

# Pharmaceutical Sector

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U P D A T E

NOV 2020

# Pharma Sector Roundup Summary

## COVID-19 vaccine development

02

CureVac has shared phase 1/2 data on its COVID-19 vaccine candidate CVnCoV. The mRNA vaccine dose selected for further development sparked increase in virus-neutralizing antibodies and showed early indications of T-cell activation.

## Major product approval

08

- Dimethyl Fumarate DR (delayed release) capsules - Multiple Sclerosis (MS) – Dr. Reddy's
- Ilumya, subcutaneous injection (100 mg Syringe) - Plaque Psoriasis – Sun Pharma
- Divalproex sodium ER (extended-release) tablets USP, 250 mg and 500 mg - Acute treatment of manic or mixed episodes associated with bipolar disorder – Lupin
- NINDANIB (Nintedanib 100 and 150 mg capsules - Pulmonary Fibrosis – Glenmark
- Fingolimod Capsules 0.5 mg (US RLD: Gilenya Capsules) - relapsing forms of Multiple Sclerosis (MS) – Zydus Cadila
- FEVINDO (favipiravir) 400 mg tablets - RNA-based influenza virus - Indoco

## Financial insights

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- Incomes of Cipla, Dr. Reddy's, Aurobindo, Glenmark, Cadila Healthcare & Torrent have grown in Q1 (YoY)
- PAT numbers of Cipla, Aurobindo, Glenmark, Cadila Healthcare & Torrent have shown improvement in PAT in Q1 (YoY)

## People movement

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- Biocon appoints Anupam Jindal as CFO
- JB Chemicals & Pharmaceuticals appoints Nikhil Chopra as CEO
- Sanofi India appoints Vaibhav Karandikar as CFO
- Zydus appoints Sandeep Anand as CMO
- Optum appoints Alind Sharma as VP – Human Capital
- Indegene appoints Marut Setia as SVP-Emerging Markets & Devices & Atul Tewari as SVP-Global Delivery
- Piramal Pharma appoints Sridhar Desikan as Global Technical Head of Formulations R&D

## Top 3 Hiring areas

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- Manufacturing
- Digital Transformation
- Marketing



## Current Developments – Global

### J&J Covid-19 Vaccine candidate yields strong immune response in early trial

A single dose of Johnson & Johnson's experimental COVID-19 vaccine produced a strong immune response against the novel coronavirus in an early-to-mid stage clinical trial. The vaccine, called Ad26.COV2.S was equally well-tolerated at two different doses.

However, it is unclear whether elderly people, one of the populations most at risk from the virus, will be protected to the same degree as younger people with the J&J vaccine. The trial in close to 1,000 healthy adults, which is backed by the US government, began after the J&J vaccine was found in July 2020 to offer strong protection in a single dose to monkeys.

### Phase III trials of AstraZeneca Covid-19 Vaccine candidate begins in US

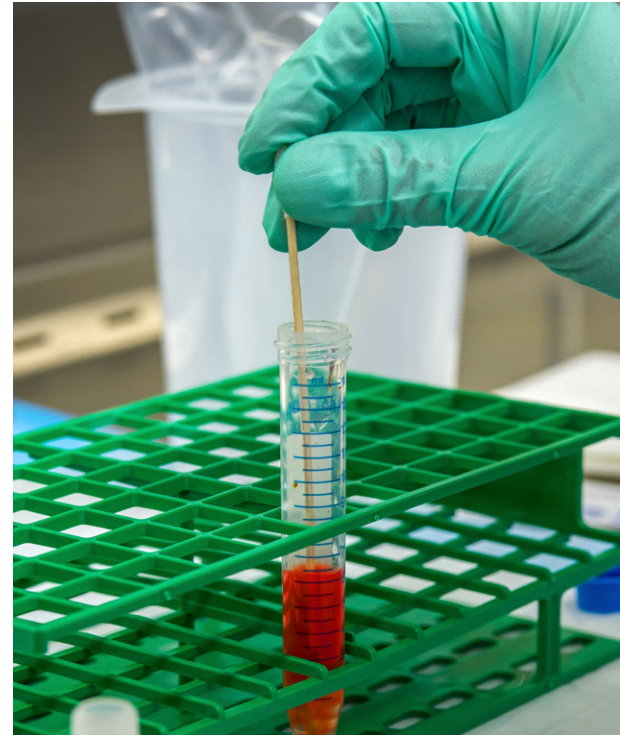
AstraZeneca said it has begun enrolling adults for a US-funded, 30,000-subject late-stage study of its high profile COVID-19 vaccine candidate. Trial participants will receive either two doses of the experimental vaccine, dubbed AZD1222, four weeks apart, or a placebo.

The trial is being conducted under the US government's Operation Warp Speed program, which aims to accelerate development, manufacturing and distribution of vaccines and treatments for COVID-19.

## Bacterial viperins prove effective against human viruses: researchers

Virus-fighting viperins, part of the human immune system, turn out to have bacterial counterparts that might boost the fight against human disease.

By tracking the evolution of what may be our oldest means of fighting off viral infection, a group at the Weizmann Institute of Science has uncovered antiviral substances that may lead to the development of highly effective antiviral drugs. These substances are made by virus-fighting enzymes known as viperins, which were previously known to exist only in mammals, and have now been found in bacteria. The molecules produced by the bacterial viperins are currently undergoing testing against human viruses such as the influenza virus and COVID-19. The study was published in Nature.



## Gilead gets approval for Jyseleca (Filgotinib) in Japan for Rheumatoid Arthritis

Gilead Sciences announced that the Japanese Ministry of Health, Labour and Welfare has granted Gilead KK (Tokyo, Japan) regulatory approval of Jyseleca (filgotinib 200 mg and 100 mg tablets), a once-daily, oral, JAK1 preferential inhibitor for the treatment of rheumatoid arthritis (RA) in patients who have had an inadequate response to conventional therapies, including the prevention of structural joint damage.

Gilead Japan will hold the marketing authorisation of Jyseleca in Japan and will be responsible for product supply of Jyseleca in Japan, while Eisai will be responsible for product distribution of Jyseleca in Japan in RA. The companies will jointly commercialise the medicine to make it available to physicians and patients across Japan.

“Physicians in Japan will be able to prescribe Jyseleca (Filgotinib) to patients exhibiting inadequate response to conventional therapies for treatment of rheumatoid arthritis (RA)”



## Curevac links Covid-19 Vaccine to immune response, setting it up to enter pivotal trial

CureVac has shared phase 1/2 data on its COVID-19 vaccine candidate CVnCoV. The German biotech said the mRNA vaccine dose selected for further development sparked increases in virus-neutralizing antibodies and early indications of T-cell activation. While BioNTech and Moderna raced mRNA vaccines into the clinic, CureVac advanced its candidate into human testing more slowly, albeit still at a breakneck speed by historical standards.

CureVac used the extra time in preclinical to design a differentiated asset. Rather than build upon chemical modification of the RNA, CureVac optimized the nucleic acid itself. The result is an mRNA vaccine that CureVac expects to generate a balanced immune response and be more straightforward to scale up. The phase 1 data provide an early, incomplete look at whether the candidate can live up to those expectations.

## Global opioid use disorder market to reach \$3.7 bn by 2028

The opioid use disorder (OUD) market is expected to grow from \$1.6 billion in 2018 to \$3.7 billion by 2028 across the eight major markets (8MM) at a compound annual growth rate (CAGR) of 8.8 per cent, according to GlobalData.

The company's latest report, 'Opioid Use Disorder-Opportunity Analysis and Forecasts to 2028', reveals that the main driver of growth will be the launch of reformulations of buprenorphine, in particular extended-release formulations including Indivior's Sublocade and Camurus' Buvidal.



## Vivet, Pfizer sign pact for gene therapy to treat Wilson disease

Vivet Therapeutics and Pfizer announced that they have entered into a manufacturing agreement, under which Pfizer will provide clinical supply for a Phase 1/2 clinical trial evaluating Vivet's proprietary, investigational gene therapy, VTX-801, for the potential treatment of Wilson disease, a rare and potentially life-threatening liver disorder. The trial is expected to commence in early 2021. Terms of the agreement were not disclosed.



## Current Developments – India

### Pharma sector needs global collaboration

The need of global collaboration in the pharma sector from research and development to drug manufacturing has never been as great as it is now amid the deadly COVID pandemic. Ahead of the 14th edition of the annual BioPharma and Healthcare Summit, that bring stakeholders from India and the United States on one platform, officials and industry leaders said the global health crisis requires a global solution, which can be achieved through global collaboration. It was highlighted that India and the United States can play a lead role in this.

### ICRA revises domestic pharma industry outlook to negative

Rating agency ICRA has revised its outlook on Indian pharmaceutical industry to negative from stable due to ongoing lockouts in parts of China following the outbreak of coronavirus. The domestic drug industry is highly dependent on imports, with more than 60 % of its API requirement being shipped from overseas locations, especially China.

In some specific active pharmaceutical ingredients (APIs), like cephalosporins, azithromycin and penicillin, the dependence is as high as 80-90 % of the total imports of APIs and intermediates into India, China accounts for 65-70%.



## Indore SEZ exports log marginal decline in Apr-June amid Covid-19 pandemic

Exports from Indore Special Economic Zone (SEZ) have not been impacted much due to the coronavirus outbreak, with outward shipments dropping merely 1.14 per cent in April-June. The multi-product Indore SEZ logged exports worth Rs 2,555.42 crore in the first quarter of the ongoing fiscal as against Rs 2,584.88 crore in the corresponding period a year ago.

In this, 70 per cent contribution was of medicines, according to a union commerce ministry official. Despite the lockdowns imposed due to COVID-19, the production in pharma units continued as the government kept it under essential services category.

“ Indore SEZ exports not impacted during COVID-19 lockdown as production of pharma units was categorized under essential services ”

## UCPMP should be made mandatory without further delay: experts

Recently, D V Sadananda Gowda, Minister of Chemicals and Fertilizers, informed that the Uniform Code for Pharmaceuticals Marketing Practices (UCPMP) is voluntary in nature and the Government has not yet decided to make it mandatory. This announcement did not go down well with patient activists and the medical fraternity.

Extending benefits to doctors through associations is unethical. But this is being flouted with impunity. The Medical Council of India (MCI) had amended the Indian Medical Council (Professional conduct, etiquette and Ethics) regulations, 2002 at its meeting on February 18, 2014, and exempted the "Professional Associations of Doctors" from the purview of Medical Ethics. Industry experts feel there is an urgent need to take steps to reverse this amendment of the MCI and make the UCPMP mandatory.



## NPPA caps price of liquid medical oxygen and medical oxygen cylinders

The Ministry of Health & Family Welfare (MOH&FW) has conferred the delegation of powers under Section 10(2) (I) of Disaster Management Act, 2005 to NPPA to take all necessary steps to immediately regulate the availability and pricing of LMO and medical oxygen in cylinder.

The Authority deliberated upon the matter in its meeting held on September 25, 2020, and has been decided to invoke extra-ordinary powers in public interest, under Para 19 of DPCO, 13 and under Section 10(20) (I) of Disaster Management Act, 2005 to deal with the emergent situation arising due to the pandemic.



## Govt. regulation may hamper pharma sector growth: Pfizer

Pharma major Pfizer fears that the pharma industry is expected to face challenges due to government regulations. "While implementation of large scale healthcare initiatives expected to provide a boost to the pharma industry, there will be continued challenges in the areas of price controls, ad-hoc regulatory changes and new policies that may impact predictability and sustainable growth," it further said.





# Product Approvals / Launches - Indian Companies

## DRL launches Dimethyl Fumarate DR capsules in US

Dr Reddy's has launched dimethyl fumarate delayed-release capsules, a therapeutic equivalent generic version of Tecfidera (dimethyl fumarate) delayed-release capsules for Multiple Sclerosis (MS), approved by the USFDA. The Tecfidera brand and generic market had US sales of approximately \$3.8 billion MAT for the most recent twelve months ending in June 2020 according to IQVIA Health.

## Lupin launches Divalproex Sodium ER Tablets

Lupin announced the launch of divalproex sodium extended-release (ER) tablets USP, 250 mg and 500 mg, having received an approval from the USFDA earlier. Divalproex sodium ER tablets USP is the generic equivalent of depakote extended release (ER) tablets of AbbVie indicated for Acute treatment of manic or mixed episodes associated with bipolar disorder (with or without psychotic features), Monotherapy and adjunctive therapy of complex partial seizures and simple and complex absence seizures; adjunctive therapy in patients with multiple seizure types that include absence seizures and Prophylaxis of migraine headaches.

## Glenmark launches Nintedanib (Nintedanib) for Pulmonary Fibrosis in India

Glenmark Pharma launched NINDANIB (Nintedanib 100 and 150 mg capsules) for the treatment of pulmonary fibrosis in India. Nintedanib is approved by the Indian drug regulator for the treatment of idiopathic (unknown cause) Pulmonary Fibrosis. In a recently published INBUILD trial, Nintedanib showed significantly lower annual rate of decline in FVC (Forced Vital Capacity) – a measure of lung health – with various progressive fibrosing interstitial lung diseases. Moreover, two clinical trials are being rolled out for to study the efficacy and safety of Nintedanib as a treatment of SARS-COV2 induced Pulmonary Fibrosis in moderate to severe COVID-19 patients," informed the company through a statement.

## Sun Pharma arm launches Plaque Psoriasis treatment drug in Japan

Sun Pharma's Japanese subsidiary has launched its specialty product Ilumya, indicated for treatment of Plaque Psoriasis in adult patients in Japan. It has got approval from the Japanese government. It is a subcutaneous injection (100 mg Syringe) for the treatment of Plaque Psoriasis in adult patients who have an inadequate response to conventional therapies. It is Sun Pharma's first innovative drug to be launched in the Japanese market.

## Zydus Cadila gets nod for Fingolimod caps & Verapamil Hydrochloride injection

Zydus Cadila has received final approval from the USFDA to market Fingolimod Capsules, 0.5 mg (US RLD: Gilenya Capsules). Fingolimod is an immunomodulating drug. It is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of Multiple Sclerosis (MS). The Company has also received the final approval from the USFDA to market Verapamil Hydrochloride Injection USP, 5 mg/2 mL (2.5 mg/mL) and 10 mg/4 mL (2.5 mg/mL), Single-Dose Vials (US RLD: Ioptin Injection). Verapamil injection is used to rapidly or temporarily restore normal heartbeats in people with certain heart rhythm disorders.

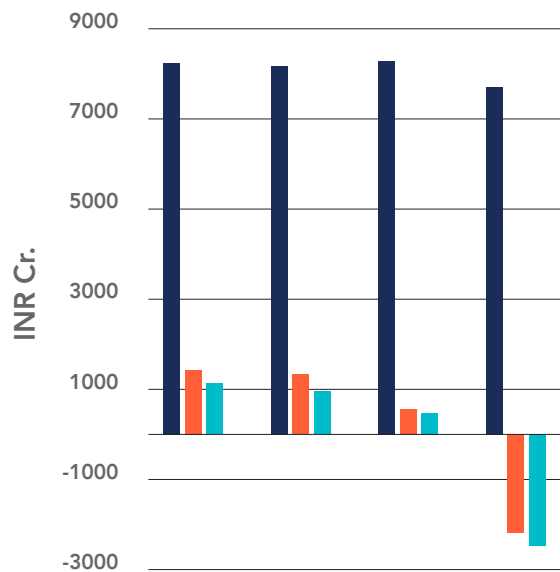
## Indoco launches Favipiravir 400 mg tablets

Indoco Remedies announced the launch of FEVINDO (Favipiravir) 400 mg tablets in India. Fevindo – 400 is an antiviral drug, effective against the RNA-based influenza virus. The drug has been approved by DCGI in the treatment of COVID-19.



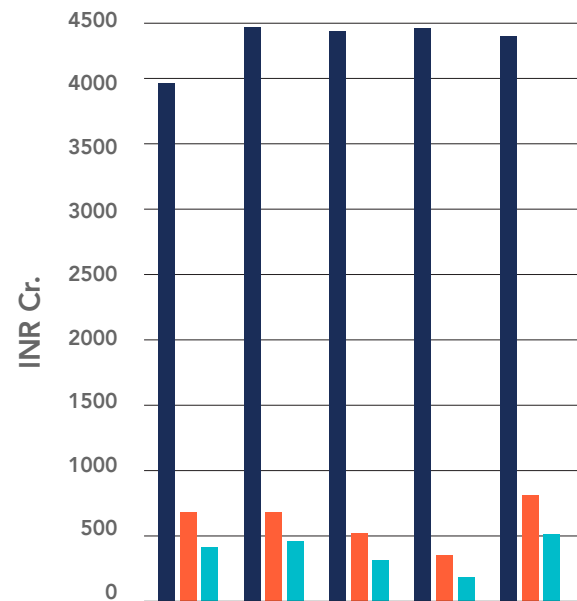
# Financial Performance of Some Key Players

## Sun Pharma Ltd.



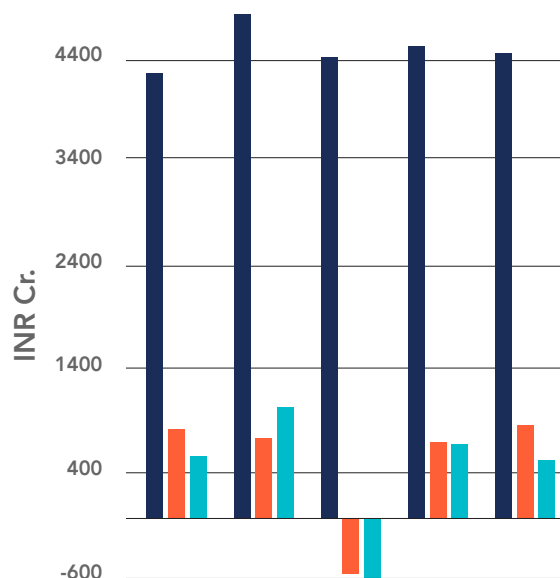
	Q1 JUN 19	Q2 SEP 19	Q3 DEC 19	Q4 MAR 20	Q1 JUN 20
Total Income	8587	8324	8274	8287	7739
EBITDA	1751	1517	1414	629	-2131
PAT	1501	1167	1023	494	-2429

## Cipla Limited



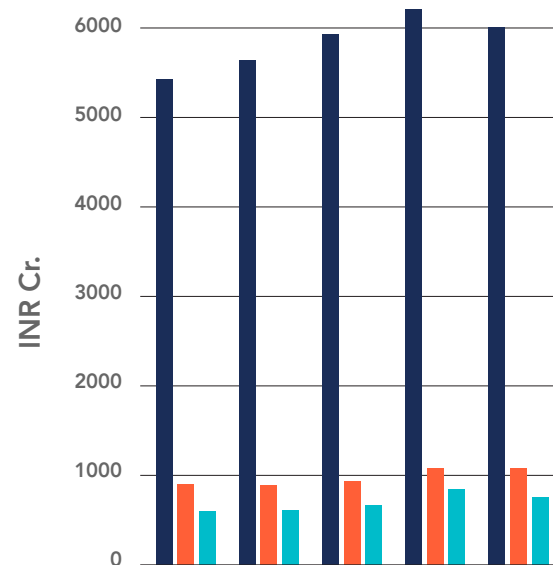
	Q1 JUN 19	Q2 SEP 19	Q3 DEC 19	Q4 MAR 20	Q1 JUN 20
Total Income	4067	4496	4443	4469	4411
EBITDA	715	727	552	380	845
PAT	470	480	353	242	571

## Dr. Reddy's Labs Ltd.



	Q1 JUN 19	Q2 SEP 19	Q3 DEC 19	Q4 MAR 20	Q1 JUN 20
Total Income	4288	4866	4464	4522	4513
EBITDA	882	804	-508	748	916
PAT	660	1095	-556	770	586

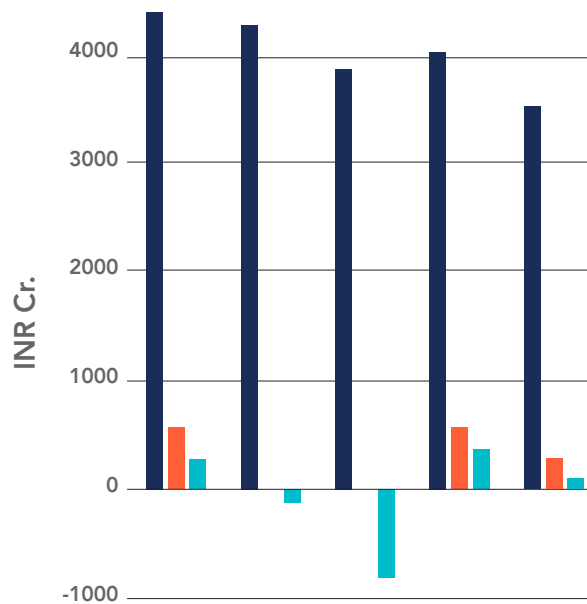
## Aurobindo Pharma Ltd.



	Q1 JUN 19	Q2 SEP 19	Q3 DEC 19	Q4 MAR 20	Q1 JUN 20
Total Income	5460	5621	5925	6191	6040
EBITDA	908	904	975	1128	1117
PAT	630	639	705	868	792

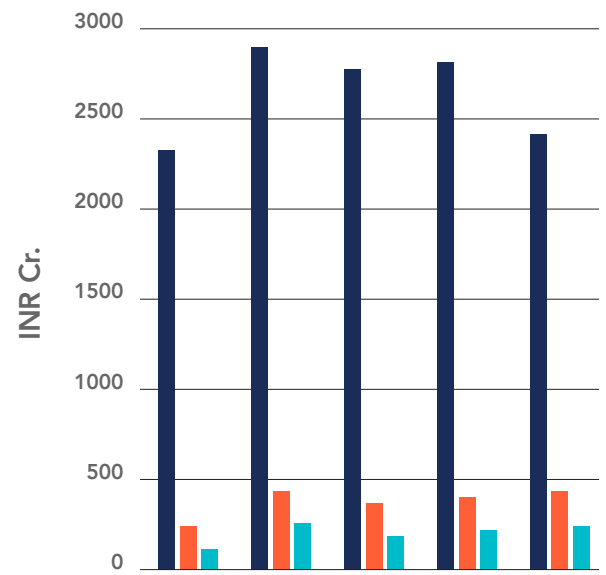
# Financial Performance of Some Key Players

## Lupin Ltd.



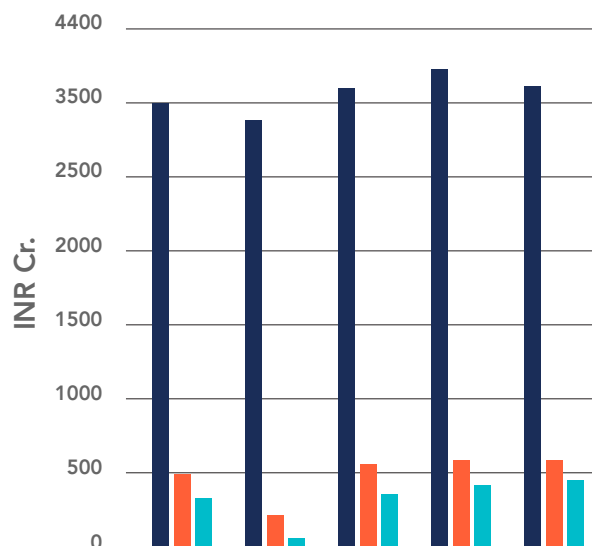
	Q1 JUN 19	Q2 SEP 19	Q3 DEC 19	Q4 MAR 20	Q1 JUN 20
Total Income	4490	4492	3862	4054	3571
EBITDA	625	-3	24	602	316
PAT	301	-124	-841	390	108

## Glenmark Pharma Ltd.



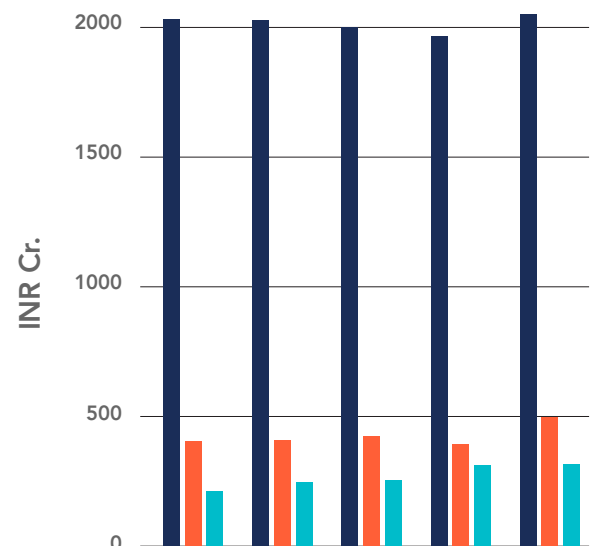
	Q1 JUN 19	Q2 SEP 19	Q3 DEC 19	Q4 MAR 20	Q1 JUN 20
Total Income	2324	2895	2768	2811	2403
EBITDA	252	437	367	416	451
PAT	109	255	190	220	254

## Cadila Healthcare Ltd.



	Q1 JUN 19	Q2 SEP 19	Q3 DEC 19	Q4 MAR 20	Q1 JUN 20
Total Income	3518	3393	3658	3796	3662
EBITDA	483	212	537	604	661
PAT	314	82	364	413	469

## Torrent Pharma Ltd.



	Q1 JUN 19	Q2 SEP 19	Q3 DEC 19	Q4 MAR 20	Q1 JUN 20
Total Income	2042	2039	2019	1961	2060
EBITDA	401	412	430	395	504
PAT	216	244	251	314	321

(Source: ET Markets, Moneycontrol, Company Financial Reports)



## People Movement

### Nikhil Chopra is the new CEO of JB Chemicals and Pharmaceuticals

The Board of directors of JB Chemicals & Pharmaceuticals appointed Nikhil Chopra as Whole-time Director and Chief Executive Officer of the Company for a period of five years.

Earlier, Nikhil Chopra worked as Head-India Business at Cipla. He holds M.Sc. (Organic Chemistry) from Gujarat University. For over two decades, he has spearheaded breakthrough ideas focused on creating greater access to high quality treatment and medicines, and gain a significant competitive advantage over peers, especially in therapies such as respiratory, urology HIV and paediatric care.

### Biocon appoints Anupam Jindal as its CFO

Anupam will head the finance function at Biocon and be part of the Executive Leadership Team. He will report into the company's CEO and MD, Siddharth Mittal. Prior to joining Biocon, Jindal worked with the Vedanta Group of companies for 22 years, where he held the position of Group CFO at Sterlite Technologies since 2006. He holds a Bachelor of Commerce (B Com) degree from ML Sukhadia University, Udaipur. He is also a Chartered Accountant from the Institute of Chartered Accountants of India and a Company Secretary.

### Vaibhav Karandikar is the new CFO of Sanofi India

Sanofi India announced the appointment of Vaibhav Karandikar as Chief Financial Officer (CFO), effective October 6, 2020. Karandikar joined Sanofi 13 years ago. He is a Chartered Accountant, Cost Accountant & Company Secretary. He has held growing responsibilities in business controlling, accounting and in various M&A and transformation projects, for both commercial operations and manufacturing facilities. Prior to joining Sanofi, Vaibhav has worked with Sandoz India, Tata Power and Hindustan Ciba Geigy.

## S Aparna appointed as Secretary, Department of Pharmaceuticals

S Aparna, an IAS officer from the Gujarat cadre 1988, has been appointed as Secretary, Department of Pharmaceuticals (DoP), under the Ministry of Chemicals and Fertilizers. She will succeed PD Vaghela, who demitted the office on his superannuation on September 30, 2020, as per an order issued by the Department of Personnel and Training. In 2017, she was appointed to the post of Executive Director, World Bank, representing the Constituency of India, Bangladesh and Sri Lanka. In 2019, she was given a proforma promotion as Additional Chief Secretary (ACS) while she was on deputation in Washington DC as Executive Director, World Bank.

## Manjiri Gharat elected as VP of FIP for 2020 – 2024

Manjiri Gharat, VP & Chairperson, Community Pharmacy Division of Indian Pharmaceutical Association (IPA), has been elected as Vice President of the International Pharmaceutical Federation (FIP) for 2020 – 2024. She is the first woman pharmacy professional and second pharmacy professional from India to be elected as FIP Vice President. In the past, Praful Sheth had been Vice-President of FIP for the term 2006 – 2010 & 2010 - 2014. The International Pharmaceutical Federation (FIP) is a global body representing over four million pharmacists and pharma scientists.



## Zyklus wellness appoints Sandeep Anand as its new Chief Marketing Officer

Sandeep Anand was earlier the CMO for the Food Delivery business of Zomato. He focused on Offline marketing (Consumer Advertising), Digital (Performance Marketing, CRM, Growth Analytics, and Alliances). He is an alumnus of Jamia Milia Islamia & Management Development Institute (MDI). Sandeep joined Zomato in December 2018 from GSK Healthcare known for Horlicks. Sandeep has worked with GSK, Ranbaxy, and Reckitt Benckiser in his career.



## Alind Sharma joins Optum as Vice President – Human Capital

Optum, a health services and innovation company, has announced the appointment of Alind Sharma as VP – Human Capital. In his earlier role, Alind was with Pfizer as Senior Director in charge of HR responsibilities across all Pfizer manufacturing sites in the APAC region. He has worked with Monsanto, Tata International, Glenmark Pharma and Ranbaxy. He is a Mechanical Engineer and completed his management studies at IIM Ahmedabad.

## Indegene hires C-suite Executives from GE & Quikr

Healthcare technology company Indegene has brought on board Marut Setia, former chief marketing officer for GE's South Asia region, as Senior VP-Emerging Markets and Devices. Atul Tewari, former COO of Quikr, has also joined as Senior VP-Global Delivery. Setia was part of the executive leadership team at GE. His main areas of expertise are in incubating new businesses, P&L leadership, business transformation, revenue marketing and finance management. Tewari, in his most recent experience as COO of Quikr, was part of the team that has built India's largest horizontal classifieds with deep vertical focus into real estate, jobs, goods, services and automobiles. Prior to Quikr, he was managing director at BlackRock in Gurugram.

## Sridhar Desikan of Dr. Reddy's joins Piramal Pharma Solutions in a global role

Dr. Reddy's Head of Technology Strategy & Innovation, Dr. Sridhar Desikan, has joined Piramal Pharma Solutions as Global Technical Head of Formulations R&D. He will be based in the United States and will lead R&D teams across the globe. Before DRL, he worked with Biocon where he was part of the team to establish Biocon's BMS R&D center. He was also with Dupont Pharma and Novartis as a Research Investigator earlier in his career. He completed his Chemical Engineering from BITS Pilani along with Masters and PhD from the United States.

# Talent Insights

Indian Pharma industry has always primarily focused on generics as a business model. Some companies have tried to go the innovation route but it has yielded limited results. The pipeline of new molecules has come down, thereby reducing opportunities in generics.

COVID-19 has led to an increased demand for Digital Transformation and Manufacturing professionals. In addition, with new product launches being postponed, Life Cycle Management (LCM) is a major area where increasing number of companies are focusing. Top areas where we are seeing an increased talent demand are the following:



## Manufacturing

Scaling up is one of the major areas where talent is needed and a lot of companies are gearing up for the challenge.



## Technology and Digital Transformation

COVID-19 has spurred a sharp rise in demand for specialists with expertise in new-age technologies along with cross functional experience in Pharma.



## Analytics

Analytics is here to stay and more and more industries are implementing it in their plans. This holds true for both Product Development and Marketing/Sales Force Effectiveness.



## Regulatory and Govt Affairs

With the pricing pressure likely to continue for next few quarters, this is a strong area that has emerged and many companies are strengthening their expertise.



## Business Development/Licensing

With the generics market not giving the right growth, companies are moving towards collaborations and licensing opportunities. Deal makers in this area are in high demand.



## Medical Affairs and Real World Evidence

This is another area that is seeing an uptrend given the importance of Real World Evidence and HEOR.



## Marketing

With the digital boom, Marketing is seeing an overhaul and is seeing a dynamic shift. Companies are increasingly focusing on newer ways to maximize their marketing and outreach.



# References

EMA Partners – Research Team

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Fierce Pharma News

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Moneycontrol

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Company Annual Reports

Since 1988, EMA Partners has been serving local and international businesses across multiple industry sectors. The firm has been instrumental in helping its clients recruit numerous leaders who have made a significant impact in their organizations.

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