SPARK CAPITAL

INVESTMENT BANKING NEWSLETTER

HEALTHCARE AND LIFESCIENCES

APRIL 2018

FROM THE DIRECTOR'S DESK

Dear Reader,

I take this opportunity to welcome you to the second edition of the Healthcare and Lifesciences Newsletter by Spark Capital and thank all our well-wishers and friends for the phenomenal response to the Inaugural Edition. We have attempted to take all your feedback on board and sincerely hope that you will find this newsletter enriching and worth your time.

A number of themes we had listed as ones to watch out for in our Inaugural edition have been playing out in the market. First there is a massive consolidation potential in healthcare delivery – this was evidenced by the binding & non-binding bids received by Fortis Hospitals from a bunch of bidders. Additionally, we are increasingly seeing interest from market participants – across sub-segments of healthcare delivery - in pursuing bolt-on acquisitions to build scale in their domain and believe this trend will only accelerate from hereon.

Another theme we had outlined in the earlier edition of the newsletter was that of scaled-up players preferring to provide liquidity to shareholders through a public listing rather than through a secondary private trade. Q4FY18 was a busy time in this regard with Aster DM getting listed following in the footsteps of Shalby Hospitals which listed earlier in the year. And as I write this, another major chain is sitting with an approval from the regulator to launch its initial public offering, and a clutch of lifesciences companies are busy preparing to file the draft red herring documents with the regulator.

And thirdly, as we had highlighted, from an investment standpoint, we are continuing to see some shifting trends and formation of a 'new normal' both in public and private markets.

In continuation of our efforts to deep dive into contemporary topics of interest for the sector (the last edition had focused on the Regulatory Landscape in India for Medical Devices and Healthcare Delivery), in this edition we look at **Specialty Pharma** from an Indian context– a perspective not very often described. We then expand our horizons to the US and developed world as we look at the **Biosimilars** sub-segment of specialty pharma and how that has played out in the recent past, given its high voltage headline grabbing entry onto the specialty pharma scene.

The motivation to cover these concepts is the constant talk we hear from eminent persons in the industry of these being the next big growth drivers. Of the generic story coming to an end and of Indian companies betting on specialty pharma including biosimilars for their growth over the next decade. Strangely enough, many sell side research analysts also refer to these concepts loosely in their notes on the sector and on specific companies but have stopped short of giving out a numerical impact on the earnings and share prices of the respective stocks.

While Specialty pharma is usually spoken of in the context of US market opportunity for Indian pharma companies, and more from a B2B perspective and R&D/manufacturing capabilities, it is interesting to understand this upcoming sector in the context of the Indian domestic market and where one could find pockets of attractive investable opportunities.

Like the generic-generic market in US, which is witnessing excessive competition and compressing margins below attractive levels, Indian branded generic market while still offering reasonably attractive margins, has always been rather fragmented and a competitive space, with little scope of product/service differentiation. This situation makes it difficult to discern one company from another in general, while evaluating an investment bet for a larger play (Although we clearly agree that there are pockets which are differentiated on account of execution capability, quality of governance and therapy focus).

By clearly understanding the definition of specialty pharma, we will be able to discern opportunities spanning formulation segments like biologicals especially biosimilars as well specialised API segments like Peptides, Oncology APIs, Hormones,

FROM THE DIRECTOR'S DESK

Enzymes. Beyond the product space, we look service segment opportunities in Specialty pharma, which include supply chain (Specialty distribution),Delivery (Home infusion services) & Diagnostics (High-end diagnostics).

While biosimilars have been in existence for close to two decades now, their adoption can broadly be classified into three geographical buckets – Europe, Rest of the World and the USA. Strangely, biosimilars have had a fair shares of success in the EU and RoW markets with established approval pathways, large scale commercialization and impact on innovator drug pricing, while they continue to remain an immaterial entity in the USA. Nearly a decade after the USA came out with its first guidance on the approval pathway for biosimilars, there are less than 10 approved biosimilars of which less than 5 are commercialized. And what is even more interesting to note is that none of these have been approved as interchangeable.

The premise was set perfectly well for the rise of biosimilars in the US market – large chronic and complex disease incidence population already on biologic drug prescription, patent cliff for several blockbuster biologics, lower cost of development of biosimilars allowing predatory pricing compared to biologics and payer driven health economics always on the lookout for cost reduction initiatives. With the hope came the hype – guidance were issued without extensive stakeholder consultations, physician consent towards adoption given the cost arbitrage was assumed as a given and interchangeability was thought of as inevitable. But then came the reality check – innovator biologic companies were just not willing to take the onslaught lying down and see their value erode overnight – and that too in a litigation happy market like the USA. Lawsuits after lawsuits followed on almost every biosimilar. Approval timelines were stretched. Development costs now also had to account for imminent legal battles. Innovators came up with unique and potent turf protection strategies (some almost bordering on being anti-competitive) and physicians just refused to be drawn into the lure of prescribing a 'similar' drug which didn't have the absolute 'same' results. Suddenly things weren't as rosy as they seemed. In the article titled 'Biosimilars in the United States – The Hope, the Hype and the Reality!', we chronicle the happenings in the US biosimilar market, outline trends and potential scenarios based on current US market dynamics and evaluate scope for play by Indian pharma companies.

We continue with our series on the "Expert Speak" wherein we bring in a direct perspective from leading industry operators in the chosen segments of the broader sector. For this edition, we have picked domestic pharma as the sub-segment of choice and accordingly have included interviews of a two industry flag bearers - in the sector in our 'Expert Speak' section. I would like to take this opportunity to whole heartedly thank and express our gratitude to Pankaj Singh, Chairman and CEO, LaRenon Healthcare and Deepnath Roy Chowdhury, National president- IDMA & MD, Strassenburg Pharma for being of great help and for providing their thoughts on several of our questions captured later in this newsletter.

Also covered in this newsletter are some of the latest developments in deal making in the sector coupled with an update on the Regulatory Environment which we had covered in the Inaugural Edition. Additionally, we hope you find the section on "From our Equities Desk" an interesting read on listed companies and our outlook on various sub-segments of the sector.

I hope you find the content in this newsletter insightful and would be grateful if you could connect with us with any views / information relating to the topics we have attempted to cover in this edition. Like always, we assure you of taking any feedback (including critique!) you may have on board for subsequent editions. We hope you enjoy reading it as much as we did putting it together.

With best wishes,

Virendra Pandey

Director and Head – Healthcare & Lifesciences
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Investment Banking

USD 5.5 Bn
Total transaction value till date

USD 3.7 Bn
Capital raised till date

USD 1.8 Bn
M&A transaction value till date

300+
Number of fund relationships globally

USD 700 Mn
Average annual deal closure value for the last 3 years

11
No. of transactions > USD 100 Mn

~USD 1.2 Bn
Current value of transactions being executed

Healthcare & Lifesciences

~USD 500 Mn
Total transaction value till date

~USD 100 Mn
Current value of transactions being executed

'CHRONIC' APPETITE FOR GROWTH

INSIGHTS FROM AN INDUSTRY VETERAN

La Renon®

We interacted with Pankaj Singh, Chairman & CEO of LaRenon Healthcare, on how LaRenon has grown rapidly to become one of the largest companies in its segment in just over a decade

Pankaj Singh
Chairman and CEO, LaRenon Healthcare

LaRenon is an emerging leader in specialty pharmaceuticals. Founded in Ahmedabad in 2007, it was the first to foray into the domain of Nephrology with a focus on early stage Chronic Kidney Disease (CKD) Patients.

It also gradually entered into other chronic management therapies of Critical Care, CNS, Urology, Gastroenterology, Respiratory and Cardio Metabolic

1. Between 2011-15, Indian pharma story was all about US generics, even overshadowing a strong domestic market. Given all the headwinds in the US markets that seems to have changed with renewed interest in the domestic pharma business, as a relatively safer bet. In this context, how do you see the overseas opportunity for regulated markets pan out over the next 5 years?

US generics market has become a different ballgame altogether with its risk-reward equation perhaps changing in comparison with that of domestic formulation opportunity. Our strategy is to first strengthen India and, then focus on selected emerging markets followed by an entry into the European markets. The US market, while remains attractive, may not be amongst the top priorities for us in the medium term. However, to be sure, we plan to test the waters by planning an entry in the US market through patented Medical foods segment.

2. Unlike some of your peers, La Renon started off as a Super Specialty focused company focused on renal care, subsequently selectively entered chronic & semi chronic segments like CNS & GI. Can you share your thought process on this approach?

Yes, that's true. To begin with; we adopted a different strategy by focusing on the early stage of CKD (Chronic Kidney Disease), while the then existing incumbents were largely operating in the end stage renal disease. It is interesting to note that approx. 60% to 70% of our revenue comes from the early stage CKD, while only 25% to 30% comes from the end stage renal disease.

Further, as one would notice, people have become increasingly aware of the cardio metabolic disorders, and proactively approaching specialists such as Cardiologists, Diabetologist and Nephrologists along with getting themselves tested for various health conditions including kidney function disorders. Considering the paradigm shift in the present generation of fostering a proactive approach towards one's health; I believe the development in Cardio Metabolic therapy is going to be mimicked by the Nephrology segment in the near future, enabling it to become a much larger super-specialty therapy.

EXPERT SPEAK

Full Service, Mid-Market I-Bank

- Investment Banking (VC, PE, M&A, IPO, QIP, PIPE)
- Institutional Equities
- Fixed Income solutions
- Investment Advisory

Knowledge Banking

- Dedicated sector teams with deep domain expertise
- Ability to bring new ideas to the market
  - Medall (2009)
  - Vaatsalya (2011)
  - Cloudnine (2013)
  - Apollo Health & Lifestyle (2015)

Relationship Banking

- Several clients for whom we have closed multiple transactions
- Consummated ~USD 300 Mn of transaction value in repeat business

Deep Distribution

- Extensive reach to over 300 funds across
  - Private Equity & Hedge Funds
  - Family Offices
  - Sovereign Funds
  - Corporates

If we take a look at Neurology, market is quite consolidated with 60% to 70% market being accounted for by top 4 or 5 players. A number of new entrants have unsuccessfully tried to enter the segment. Given this background; before taking a plunge, we did some research as to why companies trying to enter this segment had a high failure rate. We found one thing which was strikingly common. All the concerned companies came from an acute therapy background. In our experience, managing acute and chronic therapies is very different. Since we started as a super chronic segment, we have well-established culture, processes and systems to successfully execute these strategies.

In India, we are planning to commence operations in new therapeutic segments of Orthopaedics and Gynaecology. The Unique selling point that will differentiate us from the me-too players is the introduction of first of its kind products by us.

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3. In the product patent regime since 2005, access to new product opportunities have been limited by in-licensing or fixed drug combinations or OTC/Semi OTC nutrition based products. What has been your strategy for new product selection?

Our strategy is clear, to enter the chronic disease segments and even with chronic segment, our product selection is focused on super chronic drugs & drug combination.

For instance, let's look at our focus on early stage CKD. For starters, no player was focusing on early stage CKD in a comprehensive manner. Take the example of multi vitamin like Becosules, which was given to Kidney patients when we started in 2007. But Becosules is a combination of water soluble and fat soluble vitamins. However, we know that kidney patients should never be given fat soluble vitamins. In light of this, we were the first ones to launch a vitamin supplement meant for kidney patients with only water soluble vitamins. In the US, there is a concept of alternate day dialysis. But in countries such as India conditions are very different especially in Tier 2 and 3 cities wherein patients come for dialysis either once or twice in a week, which leads to build up of Toxins in the body, without dialysis. To address this, we have launched a first time product in India which helps reduce the nitrogenous toxins in the body. For this we successfully litigated with a USA based company, which had a process patent for this product and we were able to revoke their Indian patent. Many of our products have implemented from product ideas which originated with an unmet medical need.

FDCs have not been a key part of our portfolio. Super Specialists are very particular about compositions, unlike the general physicians, where creative FDCs have been a big part of the new product portfolio. Even drug dosage/strengths are different for super speciality segments in comparison with general segment patients. Let's look at the example of Torsemide, wherein a dose of 100 mg is given by a super specialist to a kidney patient, while a dose of 10-20mg is preferred by a general physician.

On a related note, we have developed 3 patented medical foods for which we have filed our patent applications in over 40 countries including USA, Canada, European countries and a number of those in the emerging markets. We plan to pursue the medical food approach primarily as regulatory barrier is low in most markets including regulated markets. Similarly, we are exploring in-licensing opportunities as well with players from US & Europe.

In April, we are launching a first of kind product in India, for Iron deficiency in Kidney disease. For this, we have developed, a non-infringing API & formulation, in house.

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4. The domestic formulations space has seen quite a bit of M&A activity over the past 12 months which is only expected to intensify. Some of these have been succession related, while others have been due to rationalisation of non-core business areas. Historically, pharma companies have resisted from any divestment/restructuring. Do you see this trend changing and foresee more transactions in future?

Yes, there seems to be a trend though I would say consolidation is still episodical. You see, the next generation is becoming more logical and decisions

Select Sector Transactions

August 2017

Exclusive Advisor

To

OMNI Hospitals

Structured Debt

By

IFMR Capital

Undisclosed

June 2017

Exclusive Advisor

To

A South India pharma company

Banking Facilities

By

A private sector bank

~USD 12 Mn

Multiple tranches - 2017

Advisor

To

Select Institutional Buyers

Block Deal

In

HOG

Undisclosed

Multiple tranches - 2017

Advisor

To

Select Institutional Buyers

Block Deal

In

Narayana Health

Undisclosed

are based less on emotional connections. There is also more business pressure nowadays in certain segments of business like the US. So some large Indian companies are seeing domestic formulation as a relatively more attractive opportunity for acquisitions. Even on in -bound acquisitions, while the sentiment are slightly dampened with the experience of Daichii-Ranbaxy and sky high valuation expectations, large multi therapy deals might not be as common. But in certain segments like Injectables, deals have continued to happen for likes of Gland-Fosun, Baxter – Claris and even before that Otsuka – Claris. Such in-bound acquisitions in specialty/ differentiated areas are also likely to continue, in my opinion.

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5. We are also seeing a spike in activity on domestic brand acquisitions with more meaningful play unlike the earlier divestitures of 'tail brands/high vintage' by MNCs. Do you believe there is scope to make money of such acquisitions, which come at rich valuation multiples and what areas are you focusing on for La Renon?

From La-Renon's perspective, I believe that organic growth should be the most preferred strategy; till a certain scale is achieved. Even in today's market, there are many new product opportunities still available to launch on your own. For inorganic, one needs to be careful in target brand selection on the basis of scale, penetration, reach and supply chain. One also needs to make sure that the targets are not compromised in some way or the other. Once you carefully apply such filters, you will find that only a few opportunities are genuinely good.

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6. In the past decade, several new age pharma companies like Eris, La Renon, Corona & Koye have emerged successfully. What do you think has been the reason for this trend? Do you see more such promising companies in the making?

Yes that's a promising development in my view. We always ask ourselves, why 80% to 90% of pharma market has to be controlled by top 50 players, ranging from 10000 Cr. to 400 Cr. in revenues? Top 30 companies will cover 55% to 60% of market and most of them were launched in 80's & 90's. You need to realise that while there are nuances, this business is not rocket science. With good experience and decent infrastructure, there is a significant scope to grow the business through a differentiated strategy. You mentioned Eris, who are strong, in Cardio Metabolic segment, and their founders had lot of experience in these therapies. Similar is the case with some of the other companies that you mentioned.

It is to be noted that when we started, Nephrology was a relatively small therapy, fragmented within the top 20 players present in this therapy, who hold 3% to 4% market share each. While the start was challenging, we got some very interesting product ideas, which were very well accepted by the Nephrologists. Fortunately, even the availability of Nephrologists, has increased significantly since we commenced. For an example, of Kerala for instance, wherein with many good institutes today, there are over 100 nephrologists operating successfully. Most of them have over 100 patients a day, which is a benchmark for a very good practice. This is mainly because Kerala comprises of highly educated and health-aware patient population. A vibrant doctor/Physician ecosystem prevails, which ensures that patients are referred to specialists at an early stage itself, before their condition worsens.

After the 4 to 5 successful new companies, a lot of new regional companies have been setup with a revenue traction of 30 Cr. to 40 Cr. But most of these have been setup by regional or zonal managers of established pharma companies, who eventually find it difficult to scale up beyond their state. Also many of them are not ambitious as well and do not have a strategic vision, as they accrue enough profits in their focus geographies. The question these local entrepreneurs ask is why risk entering into unfamiliar territory? That is why we have not seen many large emerging companies yet, post the initial few. It depends on risk appetite and confidence in successful execution on entry.

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7. In terms of emerging markets, forex and protectionism have been challenges for

EXPERT SPEAK

Select Sector Transactions

November 2016
Exclusive Advisor
To
Apollo
Private Equity Fund Raise
By
IFC
USD 68 Mn

July 2016
Exclusive Advisor
To
CORONA Remedies Pvt. Ltd.
Private Equity Fund Raise
By
Creador
USD 18 Mn

May 2016
Exclusive Advisor
To
RAMESH HOSPITALS
Majority Stake Acquisition
By
Aster
USD 28 Mn

March 2015
Exclusive Advisor
To
HealthHiway
Private Equity Fund Raise
From
Piramal
Undisclosed

Indian companies' expansion. Do you think it is wise to pursue a low risk B2B approach like some of the players in the past or direct presence would be the right approach?

When we enter an emerging market, we look at it as just a single pharma market. We objectively look at them from the lens of specific therapies and doctor ecosystem. It becomes very clear that some countries are much better established in these therapies which makes it very attractive for us. They can be regionally diverse such as a Philippines, Vietnam and Cambodia in South East Asia to Ghana in Africa.

Let's take a look at the example of Philippines. Pharma market there is as large as USD 4 Bn (one fourth of the Indian market), but 1/14th of population and prices are similar to India. Being a branded generics market, it has a well-developed clinical practice, better Insurance systems advantages like incentives for healthy lifestyle, health check-ups etc. Thus, all the foundations are in place, which makes it a very attractive emerging market.

In many large companies; emerging market product selection, is decided by their regulatory team or distributors. Though we are looking at it differently, from therapy lens. We engage with the regulators using data of renal care infrastructure along with gauging the lack of it in the country and seek an approval for a large number of products in a short span of time. We are similarly, entering over 20 emerging markets focused only on our core therapies – Nephrology & Neurology.

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8. While Pharma companies have historically focused on service to doctor and not focused on Patient, Do you see that trend changing with new service modalities like home healthcare, online pharma?

That's a good point but you see, it depends on what the target population looks like. For certain segments of population, especially urban, educating the direct consumer could make sense. But we need to appreciate that a large part of the population is still dependent on doctor, who influence their drug consumption and patient care decisions. What we also see in our super chronic therapies is that, we engage the patients to provide them frequent diagnostics tests like Kidney function test and Serological tests, without any financial burden along with providing them timely reminders. While we do this predominantly in Nephrology, we plan to do something similar in Dementia, which is not even recognised as a disease and many even consider it as a natural age related issue! We plan to change this in a small way in order to sensitise people about the disease and thus market the drugs to address them.

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9. In the domestic market business, regulatory risk has been an area of concern – MCI regulations, FDC ban, price control, Generic-Generic? What is your view are bigger concerns in the near future? What risk mitigation strategies do players need to adopt?

Regulations have always been around. So on that front, some risks and uncertainty will continue to exist; to various degrees. However, regulators today have slowly started to realise that we are the cheapest in drug prices in comparison with other countries. But the issue has been, that the cost of production at current standard is low due to very low standards of compliance sought by regulators. Regulatory authorities are focusing on improving the quality control and quality assurance standards for medicines for India since such infrastructure is already available for drugs exported to regulated markets.

Even in the case, generic-generic becomes a reality (I am not saying that it will), quality of manufacturing becomes a big differentiator. For example, there are companies in India which follow a uniform manufacturing infrastructure; making the medicine for both India and US market in the same plant with same quality standards.

I understand that FDC issue has been stayed by court. Court has asked these cases to go to DTAB/ or its subcommittee formed by DTAB for the purpose of having a relook on the cases to establish if the FDCs should be regulated, restricted or out rightly banned, but only after hearing the arguments of the industry.

EXPERT SPEAK

Select Sector Transactions

May & Nov. 2014
Exclusive Advisor
To
vasan healthcare
from a tradition of care
Private Equity Fund Raise
From
GIC SEQUOIA
WESTBRIDGE | CAPITAL
USD 68 Mn

September 2014
Exclusive Advisor
To
OMNI Hospitals
Minority Stake Acquisition
By
ASK PRAVI CAPITAL ADVISORS
Undisclosed

July 2014
Exclusive Advisor
To
OMNI Hospitals
Majority Stake Acquisition
By
UDAI
Undisclosed

October 2013
Exclusive Advisor
To
cloudnine
Private Equity Fund Raise
From
SEQUOIA matrix PARTNERS INDIA
USD 17 Mn

Another way to mitigate risks to growth and base business, is to diversify the business across markets and beyond India into emerging and regulated markets as well. In 5 years, we expect meaningful part of our revenues coming from markets outside India. We are already investing into this business well ahead of time in likes with, be it 400+ dossier filings in over 20 emerging markets, patenting our medical foods products in over 40 countries or even setting up our green-field EUGMP compliant manufacturing plant. Thus, a strong foundation is in place.

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10. Do you believe having own manufacturing facility for domestic market critical in the future? Do you believe own API facility also provides a meaningful competitive advantage?

I think it is very important to have one's own manufacturing facility for domestic as well as export markets.

With this perspective, we created Stanford labs, which is our own subsidiary and accounts for approximately 60% of our total revenues. In India, very few contract manufacturers are large enough or have decent infrastructure to maintain the high quality standard.

Likewise, it is critical to have in house API facility. Many niche APIs have few manufacturers and many of these are in-house arms of large domestic pharma competitors. For 3rd party buyers, buying APIs is a risk from getting timely delivery, as their priority is always in house supplies. Realising this, we have setup an in house API R&D, which has developed some APIs, which we are currently contract manufacturing with a 3rd party. We are taking this approach for API supplies for all our key large brands, which secures our supply chain. We plan to take a similar approach for some of our promising pipeline products

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11. La Renon has been one of the fastest growing companies in the domestic pharma segment with focus on 2-3 therapies – what are your views on the growth of the market in your therapies and what's your medium and long-term vision for La-Renon?

I believe in focusing on processes which should bring the numbers and the numbers are only incidental. We are creating systems, processes, culture and infrastructure to achieve growth and rich new product pipeline, entering new markets, speedy regulatory filings and manufacturing infrastructure. I mentioned to you that we are planning to enter over 20 emerging markets which would provide further alpha to growth.

Our past performance can be exemplified. I would not like to comment specifically on any future numbers but suffices to say that we see enough growth levers up our sleeve to grow well in excess of the industry growth.

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12. While the pharma sector overall has witnessed muted public market sentiment since Jan 2016, A few focused mid cap players & domestic only companies have been an exception to this trend. Do you think it is a good time for such focused mid-sized pharma companies to tap public markets?

Markets are sentimental as we all know and flavours of the season keep changing. In my view, Companies dependent on significant portion of revenues coming from US, could be challenged. Companies having a market diversification and/or a solid India franchise could be more sustainable. You see the gap is further widening in the listed space between US dependent franchises and other diversified scaled-up, plays. But to each his own and I guess companies should look at their stage of the life-cycle, fund requirements, shareholder exit requirements and their own preparedness before they take a plunge in the listed market. I think we have interesting times ahead.

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EXPERT SPEAK

Select Sector Transactions

July 2013
Exclusive Advisor
To
OMNI Hospitals
Private Equity Fund Raise
From
ASK PRAVI
Undisclosed

March 2013
Exclusive Advisor
To
SUTHERLAND GLOBAL SERVICES
Minority Stake Acquisition
In
Apollo Health Street
USD 182 Mn

March 2012
Exclusive Advisor
To
vasan healthcare from a tradition of care
Private Equity Fund Raise
From
GIC
USD 100 Mn

March 2012
Exclusive Advisor
To
MEDALL
Private Equity Fund Raise
From
PEEPUL
USD 32 Mn

CHANGE IS THE ONLY CONSTANT

INSIGHTS FROM A LEADING INDUSTRY VOICE

Strassenburg

We interviewed Deepnath Roy Chowdhury, National President- IDMA(Indian Drug Manufacturers Association) & MD- Strassenburg pharmaceuticals to seek his first person view on regulatory developments affecting the pharma sector & structural issues facing small & medium sized pharma companies

Deepnath Roy Chowdhury
National President- IDMA(Indian Drug Manufacturers Association) & MD- Strassenburg pharmaceuticals

1. Among the many headwinds Indian pharma faced over the past couple of years, the threat posed by potentially turning branded generic market into a generic-generic one, was the most worrisome. Do you think it will happen in near future? What are the challenges you foresee for this implementation?

Not sure what is going to happen. Government might not take a stance right away to ban branded generics. But they have decided to popularise generic-generics and have started taking measures like opening more Jan Aushadi stores, amending the labelling provisions to highlight the generic formulation, making BA/BE studies mandatory for certain product categories and so on. The government also plans to introduce UCPMP (Uniform Code for Pharmaceuticals Marketing Practices) to regulate Pharma Marketing Practices.

Branded generics have served Indian market well for several decades. Shifting the right to choose the product from the doctors to the chemists might have serious implications regarding margins & accountability. We are not against generic products but our only request is to allow both the branded and generic products to be co-prescribed so that the doctor can exercise his right to show his preference for a brand and the patient may decide whether to buy the brand or the generic version. Both the branded and the generics markets can co-exist in India without much disruption.

2. With the emergence of CRM based pharma business model with multiple divisions selling same combinations under difference brand names, do you think the era of large brands is over? How valuable are brands? Can we ascribe value to revenue alone or vintage/ reach also counts?

While the first part of the question should be addressed to companies employing the CRM model or operating multiple divisions, all I can say is that small brands can never be as valuable as big brands. In the recent past, most companies have been applying even more focus on their big brands given that there is a huge difference in revenue impact for a 20% growth on a INR 5 cr brand vs even a smaller percentage of growth for a INR 50 cr brand. It is much easier to establish better brand recall among doctors through bigger brands.

3. While Indian pharma market is highly fragmented one, more so at the sub INR 100 cr revenue level, with multiple players operating in limited geography at a state/regional level or single therapy level.

Source: News Publications

EXPERT SPEAK

Select Sector Transactions

March 2012

Exclusive Advisor

To

vasan healthcare

Majority Stake Acquisition

In

SHEKAR NETHRALAYA Superspeciality Eye Hospital

Undisclosed

June 2011

Exclusive Advisor

To

Vaatsalya

Private Equity Fund Raise

From

AQUARIUS

Undisclosed

October 2010

Exclusive Advisor

To

vasan healthcare

Private Equity Fund Raise

In

SEQUOIA | WESTBRIDGE CAPITAL

USD 26 Mn

January 2010

Exclusive Advisor

To

MEDALL

Majority Stake Acquisition

In

CLUMAX DIAGNOSTICS

USD 11 Mn

Would you think the market is ripe for consolidation for players with complementary geographical/therapy coverage?

These are difficult times for very small pharma companies. On one side, there is serious regulatory pressure which increases costs and on the other side, there are pricing pressures that are reducing revenues. Economies of scale on both production front and sales front are becoming increasingly critical for survival.

Even strong regional companies are finding it difficult to cross the INR 100 cr threshold. A large number of very small companies are going out of business. Many of them have succession issues with the next generation not interested in running the business because of future uncertainties. Many feel that if they invest further for expansion, they are not sure they will get the returns. The bottom line is that either you build great manufacturing capability or create big established brands. If you have neither, then there is a serious concern about the value and potential of the business.

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4. What are your thoughts on Department of Pharmaceuticals (DoP)'s proposal for compulsory BA/BE studies for drug approvals as well as discontinuation of P2P & Loan licensing based manufacturing arrangements?

We have expressed our serious reservation regarding the proposed discontinuation of P2P & Loan licensing based manufacturing arrangements. We understand these measures are unlikely to be implemented in their current form.

• • •

5. Trade channel margins in retail pharma is among the highest in comparison with other consumer facing industries. Many attempts to disintermediate the channel by online pharma companies, have been met with regulatory hurdles/lobbying pressure? Do you think government might possibly intervene to cap the margins in future?

Existing trade margins for branded generics is reasonable - 10% for wholesale & 20% for retail. There may be instances of unreasonable channel margins prevalent in the generic-generic supply chain. This is being closely monitored by the Government.

• • •

6. In view India's improving competitiveness vis-a-vis China in bulk drug manufacturing, due to removal of custom duty exemptions, growing labour costs & higher EHS compliance in China, do you think Indian bulk drug industry is on its way to regain past glory? Are there any lessons to be learnt from API manufacturers in Europe & Japan, who have sustained their business despite the threat of low cost manufacturing from India & China in last decade and half?

IDMA has been closely associated with the API industry with around 75 members from the industry sub-segment. We have placed recommendations before the government to improve the competitiveness of the sector, though no concrete steps have been taken yet. We have suggested that Government take appropriate measures to streamline Environment related issues and expedite necessary permissions required by the existing API manufacturers. To encourage more investment & new projects in the API sector we have requested the Government to set up dedicated API Parks with CETP and continuous supply of power & water at economical rates.

India's import of APIs from Europe has gone down considerably. Nearly 70% of the demand is met from China which is a huge risk for the industry in the event there are negative surprises – political, or economical. The nearly USD 40 bn Indian Pharma Industry's (domestic & exports) critical dependence on China is a matter of National Health Security and should be accorded due importance. It is imperative that we develop alternate domestic supply sources.

• • •

Source: News Publications

SPECIALTY PHARMA IN INDIA – INSIGHTS & OPPORTUNITIES (1/4)

Select Sector Transactions

December 2009

Exclusive Advisor

To

vasan healthcare
from a tradition of care

Private Equity Fund Raise

From

SEQUOIA | WESTBRIDGE | CAPITAL

USD 12 Mn

October 2009

Exclusive Advisor

To

MEDALL

Private Equity Fund Raise

From

PEEPUL

USD 19 Mn

February 2009

Exclusive Advisor

To

vasan healthcare
from a tradition of care

Private Equity Fund Raise

From

SEQUOIA

Undisclosed

Specialty pharma in India: Insights

While Specialty pharma is usually spoken of in the context of US market opportunity for Indian pharma companies, and more from a B2B perspective and R&D/manufacturing capabilities, it is interesting to understand this upcoming sector in the context of the Indian domestic market and where one could find pockets of attractive investable opportunities.

Like the generic-generic market in US, which is witnessing excessive competition and compressing margins below attractive levels, Indian branded generic market while still offering reasonably attractive margins, has always been rather fragmented and a competitive space, with little scope of product/service differentiation. This situation makes it difficult to discern one company from another in general, while evaluating an investment bet for a larger play (Although we clearly agree that there are pockets which are differentiated on account of execution capability, quality of governance and therapy focus).

One of the apparent opportunities that offer genuine business differentiation in our view is Specialty pharma, which albeit small today relatively, has the potential to become meaningfully large in the near future.

What exactly is a specialty drug?

We have defined Specialty drugs as high-cost oral or injectable medications used to treat complex chronic conditions. These are highly complex medications, typically biology-based, that structurally mimic compounds found within the body.

Medications must have at least one of the following characteristics to be classified as a specialty medication:

High Cost

High-cost medications are typically priced at more than $1,000 per 30-day supply; including self-administered injectables, professionally administered injectables/ infusions, and oral medications.

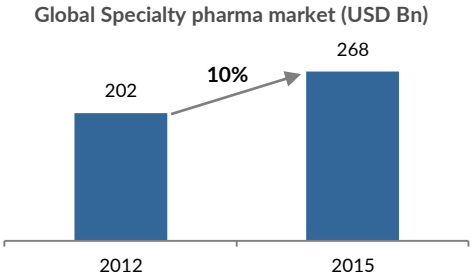
High Complexity

- Biological/Biotech products requiring complex R&D, manufacturing & regulatory approvals
- Orphan or Ultra-Orphan drugs requiring specialised licensing requirements
- Medications that are included in a specialty therapeutic drug class strategy

High Touch

- Medications that require temperature control or other special handling/shipping requirements (i.e., refrigerated or frozen shipping)
- Medications that require ongoing drug management by a pharmacist and/or physician specializing in treating the member's condition
- Medications that require focused, in-depth member education, compliance monitoring, side effect management and, often, injection technique education

How big is the Specialty pharma Market opportunity?



Specialty pharma is a huge opportunity globally, accounting for over 28% of global pharma market, It is heavily skewed towards developed markets such as US & EU where they account for 35 – 40% of total pharma market.

In developing geographies such as India, Brazil & China, the penetration of specialty pharma is at high single digits to low teens levels. Given that these developing geographies account for significant share of overall global population as well as patient population in key disease areas, there is a tremendous scope of growth if some structural issues were addressed.

2015	Total pharma market (USD bn)	% share of Specialty drugs
Global	940	28%
US	390	36%
India	14	8%

SPECIALTY PHARMA IN INDIA – INSIGHTS & OPPORTUNITIES (2/4)

Select Other Sector Transactions

January 2018
Exclusive Advisor
To
GO COLORS!
Private Equity Fund Raise
By
ICICI Venture
~USD 16 Mn

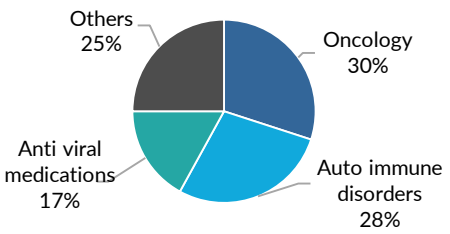
December 2017
Exclusive Advisor
To
Next Wave Multimedia
Majority Stake Acquisition
By
Nazara
Undisclosed

December 2017
Advisor
To
SK FINANCE
Private Equity Fund Raise
From
NORWEST VENTURE PARTNERS, evolvence India, BARING PRIVATE EQUITY PARTNERS INDIA
~USD 32 Mn

December 2017
Advisor
To
Specsmakers
Private Equity Fund Raise
From
8° EIGHT ROADS
~USD 10 Mn

Looking at Specialty pharma from therapy lens, Oncology, Auto immune disorders & Anti viral medications account for top-3 therapy segments.

Global therapy wise breakup



When we conversed with some healthcare experts to understand the level of usage and challenges in adopting Specialty pharma, the biggest hurdles we found out have been affordability, followed by supply chain issues and the lack of diagnostics services.

Outside super specialists mostly operating out of large cities, awareness level among physicians among specialty drug treatment protocols are low, who continue to prefer less effective treatment options

Since many of specialty drugs are difficult to administer in a non-healthcare setting, low level of compliance is a big challenge for many patients ensure continuity of care.

Therapy	Sub segments	Current Indian context
Oncology	Chemotherapy, Immune stimulants, Pain management	Available but biologics which are very highly priced have low penetration
Auto immune disorders	Treatments for Crohn's disease, Multiple Sclerosis, Psoriasis & Rheumatoid Arthritis	Corticosteroids are still preferred over expensive biologics, low penetration of diagnosis
Anti viral medications	HIV/AIDS, Hep. C & Hep. B	Available at a fraction of US prices due to licensing model with players like Gilead
Others	▪ Transplants (Immune suppression) ▪ Hormone therapy (Infertility/growth hormones) ▪ Genetic disorder therapies (Enzymes, blood fractions)	▪ One or two Indian players manufacture locally ▪ low penetration of diagnosis in genetic disorders ▪ poorly managed cold chain distributor

Given the obvious market opportunity, a number of Indian companies are actively working towards addressing the structural challenges facing the market.

1. Pricing:

a. Many Indian companies such as Biocon, Dr. Reddys, Intas, Bharat Serums and Reliance Lifesciences today have mastered the process of developing biologicals, in-house complex biotech products and bringing these products to the market at a rapid clip.

b. While these Indian companies, having lower R&D costs to amortise and combined with a lower cost of production, can offer biologicals at significantly lower pricing in comparison with global majors, subject to patent hurdle being overcome.

c. Since many large biologicals, complex biotech products like peptides have patents expiring in the 2017-20 period, market volumes are likely to increase exponentially in near future.

d. While a few players like Biocon along with their commercialisation partner – Mylan are pursuing a strategy to enter the US market, other players are taking a less risky, less capital-intensive strategy to grow the market in India and in other emerging countries through a penetrative pricing strategy.

e. Within the R&D and manufacturing segment, there are specialised players operating in standalone API segment or formulation segment or both.

f. While most of the biological manufacturing is integrated, there are specialised API players manufacturers

Category	Key players	Investor
Immunosuppresants	Concord biotech	Quadria
Hormones	Symbiotec pharma	Actis
Peptides	Hemmo pharma	NA
Oncology APIs	Shilpa medicare	TA associates
Controlled substances	ZCL chemicals	Morgan Stanley
Blood derivatives	Plasmagen	Eight road ventures
Anti Virals	Laurus	IPO

SPECIALTY PHARMA IN INDIA – INSIGHTS & OPPORTUNITIES (3/4)

Select Other Sector Transactions

November 2017

Exclusive Advisor

To

Quess

51% Acquisition

of

TATA BUSINESS SUPPORT SERVICES LIMITED

~USD 24 Mn

November 2017

Advisor

To

KINARA

Private Equity Fund Raise

From

unituscapital · Gaja Capital · GAWA Capital

~USD 15 Mn

October 2017

Advisor

To

Yellow Diamond

IPO

~USD 74 Mn

September 2017

Exclusive Advisor

To

intellect Design for Digital

Rights Issue

USD 31 Mn

g. Most of the companies in the above list have attracted PE investments or provided successful exits for PE players.

h. Most of the specialty pharma drugs are formulated at infusions or pre-filled injectables. Scaled up players in this segment have attracted investments and also witnessed successful exit to global strategics in the recent past

1. Sales of Gland pharma to Fosun
2. Sale of Claris to Baxter
3. Sales of Agila to Mylan
4. Orbimed's investment in Eurolife Healthcare

2. Affordability:

a. With higher per capita income and level of savings, a larger share of population is now able to afford specialty drug treatment in comparison with the past.

b. With health Insurance policies becoming more comprehensive in covering critical illness & having dedicated packages for diseases like cancer, it has become easier for patients to access specialised treatments unlike in the past when one had to shell a large sum out of pocket.

3. Availability of High end diagnostics

a. Several independent high-end diagnostics companies focused on specialised oncology testing or pre/neonatal genetic screening are enabling greater adoption of specialty drugs.

b. While traditional pathology labs focused on basic biochemistry / immunology tests with little need for prescriber education, these high-end labs actively educate / promote their tests to prescribers leading to better awareness & adoption, giving such independent lab a definite edge over large pathology chains, which are looking to enter this space & shore up their high value test portfolios.

c. Many of these labs are also innovating in-house/partnering with global players to bring the latest technologies to India and make it accessible to Indian population.

d. While Oncology & Genetic screening are better established with players such as Core diagnostics in Oncology & Babyshield (Lifecell) in New born screening, high-end diagnostics for Cardiology & Neurology have tremendous potential, which is still untapped in India despite a large patient base.

4. Specialty sales teams:

a. Specialty drugs require a significantly higher degree of scientific selling than typical Indian pharma sales representative is used to.

b. To address this gap, many Indian pharma companies have created small teams of qualified MBBS doctors to promote the drugs. This ensures physicians receive the inputs with more intent and are more open to try out newer treatment options.

5. Supply chain issues:

a. Supply chain issues in specialty drugs start all the way from getting a license to actually importing the drug, followed by controlled storage and transportation, dealing with a shorter shelf life. Strong regulatory expertise is required to get import license for specialty drugs, many of which are usually launched for the first time in the country, while others might be orphan drugs for rare diseases, which in many cases are imported on a name patient basis.

b. Sometimes, many not so complex specialty drugs also face significant availability challenges usually in tier-2/3 hospital settings. With low & unpredictable usage trends, it is difficult to stock these medicines in hospitals or pharmacies.

c. Some of these have short shelf lives, require narcotic licenses making an efficient supply chain a much-needed imperative. Unfortunately, India's pharma supply chain is a highly fragmented one with very low level of storage compliance.

d. Unfortunately, Pharma distribution in India is highly unorganised, with only a few specialty distributors like Sandor Medicaids having a nationwide cold chain network, as well as a dedicated

SPECIALTY PHARMA IN INDIA – INSIGHTS & OPPORTUNITIES (4/4)

Select Other Sector Transactions

July 2017

Exclusive Advisor

To

FIVE STAR

Private Equity Fund Raise

From

SEQUOIA | Morgan Stanley | NORWEST VENTURE PARTNERS | matrix PARTNERS INDIA

~USD 52 Mn

March 2017

Exclusive Advisor

To

hffc home first We'll take you home

Private Equity Fund Raise

From

truenorth

USD 100 Mn

March 2017

Exclusive Advisor

To

CreditAccess Asia

Private Equity Fund Raise

From

ADB Asian Development Bank

USD 32 Mn

February 2017

Co-Book Running Lead Manager

To

BSE EXPERIENCE THE NEW

IPO

~USD 183 Mn

regulatory team to obtain regulatory approvals for novel products including orphan products.

e. Companies focusing on product niches with supply chain complexity like Plasmagen, which offers specialty blood products have been backed by private equity players.

f. In a more mature market like US, Specialty distribution market is dominated by divisions of Big-3 wholesalers – Mckesson, Cardinal & Amerisource Bergen, who have consolidated their presence through acquisitions of independent specialty distributors such as ASD healthcare, Oncology supply, Besse Medical etc.

6. Continuity of care:

a. Specialty drugs are typically used to treat complex diseases like cancer, auto immune diseases, for treatment options are available only in major cities. For this, patients usually travel very long distances to major metros, where accommodation is very expensive for long term hospital admission. Since many of the specialty drugs require long term care, it is not economically possible for the patient to stay admitted for longer durations.

b. Since most of the drugs are controlled infusions, which can be provided only by trained technicians, it becomes a challenge for patients to continue care in a home setting. To address this need, a bunch of Home healthcare players like Health Care at Home, Portea and others are focusing on providing infusions at home as a service for specialty medications mainly Oncology.

c. Home infusion service providers have the potential to become distributors and sellers of specialty drugs since they have strong adjacencies.

d. In a more mature market like US, Home infusion is a highly fragmented market with leading players operating divisions of specialty pharmacies like CVS, Express scripts, Walgreens & Bioscrips.

Key factors investors must look for while evaluating options in specialty pharma are as follows:

1. Addressable market for the products in India considering disease incidence, treatment alternatives & price sensitivity as some of the disease segments might be niche, while in others treatment might only offer incremental benefit
2. Core competencies - Defensibility of the business model considering current and potential competition
3. Adjacencies available to tap and company's strategy to be able to successfully enter a related business
4. Exit options for the investment through consolidating on a larger platform for scale or strategic exit to an MNC

Conclusion:

In conclusion, speciality pharma is a high value, high growth market segment with companies having specialised / differentiated competencies. This makes the opportunity very attractive from an investment standpoint. Needless to add, investors would require comfort regarding scalability and their exit when it comes to investing in a target company.

BIOSIMILARS IN THE USA – THE HOPE, THE HYPE AND THE REALITY! (1/9)

Select Other Sector Transactions

August 2016

Exclusive Advisor

To

Qwikcilver

Private Equity Fund Raise

From

SISTEMA helion ACCEL PARTNERS a

USD 10 Mn

June 2016

Exclusive Advisor

To

Suryoday

Enabling Dreams. Empowering Lives.

Private Equity Fund Raise

From

IDFC BANK | ASK PRAVI | HDFC Life | LNB GROUP | AMERICORP GROUP | Gaja Capital

USD 32 Mn

March 2016

Exclusive Advisor

To

UNBXD

Private Equity Fund Raise

From

NIRVANA | ICP INVENTUS CAPITAL PARTNERS | IDG Ventures | Indian Angel Network

Undisclosed

February 2016

Exclusive Advisor

To

SUMERU Frozen Foods

Buyout

By

PEEPUL

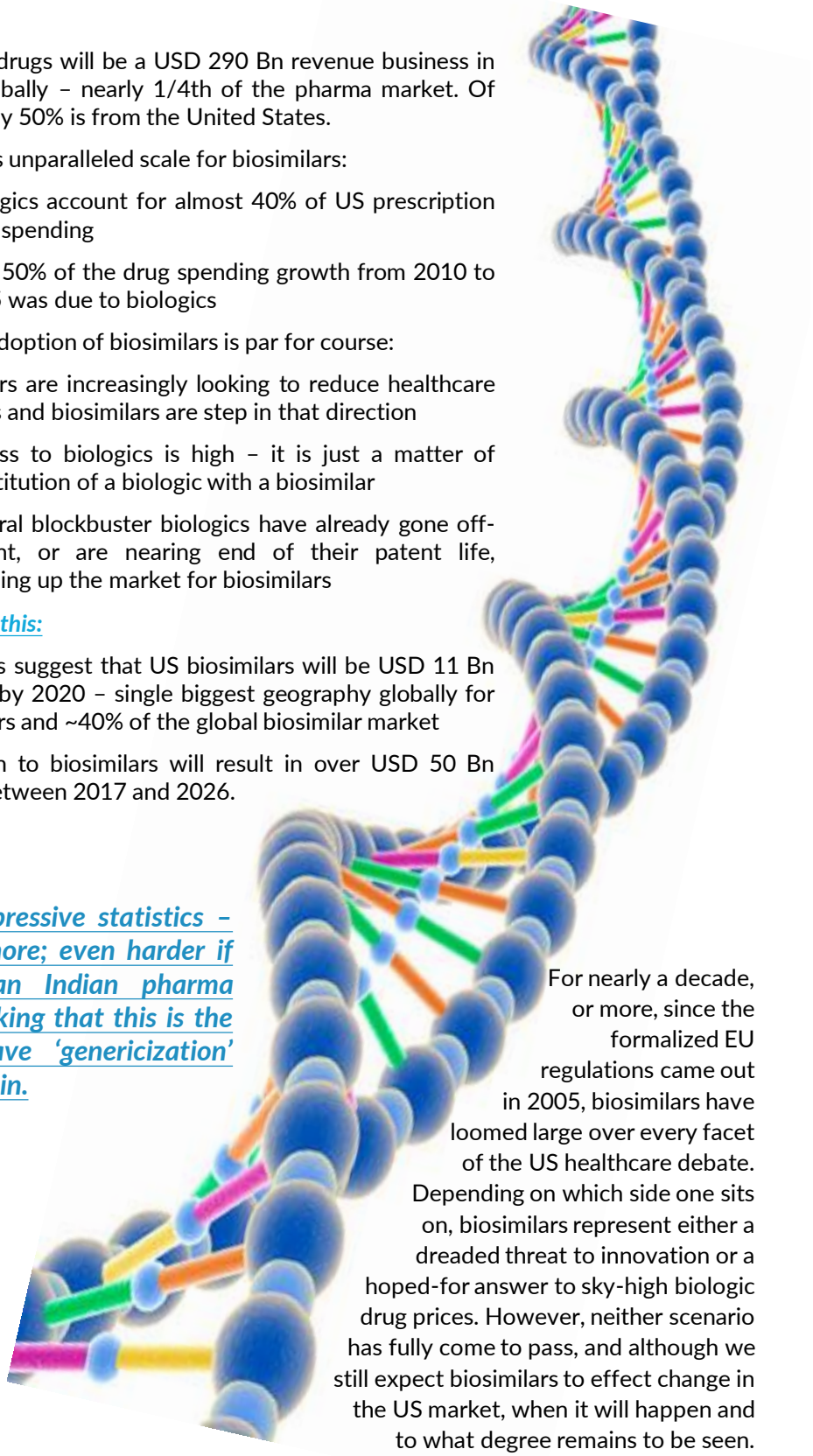
Undisclosed

Facts:

1. Biologic drugs will be a USD 290 Bn revenue business in 2020 globally – nearly 1/4th of the pharma market. Of this nearly 50% is from the United States.
2. US offers unparalleled scale for biosimilars:
   a. biologics account for almost 40% of US prescription drug spending
   b. over 50% of the drug spending growth from 2010 to 2015 was due to biologics
3. Robust adoption of biosimilars is par for course:
   a. Payers are increasingly looking to reduce healthcare costs and biosimilars are step in that direction
   b. Access to biologics is high – it is just a matter of substitution of a biologic with a biosimilar
   c. Several blockbuster biologics have already gone off-patent, or are nearing end of their patent life, opening up the market for biosimilars

Also consider this:

1. Estimates suggest that US biosimilars will be USD 11 Bn industry by 2020 – single biggest geography globally for biosimilars and ~40% of the global biosimilar market
2. Migration to biosimilars will result in over USD 50 Bn saving between 2017 and 2026.



Mighty impressive statistics – hard to ignore; even harder if you are an Indian pharma player thinking that this is the second wave 'genericization' all over again.

For nearly a decade, or more, since the formalized EU regulations came out in 2005, biosimilars have loomed large over every facet of the US healthcare debate. Depending on which side one sits on, biosimilars represent either a dreaded threat to innovation or a hoped-for answer to sky-high biologic drug prices. However, neither scenario has fully come to pass, and although we still expect biosimilars to effect change in the US market, when it will happen and to what degree remains to be seen.

In this article, review the happenings in the US biosimilar market, outline trends and potential scenarios based on current US market dynamics and evaluate scope for play by Indian pharma companies. *The numbers could well play out in reality as estimated - but before the prospect of Reality, it is imperative that we lay down the premise of the US Biosimilars Saga - the Hope and the Hype!*

BIOSIMILARS IN THE USA – THE HOPE, THE HYPE AND THE REALITY! (2/9)

Select Other Sector Transactions

January 2016
Exclusive Advisor
To
CreditAccess Asia
Structured Capital Raise
From
Olympus Capital Asia
USD 30 Mn

December 2015
Exclusive Advisor
To
aasaanjobs
Private Equity Fund Raise
From
Aspada, ICP, INVENTUS CAPITAL PARTNERS, IDG Ventures India
Undisclosed

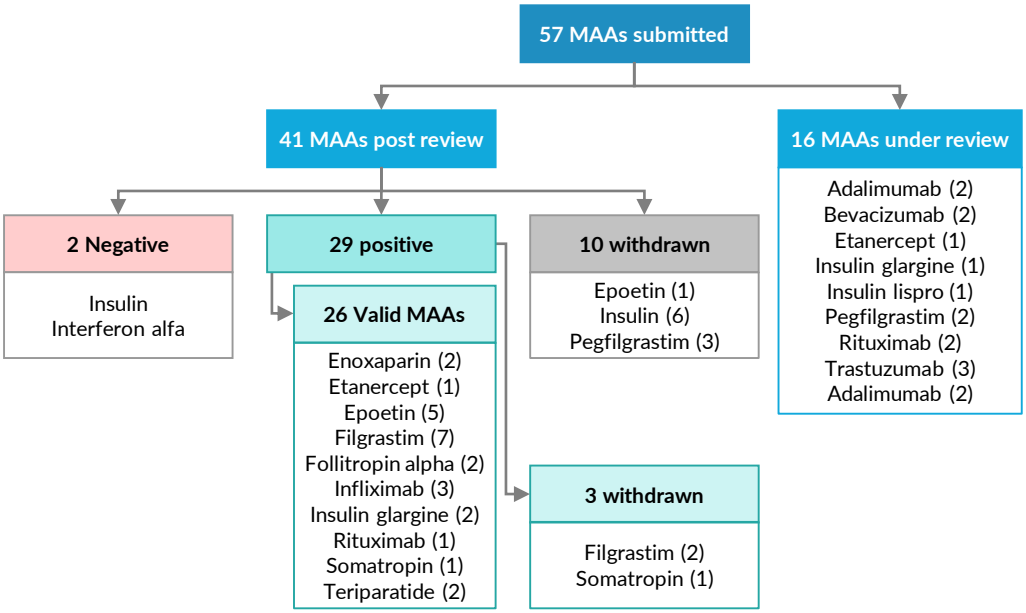
November 2015
Joint Advisor
To
POLARIS live your dream
Majority Stake Acquisition
By
virtusa
USD 270 Mn

November 2015
Exclusive Advisor
To
Sportz Village
Private Equity Fund Raise
From
Gaja Capital
USD 10 Mn

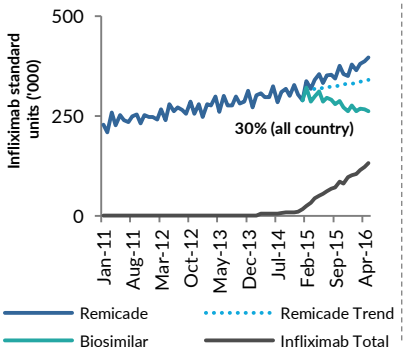
The Hope:

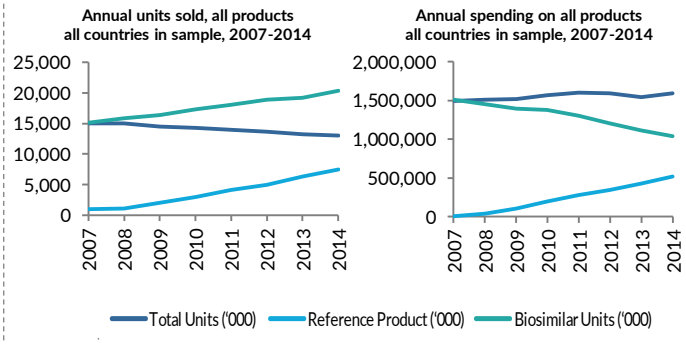
Branded biologics are essentially large molecular-weight, complex molecules that are produced in living cells through genetic engineering and are used in treatment of complex diseases like cancer, rheumatoid arthritis and several auto-immune disorders, among others. These drugs are extremely expensive and hence while they form a large chunk of payer monetary outgo, by definition, are accessible only to a miniscule patient population. High cost of branded biologics is placing enormous financial pressure on the nationalized healthcare systems and insurance companies. Substituting lower-cost branded biologics for biosimilars would help reduce government healthcare costs and lessen the financial burden of insurance companies and third-party payers.

When the concept was first introduced, biosimilars were seen as a potential replacement for many biologics, offering comparable benefits at reduced cost. Passage of the Biologics Price Competition and Innovation Act (BPCIA) of 2009 was intended to encourage the development of low-cost biosimilars. EU had shown the way on overcoming the regulatory hurdle - even before the first biosimilar was approved by the USFDA, there were over 20 biosimilars having been granted the marketing authorization approval (MAA) in the European Union (EU) with twice as many under development including many in Phase III clinical trials. By March 2017, there were 26 products in the EU existing for 10 different reference biological products as depicted below and although some products like Enoxaparin and Insulin aren't considered biosimilar in the USA, the number is still significantly higher compared to the US market:



Data also suggested that in the EU, between 2014-16, for Infliximab as an example, prescription rate for the biosimilar grew from 0 to 30% and was further expected to go up to 50% by 2018. A study of sales and spending on biosimilar products also revealed significant uptick in the volume/spend on the biosimilar with a corresponding decrease in the reference product sales and spend. *This indicated strong adoption rates amongst clinicians and patients alike, in the EU – creating Hope for a similar roadmap in the US.*





BIOSIMILARS IN THE USA – THE HOPE, THE HYPE AND THE REALITY! (3/9)

Select Other Sector Transactions

April 2015
Exclusive Advisor
To
enzen
Structured Capital Raise
From
KKR
USD 60 Mn

January 2015
Exclusive Advisor
To
INDIAN TERRAIN
QIP
Book Running Lead Manager
~USD 13 Mn

November 2014
Exclusive Advisor
To
SUTHERLAND GLOBAL SERVICES
Private Equity Fund Raise
From
TPG
USD 346 Mn

October 2013
Exclusive Advisor
To
WILDCRAFT
Private Equity Fund Raise
From
SEQUOIA
USD 11 Mn

With how the story had played out in the EU, "Biosimilar" had become the new buzzword in the US. The floodgates had opened for the first wave of biosimilars in the most rewarding pharmaceutical market. There was Hope, then came the Hype!

The Hype:

The "disruptive force" theory for US biosimilars success was based on three key pillars:

a. *Time to market is low:* Going by approval roadmaps in EU, India, South Korea or Latin America, proving similarity needs lesser data, lesser clinical trials and hence 'application to commercialization' time is low;

b. *Pricing is the end game:* Lower the price, higher the uptake - Higher volumes justify recovery of R&D costs even at lower prices creating a virtuous spiral; and

c. *Interchangeability is inevitable:* Similarity in attributes will ensure that biosimilars replace the existing reference biologic as payers and clinicians insist on biosimilar adoption on cost-saving grounds.

Despite predictions that biosimilars would become as disruptive a force in the market as generics, this has not yet occurred. While biosimilars have been approved and are entering the US market, the rate at which they are coming to market and the pace of their subsequent growth in market share has been slower than anticipated. This slow rate of adoption could be due to several factors, including, in some cases a lack of interchangeability, the drug's breadth of label and targeted indications, and the need for increased physician awareness. The most important factor, however, could be that biosimilar drugs are simply not yet cheap enough.

In the section below we examine how exactly the Hype has played on to the Reality with none of the three factors mentioned above coming to the party – at least as yet!

The Reality:

Underestimating the Regulatory and Litigatory Hurdle in Time to Market

While the BPCIA was approved in 2009 (as part of the famous Obama-care), the first approval from the USFDA for a biosimilar came about only in 2015. To put things in perspective, between that period, India came up with its guidance for approval pathways for biosimilars, the EU issued product-class specific guidelines and guideline revisions to the base guidelines approved in 2005 and a whole host of biosimilars were approved in South Korea, India, Mexico, Russia and other parts of the world. *By comparison, the US has less than 10 biosimilars approved to this date (Feb 2018), of which a mere three have been commercialized.*

One of the reasons behind the steep 'time-climb' for the US biosimilars market was that the base guidelines itself were written with little or no consultations, were ambiguous on several key points (naming of biosimilars with biologic players lobbying to prevent biosimilars from using the same INN, need and scope of the patent dance protocols, timing and point of notice to the reference biologic provider before commercialization of the biosimilar and interchangeability with the reference biologic, to name a few key ones) and hence were prone to litigation at each stage. Unlike the considerably 'time and litigation' mature Hatch-Waxman Act of 1984 in place at the time, *the BPCIA lends itself to litigation at each stage*, so much so that there are several cases arguing the basic tenets of the Act even as this article is being written and on which clarity will emerge only over the next 18-24 months.

As an indicator of the extent of litigatory activity, we have put below new cases filed by competing players in CY17 (11 v/s 7 in CY16) and CY18 YTD even as we wait for verdicts in the Janssen v/s Celltrion, Jannsen v/s Hyclone (Remicade is the reference biologic in both cases) and the Immunex v/s Sandoz (Enbrel is the reference biologic) cases which were filed at least 12 months back:

BIOSIMILARS IN THE USA – THE HOPE, THE HYPE AND THE REALITY! (4/9)

Select Other Sector Transactions

July 2013
Exclusive Advisor
To
Hinduja Leyland Finance
Private Equity Fund Raise
From
Everstone
USD 33 Mn

December 2012
Exclusive Advisor
To
Vijay Nirman Company Pvt Ltd
Private Equity Fund Raise
From
ICICI Venture
USD 16 Mn

October 2012
Exclusive Advisor
To
equitas
Private Equity Fund Raise
From
IFC International Finance Corporation | IDFC
USD 31 Mn

August 2012
Exclusive Advisor
To
Craftsman Automation
Private Equity Fund Raise
From
Standard Chartered
USD 18 Mn

Litigating Companies	Filing Date**	Biologic at Issue	Number of Patents Under Litigation
Genentech v/s Amgen	Feb'17	Avastin (Bevacizumab)	0 (case filed for an alleged BPCIA violation)
Amgen v/s Coherus	May'17	Neulasta (Pegfilgrastim)	1
Janssen v/s Samsung Bioepis	May'17	Remicade (Infliximab)	3
Janssen v/s Celltrion	May'17	Remicade (Infliximab)	
Abbvie v/s Boehringer Ingelheim	Aug'17	Humira (Adalimumab)	8
Amgen v/s Mylan	Sep'17	Neulasta (Pegfilgrastim)	2
Amgen v/s Genentech*	Oct'17	Avastin (Bevacizumab)	25
Genentech v/s Pfizer	Nov'17	Herceptin (Transtuzumab)	40
Genentech v/s Sandoz	Dec'17	Rituxan (Rituximab)	24
Celltrion v/s Genentech	Jan'18	Herception Transtuzumab)	35+
Celltrion v/s Genentech	Jan'18	Rituxan (Rituximab)	35+

** New cases filed compared to the Feb, 2017 case on different patents*
*** Updated till January 18, 2018*

There are two points of note here: (i) one is that *for the same reference biologic, courts have allowed filing of different cases* with different underlying issues of dispute – so this is not a one molecule one litigation kind of market; and (ii) *Companies are now preferring to litigate on an ever increasing lists of patent disputes* – up from 1-10 at start of CY17 to nearly 40+ patents by the close of the year.

One of the reasons for the trend mentioned above is increasing number of rulings in favour of biosimilar companies on "principle-based' litigation. As an example, Sandoz won its dispute against Amgen at the Supreme Court (June 2017) which ruled that it was not necessary for the biosimilar sponsor (BS) to engage in a patent dance with the reference product sponsor (RPS) – a landmark judgement in many ways since the patent dance was construed as an important step in the BPCIA approval pathway allowing the RPS to gain more access to the biosimilar design and manufacturing processes. The Supreme Court also ruled that the 180 day notice to the RPS can be provided any time before or after the USFDA approval of the biosimilar – again a watershed moment considering that a plain read of the BPCIA indicated a six month exclusivity for the RPS after the FDA approval – a window most RPS were actively looking to litigate in as this would have been the highest loss window for the BS with all clinical trials completed. Other cases favouring BS include (i) Hospira's win over Amgen (August 2017) for biosimilar of Epogen where Amgen had disputed that the manufacturing process of Hospira was in violation of its patent but the court ruled against Amgen since it hadn't listed down that patent violation as part of the patent dance; and (ii) Apcotex's win over Amgen for the biosimilar of Neulasta where Amgen had disputed that the information for protein concentration provided by Apcotex during the patent dance was untrue and in violation of its patent, but the court ruled that so long as the concentration was proven different from the existing Amgen patent during trials (and under a threshold range), the patent dance information is only representative and hence a case for patent infringement does not arise.

On the other side of the spectrum is the first BPCIA damages award case, which also panned out in 2017 (award in September 2017) and interestingly for the same biosimilar of Epogen which was mentioned above, with the BS (Hospira) having to pay USD 70 Mn to the RPS (Amgen). The interesting facets of the case were that the Amgen patent had expired by the time of the trial and Hospira's biosimilar was neither approved by the USFDA nor launched. None the less, Amgen had disputed that Hospira had made more batches of the biosimilar (and was stockpiling these) than required for the USFDA approval and had sought damages of USD 170 MM, which the jury found to be true (for 14 of the 21 batches) and awarded USD 70 Mn in the RPS' favour.

BIOSIMILARS IN THE USA – THE HOPE, THE HYPE AND THE REALITY! (5/9)

Select Other Sector Transactions

April 2012

Exclusive Advisor

To

Select Institutional Buyers

Secondary Stake Acquisition

In

Karur Vysya Bank

USD 55 Mn

March 2012

Exclusive Advisor

To

Select Institutional Buyers

Secondary Stake Acquisition

In

MANAPPURAM FINANCE LIMITED

USD 32 Mn

March 2010

Exclusive Advisor

To

equitas

Private Equity Fund Raise

From

helion venture partners CLSA CAPITAL PARTNERS AQUARIUS

USD 46 Mn

February 2010

Exclusive Advisor

To

MANAPPURAM FINANCE LIMITED

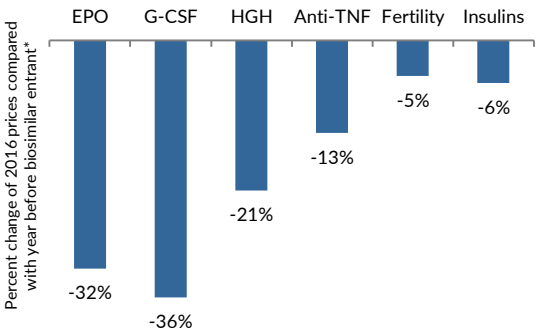
QIP

USD 55 Mn

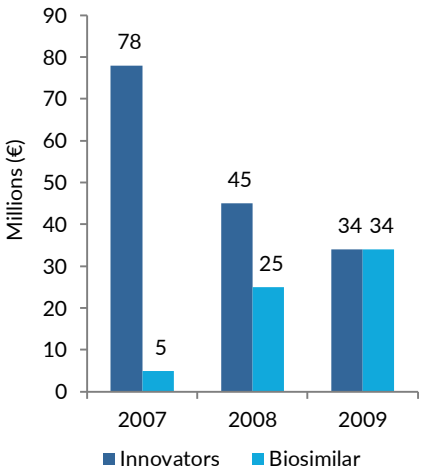
In a nutshell, while the application to approval timeline for biosimilars in 2017 has come down to an average of 10-12 months (7 months at minimum and 20 months at max), *companies had massively underestimated time and resources to be spent on litigations in the US for their biosimilar approvals.* It was evident that the RPS were in no mood to let go off their biologic product's grip over the market and this trend will only get more pronounced and more time consuming with disputes over an increasing number of products and patents, represented in the table above.

Pricing may be the end game in developing markets, even in the EU – but the US is different

When a small molecule generic was launched in the past, it was observed that the extent of price erosion for the originator could be as high as 80-90% in some cases. For biologics also, the European experience has demonstrated that biosimilar entrance ultimately affects innovator prices, as well as prices for follow-on biologics. Such reduction in prices spurs early adoption of the biosimilar on a large scale.

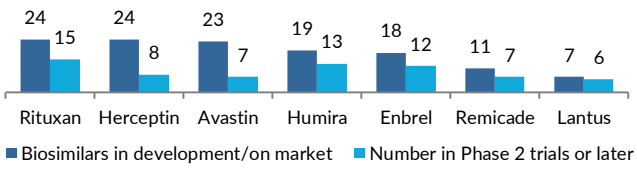


*Change is between prices for the class in year before biosimilar entrance and 2016 in the European Economic Area (EEA).



Consider the case of Germany, where insurers incentivize hospitals and clinics to use cheaper alternatives when possible. While that alone does not guarantee biosimilar uptake, the drug epoetin (biosimilar to the biologic erythropoietin) enjoyed early and rapid success, and quickly gained substantial market share - So what made epoetin such a successful biosimilar? In this case, it was a combination of price and market acceptance. Epoetin was introduced at a discount of 20% off net price, a clear but not radical discount to the innovator product. This discount, however, prompted early adoption by the Kuratorium für Dialyse und Nierentransplantation (Curatorium for Dialysis and Renal Transplantation; KfH), the largest network of dialysis centres in Germany, which manages 30% of Germany's dialysis patients. The KfH uses a limited, centralized set of Group Purchasing Organizations (GPOs) to negotiate with manufacturers, and thus delivered a large set of accessible patients. Although there was no mandated substitution, uptake was spurred by peer-to-peer education among practicing nephrologists and associations regarding epoetin and its efficacy. But in the end, it was the price discount and approval by a leading national network, along with coordinated delivery via a network of providers, which allowed this biosimilar to outperform.

Similar is the story of pricing of biosimilars in the developing markets – ultimately it boils down to the fact that given the cost of clearing the regulatory hurdle is low in these markets,



the cost benefits can be passed on to the consumer which in turn will result in a spurt in adoption (either payer led or consumer led) and will force the BS to reduce prices further in a bid to remain competitive. The fact that there is also an overcrowding of competition for certain biologics in non-US markets means that there is and will continue to be pricing pressure to garner market share as is evident from the number of biosimilars at various stages of development for some blockbuster biologics as shown in the chart above.

BIOSIMILARS IN THE USA – THE HOPE, THE HYPE AND THE REALITY! (6/9)

Select Other Sector Transactions

November 2008

Exclusive Advisor

To

MANAPPURAM FINANCE LIMITED

Private Equity Fund Raise

From

Ashmore SEQUOIA

USD 23 Mn

April 2008

Exclusive Advisor

To

TVS Finance & Services Ltd.

Delisting

From

Undisclosed

December 2007

Exclusive Advisor

To

MANAPPURAM FINANCE LIMITED

Private Equity Fund Raise

From

SEQUOIA

USD 18 Mn

December 2006

Exclusive Advisor

To

SHRIRAM City

Private Equity Fund Raise

From

Merrill Lynch Global Private Equity, ChrysCapital, Cambridge Place Investment Management

USD 55 Mn

There are three reasons why a similar trajectory for biosimilar pricing hasn't panned out in the US: (i) regulatory and litigatory hurdles demand lot of resources for clearance; (ii) only three biosimilars have been commercialized of the nine approved for different reference biologics; and (iii) there is very limited competition existing today. As an example, Zarxio from Sandoz and Inflectra from Pfizer/Celltrion were launched at 15% discount over the RPS product. Samsung Bioepis and Merck launched Renflexis at a 35% discount, nowhere near the 50-60% discount levels which would cause physicians and payers to evaluate the risky switch from the biologics to biosimilars - all of this has led to these biosimilars having a low single digit market share in their respective categories.

In a nutshell, while biosimilars ride on the price differential positioning globally, *we believe the US market is still far off from the kind of price erosion that merits large scale adoption* – and if this plays out over the next 24-36 months with the biosimilars not gaining volume traction, companies may need to evaluate their future strategies given that the R&D for the same is highly capital intensive.

The EU may be a good template for evaluating impact of interchangeability – But the US doesn't even have a Regulatory Guidance for the same

What is an interchangeable biosimilar as per the BPCIA?

A biological product found to be biosimilar; that can be expected to produce the same clinical result as the pioneer in any given patient; and if the product is administered more than once to an individual the risk in terms of safety or diminished efficacy of alternating or switching between use of the product and the pioneer is no greater than the risk of using the pioneer without such alteration or switch.

A biosimilar found to be interchangeable may be substituted for the pioneer without the intervention of "the health care provider who prescribed the reference product".

Major proponents of the US biosimilar story use the evolution of the concept of interchangeability in the EU to extrapolate a similar outcome in the US – for example, the EMA approves a biosimilar basis applicable guidance and allows member states to take individual calls on automatic substitution. Several national regulatory authorities, including the Dutch Medicines Evaluation Board, the Finnish Medicines Agency, Healthcare Improvement Scotland, the Irish Health Products Regulatory Authority, and Paul Ehrlich Institute in Germany, have already taken national positions to endorse the interchangeability of biosimilars under the supervision of the prescriber. France allows for automatic substitution of select biosimilars over the reference product under certain conditions. Such proponents however extrapolate such outcome without necessarily a regard for the differences in regulatory environments governing use of biosimilars in the two regions.

As mentioned above, the BPCIA expressly defines what an interchangeable biosimilar is – the EU on the other hand, doesn't have any such standard definition. The 351(k) application in the US allows only for establishing bio-similarity. Additionally, if interchangeability is desired, there is a separate application but here is the catch – the regulatory guidance for an approval pathway for interchangeability is still not in place. This despite there being 14 applications for interchangeable biosimilars filed by 9 companies. The FDA issued the draft guidelines for biosimilar interchangeability in January 2017 with recommendation for switching studies to show that the patient can alternate between the biologic and the interchangeable safely. The draft made provisions for public comments by May 2017 – 53 comments were received in all from innovator companies, biosimilar companies, healthcare providers, insurers and other interested organizations. *However, till date no finalized guidelines have been issued for the same nor have any interchangeable biosimilars been approved.*

Another issue that needs to be thought of while proposing a fully interchangeable mechanism in the US in the near future is the cost. Given that separate applications need to be made for each indication, interchangeability, even if it does come in, will come in at significant capital outlay which may limit the ability to cause price erosion in comparison to the original biologic. And given that the products are similar and not equivalent, physician's

BIOSIMILARS IN THE USA – THE HOPE, THE HYPE AND THE REALITY! (7/9)

Select Other Sector Transactions

November 2006
Exclusive Advisor
To
ADIL
Private Equity Fund Raise
From
SAIF Partners
USD 8 Mn

October 2006
Exclusive Advisor
To
Vivek Hire Purchase & Leasing Limited
Minority Stake Sale
To
AIG
USD 3 Mn

October 2006
Exclusive Advisor
To
VisualSoft Technologies
Majority Stake Acquisition
By
MEGASOFT
USD 37 Mn

September 2006
Exclusive Advisor
To
Packaging India Pvt. Ltd.
Majority Stake Acquisition
By
essel
USD 20 Mn

willingness to cause the patient to switch is little – especially given that minor changes in the treatment protocol could result in major ramifications in the health and well-being of the patient, that too in a litigation happy society like the US. An additional barrier to the adoption of biosimilars may be consequential clinical differences between biosimilars and their reference biologics. A recently published trial showed that nearly 25% of patients with autoimmune diseases (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis) discontinued biosimilar treatment when converted from the originator, having reported worsened subjective symptoms. In fact, the potential for patient pushback against biosimilars may lead physicians to choose the established innovator biologic.

Uncertainty as to which indications are appropriate for biosimilar use poses still another challenge. Approval for one indication for a biosimilar can be followed by documented effectiveness in treating other indications. A biosimilar, however, lacks the same clinical history as a biologic, and so it is often unclear whether the similarity of a biosimilar would translate to the same additional indications being treated by the innovator's product.

Additionally, as was seen in the case of Johnson and Johnson's original biologic Remicade, when Inflectra tried to lower prices by as much as 35%, J&J which has a significant amount of market share, preserved Remicade's preferred status by (i) introducing corresponding price reductions, (ii) signing contracts with insurers requiring them to cover only cases where Remicade has been used first before trying other treatments for new patients; (iii) allegedly cutting rebates on it's portfolio of other products for insurers which took away the savings for insurers from Inflectra adoption, among others. The combination of aggressive innovator protection policies, physician familiarity, and confidence in J&J's product helped the company retain a dominant share of the market. In fact, Pfizer and J&J are locked in a bitter legal battle over use of what Pfizer claims to be anti-competitive policies from J&J. Another strategy that innovator biologic companies are following is to cut rebates for insurers for the reference biologic product – meaning that the insurer now has to pay more for 70% of the biologic even though the 30% volume of the biosimilar is being procured at a lower cost – effectively increasing the cost of overall procurement for the payer.

As the example of Remicade shows, innovators can incrementally reduce prices and maintain preferred status by leveraging their majority market share while unencumbered by the need for new sales forces and other switching costs. The same cannot be said for a comparable price reduction for the biosimilar, and so such an adaptive pricing and marketing strategy can pay off when competing with discount biosimilars.

Insurer	Lives Covered	Infliximab
United Healthcare		Remicade preffered
Anthem		Remicade preffered
Humana		Remicade preffered
Aetna		Remicade preffered Inflectra preferred as of Jan 2018
BCBS - Illinois, Michigan		Remicade preffered
Cigna		Remicade preffered
Centene		Inflectra preffered
Kaiser Permanente		Inflectra preffered

Represents 5M people

Biosimilar makers have hoped that payer universe will come in and recommend and pay for biosimilars at some stage – but as mentioned above, unless the product can result in significant cost savings (40-60%) and has a long documented history, it would be unwise to rely on the insurers to prefer the biosimilar over the reference biologic. A primary study of insurers in the US for Infliximab again shows significant bias towards Remicade compared to the biosimilar Inflectra – indicating that several things need to change before the push from the payer universe can be expected to come in favouring biosimilars.

In a nutshell, while interchangeability is inevitable, under the current regulatory regime, *effective and meaningful level of switching is still some years away*. Further, our read is that *first successful interchangeable biosimilars will be the ones that are used for relatively minor aspects of an ailment rather than aimed as the primary cure for the ailment itself* – e.g., treating a chemotherapy side effect rather than being a cure for cancer itself.

BIOSIMILARS IN THE USA – THE HOPE, THE HYPE AND THE REALITY! (8/9)

Select Other Sector Transactions

August 2006
Exclusive Advisor
To
Select Buyers
Private Placement
in
ALLSEC TECHNOLOGIES
BUILDING LASTING RELATIONSHIPS
USD 36 Mn

May 2006
Exclusive Advisor
To
calsoft
Rights Issue
USD 5 Mn

April 2006
Exclusive Advisor
To
SERVION
Private Equity Fund Raise
From
SANSAR CAPITAL
USD 8 Mn

March 2006
Exclusive Advisor
To
CONSOLIDATED CONSTRUCTION CONSORTIUM LTD.
Private Equity Fund Raise
From
ASCENT CAPITAL
USD 27 Mn

So what does all this translate into for business for Indian Companies?

MNC Competition Not Going Away: A look at the biosimilar approvals and pipeline gives a fair indication of who the major players are – Pfizer, Amgen, Merck Sandoz, Samsung Bioepis, Boehringer Ingelheim and others - large multinationals with deep pockets. A look at the pipeline of some of these companies reveals an interesting trend – a focus on oncology with biosimilars targeted at different types of cancer. What is also interesting to note is that some of these MNC majors have forged alliances to develop biosimilars – Pfizer and Celltrion for Inflectra, Samsung Bioepis and Merck for Renflexis and Amgen and Allergan for Mvasi. Companies like Amgen, Genentech and Celltrion have also been at the forefront of most of the litigation to protect their biologic market share and are now working on a biosimilar pipeline of their own. Amgen for example has an impressive pipeline for biosimilars for Bevacizumab, Cetuximab, Infliximab and Transtuzumab – all drugs for which at least one of the target indications is cancer of some kind.

Indian Companies First to Develop; But EU and US presence very limited: Historically, most Indian drug makers have been small-molecule generic manufacturers, & increasing competition in the global generics space over the last five years has forced them to differentiate. To that end, the domestic market has been flooded with biosimilar launches. World's first rituximab biosimilar (Reditux by Dr. Reddy's Laboratories), adalimumab biosimilar (Exemptia by Zydus Cadila), and trastuzumab biosimilar (CanMab by Biocon) were all developed and launched in India. Other companies to have a strong biosimilar portfolio include Hetero Drugs, Torrent Pharmaceuticals, Intas Pharmaceuticals, Emcure, Cadilla Healthcare and Lupin, among others. Add to that Syngene's Biologicals vertical on the services side. However, all of these companies (exception of Biocon) have been emerging market players with limited exposure to US / EU.

Biocon is one of the only Indian companies to have a US biosimilar presence through its tie-up with Mylan and Sandoz. For the US, where regulatory confusion is high and development costs plague affordability of biosimilars, we believe that Indian companies could be at the core of the strategy for international giants and that the partnership could be mutually effective. We believe that partnerships like Intas-Apotex and Biocon-Mylan / Biocon-Sandoz will continue to be forged since it means that the international partner gains access to the Indian partner's biosimilars, which have been developed in a cost-effective manner, and the Indian partner has expanded its ability to commercialize its products in Western markets. We believe such association will also help domestic companies address the perception issue as regards the safety and efficacy concerns about Indian biosimilar products and build credibility much faster compared to the branded generics cycle. Additionally, it also provides an effective hedge against the behemoth of potential US litigation.

The Emerging Market Strategy v/s the Regulated Market Strategy: From the 50 odd companies actively exploring the biosimilar market in the emerging markets, there are less than ten companies that have a tie-up with a global major for exploring sales to the regulated markets. Unlike the generic development and manufacturing which is relatively easier and is a far lower time and cash guzzler, biosimilars are capital intensive R&D products with a low hit rate to commercialization. Further, between the emerging market and the regulated market itself, there are differences in factors that impact the growth of the biosimilar market – while the emerging markets are essentially price sensitive, the adoption in regulated markets is not a linear function of price alone. Factors such a payer propensity to cover the biosimilar, physician education and adoption probability and innovator protectionism will play a big role in growth of the market. With that background, we believe that most Indian companies will continue to play the

BIOSIMILARS IN THE USA – THE HOPE, THE HYPE AND THE REALITY! (9/9)

EM game and may probably venture increasingly into the EU in due course, but the US market is far away from any meaningful contribution to sales and margins.

Biosimilars	Generics
Similar to, and not identical to reference product	Bioequivalent and identical to reference product
20-30% discount over reference product	80-90% discount over reference product
$100-$200M in development costs	$1-$5M in development costs
8-10 year development timeline	3-5 year development timeline
No interchangeability or automatic substitution*	Interchangeability with reference product

The Final Word

Biosimilars will likely become an increasingly important part of the pharmaceutical ecosystem. However, they continue to face barriers to adoption, including questions of interchangeability, a typical lack of approval for all the reference biologic's indications, the need for biosimilar manufacturers to negotiate with payers, the challenge of overcoming unique patent dynamics, and innovators' established positions within the physician community.

As these challenges play out in the coming years, manufacturers of biosimilars will become more adept at navigating the complex US drug market. To achieve their goals, they must demonstrate strong, evidence-based clinical value (such as switching studies) to convince payers and providers of their product's value and reliability, as well as ensure a high-quality drug and robust supply.

Although it is not clear who the winners and losers will be in the biologics and biosimilars market, what is certain is that the landscape is shifting. *The Hope and the Hype have prepared the pitch – it is now time for the Reality to do the batting.*

Select Other Sector Transactions

February 2006
Exclusive Advisor
To
SUTHERLAND GLOBAL SERVICES
Private Equity Fund Raise
From
TEMASEK HOLDINGS · Standard Chartered
USD 30 Mn

January 2006
Exclusive Advisor
To
SlashSupport
Private Equity Fund Raise
From
SAIF Partners
USD 23 Mn

January 2006
Exclusive Advisor
To
ALLSEC TECHNOLOGIES – BUILDING LASTING RELATIONSHIPS
Majority Stake Acquisition
in
B2K – PROFIT from ANALYTICS
USD 4 Mn

October 2005
Exclusive Advisor
To
EFX – MAGIC IN MOTION
Private Equity Fund Raise
From
IL&FS | Private Equity – IL&FS Investment Managers Limited
USD 7 Mn

RECENT HEALTHCARE & LIFESCIENCES INDIA TRANSACTIONS

A M&A Transactions in the Sector

Company	Description	Buyer / Investor	Transaction Date	Deal size
Fortis	**Acquisition** *(announced but not closed)*	Competing binding offers from (i) Manipal Hospitals and TPG combined; and (ii) Hero Group and the Burman family and a non binding offer from IHH	*April 2018*	**Outcome awaited**
Healthium	**Outright Acquisition**	Apax Partners	*April 2018*	**USD 306 Mn**
Bio-Pharm	**Outright Acquisition**	Torrent Pharma	*January 2018*	**Undisclosed**

B Private Equity Transactions in the Sector

Company	Description	Buyer / Investor	Transaction Date	Deal size
Curatio (We listen... innovate)	**Invested into By**	ChrysCapital	*March 2018*	**USD 20 Mn**
Asian Institute of Medical Sciences	**Invested into By**	CDC	*February 2018*	**USD 21 Mn**
Axio Biosolutions	**Invested into By**	IDG Ventures, Accel, RNT Capital Partners	*January 2018*	**USD 7 Mn**

C Equity Capital Market Transactions in the Sector

Company	Transaction type	Launch date	Deal size
Aster DM Healthcare	**Initial Public Offering**	*February 2018*	**USD 153 Mn**

Source: Deal Databases
Deals between Jan'18-April'18

FOLLOW-UP: REGULATION IN HEALTHCARE

NPPA HEAD BHUPENDRA SINGH TRANSFERRED

Move comes amid growing clamour of excessive regulatory activism

Known best for introducing several decisions such as capping prices of stents and essential drugs, NPPA chairman Bhupendra Singh was transferred to the National Authority for Chemical Weapons Convention in the Cabinet Secretariat.

Interestingly, his predecessor Injeti Srinivas was also unpopular with the pharma industry for his proactive measures to implement price control and was also transferred before the expiry of his term.

ANOTHER ROUND OF PRICE CUTS ON THE ANVIL?

NPPA gives medical devices companies 'last chance' to submit price data;

NITI AAYOG recommends cap on trade margin for scheduled and non-scheduled drugs

On March 5, 2018, the NPPA again asked device manufacturers and importers to part with price data for 19 of the 23 devices notified as drugs under the Drugs and Cosmetics Act. The price information requested for includes prices for these devices at several points in the value chain and is an attempt by the NPPA to understand and rationalise profit structures for several intermediaries in the value chain from the maker/importer to the customer.

On April 11, 2018 NITI AAYOG recommended (and the key to note here is that this recommendation is for both scheduled and non-scheduled drugs) that the maximum trade margin at first point of sale for drugs should be 24% (i.e. stockist, distributor or at hospital) for scheduled drugs and 30% for non-scheduled drugs. DPCO to be soon amended to incorporate this change and ceiling price fixation by the NPPA to be as per this formula.

Are more price cuts on the anvil or is this just a recommendation that won't see converting itself to law – time will soon tell!

ULTRASOUND, OTHER IMAGING EQUIPMENT NEXT IN LINE?

Included as 'medical devices' paving way for further action, including price caps

The Drug Technical Advisory Board (DTAB), the apex body advising the CDSCO (the central drug regulator), has on February 12, 2018 included ultrasound machines, CT scanners, X-ray machines and MRI machines under the purview of the Drugs and Cosmetics Act so that the government can now regulate their import, manufacture and sale.

Undertaken under the pretext of prevention of misuse of sex selection techniques, the classification as 'medical devices' paves way for price regulation regime for these categories of equipment similar to those of stents and knee implants. Whether and how the government moves in this regard ahead remains to be seen.

INDIA TO CREATE NEW ESENTIAL LIST TO IMPROVE ACCESS TO LIFE_SAVING DIAGNOSTIC TESTS

Is this stage 1 in the effort to bring down price of such tests?

The government is expected to form a working group to focus on creating an essential diagnostics list as per a press release issued by the Indian Council of Medical Research (ICMR) on March 12, 2018.

While the first phase of the initiative will focus only on improving access and reliability of these tests in the public healthcare system, at a later stage the idea is to bring down the prices of such tests in private sector diagnostics as well as per a senior unnamed government official.

Is this just the start of price regulation in diagnostics – if yes, PEs could look to platformize and list before margins start coming under pressure.

NO MOVE TO STOP WITHDRAWAL OF STENTS

Major symbolic gesture with government daring MNCs threatening to pull out their high-end stents from India to walk the talk!

On the first anniversary of the stent price regulations, much against popular anticipation, the government further reduced the prices of drug eluting stents.

The move comes after some MNCs threatened to not introduce technologically advanced devices and equipment in India given lack of incentive and had publicly voiced desires to withdraw already introduced products.

The NPPA on Feb 22, 2018 announced that it would not oppose any such move and by doing so has cleared decks for the MNCs to walk the talk.

SPARK CAPITAL

Source: News Publications

LATEST NEWS AND ANNOUNCEMENTS

MNC vs Local

MNCs NOT PLAYING BY SELF-REGULATION RULES PROPOGATED BY INDIAN COMPANIES

NPPA's divide and rule policy bears fruit

Indian manufacturers of needles and syringes under the aegis of All India Syringes and Needles Manufacturers Association (AISNMA) approached the NPPA to take action against MNC companies not sticking by the 75% trade margin voluntary cap introduced by them.

Domestic manufacturers allege that hospitals have started shifting contracts to multinational companies that are willing to print MRPs that give them higher trade margins.

Once a united industry, its now us v/s them with the regulator called in to become judge!!!

e-pharmacy

HERE COMES AMAZON!

Breaks into drug sales with Perrigo's store-brand OTC medications

While industry watchers were eagerly anticipating Amazon's move into prescription drugs, the e-commerce behemoth snuck into OTC sales with help from store brand expert Perrigo. It rolled out a line of consumer health products, called Basic Care — consisting of 60 Perrigo-made treatments.

Industry insiders claim that the company has already built an internal PBM, which could be an early step toward applying its capabilities in the larger market.

Now, later or not at all? Amazon's (potential) move into meds spawns a slew of scenarios!!!

Insolvency

NCLT PROCEEDINGS FOR ORCHID PHARMA UNDERWAY – RESPONSE TEPID

Gets bids from three suitors but at liquidation value

Ingen Capital, Fidelity Trading Corp and Union Quimico Farmacéutica have submitted bids at par to liquidation value to acquire distressed drug maker Orchid Pharma, news reports suggest.

Ingen Capital is a manager of fixed income and distressed asset funds that invest globally in transportation infrastructure, renewable power utilities and healthcare. Fidelity Trading Corporation is an offshore fund and Union Quimico is a subsidiary of Hyderabad-based Vivimed Labs.

When bids for Orchid were invited initially, 25 applications were received but interest clearly seems to have fallen off.

Specialty Pharma

INDIAN PHARMA'S SPECIALTY MOVES

Moving from becoming an option to a necessity for Indian firms

While Sun Pharma is the only Indian player with an advanced specialty pipeline, most leading Indian players have declared intent to step up initiatives. Several small & mid-sized pharma/biotech companies have been receiving NME approvals in recent years and novel drug discovery is no longer considered an exclusive domain of big pharma.

Specialty activities are likely to remain US-centric with focus on ophthalmology, dermatology, oncology, neurology and sub-therapies within these segments. Given the significantly higher R&D skills and financial resources required, Indian players are taking the inorganic route and expect pick up in M&A/licensing of promising phase II/early phase III assets.

M&A Hunger

INDIAN COMPANIES BOOK VISAS TO THE EUROPEAN UNION

Move aimed to diversify and reduce US dependence

Slowdown in sales due to drug price erosion in the US is pushing home-grown pharmaceutical companies to evaluate opportunities in Europe, the third-largest market for Indian drug makers after the US and Africa.

Torrent putting together a bid for Sanofi's European business (Cadila and Aurobindo were also rumoured to be in the fray), Aurobindo and Dr. Reddy's expanding in Europe through acquisitions in 2017 and even devices manufacturers looking at several acquisition targets in Europe are clear indication that companies are wanting to defray the US exposure risks and are out with a shopping bag in Europe!

SPARK CAPITAL

Source: News Publications

FROM OUR EQUITIES DESK

Institutional Equities Highlights

236
Stocks under coverage

USD 1.2 Tn
Total market cap of stocks under coverage

INR 260 Bn
Total cash market volume in H1FY18

350+
Number of fund relationships globally

"Go-to" broker for stocks in the mid-market space

THOMSON REUTERS 2017 INDIA ANALYST AWARDS
THOMSON REUTERS ANALYST AWARDS 2017 WINNER

Institutional Investor

5th position in 2017
All India research team
Amongst 2 Indian Houses in Top 5

Healthcare & Lifesciences

19
Stocks under coverage

~USD 74 Bn
Total market cap of Stocks under coverage

Key snippets from some interesting notes by Spark's Equities Team

1 *Indian pharma's US woes – Unabating, but priced in*

- The report evaluates progress made by Indian players w.r.t. key challenges faced by the sector in the last 2-3 years 1) GMP compliance 2) Pricing pressures 3) Complex generic approvals. The conclusion is that these headwinds are unlikely to ease materially in the near-term and a turnaround in the medium-to-long term will require significantly better execution vs. what we have witnessed in the past, both on GMP compliance and pipeline execution.
- That said, consensus estimates fully reflect the near-term challenges in the US and for several frontline pharma stocks, the more stable domestic & EM businesses account for substantial part of current valuations, with back-ended improvements in the US from specialty/complex generic pipelines providing reasonable risk-reward.
- **GMP compliance – one step forward, two steps back:** Negative outcomes in recent inspections at key facilities have dented confidence in Indian pharma's progress on the GMP front. Players with a strong track record in FDA inspections historically, have seen GMP violations at key facilities in recent months. Repeat nature of observations and inability to resolve issues completely at critical sites, even post 12-15 months of remediation and engagement with 3rd party consultants have disappointed investors. Shifts in the nature of inspectional observations flagged by FDA at Indian sites have added to the concerns. Next 6-12 months are critical for Indian players, as investors look for completion of remediation activities, re-inspections and final clearance of key non-compliant facilities.
- **Pricing challenges – far from over:** With the 3 buying consortiums accounting for ~90% of generic buying, potential for further consolidation of the generic channel is limited. However, return of a more favourable generic pricing environment will require consolidation on the supplier/manufacturer side.
- **Complex generics – gradual progress:** Indian pharma's execution in complex generic opportunities has been mixed. Segments such as transdermals, long-acting injectables and inhalers remain challenging for Indian players and progress has been limited despite multiple years of R&D efforts. Further, competitive intensity has increased sharply in segments where Indian players have invested significantly, such as derma, ophthalmology, oncology and hormonal drugs.
- Consensus estimates fully reflect the near-term challenges in the US and for several frontline pharma stocks, the more stable domestic & EM businesses account for substantial part of current valuations. Potential upsides from back-ended improvements in the US from specialty/complex generic pipelines provide reasonable risk-reward.

2 *Indian Hospitals – Ready to Consolidate*

- **Hospitals account for 70% of India's healthcare market** of which private hospitals account for 70% again. The hospital industry is quite fragmented with top corporate hospital chains accounting for <10% of the total installed private beds, implying significant scope for consolidation.
- Most leading players (including listed ones) have expanded aggressively over last 4-6 years, partially aided by significant PE investments in the sector (~USD 2.5 Bn between 2012 and 2016). Focus on acquisitions/ greenfield bed additions, coupled with regulatory activism, have led to **muted financial performance for most players in recent years**.
- However, the segment continues to grow given (i) shifting demographics in India; (ii) Changing disease profiles and rising prevalence of communicable diseases; (iii) rising income levels; and (iv) improving health insurance coverage (private and state funded).
- Expect pace of greenfield bed additions to moderate with scope for consolidation of operations at new hospitals to drive material improvements in operational and profitability metrics – gross block per bed remain high, should reduce going forward as asset-light models gain traction.

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Source: SPARK Research

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- All enquiries relating to this document should be directed to Spark Capital personnel mentioned in this document.

HEALTHCARE AND LIFESCIENCES TEAM

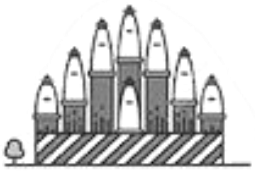
Virendra Parasnath Pandey
Director
virendra@sparkcapital.in

Laasyaa Chadaga
Vice President
laasyaa@sparkcapital.in

Shreyan ML
Vice President
shreyan@sparkcapital.in

Shreyas Subedar
Assistant Vice President
shreyas@sparkcapital.in

CHENNAI
No.2 'Reflections', Leith Castle Centre Street,
Santhome High Road,
Chennai – 600 028



BENGALURU
Unit Nos. 503 & 504, 5th Floor, Prestige Towers,
No. 99/100, Residency Road,
Bengaluru – 560 025

MUMBAI
Unit No. 1116-C, 11th Floor, ONE BKC,
Bandra Kurla Complex,
Mumbai – 400 051

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