

Annual Report 2017-18

## Good Health Can't Wait



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## **Our Promises**

Our five promises clarify what we do, what we offer and the commitments we make to our stakeholders. Our patients trust our medicines. We focus our energies on renewing this trust every day. As we keep the interests of our patients at the center of all that we do, our promises drive us to reach higher levels of excellence.



## Letter from the Chairman and Co-Chairman





Let us begin with your company's performance in FY2018.

- Consolidated revenues were at ₹ 142 billion, which was ~1% more compared to the previous year.
- Consolidated gross profit was ₹ 76.3 billion, or 2.6% less vis-à-vis the previous financial year.
- The gross profit margin was 53.7%, versus 55.6% in FY2017.
- EBITDA reduced to ₹ 24.1 billion, a fall of 5.5% compared to the previous year.
- Profit before taxes (PBT) was ₹ 14.3 billion, compared to ₹ 14.7 billion in the previous year.
- Profit after taxes (PAT) was ₹ 9.8 billion, versus ₹ 12 billion in FY2017.

Frankly, these are disappointing results – especially coming after a financially difficult year in FY2017.

Last year, we described the reasons for your company's unfortunate performance as the consequence of a 'perfect storm' when a host of negative factors simultaneously came into play. We had then hoped that some of the dark clouds would disappear and make way for better performance in FY2018. Unfortunately, that has not happened. It is important to highlight the negative factors. First, the US market, which accounts for 52% of your company's global generics sales and 42% of all sales, continued to witness further consolidation of sales channels, which has given the fewer big US buyers even greater pricing power. The negative price effects of substantial channel consolidation have been further aggravated by intense price competition among multiple suppliers for each generic product. Over the last three years, the average price decline for generic drugs in the USA has not only been high, but has also significantly increased in every passing year. Moreover, growing competition from various international suppliers has made it very difficult, if not impossible, to overcome the price fall by volume increases. These factors are not unique to Dr. Reddy's. They have negatively affected all major pharmaceutical companies exporting to the USA.

Second, we have been affected by regulatory interventions, especially from the USA. As you know, in November, 2015, the USFDA issued a warning letter regarding three plants: an API manufacturing facility at Miryalaguda (Telangana), another API plant at Srikakulam (Andhra Pradesh), and an oncology formulation manufacturing facility at Duvvada, near Visakhapatnam (Andhra Pradesh).

In consultation with international experts and the USFDA, your company has continuously worked on instituting corrective and preventive actions across



these three sites and has had follow-up meetings with the regulator. The USFDA re-inspected these facilities during February-April, 2017. Based on their observations, further corrective actions were undertaken, and such information was shared with the regulator. Post this inspection, Miryalaguda API manufacturing facility received an EIR indicating closure of the audit. However for the other two plants, there is no change in status vis-a-vis the USFDA.

Consequently, launches of key molecules, injectables, as well as certain APIs from these sites have been delayed. Although your company has successfully secured regulatory and customer approvals to transfer the production of some of these products to alternative facilities, the outcome has been a significant loss of revenue from the USA for both FY2017 and FY2018.

There was also a regulatory hiccup when the Federal Institute for Drugs and Medical Devices (BfArM) of Germany audited your company's formulation unit 2 (FTO-2) at Bachupally, Hyderabad (Telangana). This resulted in the good manufacturing practices (GMP) compliance certificate not being renewed in August, 2017. Corrective work was immediately undertaken. After a follow-up audit, the GMP non-compliance status was withdrawn in January, 2018. However, stoppage in sale to Europe for four months led to lesser revenues. Thankfully, this is over, and we expect to increase sales in FY2019.

Third, during India's transition to the GST regime from 1 July 2017, your company's performance was impacted due to reduction in channel inventory and absorption of higher tax on drugs that were not in the National List of Essential Medicines (NLEM). Moreover, price controls under India's drug price control orders affected revenue across selected products. As a result, sales performance in India was more muted than it should have been.

#### WHERE DO WE GO FROM HERE?

Regarding pricing pressures in the USA, it is difficult to predict how long these trends will last. Instead, our task should be to overcome this reality. The only way of doing so is to have a strong pipeline of difficult-to-manufacture complex formulations that address key therapeutic needs – one that allows us to introduce several value-added products each year, so that each such launch steps-up revenues to combat the price erosion in those products that were brought to the market earlier.

Your company has such a pipeline. In FY2018, we filed 19 new abbreviated new drug applications (ANDAs) and one new drug application (NDA) under 505(b)(2) route with the USFDA. As of 31 March 2018, we had 110 generic filings pending approval from the USFDA, comprising 107 ANDAs and three new drug applications (NDAs) filed under the 505(b)(2) route of the US Federal Food, Drug and Cosmetic Act. Of these 107 ANDAs, 63 are Para IV applications – of which we believe 30 have 'First to File' status.

We have to match this robust pipeline by securing timely approvals from the USFDA and complement those with rapid ramp-up of production and delivery to the USA. We have to do this without fail, and with best-in-class cost of production. That is the way out.

As far as the USFDA regulatory hurdles go, your company remains fully committed to follow the highest standards of quality. We have significantly enhanced quality management systems and operations, which include improvements in rigor of investigations and document control systems, standardization of instrument calibrations, strengthening shop-floor level IT controls as well as shop floor training programs, and simplifying and standardizing standard operating procedures and batch records. We have requested the USFDA to schedule an inspection of the oncology formulation manufacturing facility at Duvvada. Hopefully, the regulator will recognize the scale and scope of improvements undertaken at the facilities and give us the green light.

There exist significant opportunities in Emerging Markets, which are now on a longer-term upswing. We should be able to increase revenues from these geographies through greater sales of simple and complex generics as well as hospital and institutional sales of oncological biosimilars. There are also major prospects in key emerging markets for speciality generics and biosimilars, and your company will be doing its utmost to increase its market presence in these countries.

With the German regulatory problem behind us, we expect to increase our sales to that country as well as Romania. Moreover, having opened operations in France, Italy and Spain, we should be working on generating higher revenues from these countries, and to increase our market presence in Europe in the near future.

Relative to the competition that matters, we have underperformed in India. Your company now needs to put all its efforts in ensuring that it grows at least as fast as the market – ideally faster – and achieve the kind of double-digit growths that it attained in the past. This is doable. It needs totally focused effort by the team.

After three years of lacklustre performance, the pharmaceutical services and active ingredient (PSAI) business has turned around. We expect the business to now generate double-digit growth, as it has in the past, and it surely can. Though small, the proprietary product (PP) business has done well. The two new products that were launched in FY2017 – ZEMBRACE<sup>™</sup> SYMTOUCH<sup>™</sup> (a 3 mg sumatriptan injection for acute migraine) and SERNIVO™ (a betamethasone dipropionate 0.05%) spray to treat mild-to-moderate plaque psoriasis) have found market traction. In FY2018, the USFDA approved a third product, IMPOYZ<sup>™</sup> (clobetasol propionate) cream. We expect to see greater revenues in the USA driven by these three products. Towards the end of the year we have filed our lead migraine candidate DFN-02 with the USFDA.

A positive upshot of the revenue crunch in FY2017 and FY2018, has been your company's attention to costs. From the beginning of FY2018 there has been a totally focused drive on eliminating needless layers and unnecessary costs. This will continue throughout FY2019 and thereafter, with the aim to create a leaner, internationally cost-competitive and more nimble organization.

Your company's management has accepted several challenging goals for FY2019. These involve better plant management; an unwavering focus on institutionalizing best-in-class manufacturing and quality practices; bringing about greater efficiency in R&D, product development, and speed-to-market for new products; driving hard to perform better in sales in the USA, Europe, India and the Emerging Markets; and maintaining a tight leash on costs.

We hope that these initiatives, backed by the resolve of each employee of your company, will deliver better results in FY2019. Because Dr. Reddy's and you, the shareholder, deserve it.

Thank you, as ever, for your goodwill and support.

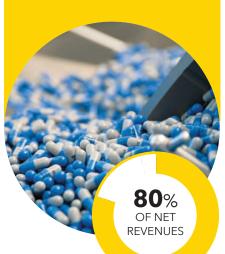
With best regards,

K Satish Reddy Chairman

**G V Prasad** Co-Chairman and CEO

## **Our Businesses**

#### **GLOBAL GENERICS**



#### **₹114** bn

- Revenue from the GG segment declined 1% to ₹ 114 billion.
- Revenue from North America declined 6% to ₹ 59.8 billion.
- Revenue from Emerging Markets increased 8% to ₹ 22.7 billion.
- Revenue from India grew by 1% to ₹ 23.3 billion.

#### **GLOBAL GENERICS**

Global generics is our biggest business driver. We offer more than 200 high-quality generic drugs, keeping costs reasonable by leveraging our integrated operations. Our expertise in active ingredients, product development skills, a keen understanding of regulations and intellectual property rights, as well as our streamlined supply chain, makes us leaders in this segment.

#### BIOLOGICS

Our biosimilars, generic equivalents of the innovator's biologics, offer affordable yet equally effective alternatives. Our product development capabilities and commercial reach have made us global leaders in this therapeutic area. We have four products in the market and an industry-leading pipeline spanning oncology, nephrology and auto-immune diseases.

# PHARMACEUTICAL SERVICES & ACTIVE INGREDIENTS

• Revenue from the PSAI segment increased by 3% to ₹ 22 billion.

#### ACTIVE PHARMACEUTICALS INGREDIENTS

We are one of the world's largest manufacturers of Active Pharmaceuticals Ingredients (APIs) and partner with several leading generic formulator companies in bringing their molecules first to the market. Our focus on innovation-led affordability gives our customers access to the most complex active ingredients, while maintaining a consistent global quality standard. Besides, our APIs development efforts enable our own generics business to be cost competitive and get to market faster.

#### CUSTOM PHARMACEUTICAL SERVICES

Dr. Reddy's has one of the largest custom pharmaceutical services businesses in India. We offer end-to-end product development and manufacturing services and solutions to innovator companies. Further, our rich and extensive knowledge repository of various types of formulations helps shorten time to market and support lifecycle management.

#### PROPRIETARY PRODUCTS & OTHERS



• Revenue from Proprietary Products and others was ₹ 6 billion, an increase of 46%.

#### **PROPRIETARY PRODUCTS**

Our Proprietary Products business focuses on developing differentiated formulations that present significantly enhanced benefits in terms of efficacy, ease of use, and the resolution of unmet and under-met patient needs. The aim is to improve the patient's holistic experience with our medicines, so as to strengthen compliance with the therapeutic regimen and ensure positive outcomes.

#### MORE THAN 200 HIGH-QUALITY GENERIC DRUGS

ONE OF THE WORLD'S LARGEST MANUFACTURERS OF APIs

DIFFERENTIATED FORMULATIONS THAT PRESENT ENHANCED BENEFITS

#### **GLOBAL PRESENCE**



#### FY2018 HIGHLIGHTS

**REVENUES ₹ 142** bn

### **EBITDA** ₹ **24.1** bn

PROFIT AFTER TAX
₹ 9.8 bn

## DILUTED EPS ₹ **59**

#### FY2018 FILINGS AND LAUNCHES

#### GENERIC FILINGS (19 ANDA FILINGS & 1 NDA FILING)

As on 31 March 2018, 110 generic filings are pending for approval (107 ANDAs and 3 NDAs). Of these, 107 ANDAs, 63 are Para IV filings of which we believe 30 to have 'First-to-File' status.

#### **DMF FILINGS**

12 DMFs were filed in the US.

#### **139 NEW PRODUCTS**

139 new products were launched in FY2018, of which 15 are in NAG, 18 in Europe, 86 in Emerging Markets and 20 in India.





## **Key Performance Indicators**

#### **REVENUES** (₹ IN MILLION)

FY2018	142,028
FY2017	140,809
FY2016	154,708
FY2015	148,189
FY2014	132,170

#### **GROSS PROFIT** (₹ IN MILLION)

FY2018	76,304
FY2017	78,356
FY2016	92,281
FY2015	85,403
FY2014	75,801

#### **EBITDA** (₹ IN MILLION)



#### **PBT** (₹ IN MILLION)

FY2018	14,341
FY2017	14,653
FY2016	27,140
FY2015	28,163
FY2014	26,606

#### PAT (₹ IN MILLION)

FY2018	9,806
FY2017	12,039
FY2016	20,013
FY2015	22,179
FY2014	21,512

#### NET WORTH (₹ IN MILLION)

FY2018	126,460
FY2017	124,044
FY2016	128,336
FY2015	111,302
FY2014	90,801

#### ROCE (%)



#### EPS (DILUTED)

FY2018	59.0
FY2017	72.1
FY2016	117.0
FY2015	129.7
FY2014	126.0



## Good Health Can't Wait

At Dr. Reddy's, we are driven by our purpose of accelerating access to innovative and affordable medicines because good health can't wait. We strive to do all it takes to reach the right medicines to patients, when and where they need them. The need for affordability, better disease management and higher efficacy are key priorities for us, and they guide our efforts across operations, supply chain, and R&D.

Patients are at the center of everything we do and the pivot around which our organizational strategy revolves. Our work around the world, be it in mature geographies or in the emerging ones, is geared towards addressing unmet patient needs and bringing expensive medicines within reach, while delivering high-quality and efficacious drugs. We dedicate ourselves to ensure on-shelf drug availability so that no patient is denied access to the treatment they need for their good health.