



*Annual Communique*

**2023**

**From the Chairman's Desk**



*Mr. Rahul Bishnoi  
Chairman, Medicamen Biotech Ltd*

*Spent Rs 45 cr for upgradation of production and meet global standards*

*Rs 75 crore – FDA USA compliant Oncology plant – operational from January 2022*

*150 SKUs across 20 therapeutic segments*

*80% - Direct Exports*

*Focus on product registrations in new markets*

My Dear Shareholders,

Let me take the privilege to wish everyone a very happy, healthy and a prosperous year 2023 ahead. We have come a long way since we came on the Board of Medicamen in 2016. We are working harder than ever since to grow your company and to make it a highly progressive Pharma Company.

It gives me great satisfaction to communicate with you on the very first day of 2023. I would like to take this opportunity to update you on the work done so far and would also like to share the vision of the Management about your company.

First and foremost, I would like to discuss about the upgradations, improvement in plants, improvement in processes and QA so as to make Medicamen's products acceptable by stringent regulatory authorities (SRA).

The challenge after taking over Medicamen was to strengthen its foundation to achieve our vision. We started investing in upgradation of plants and till date have invested Rs.45 crores from internal accruals in the following upgradation efforts (detailed provided at end in Annexure 1):

- **Upgradation of Oral Solid Block / Liquid Block**
- **Upgradation of Quality Control Laboratory**
- **Upgradation of Raw Materials & Finished Goods storage**
- **Upgradation of Haridwar Unit 1** to meet requirements of WHO-GMP.

Since the vision of the new Management was to make an impact in the pharmaceutical domain, this investment was essential to achieve data integrity objectives and adhere to the norms of stringent regulatory authorities like EU and PICS.

We perceive that Oncology has become one of the most crucial segments in the healthcare industry. Your Management decided to setup a dedicated Oncology plant with an investment of Rs.75 crores to manufacture Tablets, Capsules and Injectable RTU including Lyophilized. The plant was delayed due to Covid. However, we have worked overtime and made the plant operational from January 2022.

The current revenue of Medicamen comes from 150 SKUs across 20 different therapeutic segments. Out of the total revenue, 80% comes from Direct Exports and 20% from Merchant Exports. The majority of the revenue is from Africa, Latin America and Southeast Asia.

Henceforth the focus of the management will be on product registration in various territories and on marketing of its products in domestic, Rest of the World (ROW) and regulated markets.

***Targets 100 branded products in each of the 10 Francophone countries (Total 1000).***

***Expecting 200 product registrations in next 6 months***

***Ethiopia – to file 100 product registrations in next 12 months***

***Oncology – new products launched with 30 senior executives in 4 zones; Global roll out plans***

***To file first ANDA with USFDA for Bortezomib Injection***

***Bhiwadi Plant – audited by EU authorities – implementing minor suggestions***

***Collaboration with Vital Pharma of Denmark***

***ANVISA approval for Bhiwadi plant***

***Eying some share of lucrative Rs.56000 crores CVD market in India through its subsidiary Medicamen Life Sciences Pvt Ltd – 33 products launched***

It gives me pleasure to inform you that management has plans to market 100 branded products in each of the 10 Francophone Countries making a total 1000 product registrations targeted in the next two years. The company has started receiving product registrations and is hopeful to get approximately 200 product registrations in the next six months out of these 1000 targeted product registrations. The management expects to generate decent revenue starting next financial year from this market.

Currently the company is having 21 product registrations and it plans to file 100 product dossiers in Ethiopia in the next twelve months, since Ethiopia is a big and established market for Medicamen.

In the oncology domain, Medicamen has launched its oncology products in the domestic market during this financial year with a team of 30 senior experienced executives in four zones. Medicamen shall file its first ever ANDA with USFDA for Bortezomib Injection. Medicamen has firm plans & investments for global roll out of its oncology products, including in USA, Europe, Latin America, Asia Pacific, MENA, Etc through a combination of its own team and alliance partners.

I would like to place on record that the Bhiwadi plant was audited by EU authorities and no critical deficiency was reported, however there were some minor suggestions given by them. Likewise, the USFDA audit for the oncology plant unit-2 would trigger once we submit ANDA in the month of April 2023.

Your company has collaborated with Vital Pharma of Denmark for Marketing of Clonidine 25mcg & 150 mcg and Paracetamol 665 SR for Arthritis for Europe market. The dossiers for Clonidine tablets are ready however the bioequivalence for Paracetamol 665 SR is under way. Both the dossiers shall be filled once Medicamen gets EU approval for its plant.

Recently Medicamen has received ANVISA approval for its Liquid Oral Line, Capsules and PFS for Bhiwadi Plant. The process of submission of product registration is in progress.

India's domestic pharma market has a potential of Rs 1.75 lakh crores. It was one of the objectives of the Management to target a small share out of this big size. Out of total domestic pharma market, Cardio-vascular therapeutics contribute the maximum share to the tune of Rs 56,000 crores growing at a CAGR of 11%. To attain this objective Medicamen has formed a subsidiary Medicamen Life Sciences Pvt Ltd., with 51% holding and has entered the domestic market to offer Cardio-vascular & Diabetes (CVD) formulations for Indian market.

Medicamen has launched 33 products of CVD in India and many more products are in the pipeline.

Despite what we have accomplished, we are clear that we need to work even harder to achieve bigger goals.

I can assure you that Medicamen is on the fast track now. All the investments made so far will start generating revenues in the next financial year. We remain optimistic in our journey of exploring possibilities while envisioning growth. We are confident of translating our determined efforts into a progressive performance.

We remain thankful to the trust bestowed upon us and look forward to your continued support. Once again, I wish a happy and prosperous new year to all of you.

With warm regards

Rahul Bishnoi

## Annexure 1

### Details of the upgradation

#### **UPGRATION OF ORAL SOLID BLOCK/LIQUID BLOCK**

- Revamped completely general tablet, capsule and PFS blocks to accommodate two granulation lines with 600 litre RMG capacities and other with 250 litre RMG forming two different manufacturing suits, installed new automatic capsule filling machine, a new automatic filling line for PFS, automatic 60 inches' auto coater, two new blister machines, increased AHU from 40 to 72 in numbers in different blocks, two new air compressors with 200 CFM capacity.
- Two new automatic fabrication and filling lines installed for 2500 litre each thereby increasing capacity from existing 1000 Litre to 5000 Litre.
- Completely revamped the whole Beta Lactum Block having manufacturing facility for tablet, capsule and PFS by doubling the capacity to 50,000 bottles per shift. The entire Beta Lactum block is adhering to WHO pre-qualification standard.
- The total upgradation of the solid/liquid/Beta Lactum costed Rs.20 crores.
- Built a dedicated new block for manufacturing of Iron Folic Acid tablet in 10,000 sq. ft. area having a capacity to manufacture 6 million tablets per day by investing Rs.7 crores.

#### **UPGRATION OF QUALITY CONTROL LABORATORY**

- The total area of Lab increased by 2000 sq. ft., more.
- Added new HPLC's from Shimadzu, Japan / waters Inc, USA, to increase the number from 4 to 11.
- New Gas Chromatography (GC) installed.
- New FTIR and UV from PerkinElmer installed.
- New automatic Absorption System (ASS) installed from Agilent.
- Whole of the Microbiology Lab has been revamped to meet stringent norms.
- All the equipment's in the Lab and documentation have been linked to Lab Information Management System (LIMS) to achieve data integrity.
- The total investment in upgradation of lab is Rs.5 crores.

#### **UPGRATION OF RM & FG STORGE**

- Medicamen has built a new 32,000 sq. ft., Finished Goods storage area with complete temperature control through data logger.
- Complete upgradation of the raw material/packing material storage putting each and every item on ERP along with the identification/location of each RM/PM item. A separate testing Laboratory for packing material is established.
- The total investment in upgradation of storage is Rs.6 crores.

#### **UPGRATION OF HARIDWAR UNIT-1**

- This plant has been upgraded from Schedule-M standard to meet the requirement of WHO-GMP by investing Rs.7 crores. The plant has been approved by Ethiopian EFDA recently. And is also WHO GMP certified
- This plant will cater to the domestic as well as ROW market for Exports.