



22nd October, 2020

To, Department of Corporate Services BSE Ltd. Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001.	To, The Manager, Listing Department, National Stock Exchange of India Ltd. “Exchange Plaza”, C-1, Block G, Bandra-Kurla Complex, Bandra (E), Mumbai – 400 051.
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SUB: TRANSCRIPT OF CONFERENCE CALL - QUARTER ENDED ON 30TH JUNE, 2020 EARNING CALLS

Dear Sir,

With reference to captioned subject, please find enclosed herewith transcript of conference call arranged by the Company with Analyst & Investors, on Wednesday, 9th September, 2020 to discuss the financial result and performance of the Company for the quarter ended on 30th June, 2020.

Kindly take the same on your record.

Thanking You,

Yours faithfully,
For, Dishman Carbogen Amcis Limited


Shrima Dave
Company Secretary



Encl.: As above

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Dishman Carbogen Amcis Limited

Earnings Conference Call Transcript

Event: Dishman Carbogen Amcis Limited – First Quarter Ending June 30, 2020 Earnings Call

Event Date/Time: September 09, 2020/1600 HRS

CORPORATE PARTICIPANTS

Arpit J. Vyas

Global Managing Director - Dishman Carbogen Amcis Limited

Mark Griffiths

Director – Global Marketing and Strategy - Dishman Carbogen Amcis Limited

Sanjay S. Majmudar

Director - Dishman Carbogen Amcis Limited

Harshil Dalal

Global CFO - Dishman Carbogen Amcis Limited

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Moderator: Ladies and gentlemen, good day, and welcome to the Dishman Carbogen Amcis Limited Q1 FY '21 Earnings Conference Call. We have with us today from the management Mr. Arpit Vyas – Global Managing Director; Mr. Harshil Dalal – Global CFO; Mr. Mark Griffiths – Director – Global Marketing and Strategy; and Mr. Sanjay Majmudar – Director.

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 touchtone phone.

Please note that this conference is being recorded. I now hand the conference over to Mr. Arpit Vyas, Global Managing Director of Dishman Carbogen Amcis Limited. Thank you and over to you, sir.

Arpit Vyas: Thank you very much, moderator. Dear all, current and potential shareholders and analysts, thank you for being on the call today. This has been a challenging year for the company, and we have accepted the challenges with nothing but open arms and excitement.

The first challenge, as mentioned previously, was the negative EDQM and Swissmedic Audit. I am happy to inform you that the company as of last week has submitted a 50-page corrective and preventive action plan, which has been acknowledged by the EDQM.

Apart from this, the company was asked to do a risk assessment of all the APIs and marketable molecule made and sold over the previous year to give assurance to our customers that no products were negatively affected. We are glad to inform you that we have completed the detailed risk assessment of more than 90% of the products, and further glad to inform you that there has been no negative outcome of any of the products.

Further, the customers have been extremely pleased with the support that the company has provided them to not allow their business to be affected. This exercise was crucial for us to not only maintain the trust and the faith, but even increase it further with our customers.

The second challenge was to analyze the reason for the unsuccessful audits. The conclusion was the inefficient and lack of capability of people, including some of the management. For that reason, the company has gone under a complete restructuring of its people. From the weakness of 1,600 people, we have been going down to the strength of 600 to 700 people. Currently, we are down to about 850 people.

Paolo Armanino, who headed our highly potent unit, unit-9, who is an expat Italian, who has been with us for more than 12 years, and believed in the company more than anyone we have seen, we are glad to inform you that the company has appointed him as the COO of the India operations, and he has accepted this challenge. Paolo, along with Martin Schneider, who is our Global Quality Officer, have worked together day and night along with the teams, which also include competent consultants such as Rephine UK and Lachman USA to help and create, and

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more importantly, implement a successful corrective and preventive action plan. These are some of the major internal activities that the company has been working on and implementing, which has taken much of time of the first and second quarter as you can imagine.

COVID further added to the challenge in terms of time taken. But we are more than confident and confident as ever to be stronger than ever. These challenges have been seen as an opportunity for us to be united at a global level, to truly become a singular organization. Our mission of serving the patient through our customers, but not just through our customers is now going to be our vision and goal to be accepted and followed globally.

We thank you all for believing in us and supporting us in the thick and thin. And as mentioned, as always, we will not let your trust and faith and support go in vain. With that, I would like to hand over the call to our beloved Global CEO, Mark Griffiths, to elaborate further adding his inputs. Thank you.

Mark Griffiths:

Thanks, Arpit. Good afternoon, everybody. And thanks for taking your time to join the call. We will get into the presentation and information. What you will see today is a slightly more focused, more targeted series of discussions based predominantly on the number of questions and the type of questions that we have received over the last year or two. We have taken the opportunity to consolidate that data, present that to you factually in written format. And those we hope will precipitate good effective discussions.

So, what we would like to do is to hand over very briefly to Mr. Harshil Dalal, who is our Global CFO. Harshil will give you a very, very quick update and then we would like to get into the presentation. So Harshil, would you like to take the floor briefly?

Harshil Dalal:

Sure. Thank you very much, Mark. And thank you, Arpit bhai, for the introductory remarks. Hello, everybody. I hope everybody is having a good evening. I am sure all of you have had a chance to go over the results. As you can see in the presentation that we have given on the stock exchange and uploaded on our website; this quarter, that is the quarter ended June 30, 2020, is sort of uncomparable to the previous quarter and the last year same quarter, largely because of the adverse impact of two events, one the observations of the EDQM audit that we received in the last quarter, and the COVID-19 impact.

However, on a turnover basis, there was a good amount of contribution by all the subsidiaries, especially Carbogen Amcis AG and our Dutch entity because of which we achieved the revenue about Rs. 474 crores as compared to Rs. 522 crores in the comparable quarter last year. One of the things that include as part of the total revenue is the operating income. So, in the last year first quarter, we had an operating income of about Rs.20.61 crores, which included a positive realized foreign exchange gain, as compared to that this year Q1 we had a loss of Rs. 8.2 crores. The entire realized gain or loss on account of the hedges that we undertake on a rolling basis to cover our exports from India as well as the cross-currency fluctuation that we have across the globe are classified as part of the operating income.

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Since there was a significant depreciation of the rupee in the first quarter, and part of the second quarter as well, we had to book these losses in the first quarter. But we believe that the rupee should appreciate going forward. And since we have our hedges on a rolling basis, we expect to see some amount of profits getting realized, during the remainder part of the year.

As far as our COGS are concerned, we saw an increase in the COGS from about 21% to about 31%. This increase was largely on account of the India operation. Regarding the India operations, since the production was not up to the mark because of the EDQM observations, the risk analysis that we were performing, and also because of the COVID, we had to charge out most of the expenses in the P&L and the unabsorbed expenses could not be capitalized as part of inventory.

As far as our employee expenses are concerned, as compared to last year same quarter, there is an increase. This increase of about Rs. 20 crores were largely on account of two factors; one, because of increase in the employee strength at Carbogen Amcis, number one. And number two, because of the FOREX fluctuation, where the average exchange rate, which fluctuated by almost 11% to 12% in the first quarter as compared to the comparable quarter last year.

The other expenses, they were more or less similar to, well, actually they declined a bit as compared to comparable quarter last year. The other expenses in the first quarter also included a foreign exchange loss, so that was to the tune of about Rs. 6.7 crores as compared to a loss of about Rs. 3.4 crores in the comparable quarter last year. Whatever are the mark-to-market losses on the borrowings that we have related to working capital, that gets classified as part of the other expenses and that was the foreign exchange loss which is part of the other expenses.

The EBITDA for the quarter was about 9%, so at Rs. 43 crores, which includes Rs. 15 crores of the FOREX loss, as compared to an EBITDA of Rs. 119 crores which was achieved in the comparable quarter of last year.

The finance cost was more or less in line with what we had last year. So, it was at about Rs. 11.5 crores as compared to Rs. 13.8 crores in the comparable quarter. And hence, largely because of the India operations not being up to the mark, overall, on a consolidated basis, we reported a loss of about Rs. 21 crores on PAT basis.

Having said that, on a cash basis, we had a cash profit for the quarter which was about Rs. 43 crores, as compared to Rs. 96 crores in the comparable quarter last year. And as we move forward, we expect the cash profit to increase, especially because of the improvements in the operations in the third and the fourth quarter.

As far as our subsidiaries are concerned, the performance of our subsidiaries is concerned, the Swiss entity, the revenue grew by almost 18% as compared to the comparable quarters, so we reported a revenue of about Rs. 309 crores as compared to Rs. 263 crores. CRAMS UK was at about Rs. 25 crores, but business is obviously non-linear, because it just manufactures the intermediates and the starting material.

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Carbogen Amcis BV, which is the entity which manufactures the cholesterol and the Vitamin D analogue, the revenue was flattish as compared to the comparable quarter last year. However, compared to Q4 the revenue increased by about Rs. 8 crores. And the marketable molecules for those, which includes our disinfectant business, the quaternary compound, specialty chemicals, generic APIs, that was at about Rs. 53 crores as compared to Rs. 51 crores in the comparable quarter.

On the margin front, CRAMS India reported a loss for the quarter, again, because of the reasons that we have cited. CRAMS Switzerland, France and China altogether reported an EBITDA of about 16%, as compared to 18% in the last year's same quarter. This decrease in the margin was largely on account of more share of the revenue being contributed by the Phase I pre-clinical and Phase II molecules, where typically the margins are lower as compared to Phase III and commercial. So, we expect that the margins would improve in the remainder part of the year as we have more revenue contribution from the Phase III and commercial.

In CRAMS UK, the margins were at about 15%. Carbogen Amcis BV showed, again, a healthy margin of about 32%. So, as you remember, in the last year Q4 the margins had come down to about 27%, which was largely on account of more share of revenue being contributed by the cholesterol sales as compared to analogue. Again, in this quarter, we saw more contribution of the analogue sales, and hence the margins are higher. The margins were at about 13% as compared to about 10% in the last year's same quarter.

The net debt as on 30th June was at about \$99 million, pretty much similar to what we have at 31st of March, 2020, which was at about \$100 million. We expect that the net debt, while because of the CAPEX program that we are going to undertake at Switzerland and France, it may increase in the intermittently, the net debt over a period of next three years with amount of cash generation that we expect, should not increase substantially. We expect the net debt-to-EBITDA to remain around 1.5x.

So that's more or less the financial highlights for the quarter. With that, I would like to hand over the call to our Director, Mr. Sanjay Majmudar.

Sanjay Majmudar:

Good afternoon, good evening to everyone. Of course, Harshil has briefed the key numbers. But from a broader perspective, obviously, the standalone negative performance because Bavla is significantly or practically not in operation largely due to EDQM, and then in the initial phase of the quarter also partially, very partially due to COVID. And therefore, the entire burden was shared or tried to be pulled around by the Naroda facility.

However, as Arpit explained and as we have been indicating also, we had indicated earlier also, we believe that with most of the other European customers nearing the completion of the risk assessment, we believe that from third quarter, sales from Bavla should re-commence and I think by fourth quarter they should become reasonably normal. I am not talking about the specific generic product for which EDQM audit observations were received, that procedure will take a little longer.

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So overall, I think from an India standpoint, the second half should be much, much better than the first half. And therefore, whatever aberration you see in the form of losses contribution at the operating level by India standalone should be significantly mitigated in the second half. And from a global perspective also, coincidentally, in Q1, Carbogen Amcis saw a lot of sales coming from the developmental products where historically, and as we have said, as compared to commercial, although the sales have shown a positive trend of 17%, 18% growth, the problem is that the margin at the developmental level are a little low. So therefore, or even while all our subsidiaries have collectively shown a profit, the profit was relatively lower because of this typical business mix that we saw coming from Carbogen Amcis' Switzerland operation.

And therefore, even on a consolidated basis, as an exceptional thing, you see the loss. But if you look at the broader picture, so as I explained, the second half should look much, much better. Dishman will be back, absolutely, on growth track. And I would request Mark, if Mark can just highlight few important key developments from a medium to long-term perspective, both in terms of pipeline and the expansion that is being planned in France and Switzerland, and just to give a broader view of next two to three years that should be really helpful. So over to you Mark. Before just four, five minutes, and then we can go on to the Q&A.

Mark Griffiths:

Yes. No problem. So, the pipeline remains very strong indeed, especially the pre-clinical Phase I, Phase II, which obviously is very important. We are working at the moment on a significant number of late phase projects. And those are heading slowly, but surely towards launch with our customers. So, there are 18 in the pipeline right now, we expect at least two to go forward within the next six to eight months. We are getting very interesting noises on a couple of compounds where the customers have filed with the relevant agencies.

So, it's important for us to continue to feed our pipeline and feed the funnel with our early phase work as well, because otherwise the pipeline will dry up on the late phase. So, we need to maintain a focus on keeping a good balance between pre-clinical Phase I, Phase II and then the Phase III validation and launch into commercial. If we get out of balance there, then what happens is that we have some very good years or good month or two, and then, of course, the pipeline starts to dry up. So, we need to continue to prioritize early in each phase.

Because the pipeline is so strong, we have essentially reached the limit with the facilities that we have in Europe today to significantly move the needle forward on a top-line and bottom-line growth. We have finally clarified what we are going to do, both in drug products and drug substance. So, you will have seen in the press and we have been talking about this with you that we have announced that we will be doing an expansion of our API capabilities, the manufacture of synthetic API in Switzerland. The land has been acquired and the project is under detailed design right now.

And we have also announced that we are going to significantly enhance our capability to manufacture finished dosage form in France. You may remember, we purchased that facility 10 years ago at a very low price to learn about the formulation business. We have been very

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successful in growing that business to a point now where it is absolutely full, and we can take it no further.

Strategically, we had a very simple decision to take, either we invest in the facility going forward in the business and go forward, or we divest. We took the decision to continue to invest in that facility. We believe that there is a market opportunity for Carbogen Amcis, specifically as a subsidiary, but Dishman is a wider group with our own products, especially things like the Vitamin D analogues, which we will come to a discussion.

So, we are expanding that business significantly. We have acquired some land on the sites part about five kilometers from the existing site. The existing site is not big enough to take an expansion of the scale that we want to do. And we are going to be focusing on niche, sterile liquids and solid formulations.

Focusing on highly potent products, focusing on very difficult and challenging molecules, Vitamin D analogues, Lanolin virus, etc., the sort of business where we have been very, very successful in France to this stage. So those two expansions have been announced now, the funding has been put in place by Harshil and his team. And we believe that now we will set Carbogen Amcis in Europe forward in significant amount of additional capacity where we see the market still having a very high appetite for the services, we have been providing for the last 30 years.

Okay, so that's a pretty decent picture of where we are. Maybe a word on COVID. I mentioned the last time we spoke, we still from an operational perspective don't see a massive impact on the business with COVID, certainly its not impacting our customer per say, I think. The biggest concern with customers at the moment is securing partner and securing supply chain, which plays to us, of course, we are quite happy that they are doing that.

We are still maintaining a fairly large proportion of office-based staff outside of the company on a day-to-day basis working remotely. That is starting to have some minor inefficiency issues, but we are working through those. As you may know, Europe is seeing the predicted second wave of infections, so we are maintaining our watchfulness in that area. But it's not having a significant material impact on our capacity at this stage and our capabilities, but we are watching that, of course.

So with that, I think, moderator, we can probably open up the conference for questions.

Moderator: Thank you very much. We will now begin the question-and-answer session. The first question is from the line of Nitin Agarwal from IDFC Securities. Please go ahead.

Nitin Agarwal: Mark, you mentioned about the restructuring in the India business. I mean, so if I heard you guys right, you mentioned something about 1,600 people being reduced to 800-odd? So A, just to reconfirm those numbers. And two, I mean, from a near to medium-term what does this restructuring will mean for the business?

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I mean, how does the business really change the restructuring that we really talked about? It would be helpful if you can throw some light on it, because in our business while our subsidiaries continues to do well, it's the India parts of the business which has essentially been a bit of a drag in the recent years.

Mark Griffiths:

Yes. I think as Arpit mentioned about the restructuring, what we have done with the restructuring, the focus is to maintain some focus. We have a management team now rather than what we had in the past, that management team has a very nice complementary set of capabilities, which means as a singular group they are very, very motivated and forward looking. So that is the first thing.

Second thing is that we want to make sure that we are a bit leaner and a bit more focused. So, we are restarting production in this coming month, and we are restarting production on a number of CRAMS projects which are our supporting customers right now. And we are taking appropriate steps with a smaller team and a more focused team. So that's basically why we have done it.

And Paolo has been with us, as Arpit shared, over a long time. He knows the business very well. He is a scientist by nature, but a production specialist also. Supported by Harshil, those two guys are the leadership team for R&D or operations now, under the guidance and support of Arpit and myself when needed. So, it mirrors basically what we have in the rest of the world from an operational perspective. Which means that we can liaise, we can consolidate, we can communicate much more effectively, because the lines of communication are open and uncluttered, shall we say.

Arpit Vyas:

And Nitin, the main idea behind the restructuring is that we would like to take control in terms of science driving the business rather than business driving the science. What we have seen in India and what we have faced in India, as you mentioned it as a drag is that, people are inefficient because of the unwillingness to pay higher salaries, that is not just in our company it's been in many of the companies which is related to science and otherwise.

And we would see that the majority of the talent which comes out of India is accepted predominantly in the western company, its only because they had not been paid of what they actually deserve. The idea behind the restructuring is to reduce the manpower and to increase the efficiency of the people and to hire the people paying them what they deserve. So essentially, four people who were doing a job of one person, to change that scenario of one person being capable of doing the job of four in terms of the relevant talent and expertise.

Nitin Agarwal:

And Mark, from a business perspective, apart from the efficiency power play, from a business perspective how do you think it's going to change things? Does it translate into more contract wins or how should one sort of look these things going forward from an impact perspective?

Mark Griffiths:

Well, I don't think it's not going to substantially change the strategy, Nitin, that we have been talking about in terms of our focus. What it's going to do is it's going to substantially increase

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our ability to work across the platform globally, cut out some of the internal competition that existed and get everybody's minds focused on what we are trying to do there, which is to help patients ultimately, and along the way to have a successful and sustainable business. So that's really the output in media that is going to occur that way. Paulo is very, very familiar and very integrated into the Carbogen Amcis Group over in Europe. He knows all the key people there, he is been working with them for many years. There is no competition per say between the group, it's all about complementary capabilities.

And with, as Arpit said, the addition of a fewer number of better-quality people within India operations, we are going to basically lift the entire organization forward. So that's the goal behind it. It is less people but more effective people.

Harshil Dalal: Also Nitin, what we are doing is that we are investing a lot on the systems, on the technologies, which is also going to help us not require those many people as well or replace those people with more talented people, who can actually be more efficient and use the systems in the right manner. So that is another step that we are taking in India, and eventually globally.

Nitin Agarwal: Thank you for that. And last one on India before I join the queue. You have talked about the fact that India production is going to start sometime this month. So effectively we have sort of lost two quarters in the domestics or on India CRAMS sales. I mean, how much do you think we will be able to make up for this lost sales in the second half of the year?

Harshil Dalal: So, I think in the second half of the year, I mean, obviously it's going to be much stronger than the first half. In terms of making up, we have orders on hand from the customers, so we should be able to cater to most of those orders between the third and the fourth quarter. So overall, if you see last year, India CRAMS was in excess of Rs. 300 crores, which could see possibly a drop of about, I would say, atleast 15% to 20%.

Moderator: Thank you. The next question is from the line of Deepan Shankar from Trustline PMS. Please go ahead.

Deepan Shankar: Good evening, everyone. And thanks a lot for the opportunity. Just wanted to check, currently the Vitamin D3-500 prices has been upswinging over the Q2 period. So, are we seeing any upside from our sales perspective also? And what has been our pricing policy to our customers? So, when do we actually see the real impact of price thing?

Mark Griffiths: Okay. So, Vitamin D production is starting again this month. In accordance with that, we are also talking to the authorities right now about an accelerated approval of a drug product to enable us to address the potential that Vitamin D has in strengthening the immune system to fight COVID. But in conjunction with that, we are already in a clinical trial in the Middle East, studying the effects of Calciferol on the immune system. And we are hoping that, that is going to give us some nice information fairly shortly.

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Arpit Vyas: And apart from that, you are right, Deepan, that a lot of customers have approached us asking for the Cholecalciferol, which is the D3-500 that you speak about. And we have a lot of orders in hand regarding that as well, as a part of the orders in hand that Harshil just mentioned sometime back. As Mark mentioned, starting the production of D3 this month and would be catering to those orders. The pricing is very decent and comes with a decent in margin for the group.

Deepan Shankar: Okay. And this will form part of marketable molecules Carbogen Amcis BV, Vitamin D?

Arpit Vyas: Cholecalciferol, whatever is coming out of India will be a part of the Indian marketable molecule. And whatever is coming out of Netherlands, even if serviced by India, will be coming as a part of which sold in Europe and elsewhere, will be coming as a part of marketable molecules of Carbogen Amcis BV.

Moderator: Thank you. The next question is from the line of Dipan Mehta from Excelsior Equities. Please go ahead.

Dipan Mehta: Good evening. I just want to confirm the statement which made about the EDQM related issue. So, what exactly is the present position? And why it would take one more quarter for the revenues to start from the Indian operation on this count?

Mark Griffiths: So first of all, we have to submit a corrective action plan, a detailed corrective action plan which, as Arpit said, we did. The EDQM have acknowledged they have received that, now we have to deliver those action plans. And that's a mix of organizational structure, that's a mix the physical modifications and also a large number of changes in procedures. So that sort of work is ongoing now. We are not waiting for the EDQM to come back and comment on the document, of course, they will. But we are moving forward with our plans with the task force. So that's why it's going to take some time because there is quite a bit of work to do, very frankly.

We have started production in a limited number of buildings right now because we prioritize those products, both for the customer and the patient, and also for the business. So, starting materials that support sales in Europe are obviously prioritized and there is a couple of other CRAMS projects which are important CRAMS projects, clients that we want to start up. So, it will take time because the resolution in some of the challenges that EDQM identified are not straightforward simple things to fix.

Dipan Mehta: Okay. Sir, second question is relating to the EBITDA margin for CRAMS Switzerland, France and China, which has declined from 20.8% to 16.2%, despite a handsome increase in the revenues. Normally one would expect operating leverages to benefit, but I think the opposite has happened over here?

Mark Griffiths: Now it's a mix between the types of projects. We make a lot more money on commercial and late phase projects. But you cannot just prioritize those because to get those you need to work on the early phase stuff, which doesn't have quite the same margin. So, what we are doing is we

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are selling pipeline again, so what we are doing is replenishing our pipeline. So, I have a reasonable proportion of people working on late phase projects, a couple of which we are now waiting for commercial approvals or customers are waiting for commercial approvals.

And in the meantime, the rest of my development staff is working on filling the pipeline with pre-clinical Phase I and Phase II projects, which then carry the same margins. There is more compensation at the earlier phase and to be successful there we have to play around with the margins, as simple as that. It's not linear, that's the thing about the business, its not linear. The more successful we are in Phase III and near late phase commercial, the more we have to replenish the pipeline of early phase. So, in two or three years' time those projects come into the late phase.

Dipan Mehta:

And sir, one last question. Because of this COVID-19 pandemic, on a medium to long-term, do you expect that overall business environment would improve for the company? Because many more new molecules maybe taken up for research and development and then taking it to the commercial, is there any perceptible change in the mood and environment?

Mark Griffiths:

No, there is no perception, there is no significant perceptible change in the introduction of more new chemical entities per se. We are not in antivirals, so that's not our business, we are not into biologics and antivirals. So, if we are in the antivirals, I think the answer would be a very firm yes, but we are not, we are synthetic chemist basically.

However, there is a short-term opportunity which Arpit and I are actively pursuing, which is on the disinfectant side, driven by COVID. So, products that are in our marketable molecule portfolio such as Cetrime and DKC products like that we are seeing quite a lot of activity, we are seeing increased orders and we are seeing opportunity to increase price. And that is what is happening with those products, they are what we would call legacy products, but they are having some efficacy in disinfection.

So short-term, we see opportunity there. And hopefully, we might start to see some of that fructify for our Naroda facilities in the next sort of, I would say, the next quarter or so we will start to see that impact coming through a little bit. So short-term is that. I think this interesting stuff on Vitamin D and the mechanism of action with Vitamin D has been a lot in the press about that and we are doing the trial anyway in the Middle East, as I mentioned, and we started that trial I think, Arpit, two months ago, three months ago?

Arpit Vyas:

That's right.

Mark Griffiths:

Yes. Not because we felt that there was anything potentially that could be strong with COVID. But we are doing a clinical trial, we are extending the clinical trial in the U.S. for the other indication for our Vitamin D analogues, and we started another one in the Middle East on a different indication, and actually it is showing some efficacy. And I think it's because we are strengthening the immune system which enables patients to fight a disease or fight the virus more effectively.

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So yes, I think yes short-term, the disinfectants we are going to see an uplift, we are already seeing an uplift. Longer-term, I think the impact is more on the public awareness of the pharmaceutical industry first time. And I think that's where we see the benefit is drugs curing disease, trying to cure this disease has been brought to the forefront. It's in the press everywhere and I think that's raising awareness of the pharmaceutical industry. And I think everybody who is in the pharma industry is ultimately going to take some benefit from that additional awareness. That is where I see the biggest impact, to be perfectly honest.

Dipan Mehta: And sir, one last question if I can squeeze in. Any progress on progress on the income tax related issues? Any demands have come or has the matter been closed, so could you just brief us on that? Thank you.

Harshil Dalal: Sure, Nitin. So, on the income tax front, you know there has nothing any kind of for notices that have been received by us. So, we have provided all the necessary required information to the tax department. And what we believe is that assessments of the income tax returns for the previous year should command pretty shortly. And if there is any sort of update, we shall let you know. But as of now no more notices which have been received by us.

Moderator: Thank you. The next question is from the line of Satish Bhatt from Anvil Stock Broking. Please go ahead.

Satish Bhatt: Mark, this is a question regarding your next phase of Vitamin analogue. So, you are filing two patent applications for Phase I and II trials for obesity. Can just throw some light on what exactly this project is and what type of cost we may have to incur?

Mark Griffiths: Okay. Well, this is specific to a certain subset of patients. So, our strategy in looking at the Vitamin D analogues was not to go for the biggest indication in the world and then hit that, because obviously the cost of doing that without demonstrating the technology effectively could be quite a risk. So, we looked at various subsets with our advisors across the university, and we found a subset of patients where there was good indication that the Vitamin D analogue could have a significant positive impact on those patients.

So that's where we performed the first trial with 20-odd patients. That has showed very good efficacy in that subset. So, the next phase now is to go to a patient population, we are going to a larger study and that's only just recently kicked off within the last few weeks. And again, what we are looking at is to be able to do a launch for that particular subset of patients on the back of an orphan indication, which shouldn't be too difficult to do from a financial perspective.

The wider one with COVID, I suspect if there is real proven efficacy and, again, I don't believe everything I read in the press. But if there is proven efficacy that could be an accelerated approval for a number of territories, especially in countries like North America and India where the infection rate appears to be out of control. So, you may actually end up having to bypass a number of clinical trials of our product which is reasonably well-known. So, you may not actually have to spend an awful lot of money to get access to the mark. So, we are on budget for

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both of those indications, at the moment we are not particularly concerned that we are going to have to spend any more money than we budgeted for.

Satish Bhatt: Mark, forget the COVID, I don't know whether it clicks, what about the obesity, you said a Phase I trial is going on. So, what type of market we have for orphan category status for obesity? What's your market size that you can capture?

Mark Griffiths: The market size in particular is not huge, it's not going to be \$100 million, \$500 million. What it's going to be is a relatively small subset which allows us to have a commercial product. Once we have got a commercial product, we can extend the use, that's the strategy behind it. So, the target is not obesity, we want to solve the obesity problem for gastric bypass patients who cannot absorb Vitamin D problem. When we do this, we prove that works and we have a small commercial product which brings in some nice revenue, but not huge. We then are using that as the vehicle to enable us to widen the label use of the product, it is already a commercial. Did you see, that's the strategy behind it?

Satish Bhatt: So maybe the market may be small, \$40 million, \$50 million?

Mark Griffiths: Yes. In fact, yes. That's not the focus of it. As I said before, the focus is not just to say we have got obesity drug and sit back. The focus is the obesity drug is the vehicle to enable us to widen the label range to open up bigger markets. So that's the strategy, that's why we did it that way.

Moderator: Thank you. The next question is from the line of Nishid Shah from Ambika Fincap. Please go ahead.

Nishid Shah: Thanks for taking my question. First of all, congratulations on a good annual report. My question is to Mark. In your comments in the annual report, you have mentioned that there are almost 18 products closer to commercialization. Can you give some color on these 18 products? How many of them are already filed with FDA under the validation process? How many of them are in cancer or how many of them are ADC products?

Mark Griffiths: Okay. Have you got a pen ready?

Nishid Shah: Yes.

Mark Griffiths: Okay. So, there are two right now that have been filed, all the final submissions have been made, all the clinical studies have been submitted, and we anticipate approval for those two products, okay? Those two products, one is in breast cancer and the other is in, let me just have a look for a second so that I can give you particular. So, the other one is in cardiovascular.

And we are anticipating that if the customers are successful with those filings, and again I say, we are not doing the filings, we are just giving the information to the customer and the customer is making his own filings. But we believe that certainly one of them is almost a sure fire hit because the product itself has been approved, and we are just finalizing our validation process. So, one of them is an absolute sure fire, unless something really weird happens with that one.

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And the other one is a pretty good shot as well. So, we anticipate we are going to get commercial notifications about those in the next six months. So that's the first two.

Then we have got one in vasospasm, so cardiovascular again. We have got one, two, three, four, five in oncology and various forms of oncology, ranging from leukemia to soft cell carcinoma. We have two ADCs, they are not full conjugates, there we make a linker in the payloads of its synthetic parts. And two of those are already seasoned and they are both targeting cancer, of course. We have another one which is targeting hypoglycemia. We have one in celiac disease and we have a couple of anti-infectives. So, these are synthetic antibiotics, smaller volumes, but targeted in certain types of biological infections of asynthetic material. So, it's a spread. And that spread, I kind of believe that's always been the kinder mix, the majority are in oncology because we have an expertise now, a well-established expertise in the oncological drugs, and then cardiovascular central nervous system, etc. So yes, that kind of represents what we would expect to see, that's correct, to be perfectly honest.

And then on top of that we have got our two Vitamin D analogs, Calcifediol and Calcitriol. And we are also starting to look now at other analogs, so we are also looking at Vitamin D2 as well. Because we may have a very interesting route to the starting material there which may give us an advantage, but that's an early phase development project. So, part of it is for the CRAMS business, we are continuing to invest in the way we always have, which is kiss frogs to find a prince. And Arpit reminded me, we need to go back to that analogy because that's the one that everybody can latch on to very quickly. So, what we have to do is we have to kiss the frog, if we don't kiss any of these frogs, we are not going to find the prince. The frogs don't earn as much money as the princes do, but if we don't kiss frogs, we won't find princes, it's very straightforward. And one of the previous management of Carbogen's back before I came back to the business, just wanted to focus on Phase III work. And if you don't kiss frogs you don't find the princes, it's very simple. So, we have to kiss frogs in the CRAMS business.

On our product side, Arpit and I are taking a much more proactive view on investment, internal investment of time and effort on developing our own pipeline of marketed molecules, and potentially even new drugs. So, the Vitamin D analogues, something which Mr. Vyas Senior kicked off a number of years ago with the acquisition of Carbogen Amcis Netherlands from Solvay. Those are starting to fructify a little bit. So, as you know, with Calcifediol and Calcitriol. But Arpit and I are now looking at other opportunities within that technology to also develop our own products and our own roots to existing products to gain competitive advantage. And there is a number of those programs which we are kind of not prepared to talk about too much in open forum, because obviously we have got competitors. And this is all public knowledge.

So, there may be the opportunity to have face-to-face discussions with various people who are interested at a later date. But in an open forum, we want to keep our powder dry on those. But that's a different strategy than we kind of looked at before, it's really focusing on investing a little bit in R&D to grow around pipeline when it comes to products.

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Nishid Shah: Okay. So, my next question is on the Vitamin D formulation plant that you have put up in Bavla, now when onwards you expect that to start formulating the analogs of Vitamin D? Will it start contributing in FY '21 or will it start in FY '22?

Mark Griffiths: There will be a few small contributions this year. They are manufacturing some factories for the clinical trials, but if this COVID indication sets up, and that formulation facility, if the COVID immune build comes through, and we are talking to the authorities at the moment, if that comes through then that plant's going to be very busy very quickly, as I already said, within the next six to eight months.

Nishid Shah: So that's a good news. And on the commercial products, last year you had four commercial products which went commercial. And can you give some color on that without specifically naming the products, what areas, what therapeutic groups and what kind of potentials you see there?

Mark Griffiths: Well, two were oncology, one was CNS and one was cardiovascular. We have manufactured some launch batches, basically the validation batches have been used for launch. These are slow build, so one of them is moving quite nicely, that's for a U.S. based company that's moving quite nicely. So, it looks as though with the investment that we talked about, we mentioned in Switzerland for more API, that's one of the projects which is driving that, because we know that we are going to need additional volumes.

There is another project which I mentioned, which is the one that's already been approved, it's an oncology drug, and we are just going through the final formalities of finalizing our validation. That's another project which is driving that additional investment, because we are full. And when these start to go, and there is normally a year or so between approvals to really ramping up production, we are going to need that capacity. So, we are looking at the pipeline, the pipeline continues to strengthen and that's what's driving the additional investments which require things to expand our capacity where it needed. It's not a massive plant, it's not going to be many millions of liters of capacity. It's very similar to what we have got in small-scale complex chemistry. But we know we need the capacity, otherwise, we are not going to be able to meet market demand.

Nishid Shah: On the ADC, two years back in your annual report you had mentioned that you are a leading technology player in ADC and I think a lot of companies in NASDAQ we traded 10x and 15x turnover in ADC, and you have five or six molecules based on the pie chart you gave in the annual report, I could make out that you have five or six molecules in ADC and one molecule has already gone commercial. And we have seen in the press that a lot of money has been paid to licensing products from Daichi by AstraZeneca on the ADC sides. So, on your own ADC pipeline, would you like to give some color? And how do you see it going forward for us?

Mark Griffiths: The pipeline is still reasonably strong. And bear in mind, apart from one product where we are doing everything part from making the antibodies, our focus is in manufacturing of ADC and payloads, okay? That's where we have a real skill set. That link of payload business continues to strengthen, okay? It's complex work, and compared to the price of the antibody, it's not expensive

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work for the customer, its synthetic chemistry. And we have a skill set in developing and manufacturing those molecules.

So, the product you mentioned, yes, that's an ADC. We don't do the A bit, we do the DC, okay? And we have a number of those programs working through, so there are two in late phase right now, plus the one I spoke about which is in cancer, in oncology for a customer. And that's the one which has been approved and we are just finalizing our validation. So that will be a commercial product, that's one of the drivers for the new investments. So, drug conjugate still is a big opportunity for us.

Nishid Shah: Yes. Indeed, this is a big opportunity. And the other excitement that I wanted to ask you on was on the manufacturing line on formulation injectables that you are putting up in France. These would be slowly transiting you from an API manufacture to contract formulation manufacturer on the line of Lonza?

Mark Griffiths: Yes, on the line of Lonza, but not copying Lonza. We are not going for capacity; we are going for technology and complexity. So, this is not going to make a million vials a batch, that's not where we are. There is a number of customers out there or players out there who can do that business, we don't want to go and me-to that. But we know that there is a significant gap in the market between clinical trials supply Phase I, to small scale niche commercial and very complex molecules. We absolutely know there is a market there.

And that is what we are addressing, and there are very few players who can offer that. We'd be happy to make one vial, and we do that in France at the moment, we make some money out of it, relative terms. That business was losing money 10 years ago and that business has contributed consistently for the last five years and we are now forward. We cannot do anymore, and we know the markets there. So that's one part of it from a contract manufacturing perspective. But we should not ignore the fact that we also have our Vitamin D analogs, we also have, as we have mentioned before, our contrast imaging agents, our dyes, low volumes, complex to make solutions. So this facility, with the two lines, one solid sterile and one liquid sterile line is also targeted to be able to take a proportion of this capacity to support internal projects. And by that, I mean our own products. Which again is part of the longer-term strategy, not to become a product company, but to be a little bit more of a product company, given our skill sets and our knowledge. So, it plays on both sides.

Nishid Shah: I understand that. But that's a really exciting area where you are trying to translate onto. And my next question is for Harshil, on the India CRAMS business, Harshil, if you look at the first quarter against Rs. 91 crores of India CRAMS business last year you did about Rs. 30-odd crores, Rs. 15 crores rather. So, if I have understood you correctly, based on what guidance you might see in India CRAMS business, about 10% degrowth overall, that would translate into a 20% year-on-year growth from second quarter onwards till the fourth quarter. Is that correct?

Harshil Dalal: Yes, however, the overall degrowth could be around 15-20% in the India CRAMS business this year. Since there was no or hardly any sales of the CRAMS products in the first quarter,

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obviously, the orders that we have on hand, we would expect to service those orders in the second half of the year and partly in the next year, which would mean that the second half would show a good amount of growth over the first half. Yes, so your understanding is correct that we should see a good amount of growth as far as India CRAMS is concerned in the second half as compared to the first half.

Arpit Vyas: And Nishid, what we could also foresee is that due to the lag that has been created in the first half quarter, which will not be completed in the second half, of course, but it should come at an uptick in the next fiscal year till the backlog of this line which has been created for our customer.

Nishid Shah: Yes. Actually Arpit, you mentioned in the last call that your entire effort is to create one of the best pharma companies from India. And after reading the annual report and listening to Mark, I think you guys are on a journey towards that.

Arpit Vyas: Thank you. Thank you for the positivity, Nishid. Thank you very much.

Moderator: Thank you. The next question is from the line of Arun Loharuka from MH Capital. Please go ahead.

Arun Loharuka: My question has been answered, so you can take me off the queue. Thank you.

Moderator: Thank you. The next question is from the line of the Dhiren Bansali, an individual investor. Please go ahead.

Dhiren Bansali: Good evening. Thanks for the opportunity. My question is regarding Niraparib. Glaxo conducted some trials which were completed in the month of April where they found the efficacy of Niraparib as a first-line treatment, and which had a progression-free survival of 22 months. So, are we seeing any traction on that front in Niraparib?

Mark Griffiths: No, we are not seeing any traction at all.

Sanjay Majmudar: The problem, Dhiren with Niraparib is that after the Glaxo takeover it was previously with a company called Tesaro. The issue there was that Desaro has built up a significant quantity than the action usage. From our analysis of the numbers that we saw, they had procured more than 6 metric tonnes or 8 metric tonnes of the material and not use than 200 kilos of the material. So as Glaxo took over the company, they would be sitting on significant amount of stock. It is great news that it has approved for the first line therapy or going to be approved for the first line therapy. But still they sit on significant quantities, which will not see any noise in the coming years, is what we expect at this time.

Dhiren Bansali: And also, like Glaxo gave a guidance that they are expecting \$1 billion of sales from Niraparib by 2023. So if that happens, are we in a position to get more business?

Arpit Vyas: This quantity will still cater to the \$1 billion of sales.

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- Moderator:** Thank you. The next question is from the line of Charo Mehta from Dalal & Broacha. Please go ahead.
- Charo Mehta:** My question pertains to the EDQM observations. They are for four molecules, so what is the rate at which the molecules will get resolved? And what is the opportunity of the molecules in terms of timeline and the market size?
- Arpit Vyas:** Charoji, the issue of the EDQM is not of the molecules per say, about seven or eight molecules have been affected, but overall revenue of the seven or eight molecules for the company was not more than \$4 million to \$5 million, if at all. The major issue of the observation is related to the quality assurance aspect of it and the quality assurance oversight, which was common under critical observation, which is impacting not just the generic molecules, the niche generic that we make but the overall CRAMS molecule as well, which is putting the customer on a back foot till we finish the submission of the Kappa, which we have successfully done two weeks ago, which have been acknowledged by the EDQM as well.
- So now we are again in talk with the customers to restart the CRAMS side of business. And that is going positively, the conversations are positively ongoing. And hence we mention that in the second half of the year we should be substantially better than the first half of the year. And the backlog which has been created due to this six-months lag, will be completed in the next year, which again should see a substantial increase in the overall CRAMS segment.
- Charo Mehta:** Okay. And if you could repeat the revenue from this for seven to eight molecules?
- Arpit Vyas:** About \$4 million to \$5 million, on a higher side.
- Charo Mehta:** Okay. Right. And in terms of the product pipeline for commercialization, how many molecules would you expect in the next two years?
- Mark Griffiths:** Well, as I said earlier, I think there is a very strong likelihood that two will get approved in the next six months. And then I would expect to see one and a half per year going forward, that's about the average rate that we tend to see if we have somewhere between 15 and 20 in late phase. So somewhere around that sort of number, 15 to 20 late phase molecules, one to one and a half per year. Sometimes we get a spike and then we then we get nothing for a while. But on average, over a five to ten year period it's about one and a half per year, if we have 16 to 20 in late phase.
- Charo Mehta:** Okay, right. And how much would be the additional spend on R&D and also the remedial measures?
- Mark Griffiths:** I think for our own products, because most of our R&D resources are deployed on customer projects, so free for service work. But for our own projects, I think I see a modest increase in R&D spend, 5% to 10% I think, Arpit, it would not be unreasonable over the next two years?
- Arpit Vyas:** No, not at all. So, a 5% to 10% increase.

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Mark Griffiths: Yes, 5% to 10% increase in R&D cost as we start to deliver more products and more concepts into our own portfolio.

Charo Mehta: Okay. And further remedial measures, what would be the additional spend?

Mark Griffiths: Sorry, I missed the question.

Sanjay Majmudar: She is asking, what will you spend in India for the remedial measures?

Arpit Vyas: So the remedial measures, Charoji, what is good for us is that the company was anyways going in a major upgradation program of its facility which included technological aspect of it as well, where we will be going more towards focusing on science and that data generation of it and analysis of the data between services of it. So, this was all. And fortunately for us as, the upgradation program that we made should be catering to 90% of the corrective action plan of the EDQM and Swissmedic. So, the spend had already been allocated which should be coming to the tune of anywhere between \$10 million to \$15 million over the next three to four year period.

Moderator: Thank you. The next question is from the line of Dhiren Bansali, an individual investor. Please go ahead.

Dhiren Bansali: Yes. Thanks for the opportunity again. If you could just share as to what is the total value of Niraparib, the API we be sold for Niraparib till now?

Mark Griffiths: The total would be about I think not less than \$20 million for all the years put together. If you just ask for the last year, it was about \$3.5 million.

Dhiren Bansali: Okay, \$3.5 million. Okay, fine. And what would be the API component of any new chemical entity that is approved once it goes for commercialization. What could it be the API component, I mean, value wise?

Mark Griffiths: I think we need a very long con-call for that one. ADC for example, let me tell you that ADCs in terms of the volume, physical volume of the content in the final drug form is parts per billion. But the cost of an ADC, not the synthetic piece but the cost of the entire antibody drug conjugate would be many, many millions for a normal synthetic drug. So, let's take a heart kill of some sort, the API content, the bit we do, might be 5% or 10% of the total cost. But again, it depends on how many pills they sell. If it's a huge product like paracetamol, then the price of the API is rupees per kilo almost.

So that's a really brutal question for somebody to answer. If you wanted to never down the question and shoot an email to Harshil, we can give you a specific answer about a specific type of indication. But it's such a wide question, its almost how long is a piece of rope, it depends on how we cut it.

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Arpit Vyas: And Dhiren, it's all dependent on what is the final pricing of the customer, which we have no part of actually. So for example, Eprosartan we are made to believe like it's coming at 24% cost is of the API, which is in the brand name Teveten which is extremely high, and the size of the pill is also very big. But what we have seen in the product that we have developed, which has gone commercial and which has failed the range because of Eprosartan **1** for us the cost of the API is anywhere between 0.5% to 24%.

Mark Griffiths: Yes. So, that's a very broad base, and difficult to come to a point.

Arpit Vyas: Exactly.

Mark Griffiths: It is impossible, unless you say what is the component of ADC, then I can split that down. But I can tell you that the biggest single cost in the manufacture of an ADC is the antibody. Not the synthetic chemistry, we charge a lot of money for that, but it pales into insignificance with the antibody.

Moderator: Thank you. As there are no further questions, I now hand the conference over to the management for closing comments.

Arpit Vyas: Thank you, everybody, for the wonderful series of questions. These were the best line of questions that we as a team faced in terms of the con-call and I will be very honest about that. And thank you for giving us these unabated questions to pick our brains and answer them as effectively and as honestly as possible. It gives us the confidence that yes everything is not lost, and trust is not lost. And positive comments by you gives us, to be honest, goose bumps that people are now at least going in the right direction and have confidence they will achieve in Phase II. So, thank you again for all of you and your continued trust and belief. And as always, we will not let you down.

Moderator: Thank you very much. Ladies and gentlemen, on behalf of Dishman Carbogen Amcis Limited, that concluded this conference. Thank you all for joining us. And you may now disconnect your lines.