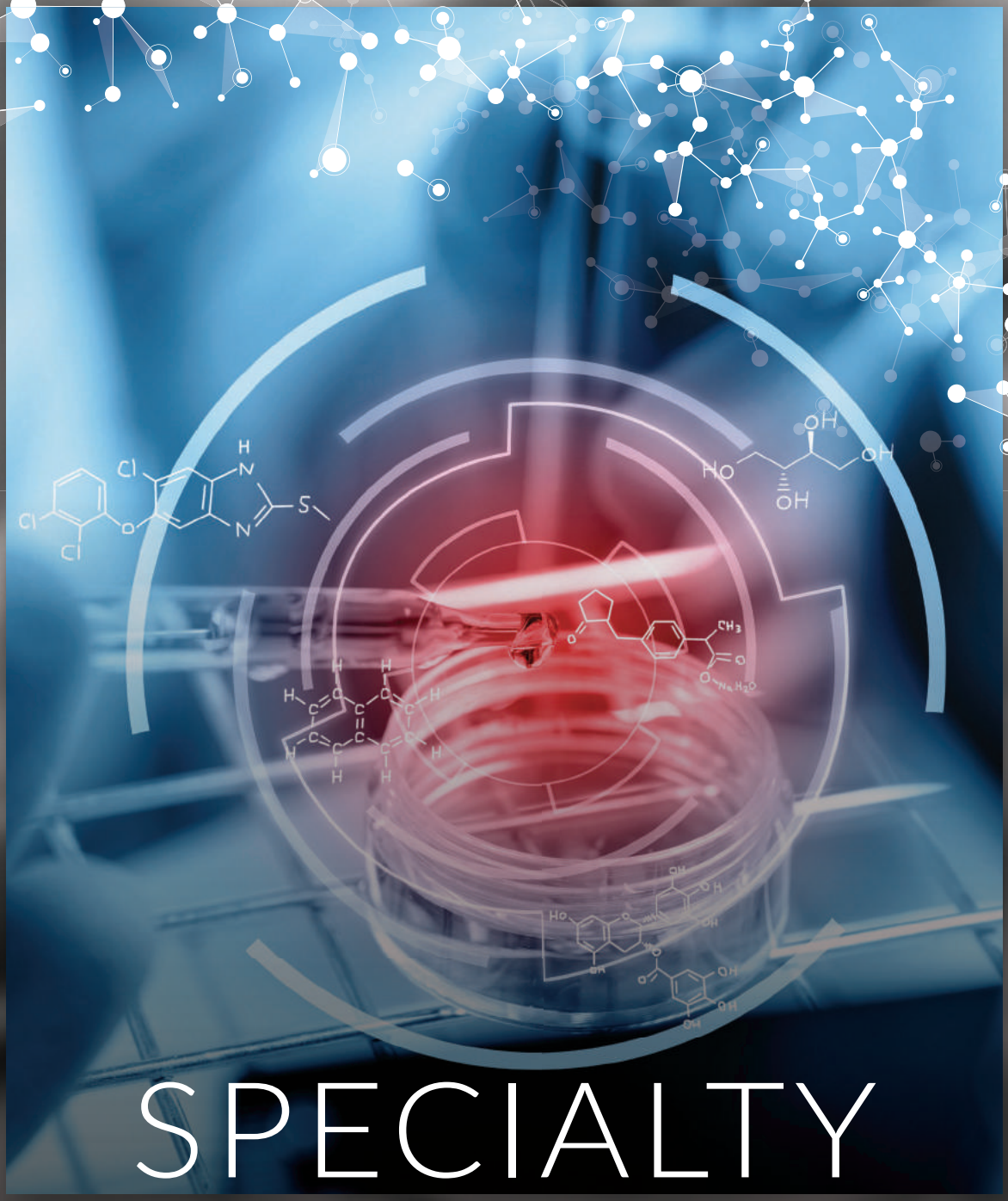
ANNUAL REPORT 2018-19



SPECIALTY *IN PROGRESS*

Sun Pharmaceutical Industries Ltd.

Reaching People. Touching Lives.

SUN PHARMA

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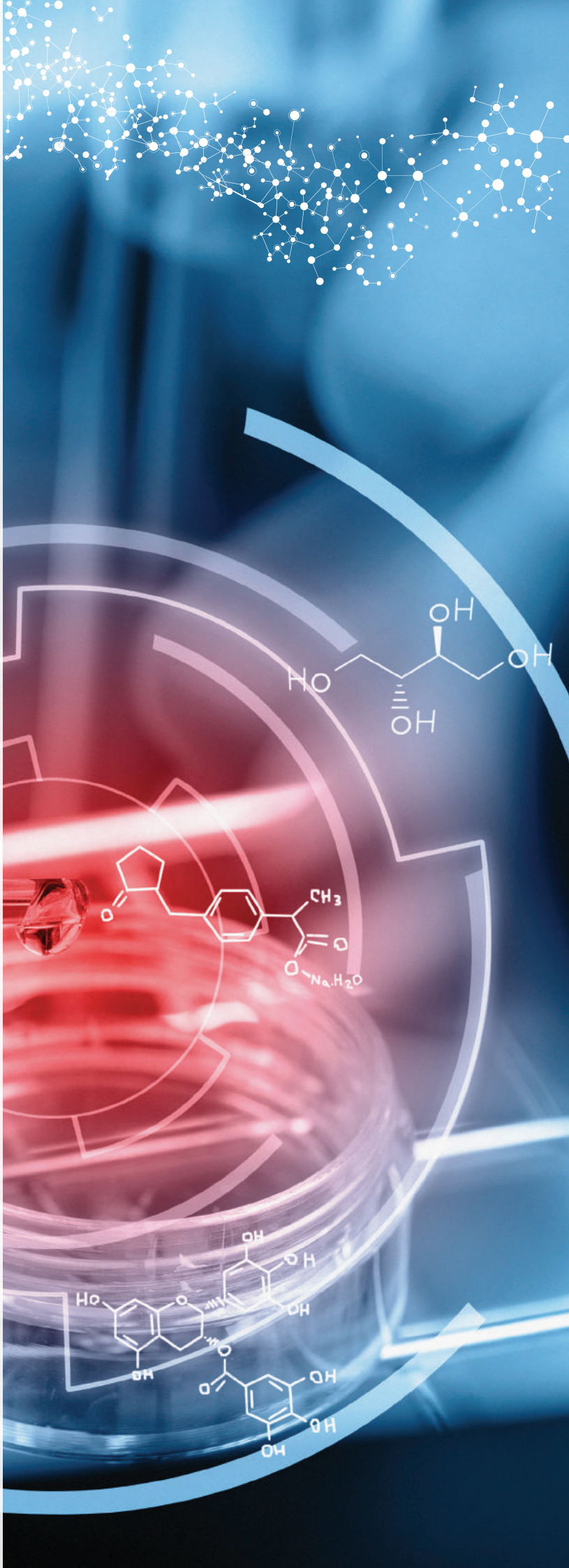


SPECIALTY IN PROGRESS

We, at Sun Pharma, view our specialty business as an additional engine of sustainable growth and cashflows over the long term. The specialty business also represents our important initiative to move up the pharmaceutical value chain and usher in enhanced innovation for our business. Over the preceding few years, we have sharpened our focus to develop a strong portfolio of specialty products, funding their clinical trials and establishing the requisite front-end capabilities for this business.

We have built our specialty expertise with industry-leading know-how, highly skilled team and best-in-class technologies. We will continue to build a global specialty pipeline with focused research and development (R&D) investments. The principal focus areas for our specialty portfolio include segments like dermatology, ophthalmology and oncology.

Our specialty initiatives are progressing well and we crossed some important milestones during the year. We commercialised ILUMYA™, YONSA™ and XELPROS™ in the US in FY19. ILUMYA™ was also commercialised in Australia while ILUMETRI™ was launched in Germany by our partner during the year. CEQUA™ is expected to be launched in the US in FY20. We have now entered the commercialisation phase for most of our specialty products. At the same time we continue to, invest in development of our specialty pipeline, and in evaluating new markets for commercialising our specialty products.

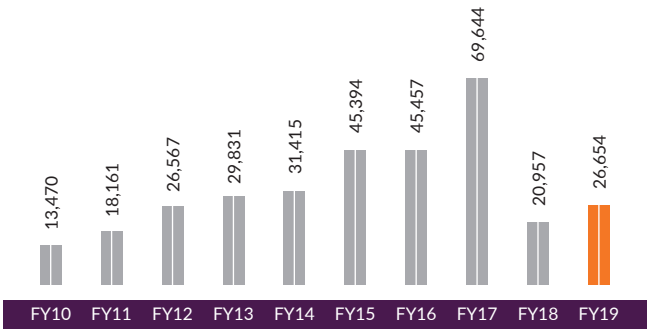
Key Performance Indicators (Consolidated)

Total income

(₹ Million)

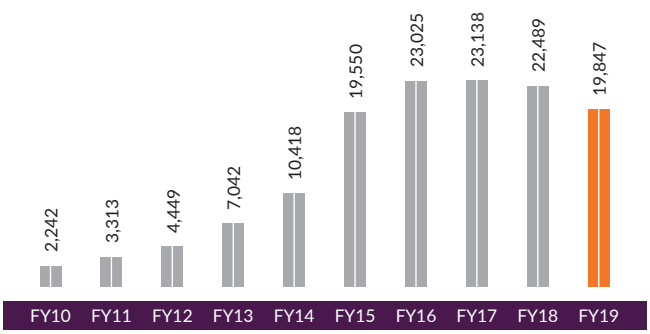
Net profit after minority interest

(₹ Million)



R&D investment

(₹ Million)

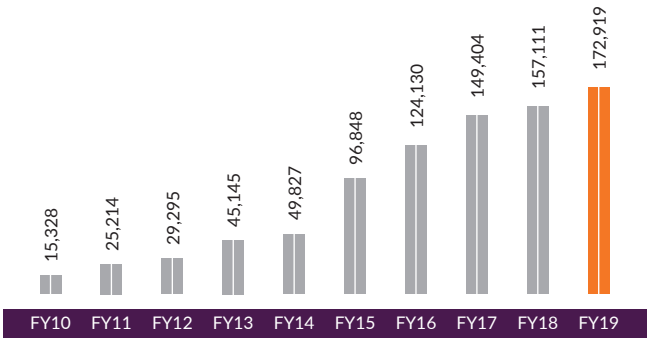


Reserve and surplus

(₹ Million)

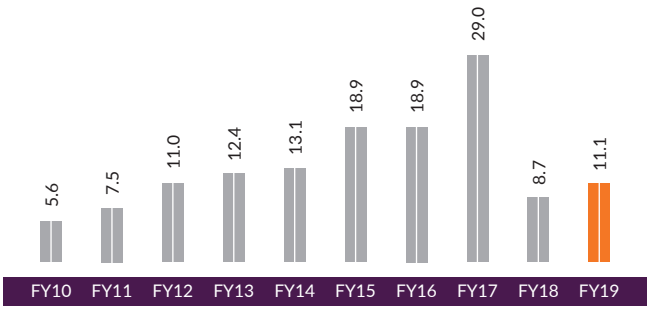
Carrying value of property, plant & equipment and other intangible assets

(₹ Million)



Adjusted earning per share (post exceptional items)*

(₹ per share)



* During FY11, each equity share of ₹5 was split into five equity shares of ₹1 each.
* During FY14, the Company issued bonus shares in the ratio of one equity share of ₹1 for every share held.
* During FY16, the Company's equity shares have increased to 2,407 Million due to the merger of erstwhile Ranbaxy Laboratories Ltd. (RLL) with the Company, wherein 0.80 equity share of ₹1 each of the Company have been allotted to the shareholders of RLL for every 1.00 share of ₹5 each held by them.

The Company had adopted Ind AS accounting standard w.e.f April 1, 2016 with prior period restated from April 1, 2015. Hence, FY16 onwards the financials are reported as per Ind-AS and are not strictly comparable with previous years.

Ten-Year Financial Highlights (Consolidated)

(₹ Million)

Particular	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19
Operating performance										
Revenue from operations	38,086	57,279	80,195	112,999	160,804	273,920	284,870	315,784	264,895	290,659
Total income	42,123	60,827	84,910	116,880	166,326	279,397	291,453	322,016	273,282	300,914
Net profit for the year (after minority interest)	13,470	18,161	26,567	29,831	31,415	45,394	45,457	69,644	20,957	26,654
R&D expenditure	2,242	3,313	4,449	7,042	10,418	19,550	23,025	23,138	22,489	19,847
a) Capital	159	236	362	427	556	1,178	783	1,679	1,819	718
b) Revenue (excluding depreciation)	2,083	3,077	4,088	6,616	9,862	18,373	22,242	21,459	20,669	19,129
c) % of sales	6.0	6.0	5.6	6.3	6.5	7.2	8.3	7.6	8.6	6.9
Financial position										
Equity share capital	1,036	1,036	1,036	1,036	2,071	2,071	2,407	2,399	2,399	2,399
Reserve and surplus	77,254	93,798	121,322	148,862	183,178	278,009	327,418	363,997	380,742	411,691
Property, plant & equipment and other intangible assets (at cost/ deemed cost)	23,340	45,473	54,269	75,763	86,505	143,616	187,212	217,315	238,073	271,424
Carrying value of property, plant & equipment and other intangible assets	15,328	25,214	29,295	45,145	49,827	96,848	124,130	149,404	157,111	172,919
Investments	31,664	26,557	22,129	24,116	27,860	35,028	18,299	11,919	71,429	79,025
Net current assets	28,542	58,622	76,749	86,618	126,969	135,488	167,973	150,666	117,716	137,296
Stock information										
Number of shares (in Million)	207	1,036	1,036	1,036	2,071	2,071	2,407	2,399	2,399	2,399
Adjusted earning per share (post exceptional items) (in ₹)*	5.6	7.5	11.0	12.4	13.1	18.9	18.9	29.0	8.7	11.1
Earnings per share-Basic (in ₹)*	65.2	17.5	25.7	28.8	15.2	18.9	18.9	29.0	8.7	11.1
Earning per share-Diluted (in ₹)*	65.2	17.5	25.7	28.8	15.2	18.9	18.9	29.0	8.7	11.1

* During FY11, each equity share of ₹5 was split into five equity shares of ₹1 each.
* During FY14, the Company issued bonus shares in the ratio of one equity share of ₹1 for every share held.
* During FY16, the Company's equity shares have increased to 2,407 Million due to the merger of erstwhile Ranbaxy Laboratories Ltd. (RLL) with the Company, wherein 0.80 equity share of ₹1 each of the Company have been allotted to the shareholders of RLL for every 1.00 share of ₹5 each held by them.

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Managing Director's Message

Dilip Shanghvi, Managing Director

Dear Shareholders,

The global pharmaceutical industry is at crossroads. The type of drugs being developed by the industry and the role played by technology are being juxtaposed against the value that healthcare delivers to patients. On one hand, the industry is developing new generation specialty drugs in gene therapy, monoclonal anti-bodies and immunotherapy categories, which have improved medical outcomes for patients; but on the other hand, the industry is facing increasing resistance from governments and payors over escalating drug prices, which impacts healthcare budgets. The need of the hour is for innovation and affordability to co-exist for the long-term benefit of all stakeholders.

The scenario for the generics industry is markedly different from its much larger branded counterpart. Generics pricing in the US, the largest and most important of all generics markets, has been under severe pressure over the last three years. The business profitability in the US generics market has suffered significantly over this period. Although there are early signs of price stabilisation for some products, the overall US generics pricing continues to be competitive.

The industry has started responding to these changes through a combination of multiple initiatives. These include a focus on developing innovative and differentiated products, withdrawal of non-remunerative products and persistent emphasis on cost control.

With business becoming more challenging, it has become imperative for companies to be more innovative and identify new engines of growth. Sun Pharma's significant investments in building a global specialty business is an important step in this direction. This initiative will enable us to build an additional engine of growth as well as move up the pharmaceutical value chain over the long term.

Our unwavering focus on cost control continues, with these efforts spread across generic R&D projects, rationalisation of manufacturing footprint and other areas. These steps will release resources which can be deployed in the specialty business.

FY19 highlights

We are back on the growth path with our FY19 revenues growing by 10% to ₹287 Billion. We have recorded steady growth in all the markets where we operate.

Operational performance

Revenues in the US increased 22% to ₹107 Billion and accounted for 37% of our consolidated revenues for FY19. The key growth drivers include increase in generics sales, incremental contribution from specialty product launches and a favourable foreign exchange rate. Our subsidiary, Taro recorded a marginal growth in overall revenues to US$ 670 Million for the year. This was mainly the result of more intense competition among manufacturers, new entrants to the market, buying consortium pressures and a higher abbreviated new drug application (ANDA) approval rate from the United States Food and Drug Administration (USFDA).

We recorded 8% decline in our India formulations business, however, our adjusted growth, excluding one-offs, was 5%.

We grew by 11% in emerging markets for the year. This growth was broad based across various markets. Our sales in the rest of world (RoW) markets grew by 16% for the year, driven by increased sales in some Western European markets and partly driven by the Pola Pharma Inc. (Pola Pharma) acquisition in Japan.

R&D

R&D is the lifeline of our business as it enables us to develop and launch differentiated generics as well as innovative specialty products. It is a key determinant of our future growth and profitability. Our efforts to build a global specialty pipeline mandates that we keep investing in R&D.

Our R&D investments for the year were ~₹20 Billion, targeted mainly at developing complex generics and specialty products. Given the intensely competitive nature of the US generics market, we continue to be disciplined in identifying future R&D projects for the generics market. Investments for

developing the long-term specialty pipeline are expected to continue. We are also investing in developing specific products for emerging markets and other non-US developed markets.

Progress on specialty initiatives

We have further progressed in our global specialty initiatives, which commenced a few years ago. We view the specialty business as an additional engine of sustainable growth and cash flows over the long term. It is also an initiative to move up the pharmaceutical value chain and bring in more innovation to our business. We have allocated significant resources over the past few years in building this business for acquiring specialty products, funding their clinical trials and establishing the requisite front-end capabilities. We have now entered the commercialisation phase for most of our specialty products.

The focus areas for our specialty portfolio include segments like dermatology, ophthalmology and oncology.

Specialty products – Approvals and launches in FY19

We crossed many important milestones for our specialty business in FY19 with USFDA approvals for four specialty products and commercialisation of three specialty products. Some of the key highlights for the year were:

- We launched ILUMYA™ (tildrakizumab-asmn) 100 mg/mL in the US for treating moderate-to-severe psoriasis in October 2018. We have received a good initial response for the product and we expect ramp-up in ILUMYA™ sales in the US over the next few years. We have also commenced a direct-to-consumer advertising initiative for ILUMYA™ in the US.
- Our European partner, Almirall, received approval for tildrakizumab from the European Commission (EC) under the ILUMETRI™ brand name. Almirall has commenced commercialisation of ILUMETRI™ in Europe in a phased manner across different markets.
- Sun Pharma also received approval from the Australian Therapeutic Goods Administration (TGA) for ILUMYA™ during the year. The product has already been commercialised in Australia.
- During the year we received USFDA approvals for CEQUA™ (cyclosporine ophthalmic solution 0.09%). CEQUA™ increases tear production in patients with dry eyes. It is the first and only approved dry eye treatment to combine cyclosporine A with nanomicellar technology. CEQUA™ will be commercialised in the US in FY20.
- In May 2018, Sun Pharma received USFDA approval for YONSA® (abiraterone acetate), a novel formulation in combination with methylprednisolone to treat patients with metastatic castration-resistant prostate cancer (mCRPC). This approval has further strengthened Sun Pharma's oncology portfolio in the US. The product was commercialised in the US in the first quarter of FY19.
- During the year, Sun Pharma also received USFDA approval for its New Drug Application (NDA) of XELPROS™ (latanoprost ophthalmic emulsion 0.005%) used for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. XELPROS™ is the first and only form of latanoprost that is not formulated with benzalkonium chloride (BAK), a commonly used preservative in topical ocular preparations. XELPROS™ was launched in the US in January 2019.
- In July 2018, Sun Pharma announced the USFDA approval for INFUGEM™ (gemcitabine in 0.9% sodium chloride injection), for intravenous use in a ready-to-administer (RTA) bag. INFUGEM™ uses a proprietary technology, which allows cytotoxic oncology products to be pre-mixed in a sterile environment and supplied to the prescribers in RTA infusion bags. These RTA bags will provide greater safety, by preventing problems of over-dosing or under-dosing and eliminating contamination risk. INFUGEM™ was commercialised in the US in April 2019.
- In August 2018, Sun Pharma launched KAPSPARGO SPRINKLE™ (metoprolol succinate) extended-release sprinkle formulation in the US. The product will help treat hypertension, angina pectoris (chest pain) and heart failure. These extended-release coated pellets can be sprinkled over soft food or administered via a nasogastric tube to facilitate long-term, once-daily administration for patients who experience difficulty while swallowing.
- We have also initiated investments in the development of new indications for ILUMYA™. Although the clinical trials for these new indications will require upfront investments, a successful outcome of the trials will significantly expand the addressable market for ILUMYA™ globally.

Enhancing presence in Japan

In January 2019, we announced the closure of the acquisition of Pola Pharma, a Japanese pharmaceutical company. Pola Pharma's portfolio primarily comprises dermatology products and it also has two manufacturing facilities in Japan with capabilities to manufacture topical products and injectables. This acquisition strengthens Sun Pharma's presence in Japan and accelerates its access to the Japanese dermatology market.

Regulatory compliance in pharmaceutical manufacturing

Regulatory standards for pharmaceutical facilities have been undergoing constant upgradation over the past many years, with regulatory agencies demanding the highest quality products. To adhere to these stringent standards, pharmaceutical companies need to have an unwavering focus on 24x7 compliance, which, in turn, raises compliance costs. Ensuring that each manufacturing facility remains compliant has become a key priority for pharmaceutical companies worldwide.

During the year, many of our facilities underwent successful audits by multiple regulatory agencies, including the USFDA.

Our Halol facility, which was impacted by cGMP deviations in FY15, was cleared by the USFDA in June 2018. With this clearance, new approvals from this facility for the US market have started coming through gradually.

Restructuring and rationalisation

We also continue to focus on optimising our costs, given the tough phase that the global generics industry is passing through. We strive to optimally utilise our resources with greater involvement of people, to make the Company more efficient.

We continue to emphasise on optimising our manufacturing footprint, to strike a pragmatic balance between current costs and future capacity requirements. We are constantly evaluating our generics R&D investments, to ensure a reasonable return on investment.

Overall outlook

Our consistent focus is on growing each of our businesses faster than the market in which they operate. Our global specialty initiatives will supplement this objective as an additional growth engine.

Although the US generics industry continues to face pricing pressure, the industry has started responding to these challenges by rationalising product portfolios and discontinuing non-remunerative products. These steps have been taken to ensure that generics products are able to generate reasonable returns to manufacturers.

In US, generics account for more than 80% of overall pharmaceutical volumes. In Western Europe, generics account for a significant portion of volumes as well. In Japan, the government has been encouraging higher generics penetration to bring down healthcare costs. All emerging markets rely on branded generics and/or pure generics to service their healthcare needs, given the lower purchasing power of their population. Hence, generics will continue to be an integral part of the solution to control global healthcare costs and has an important role to play in overall healthcare management.

Sun Pharma continues to invest in the generics business, with a focus on developing differentiated complex generics and building a product pipeline across markets. Our strong positioning in the global generics space will ensure that we remain an important player in the generics industry.

We are gradually ramping up our global specialty business. One of key ailments that we are targeting is psoriasis. As per a EvaluatePharma report, the size of the US psoriasis market was estimated at ~US$ 10 Billion in 2018 and is expected to grow at 9% CAGR till 2024. The report also estimates the global market for psoriasis at ~US$ 15 Billion in 2018, which is likely to grow at 9% CAGR to US$ 24.6 Billion by 2024.

We have started commercialising ILUMYA™, useful for treating moderate-to-severe plaque psoriasis in various markets globally. It was launched in the US in October 2018 and in Australia in December 2018. Our partner in Europe has commenced a phased launch of the product, starting with Germany, under the ILUMETRI™ brand name. The product has received a good response from doctors in these markets. We continue to evaluate other potential markets for commercialising ILUMYA™.

We recently announced long-term clinical insights for ILUMYA™ at the 2019 American Academy of Dermatology conference. The data presented showed sustained skin clearance in some patients living with moderate-to-severe plaque psoriasis after three years of ongoing treatment with ILUMYA™. The product was also well tolerated with low rates of adverse events. We believe that these positive data points will enable the product to do well in the large US$ 15 Billion global psoriasis market.

Our initiatives in the specialty ophthalmology segment are also gaining momentum. Our dry eye specialty product, CEQUA™, is expected to be commercialised in the US in FY20. We have recently launched XELPROS™ (latanoprost ophthalmic emulsion) 0.005% in the US for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Sun Pharma will continue to invest in branding and promotion of its various specialty products. R&D investments for funding clinical trials of some of the specialty products are also likely to continue in future.

For FY20, we expect our consolidated revenues to grow by low-to-mid teens, while R&D investments are estimated at ~8-9% of sales.

Our talented team of employees will be the key driver of all the above initiatives. We are grateful to our Board of Directors for their guidance and support.

We are thankful for your support as a shareholder and we hope that you will continue to repose your confidence in us in future as well.

Warm regards,

Dilip Shanghvi
Managing Director
Sun Pharmaceutical Industries Ltd.

Board of Directors

Israel Makov
Chairman

Dilip S. Shanghvi
Managing Director

Sudhir V. Valia
Whole-time Director*

Sailesh T. Desai
Whole-time Director

Kalyanasundaram Subramanian
Whole-time Director

Vivek Chaand Sehgal
Non-executive and
Independent Director

Rekha Sethi
Non-executive and
Independent Director

Gautam Doshi
Non-executive and
Independent Director

*Designation changed from Whole-time Director to Non-executive and Non-Independent Director w.e.f. May 29, 2019

Leadership Team

Abhay Gandhi
CEO, North America

Dr. Pradeep Sanghvi
Executive Vice-President,
Global Head - Oral Solids

Dr. Sapna Purohit
Senior Vice-President,
Head of Human Resources

Dr. Azadar H. Khan
Senior Vice-President - Corporate
Relations and CSR, India Regulatory Affairs

Aalok Shanghvi
Senior Vice-President –
Emerging Markets and Global R&D

C. S. Muralidharan
Chief Financial Officer

Anilkumar Jain
CEO, API Business

Davinder Singh
Senior Vice-President,
Sun Pharmaceutical Global Operations

S. Kalyanasundaram
Whole-time Director
Head - India and Emerging Markets