensure affordability. However, this regulation often leads to a situation where the substantial investments in research, development and marketing of new drugs are not fully recovered due to price controls. While price regulations benefit patients by making medicines more affordable, they negatively impact pharmaceutical companies. A balance between allowing companies to price their products freely and maintaining public affordability is crucial for sustaining investment in new drug development.

Global Supply Chain Disruptions

Indian pharmaceutical market relies heavily on China for active pharmaceutical ingredient (API) supplies. Price fluctuations due to policy changes and geopolitical factors affect API costs, disrupting the global supply chain. Such disruptions can hinder the manufacturing and availability of medicines in India. Companies are compelled to seek alternative local sources for raw materials to mitigate these challenges. Company is dependent upon China and other sources for 60-65% of Raw Material requirements.

Key Concerns

Adverse changes in government regulations: The pharmaceutical industry is highly regulated by state governments and various government agencies, which approve new drugs and clinical trials, control the quality of imported drugs and set prices for many critical drugs; while state authorities regulate manufacture, sales and distribution.

Any unfavourable regulation may adversely impact the business and profitability.

Exposure to risks related to the stabilization of ongoing project: Company has undertaken a greenfield project at Indore, Madhya Pradesh, to expand capacities of existing formulations/injectable and introduction of new products. While the project has been completed, with commercial production expected to commence from Oct-2024, timely stabilization and subsequent ramp up remains a key for the medium term.

Competitive intensity in formulations industry: Domestic formulation industry faces stiff competition from contract manufacturers, multinational companies as well as established domestic brands. The intense competition in the industry keeps revenue growth and margin under check. The total project cost is pegged at around Rs 350 crore, which would be funded through term loans, equity infusions and internal accruals. Its ability to achieve healthy capacity utilisation levels through desired scale up would be critical and remain a key monitorable.

Profitability susceptible to volatility in raw material prices and foreign currency exchange rates – With limited control over the prices of its key inputs, overall margin and profitability remains exposed to volatility in raw material prices. Although the pricing for its contract manufacturing revenue is based on a fixed cost conversion model, limiting the volatility risk. With the presence of a sizeable import volume, its profitability remains vulnerable to fluctuations in foreign currency exchange rates.

Elevated price erosion in the US generic business could hurt revenue though pricing pressure has moderated and is currently in high single digit. Company has minimal exposure to US markets.

Regulatory Challenges - Gufic sells its products in more than 40 markets across the world. Also, the company has entered into various in-licensing agreements with various global partners across countries for manufacturing and marketing of various drugs. Hence, the company is required to comply with various laws, rules and regulations and operate under the strict regulatory environment.

Company Background

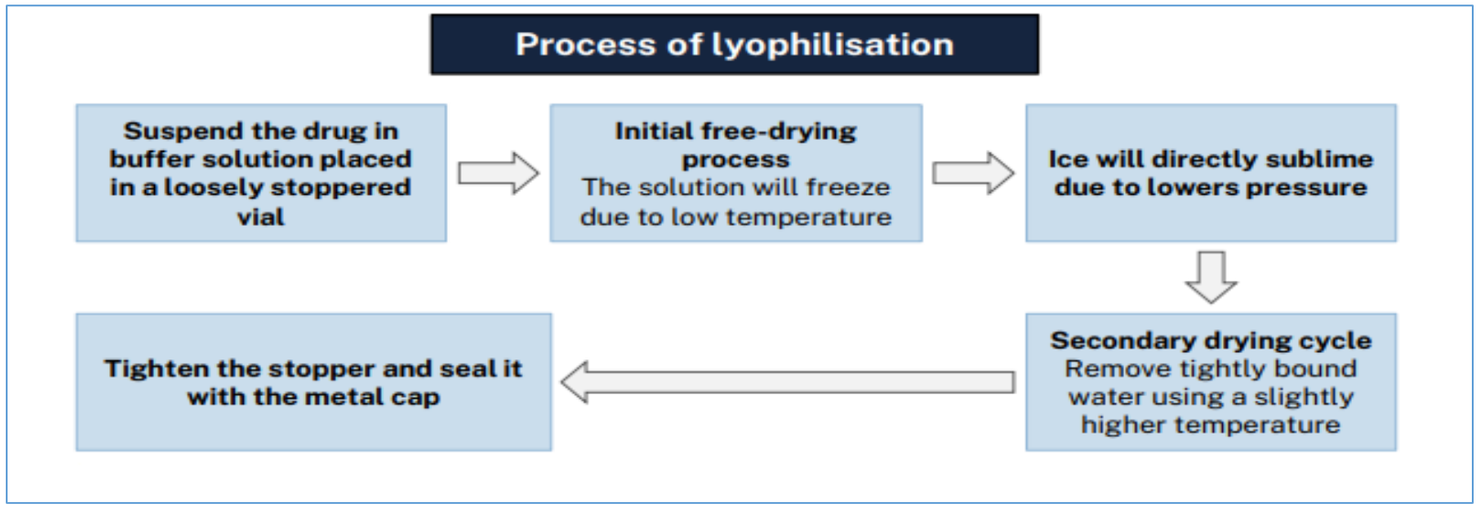
Gufic Biosciences Limited (Gufic) is a prominent global pharmaceutical enterprise dedicated to delivering a broad spectrum of pharmaceutical services to its clients. Gufic operates in both domestic and international markets, supported by a robust distribution network. Company is ranked among the top 100 pharmaceutical companies in India. Gufic is a leading manufacturer of lyophilized injections in India, with an automated lyophilization plant located in Navsari, Gujarat. It is engaged in manufacturing and marketing pharmaceutical formulations in various dosage forms, such as injectables, syrups, ointments and lotions. It is also backward integrated into manufacturing APIs/ bulk drugs, some portion of which it captively consumes. It also operates in the herbal formulations and consumer/ personal care sectors. The recent addition of the Indore manufacturing facility has further strengthened Gufic's position as one of the world's largest

producers of lyophilized injections. These products cover a wide range of therapeutic areas, including antibiotics, antifungals, cardiac medications, infertility treatments, antiviral solutions, and proton pump inhibitors (PPIs). Strategically, Gufic focuses on expanding its global footprint, targeting key markets such as India, Germany, Switzerland, South Africa, Russia, Canada, Brazil, Europe and other emerging regions. Its manufacturing plants are located at Navsari in Gujarat (injectables and API) and at Belgaum in Karnataka (API and herbal formulations).

Manufacturing Facilities

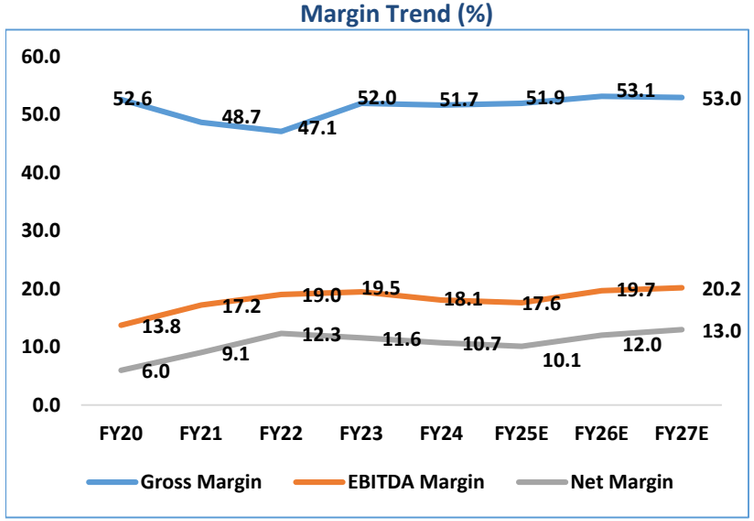
Unit - I at Navsari	Unit - II at Navsari	Gufic - Belgaum	Penem Block	Unit - III at Indore
Botulinum Toxin Facility Lyophilized/Powder Injectables Facility Natural Products (Topical/Liquid) API Facility	Lyophilized Injectables Facility Capability to manufacture Liposomal Amphotericin B and Depot Injections	Natural Products Facility	Dedicated facility for Penem Carbapenems (Lyophilized / Dry Powder Inj / Oral Solids / Dual Chamber Bags)	Lyophilized/Powder Injectables Facility Capability to cater to regulated markets such as US & EU
Capacities				
▪ Lyophilized – 1.8 Cr vials p.a. ▪ Ampoule – 1.2Cr p.a. ▪ Ointment – 0.6Cr tubes p.a. ▪ Lotion – 0.6Cr bottles p.a. ▪ Syrup – 0.6Cr bottles p.a. ▪ PFS – 0.28Cr PFS p.a.	▪ Lyophilized – 3.0Cr vials p.a. ▪ PFS – 3.0Cr PFS p.a.	▪ 6.0Cr capsules p.a. ▪ 0.36Cr powder p.a.	▪ Lyophilized – 0.3Cr vials p.a. ▪ Dual Chamber Bags 0.24 Cr IV bags ▪ Dry Powder Inj 3.0Cr Vials	▪ Lyophilized Inj – 5.2 Cr vials p.a. ▪ Liquid Inj (Ampoules) – 6.0Cr p.a. ▪ Liquid Inj (Vials) – 3.0 Cr units p.a.

- With the Indore facility expected to be commissioned by the end 1Q, the capex phase of the company is coming to the end, and it shall concentrate on ramping up volumes from the newly commissioned unit.
- The Indore plant will also help free up capacities at the Navsari plant, which is currently operating at full capacity. Gufic plans to shift a portion of its domestic demand to Indore and cater to export markets (such as Russia, Brazil, Canada, South Africa, and Europe) from the freed-up capacity at Navsari. Gufic intends to start penetrating the US market by the end of 2025.
- The penem block operated at a ~40-50% capacity utilisation in FY24.

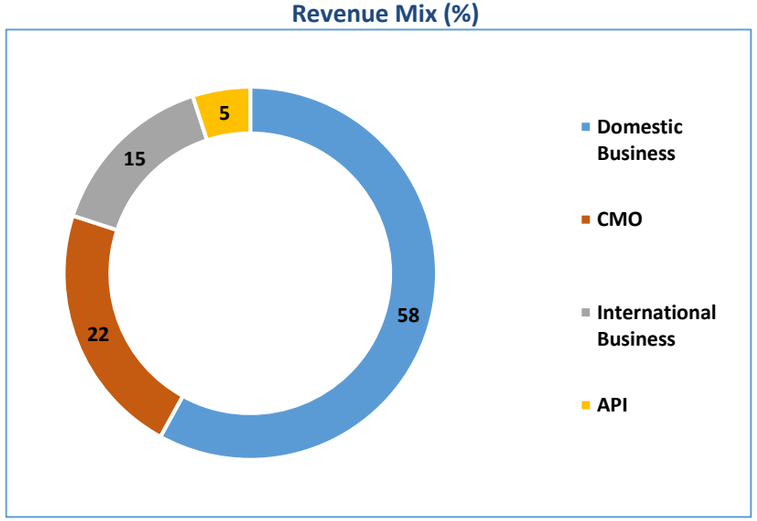


(Source: Company, HDFC sec)

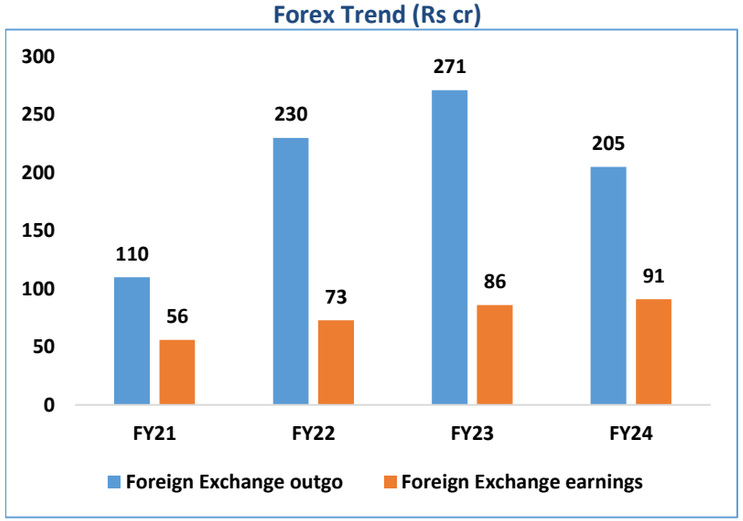
Margin Trend (%)



Revenue Mix (%)



Forex Trend (Rs cr)



(Source: Company, HDFC sec)

Financials

Income Statement

(Rs Cr)	FY23	FY24	FY25E	FY26E	FY27E
Net Revenue	**691**	**807**	**920**	**1094**	**1319**
Growth (%)	-11.4	16.8	14.0	19.0	20.5
Operating Expenses	556	661	757	879	1053
EBITDA	**135**	**146**	**162**	**215**	**266**
Growth (%)	-9.0	8.3	11.2	32.7	23.7
EBITDA Margin (%)	19.5	18.1	17.6	19.7	20.2
Depreciation	22	17	20	25	29
EBIT	112	129	142	190	237
Other Income	3	2	3	3	5
Interest expenses	8	15	20	17	13
PBT	107	116	125	176	229
Tax	27	30	32	45	58
RPAT	**80**	**86**	**93**	**131**	**171**
Growth (%)	-16.8	8.0	7.8	41.4	30.3
EPS	8.2	8.6	9.3	13.1	17.1

Balance Sheet

As at March	FY23	FY24	FY25E	FY26E	FY27E
SOURCE OF FUNDS					
Share Capital	9.7	10.0	10.0	10.0	10.0
Reserves	338	523	611	738	899
Shareholders' Funds	**348**	**533**	**621**	**748**	**909**
Long Term Debt	191	154	176	165	134
Net Deferred Taxes	-1	-1	-1	-1	-1
Long Term Provisions & Others	35	34	42	50	63
Total Source of Funds	**572**	**720**	**838**	**962**	**1105**
APPLICATION OF FUNDS					
Net Block (incl. CWIP)	328	460	531	590	576
Goodwill & Intangible Assets	1	6	6	6	6
Long Term Loans & Advances	67	25	29	34	37
Total Non-Current Assets	**396**	**491**	**565**	**630**	**618**
Current Investments	0	0	0	0	0
Inventories	184	201	227	273	337
Trade Receivables	206	330	360	410	505
Cash & Equivalents	47	13	18	15	50
Other Current Assets	29	57	63	58	60
Total Current Assets	**464**	**601**	**667**	**756**	**951**
Short-Term Borrowings	121	163	168	149	131
Trade Payables	130	166	178	217	263
Other Current Liabs & Provisions	33	38	43	50	61
Short-Term Provisions	4	5	6	7	9
Total Current Liabilities	**288**	**372**	**395**	**424**	**465**
Net Current Assets	176	229	273	332	487
Total Application of Funds	**572**	**720**	**838**	**962**	**1105**

(Source: Company, HDFC sec)

Gufic BioSciences Ltd.

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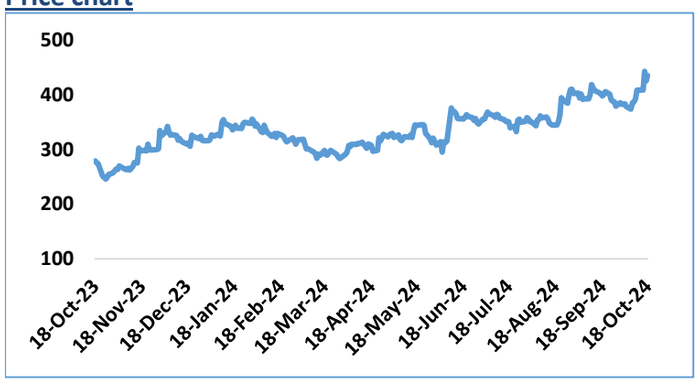
Cash Flow Statement

(Rs Cr)	FY23	FY24	FY25E	FY26E	FY27E
Reported PBT	107	116	125	176	229
Non-operating & EO items	-3	-2	-3	-3	-5
Interest Expenses	8	15	20	17	13
Depreciation	22	17	20	25	29
Working Capital Change	-134	-127	-40	-62	-120
Tax Paid	-28	-27	-32	-45	-58
OPERATING CASH FLOW (a)	**-27**	**-8**	**90**	**109**	**88**
Capex	-188	-108	-90	-85	-15
Free Cash Flow	-214	-116	0	24	73
Investments	-6	3	-4	-5	-3
Non-operating income	3	2	3	3	5
INVESTING CASH FLOW (b)	**-191**	**-103**	**-91**	**-87**	**-12**
Debt Issuance / (Repaid)	244	99	30	-3	-18
Interest Expenses	-8	-15	-20	-17	-13
FCFE	21	-32	10	4	42
Share Capital	0	0	0	0	0
Dividend	-1	-1	-5	-5	-10
FINANCING CASH FLOW (c)	**235**	**83**	**6**	**-24**	**-42**
NET CASH FLOW (a+b+c)	**17**	**-27**	**4**	**-3**	**35**

Price chart



Key Ratios

	FY23	FY24	FY25E	FY26E	FY27E
Profitability (%)					
Gross Margin	52.0	51.7	51.9	53.1	53.0
EBITDA Margin	19.5	18.1	17.6	19.7	20.2
EBIT Margin	16.3	16.0	15.4	17.4	18.0
APAT Margin	11.6	10.7	10.1	12.0	13.0
RoE	25.9	19.6	16.1	19.2	20.7
RoCE	19.6	17.9	16.9	19.7	21.4
Solvency Ratio (x)					
Net Debt/EBITDA	2.0	2.1	2.0	1.4	0.8
D/E	0.9	0.6	0.6	0.4	0.3
Net D/E	1	1	1	0	0
PER SHARE DATA (Rs)					
EPS	8.2	8.6	9.3	13.1	17.1
CEPS	10.5	10.3	11.3	15.6	20.0
BV	36	53	62	75	91
Dividend	0.1	0.1	0.3	0.4	0.8
Turnover Ratios					
Debtor days	109	149	143	137	140
Inventory days	79	87	90	91	93
Creditors days	102	118	110	115	117
VALUATION (x)					
P/E	52.8	50.6	46.9	33.2	25.5
P/BV	12.1	8.2	7.0	5.8	4.8
EV/EBITDA	34.9	32.3	29.0	21.9	17.7
EV/Revenue	6.8	5.8	5.1	4.3	3.6
Dividend Payout (%)	1.2	1.2	2.7	2.7	4.7

(Source: Company, HDFC sec)

Kushal Mahendra Rughani

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HDFC Sec Retail Research Rating description

Green Rating stocks

This rating is given to stocks that represent large and established business having track record of decades and good reputation in the industry. They are industry leaders or have significant market share. They have multiple streams of cash flows and/or strong balance sheet to withstand downturn in economic cycle. These stocks offer moderate returns and at the same time are unlikely to suffer severe drawdown in their stock prices. These stocks can be kept as a part of long term portfolio holding, if so desired. This stocks offer low risk and lower reward and are suitable for beginners. They offer stability to the portfolio.

Yellow Rating stocks

This rating is given to stocks that have strong balance sheet and are from relatively stable industries which are likely to remain relevant for long time and unlikely to be affected much by economic or technological disruptions. These stocks have emerged stronger over time but are yet to reach the level of green rating stocks. They offer medium risk, medium return opportunities. Some of these have the potential to attain green rating over time.

Red Rating stocks

This rating is given to emerging companies which are riskier than their established peers. Their share price tends to be volatile though they offer high growth potential. They are susceptible to severe downturn in their industry or in overall economy. Management of these companies need to prove their mettle in handling cyclicality of their business. If they are successful in navigating challenges, the market rewards their shareholders with handsome gains; otherwise their stock prices can take a severe beating. Overall these stocks offer high risk high return opportunities.

Disclosure:

I, **Kushal Rughani, Research Analyst, MBA**, author and the name subscribed to this report, hereby certify that all of the views expressed in this research report accurately reflect my views about the subject issuer(s) or securities. SEBI conducted the inspection and based on their observations have issued advise/warning. The said observations have been complied with. We also certify that no part of our compensation was, is, or will be directly or indirectly related to the specific recommendation(s) or view(s) in this report.

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