Management Discussion

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Thank you. Good afternoon, everyone, and a warm welcome to the Q2 and H1 FY27 Earnings Call of Bharat Parenterals Ltd. I am Bhahim Desai, Director, Strategy and Investor Relations. I hope you have had a chance to look at our results, the investor presentation, and the management discussion and analysis. All of them are on the stock exchange and on our website. Before I begin, a quick disclaimer. Some of what I say today is forward-looking. It reflects our current expectations and carries risks and uncertainties, so actual results may differ.

In May, I called FY26 our bridge year, and I said FY27 is where we expect the commercial inflection. I am pleased to say that Q2 is the first quarter where that inflection shows Up in the group's profit. Our teams have worked towards this for several years, so I want to walk you through it carefully, what drove it, what's structural, and what will move around from quarter to quarter. Let me give you the consolidated picture first, and then I'll go business by business. Consolidated revenue for the quarter was INR136.3 crores.

That is up 110% on INR64.6 crores in Q2 last year. And up 45% on Q1 basis FY27. Last year's Q2 was a soft base. Export shipments were deferred and our general injectables line was shut for close to a month. So I would point you to a 45% sequential growth as the cleaner measure of progress. And even on that basis, it is a strong quarter. EBITDA was INR 23.6 crores, a margin of 17.3%. A year ago it was INR0.8 crores. Last quarter it was INR8.5 crores at 9.1%. So the margin expanded by more than 800 basis points in a single quarter. Profit after tax was 11.8 crores against a loss of INR8.6 crores in Q2 last year and a loss of INR3.6 crores in Q1. Of that INR11.8 crores, INR9.4 crores belongs to BPL shareholders. The remaining INR2.4 crores is our minority partner's share of Innoxel's profit since we own 55.9% of Innoxel.

For the first half, revenue was INR240 crores, up 27%. EBITDA was INR32.1 crores, up 120%, and the margin moved to 14% from 8.1%. Profit after tax was INR8.3 crores against a loss of INR9.5 crores. Profit attributable to owners was INR10.4 crores, roughly 10 times the INR1 crore of H1 last year. The minority share is still a loss of about INR2.2 crores for the half because Innoxel's first quarter was a loss. Just as important as the numbers is where they are coming from. Innoxel and Varenyam Healthcare, our high-margin growth platforms, together made up 45% of our revenue before eliminations this quarter, up from about 40% a year ago. Innoxel is now the largest EBITDA contributor in the group, producing more than 60% of the EBITDA across our four companies. That is the shift in mix our strategy was built around.

Going to BPL standalone now. Coming to the standalone business, which is the parent company and the foundation of the group. Revenue for the quarter was INR78.6 crores, up 88.4% year-on-year and 41.5% on Q1 FY27. Part of the year-on-year jump is recovery from last year's weak Q2. So the sequential growth is the better guide. For the half year, standalone revenue was INR134.1 crores against INR136.1 crores last year, which is broadly flat. That is the honest comparison, and it means that the second half has to carry the year's growth.

This was an execution quarter. Our domestic tender book came down from INR119 crores at the end of June to INR65 crores at the end of September, largely as supplied against it. Capacity use tells the same story. In the first half, general block ran at 70% against 48.5% FY26. Beta-lactam was at 33% and Cephalosporin was at 31.5% against 21% and 24% respectively last year.

That leaves meaningful headroom. We do not need new capacity to deliver the standalone growth

we have guided, and the additional volume can be absorbed on our existing cost base. Our total order book stood at INR117 crores at the end of September across domestic tenders, exports, and international tenders, which gives us good visibility into the second half. Now margins, I want to be straightforward with you here. EBITDA was INR7 crores, 3 times last year's INR2.3 crores, but the margin was 9%, down from 12.3% in Q1 FY27. The reason is input material cost. Prices of several of our inputs rose sharply because of the ongoing geopolitical conflicts. Our material cost went up by about 5 percentage points of revenue in a single quarter, and the gross margin came down to 3 5% from 8% in Q1 and 44.1% in Q2 last year. What was within our control, we managed well. Employee costs fell to 9.3% of the revenue from 11.7%.

Marketing e xpenses grew 33% year on year against revenue growth of 88%. Profit after tax was INR5.4 crores, up 98.7%, and net margins improved to 6.9% from 6.6% in Q1 and 6.5% a year ago. I'll also be clear about the risk. A good part of our order book was priced before input costs went up. Until those prices ease or the books turn over to orders priced at current costs, margins on that book will stay under some pressure. For the first half, standalone EBITDA was INR13.9 crores at 10.3%. That is inside our 10% to 15% range even after absorbing this quarter's input cost increase.

The balance sheet continues to strengthen. The standalone business generated INR65 crores of cash from operations in the half and spent about INR15 crores on capex, leaving roughly INR50 crores of free cash. Trade receivables are down INR205 crores from INR120 crores in March and INR130 crores a year ago. Debt-to-equity is 0.08 times. You will also see investments go from about INR1 crore to INR56 crores. This is surplus cash placed in various market instruments, not new investments in businesses.

Moving on to Innoxel Lifesciences , I'll spend a little bit more time on Innoxel because this is the quarter where its model started to show in the numbers. Revenue was INR44.5 crores, up 253% year-on-year and more than double of Q1's INR21.4 crores. EBITDA was INR 14.6 crores at 33% margin against losses of INR2.1 crore a year ago and INR1.8 crore in Q1 FY27. Innoxel also made a profit after tax of INR5.4 crores after losses of INR11 crores a year ago and INR10.4 crore last quarter. This is the operating leverage we have been talking about. Innoxel's cost base is largely fixed. Between Q1 and Q2, revenue went up by INR23.1 crores and EBITDA went up by INR16.5 crores. Put simply, most of each additional rupee of revenue is now flowing through to profit. I would keep the 33% in context, this revenue is still mostly licensing milestone and development income, and that arrives when our partners reach milestones, not evenly every quarter. A lighter milestone quarter will bring the margin down, so the half year is the more representative read. Innoxel's H1 revenue was INR65.9 crores, up 219%, and already close to the INR 72.4 crores it did in the entire of FY26. EBITDA for the half was INR12.8 crores, just under the 20% floor of our margin guidance. After tax, the half is still at a loss of about INR4.9 crores because of the first quarter.

The bigger news came after quarter closed. On 20th October, the first product Innoxel makes under a CMO agreement was exported to the U.S. by our sponsor partner. This is a milestone we have been building towards since Innoxel was founded, and it moves Innoxel from development and validation work into recurring commercial supply. In May, I said we expected first commercial supply in Q2. It came about three weeks into Q3. None of that supply revenue is in these numbers. It builds through the second half, but this year will still be mainly a licensing and milestone year for Innoxel, w ith manufacturing revenue starting. We expect the second contract manufacturing product to be commercialized within FY27 upon receiving the approval from the U.S. FDA. The platform behind this is in place. Innoxel has its EIR from the U.S. FDA inspections and its EU GMP certificate from the

Belgiun regulator covering all four of the lines. That combination is not common for a dedicated contract manufacturer, and it is what our partners are building their U.S. programs on. As always, I won't name our partners or the [Indecipherable]. Those agreements are under confidentiality.

Moving on, Varenyam Healthcare. Moving to Varenyam Healthcare, our domestic branded business, which I founded in 2016. Quarter two revenue was INR19.7 crores, up 33.2% year- on- year. EBITDA was INR1.8 crores at 9.2% margins, and profit after tax was INR1 crore. Revenue was down 21.5%, vis-a-vis Q1 FY27, which is this business's normal cycle. Our sales are highest in Q1 and taper through to Q4. So Varenyam is best judged on year-on-year and half-year numbers. On that basis, H1 revenue was INR44.9 crores, up 43.2% year- on- year, at an EBITDA margin of 11%, with profit after tax of INR3.8 crores. Our guidance for the year is 20% to 25% growth at an 8% to 13% margin. So we are running well ahead on growth and inside the band on the margins. We ended September with 229 approved field representatives against our target of 250 by year-end. Our second division, Bhuvah in gynecology and women's health launches later this year and takes the franchise beyond the anesthesia and critical care portfolio we have built in the hospitals. It will be a cost before it is a revenue, and that is already built into our margin range.

Moving on to Varenyam Biolife Sciences. VBPL is pre-revenue. Its operating cost in Q2 was INR0.14 crores and the capital work in progress stood at INR33.7 crores. We are targeting completion of the construction by second quarter of calendar year 2028 subject to commissioning and regulated payments.

Moving on, cash generation from the group was strong in the half. Consolidated cash from operations was INR83.3 crores, more than double of the INR38.4 crores we generated in the whole of FY26. Before tax paid, INR39.4 crores of that came from operations and INR48.4 crores from releasing working capital came . This number reflects our underlying earnings power, and it is encouraging to see it build. The second is a release that we would not expect to repeat at the same scale.

Consolidated borrowings stood at INR160 crores at the end of September, most of it being at Innoxel. On 29th September, our Board approved a preferential issue of 9 12,759 shares at INR1,522.85 per share, raising roughly around INR139 crores from 15 non-promoter investors.

White Oaks Funds are the largest participants, with Nine Diverse Capitals, Aurum Rising Fund being the second largest, Ashoka India Equity, and Perpetuity amongst the other Investors. Shareholders approved the issue at our EGM on 23rd of October. Up to INR135 crores will go into our subsidiaries over the two n ext 2 years, and CRISIL Ratings is the monitoring agency. After allotment, promoter holdings moved from 67.2% to just about under 60% at 59.3%, and there is no promoter pledge. This money is not in the 30th September balance sheet.

To the investors who have joined us, thank you. We see your participation as an endorsement of the path we have set out, and we take the responsibility that comes with it very seriously. Lastly, since, 17th August, our shares have also been tradable on NSE under the symbol BPL Pharma. And our shareholder base grew by 22% from the June quarter end to September quarter end. On the guidance front, we are maintaining our FY27 guidance. Innoxel and Varenyam Healthcare are running ahead on growth in the first half, and the standalone business goes into the second half with the order book and the capacity to deliver.

For the standalone business, revenue growth of 10% to 15% on FY26 pays of INR234 crores. And an EBITDA margin of 10% to 15% remains consistent in line with what we guided at the start of the year. For Innoxel , revenue growth of 35% to 45% at a margin of 20% to 25%, with out-licensing income

of roughly INR80 crores to INR90 crores. The first half is well ahead on revenue and just under the band on the margins front. Because milestones do not come in a straight line, we would rather see the second half's licensing timing and the supply ramp before we look at these ranges again.

For Varenyam Healthcare, growth of 20% to 25% at a margin of 8% to 13% was the guidance. The half year is ahead on both, but the business tapers going into Q4, and the new division is still a cost, so we are not revising at present. Varenyam Biolife Sciences stays pre-revenue this year. With that, I'll hand it back to the moderator. We are happy to take your questions.

Questions & Answers

Operator
Thank you. We will now begin with the question and answer session. [Operator Instructions]. The first question comes from the line of Henil B with Equicorp Partners. Please go ahead.

Henil B. - Analyst, Equicorp Partners
Thank you for the opportunity, sir. I hope I'm audible.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Yes, you are.

Hennal B - Analyst, Equicorp Partners
Yeah, so starting with -- congratulations on good set of results. So starting with Innoxel , I think so we've got about 42 total assets and about eight of assets on the BE stage and five are in the pre-filing stage. So if you could give some understanding, what is the typical gestation period when we actually go from B or BE stage to filing and commercialization? And how many of these 13 advanced stage assets do you expect to be launched across FY28, '29, and '30? And what kind of potential do you actually see in these assets?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So the gestation period, first of all, to answer your question, firstly, thanks for your congratulations on the setup results. Going forward on your question, as far as the gestation period is concerned, it depends on the type of filing that there is that we are going ahead with. If it's an ANDA filing, the gestation period is much shorter. Because the stability requirement for an ANDA filing remains six months on the exhibit batches. If it's a 505(b)(2) NDA filing, then the stability requirements for filing is 12 months real-time data.

So generally, an ANDA takes, I would say, roughly between 15 to 18 months from manufacturing of exhibit batches to the approval, obviously depending on the U.S. FDA. Typically, that is a much longer process when we talk about the 505(b)(2) NDA. In Innoxel's pipeline, we have a mix of both ANDAs as well as 505(b)(2) NDAs. So I would say to answer your question on FY28, '29, and '30, it's I would say most of our assets which are currently under development would be in the market by FY30. Sequentially, FY28 would be our ANDAs that we expect to be there, as well as a couple of our 505(b)(2) NDAs which would be filed in this year. We are looking at filing of various of our products between now and end of the year. So we expect the approvals to come in 12 to 15 months, making it possible for us to launch in FY20 -- I would say calendar year '28, so it would be FY29.

Henil B. - Analyst, Equicorp Partners
Okay. So with respect to scaling of the liposomal and the extended release injectables that we have

in our portfolio, I think it's very difficult because if we actually see we have to scale it up without altering the drug's pharmacokinetic release profile is a very difficult task. So with the new installed liposomal SKID that we have in the general block, have we actually completed the exhibit batches? And how the yields are we seeing yield losses? Are we seeing yield gains? And how do you actually see the scale-up actually coming up here?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So the scale-up process is almost completed. We are going for exhibit batches sometime in November. So we are not too far away from taking our scale I would say exhibit batches for our liposomal program. Following the installation of this SKID, obviously there were qualification activities. We had to qualify the line first in order to start the scale-up process. And subsequently, you are right, it does take a lot of effort in ensuring that the lab scale versus an actual commercial scale-up is actually in line with the parameters of the product. And it does take, I would say, few attempts to do that. As far as our current progress is concerned, we are seeing results which are absolutely in line with the results that were there in the lab. So we are confident that we'll be able to take our exhibits in November and subsequently be ready for filing the product in Q1 of next financial year.

Henil B. - Analyst, Equicorp Partners
Okay. So with respect to our focus, I think so currently we are most so focused on onco and the CNS sides. But we've also got a good expertise on the extended release and the depot technology. So in terms of the significant capacity that's actually unutilized, are you actually seeing, evaluating opportunities on the GLP-1 sterile side or on the specialized hormone capabilities because you've got a depot therapies in place also?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So see, over at Innoxel, I would say that we have good number of projects across various lines. As far as capacity utilization is concerned, Innoxel is not the typical CMO that relies on capacity utilization in order to generate revenues. So I wouldn't say that you necessarily need to look at the capacity utilized in order to see the revenues on the books of Innoxel. The products and the kind of projects that we are undertaking are usually complex in nature, have lowered volume thresholds than your general generic, and has a higher margin as well as cost base. So capacity utilization or blocking of capacity is not to be looked at in terms of revenues at Innoxel.

Hennal B - Analyst, Equicorp Partners
Okay, so we've got about 4 European partners who I'm actually working with for some US filings. Is it a part of a strategy that we actually want to act as a regulatory bridge and also CMO or a CDMO partner for the mid-sized European clients and who actually want to enter the US but do not have an FDA certification for the sterile facilities? And I mean provide end-to-end service and also help them in scaling up there. Is that what we're actually hinting out here?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So we work with global clients. Predominantly, we want to work with clients who operate within the US, but we definitely are also catering to a few other markets. These markets include Western African, Western European countries, the UK market, and the Canadian markets. So any clients who are operating within these markets are the clients that, you know, we would want to onboard. As far as our European clients who we already have on board, they are a mixed bag. A lot of these clients

are already present in the US but have partnered with us for specific products.

And a few of our clients which are European clients are not necessarily for the US markets. They are for EU and UK markets as well. So I would say that to the point which you mentioned about a regulatory bridge, Yes, we would want, I would say, few European clients so that our entire business is not concentrated for the US markets. And that's exactly how we have, you know, our deals have been structured and our products have been selected along with our partners and geographies to mitigate that risk.

Henil B. - Analyst, Equicorp Partners
Okay. So on the standalone side, what would be the split between the oral solids versus sterile FTF? And going forward, how do you actually see it? Because if I actually see some of these Indian pharma peers, where the [Indecipherable] ones are exiting the oral solids because it's very competitive and they're getting on the sterile injectables where they see better margins also. So some of your understanding out there. And also going forward, do you see a potential that the general block where exactly a lot of oral solids, OSDs, are actually made, can it be actually repurposed for some other use if you actually see a lot of competitive intensity or pricing issues from some of the Chinese peers out here?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Okay, so as far as oral solids, and the injectable split is concerned, our core competency at standalone business remains injectables. Roughly around 45% to 50% of our total revenues come from injectable products. And the next biggest heading under which the revenues come from at standalone is from oral solids. So I would say that yes, oral solids predominantly would have more, I would say, margin pressure because the entry barriers are much, I would say, lesser in comparison to the sterile injectable products. But at the same time, the products, the market, the brands, the way of doing business matters. So [Technical Issues] necessarily need to look at the entire section to be removed for us to make way for something else, going forward. I would say that working on a well-defined, strategy and well-defined markets with a good business model is something to be considered and something to be looked at.

Henil B. - Analyst, Equicorp Partners
So how are the margins working on the newly launched therapies, the specialized one that is the atropine therapy versus our legacy portfolio? And actually, how do you actually see the churn happening between new therapies versus the old therapy in terms of the correlation, the percentage on the revenue side?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So the new therapies that we have developed and the new products that we work on are usually more differentiated. They would be, I would say, the number of competitors on those products would be lesser than the typical age-old generic that used to have a lot of volumes at our end. But at the same time, it's a volume and value split. You have to understand that there is a reason why antibiotics and the generic side has a certain volume which the newer therapies may not be able to generate the same. So it is a good split at our end right now where We are trying to grow our value realizations and our bottom line realizations through new products, but keep a stable base with the older products having a more volume contribution to the overall business.

Henil B. - Analyst, Equicorp Partners
Okay. So thanks a lot for the opportunity. I actually have more questions. I'll get back to the queue to give opportunity to others. Thank you.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Thanks.

Operator
The next question comes from the line of Aryan Bhatia with InvED Research. Please go ahead.

Aryan Bhatia - Analyst, InvED Research
Hi, thanks for the opportunity. So my question is on the standalone business. So we were looking for an EU GMP audit in this financial year after the update of our line, some of the lines. So just wanted to know what's the update and when can we expect the audit? And on the continue of this, so this quarter on the standalone side we posted INR80 crore top line. I just wanted to know like how much is the contribution for the from the deferred export tender?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Okay, as far as the EU GMP inspections are concerned, right now we are preparing for it. All the necessary changes in our water systems, oRABS upgrades, and QC lab expansions are completed. We will disclose the inspection and the outcome as and when it happens. Since we don't have the dates yet from the regulators, it would be preemptive for me to give you a timeline. We do expect it in this financial year, but cannot give you an expected timeline as of now since I didn't have a confirmed date from the regulator as of now. As far as the other question of -- can you please repeat your other question?

Aryan Bhatia - Analyst, InvED Research
Yes, my question was on the export deferred export tender. So in this quarter, on the standalone side, we posted INR80 crores, right? So just wanted to know how much is from the deferred export tender?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So that would be somewhere close to around INR30-odd crores, and I would say that part of it was also in Q1. So between Q1 and Q2 that was completed, and in Q2 I would say that closely around INR25-odd crore to INR30-odd crores from that.

Aryan Bhatia - Analyst, InvED Research
Got it. And second question is on Innoxel. So in the start of the financial year, we were guiding for 35 to 40% growth on the INR72 crore base on FY26. But if I look at H1 ' 27, we have already done INR65 crores of revenue. So how should we think for H2? Because we will be having some commercial supply in Q3 as well as Q4. So shouldn't we be posting more than 35%, 40% growth in the overall financial year? And on the margin side as well, considering CMO will be there in H2, so how should we think about the margins?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
See, as I already mentioned , in my earnings presentation that -- sorry, my earnings address, that most of the Innoxel's revenue is going to come from milestones and licensing income, and that can be a lumpy nature in terms of when it is realized. So I will wait for Q3 before I give any -- if at all

there is any guidance revision on Innoxel numbers, because we have to see what kind of licensing and milestones can be achieved in H2. We are currently doing that exercise as we speak. So at Q3 close, we will be in a position to give you a better answer on the final numbers expected at Innoxel. As things stand, we are going to achieve the numbers that we had guided on. That is quite clear. On the margins front, as I said, that the higher the base, the higher the margin percentage looks like. So a quarter where the overall numbers from milestones and licensing income is on the lower end, the margin percentage can come down based on that, which is why we would maintain our guidance of 20% to 25% for the entire year as of now. If there are any revisions, those revisions would be given at the end of Q3.

Aryan Bhatia - Analyst, InvED Research
Got it. And so just last question is on the fundraise. So we have done a INR139 crores of pref issue. So the investment will be solely for the Varenyam Bio subsidiary, or it will be used for Innoxel as well?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So, it is earmarked for all the subsidiaries as and when the requirements are going to be and on the earnings potential of each of these subsidiaries. So and when the disclosures -- as and when investments would happen, there is an agency which has been appointed for monitoring and the subsequent disclosures of that would be given. As of now, I don't have a split that I can give you.

Aryan Bhatia - Analyst, InvED Research
Got it. Thank you. Thank you for the answers and best of luck for the future.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Thank you.

Operator
The next question comes from the line of Nishit Sanghvi [Phonetic].. With Prospero Tree. Please go ahead.

Dhruvesh Sanghvi - Analyst, Prospero Tree
H i , Bhahim Dhruvesh here. G reat set of numbers and thank you for the opportunity. So just wanted to ask in terms of Innoxel , do we estimate that FY29 we will easily cross INR300 crores now? I mean, with the pipeline established, etc., some sort of a broader number there if possible for FY29?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Again, something that we -- I won't be comfortable in giving the answer out at present, because FY29 is still a year and a half before it starts. So closer to the -- somewhere in FY28, I'll be able to give you a more confident answer on that number. The work with which we are going ahead and the number of approvals that we are expecting, there is a good likelihood that that can happen, but I can only comment on it on the certainty sometime next year, not this year.

Dhruvesh Sanghvi - Analyst, Prospero Tree
Okay. And just to understand the profile of the margins for Innoxel once it scales up above a certain number, let's say INR200 crore to INR300 crore range, can we say that this is not a model which will only give us a 25%, 30% margins on EBITDA level, but in fact it should be easily more than 50% or maybe 60%, 65% also. If we end up scaling to that number is what I'm saying, let's assume there,

what should be the margin profile that we should consider?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
See, the margin improvement will happen. The way in which the Innoxel model is, there are three different revenue streams that Innoxel has. Obviously, the licensing and milestone income is just one part of it. The commercial part, which has now started from October, that would be the second part. And the last part would be a profit share once our own developed products hit the market. So when we reach the profit share stage, we expect the margins to shoot up due to that profit share going straight to the bottom line. And it can go up above 35%, 40% as well. I would not give a clear number yet. Again, I would wait for things to pan out before giving a number, certain number out.

Dhruvesh Sanghvi - Analyst, Prospero Tree
Sure, snd you used the word profit share. So this is molecule to molecule, will it be profit share or revenue sharing? I mean, because how will we calculate the costing that the partner is going to provide to us? And that is why I'm asking from that lens.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So each of our contracts come with a definition of net sales and profit share calculations. And there's a fixed formula which is there. And so it is not a revenue share because obviously no one will give any part of the revenue before taking the costs that they would incur in selling those products in the said markets. So we are looking at a profit share and not a revenue share. And, like, I said, everything is built out in individual contracts.

Dhruvesh Sanghvi - Analyst, Prospero Tree
Okay. Second part, even though I understand that INR135 crores we have not earmarked internally that how much will go where, but the only question comes from an angle that -- in the presentation we have said that probably we will require INR300 crores for Varenyam, out of which we have only spent INR30 crores - INR40 crores so far. In terms of building that entity. And naturally, my sense was that Innoxel will also require some money for the future expansions or more addition of products or maybe some lines. Without quoting the numbers, can you give us some sense, because there is still a lot of gap in terms of what you will need versus what you have. So where will it come from? Should we expect more dilution or there is some...

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
No, no, we, we expect no further dilution at this moment in time. I would say that looking at the current revenue streams that we have across various businesses and looking at the free cash flow that is there at the standalone level, as well as the money raised in the current press, we are very well positioned to fund everything internally at this moment in time, both at Varenyam Bio as well as Innoxel whatever further is required at all these entities. Obviously, Varenyam Bio is not going to be 100% funded through equity alone. There would be certain b ank debts that would come on the books of Varenyam. So using bank debts as well as the equity the balance of the capex would be funded at Varenyam as well as Innoxel .

Dhruvesh Sanghvi - Analyst, Prospero Tree
Right. And the last one, pleasantly surprised at looking at Varenyam Bio's expansion plan that you have said. And first we were only focusing for non-U.S., non-Europe, and now we are seeing the entire biologic shift there. Can you give us some sense on like where is the confidence coming, what are the opportunities that you are seeing? Of course, part of it is given in the presentation, but if you

can lay down a little bit more in terms of what has shifted in your mind and where is the opportunity arising for you, and a little bit more detail on this part, on the change of plan there.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
See, that's I would probably be repeating a lot of it which is there on the presentation, so bear with me. See, customers very short of qualified mammalian scale-up capacity. Biologics developers often lack the capacity to take a molecule from clinical supply to a commercial scale. So a CDMO partner that does both, it is a stickier business than an ROW formulation plant copying Innoxel model, right? So that is the reason for the pivot. There is also a lot of, I would say, opportunities coming from, I would say, other SRA countries outside of the U.S. from a biologics perspective. Not many operators within the biosimilar biologic space operate in all these markets. There is constantly a supply gap which you can see, and the need for these products are on the rise and will continue to rise due to various ailments which are lifestyle-related and the era in which we live in, which also continues to rise across the globe. So I would say that the opportunities are there. Sooner or later there would be a shift and a lot of companies would enter this space as well. We just acted on it sooner.

And apart from that, yes, the confidence comes from the fact that we have a successful model that we have done in the past through Innoxel. And similarly, we would be working for Varenyam Bio as well, where we would be able to successfully scale up a plant where we usually were not present per to say, from a standalone perspective of yours before. So that's the confidence, underlying confidence, and the business opportunity which made us pivot.

Dhruvesh Sanghvi - Analyst, Prospero Tree
Thank you, Bhahim. Thanks a lot.

Operator
The next question comes from the line of Vishal Prasad with Rajmahal Capital. Please go ahead.

Vishal Prasad - Analyst, Rajmahal Capital
Hi, thank you. So, Bhahim, let's say we talk about 505(b)(2) and we partner with others on that. So when we launch the molecule in U.S., what kind of marketing effort is required? And let's say, if the current market size is USD500 million, is it feasible to capture 10% of it in two - three y ears after launching?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Okay, great question, Vishal. So a 505(b)(2) NDA requires marketing support first of all. It's not a distribution play like an ANDA. So the right front-end marketing partner is very important because we are therapeutically agnostic and have no role or no front-end marketing of our own. We partner with the companies who already have some exposure in those therapeutic segments, and addition of our product becomes a synergistic effect for them and their marketing team. That's how we try and identify our front-end marketing partners specifically for 505(b)(2) NDAs.

So that is the first major point. The second point about market conversion, as you said, if a market is there for USD500 million within the two - three years, can we capture 10%? That entirely depends on the fact that how well, is your 505(b)(2) NDA. There in the U.S., if you just change one of the excipients also, it could be classified as a 505(b)(2) NDA. So if you are not solving an actual problem that the other molecules are, or which are already available in the market, are -- you are not solving a problem which is greater than that, then your 505(b)(2) NDA becoming a commercial success goes down.

So if your 505(b)(2) NDA is able to solve any unmet patient requirements, if it's going to help the doctors in administrating the product, and if there is an inherent advantage of the product over existing therapies, then definitely the conversion can be 10% or maybe higher in the first couple of years itself.

Vishal Prasad - Analyst, Rajmahal Capital
So, given that we have few molecules there and you must have looked at the kind of problems we are trying to solve, so do you think we have something up our sleeve where we will be able to execute and capture probably 10% of the market probably two - three y ears after launching. Is there something you see that can happen, possibly?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
No, definitely. We -- our partners very confident on a lot of our 505(b)(2) NDAs that we'll be able to capture 10% to 20% of the market in the couple of years of launch. So, obviously, see, as of now, I can only give you a sense of understanding based on what our partners tell us because the products are still to be launched. B ut from there, on the basis of our partner's confidence, we get the confidence that yes, at least in the first couple of years, we can expect 10% to 15% of market conversion in the 505(b)(2) NDAs that we are operating on, which is not a bad number to begin with. It's a -- it would be a sizable number and a good number for us at Innoxel as well .

Vishal Prasad - Analyst, Rajmahal Capital
So let's say, I'm trying to understand the difference between 505(b)(2) and [Indecipherable] . So when somebody launches a generic product after patent expiry, there is significant price correction. But in our case, when we go with 505(b)(2) and there is a patented molecule available, so probably if that is selling for USD100 , what would be the differential between our product and what is the patented product?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So that depends on the pricing strategy our partner adapts, because since they are the ones to market the product and they are the ones who will be holding the IP usually what happens is their team, their sales team and marketing team takes a call on the pricing strategy. But a 505(b)(2) NDA will be at a discount, at least 20% - 30%, 40% discount of that of the innovator product on the market, but it would be well above the generic level as well. Our 505(b)(2) NDAs currently, what we are in advanced stages and what we would be filing, are not, I would say, genericized. Only the innovator would be there in our case. And so that eliminates the competition from a pricing perspective with any generic players in the immediate future. So I would say that there would be a good number of, at least a couple of years, two to three years of time when there won't be generic entry and it would just be our 505(b)(2) and the innovator.

Vishal Prasad - Analyst, Rajmahal Capital
So let's say you mentioned that two to three years down the line, I mean, at least we'll have a runway of two to three years. So once a patent expires and we have generic products in the market, so usually not since we have not done it, but you must have noticed what is happening in the world. What happens to 505(b)(2) molecules? Do they get out of the market or they remain there with significant price corrections?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
No, on the contrary, if there is a advantage of your 505(b)(2) over the generic or the innovator, and t hat's why the market adapts and converts from the innovator to your product. It's not only about the pricing aspect, then that continues. Obviously, there would be some pressure on the margin side because the, I would say the insurance companies would be putting a lot of pressure on our front-end marketing partners to have some sort of further rebates on the 505(b)(2), but it would not be a complete genericized version. There is a good life of every 505(b)(2). I wouldn't say again, I would put the question back on how well of a 505(b)(2) there is and what unmet need it is solving. If there is a genuine case of any unmet need and a patient compliance issue that is being solved, then the generic entry does not really make a big dent on the pricing structure of the 505(b)(2) NDA.

Vishal Prasad - Analyst, Rajmahal Capital
Okay, last question. So let's say there is a molecule of USD500 million and our partner is able to capture USD50 million out of it. So what comes to us? I mean, I know all the NDAs and contracts are different, but can you give us some sense on out of USD50 million something comes to us? Is it USD10 million, USD20 million, or how is it?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
It's a very difficult question for me to answer right now because it's quite hypothetical at the moment. I cannot give you a straight answer what would flow to us because each contract is different, product pricing is different, the margin structure of each product would be different. I can only say that typically these guys don't work under 80%, 90%, I would say 70% to 80% of gross margins. So rest is up to you for interpretation as to how you interpret that, but I cannot give a single digit as to what can come down from USD50 million to Innoxel.

Vishal Prasad - Analyst, Rajmahal Capital
And we are going to manufacture everything in Innoxel, or is there something we are going to outsource as well?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
No, no, no, everything would be in Innoxel .

Vishal Prasad - Analyst, Rajmahal Capital
Okay, I think that is all. Thank you, Bhahim.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Yeah, thanks.

Operator
The next question comes from the line of Kaushal Sharma with Equinox Capital Venture. Please go ahead.

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
Hi sir, very good evening. Am I audible?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Yes, you are audible.

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
I just want to understand your out-licensing the business model in Innoxel, like the total revenue of around INR66 crore in H1, out of which INR45 crore approx in Q2. So how much upfront fees of the proportion is going to the upfront fees or the milestone basis, and could you please explain the terms, how will it go in the milestone basis, like the terms and what is the existing project in this based on the milestone and the upfront, and what kind of potential going ahead in this kind of revenue going ahead?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
I'm sorry, you will have to repeat your question. I did not understand.

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
Yeah, I'm saying, like, you have out-licensing income coming in the Innoxel around INR45 crore in Q2 approx and INR65 crore in overall H1. So just want to understand, because this kind of out-licensing, is the bifurcation in upfront fees that we are charging or a milestone basis. So just want to understand how you are recognizing the revenue and what is the terms and what kind of revenue potential and what is current existing projects as of now.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So the number of projects is already well disclosed from on our end. We are currently working on eight different projects under both CDMO and CMO banner across 18 to 19 different clients. As far as the revenue recognition is concerned, upfront revenues are basically our first milestones which is upon signing of a contract. That usually constitutes 10% or less of the total revenue at Innoxel. It's a very small amount. Most of the revenue is recognized as and when we hit a particular milestone. So those milestones can be a completion of a tech transfer process from our lab to the manufacturing site. It could be a scale-up batch, it could be exhibit batches, it could be six-month stability data, could, could be filing of a product, it could be approval of product. So there are various milestones, and we only recognize the revenue once we hit those milestones. There are amounts are recognized upfront where the milestones have not been achieved.

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
So what is the period of milestone? Like, how long will it persist in terms of revenue recognition once you sign the deal?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
It depends on the product, the kind of product it is, if it's an ANDA filing or a 505(b)(2) NDA filing, because the gestation period from signing a contract to the commercial execution of a particular contract depends on the product and the filing route that we take. The milestones are usually recognized from the time that we sign the product all the way up to when the product is ready for commercialization. So it, like, I said, depends, for an ANDA, it could be 15 months to 18 months. For a 505(b)(2) NDA, it could be 2.5 to 3 years as well. So it depends on the product and how the product -- the route of filing of the product.

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
Okay, so what is the potential deals that we are going to sign in out-licensing in the financial year '27 and '28?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So there is -- we target at least, 12 to 15, new deals every year. That's our normal target. As of now in H1, we have signed six deals. We are in advanced talks with six to seven other customers for various projects. We are in advanced due diligence. So we can expect that by end of Q3, we should be sitting at 10 to 12 signed contracts, which would do in FY27. For FY28, I will not be able to give you a number as of now.

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
What is the unit economics of like EBITDA and per deal revenue on a recurring basis? If you could highlight on this.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Sorry?

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
Like the deeper deal revenue from this out licensing fee or EBITDA in this in general?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
I am unable to understand your question. Can you please repeat?

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
Like, you have told that we have just signed six deals in H1 2026. So what is the revenue potential of the deals that you are going to sign going forward?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So the revenue potential depends on product to product. I will not be able to give you a generalized answer as of now. And the milestone revenues or the licensing revenues are a one-time revenue, so we don't consider that as our potential revenue. What we consider is how well the molecule deal can do once it's commercialized, because that is what forms the part of recurring revenue for Innoxel. So, yeah, I don't have a summation of the six deals signed, what that total is at the moment.

Vishal Prasad - Analyst, Rajmahal Capital
Okay, my next question, on your CMO product launch that you just told that 20th October you have launched CMO product, so what kind of fully ramped up revenue potential from this and what share of [Indecipherable] as of now?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So the first commercial order has just been exported. We are waiting for our partner to give us some sort of a binding forecast on this product. I would say that this question can be answered more better in the next quarter when the sale process of this has already started and the partner gives us a binding forecast of this particular product, then I'll be able to give you a better suited answer that what is the revenue potential in terms of fixed, I would say manufacturing revenues we can expect from this product.

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
Okay. And the last question I have, standalone price, like the revenue mix is more increasing towards the tendering business than the branded one. And the gross margin has been impacted. So what kind of revenue mix are we targeting going ahead? Like currently 52% of revenue is coming from tendering business. And could you explain the gross margin from the branded export and the

tendering?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So if you see last year, last quarter, that mix was somewhere close to 78%, 22%. So in fact, we are improving our bit on the branded business more than the tender business. The tenders are which have already been undertaken. We have to supply them [Indecipherable] . But now our growth engine is coming from newer registrations, more dossier filings, newer country registrations, exploring new countries through EU GMPs and PICs approvals that will subsequently come at the standalone business. So while the tender business is ongoing, our continued focus is to grow outside of the tender space. Whatever has been under contract has been supplied and will be supplied, but going forward, the growth engine will not be on tenders. It would be more on the branded business.

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
And any differential margin in both of them, like gross margin?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
I can only give the EBITDA numbers at present. I cannot give a differentiated gross margin.

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
[Speech Overlap] That would be helpful to us.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
I've already given at the standalone basis, right? 10% to 15% EBITDA margins at the standalone business this year. That's the expectation that we have for...

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
No, no. What about the contribution of the brand when we tender the product on an average?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
I don't have that information on hand at the moment.

Kaushal Sharma - Analyst, Equinox Capital Venture Private Limited
Okay, sir. Thank you very much for answering the question.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Yeah, thank you.

Operator
The next question comes from the line of Manpreet Arora with Northern Lights Wealth. Please go ahead.

Manpreet Arora - Analyst, Northern Lights Wealth
Yeah, thank you. So just a clarification first, your slide number 34 of presentation says, the order book is INR180 crores as of September 30th, but the rest of the presentation talks about INR117 crores of order book. So just want to clarify which is the correct number.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Sorry. Okay, I think, that is an error on our side. I will ask my team to correct that. That was the old number. The correct number is as per what I had just mentioned and what was presented in the first

slide. I would say under the standalone business part of the presentation.

Manpreet Arora - Analyst, Northern Lights Wealth
Okay, so INR117 crores?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Yes, that's the correct number.

Manpreet Arora - Analyst, Northern Lights Wealth
Thank you. Yeah, so my first question is on CMO versus CDMO. I understand that CDMO is where we develop the molecule and then we also get profit share. So I just want to understand, is it fair to assume that all the CMO contracts are probably ANDA filings and our 505(b)(2) are CDMOs? Is it?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
No. So it's a mix. Even we work as a CMO for various of our partners' 505(b)(2) NDA programs as well. So the way to look at this is not that a CMO would be an ANDA and a CDMO would be 505(b)(2). We have our own products which are split between the both, as well as we have CMO products where again it is a few of them are ANDA products and a few of them are 505(b)(2) products.

Manpreet Arora - Analyst, Northern Lights Wealth
Okay, so which means there will be some 505(b)(2) where we will not have a profit share?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Correct. Any CMO which is either ANDA or 505(b)(2) there won't be any profits attached to it. So that's the understanding. Only the CDMO products will have a profit share to it.

Manpreet Arora - Analyst, Northern Lights Wealth
Okay. And so the you have given that your first own CDMO product will be Q3 FY28. Can you also give some indication of when will when do you expect the first 505(b)(2) to start?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So that Q3 FY28 is a 505(b)(2). It's not an ANDA. It is 505(b)(2).

Manpreet Arora - Analyst, Northern Lights Wealth
Yeah, your wording is first on CDMO product, so I'm just asking if there's a 505(b)(2) where we are CMO which may start earlier?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Okay, sorry. So as a CMO, a 505(b)(2) NDA where we can start, I will have to check. I don't have that information off my heart right now, but I shall get back to you on that information. I don't have that off by heart right now, but our first 505(b)(2), which is a CDMO product and not a CMO product, is the Q3 FY28, what I mentioned.

Manpreet Arora - Analyst, Northern Lights Wealth
Okay. And one last one, you beautifully explained how the 505(b)(2) economics will work and how it's a marketing thing and not a distribution, but we also have ANDAs for which we have CMOs. A nd so which means they're already probably generic right now. And so what will define our success in that? Because they're already generics, and there will be some pricing pressure a lready there.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So, okay, so the way to look at Innoxel CMO business is that, see, Innoxel is a complex generics manufacturing site. Even our CMO projects are not plain vanilla generic projects. Our CMO projects are projects which are differentiated products which has difficulty in either manufacturing requirements or, I would say formulations which would not be there with 20 different generic players in the market. So we are looking at limited, I would say, competition. A lot of our CMO projects are also 505(b)(2)s, which generally eliminates any and all competition because there would be only one first filer would be under the 505(b)(2) category.

Apart from that usually all our products are products where t here is some value add by Innoxel in terms of the facility that we have and the manpower that we have, the talent tool that we have to successfully make those kind of products. So, as far as margins are concerned, our CMO margins are also well above industry average. And we expect even further future CMO deals to be in the same complex space and not a vanilla generic space.

Manpreet Arora - Analyst, Northern Lights Wealth
Okay, wonderful. Thank you. Thanks a lot.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Yeah.

Operator
The next question comes from the line of Henil B with Equicorp Partners. Please go ahead.

Henil B. - Analyst, Equicorp Partners
Thanks a lot for the opportunity again. So if I actually take out the healthcare division, the Varenyam Health part, so I think, sir, if we actually see our current portfolio was mainly around acute, I think, sir, you just mentioned about anesthesia and also something on critical care. So do we have any plans to launch some of the complex molecules that's there in Innoxel and or using some of the capabilities of Innoxel and the delivery system? For the Indian hospitals, or do you think that the domestic price ceilings are currently too low to justify any transfer?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Yes, so we have pondered on this, how we can utilize these complexity-based products for the Indian markets. But unfortunately, right now, the pricing dynamics does not work in our favor. The Indian markets are quite price sensitive, and the product costing coming out of Innoxel does not support us to launch these products within India. As of now, we don't have any immediate plans of launching any of Innoxel products through Varenyam in India. That can change based on product to product in the future. When something of that sort happen, I would be sharing that information under the disclosures.

Henil B. - Analyst, Equicorp Partners
So we've actually in the VBL, we're also working a lot around onco. And if you recently see, the Supreme Court actually come up with trade margin rationalization. So could this regulatory disruption actually again, this can can this also be taken under Varenyam Healthcare where if the company can try to develop a cost-effective solution in the generic oncology space, at least initially? And I think so, try to capture the market share as soon as possible. And this would actually work not just for India but even for Europe, because in Europe, if I see compared to the U.S. markets where

tenders are actually more on a pan-U.S. basis. In Europe, it is very regional, and actually you have to go as per every country, as per every region i t's very different. So can this actually help us across these two-pronged strategy?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So obviously, keeping the cost of goods low is one of the primary tasks of us being a manufacturer. But at the same time, we have to see that what molecule it is. As a generalized statement, yes, we're in bio. We would want we would be keeping our COGS as low as possible. I t's not an exact replica of Innoxel, so the products that we deal with are not going to be as complex as Innoxel as well. So there would be some sort of a cost rationalization that will happen at Varenyam Bio. But as a general strategy, I will not define Varenyam Bio as a cost haven to enter into generic oncology products within India or within Europe. But at the same time, there would be cost of goods on the lower end than in comparison to Innoxel . That's all that I can say at the moment.

Henil B. - Analyst, Equicorp Partners
Okay. So if you actually see, we had actually in past mentioned a lot of strategy and a lot of benefits that could actually come out of Biosecure Act. And the Chinese CMOs actually being curtailed with respect to the American markets. So is there any thought where we actually plan to have certain capacity of Innoxel that is only going to be for the innovators? It's only going to be towards specialized molecules because you actually said you are more focused on having a value approach compared to a volume approach. So on the CMO side, what kind of opportunities do you see that would happen out here? And if there's a potential of a trade deal or if there are further potential arrangements between India and U.S., especially on the pharma collaboration side. Do you see that nearshoring or the friendshoring could actually help us get significantly more orders in the U.S. market?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So basically, I'll answer this in two parts. First, from Innoxel business perspective, BioSecure Act is not a means for us to increase our business. That's not how we have positioned our business. Our ideology comes from creating complexity-based products and out-licensing these products to various mid to large pharma giants based out of EU and the U.S. with specialty generics as their approach to marketing. So our approach is not dependent on the BioSecure Act or the U.S. banning Chinese manufacturers and that capacity coming back to India or more business coming to India.

Secondly, if an innovator does approach us for any of their product manufacturing, that would be an interesting prospect, and that is not something that, would be plainly declined. There would be a lot of thought given to it, and there would be -- if required, any type of capacity enhancements required, we would be taking that call at that point in time. But as things stand, our primary growth driver at Innoxel remains our own products. And licensing of those products is the only way that we see in the next few years how Innoxel is going to do.

Henil B. - Analyst, Equicorp Partners
So how is the competition from some of the Chinese CMOs and the market supplies that we're actually doing in terms of pricing and in terms of volume growth?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Like, I said, we are not in comparison with the Chinese CMOs because we are more product-specific even when it comes to CMOs. So our product selection within CMOs, our product that we already

have signed, are still they fall under differentiated products. So I'm not competing with 10 different manufacturers for that molecule because there aren't 10 people of that molecule in the U.S. markets at present, is what I'm trying to say. So we are not really competing with the likes of any of the Chinese CMOs where they are more volume or I would say cost of goods approach that they may take.

Henil B. - Analyst, Equicorp Partners
So it's very interesting from this. So right now, as you even alluded in your presentation, there's a big shortage of sterile injectables in the U.S. And if I actually see sterile injectables, about 50% of the U.S. market in terms of, at least in terms of value. So when you actually sign an out-licensing deal, is the pricing formula or the pricing pattern actually fixed from the very beginning, or as the shortage increases, do we get some windfall gains because of this increase in shortages? And also, I think so before it used to be Obamacare, which is more volume driven. Right now it's actually Trump has actually come and changed a lot of around policies, which is more around curing a particular patient, more focused out there. So with this, how is demand for a lot of value added complex generics or specific complex generics actually increasing? Because I think, so this opens a very big potential for us to do a lot of value led mo lecules for a lot of customers out there?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So I would say that historically, if you see over the last five years, the majority of I would say focus has been on specialty generics. It is more about value-add products. If you see your Indian giants also, their focus has always been on specialty products rather than the number of ANDAs that they file or the number of first-wave generics that they -- be your Lupins and your Suns and Ciplas have all changed their strategies to being more of specialty generics player within the U.S. market.

So yes, the market is rewarding specialty generics. It depends on what type of product you are able to crack, what type of product you are able to successfully develop as well as scale up and then commercially manufacture and supply. As far as so to answer your question, yes, there is a lot of headroom for growth when it comes to specialty generics. And the pricing in contracts at the time of signing of contracts is usually an indicative pricing based on the assumptions taken at the time of signing. There is always clauses where there would be pass down of any increase of pricing, may it be API or different devices if there are any devices in the product. So yes, it is more or less there is an indicative pricing which is given, but the final pricing is always derived when the commercial readiness of the product and filing of the product has taken place.

Henil B. - Analyst, Equicorp Partners
Okay. So lastly, with respect to the VDL part, I think so you increase the capex. I think so a lot of plans have actually been altered and become more expensive. The Phase 2 ADC capabilities that we actually plan to do, I think so a lot of global players actually pouring in hundreds of millions of dollars and right now our plan is just for a INR300 crore capex. So is there something more that we actually plan to do out here and the other plans actually not been released or is there something very specific that you plan to target? Because I think so even across a lot of molecules that are actually expiring, I think so it's about USD2 30-plus billion worth of molecules that's expiring. Are we going to be focused on the autoimmune side, on the oncology side, or a different side? Some more clarity out here would actually help us get more understanding of what can happen actually in VBL.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So, see, this is the Phase 1 capex that we have catered to, and under the Phase 1 capex, we intend on making a CDMO. So the idea for us is to have a R&D and a pilot scale with a small commercial scale-up. The second phase would have larger bioreactors put in, which would obviously require additional capex at that point in time. So right now the focus is on getting the site completely ready and qualifying the site and getting the regulatory approvals in place so that commercialization cycles can start. The main way of looking at this is we are not competing with other giants, like we're not competing with, like, Aurobindo, which has signed a deal with Merck for 15,000 KL capacities towards innovative product. That's not something that we are targeting. What we are targeting is a lot of the biosimilar players or a lot of biologics innovators who want smaller setups for improving their processes. Getting their clinical batches, they are getting their filing batches, and then subsequently scaling up to commercial production. Those are the clients that we are currently targeting, and that's the real shortage right now that the market is currently seeing, that there are large capacities for commercial products and commercial productions, but there aren't that much capacities for taking scale-ups and regulatory batches.

Henil B. - Analyst, Equicorp Partners
Okay, sir. And, just to follow up here, after the Q2 FY28, when the facility actually starts commercial runs, how do you actually see the timeline for getting approvals and then, yeah, I mean, getting customers? Or do you have customers currently in the inquiry stage, and as we actually commercialize with certain approvals we will actually go forward into getting the test batches at the laboratory scale to the commercial scale done?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
See, the business development runs alongside construction. So as soon as there is something substantial -- if there are any substantial contracts which are signed and material, then at that point we will be putting that disclosure out. So right now I would leave it at that. Apart from that, like -- yeah, and sorry, what was your other question, the second question?

Henil B. - Analyst, Equicorp Partners
Once we actually commercialize the facility in Q2 FY28, how fast do you actually see us getting the regulatory approvals?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Again, this is something too far out for me to give you a firm answer. This is not something that is completely in our control as well. We can be ready for the regulatory audits, we can file the products, but when the regulators come is not something in our control. And it could be , like, closer to the time when we are ready to file the product is something that I'll be able to give a better answer on. Right now, whatever I would say would be speculative.

Henil B. - Analyst, Equicorp Partners
And we'll be therapy agnostic, so based on the customer needs and requirements, we'll be therapy agnostic in this.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Correct .

Henil B. - Analyst, Equicorp Partners
Okay. So thanks a lot for the opportunity and wish the team all the very best. And it was very interesting hearing you.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Yeah. Thank you.

Operator
The next question comes from the line of Ankit Zaveri [Phonetic], an individual investor. Please go ahead.

Ankit Zaveri - Analyst
Yeah, thank you, sir, for the opportunity. Congratulations for your U.S. commercial launch.

Operator
I'm sorry to interrupt, Ankit, you are not audible. Please use your phone on the handset mode in case if you are on a hands-free device.

Ankit Zaveri - Analyst
Can you hear me now, sir?

Operator
Yes.

Ankit Zaveri - Analyst
Yeah, congratulations, sir, for the U.S. commercial launch. Sir, my question is this product, CMO product, is in the injectable or depot category or oral liquid category? And, sir, without naming the partner, can you give some light on is the partner is a generic end of filer or a specialty pharma company?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Okay, so, it is an oral liquid product, which has been supplied as of now, the first product. A s far as the partner is concerned, the partner is a specialty generics player within the U.S. market. And, yeah, that's I think that answers both of your questions.

Ankit Zaveri - Analyst
Yeah, thank you. And now, sir, the next question is, at the 33rd AGM, you spoke about reporting against your milestones with the same candor you always shown. So now the H1 is completed and the commercial supply has also commenced. How are you tracking against the milestone you set for yourself at the AGM? What is going better than expected and where are you still working on close the gap? Thank you, sir.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
You'll have to explain a bit. I didn't understand the question. Can you please explain again what the question is?

Ankit Zaveri - Analyst
Sir, you at the AGM, the recent AGM, you spoke about reporting against your milestone with the same candor you have always shown. So I am asking that now H1 is completed. And commercial

supply is also begun. So how are you tracking against this milestone you set for yourself, sir?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So, sir, as I have always - as we as an organization have always given out disclosures as and when we have something meaningful, we'll continue to do that. As far as the milestones are concerned, we are on track, as we speak for the year-end. None of our products are delayed in terms of timelines from our end. We expect our products to be filed with the FDA in the timelines that have been stipulated by the organization time to time. On the other businesses front also, we are on track on meeting all our, I would say, guidances that we have given at the start of the year. So I think that's all that I can say. I don't know if I've answered your question correctly or not because I'm still not able to understand what exactly the question is.

Ankit Zaveri - Analyst
No, sir, thank you. I got my answers and all the best for the future. Thanks a lot.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Thank you.

Operator
The next question comes from the line of Vishal Prasad with Rajmahal Capital. Please go ahead.

Vishal Prasad - Analyst, Rajmahal Capital
Yeah, thank you. So for Varenyam Bio, you mentioned that we may work with innovators as well. So since we are into ANDA and 505(b)(2), most of the innovators get worried about problems with their IP since they are into a different set of business as well. So what in your mind is that we are doing or we will do so that innovators are very comfortable doing business with us?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So Varenyam Biolife Sciences, when I spoke about the innovator, that was in biologics. A s far as ANDAs and 505(b)(2)s are concerned, that's in Innoxel Lifes ciences, which is a completely different set of products which cannot be replicated or copied at Varenyam Biolife Sciences. So there is no question about any type of worrying that the innovator will have that we'll copy anything. As far as innovators are concerned, the contracts are pretty rock solid and there cannot be -- usually there is no, I would say, copying that happens specifically.

Most of the innovators, when they come, they already have a lot of patents which are already filed around their product. So obviously they have entrenched their product and technology. We just help them in scaling up that product. So as far as that is concerned, I don't think that's a valid concern that any innovator would have. And the 505(b)(2), like, I said, is for small molecules. Biologics come under large molecules. Both are completely different sets of products, and both are at different companies to begin with. So there again there is a -- I don't foresee any type of, I would say, problems with the innovator or innovators having any problems with us.

Vishal Prasad - Analyst, Rajmahal Capital
So are we, or have we spoken with innovators for the Indian bio?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
As I've already said , I already said the same thing, that the operations -- the construction is ongoing and the business development runs alongside construction. And there is anything meaningful, I will

give those disclosures out. At this moment, I don't have further to add in this regard.

Vishal Prasad - Analyst, Rajmahal Capital
So you have mentioned that INR300 crore is the Phase 1, capex , which will include onco as well as the biologics block as well. So this 200,000 sorry, 2,000 c apacity of this that we are putting up, so this will come into INR150 crore of capex that we are doing in biologics, or it will come into Phase 2?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So right now it will fall under it will be both Phase 1 and Phase 2. There would be one tank of 2,000 liter right now, and then the subsequent Phase 2 will have additional capacities which would be 2,000 and more.

Vishal Prasad - Analyst, Rajmahal Capital
So you mentioned that it will be bigger in Phase 2. So 2,000 is what you mentioned will be bigger, or we can go for larger capacities as well.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
At this moment, we are building the Phase 1 yet, which is still a couple of years away. T alking about Phase 2 would purely be speculative because the time and the opportunity at that point may be different. Contracts would be there in hand and the need for expansion would be clear in terms of a business case. So giving you an answer would be quite vague at this moment, I believe. So we will w ait for the Phase 1 build-out to be completed, and once we are ready for Phase 2 expansions, I'll be in a better place to give you an answer which would be more accurate.

Vishal Prasad - Analyst, Rajmahal Capital
Yeah, thanks, Bhahim.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Yes. Thanks.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Are there any more questions, or are we done with the Q&A round?

Operator
The next question comes from the line of Manpreet Arora with Northern Lights Well, please go ahead.

Manpreet Arora - Analyst, Northern Lights Wealth
Yeah, thank you for the follow-up. On e question on the Varenyam Healthcare. You mentioned that we'll get into the gynecology division. Can you highlight what sub-therapies in gynecology, like hormones, fertility, contraception, which area?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
So we're looking at, a s a division, we'll be looking at it as a it won't be a single, like a prenatal or a postnatal sort of care. We are looking at it as a holistic women's health. So for it would be prenatal as well, it would be postnatal, would be premenopausal and postmenopausal medicines. In Phase 1, we don't have any plans of launching any hormones. There would be a phase-wise launch in this particular division. So there would be more of products which could be used in a more broad section of the women's health are planned in Phase 1. The exact details I will not be able to give you at the

moment since we have not yet launched the products. Once the launch is done, I'll be in a better position to give the detailed analysis on the products launched. B ut in Phase 1, there are no hormones or contraceptives, as you pointed out. Hormones are planned for in the next phases of launch within this division.

Manpreet Arora - Analyst, Northern Lights Wealth
So these will be mostly oral solids or injectables?

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
It would be oral solids. There would be a few injectables as well, but mostly this would be oral solids.

Operator
Ladies and gentlemen, that was the last question for today. I would now like to hand the conference over to Mr. Bhahim Desai for the closing remarks.

Bhahim Desai - Director, Strategy and Investor Relations, Bharat Parenterals Limited
Thank you. Thank you all. To sum up, Q2 is the quarter, the group moved from a loss to a profit, and Innoxel moved from an EBITDA loss to a 33% margin. U.S. commercial supply started on 20th October and is not yet in these numbers. The standalone business recovered strongly on volume and nearly doubled its profit, even as input costs outside our control weighed on gross margins. There is more work ahead, but the pieces we have spent the last few years putting in place are now starting to work together, and we go into the second half with momentum.

I want to thank our teams at Bharat Parenterals, Innoxel Lifes ciences, Varenyam Healthcare, and Varenyam Biolife Sciences, to our new shareholders, and to all of you for your time and your questions today. Thank you and Jai Hind.

Operator
Thank you, sir. Ladies and gentlemen, on behalf of Phillip Capital PCG, that concludes this conference call. [Operator Closing Remarks]