"Alembic Pharmaceuticals Limited

Q3 FY '23 Earnings Conference Call"

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.

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Moderator: Ladies and gentlemen, good day, and welcome to Q3 FY '23 Earnings Conference Call of Alembic Pharmaceuticals Limited. We have with us today Mr. Pranav Amin, Managing Director; Mr. Shaunak Amin, Managing Director; Mr. R.K. Baheti, Director, Finance and CFO; Mr. Mitanshu Shah, Head of Finance; Mr. Jesal Shah, Head of Strategy; and Mr. Ajay Kumar Desai, Senior VP Finance.

As a reminder, all participant lines will be in the listen-only more, and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an Moderator by pressing star then zero on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. R.K. Baheti. Thank you and over to you, sir.

R.K. Baheti: Thank you, Yashasvi. Good afternoon, everyone. Thank you all for joining our third quarter results conference call.

During the quarter, our total revenue was up by 19% to Rs. 1,509 crores. EBITDA was Rs. 236 crores and net profit is Rs. 122 crores. EBITDA margin for the quarter was 16%. For 9 months FY '23, EBITDA was Rs. 476 crores and net profit was Rs. 189 crores.

The Company, like in the previous few quarters, continue to expense out previously amortized R&D (in erstwhile Aleor -- now Derma division), amounting to Rs.13 crores in the current quarter and Rs. 144 crores for 9 months period. The Company's profit before tax would have been higher by Rs. 13 crores in the quarter and Rs. 144 crores in 9 months and profit after tax would have been higher by Rs. 11 crores and Rs. 119 crores respectively before considering this effect.

Residual intangible assets in the books is now Rs. 11 crores.

Our consolidated profit before tax would have been Rs. 168 crores and Rs. 382 crores for Q3 and 9 months period respectively before considering the above effect.

EBITA on likewise basis for 9 months FY '23 would have been Rs. 574 crores, which is 14% of sales.

EPS for the quarter before non-recurring item is Rs. 6.76 per share versus Rs. 8.74 for the previous corresponding quarter, while for 9 months, it is Rs. 15.68 per share versus 25.39 in the previous year.

Our gross borrowing continues to be in almost the same zone; as on 31st of December, it is Rs. 686 crores. As on March 22, it was Rs. 630 crores.

We have cash on hand of Rs. 146 crores. In March '22 it was Rs. 61 crores. Net debt equity gets further improved to 0.10.

Now I would request Shaunak to take you through the India business presentation. Shaunak.

Shaunak Amin: Yes, thank you Mr. Baheti. Good afternoon, everyone.

For the quarter, we continued with the same level of performance. We had a topline growth of 12% . We did Rs. 545 crores for the quarter.

As per the IQVIA, Industry grew by 10% and Alembic reflected as 15% growth, which is outperformance compared to Industry.

On the Specialty segment, our performance was significantly higher. We recorded 14% growth versus 10% growth in the Industry which is largely driven by three key therapies, gynecology, anti-diabetics and ophthalmology.

In Q3, the Acute part of our business grew by 21% versus Industry growth of 11%.

In Anti-infective we recorded 24% versus 12% for the Industry

In cough and cold, which is another large important segment for Alembic, we grew by 16% versus Industry growth of 10% as per the IMS.

Animal healthcare continues to run a strong performance by recording a growth of 19% over last year Q3.

I will hand over the discussion to Pranav for his comments on the International Business.

Pranav Amin: Thanks Shaunak.

The US business, as you all know, it continues to remain challenging on account of the competitive intensity, but we managed to grow the business by 10%, some of it was due to the current strong flu season that we saw in the US. Our goal is to work on improving the efficiencies and execution in the midterm. We are looking at cost reduction, as well as reducing R&D grid going forward for the US market.

R&D expense is Rs. 157 crores, an ex of one-time Aleor product write-off is Rs. 144 crores, which is 10% of sales in the quarter, whereas for the nine-month period, R&D expense is Rs. 586 crores and ex of the Aleor onetime, it is Rs. 442 crores, which is also 10% of sales.

We filed 4 ANDAs during the quarter and cumulative ANDAs are 246.

We also received 9 approvals in the quarter and cumulatively have 178 ANDA approvals. We launched 2 products in the US and plan to launch another two in the fourth quarter.

In terms of regulatory agencies and compliance, the USFDA conducted an inspection at our Onco facility F2 and issued four observations. We have replied to the observations already and sent the responses. After that, we have already received three ANDA approvals from this particular site.

That USFDA also inspected a new oral solid dosage facility F4 in December. They have issued five observations. We have sent our responses, and we have already received approval for one product from this facility.

In terms of pure numbers, as I mentioned, the US generics grew by 10% to Rs. 432 crores for the quarter and 10% to Rs. 1,200 crores for the nine-month period. In dollar terms, we were at $52 million, which was a growth of about 1% or the quarter.

Ex-US generics grew by 7% to Rs. 206 crores for the quarter and it grew by 3% to Rs. 602 crores for the 9-month basis.

The API business had a good quarter, robust quarter and grew by 65% to Rs. 326 crores for the quarter, and it grew by 19% to Rs. 853 crores for the nine months. What's important is both the ROW and the API business had both come off strong base of the last year. Hence, it's been a decent performance in these verticals.

With that, I'd like to open the floor open for Q&A. Thank you

Moderator: We have a first question from the line of Prakash Agarwal from Axis Capital.

Prakash Agarwal: First question on, you had some 7 to 9 approvals and there are two launches. So, are we waiting for the launches for the new facilities that we have already started launching in January to March quarter? And if so, the expenses quarterly run rate would be how much?

Pranav Amin: Prakash, from the new facility, we haven't launched as yet. We will launch from one of the facilities in the quarter, hopefully this month and the rest are in progress right now. So, we will see from F2 i.e. Onco facility is where we will launch this quarter.

Prakash Agarwal: And this Diclofenac product is from have we launched this and from which facility is it?

Pranav Amin: Diclofenac is Aleor product, and we haven't launched this yet. It should be in the next couple of weeks as we launch it.

Prakash Agarwal: So can this be sizable on our list?

Pranav Amin: It's a decent product. As far as I believe I don't have the exact figures, but it's a good product with decent opportunity.

Prakash Agarwal: Okay. And what would be the quarterly run rate since you start -- Aleor is already on, I think, in terms of expensing, but a couple of other facilities also understand they will start expensing out or?

R.K. Baheti: Up to 31st of December 2022, no expense was charged off. It continued to get capitalized because the commercialization of these facilities will start from this quarter onwards. And we will start charging off as and when they get into the commercial production. But as was informed by Mitanshu earlier multiple times, our annual run rate on all these facilities is about Rs. 200 crores.

Prakash Agarwal: Rs. 200 crores all the facilities put together?

R.K. Baheti: All the facilities together. Yes

Prakash Agarwal: But it will be not fair to understand that it would be a Rs. 50 crores kind of cost every quarter. It will be in tranches before it touches the run rate of Rs. 50 crores, right?

R.K. Baheti: That's right.

Mitanshu Shah: Prakash, Mr. Baheti is talking about cash expenses here of Rs. 200 crores, and that would be another depreciation on that.

Prakash Agarwal: Yes, operating expense and the depreciation on the overall gross loss.

Mitanshu Shah: Yes.

Prakash Agarwal: And this gross loss pertains to how much, is it in the range of Rs. 2,000 odd crores?

R.K. Baheti: We have about Rs. 1,200 crores of hard assets and the rest is -- accumulated pre-op expense.

Prakash Agarwal: And this product also, this Pregabalin also comes from Jarod. So that also you're awaiting EIR or it should be ready for launch for this quarter?

Pranav Amin: So Pregablin is a product that we are already selling currently from an existing facility, the F1 facility. It's already commercial product. This was transfer that we did from here. So we'll just decide when to start commercial operations from F4. We'll probably bundle up a few products together and then we start the commercial operations.

Prakash Agarwal: Yes. So there's no worry there. Okay.

Pranav Amin: Yes, there is no worry there.

Prakash Agarwal: And lastly, on the API part is doing fairly good. So you mentioned that fiscal '23, there is sufficient visibility. If we want to look at beyond and how does it look?

Pranav Amin: This quarter is little lumpy because as you know, we do a CMO business for a large MNC and sometimes those orders come once in a while. So that was a big chunk of that order came in this quarter. But ex of that also, there's been a growth of about 30%, 40% if you take that part of it out. On a year-on-year basis, as I've been saying, the API business should grow at least by 10% to 15% for the year.

Prakash Agarwal: From fiscal '24, you mean.

Pranav Amin: I think we're seeing that trend. I'm seeing that so even next year, you'll see about it, I would expect it at least a 10% growth in the API business.

Prakash Agarwal: But this run rate is possible in Q4 also?

Pranav Amin: No, it won't because as I said, it's really lumpy. There was one big business that we had and then a few more dispatches in this quarter. Sequentially, it is if we take a one-off, it's still lower than last quarter.

Prakash Agarwal: But y-on-y growth is possible?

Pranav Amin: Yes, Yes, absolutely.

Moderator: We have our next question from the line of Damayanti Kerai from HSBC.

Damayanti Kerai: My question is for Pranav. So you mentioned in your opening remarks that, due to persistent challenges in the US market, you'll be more efficient in R&D costs going ahead. So what's your thought process here? Because right now also we are spending around 10 % of top line towards R&D. So, how or where you can bring efficiencies? And if you can also tell us like what kind of returns you are seeing over for investments, which were done, say, last four, five years back? That's my first question.

Pranav Amin: Yes, two things, one is we are reducing R&D spend, we're trying to optimize the projects that we have in terms of R&D in terms of short-term issues that we're facing in the US market. Some of the high-risk projects we are putting on the back burner. At the same time, we're also increasing some of our projects for the ROW markets because there, we've been doing pretty well and consistently growing at about 10% for the last few years. So, we will start adding projects there as well.

R.K. Baheti: Sorry, on a percentage basis, a couple of quarters back, I think last year, it was about 14% of sales, which has come down to 10%. But also, that's not a right reflection because sales is a depressive if I can say so because of the US situation. Volumes have gone up, but the price realizations are low. In absolute number, in spite of all these cost increases, inflation, we have reduced the expense. And we will further prune the projects and prune the fixed costs so that effect or that impact would come in '23 -24. That's what Pranav wanted to convey.

It's very difficult to do that ROE analysis of R&D because a couple of products can take care of the entire R&D expense. But you are right, I mean, many of these new launches, which we have done in recent past, except a handful of them, have not been great success because of the price erosion.

Damayanti Kerai: I just wanted to check any number in your mind like where you would like to build down your R&D as a percentage of sales say three years from now?

R.K. Baheti: Like the scale up takes time, even the pruning takes time, you need to do it carefully. But we can target a reduction of 15%, 20% from the current cost in the next year.

Damayanti Kerai: Next year expense 15%, 20% reduction can be seen in the R&D cost from current level?

R.K. Baheti: Yes.

Damayanti Kerai: Baheti, sir, I have just one clarification on tight residual R&D for Aleor. So you mentioned INR 11 crores is remaining, which will be say done in next quarter or so and after that, nothing is left on the…

R.K. Baheti: Yes, that's it. You are right.

Damayanti Kerai: My second question is on input cost pressure. So can you comment like, what are we seeing in terms of pricing trend for raw materials, seed costs, etcetera compared to last year quarter?

R.K. Baheti; In international business, we have not seen a significant increase in raw material cost. But as a percentage of sales realization, the cost has gone up largely because, as I said, largely because of erosion in prices. In domestic market, as far as this quarter is concerned, they are pretty stable, they're still not gone to the pre-COVID level, they are stable or have come down a bit for the domestic market.

Damayanti Kerai: And my last question is on India business so most of the therapies, you have seen outperformance versus the market except gastrology. So anything specific to call out there?

R.K. Baheti: So Shaunak, are you responding or you want me to continue?

Moderator: Sorry, you not audible. Damayanti, can you use your handset, please?

Damayanti Kerai: Yes, so I was just asking like anything specific on the Gastrology segment where we have seen as a store performance versus the market growth?

R.K. Baheti: So you are right. I mean you have observed correctly. Gastrology is the only probably large division where we have done less than the market and less than our own expectation. There were some leadership issues. There were some inventory issues of old times. We have done all these corrections and we expect that '23, '24 should be much better results for that division also.

Moderator: We have our next question from the line of Tushar Manudhane from Motilal Oswal Financial Services.

Tushar Manudhane: Just a clarification first, the one-off that has been called out with respect to only Aleor or is there anything else? I joined the call late. So, if you could clarify?

R.K. Baheti: It's only Aleor, that's only Rs. 13-odd crores this quarter.

Tushar Manudhane: And just secondly, among the peer side, a couple of companies have got significant regulatory issues and that has to some extent led to shift of the supplier base, particularly on the injectable side. So, are we going to see a good business benefit out of it? I mean historically, we definitely have tried to do a good benefit of such event. So, anything going forward?

Pranav Amin: It's a good question. Strategically where we've done well is when there are regulatory issues in the industry that leads to shortages. And we've been able to do well on the shortages when we do see it. Injectables are still early days for us because it's just that we just got the first few product approvals.

Once we commercialize it and then once our rest of our portfolio earnings pick up in injectables, yes, definitely, we could see that. Strategically, one of the reasons we did get into injectables is because there has consistently been shortages and compliance issues. So we thought there would be opportunities. So long run, yes, we do hope to see some.

Tushar Manudhane: So anything over the next 12 to 15 months, given that or let it be other given current quarterly run rate of INR 50 crores, INR 52 crores, how do we see FY '24?

Pranav Amin: it's tough to say right now. the whole thing depends on how the new launches go. Like this time, as you've seen, we've got about in rupee terms, a 10% growth. That's predominantly because while we had erosion in the quarter compared to last year, but we also had some new launches that picked up some steam. So, it's a combination and with injectables, as we launch more and more injectables, that will keep adding to our basket. Of course, FY '24 will be a little tougher one because we will have a little bit of a pressure on the profit due to the two new facilities coming up on stream.

Tushar Manudhane: But that is because of taking expenses from balance sheet, which you earned, but the opportunities on the US side, you…

Pranav Amin: Yes, absolutely.

Tushar Manudhane: Okay. For the next 12 to 18 months?

Pranav Amin: Yes, yes, absolutely.

Moderator: We have a question from the line of Rahul Jeewani from IIFL Securities.

Rahul Jeewani; Allow me for the bad throat which I'm running. But sir, with this rationalization in R&D expenses, which you are targeting for next year, do you think that you can offset the incremental operating expenses from the new plans through this R&D rationalization, which you are talking about. And then given that scenario, how are you looking at your EBITDA margins for the next two-year period?

R.K. Baheti: No projections or no estimations -- internal estimations, which we are doing are holding valid for more than six months. So, it's difficult to give any answer. But yes, wherever possible, we are trimming our costs.

R&D, even in operations, wherever there is a possibility, we are trimming in the costs. But for the new facilities, the expense will start hitting the P&L.

Rahul Jeewani; But do you think that with the rationalization in R&D and the fact that the API prices were also on the higher speed this year and some of those benefits coming into next year, you will be able to offset this impact of the new facility costs?

R.K. Baheti: very difficult to make a comment on this -- on the EBITDA side.

Rahul Jeewani; Otherwise, if you can just comment on the fact that have you started seeing any benefit from the API cost moderation?

Pranav Amin: Rahul, in terms of immediate term, it's little tougher to say. Midterm, definitely, yes, we'll see all this offsetting whatever the additional costs. FY '25 will be a lot more comfortable in my opinion.

Moderator: We have our next question from the line of Chirag Dagli from DSP Mutual Fund.

Chirag Dagli: What do you make out of the situation where we have product approvals, but EIR is not in place. I mean it's quite a unique situation. What is your reading or sense of what is happening here?

Pranav Amin: My reading or sense is that, listen, FDA came to approve facilities. As far as they see it, they feel that all responses are in place, they feel there's no risk to anything, hence they've given it. The EIR, they're waiting for a formal EIR. But I think we've seen this not just the first time. We're seeing it because they want us to launch products in the market and they want new facilities. So that's one of the reasons.

Chirag Dagli: So, you're not worried around potential of EIR coming through?

Pranav Amin: No, then they wouldn't have given the approval also.

Chirag Dagli: And sir, do you see over the next two quarters, do you see products getting launched from all the new facilities that we have, onco, onco-injectables, the new oral solid block?

Pranav Amin: Yes, not the new oral solid block that I mentioned earlier in the call that, that we will decide when to do it because that's with a few approvals bundle up and we'll do that. But the first two that will go off the block will be the onco-injectables and then the second one would be the general injectables. Those two, we will start. Those two are the big ones. We will start seeing those commercialization's, one in this quarter, one next quarter, I believe.

Chirag Dagli: And sir, can you quantify the number of pending approvals from onco-injectables and the general injectables?

Pranav Amin: We haven't given that plant-wise. We haven't given the breakup of our injectables. I can give you just absolute amount or offline, I don't have the figure with me.

Chirag Dagli: But is it fair to say that over the next 12 months, there'll be a lot of bunching up of approvals?

Pranav Amin: yes, there would be some bunching up and hence that's why we've seen 2, 3 -- 2 approvals in F3 and one in F2. But it could have been more bunched up more, but lastly, due to the compliance and the remediation, our filing pace also slowed. But hopefully, moving forward the next 24 months, we'll see a lot faster approval rate there.

Chirag Dagli: And on the two Formoterol products -- Arformoterol, I can see we have a double-digit market share in Formoterol. Is that also an indication of what we can get in Arformoterol?

Pranav Amin: Yes. Formoterol, we picked up some decent share. Arformoterol, we will be launching shortly. It's CMO product which is waiting. We should launch it shortly in the next quarter or so.

Chirag Dagli: And for whom both these products are margin profile is feasible given that these are manufactured not internally built?

Pranav Amin: Yes, it's a decent product.

Chirag Dagli: And we can stay in the market even if the market becomes competitive?

Pranav Amin: I believe so.

Chirag Dagli: And the last question is this Aleor INR 13 crores, in which line item in the financial it is recorded?

R.K. Baheti: Amortization and depreciation.

Moderator: We have our next question from the line of Harith Ahamed from Avendus Spark.

Harith Ahamed: When you guided for 15% to 20% reduction in the R&D spend next year, does the base of FY '23 includes the amortized cost from Aleora, the INR 140-odd crores for nine months FY '23 or are you excluding it from the base?

R.K. Baheti: If I take that then the reduction would be far more. So, no, we're looking at the regular recurring expenses and savings from there or reduction from there.

Harith Ahamed: So, Pranav from a couple of years back you had – So I was asking you about this $400 million to $500 million of targets that we have set for ourselves in terms of US sales. Do you still maintain that guidance? And if so, anytime by when we'll get to those levels?

Pranav Amin: when I used to say that I also give a disclaimer that this is a company -- historical companies of our peers in the industry, which have embarked on this, have seen this kind of a growth. And we could also see the number was over $300 million to $400 million, it was really optimistic, $400 million could go $500 million. The $300 million to $400 million I still stand, $500 no. I still think there could be an opportunity to go to $300 million plus.

But as you see, everything's has got push back by about two, three years, so because of the delay in the execution of the new plants and the pricing erosion has increased -- has reduced some of the outlook. But I still believe that $300 to $400 million is still a potential for another three to four-year period.

Harith Ahamed: And lastly, just to confirm the timelines around commercial supplies from three new facilities. For the onco facility, you said we will start supplies this quarter and for Jarod probably later beyond FY '24?

Pranav Amin: Jarod, maybe I'm not -- in FY '24 or even beyond, maybe, we'll just see how it is, what makes sense for us if the products are bundled up, whether what kind of load is there on the F1 facility. And the injectable, the other general injectable is what we will see next quarter onwards.

Moderator: We have a next question from the line of Tanmay Gandhi from Investec.

Tanmay Gandhi: Sir, can you highlight the key reason for growth in US, as we have seen some bit sequential recovery there?

Pranav Amin: I mentioned earlier in the call that, two reasons why we grew in the US. On one hand, you had price erosion in the quarter as well compared to last year year-on-year. So that was quite a bit. But in spite of because we had some certain sales in Q3 of last year. But what happened is, this time as I mentioned, there was a strong flu season, so some of the anti-infectives and Oseltamivir, Tamiflu is where we have a decent opportunity.

And the second one is we have some new product launches where we picked up some share. So that's where both those put together has caused some -- has given us some growth. One thing I have not mentioned though is in the US business on a volume terms, the growth is much higher. But because of erosion, it's only about 10% in rupee terms.

Tanmay Gandhi: And for other companies as well, we are seeing some bit of sequential improvement right – in their base, isn't it, right? And so are you seeing some bit of stabilization in price erosion? And what would be your price erosion exploring pattern?

Pranav Amin: Price erosion is still there. I wouldn't say it's gone away. It's still there. It depends just on which product and which company. It's still there. Maybe slowed down, but still around. I don't have the exact figure because it just keeps changing. So it's still there, though.

Tanmay Gandhi: Any broad number which you would like to give?

Pranav Amin: No, it's very tough to say because what's happened the customers are bidding on the products a lot more often. And so hence, we're seeing a lot of erosion there.

Tanmay Gandhi: So broadly, for industry in general, are you seeing some bit of stabilization, some bit of improvement in price erosion versus last two quarters?

Pranav Amin: No, no.

Moderator: Thank you. We have a follow-up question from the line of Damayanti Kerai from HSBC.

Damayanti Kerai: My question is, again, coming back to approvals from the plants F2, F3, where we are yet to receive EIR, but we saw some approvals. So, are these products in shortage that's why FDA gave a poll before we get the official clearance or as you said, FDA is more keen on approving new plants, and that's why we got some approvals?

Pranav Amin: I'm not sure to be honest. They're not all shortage, the products. One of them has been on and off in shortage. The other ones are not in shortage as well, one of the other ones is possibly in shortage. But I think it's just a matter of the audit and the audit kind of report that was given and our responses, I believe.

Damayanti Kerai: But you're confident you should be getting the official closure very shortly and then that could maybe boost number of approvals from the plant, as you mentioned, was some bunching up, etcetera?

Pranav Amin: we're already getting approvals from the plant as we go along. So whatever spending we're getting approvals as we buy more products, then we'll do it. So yes, but it seems okay because we haven't heard back anything from the FDA. They've received our responses as well. So we haven't received back anything.

Damayanti Kerai: And my second question is, can you comment on the pricing situation for your derma portfolio? Because I think last we you heard it's very severe. So anything incremental there?

Pranav Amin: No, we don't talk product portfolio-wise pricing on any of the on anything.

Damayanti Kerai: But overall as you said, not much change in the pricing situation compared to last two, three quarters?

Pranav Amin: No, no. I said there is still enough erosion, I said nothing has changed. There is still as much erosion as before.

Damayanti Kerai: Same as what it was say a few quarters back that situation?

Pranav Amin: Yes, yes. So, the starting erosion is 40%, the regular erosion must be 10% or so.

Moderator: I would now like to hand the conference over to Mr. R.K. Baheti for closing comments. Over to you, sir.

R.K. Baheti: Thank you, everyone for joining the calls. It has been a tough day for you, analyzing budgets and then attending conference call. So still thank you for your presence and for your interest in the company and we'll say that have a good evening.

Moderator: Thank you. Ladies and gentlemen, on behalf of Alembic Pharmaceuticals Limited that concludes this conference. Thank you for joining us and you may now disconnect your lines.