# Management Discussion and Analysis



## Economic overview

### Global economy

The year under review witnessed rising trade tensions across several major economies and imbalances caused by geopolitical forces. It also faced unrestrained deficit spending in the developed world as well as low rates of growth in all the major economies. As a result, the second-half of the year moved steadily towards a slowdown.

In this scenario, the COVID-19 outbreak and pandemic dealt a major blow to the system, affecting populations around the world. Markets and economies came to a standstill as countries were forced to respond with lockdowns over extended periods of time in order to flatten the infection curve and reduce the risk of transmission, while grappling with the fallout of overburdened health infrastructure. Thus, economic growth for 2020 and 2021 has come under severe risk as nations try to recover from the impact of the pandemic.

The lockdown has hit discretionary spending. It has also resulted in loss of work opportunities which has impacted consumer confidence and overall stability.

The demand for goods and services continues to drop globally, the impact of which has been felt across almost all sectors. China, which is a key link in the global supply chains and heavily impacted by the pandemic is making efforts to revive its manufacturing. Simultaneously, major economies are trying to review the current situation, with a view to de-risk these supply chains from being localised in one single country.

## GDP growth rates



| | Projections (%) | | |
|---|---|---|---|
| Region | 2019 | 2020 | 2021 |
| World output | 2.9 | -3.0 | 5.8 |
| United States | 2.3 | -5.9 | 4.7 |
| China | 6.1 | 1.2 | 9.2 |
| India | 4.2 | 1.9 | 7.4 |
| Japan | 0.7 | -5.2 | 3.0 |
| Europe region (includes Germany, France, Italy, Spain) | 1.2 | -7.5 | 4.7 |

(Source – World Economic Outlook, April 2020 by International Monetary Fund (IMF))

The global economy is projected to contract sharply by 3% in 2020, majorly an after-effect of the COVID-19 pandemic. If the forecasts turn out to be true, the scenario would be more concerning than during the 2008–09 financial crisis.

As per IMF's World Economic Outlook revision post COVID-19 pandemic in April, 2020, the projected world output growth of 5.8% in 2021 would be possible if industrial operations resume with gradual normalisation of economic activities, along with policy support aided further by international, multi-lateral cooperation by governments across the globe.

(Source – KPMG, March 19, 2020; Franklin Templeton – Global Investment Outlook; IMF report on global economy)

### Indian economy

During FY 2019-20, the Indian economy went through a downturn largely due to low rate of growth of rural income, a fall in domestic demand and the unavailability of affordable credit from Non-Bank Financial Companies (NBFCs).

While the government took steps to support the underperforming sectors, particularly NBFC and manufacturing, the drop in private investment could not be compensated for. As a result, the economy witnessed a stark fall in manufacturing and construction and private investment slackened. Thus, GDP continued to fall. However, signs of recovery marked the beginning of the fourth quarter after the government led with some bold fiscal measures. That is when the COVID-19 outbreak took place and the pandemic gripped the Indian economy.

India declared nationwide lockdown on 25th March, 2020, which while necessary to control the transmission of the virus and prepare systems for providing support to citizens, also brought to a halt 70% of industrial activity and discretionary consumption. This has severely impacted cashflows across sectors while plunging smaller businesses into a fight for survival.

Adding to these existing problems, there has been a continued weakness in the rupee amid negative consequence of lower remittances from the Middle East, a result of the fall in crude oil prices. The IMF, as a result in April 2020, slashed India's expected growth rate for FY 2020-21 to 1.9% as against 5.6% earlier. Simultaneously, rising healthcare costs and concerns will have to be factored into any planning for recovery. With a spotlight shone on the global pharma industry due to the pandemic, the unique positioning and inherent strengths of the Indian pharma industry have also been brought to light. (Source: KPMG, Potential impact of COVID-19 on the Indian economy, ET, Business Line).

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## Global pharmaceutical market review

Global spending on medicine has increased steadily at a 10-year CAGR of 4.2% from 2009 to 2019, reaching $955 billion in 2019. This growth is expected to exceed $1.1 trillion by 2024, driven by the increased use of specialty and innovative drugs and formulations reaching the market.

Specialty medicines account for 36% of global spending, with projections to touch 40% by 2024. New product growth too is projected to contribute $165 billion over the next five years, up from $126 billion. The rise in global pharmaceutical spending would be due to increased usage and because of changes in the specialty and innovative product composition of new brands coming up in the market. However, factors countering this growth may include, to an extent, overall pricing pressures and patent expiry in the developed markets.

While the developed markets currently include 10 countries with pharmaceutical spending greater than $10 billion, namely the US, Japan, Germany, France, Italy, Spain, the UK, Canada, South Korea and Australia, pharmerging markets include countries with per capita income below $30,000 per year and five-year absolute growth in pharmaceutical spending greater than $1 billion. India, China, Russia, South Africa, Saudi Arabia, Thailand, Turkey and Vietnam are key phamerging markets, among others.

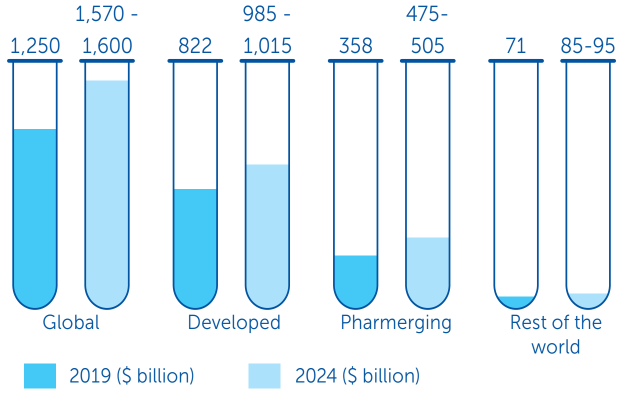


The pharmerging market is expected to reach $345 billion by 2024, and this would be majorly driven by expansion in market accessibility, leading to usage in greater volumes and adoption of more specialty medicines. The developed markets are likely to reach a market size of $695 billion by 2024, supported by pricing and market access controls.

| Markets | 2014-2019 CAGR | 2020-2024 CAGR |
|---|---|---|
| Global | 4.7% | 3-6% |
| Developed | 3.8% | 2-5% |
| Pharmerging | 7.0% | 5-8% |
| Rest of the world | 4.8% | 2-5% |

(Source: IQVIA Institute, Mar 2020 - Global Medicine Spending and Usage Trends)

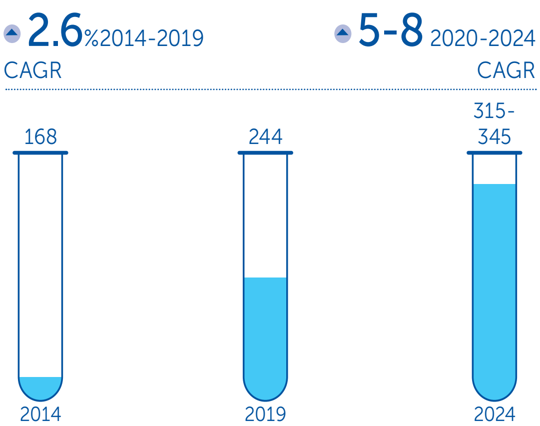
### Global pharmaceutical market growth




### US

The US continues to be the largest pharmaceutical market, capturing ~41% of global pharmaceutical spending. It also dominates pharmaceutical trends, both in consumption and development. During the period from 2014 to 2019, the US has recorded CAGR of ~4% in its spending on medicines. According to estimates, prescription drug spending stood at $500 billion in 2019. The probability of this touching $600 billion by 2023 is high. Despite it being a mature market for years, the US pharmaceutical industry is still ranked fourth in the overall growth potential, trailing high-growth emerging markets like China, India and Germany.


## Growth of pharmerging market ($ billion)




(Source: IQVIA Market Prognosis, Sep 2019; IQVIA Institute, Dec 2019)

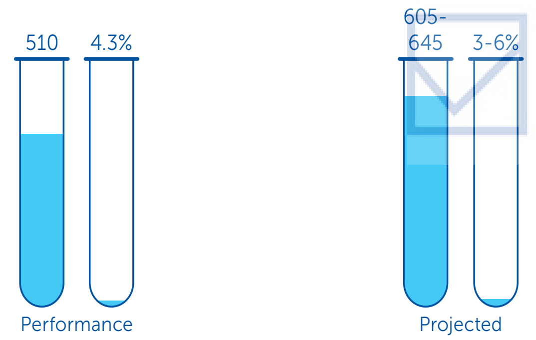
### Outlook

Among the different sections of pharmaceutical industry, pharmerging seems to be the most promising because of the expected growth rate of 5-8% CAGR till 2024, much higher than the developed markets. By 2024, ~31% of global pharmaceutical spending is expected to come from these markets.

A major driver of demand will be the consumption of branded generics and pure generic medicines. Higher volumes will aid this growth. Positive trends include acceptance of newly introduced medicines even as high costs may restrict growth in volumes.

Countries like India, China and Brazil have huge pharma spending. With all three nations focusing on improving their healthcare facilities, pharmerging markets will continue to witness increased spending.

## Growth of US pharmaceutical industry ($ billion)




(Source: IQVIA Market Prognosis, September 2019; IQVIA Institute, December 2019)

### Outlook

The US pharmaceutical market is expected to touch $645 billion by the end of 2024, growing at a CAGR of 3-6%. The development and launch of new innovative specialty drugs for oncology and some other niche treatments are being considered as the major drivers of growth, some of which might be offset by the expiry of a few major patents.

### Pharmerging markets

Pharmerging markets have seen the greatest growth, with a 12.2% CAGR between 2009 and 2014 and 7.7% CAGR between 2014 and 2019. In 2019, pharmerging markets comprised 26% of spending, which is expected to rise to 28-30% of that in 2024. Most of this growth has been driven by expansion of access to drugs and healthcare, leading to greater volume use and increasing adoption of novel therapies. This is expected to lead to rise in consumption of specialty medicines.

## India

India commands a strong position in the global pharmaceuticals sector. Being the largest manufacturer of generic drugs globally, catering to ~40% of the demand for generic medicines in the US and 25% of all medicinal requirements in the UK. Indian pharmaceutical sector meets more than 50% of the world's demand for vaccines.

Indian pharmaceuticals domestic market sales reached $20.03 billion in 2019, from $18.12 billion in 2018, a growth of 9.8%. India's pharmaceutical exports stood at $13.69 billion in FY 2019-20 (up to January 2020). By 2020, these are expected to touch $100 billion, whereas the medical device market is expected to be valued at $25 billion.

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The Indian government has been proactive in encouraging the pharmaceuticals sector. It accounted for allocation of ₹650.12 billion under the Union Budget 2020-21 by the Ministry of Health and Family Welfare, boosting the confidence of the industry. The government also unveiled the 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacturing.

Focus is on the speedy introduction of generic drugs into the market, which will greatly benefit the Indian pharmaceutical companies. Also, the time required for approval of new facilities stands reduced, which will help to boost investments. Pharmaceutical companies are also encouraged by the strong focus on rural health programmes, life-saving drugs and preventive vaccines. Medicine spending in India is projected to grow 9-12% over the next five years, which would make India count among the top 10 countries in terms of medicine spending.

(Source: IBEF)

## Business overview

NATCO Pharma Ltd. is a vertically integrated and R&D focused enterprise, engaged in developing, manufacturing and marketing FDF and active pharmaceutical ingredients (APIs) and intermediates. The Company has also initiated plans to diversify into niche agrichemical business.



The Company focuses on niche therapeutics areas and complex products, which gives it a unique positioning in the market, spread over 40 countries. It sells FDF products in the US, India, Europe and Rest of the World (RoW); with substantial clientele in Canada and Brazil as well. It holds a leading market share in the domestic oncology segment.

In India, NATCO sells its products through its own salesforce and branding whereas, in the US and RoW markets, business is done through local partnerships or subsidiaries. The Company's pharma segment has eight manufacturing facilities, which include six FDF and two API facilities that offer several advantages and help to optimise costs.

**₹20,224 million**
Total revenue

**₹4,608 million***
Profit after tax

*Attributable to owners of the company

FY 2019-20 has witnessed significant improvement in the cardiology and diabetology product segments with sales doubling against those recorded in FY 2018-19. Regarding RoW markets, Canada and Brazil, the Company has done much better than expected and has higher growth prospects going forward. It is also looking at further expansion in markets like Singapore, Vietnam, Thailand, Taiwan, and more.

The Company is applying its technical expertise and scientific knowhow in organic chemistry into agrichemicals business. It has been aggressively investing in setting up the technical as well as the formulation facilities and operations are expected to begin from the second half of FY 2020-21.

NATCO's growth is backed by strong fundamentals. Despite a challenging year in FY 2019-20, the Company is confident of growing well in FY 2020-21 and beyond.

### Business segments

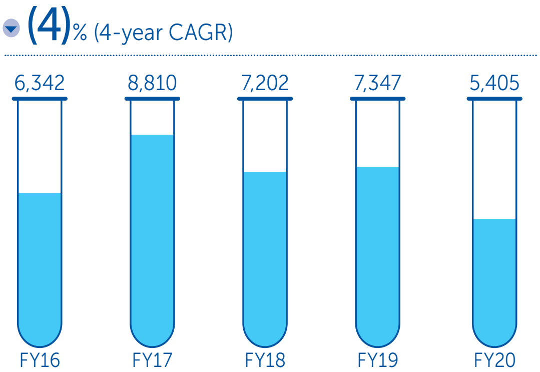
NATCO operates in two business categories, FDF and APIs. Its formulations business caters to international markets, with key focus on the US and Europe while increasing foothold in Brazil and Canada, and domestic markets, with products in oncology, pharma specialties and cardiology and diabetology (CnD). NATCO's API business leverages its unique capabilities that include multi-step synthesis, semi-synthetic fusion technologies, high-potency APIs and peptides. NATCO is also into contract manufacturing. The Company is leveraging its expertise in organic chemistry to drive its foray into agrichemicals to help improve crop health.

#### Domestic formulations

NATCO has a strong domestic formulations business led by its presence in the oncology segment and a strong portfolio of products in its non-Oncology segment including Hepatitis C portfolio products. The Company made significant progress in its cardiology and diabetology segment through the launch of five niche products during the year. Overall, during FY 2019-20, the Company launched eight products across the three key business segments. Oncology as well as the pharma speciality business faced downward revenue trends in FY 2019-20 on account of tepid demand. Despite the challenges, the Company was able to launch products catering to different therapies and segments. NATCO has established its presence in all three business segments and is geared up to launch 8-10 products every year across all its segments in the near future.

During the year, NATCO's domestic business faced multiple macro headwinds, including channel pricing controls for the oncology products and continued decline in the patient pool for the acute disease caused by Hepatitis-C leading to a decline in our pharma specialty segment. Lastly, there was COVID-19-related business decline during the fourth quarter of the year.

### Domestic FDF sales (₹ in million)

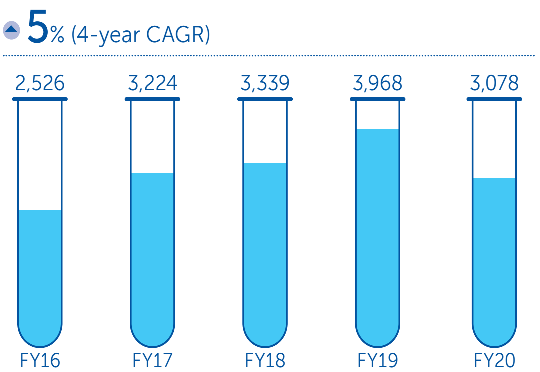



### Oncology

NATCO's product portfolio is among the most extensive in the Indian oncology market, with 33 active products as on 31st March, 2020, During the year, the Company launched three products with several more launches expected in the future. The company has 10 brands which have recorded sales over ₹100 million during FY 2019-20.

The oncology segment is core to NATCO's base business and is expected to continue its growth trajectory over the next several years. The Company's revenues from this business segment fell from ₹3,968 million in FY 2018-19 to ₹3,078 million in FY 2019-20, primarily due to certain macro pressures. These include new pricing controls by National Pharmaceutical Pricing Authority (NPPA), which impacted the margin along the sales channels and the pressures surrounding COVID-19 during the fourth quarter. We expect to regain growth momentum for the segment going forward.

### Oncology sales (₹ in million)




### Non-Oncology business

This comprises of products from our pharma specialty and C&D divisions apart from third party manufactured products. The Company's revenues from the non-oncology business fell from ₹3,379 million in FY-2018-19 to ₹2,327 million in FY 2019-20.

**Pharma Specialties**

NATCO has 18 active products in its pharma specialities portfolio that caters largely to gastroenterology, hepatology, orthopaedics, neurology and critical care. The gastroenterology range deals with the novel drugs for chronic Hepatitis-B and Hepatitis-C and the orthopaedics range covers all the important bisphosphonates, including the oral and injectable ones.

Over 90% of the business in this segment is contributed by the Hep-C portfolio products. The primary reason for the decline in the Hep-C portfolio is the shrinkage of the market size as more patients got treated from this acute disease. We have an interesting list of gastro-hepatology products to be launched in the ensuing years.

**Cardiology and diabetology**

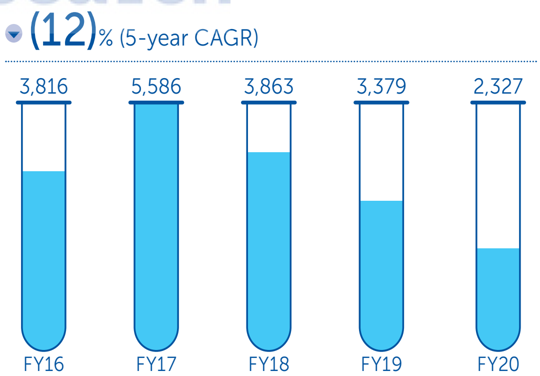
Since its launch in 2017, NATCO has gradually built the portfolio of products in the segment but FY 2019-20 was a defining year with the launch of five notable products. Of these, Vildagliptin was the first to launch after the innovator in spite of a plethora of competitors.

**Third Party manufacturing**

Contract manufacturing of products for third party companies is the revenue component for this segment.



### Non-Oncology revenue* (₹ in million)




*includes third party

# Management Discussion and Analysis

The segment grew exponentially in revenue terms, garnering ₹150 million during FY 2019-20 as compared to ₹70 million during the previous year. NATCO is working to develop a pipeline of products, which will help to distinguish the Company's products from those of its competitors.

### International formulations

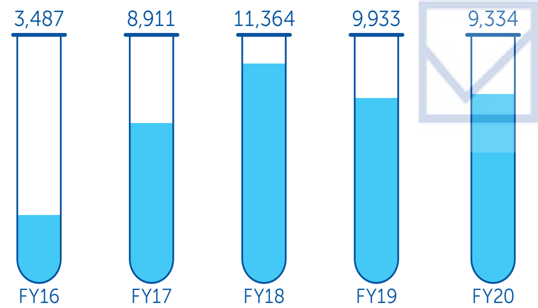
It's been more than a decade that NATCO established a presence in the US and other international markets. In the US, it follows a partnership-driven business model, wherein, NATCO brings the manufacturing strength and know-how while its partner brings the marketing strength. In Canada, Singapore and Brazil, NATCO functions through its subsidiaries.

During FY 2019-20, the Company's revenue from international business stood at ₹9,334 million, as compared to ₹9,933 million in FY 2018-19. Of this, earnings from exports from India stood at ₹8,249 million, whereas subsidiaries contributed ₹1,085 million of net revenue.

### International formulations

(₹ in million)

28% (5-year CAGR)




### US

The exports (including FDFs and APIs) to the US clocked revenue of ₹7,834 million in FY 2019-20. NATCO is positioned strongly in its business in the US, which is primarily driven by the continued growth of revenue coming from Glatiramer Acetate and Liposomal Doxorubicin. The revenues from Oseltamivir continue to be appreciable in spite of competition and the launch of the product over three years ago. During the year, the Company filed for four niche ANDAs with several others in the pipeline.

All NATCO's manufacturing facilities which cater for the US business continue to be in good standing from USFDA. NATCO's Vizag facility, which is part of an SEZ for the export market was also successfully inspected during the financial year by USFDA.

We continue to face pricing pressures for older drugs in the NATCO US portfolio. Despite these challenges, we have managed good revenue from the US markets.

Key Para-IV products in the pipeline

| Key Brand | Molecule | Therapeutic Segment / Primary Indication |
|---|---|---|
| Nexavar | Sorafenib | Cancer/Kidney and Liver |
| Tykerb | LapatinibDitosylate | Cancer/Breast |
| Revlimid | Lenalidomide | Cancer/Multiple myeloma |
| Afinitor | Everolimus (higher strength) | Cancer/Breast |
| Zortress | Everolimus (lower strength) | ImmuneSupression/ OrganTransplant |
| Aubagio | Teriflunomide | CNS/Multiple sclerosis |
| Kyprolis | Carfilzomib | Cancer/Multiple myeloma |
| Pomalyst | Pomalidomide | Cancer/Multiple myeloma |
| Sovaldi | Sofosbuvir | Antiviral/Hep-C |
| Imbruvica | Ibrutinib | Cancer/Leukaemia |
| Lonsurf | Trifluridine/Tipiracil | Metastatic colorectal cancer |
| TracleerTFO | Bosentan | Pulmonary Arterial Hypertension |

### RoW markets

#### Canada

During FY 2019-20, NATCO Pharma Canada Inc. did a business of ₹1,283 million, as against ₹960 million in FY 2018-19. In spite of global headwinds, our subsidiary in Canada has shown resilience and growth. NATCO had total 12 active products with 18 approvals as of 31st March, 2020. As of Q1 FY21 Board meeting, the Company has disclosed a settlement with Celgene (now part of Bristol-Myers Squibb) for the product Lenalidomide Capsules in Canada. The Company is excited about its growth in the next few years in Canada.

#### Brazil

In Brazil, the government and regional tenders account for most of the medicine sales. NATCO services this market through its subsidiary NATCOFARMA Do Brasil. During the year, the Company witnessed four filings. As on 31st March 2020, NATCO had nine filings in Brazil. During FY 2019-20, it has registered a business of ₹390 million. Regulatory factors remain a key challenge in this market apart from the tender to sale conversion challenges. The Company expects incremental growth in the coming years.

| | Total filed | Total number of approvals | Total number of active products |
|---|---|---|---|
| Brazil | 9 | 3 | 3 |
| Canada | 28 | 18 | 12 |

#### Other RoW markets

NATCO is venturing into newer territories in RoW markets, apart from strengthening its presence in markets where it already operates.

The Company has gradually gained market in Singapore with its generic branded products in spite of the strong affiliation towards innovator brands prevalent in the market.

FY 2019-20, however, turned out to be the year of a breakthrough and NATCO won a major tender worth more than SGD$1 million.

The Company has been gradually increasing its presence in the Philippines, Thailand, Vietnam, China and Australia.

### Active Pharmaceutical Ingredient (API)

NATCO enjoys a strong reputation for its API products. Generally, the Company focuses on the manufacture of niche APIs to support its formulation business.

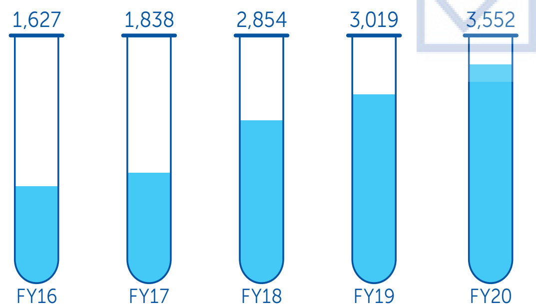
The Company's move to vertically integrate its API facility helps to ensure business sustainability both in periods of margin pressure as well as disruption in raw material supply.

Revenues from the API division during FY 2019-20 stood at ₹3,552 million as compared to ₹3,019 million in FY 2018-19. As of 31st March, 2020, NATCO has a total of 49 active DMFs with the USFDA for products in the areas of oncology, cardiology and orthopaedic therapies. We filed for four DMFs for the US market in FY 2019-20.

### Gross API revenues

(₹ in million)

22% (5-year CAGR)






### Segmental Breakdown

| Revenue division | (₹ in million)* | | | |
|---|---|---|---|---|
| | FY 17 | FY 18 | FY 19 | FY 20 |
| API Revenue (total) | 1,838 | 2,854 | 3,019 | 3,552 |
| **Formulations** | | | | |
| Domestic | 8,810 | 7,202 | 7,347 | 5,405 |
| International (including subsidiaries) | 8,911 | 11,364 | 9,933 | 9,334 |
| Other operating and non-operating incomes | 1,230 | 1,004 | 1,948 | 1,933 |
| **Total revenue** | **20,789** | **22,424** | **22,247** | **20,224** |

*Figures regrouped wherever appropriate

### Crop Health Sciences

NATCO has forayed into the agrichemical space through its Crop Health Sciences Division recently. Currently it is in the process to complete the manufacturing facilities for both technical (active ingredient) and formulations. NATCO is targeting the release of a key technical product from its CHS division for Chlorantraniliprole (CTPR), a broad-spectrum insecticide used in several crops, and is hoping to bring formulations based on this product with affordability and accessibility to farmers across the country. NATCO is awaiting regulatory approval for the CTPR product and litigation outcome.

The Company also has other niche products in the pipeline, to differentiate itself from other agrichemical companies.

# Management Discussion and Analysis



## Financial overview

During FY 2019-20, NATCO's consolidated revenue from operations stood at ₹20,224 million, growing at a CAGR of 16.7% over the last four years. The EBITDA for the year was ₹6,900 million, with an EBITDA margin of 34.1%. The Company's EBITDA has been growing steadily at a CAGR of 25% over the past four years. Profit After Tax (PAT) stood at ₹4,608 million, with the PAT margin being 22.8%. CAGR of NATCO's PAT over the past four comes to 30.9%.

The market capitalisation of the Company as on 31st March 2020 stood at ~₹92 billion. For the year ending March 31st 2020 NATCO has declared an equity dividend of 337.50%, amounting to ₹6.75 per share (face value of each share being ₹2). Altogether, dividends worth ₹1,536 million (including dividend distribution tax) have been paid to the shareholders in FY 2019-20, as compared to ₹1,108 million (including dividend distribution tax) in FY 2018-19.

Moreover, even in such tough and challenging market, the Company has been able to maintain its Return on Equity (ROE) at 12% and Return on Capital Employed (ROCE) at 15% for its shareholders during FY 2019-20. Based on the business prospects for the coming years, we expect both metrics to make appreciable improvements.

### Threats, risks and concerns

Adverse assessment of a manufacturing facility by any key regulatory body has the potential to significantly change the business prospects of any pharmaceutical company.

### Environment, health and safety

At NATCO, we recognise the importance of a clean environment and it is our constant endeavour to go beyond regulatory compliance to contribute to it. Compliance is our cornerstone. Every employee is encouraged to be an environment custodian.

This consciousness underpins our strategy and business model, which are focused not just on mitigating the environmental after-effects of business, but on containing them from the very start.


As we continually seek new and more effective ways of minimising our impact on the environment, we are keenly aware of the correlation between global warming and the incidence of infectious diseases.

In an effort towards continuous improvement in Safety, Health and Environment, we have reviewed and improved our various processes:

- Enhancement of Zero Liquid Discharge capacity at Mekaguda is completed, required permissions obtained and is ready for operation to handle additional loads and to produce more products to reach out the more unmet medical needs
- Upgradation of ETP is in progress at Nagarjuna Sagar and at Kothur unit
- Energy audits conducted across the group units to assess the energy efficiency and to identify the opportunities for improvement
- Monitoring the Scope-I and Scope-II GHG emissions to assess the performance of our carbon footprint and to roll out action plans for further mitigation
- Developed an Eco-Forest by using 'Miyawaki' concept along the boundary at Mekaguda unit
- Implemented the 'Behaviour Based Safety' management system to inculcate the safety culture among the employees at Kothur unit in association with Administrative Staff College of India