BETA DRUGS

* Beta Drugs is a pharmaceutical company specializing in branded generics in niche oncology therapy. The company is listed on National Stock Exchange’s Emerge platform for small and medium-scale enterprises. One of the Very few(probably only) companies in india which is totally focused on Oncology (Cancer related). The company is amongst the top ten players in the cytotoxic Oncology space.

Company has two main wholly-owned subsidiaries, Adley Formulations Pvt Ltd (AFPL) and Adley Lab Ltd (ADL).

* The company has 2 formulations (Beta drugs plant and Adley formulations plant) & 1 API (Adley Labs ltd) state-of-the-art manufacturing facilities. 15+ accreditations including ANVISA & INVIMA. (Beta Drugs is expecting : • EAEU (Eurasian Economic Union) audit in the month of June’23 • EuGMP audit in the month of December’23.)
* Company has 5 divisions:

**Domestic Own Brand Business** – 33 -> 55 -> 68cr sales over last 3 years.

**International business –** 18.6 -> 21.3 -> 28cr sales over last 3 years.

**API Business** – 7 -> 11 -> 18cr sales over last 3 years.

**CDMO Business** – 58 -> 96 -> 109cr sales over last 3 years

**Dermatology division (New)** – 3cr sales.

(All segments showing great growth)

* 64 products, 112 SKUs. 36 Solid tumor, 18 Haematology, 10 Supportive care.

***KEY INVESTMENT THESIS POINTS:***

* **LONG RUNWAY FOR COMPOUNDING GROWTH:**

**Oncology is the fastest growing pharma segment across the globe**. The number of patients who have been detected by cancer is increasing tremendously. So the scope of this oncology is huge. Cytotoxic plays a very important role in giving a treatment to a patient. The first line therapy, the first line treatment is Cytotoxic only. Beta Drugs is one of the leading manufacturers in India.

Current size of Oncology market is ~4750Cr and market share is 3.75%. Intend to have 14-15% market share. Manufacturing for 10 Indian MNCs. 60-70% of their portfolio is manufactured by Beta. (FY22)

Given the nature of the business and the oncology market, the company can easily keep on growing for the next 10-20 years, giving it a long runway for compounding shareholder wealth.

* **LOW COST PRODUCTION AND PRESENCE ACROSS THE VALUE CHAIN (BACKWARD INTEGRATION):**

BDL is among the few companies that work across the Oncology value chain. Developed API of 37 Oncology products.

**COST LEADERSHIP THROUGH BACKWARD INTEGRATION. Given the fact, that the company operates in a highly competitive generic formulations industry, backward integration becomes a big competitive advantage.** It is also a sustainable and long term advantage.

As company is making its own API, it is a low-cost producer. That helps in applying for low cost tender at cancer hospitals. This helps in increasing hospital network for branded business.

Backward integration has also resulted in increasing margins over the last few years for the company and the prospects of further increase remains.

Management: “So, we are not based on the raw material being procured from outside parties. The strategy is very simple and clear. If the molecule is getting off-patent, the API needs to be developed first, the batches need to be taken for formulations first and then when they are becoming off-patent, it should be launched as the first one to be launched to Indian market”

* **BRILLIANT PAST NUMBERS FOR ALL PARAMETERS (GROWTH, MARGINS, BALANCE SHEET, CASH FLOWS)**
  + **5 YEAR CAGR GROWTH –**

Sales growth – 35%

EBITDA growth – 40%

Net Profit growth – 36%

* + **Consistently High and increasing EBITDA Margins** – 23.35% for FY23, 5-year average - 21.2 %
  + **Consistently High and increasing ROCE (Return on Capital Employed)** – 36% for FY23, 5-year average - 29.2%
  + **NET DEBT FREE COMPANY**
  + **DECENT CASH FLOWS (66% ocf/ebitda, 13% fcf/ebitda).** Company has done 80cr of capex over last 5 years, all funded through internal accruals. Also, company has done filing of registrations and Facility Audits without any capital dilution
* **STRONG SALES GROWTH GUIDANCE ALONG WITH PRESENCE OF MULTIPLE GROWTH DRIVERS:**

**MANAGEMENT GUIDANCE: The company expects revenues to double in the next three years. While EBITDA margins are expected to improve further to be in the range of 25%-26%.**

Management believes that with strong tailwinds coupled with momentum across all its segments; Own Brands, Exports, API, CDMO & Derma, Beta is poised for strong growth for the next many years

**GROWTH DRIVERS**:

* + - **Geographical Expansion**: Company is targeting increasing exports as a big growth driver. The recent approvals of ANVISA & INVIMA will drive strong sales from exports in the next three years. The company has also started registration in many PICS countries.

LatAm - No. of targeted countries: 15 - Total dossiers submission plan in next 2 years: 86.

ASIA - No. of targeted countries: 6 - Total dossiers submission plan in next 2 years: 134

MIDDLE EAST & AFRICA - No. of targeted countries: 11 - Total dossiers submission plan in next 2 years: 127

CIS - No. of targeted countries: 4 - Total dossiers submission plan in next 2 years: 10

* + - **Domestic Branded business**: Newer product launches and Increasing distribution network with Hospitals and doctors. (“So now, in the coming years, our main focus is towards the major cancer treatment institutions, mainly the regional cancer centres, the Tata hospitals and the railways. Already, we have got some go-through with these institutions. We will make our presence felt with our dedicated team, in the coming years.)
    - **API Business**: Geographical expansion: Foraying into the European market • In FY’24 planning to file 5 CEPs • Focus on export in the nonregulated, semi-regulated, and regulated market.

“The other part of the API business where we want to expand is the direct marketing, whether it is in the terms of domestic market or it is in the term of exports. So, we have already started communicating with 12 of the countries, where we want to export our business, export our APIs also.”

* + - **CDMO Business**: CDMO business will grow as per Onco market growth. It’s a stable business.

Company has a well established CDMO business having built long term relationships with many top domestic and international customers.

*EXPORTS,DOMESTIC BRANDED, AND API SALES* are the 3 main future growth drivers.

* **INCREASING MARGINS. HIGHER MARGIN SEGMENTS TO DRIVE FUTURE PROFIT GROWTH :**

Company margins have been increasing due to rise in sales of higher-margin products (Own brands, Exports and API’s)

EBITDA margins: 18-19% in CRAMS. 30-31% in own brands. 27-30% in Exports. 24-26% in APIs

**Given that most of the future growth will come from the higher margin segments, along with more complex product launches and vertical integration and lower contribution from CDMO, Margins have a high chance of increasing and There is a good chance of disproportionate profit growth.**

* **STRONG PRODUCT DEVELOPMENT PIPELINE AND RECORD**

Company’s record has been very strong in terms of development and product launches.

* + 22 new products launched in last 4 years. 12 First few to launch (FFTL) products in last 4 years.
  + 22 New products in the pipeline. 8 New brands to be launched in FY24. 7 each in fy25 and 26.
  + API Division: Developed API of 37 Products. 10 New products developed in FY’23. BDL is among very few companies to develop API of Carfilzomib, Cabozantinib, Afatinib, Pazopanib & Rucaparib

Company will be undertaking more complex products over the next years. The company has a strong product pipeline of FTLs, NDDS, PARP inhibitors, and TKIs which will be launched in the coming months & years. (For note on NDDS and other products, see MISCELLANEOUS)

“This year, we are launching four new products. Those will be the first to launch in India, plus we are in the process of developing four NDDS products. These products will be launched by December end. So these NDDS technologies, what we have developed in-house, will drive the future growth for the domestic market.”

* **CAPACITY EXPANSION COMPLETED FROM INTERNAL ACCRUALS:**

Company has expanded capacities in a big to fuel future growth and back up the growth drivers of Export, branded and API sales. All done through internal accruals.

**BDL plant:** The overall addition is mainly in the injectable side, where the company has increased lyophilized injectable capacity to 3x

**Adley formulations plant:** Company has added more machinery in the oral block to enhance further production capacity. There is one entirely new dedicated line for injectables, which has been added with two new lyophilizers keeping in mind, the domestic market. This capacity has further increased the production 3x to 4x.

**API business.** We have expanded our production capacity 3x

**No major capex will be required in next two years to three years to achieve the 2x top line revenue guidance.**

**YOUNG, AMBITIOUS AND PRO-ACTIVE MANAGEMENT**

The company’s management is very young and has executed everything quite brilliantly over the last 7-8 years.

All answers in the concalls as well have been very good and precise. Also, the management has always delivered on stated guidance and strategies.

MD Rahul Batra is 39, Joint MD Varun Batra is 37 years old.

“Risk or the speed bump, we can only see if we guys become reluctant and we become lazy. So, as of today, I myself am 39 years old. Varun is 37 years old. Mr. Ashutosh who is driving sales and marketing is 44 years old. And Nipun who is the CFO is around 39 years old. So, we are actually a very young company. And to be very honest, we start working till 8pm, 9pm in the night. And we don't feel ourselves reluctant.”

**Management is also very pro-active in taking measures against headwinds.**

“Risk factors in terms of business, we have covered entirely. We were experiencing some risk factors 2 years 3 years back when the intermediate supplies were stopped from China, when the API was not coming on time. Then immediately we put a stop hold and we increased our API capacity also. Now, we have almost covered our risk points. But tomorrow, we don't think there is any point of stretch where we see that can be a major hurdle for us.”

“We used to source around 40%, 50% of our KSMs from China only for our API plant, but now we have reduced that also, and we brought it down to 30%-35%.”

Also, for SME Emerge company to be so thorough in everything, from presentations to concalls, is quite commendable.

**MISCELLANEOUS**:

* **Foraying into Cosmetic Dermatology**: First to launch product - Signed CDA with an European company to bring First to launch product in Indian dermatology market.

Future Plan: Plan to establish new manufacturing facility of Cosmetic Dermatology products in next 2 years

“Dermatology, we entered nine months back. Today, we are at a verge, almost at a verge of getting into the break-even. We have got a good team, good professional team, who has started this dermatology. There are total product of around 12 products, which we are marketing currently. Out of that, one niche product which we have launched that is hair growth serum, on the name of ReCapro. We intend to make this Recapro, as one of the leading brand in India in coming years, down the line.”

* **Ashish Khacholia holds 5.78% stake in the company. A big re-assurance of faith in an SME Emerge company.**
* **Additional information on future product pipeline:** Certain R&D activities that the company is engaged in, can result in massive transformation. Company is projecting launch of new products in the areas of NDDS, PARP, TKI & FTI from 2023-24 onwards. How can these innovations transform the company and its fortune together with that of early investors? For this, we need to understand what these products are and what the impact would be on the company’s revenue.

NDDS (Novel Drug Delivery System): Company is working on developing new mechanisms for precise and targeted delivery & controlled release of cancer drugs to affected tissues & cells. Successful NDDS will catapult the company to the big league. It can be 100 times or much, more

PARP Inhibitors: PARP (poly adenosine diphosphate-ribose polymerase) is a type of enzyme in human body which repairs damages to DNA in cells. PARP inhibitors stops the enzyme from repairing damage caused to cancer cells by drugs, resulting in their death

TKIs (Tyrosine Kinase Inhibitors): TKs are enzymes which promote cell growth and division. In certain tumorous cancers, it would be necessary to control these enzymes to prevent them from helping cancer cells grow. TKIs does the precise function of inhibiting their activity

FTIs (Farnesyl Transferase Inhibitors): In simple terms, a protein named RAs has been found to be abnormally active in cancer cells. It is found that by inhibiting protein Farnesyltransferase, the abnormality of RAs can be controlled. FTIs does the inhibition work

If the company can produce the inhibitor drugs with very high quality & offer at better pricing, it can bring in, sizeable revenue This is apart from the tremendous potential of NDDS.

“we are also working aggressively from last one and a half year towards a new drug delivery system, exclusively in the cytotoxic range, out of which, three molecules or four molecules will be launched by this year end. There has been a continuous development going on towards achieving on delivering the new and innovative delivery systems”

**A small company taking up the challenge of developing NDDS and the other drugs is no small matter. It shows Beta Drugs has the scientific talent pool, labs, process knowledge, cash and above all the dream to make this extraordinary effort.**

One of the few Indian companies who have successfully developed & commercialized Nanoparticle –Albumin–Bound Paclitaxel, Ready to use Docetaxel & Gemcitabine.

* The domestic market will be catered from Adley formulations and Beta plant will be dedicated to regulated markets.
* Onco products are less in quantity and more costly
* BRANDED BUSINESS

=Hospital network

=Doctors prescription

* By reading Natco’s and Beta Drug’s concalls, it seems that the **established doctor and hospital network is another moat for Beta Drugs**. A question was asked regarding Natco losing market share in the oncology segment. The answer given was high competition and lack of reach in the doctor-hospital network for oncology. Beta Drugs, on the other side, seems to have a presence in most corporate hospitals and is building a presence in railway hospitals
* R&D: Have 5 scientists. Innovator molecules are given to them and these are then developed by them over an average 6-8 months.

KEY RISKS:

1) **High levels of competition** : The generic formulations and API industry is a highly competitive one.

**(**Low cost production due to backward integration, Increasing presence of branded products, increasing complexity of products to mitigate adverse effects of competition )

2) **Exposure to regulatory risks and raw material price volatility:** The pharmaceutical industry is closely monitored and regulated, and there are inherent risks and liabilities associated with the products and their manufacturing. The contract manufacturing market is highly competitive and hence players have limited bargaining power. Furthermore, prices of key raw materials (active pharmaceuticals ingredients) are volatile. Therefore, susceptibility to risks related to variations in commodity prices persists.

(Vertical integration in almost all formulation products help offset this risk)

3**) Fairly valued:** At current valuations, the company is fairly valued with no margin of safety.

4**) Execution risk**: It’s the one unavoidable risk in all companies. (Previous history of great execution offers comfort against this)

Q4FY23:

* Beta consolidated revenues from operations for FY23 jumped by 24% to Rs. 227.11 crores from Rs. 183.84 crores compared with the same period a year ago. This increase was mainly due to **31% growth in Exports** and **24% growth in Own Brand sales**. While **API sales to third parties grew by 65%, CDMO grew by 13%.**
* EBITDA excluding Derma impact increased by 28% to Rs.55.92 crores from Rs. 43.7 crores compared with the year-ago period. While EBITDA margin expanded to 25.04% from 23.8%. **Improvement in EBITDA was on account of higher sales of branded products and exports along with the positive impact of backward integration**. However, considering the impact on Derma’s business the consolidated EBITA stood at Rs 53.88 crores.
* The company is now among the top ten players in the cytotoxic Oncology space and aims to be among top five players in the next three years.
* The dermatology division of the company will also grow at a good pace and will be EBITDA positive in the coming 3-4 months.
* **We have already initiated the business development activities and have signed our agreements with most of the clients in different countries. We have started filing the dossier and most importantly, the good number of dossier will be filed in the next coming months.** We expect to file our doses for injectables in the next two months. Our regulatory team has been, there are a lot of people, who have been added in the regulatory team and they are aligned and focused toward doing the filings ASAP.
* We have filed around 77 dossiers in last year and this year, **we plan to file close to 150 dossiers in all these countries.**
* In export markets, **it's easier to get injectables registered as orals take more time to get registered**.
* The guidance is safe. The EBITDA margins will remain close to 25% to 26% once we achieve these targets. It can go up further also, but this is what the bare minimum we are targeting.
* Colombia INVIMA: So, today as we are talking, we have already put around eight dossiers for submission and we are expecting around four dossiers registration within next 10 days to 15 days. So till now, we have not done any sales in Colombia, but the sales will happen in the month of, we are expecting in the month of June.
* In Mexico we already have a client. In Colombia we already have a partner. Almost in 12-15 Latin American countries we have a partner. We have already done the business development activity. We have already finalized our partners there
* **Modest scale of operations amid intense competition**

Intense competition will continue to constrain scalability, with revenue expected at Rs 230-235 crore in fiscal 2023, despite growing by 25% from Rs 183 crore in fiscal 2022. Revenue will improve over the medium term backed by launch of new products, demand prospects of oncology drugs and expansion in the export market, and will remain a key monitorable in the near term.

* **Exposure to regulatory risks and raw material price volatility**

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* If we’re trying to find moats in pharma, we need to look in 2 places - manufacturing and sales. Manufacturing moats could be a unique product (preferably patented), unique process (complex or patent protected), or cost advantage (lowest cost producer).

Sales moat is mainly some sort of exclusive arrangement to supply, possibly through regulatory restrictions. Or it could be brand value, especially in OTC drugs.

The kind of business Beta Drugs is in, there is intense competition. Their product portfolio is non-exclusive. They do have some unique products, but they aren’t blockbuster. In my opinion their success will depend on how aggressive they are with sales. This is the unfortunate truth of most formulation companies in India.

* “The CRAM business we right now have established ourselves very well in the Indian market. Any company who wants to launch oncology, supposing tomorrow mankind wants to launch oncology. They will approach us. They have already approached us and now we have a base in clients as Intas, Zydus, Cadila, RPG, Alchem, Torrent, Panacea, Hetero, Reliance and Caplin Point.
* Derma- Currently, they are buying from 3rd parties and selling under their brand.

If the business does well, they will look at making it themselves.