GLAND PHARMA LIMITED

January 28, 2022

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Scrip Code: 543245

National Stock Exchange of India Limited
Listing Department
Exchange Plaza, 5th floor
Plot no. C-1, Block G, Bandra Kurla Complex Bandra (East), Mumbai - 400 051
Symbol : GLAND (ISIN : INE068V01023)

Dear Sir/Madam,

Sub: Earnings call Transcript- Q3FY22

Please find enclosed the transcript of the Earnings call for Q3FY22 of the Company held on Friday, January 21,2022 at 18.30 P.M IST. This will also be available on the Company's website https://glandpharma.com/investors/financials

This is for your information and records.

Yours truly,

For Gland Pharma Limited

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“Gland Pharma Limited Q3 FY-22 Earnings Conference Call”

January 21, 2022

MANAGEMENT: **MR. SRINIVAS SADU – MANAGING DIRECTOR & CHIEF EXECUTIVE OFFICER**
MR. RAVI SHEKHAR MITRA - CHIEF FINANCIAL OFFICER
MR. SUMANTA BAJPAYEE - VICE PRESIDENT, FINANCE & INVESTOR RELATIONS

Moderator: Ladies and gentlemen, good day and welcome to the Gland Pharma Limited Q3 FY2021-22 Earnings Conference Call. As a reminder, all participant lines will be in the listen only mode. 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 operator by pressing "*" then "0" on your touch tone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. Sumanta Bajpayee, Vice President Corporate Finance and Investor Relations. Thank you and over to you sir.

Sumanta Bajpayee: Thank you. Wish you all a very Happy New Year and a warm welcome to Gland Pharma's Earnings Call for Third Quarter Financial Year 2022. We will begin this call with business highlights and overview by Mr. Srinivas Sadu – Managing Director and Chief Executive Officer followed by financial overview by Mr. Ravi Shekhar Mitra – our Chief Financial Officer. After the opening remarks from Management, operator will open the bridge for Q&A session.

Before we proceed with the call, please note some of the statements made in today's discussion may be forward looking and are based on management current expectations and this must be viewed in conjunction with risks and uncertainties involve in our business. The Safe Harbor language contained in our press release also pertains to this conference call. This call is being recorded and the playback shall be made available on our website shortly after the call. The transcript of this call will be submitted to the stock exchanges and made available on our website.

I will now hand the call over to Mr. Sadu for his opening remarks. Thank you all, over to you Mr. Sadu.

Srinivas Sadu: Thank you Sumanta. Good evening everyone. Thank you for joining our earnings call for third quarter of fiscal 22. I would like to start by wishing you and your families a Happy New Year. Every year that passes teaches us something afresh, the last year has given a greater sense of purpose to us at Gland. Our employees understand the impact their work is making in supporting the healthcare infrastructure globally. We are starting this new year with renewed optimism to accomplish many more milestones together. We would like to wish good health to our investors and analysts.

We have seen the Omicron variant of COVID-19 virus spreading across the globe recently. While in most cases the symptoms are mild, following the COVID-19 protocols and vaccination must remain the key priorities. At Gland, we continue to follow all COVID-19 protocols to ensure safety of our employees. Almost all of our employees are vaccinated with two doses of vaccine.

While there were some material supply delays experienced during the quarter, there are significant delays from pre-filled syringe supplier. Our teams are constantly communicating with our vendors to address the issue.

Looking at our business, we continue to maintain the growth momentum this quarter Q3 FY22, with a revenue of ₹ 10,633 Mn., that is an year-on-year revenue growth of 24% for the quarter Q3 FY22, which is also a growth of 28% for the nine month period 9M FY22 over 9M FY21. With a PAT of ₹ 2,730 Mn, we saw a year-on-year PAT growth of 34% for the quarter Q3 FY22, resulting in also a growth of 26% for the nine month period 9M FY22 over 9M FY21. We have generated ₹ 6,127 Mn of cash flow from operations for the 9 months FY22. Our emphasis on life cycle management of products and continued focus on revenue diversification across geographies, is helping us move forward with a strong footing.

I am glad about our R&D team's ability to ensure timely completion of developmental projects despite the ongoing pandemic. In terms of our R&D progress, we have completed ANDA filings for the four complex injectables targeted to be filed in this financial year during the quarter. The other development projects are also progressing in line with the project plan. We made 18 ANDA filings during the quarter and also filed 3 DMFs during the same period. We have filed a total of 27 ANDA filings during 9M FY22 as compared to 19 ANDA filings during 9M FY21. We also received 4 ANDA approvals during the quarter. Our R&D expenditure for Q3 FY22 was ₹ 699 million which is nearly 6.6% of our revenue from operations. For 9M period upon excluding capital R&D expenditure, the R&D expenditure stands at 4.5% of our revenue for the period. Full fiscal year 22 R&D expenditure as a percentage of revenue is expected to be in line with our historical trend. As on 31st Dec 2021, we along with our partners have 309 ANDA filings in the USA and 1,552 product registrations globally.

We have completed technology transfer and submission batches for Sputnik Light. After successful clearance of samples from Kasauli and joint inspection of our Drug Substance and Drug Product facilities by CDSCO and DCA during the quarter, we just received the Export NOC for 50 million doses from CDSCO. We hope to receive the manufacturing license soon to initiate manufacturing of Sputnik Light vaccine.

Let me take you through the business highlights across various geographies:

With respect to our Rest of the World markets, our strategy of expanding our product portfolio in identified geographies has shown good results. We have further strengthened our presence by winning new tenders in our markets. This business accounted for 19% of our Q3 FY22 revenue as against 13% of our Q3 FY21 revenue. We have seen 88% year-on-year growth in revenues for the quarter. Our key markets continue to remain MENA, LATAM and APAC. Among our key products, Enoxaparin Sodium was the biggest contributor to growth for the Rest of the World Markets. Our ability to manage our supply chain efficiently has helped us meet the shorter delivery times required for rest of the world markets.

Our strategy for our key markets, namely US, Canada, Europe and Australia has shown good results with a focus on ensuring timely commercialization of pipeline and lifecycle management of existing products to ensure market competitiveness. Our key markets accounted for 63% of our revenue during Q3 FY22 as against 70% during Q3 FY21. The new variant of COVID-19 impacted off-take of our core portfolio in the regulated markets. We have seen 10% y-o-y growth in revenues for the quarter. On including India sales for our core markets, the y-o-y growth is at 18%, which is a function of our strong execution capabilities despite the pandemic. The US market has registered a year-on-year growth of 23% for Q3 FY22. The key products helping us achieve this growth include Micafungin Sodium, Ketorolac Tromethamine and Heparin Sodium. In line with our growth targets from new launches we launched 6 molecules during the last quarter.

India market accounts for 18% of our Q3 FY22 revenue out of which domestic markets account for 6% of sales and Indian sales for export markets account for 12% of sales. We have seen 31% y-o-y growth in revenues for the quarter on account of volume growth of existing products. Ertapenem which is a new launch this year meant for export markets has shown strong demand from end market.

As we continue to scale our operations, our quality and regulatory teams have ensured our quality systems and standards are replicated across additional capacities being established. There were times during the last year when we were operating with less than optimal manpower, yet the quality systems stood the test and ensured compliance. All our plants continue to remain approved by US FDA. Our customers are conducting audits regularly and our team continues to remain prepared for any audit.

As we can see from the progress on R&D, our near-term focus on establishing a strong portfolio of complex injectables is progressing in a timely manner. We are also looking at acquisition opportunities to help expedite the development process. At the same time, we are also working towards charting down a roadmap to establish the Bio-similar CDMO vertical. Collaboration with established bio-similar players and acquisitions can help us accelerate the push in this regard.

We remain optimistic on the prospects for this year and hope to continue the growth momentum for all our stakeholders. I once again wish everyone good health.

On that note, I would like to hand over the call to our CFO, Mr. Ravi Mitra, who will share some more insights about our financial performance for the quarter. Thank you very much.

Ravi Shekhar Mitra: Thank you, Mr. Sadu. Good evening, ladies and gentlemen. Thank you very much for attending our Third Quarter Earnings Call. Let me start by sharing the financials of third quarter and nine months' period of the current financial year.

Revenue from operations for the Q3FY22 stood at Rs. 10,633 million, a year-on-year increase of 24%. We achieved steady growth of 10% across our core market of the US, Canada, Europe, and Australia. ROW market continues to record a robust growth of 88%. Our India market which also includes ultimate sales for US, witnessed growth of 31%. Revenue from operations for the nine months of fiscal'22 stood at Rs. 32,977 million, a year-on-year increase of 28%.

Other Income for the third quarter was Rs. 457 million, which includes Interest on fixed deposit of Rs. 342 million and foreign exchange gains on operations of Rs. 86 million. For the 9MFY22, the Other Income was Rs. 1,587 million, of which Interest on fixed deposit of Rs. 1,033 million and foreign exchange gains on operations of Rs. 520 million.

We have reported an EBITDA of Rs. 3,946 million in Q3FY22, compared to Rs. 2,994 million which is an increase of 32% compared to same period last financial year. EBITDA Margin for Q3FY22 stood at 36% as compared to 33% for the same period of previous financial year.

EBITDA for the nine months ended December 2021 was Rs. 13,205 million, compared to Rs. 10,621 million for the same period last year, a growth of 24%. We have reported EBITDA Margin for 9MFY22 at 38%.

Our Net Profit for third quarter was Rs. 2,730 million, a growth of 34% compared to Q3FY21. During the quarter, we have recorded PAT Margin of 25% which is an improvement of 180 BPS compared to same quarter previous financial year. During the nine months' period of the current financial year, our PAT was Rs. 9,258 million which is an increase of 26% as compared to same period last year.

The total R&D expenses for third quarter were Rs. 699 million and stands at 6.6% of the revenue. As mentioned before by Mr. Sadu, during third quarter, we have filed [18] ANDAs as compared to total 7 ANDAs during first six months of the year. In third quarter we have incurred higher filing fees due to increased number of ANDA filling and that has resulted higher R&D revenue expenses as compared to first two quarters' average R&D revenue expenditure by Rs. 299 million.

The total R&D expenses for the 9 months period were Rs.1,714 million, compared to Rs.916 million during the same period of the previous financial year. It stands at 5.2% of the Revenue.

Our effective tax rate remains at about 25% in third quarter and for the nine months' period of the current fiscal year.

Cash flow from operation during nine months' period was Rs. 6,127 million. Cash Flow from Operation has improved during third quarter due to reduced inventory level and receivables position. Net working capital has reduced to Rs. 19,227 million as on December 31st compared to Rs. 20,334 million on September 30th, 2021.

Average Cash Conversion Cycle stood at 190 days for the nine months ending December'21, which is in-line with same period last financial year. Inventory level has reduced compared to previous quarter end, and hence has enabled us to improve overall cash conversion cycle.

All our planned capex plans are progressing well. Total Capex including routine maintenance capex incurred during the year till December 2021 was INR 4,547 million.

Our ROCE on ex-cash basis was at 34% on an annualized basis for the nine months' period of this fiscal year.

Our fixed assets turnover stood at 3.2 times for nine months period of current financials on an annualized basis which has increased from 2.9 times for the same period last year due to increased capacity utilization.

As of December 2021, we had total Rs. 32,846 million of Cash, which we intend to utilize for Capex and to fund our inorganic growth strategies.

With this, I would request the moderator to open the lines for questions. Thank you.

Moderator: Thank you very much. We will now begin the question-and-answer session. The first question is from the line of Nithya Balasubramanian from Bernstein Research. Please go ahead.

Nithya Balasubramanian: My first question is on the complex injectables. Can you tell us what these products are, you've told us what the addressable market but can you throw a bit more color?

Srinivas Sadu: Yes, there are three hormonal products and one complex peptide. The addressable market is around a billion dollars for these four products.

Nithya Balasubramanian: Are you are you willing to talk about what these molecules are?

Srinivas Sadu: No, we can't reveal Nithya, sorry.

Nithya Balasubramanian: Okay, are these Gland own ANDA or partnered products?

Srinivas Sadu: Gland owned ANDA.

Nithya Balasubramanian: Got it. So, my next question is on the biosimilar/ vaccine investment. If I heard you right, you have the export permission now for up to 50 million doses. However, you're still awaiting some additional manufacturing license to start exporting, there is still a hurdle to start exporting?

Srinivas Sadu: No, so the process is initially once you made batches, you have to submit samples to Kasauli and then in parallel we submitted NOC that triggers an inspection. And that's what happened and both site got inspected, the report went and then we got issued actually NOC this morning. Now, with this NOC we have to submit for the license, which is more a documentary protocol I would say, then the license will be issued. Then we have to go and discuss with RDIF on supplies and where to supply. So, hopefully now we should start manufacturing as soon as we get manufacturing license.

Nithya Balasubramanian: So, over what timeframe do you expect to supply this 50 million doses and you have commitment from RDIF that there is demand for 50 million doses of Sputnik Light?

Srinivas Sadu: Yes, so we have a contract in place. Now that we are waiting for the NOC to get so that will initiate the discussion. So, since it's just come up today, we are going to initiate dialogue but I'm sure we are positive that it might happen in next four to five months. And there is a demand, what we've been discussing, there is demand in some Asian regions where access to the vaccines is not there for some other vaccines.

Nithya Balasubramanian: Got it. If I might squeeze just one more in, if your eventual intent is to repurpose this facility for biosimilars and biologics CDMO and the tech transfer process obviously takes depending on the product 12 to 15 months have you already started conversations with biosimilar players and is there anything you can talk about it at this moment?

Srinivas Sadu: Yes, we do. And this good interest we are seeing not just outside India, even some of the Indian players who want to enter in this space are discussing with us and some of our subsidiaries of parent company as well.

Nithya Balasubramanian: Any deals that have been signed so far?

Srinivas Sadu: No, not yet, because we still waiting for a clear cut idea on the vaccine production and how much demand. So, unless that is there, we don't want to enter the deal. So, that this will not impact the timelines.

Nithya Balasubramanian: Thank you so much and all the best.

Moderator: Thank you. The next question is from the line of Ashish Thavkar from Motilal Oswal Asset Management. Please go ahead.

Ashish Thakkar: Thank you for the opportunity So, just could you reiterate our progress on the biosimilar front in terms of like say where we are in terms of MABs, insulin, the cell therapy, the e-coli technologies probably also virus manufacturing technologies and so if you could just give us update where we are in that entire journey?

Srinivas Sadu: Yes, Ashish as we reiterated earlier, we are not into the development of products, we are only doing a development work for other companies, while we have created R&D team and a manufacturing team to address all the technologies, we will not be developing on our own any product portfolio. So, we will be doing a service for the biosimilar company, unlike the generic injectables where we are also developing products.

Ashish Thakkar: Sir, but any timelines so like this is the question which last always in the concall, but any timelines you'd like to share as to when can we see that first dollar revenue coming in for us?

Srinivas Sadu: We want to have a wrap up of vaccine project by the end of this year at least third quarter or so and then start working on the biosimilar end of this year. So, hopefully in the first quarter of next year, we should see something happening I would say.

Ashish Thakkar: Okay. One last question on this narcotics any update, like how are we planning to take our sales ahead whether it would be through M&As, acquisition of technologies, anything on the those kinds will be helpful?

Srinivas Sadu: Could you repeat that Ashish?

Ashish Thakkar: Anything on the narcotic space in the U.S. which is obviously a complex area and we are willing to take ourselves there. So, any progress and how are we planning to take ourselves to the U.S. market probably?

Srinivas Sadu: Narcotics is more than a complex I think because it has to be done in locally in U.S. That's the key issue so, we're still actively looking at assets. COVID didn't help us because there were travel restrictions. But still, I would say we are actively looking at assets in U.S. to address this market.

Moderator: Thank you. The next question is from the line of Saion Mukherjee from Nomura. Please go ahead.

Saion Mukherjee: Sir, on the ROW markets we have seen steady performance around 200, 250 crores for the last three quarters. When do you expect a step up in sales in ROW going forward?

Srinivas Sadu: Sorry, Saion what's the question again?

Saion Mukherjee: So, I was asking on the ROW markets, you have a quarterly revenue run rate of around 200 to 250 crores it's been steady for the last three quarters. When do we expect any step up in ROW revenues?

Srinivas Sadu: See, year-on-year we are growing very well. And we won tenders and we start supplying in different quarters. And they're the countries where we have tendered for two years, three years. So, where we have just started in say last quarter. So, it's a cycle, so you will be seeing the step up from April quarter because normally it's a year-on-year growth you see for our kind of business.

Saion Mukherjee: Okay. Sir, on the U.S. market in your commentary, you didn't talk about Enoxaparin as a growth driver, because I understand you had some supplies to Fresenius. So, if you can just take us through what's happening in the U.S. overall, the exports from India part has also sort of seen a good leg up. So, if you can give some more colors as to what is sort of driving growth. What is dragging down any commentary on the U.S., any details would be helpful.

Srinivas Sadu: So, even in my last earnings call I did mention some of the contracts what we won, for some of the products. Micafungin is growing very well when we see year-on-year it's almost 200% growth. We have two major contracts in place. Enoxaparin again, it's driving growth because of the last contract we have. We have several launches if you see the growth of U.S. 23% year-on-year, majority has come from these products. And products if you see like Dexmedetomidine, we have a few very good contracts in place that has done very well. Ertapenem we got contracts that is doing very well. So, four or five products, which are large are doing extremely well and that has contributed to the growth of 23% from the U.S. market. And even the bag products, where we were having the capacity utilization of 25%, 30% today, we are almost hitting in a full capacity. We got contracts in some of the bag products as well. So, we have really contributed to the growth. And we have several launches coming in next few months as well, the market size of that itself is around 1.3, 1.4 billion in next nine months in terms of launches.

Saion Mukherjee: Okay. Sir if I can ask one more question on gross margin, it's been pretty steady. Any comment on raw material price pressure, how should we think about gross margins in the quarters ahead?

Srinivas Sadu: For Gland I have been talking about this earlier, gross margin is little irrelevant because of our model, because we have what we call varied model where we do contract manufacturing where the gross margin is 100%. We have licensing income which is 100%, we have tech transfer projects where is a different set of gross margin and our own products. So, whenever the mix changes, the gross margin looks different. It doesn't mean that there's pressure on gross margin. Unlike other companies, where 100% of business comes from the product sales, we normally have to look more about EBITDA and PAT. And if you see that, it's steady and considering the 18 ANDAs file in this quarter, for which the filing fee itself costing around 30 crores. Normal run rate per quarter for filing fees is around 5 to 6 crores but this quarter been heavy in terms of that which will help in the growth of the business like you said. So, if you see last year, entire

year we have 21 ANDAs this year, we met about 28, 29ANDAs. So, there is an increase of 7 to 8 ANDAs and the bulk of it has happened this quarter. If you consider these expenditure made on the ANDAs filings adding that to the EBITDA it's in line with the historical trend.

Moderator: Thank you. The next question is from the line of Amit Kadam from Canara Robeco. Please go ahead.

Amit Kadam: I have two questions, one is on the Enoxaparin, maybe 10 days back we had this news from the Indian Government issuing some kind of notice on the banning that particular export. So, does it impact us, in that particular thing. Do we come under that particular gamut under that notification. And the second question is that we had guided earlier that our China commercialization the first product launches could happen by the end of FY22 or the start of FY23. Does that timeline remains steady?

Srinivas Sadu: So, on the Enoxaparin there are two things, one is prohibited and the other is restricted. What this product has fallen under is the restricted category because of the COVID situation, just as a precautionary measure government has put that under restricted category. So, we have to file document to get an approval for an export. But as of now, they are not really restricting any shipments and with the amount of the number of suppliers in India, we don't foresee any shortage happening in the Indian market. So, the impact won't be that much. So, as of now it's normal business. Only when some shortages happen in Indian market that's when they will look at restricting it. As of now there is no restriction to export.

Amit Kadam: So, does it happen like every shipment then we have to take an approval because it's into restricted category then?

Srinivas Sadu: No, not every shipment. Whenever we import components or materials to export we get it under advance license. So, they actually approve the advance license and whenever you file for shipping, you have to mention that advance license number and that will clear at the customs. So, it could be 40 batches or 50 batches at one shot. Once you have an advance license approval then you can ship whatever covered under the advance license.

Amit Kadam: So, in this last 10 days as a regular shipment nothing has impacted our regular flow shipments to our respective customers?

Srinivas Sadu: Not yet.

Amit Kadam: And on my second question sir?

Srinivas Sadu: On the China piece we are still waiting for the first approval, there's one piece which still deliberation is normally NMPA does inspect the facility first time when they approve a product.

So, it's under that deliberation whether it has to be a virtual audit or visit, visit could be a problem so, that stage. Probably that gets cleared this product might get approved.

Amit Kadam: So, the timelines could get a little deferment?

Srinivas Sadu: Yes, it might differ, but we did say that the first quarter of next year could be the time when we commercialize. So, all will get more clarity it might happen on it might be push by few months, but we will give a better clarity in next earnings call.

Moderator: Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

Sameer Baisiwala: Sir, just on your four complex injectables for which you have done the filing. The total combined size of the addressable market is 1 billion, is that correct and that's the gross number by IQVIA so the net number would be what 25%, 30% lower?

Srinivas Sadu: Yes, that could be correct, but most of the time these products have lesser discounts, so it's closer to the IQVIA number especially products which are single source.

Sameer Baisiwala: Okay, got it. And are all four of them without any generic or there are some players there in the market?

Srinivas Sadu: No, these are not generic yet.

Sameer Baisiwala: Excellent. And what could be the approval cycle timeline for this?

Srinivas Sadu: Normally, for complex internally we are assuming two years, that depends on the first response we get from the agency.

Sameer Baisiwala: Okay. And sir how do you see the competitive outlook for these four products, when you reach the market would it be one, two player market or there are more people in the queue?

Srinivas Sadu: It's very difficult to say because lot of people are talking about complex injectables. We have started this program few years ago. So, while we have filed four this year next year we have pipeline of filing eight complex products, it's very difficult to say which companies are working on these products. If you look at the total portfolio, that's 35, 40 complex injectables, so you don't know who are actually working on which products. I can't really comment on how many players will be there.

Sameer Baisiwala: Okay, that's very clear sir. Sir one last one from my side. And that is for your base business all the injectables in the regulated markets, some 250 odd approved ANDAs. So, as more and more Indian players broaden their portfolios, are you seeing competitive pressures over there in the market are you seeing a higher price erosion. Your thoughts on this would be great, thanks.

Srinivas Sadu: So, there will be a price pressure for any product waiting to get genericized, but because the business model our impact of the price pressure is little lower, if you see our growth has come almost 17%, 18% from the volume growth and the new launches growth has given around 6%. So, majority of the growth has come from either new launches or volume, the price will remain same or it's 1% down. So, the impact is lower for us because the business model what we have because we are protected by the Transfer Price model we have and the profit share component for the smaller part of the entire business of about 10%. So, even the impact is lower. And because of multiple players, we have partnerships with several products. We kind of average out the price pressure.

Moderator: Thank you. The next question is from the line of Tushar Manudhane from Motilal Oswal Financial Services. Please go ahead.

Tushar Manudhane: So, just clarification again on this Sputnik in terms of the timeline for starting the exports, like three, four weeks' timeline or can be faster than that?

Srinivas Sadu: I wish I give you tomorrow Tushar. So, once we get a manufacturing license, then in parallel we are discussing the RDIF on countries to which we have to start exporting. Then we have to start manufacturing, the manufacturing process from the minute it starts the drug substance to finish product itself is about 45, 50 days and then the samples have to be released by Kasauli and also Gamaleya, Russia. So, that's another 30 days or so. The dispatch may happen actually the first part of next quarter, then this quarter but at least the manufacturing will happen this quarter.

Tushar Manudhane: Understood. And just coming back to the complex generic filing are these products into the shortage list which can compel U.S. FDA for inspection or early approval if at all the file is more or less appropriate?

Srinivas Sadu: No, because these products are filed from same lines and approved facility, so this doesn't trigger an inspection as such. Anyway, it all depends on when they want to inspect because of course we are one of the key injectables suppliers to the U.S. market and other products goes from the sites. We got inspected in 2019 last, so in 2022 anyway it's due. So, we had to be ready whenever they want to come, but this for sure will not trigger an inspection, but normal course of business they might give an inspection this year.

Tushar Manudhane: Understood, and lastly on Enoxaparin, on 4Q onwards we were to start the incremental order flow on this product in terms of gaining market share from let's say the previous supplier. So, is that on track or on account of COVID related hiccups, is that getting pushed or kind of preponed some highlight there?

Srinivas Sadu: No, in fact if you see the numbers this quarter, Enoxaparin in the U.S. has gone up. So, we already started catering to that demand, specially demand for the new contract what we have,

more will come in from this quarter but the impact has already started we start supplying from last quarter more quantities to U.S.

Tushar Manudhane: Understood and just lastly, there has been a good increase in the ANDAs filings after maybe almost two, three quarters. So, is that kind of pent up into this quarter itself or with the production bit easing on account of COVID or how do we look at this the pace of filing?

Srinivas Sadu: So, we never try to postpone any ANDA filings whenever it has to happen, we do that. Because of four complex injectables, the development took longer time you can see last year it was only 21 ANDAs, normal our target is around 24 and we did 21 last year. So, complex injectables takes longer time to develop. So, these were in pipeline and we've got ready to file this quarter. So, there were additional filings which has happened. And depending on when the stability gets over, when the ANDAs batches happens that's when we file it. So, it just incidentally happened this quarter. And that's why it like the bulk up in only one quarter this 18 ANDAs and three DMF.

Moderator: Thank you. The next question is from the line of Vivek Agrawal from Citigroup. Please go ahead.

Vivek Agrawal: The question is related to complex peptides that you have filed this quarter. So, are you developing the API on your own or you're sourcing it from a third party?

Srinivas Sadu: No, these are outsourced.

Vivek Agrawal: Okay, so basically it is fair to assume that as far as the peptide filings are concerned for most of the products for example API's are outsourced?

Srinivas Sadu: Not all peptides, in some of the peptides we buy intermediate and then do a final step. But more critical APIs we are dependent on external sources. But that's one of the areas we're also looking from acquisition perspective in the long term.

Moderator: Thank you. The next question is from the line of Kunal Dhamesha from Emkay Global. Please go ahead.

Kunal Dhamesha: Sir, if we can provide some color on what was our profit share this quarter?

Srinivas Sadu: You want this number of profit share number or you want the percentage?

Kunal Dhamesha: Percentage.

Srinivas Sadu: 8% contribution for the revenue.

Kunal Dhamesha: Just for this quarter. And for the nine month also it would be similar?

Srinivas Sadu: No, For the quarter it's about 10%, for nine months is about 8%.

Kunal Dhamesha: Okay, and the second question is again on the biosimilar side. So, obviously we have sited some timeline, but there is also and we are also in the discussion with various companies, but there is also another aspect in terms of regulatory clearance of the facility and that also takes time. So, the current conversations you are having with prospective clients, whether these are for the ROW markets or for let say Europe market or U.S. market?

Srinivas Sadu: So, the facilities are designed for regulated markets, so it will be good enough for all markets from regulatory inspection perspective. And local inspection perspective, we already got approval clearance from the inspector for the vaccine, it's just that we need to give a cleaning air handling for the month and then we can start the Biosimilar production. But the design of the plant is as per regulatory requirements for the regulated markets.

Kunal Dhamesha: Sure. And these regulated market inspection would be triggered after you have certain products which gets manufactured or certain contracts in place or this can happen before as well?

Srinivas Sadu: So, there are two things, one is mostly the customer approval we need once we sign a contract, depends on the type of work you do. If you want to take a pilot scale batches, which the product has to be given to humans, then you need a regulatory approval. But otherwise, any development you do in R&D or a batches for animal studies, you don't need regulatory approval for this. The approval from the client is good enough.

Moderator: Thank you. The next question is from the line of Rahul Jeewani from IIFL. Please go ahead.

Rahul Jeewani: Now, with respect to the biosimilar CDMO business, you indicated that we would not be involved in product development and these products would essentially be tech transferred products where we will be providing, fill finish services to some of the other players. So, because this will be a tech transferred portfolio where you will be providing fill-finished services, do you think that the biologic CDMO portfolio would be a lower margin business for us and hence it will be margin diluted for us?

Srinivas Sadu: So there are two or three different aspects here. One is the products which are already generic I would say, you have to really call it, Rituximab kind of products. Doing work for them, whether it's a tech transfer, and you try to get cell lines from the client and then do a scale up on the substance and then do a fill finish. But the other key aspect is the new drugs, not the generic products. That's where the focus is now. So, all the companies who are developing new drugs, they look at the development work to be done at a smaller companies like us, we act as a service provider for that and they will, whether it could be cell line development or whether it could be scale up batches, or sometimes they have done already cell line we do the drug substance scale up or we do the pilot scale batches, so several dimensions to this business, but mostly what we're

looking at is working with companies who are working on the new drugs and less on the genericized biosimilar I would say that.

Rahul: Okay, so that essentially means you would be targeting some of the breakthrough biosimilars, which will go off patent, but you also indicated that the revenue accretion from this project could start in 12 to 18 months' time. So, how do you tie in that given that some of these products which you might be targeting will be going off patent only post FY24-25 timeframes?

Srinivas Sadu: Sorry. I think you missed one point, what we're saying is, we are not worried about the commercial production yet for these products, we are looking at development scale up and then some might not every product you do development work at a CDMO will actually get commercialized a little different than the generic business. Some will pass through the animal study, some will pass through the human studies, and some may not. And only when the products where it will get through all of this then it gets to commercialized production. So, it's mostly we are working on the development side, scale up side of the business. And whichever product is successful, that's when it gets to the commercialized stage.

Rahul: Sure, sir and with respect to the U.S. business if we look at the U.S. business, which is booked as part of our developed markets business, the U.S. business has been flat quarter-on-quarter despite the incremental supplies which you have done on Enoxaparin for the additional contract. So, what has led to sequentially the U.S. business being flat overall?

Srinivas Sadu: So, the quarter-on-quarter it varies and we really should not compare, because it depends on what kind of products got dispatch, that particular quarter, are there any launches during that quarter. So, it depends on how many product gets launched in a particular quarter. So, we should always look at an annual basis, which gets averaged out, whether it's ANDAs filings or whether it is some of the high value product might have dispatched in a particular quarter may not get dispatched. And the quantities also might vary, this all depends on the timing.

Rahul: Sure, sir one last question from my end. So, this is more of a bookkeeping question. Now, over the last two quarters you have started calling out the sales which is being booked from India for the export markets and specifically the U.S. business. So, the growth numbers which you are reporting for U.S. is including the proportion of sales, which has been booked from India, and we have seen this that you have started doing this only over the past two quarters. So, has anything changed with respect to how your account for the sales which has led to some sort of disclosure being made in this way?

Srinivas Sadu: So, if you see, two, three years ago the business what was happening to Indian companies to the U.S. was minimal, not that much, few products got sold by Dr. Reddy's in that market. But we have done a lot of contracts with different Indian companies over the last several years that kind of started to sell. So, it's only fair to say that because the products are ultimately sold in U.S. and that is also generating a growth and for example Ertapenem it's licensed to Indian company.

And we know that is selling well and we should not take that away from the U.S. business because now there are several products which we don't license to U.S. companies only to Indian companies. And that should not curtail that and because the volume of business is growing in a large way. So, we thought the investors should know how much actual domestic product is going to the U.S. market. Because there will be an ambiguity around how we are growing 30% in Indian market, it's only a smaller portion of our business. Most of the business what we're doing today, shown as India actually is going to the U.S. market but billed as INR.

Rahul: So, just one clarification on that point. So, the U.S. market sales which we are booking as part of the developed market portfolio, does that mean you don't book any sales to the Indian companies as part of that develop market portfolio so all your sales which is happening to Indian companies is getting booked as part of the India sales only?

Srinivas Sadu: Correct. It's always booked as India, we're only saying that part of that India, x amount, so much percentage and so much quantity for the U.S. market. That's what we are telling.

Moderator: Thank you. The next question is from the line of Vivek Gautam from GS Investment. Please go ahead.

Vivek Gautam: Recently, we have been getting good numbers post IPO that's great sir, keep up the good work. And sir one thing I just wanted to know about was the, what is the compliance status of our because I believe, and we have a stellar track record of maintaining great compliance since 2003, if I'm not wrong, and what are the factors behind it and any inspection in offing in post pandemic FDA team coming up?

Srinivas Sadu: Yes, all our sites are FDA approved. Many of them are approved by other regulatory agencies as well and it's intact. In fact, just today we have just finished our Dundigal plant, one of the main plant inspection from ANVISA. It was a physical inspection. This is the first inspection post-pandemic, I would say. We had Russian inspection, but was more virtual, and some other inspections virtually. FDA we don't have an inspection, we did receive some questionnaires for some of our APIs which were due for inspection in last year, and that was submitted. Other than that everything is in compliance and even inspection with ANVISA went well, so that gives us confidence that in spite of no inspections from regulatory authority for last two years, we are in line with our compliance record.

Vivek Gautam: Great sir. And sir what has been the Fosun contribution to our growth since they took over our company, and what has changed since then and how's their growth mindset and any entry in China, or rest of the world market they are opening doors for us any positive development sir?

Srinivas Sadu: Yes, if you really see it's not just before listing even before listing, we've been growing for three years.

Vivek Gautam: Since 2015.

Srinivas Sadu: Yes, correct. So, the investment what we made, whether it's infrastructure and the portfolio and the plan we made were long term that's all come into fruition. And post-Fosun, it really helped us in some of the markets, because if you see the sales in some African markets has gone up very well, where Fosun network we have been trying to sell our products to. China market, we never looked at that market actively before. Currently, we're looking at it because like you said, 1/3 of global injectable market comes from that market. So, that's a great help, in that sense. And M&A, we don't have much experience in that side as well. So, we get a lot of help from them looking at different assets and evaluating and during diligence activities. So, there are several areas where we cooperate and we get help from them.

Vivek Gautam: And sir lastly what are the CAPEX plan and any concern on increasing competition intensity in the injectable space for us from Indian companies and other companies also?

Srinivas Sadu: So, Mr. Ravi will address the CAPEX plan but on competition perspective, I've been saying any new competitor is good for us, because we get one more partner whom we can license our products to.

Ravi Shekhar Mitra: Under CAPEX plan, so we have spent about 450 crores in nine months and would be spending another 100 crores in this quarter. So, that would take care of the 550 crores we initially indicated for this financial year's CAPEX plan. So, mostly it has been incurred on the vaccine facility in Pashamylaram expansion. Next year we are estimating about 300 crores of CAPEX for further setting up the lines in Pashamylaram and also on the API side we are adding capacity for more vertical integration. So, that is the CAPEX plan for this year and next year.

Vivek Gautam: Dividend any plan sir, giving dividend?

Ravi Shekhar Mitra: Dividend the Board has to deliberate and decide, we cannot comment anything on that now.

Moderator: Thank you. The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.

Prakash Agarwal: Sir, just wanted to understand, basic question that we've been doing great growth and we have a good selection of products. But what we hear from the large Indian pharma companies also is that, the second of 23 they are also coming with complex injectables. Do you think from 23-24 the competition level will increase and our long term growth can taper a bit just from the base business, not the biosimilars?

Srinivas Sadu: So, competition is coming from last three, four years, and like I've been saying our models are different we are not a front end company. So, we cater to different companies. So, more competitors will come, we have products to license to this company that's one, the portfolio

build up happens to any company over a long period of time, it took us so many years to build 300 odd ANDAs. So, no company can build develop so many ANDAs in a year. So, they also take time to go to that stage. And the throughput we gave and the technologies we have across different formats it takes time for any company to do it. So, we're not that worried about the growth. Of course the base is increasing so not just the portfolio will help us grow the way we have been growing. So, we are looking at different avenues and that's one of the reasons we've been focusing so much on geographic growth drivers. And areas where we have not touched upon yet, if you look at the product what we have launched, it's only about $5.9 billion worth of products and the market is $130 billion across of the globe. So, there's a lot more to do and a lot of catching up even for us and even more for companies who are coming new.

Prakash Agarwal: That was very elaborate answer thank you for that. And secondly on biosimilars, so I heard you saying that currently we are adding capability of fill and finish. So, what is the three five year plan, are there any therapeutic focus, autoimmune or otherwise and do we plan to do the complete DS and drug products ability or we would carve out our specialty part of the business?

Srinivas Sadu: No, in fact we are doing both DS and fill finish, not just fill finish to start with. The vaccine, DS plant what we have created that will be converted to DS once this vaccine project gets over that's the plan. So, from beginning itself is a combination of both DS and DP. And that's why also we have a little advantage over lot of other companies with a track record we have on the fill finish. So, it's not just fill finish we're looking at both DS and DP.

Prakash Agarwal: And sir the product selection is there a therapeutic focus, are we looking at large products already identified or we are looking at the second wave which are yet to see any biosimilar entry. How are we thinking about product selection and therapeutic selection?

Srinivas Sadu: And like we said we're not getting into a development of products. So, whichever clients want for portion of that work so we will be acting like a service provider for them, unlike the business what we are doing today where we do both, we do service as well as we do develop products. But for CDMO biosimilars the idea is to work as a service provider for the biosimilar companies.

Prakash Agarwal: Okay, got it. And lastly, sir on the free cash flow generation, how do we think to use the cash over next three years, would it be largely for CAPEX and part of a dividend, or we are open to looking at large assets as well?

Srinivas Sadu: Yes, so primarily we have to look at areas where we can fill gaps what we have, there are several areas where we don't have capabilities yet, to build that it might take few years that's we have to acquire some assets. So, there is a primary focus on that without putting too much pressure on the balance sheet we are getting risk averse in terms of what we have to buy unless it fits perfectly into our long-term strategy and where we have gaps that where we are looking it from an acquisition perspective and also the investments in the complex injectable are a little higher compared to normal injectables. So, investments will go into that. But we'll evaluate on the

dividend and all that when the time comes there and the Board has to decide based on the cash flow we have.

Moderator: Thank you. Ladies and gentlemen, this was the last question for today. I would now like to hand the conference over to Mr. Sumanta Bajpayee for closing comments.

Sumanta Bajpayee: Thank you everyone for joining us today. We appreciate your participation during the call. I request you to get in touch with me if any of your queries still remained unanswered. Thank you. Good night.

Moderator: Thank you. On behalf of Gland Pharma Limited, that concludes this conference. Thank you for joining us and you may now disconnect your lines.