Questionnaire - Shilpa Medicare AGM 2016

- With the company receiving USFDA approval for both API and Formulation plant, the regulatory hurdle for the company seems to be over (although temporarily J). We have done capex of Rs.601.35 over the past six years ended March 31, 2016 majorly into projects whose revenue stream is yet to start. How is the management geared up for execution now and how excited are we for the next level of growth to come in the company?

Capex over the past few years

(Rs. Crore)

For the year ended March 31,	2011	2012	2013	2014	2015	2016
Standalone	14.93	72.01	80.55	59.93	77.13	95.64
Consolidated	21.19	79.14	97.43	104.11	141.60	157.88

- We have seen that the timelines for USFDA inspection have reduced substantially over the past few years. Although, we have cleared the regulatory issues currently, how are we ensuring that we as a company are ready to face inspection anytime? How do we ensure that we develop a culture of compliance and not taking shortcut approach in our employees?

  # Building team to manage Compliance & train them to follow processes strictly. Your learnings out of the past and steps to make systems more robust ? Role of automation and IT tools (Electronic intervention & paperless manufacturing).

  With the company getting into so many divisions and investments, do you think that the company has groomed second level of management to take care of these divisions?

Product wise revenue break-up

Particulars (Rs. Cr.)	2008	2009	2010	2011	2012	2013	2014	2015	2016
ICE Sales	52	66	89	149	171	180	234	278	361
Y-O-Y %		27%	35%	67%	15%	5%	30%	19%	30%
API Sales	34	60	143	103	99	142	260	263	241
Y-O-Y %		77%	137%	-28%	-4%	43%	84%	1%	-8%
Formulation Sales					0	0	23	30	79
Y-O-Y %								29%	164%

European and ROW API

- Despite substantial increase in capacities for ambroxol and capecitabine (as told during last AGM), the API sales declined by 8% during FY16 on a y-o-y basis. What were the reasons for the same?
  - o Our large customers like Intas have now shifted to in-house manufacturing of key molecules
  - o Significant price erosion due to entry of more players
  - o Decline in volumes
  - o Product concentration in our API portfolio
- Capacitabine Total Market (EU?) around 70T. (Divis supplied some 20T, Shilpa 15T, Dr Reddy's 15T, Hetero 5T and so on). It is now reported that some suppliers have started supplying at $220/kg vs $400 to $420/kg earlier?

- It is reported that some large scale API suppliers cost the worst-case API Sales price as 1% of Formulation at maximum price erosion levels - and accordingly work out process mechanism - before filing DMF (since luxury of process change after price erosion doesn't exist). Marginal cost reduction benefits can come from some process-optimisations possible - so is that the main reason behind our API Sales coming off - as we decide to exit non-viable APIs and enter new ones/ What are Shilpa's benchmarks for process-decisions while creating/filing DMFs?
- One of our major customers, Intas, has got approval for marketing of gGleevec (Imatinib) in Europe, gVelcade (Bortezomib) in Europe and Brazil and gAlimta (Pemetrexed). Have we started supplying APIs for these molecules.
- We were also looking to explore other countries like Brazil, Argentina, Japan, China for supply of APIs. Any updates on it?

US APIs

- Its been almost six months now since we got USFDA approval for our API facility. Have we started supplying APIs for US markets? What is the revenue potential from extending the past APIs to US market?
- Generally, how much time would it take for customers to change their API vendors ? There might be site change and other processes involved,
- Out of our 26 DMF filings, at least 15 filings are for products whose generics have been already launched. Why would a generic company already procuring APIs from other sources/in-house switch to Shilpa for supplies?
- During FY16 and Q1FY17 (as updated on USFDA website) we filed for seven DMFs, out of which six were for Para IV molecules. Are we focussing more on Para IV molecules now? How do we decide upon filing of new molecule in US and other key markets?
- Several of the pending expiry APIs are low volumes. For example: US volumes of Bortezomib is 1.7 kg and fingolimod is 4.3 kg. How does the dynamics work in such low volume APIs ? Would the formulator set up the capacity in house or would he go for API player for low volume API ?

Some of our key DMF filings for recently expired/under patent molecules:
What is the kind of capacities we are building for these molecules ?

Molecule name	Generic Name	ANDA holders	Expiry dates	Competitive Intensity	US revenues	Comments
Bortezomib	Valcade	1	Oct 2017 Already launched in EU	More than 10 incl. Teva, DRL, Hetro etc	> USD 1 billion	Already launched in EU by Intas. We were expecting high market share in this product. Current status?
Pemetrexed Disodium	Alimta	2	Jan 2017	More than 10 incl. DRL, Reliance Life Science, Neuland, Sun, MSN, Emcure	USD 1.2 billion in US 2.72 billion worldwide	Already launched in Brazil by Intas. We were filing through 505 (b) (2) route. Current status?
Bendamustin HCL	Treanda	5	Expired	More than 15 incl. DRL, Hetero, Emcure, Fresenius Kabi, Natco Pharma, Sun Pharma	USD 680 mn in US	Glenmark and Accord (Intas) have launched generic in US. Current status?
Imatinib Mesylate	Gleevec	3	Expired	More than 10 incl. 10 - Sun, DRL, Mylan, Cipla, Cadila, Perrigo, Natco, Teva, Reliance Life	USD 2.2B USD	Sun, Apotex and Teva have launched in US. DRL, Natco are others in line. Generic also launched in Europe. It was supposed to be a big molecule. Are we supplying it to any of the players?

Fingolomid Hydrochloride	Gilenya	1	Feb 2019	More than 10 incl. DRL, Alembic, Glenmark, Mylan, Cipla, Natco, Teva, Reliance Life	USD 2.48 worldwide	Current status?
Erlotinib Hydrochloride	Tarceva	2	November 2018	More than 10 incl. Natco, Apotex, Cadila, Reliance Life Science, Hetero	CHF 1.29 billion	Both Teva and Mylan show discontinued though. That means zero.
Dimethyl Fumarate	Tecfidera		April, 2018	7 DMF filers including DRL, Glenmark and MSN	USD 2.40 billion	Less competitive intensity. Can be a blockbuster product. Current status?
Axitinib	Inylta	1	Exclusivity - Jan 27, 2017 Patent - June 30, 2020???	Just 3 DMF filers	USD 430 million	A limited competition product. Current status?
Enzalutamide	Xtandi	1	Exclusivity - September 10, 2017 Patent - May 15, 2026???	Just 4 DMF filers	USD 1.50 billion worldwide	Can be a big product. Current status?

Formulations

- Unlike APIs, the cost involved in development, bioequivalence studies, filing, litigation etc are much more in formulations (the cost for filing and litigations can be upward of . How do we decide whether to go for contract manufacturing (where the customer pays for the cost) or on our own (where we bear the cost)? What is the management's thought process behind choosing a molecule for formulation?
- With USFDA approval coming in for formulation plant, have we received approval for any of our molecule till date? How many approvals are we expected to receive in the current year?
- We were planning to file our first FTF in January, 2016. Have we filed for it? How is the competitive intensity in the FTF filing now a days? Out of our total 19 ANDA filed (own – 6 and for contract manufacturing – 13), how many are Para IV and FTF?
- With the Usfda approval , how do you scale up jadcherla plant ?How many partners we have as of now ?How many products are ready with all approvals to manufacture ? Can you explain us the how revenues would shape out over the period and additional capex you are planning . As you are planning third line do we have contracts in place ?
- One of the major reasons we wanted to forward integrate into manufacturing of formulations was to lock-in clients for API supplies? Out of these 19 ANDA filings, for how many do we have our own DMF filings (in our FY16 AR we mention two DMFs in support of ANDA filings)?
- Novartis has filed litigation against us for Imatinib for Para IV filing. For which molecule, did we not receive any notice from innovator? When are we expecting for the launch of Imatinib? Have we tied up for its marketing partner? Its just a four player market currently with not much price erosion (~30 – 40%) with other players like DRL, Natco waiting for approval. Do you think it can

be a big product for Shilpa? Which other molecules do you think will have an impact on the sales of the company?

- Out product development charges have increased substantially from Rs.29.91 crore during FY15 to Rs.81.78 crore during FY16. Since this relate mostly to formulations, is this on account of validation batches of more molecules being procured from us or more quantities of same molecules?
- You had mentioned imatinib and capacetabine are the two molecules in which shilpa has a great strength in API for filing on its own formulations. What are the other four where we have filed in our own name ? Any FTF ?
- Last year you had mentioned we tie up with marketing partner at the later stage in the filing cycle to get significant profit share. Is it the same strategy currently or do we plan to use Koana and our subsidiaries in US for marketing ?
- Now that we have got the FDA approvals for Jadcherla, how long it might take to go to full utilization. Do our customers have already got the products in market and now will do a site change or these are new customers who will be filing for the products now.
- Last year you had mentioned about setting up a line(third line) for CRAMS with innovator. Could you please highlight the progress there ? Innovator CRAMS will have much higher margins. Who are the innovators we have built up relationships with ?
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Europe and ROW markets

- As per our FY16 AR, we have filed for six dossiers (MAHs; for formulations) for European markets. We have strength/speciality in four of these molecules (Bortezomib, Bendamustine, Pemetrexed and Gemcitabine) as indicated during last AGMs. Have we received approvals for any of these dossiers (European approvals are faster compared to US markets)?
- In 2014 agm you had mentioned about Bortezomib . Expiry in 2010 with less than ten filings.
- First two made stable at 25 degrees and expecting big potential . What is the status and expected launch ?
- What will be the role of Koana in marketing our products in European markets (we have already filed capecitabine through it for UK market)? What will be our overall strategy for marketing of our products in EU and ROW markets?
- Any updates on filing of formulation products for Brazil, Argentina (already approved facility) and any other markets?

Overall strategy on formulations

- Given the statements from various competitors about entry into oncology and based on dmf filings competition seems to be heating up . What is your thought process and strategy going ahead to differentiate from competition ? Could you share your thoughts on how competition will evolve over five year period ?
- What is the status of construction of third line (dry powder) for the formulation plant? What will be the costs involved and funding of the same?
- We were also planning to work with innovators for formulations. Any updates on that?

Strategy :

- As a pioneer in oncology space with focus on API and contract manufacturing ,with the priorities and strategy have been evolving , where do you see Shilpa over five year periods ? Would you like to confine to B2b or plans to become full fledged formulation player ?
- Given the statements from various competitors about entry into oncology and based on dmf filings competition seems to be heating up . What is your thought process and strategy going

ahead to differentiate from competition ? Could you share your thoughts on how competition will evolve over five year period ?

- Investing in new areas (nano, biosimilars) vs CONTINUED FOCUS on existing (oncology) areas - thoughts on capital allocation and management bandwidth allocation

ICE JV

- ICE and PCA are the market leaders in cholic acid and its derivatives with market share of 70% in the world. The market for the molecule (API) is of 1500 – 2000 MT (as indicated in the last AGM). How are the growth rates for the molecule?
- The ursodiol generic prices in the US have increased by more than 10 fold over the past two years (from 45 cents a capsule to USD 5.10 a capsule). What are the reasons for such a sharp increase in the prices? Is ICE getting the benefit of the price increase?
  We have seen pretty high growth rates for sales of ursodeoxcycholic acid in Shilpa's total sales (CAGR of 27% over the past 9 years). Even during FY16, the sales grew by almost 30%. What are the reasons for the same?
- We are currently supplying intermediates of urodeoxycholic acid to ICE through our new plant at Raichem Medicare and once ICE obtains import licence will we be supplying APIs to them instead of intermediates? Have we successfully completed registration with PMDA – Japan for the plant? There were plans to develop bile acids from chicken as well. Any updates on that?
- Apart from Urodeoxycholic Acid, PCA also has DMF for Glycholic Acid (used for skin treatment) in USA and other products like Chenodeoxycholic Acid etc. Are there plans for manufacturing other molecules for ICE? ICE was also working on developing Taursodeoxycholid Acid (used for treatment of neurological and diabetes; under trials during 2009). Have they been successful in developing it?
  We have mentioned about improved process and yields from the new facility – what kind of margin improvement this can lead to?
  Since there is strong demand for UDCA, once the JV approvals are in place, do we plan to continue manufacturing in Shilpa standalone or do we have plans of vacating the blocks and use them for Oncology or ARV (ARV was put on hold due high demand from ICE) ? How long do we plans for continued processing of UDCA inside shilpa after JV is fully operational?

Japanese CRAMS

- The manufacturing for CRAMS of Tranexamic Acid was suppose to start from end of this year. Any updates on that?
- Any updates on tie up with other Japanese pharmaceutical companies for contract manufacturing? You also have mentioned in the annual report that our subsidiary Reva pharma will forge another relationship with a big pharma company. Could you please highlight about it and also on the subsequent relationships (women's health and oncology)

Other questions

- Our employee count has increased from 954 as on March 31, 2015 to 1404 as on March 31, 2016. What is the reason for such a substantial increase in employee count? Any particular division where this additional hires have been deployed?
- Reason for resignation of CFO and CS?
- Congratulations on the USFDA approvals for API and Formulation plants. The foundation of this was laid several years ahead. Does it mean we would see Shilpa growing stronger day by the day immediately from here on? Or a little more wait?

FORMULATION / ANDA

- US: Total ANDA Filed – 19 (own 6, customer 13). Approvals – Nil. How many of these are para IV and believed to be FTF?
- US: Kindly tell us more on strategies for this important market. Your comments on - Early v/s late stage partnership, possible revenue contribution, pre-booked capacity, etc.
- Non-US market: Similar number of ANDA filings done in other markets? FY16 AR says ~75cr revenue from "product development". Does it mean Shilpa has started shipping formulations to non-US markets?
- One of the close competitor has reported ~230cr revenue from oncology formulations with 13 approved and active ANDAs. Does this give ballpark number of what to expect from Shilpa from formulation sales?
- Approx 300cr invested in formulation plant (two lines) since 2010 till date. No meaningful contribution to topline/bottomline yet. Talks of another ~150cr investment in pipeline for third line. What is the message you want us to read from here?
- India Formulation: One of the close oncology competitor has clocked ~600cr (greater than 50% of total revenue) from India. Any plans to address this market?

API

- Great to see consistent increase in DMF filings. More specifically in US and Japan. So what kind of revenue contribution we can expect from here?
- Curious - Why would US formulation partners switch to Shilpa for API sourcing, specifically for the drugs they are already selling today? Or is it that switch is rare? If latter, then only APIs for new ANDAs would contribute to additional revenue going forward. Isn't it?
- Nice to read in FY16 AR - "... another set of 18 new oncology drugs are currently under development". Does this include 13 reported as "Under development" at vbshilpa.com currently?
- Laurus Labs DRHP provides market size indication of 20 odd oncology APIs. Ranges from $1m to $65m per molecule. Multiple DMF filers (usually greater than 5) for each molecule. Portrays it is a competitive market. Many fish in not so large pond. Your comments.

CAPITAL ALLOCATION

- Formulations Capex: CRAMS Contracts - full capacity contracted out?
  Duration of typical contracts? What are the Terms?

  Capex over 2013-2016: XXX Cr (please put this figure)
  Typical Asset Turns: say 2.5x?
  Typical Revenues at full capacity Utilisation:?
  Full capacity utilisation

- ICE Capex: CRAMS Contract

Japanese CRAMS

- We were working with Japanese generic company for setting up a block for contract manufacturing for tranexamic acid. Could you please highlight how has been the progress. You also have mentioned in the annual report that our subsidiary Reva pharma will forge another relationship with a big pharma company. Could you please highlight about it and also on the subsequent relationships (women's health and oncology)

ARV

- We had earlier plans of getting into ARV(formulations) and we have strong portfolio there but we had shelved the plans due to needing the capacity for ICE. Any updates here ?

SUBSIDIARIES

- Can you explain rationale behind setting up of Koanaa Healthcare GmBH. we seem to have done registrations for Gemcitabine in UK from this subsidiary in June 2016. (Last year you had told marketing is not the strength of shilpa)
- The potential expanse of activities for INM technologies is quite diverse ranging from coating, dental products/implants to pharmaceuticals. We are indicating that by end of 2018 we will launch dental implants and nano tech based coatings. Looking at the expanse of activities and product development and commercialization effort involved in launching these products, how much additional capital will be required in next 2-3 years and how are we planning to fund it?
- We do not have any experience in marketing products in some of the proposed areas such as dentals/coating/opthalmic etc - have we already built up a team within subsidiary to carry out the launch/commercialization.
- It is difficult to understand the rationale of company diverting precious capital to developing products in area such as dental/coatings/opthalmic while the parent company will require lot of capital to scale up API and Formulation business in US markets in terms of setting up front end, fighting legal battles and ramping up capacities. Can you please help us understand what prompted management to make this capital allocation decision?
- In INM Technologies, we are talking about opthalmic formulations and getting it made through contract manufacturing. Have we identified the potential vendors who can manufacture the same for us. What is the potential market for the same in India/abroad for these formulations.
- We have set up Koanna to market API/formulations in European market and have hired experienced person like Michael Jhoaness Drexler as CTO, what prompted us to set up a separate subsidiary? Who else we have hired post July 2016? How big is the team likely to be for Koanna and what is the likely benefit accruing to the company because of a separate subsidiary marketing its products in Europe?
- For Loba, we have hired a very experienced person like Dr.Erber who has extensive experience on commercial/marketing side in Europe as CEO. Are we overhauling a team in Loba or is it just a leadership change?
- We have indicated that for Loba the focus will shift from fine chemicals to API and we have prepared an investment plan for such shift. Can you please update us on the ball park investment required (both as one time and recurring capex) for such shift? Aren't we serving API market in Europe through parent company as such and hence how the API manufactured at Loba going to be different than our Indian operations?
- At Makindus, MI-100 is the leading compound addressing Stargardt's disease, how big is the potential market size for the MI-100 in terms of value? How much additional investment is required to fund the MI-100 development till commercialization of the product? How are we planning to fund the capital requirement of the company? Being a 505 (b) 2 product, how much time/cost reduction is possible in Phase-3 trials versus full NDA?
- Apart from MI-100, what kind of pipeline we have in Makindus for ophthalmology? If you can elaborate on the status of development of molecules in the pipeline and estimated potential of the pipeline molecules?

LITIGATION

- Pending Litigations Impact (incl. that of subsidiaries). Doesn't this change our promise of a partner who respects IP and will develop products which are non-infringing?

ONCOLOGY API Infrastructure vs Normal API Infrastructure

There are some manufacturers who are able to manufacture APIS like Capecitabine from their existing normal facilities - without investing separately in cost-intensive cytotoxic facilities. It is being claimed that

70% of the Oncology drugs can actually be manufactured (with FDA Approvals) from normal facilities with some structured seclusions.

Your comments?

GROWTH, ROE, ROIC, etc

- What is a sustainable growth rate for the next 2-3 years?
- RoE (less than 20%) and ROIC (fluctuating) - Kindly give us a sense of how seriously this is tracked by Top Management?

TAX

- Tax rate dropped to 24% in FY16 from 29% in FY15. Tax concession because of SEZ? Tax rate for FY17?

MISCELLANEOUS

- During the year there has been a search and seizure u/s 132 of income tax act on the company on 16.12.2015 as per note 51 in AR 2016.
- Another listed company Arrow Greentech filed patent infringement case against NU Therapeutics Ltd and Shilpa Medicare Ltd. for ODS. What can be the implication of these?
- Accounts of subsidiaries including Raichem and Loba are unaudited. Raichem has borrowings of around 135 Crores.
- Average borrowings are around 200 crores. Interest provided is only 6.86 Crores.