Fill Finish Industry – Evaluation Criteria, Contracting & Competitive Outlook – 17 December 2020

Disclaimer

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1. Fill finish industry trends, COVID-19 impact and competitive landscape
2. Demand and contracting logistics, including pricing, margins, rates and customer relationships
3. Evaluation criteria for fill finish CDMOs, such as capacity and risk-sharing
4. 2020 growth evaluation and competitive outlook

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AA: Welcome to Third Bridge Forum's Interview entitled Fill Finish Industry – Evaluation Criteria, Contracting & Competitive Outlook. I am Lis Agosto, and I'll be facilitating today's Interview with John LaHaye, former VP of Global Business Development Services at Thermo Fisher Scientific.

John, before we start today's Interview, please state I agree or disagree to the following statement: You understand the definition of material non-public information and agree not to disclose any such information or any other information which is confidential during this Interview.

JL: I agree.

AA: Could you begin with a brief introduction to your background?

JL: Sure. 30 years in the industry, the first 20 years in what we call software as a service in the healthcare industry, mostly CROs and pharmaceutical companies, and then the next 10 years in pure service industry, mostly in the CDMO with Catalent, Patheon. A short stint in two years with the technical field of logistics, and the last year was with Tergus Pharma, a CDMO, mostly doing R&D and development. That's it.

[00:05:47]

Q: What key trends are you tracking across fill finish players and the broader CDMO industry?

JL: Two trends, mostly. Some of the products require smaller volume, and I'm going to exclude COVID-19 from this. Other products, you're seeing larger companies or even mid-sized pharmaceutical companies looking for a different business model in terms of capacity reservation. The trend, at least the last three years, is the trend for those larger companies with multiple products, is to reserve capacity, and it could multiple products. It doesn't have to be one product. At least they have a footprint on that process train. That's what we're seeing. Two trends from the CDMO perspective.

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Q: There has been a pronounced shift towards large-molecule assets and particularly autologous therapies. There seems to be a continuous decentralisation in the fill finish industry, and a push to be closer to the end patient, which is resulting in smaller batch sizes. What are your thoughts on those specific dynamics?

JL: This relates exactly to the first point I made. At least the thinking is to have much smaller batch size and equipment that can do multi format. In other words, think of clinical trial materials equipment. Instead of 200 vials per minute, it's more equipment of 20 vials per minute and being able to accommodate multi format. You're seeing a resurgence for that market space. However, having said this, there's still a demand for larger volume and capacity reservation with multiple products in line. What I mean by this is the pharmaceutical companies come with a portfolio of products and say, "I want to put these seven products onto that line, and I want to have a capacity reservation on that line, 50% capacity." That's what we're seeing, and condos. Condo model, and at some point, if you want to, I can explain a little bit more what a condo model is for the CDMO

industry.

[00:09:03]

Q: What are the key differences between the multi-equipment format and the more traditional manufacturing and fill finish practices?

JL: The multi format would accommodate not only vials but also pre-filled syringes and other are potential formats like this, that are all aseptic, obviously, where they'd be able to do this both lyophilised and non-lyophilised, that's in other words, powder, liquid and pre-filled syringes, and all on one equipment. The speed is much less, but the flexibility is there, and that's what we're seeing. Obviously, as you said, being close to the patient, this is really key, so proximity to the patient base is going to be important.

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Q: When is the condo model appropriate to use, and how would you describe its prevalence?

JL: Back in the days of Catalent, this was about 10 years ago, they had negotiated the customer in a specific space within a site. That space was equipped with basically equipment dedicated to this customer, but the customer had resources, their own resources, on-site. Now, we're seeing more and more of that trend not only with vials or pre-filled syringes but also specific oral solid dose technologies where the client comes in and says, "I want to reserve this space within your site." This is going to be very specific equipment engineered for the product, and it's a shared resource. Sometimes, it's 100% resourced by the customer. Sometimes, it's 50/50. Sometimes, it's just the infrastructure, the resources that they require. You can imagine it's almost like renting an apartment within a site. The benefit of this is you don't have to build the plant. You go and you get the equipment and you have a specific room where it's all dedicated to you and your own employees can go there. That's something that is more and more prevalent. Patheon is there. A few sites that have seen an enormous trend towards condo models. This is not just specific to Europe. It's Europe, US. At least that's the footprint.

[00:12:39]

Q: Which particular modalities are utilising the condo model, beyond the pre-filled syringes or oral solid doses you referenced? You mentioned it's essentially an ownership between the sponsor and the CDMO. How does that potentially complicate or alter the contracting model between the two entities?

JL: The contracting is interesting. The technology, most of the time, this is compensated. Condos are compensated when the technology is very specific to the product. Again, it has nothing to do whether it's oral solid dose or vials. It has to be specific to the product. That's (1). (2) The arrangement most of the time is the customer pays for the equipment. However, there's the ability to, if there's remaining capacity for the CDMO to fill that capacity, obviously, the customer needs to approve whether or not they're willing to basically allow this. This would trigger a repayment of the capital. You an imagine this. You have a space, a room in a site. You put very specific equipment paid by the customer. Capacity is, let's say that you have a capacity footprint of 40% and let's assume that 80% is the max on that process string. You can take that other 40% and offer it to other customers. The main customer or the primary customer will decide whether or not they will allow that other customer to utilise this equipment, because most of the time it's proprietary, and if they do, then let's assume that it's for different market segments. If they do, then they get a repayment of this.

For the CDMO, you have space, you're getting paid, you're getting, obviously, paid for the labour or conversion price that you have. That's another major trend. The other trend also that you're going to see, especially in the CDMO space, is the API is not paid by the CDMO. It's mostly a cash throw. The logistics to be done by the

CDMO, meaning the placing the order, receiving the API, but from the payment perspective, it is directed towards the customer. It's not embedded in the product, and the main reason for this is just to improve the cash flow perspective. That's another major trend, especially with large molecule, because the API is very expensive.

[00:16:12]

Q: How is the condo model trending across CDMOs? Do you think a lot of these contracts ultimately enter a different model as more complex therapeutics become involved?

JL: I would say that the trend overall is mostly within the top 10 CDMOs. At least from my discussions, if you were talking about the second, and the CDMO industry is quite different from the CRO industry. CRO, when you say the top 10, they own the majority of the market, even the top 10 in the CDMO business. It's just a small portion of the business, but you have a lot of CDMOs, and people are predicting, obviously, a lot of consolidation. The condo model is mostly on, let's say, the top 10 CDMOs. That's where they have the sites. They invest in sites and they can accommodate the specialised equipment in a room specific to a customer. The main reason when you think about it is time to market. When you start building sites or expanding sites vs just ordering the equipment and putting this in a room which is already qualified from air handling perspective and has the infrastructure, it's much faster than anything else. I'm not the penultimate expert, but from my discussion with my contacts, that trend is mostly in the top 10 CDMOs.

[00:18:28]

Q: What are the core criteria when selecting a fill finish provider? You referenced the condo model being concentrated mainly in the large CDMOs. How have the decision-making factors shifted amid the pandemic?

JL: I want to say strategic account management. You would think that the majority of CDMOs have that strategic approach with customers only to find out that they talk this talk but they don't necessarily have the process and they don't necessarily have the right business cadence to really what I call strategic partnerships and strategic account management. Even starting with a master agreement that is multi-product, that has governance for incentives on both sides, sharing your profit margin with those customers. The reason why I say that's the trend is that when you start asking questions to CDMOs, asking them, "Explain to me your strategic account management business cadence," you're going to see that there are a lot of holes in there and the thinking is still very old-fashioned. The trend is to revamp that strategic approach, that strategic relationship. It's on both sides. Some of the larger customers are not prepared to do that, and other customers absolutely are willing to do that and have those discussions. They're not easy discussions to have.

[00:20:48]

Q: How would you broadly characterise the strengths and weaknesses across players in the market, particularly the larger firms? Are some players strongest in larger or smaller batch sizes, for example?

JL: I don't think I would be able to explain or do a deeper dive there. If you think of, it is difficult for pharmaceutical companies, especially for new products, to have forecast. When you're coming with new products, it is a very difficult process to have a firm forecast, let alone… or it is obviously improving when you have the product after three, four, five years and you see what's happening, but you have to start with that principle in mind. It's about the supply chain, and we're hearing a lot about the supply chain with COVID, but with any other products as well, the supply chain is important. How do you go from firm orders to firm forecast to a three-year forecast period? What are the leeways that you can, in other words, how much can you change that depending on your firm order, your firm forecast? The term firm would normally assume zero change, and then you have your longer-term forecast. Why is that important? If you're a CDMO and you have

multiple products on that chain or that process string, then you need to be able to predict what is going to happen and being able to be responsive to this. It starts there and it starts with process improvement as well. If you do a kaizen, a Six Sigma and you have process improvement, sometimes it requires partnership with the customer. There could be regulatory changes, etc.

People think that just because you run a line, automatically process improvement comes. No. It doesn't work that way. This is a process which is approved by the government, by the FDA, and you can't just change the process in the middle. There's investment that you have to make. Regardless of the technology, you can always improve the process, and you need to have the appropriate mindset to do this. There could be changes in materials. All those changes, you need to have processes in place to deal with them, to discuss them, to review them on a quarterly basis and see what's impacting the business as a partnership. This is where I'm seeing a lot of failures. In other words, it's the mindset of just one side vs the other.

[00:24:21]

Q: Which specific players would you say have been particularly effective at expanding footprints to accommodate some of those smaller batch sizes?

JL: I think that Patheon is in the process of definitely looking at smaller batch sizes. Lonza, also, is there. Alchemy is looking into this. Wuxi from China is definitely. They understand that. At the same time, because of COVID-19, there's a huge demand for… in fact, somebody was calling me the other day and they were asking, I'm not going to name the name of the customer, but they wanted six million vials from May to November. Six million vials. That's something that it's not the norm. This is not something we have seen in the past. That's disrupting this whole concept. You have different trends right now. Once we're past that, the smaller batch size, multi format being able to accommodate better more difficult technologies or more sophisticated technologies, that's going to come back, in my opinion.

[00:26:09]

Q: Are there smaller players whose growth has outpaced the overall market, or who have impressed you with their capabilities to meet current capacity or unique demand?

JL: I would say if you look at the second tier, in other words if you look at the next 10, so not the top 10 but the next 10, all of those players are basically stepping up their game. All of those, without exception. It's not just one or two in particular. In other words, if you have somebody that has a USD 2.5bn revenue, then look at players that are more in the USD 500m-1bn market revenue segment, and those players are all upping their games, as far as I'm concerned. It's not just one or two. Emergent BioSolutions and companies like that, if you look at them.

[00:27:33]

Q: How do you evaluate the coronavirus-driven growth for Emergent and other comparatively small peers? Do you expect the surge in business from COVID-19 vaccines to translate to longer-term demand?

JL: I'm not sure that I can predict the future based on COVID-19. The demand is going to go down at some point. People are talking that the virus does change but not to a point where it would require, like a flu vaccine, a continuous vaccination year-after-year. It's going to depend. There's a lot of unknown. If the vaccine does mutate, then obviously, there is going to be a continuous demand the same way you have flu vaccine. You vaccinate yourself with the strain from last year. Basically, that's what you do.

AA: Do you ultimately expect vaccine-related work to position these players more advantageously for non-COVID-related work in future?

JL: The answer is yes. Whomever is able to accommodate and develop a relationship with these top-tier customers, then the answer is yes as long as they step up to that strategic relationship. The answer is yes if they're smart in not only profiting from the demand which is urgent today but also approaching it more from a strategic partnership perspective. To me, that's the answer. Quite frankly, to be honest with you, it's not just the CDMO, it's also the customer. Without naming names, Company A, a pharmaceutical company, could approach this as, "This is the demand that I have today. You answer this, you give me the price I want." It's more of a procurement, and that's it, vs Company B, "I want to form a relationship, I want to form a strategic partnership. Demand is going to change. I want to ensure that we have supply for various products." You'll see it's not a given that companies will go either part A or that first option vs the second option. It depends on the psyche of the company. I've seen both of them in the marketplace, quite frankly. Again, I don't want to name names, but I've seen both of them.

[00:31:10]

Q: You referenced the potential for a company such as Emergent to be advantaged in post-COVID-19 work. Do you think this growth would be driven by the market continuing to increase rapidly for non-COVID-19-related therapies, or could any of these companies potentially take share away from other players?

JL: No. There was a trend for diminishing OSD, oral solid dose, and going into more of a vaccines-type, the larger molecules. There is definitely a trend towards this. The good news is the profit margin for this is so from a CDMO perspective, if you do oral solid dose, your margins are anywhere from 45% or 35% to 55%, whereas those vaccine products, large-molecule products, the gross margin on this is anywhere from 55% to I've seen even 85% gross margin on that. Not only is the trend towards that, but it's also backed by a lot more profit there. Obviously, the investment has to be there and CAPEX. CAPEX is to support this, is much more than the oral solid dose. The volume in oral solid dose is going down. However, you do have some technologies that are emerging in terms of specialised coating, specialised granulation, etc, that it's not going to be large in volume, but it's going to be a sub-segment which is going to be a lot more profitable, in my opinion. You have to think about this. The other area is also that a lot of people, and not all CDMOs are equipped, is when you're talking about high potency vs hormones. Not all of them are equipped to do this. The people that have those suites, hormone suites, high-potency suites with the appropriate air-handling equipment, etc, they're going to have an advantage in this market space. That's what I'm seeing.

[00:33:55]

Q: Might the smaller players who have garnered popularity amid the pandemic take share from CDMOs who would otherwise be handling the transfer from oral solid dose to large molecule? If so, which CDMOs would you expect to potentially lose some of that business?

JL: If I look at Catalent vs Patheon, I can't really talk about. Lonza is mostly just in large molecule, but Catalent had a lot of specialised OSD product. I believe that John Chiminski has been really good at looking at what's happening in the marketplace and basically diversifying the portfolio of technologies so that they can grow and accommodate this area. One area, and the same thing with Patheon with their softgel, the softgel is mostly for OTC product. Same thing with Catalent. Their softgel plants are mostly for OTC. They have the capacity of changing those areas and investing in those areas to accommodate other emerging technologies in terms of pharmaceutical products. They've done a good job. I cannot talk about other companies because I don't have that much knowledge about the other companies other than Catalent and Patheon.

[00:36:25]

Q: Can you outline the proliferation of automation and robotics usage in the industry, and the resulting time or cost savings? What investments are necessary to develop these capabilities?

JL: At least, while the time I was there was mostly in inspection. Looking at the packaging, obviously, and inspection, especially in the area of packaging, because packaging or margins and packaging in packaging [sic] with the 25-35% gross margin. This is a focus area where what can we do to automate this and what can we do to automate inspection? There has been a tremendous investment in these areas because it's time-consuming and the margins are not really good there. The rest of the equipment in terms of the fill finish was already pretty much automated. It's not like it required a lot of resources, but the down-stream had a lot of resources on this. That's where you see a lot of investment being made.

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Q: You indicated that automation in this market is relatively mature. Does that only apply to the large CDMOs, or is that standard across the board?

JL: Only the large CDMOs, and also they need to be able to afford CAPEX. Just to give you an idea, Patheon, USD 2.5bn. Are you sitting down? Our CAPEX budget for the year is USD 400m. That's pre-Thermo Fisher, but even within Thermo Fisher, it didn't go up that much. The amount of CAPEX is not that much even for a USD 2.5bn company. You need CAPEX to do your expansion, to basically invest in automation and robotics and etc. It's not an obvious thing. Patheon, because of Thermo Fisher, they're a little bit more solid, but when you're on your own, where do you get this CAPEX? This is where they need to be really smart and partnering with customers, with strategic customers in sharing this CAPEX responsibility. It's not just being smart in terms of strategic, it's also the fact that they don't have an open bank account with lots of money to invest, when you think about it.

[00:39:48]

Q: You said automation is mostly only present in the larger players. Is automation achievable for some of the smaller CDMOs, and if so, over what timeline? What prioritisation would be in place for a smaller CDMO that doesn't necessarily have that CAPEX to invest in these areas?

JL: Prioritisation is going to be done. I'm working with a CDMO, a Japanese-based CDMO, and prioritisation, quite frankly, is about targeting the perfect match for your capacity and your margin profile. That's what they're… rather than trying to get any business, they don't have the CAPEX. If you don't' have customers to invest, let's assume that you don't have that those strategic customers to invest, then it's a question of going after that perfect opportunity in the market segment that you're looking for and bringing this. In other words, it's looking for opportunities that will match what you have. Having said this, after just doing a little bit of deeper dive on this CDMO, the top 10 customers bring 80% of the revenue. Then, I asked a question. What's the cadence, and what are your strategic discussions with those customers? It's really doing two things. (1) Looking at your footprint of customers, and can we change the relationship with those customers to improve our ability to bring more technologies by developing business models that would profit both sides? That's (1). (2) Being even more specific in the way you approach the market and be very targeted on the types of solutions that you want to offer. That would fit what you have. Like you said, they don't have the money to invest.

[00:42:29]

Q: Is fill finish pricing for COVID-19 vaccines higher, lower or in-line with the standard?

JL: It's lower. It's much lower. However, having said this, if I look at the last major contract, 50% of capacity on a sterile fill finish, both lyophilised and non-lyophilised, the price per vial was less than USD 1.70, conversion price. That did not include the API. Just the conversion, and that included 50%, basically a capacity reservation of 50% of the line and CAPEX, and it was a, roughly, USD 30m investment. 50% investment, USD 15m, 10-year contract, average price was less than USD 1.70 per vial excluding API on those seven products, roughly speaking. That gives you a little bit of idea in footprint for these types of products. The beauty about this construct was it doesn't have to be one product. You have a mix of product that you can move around, and you have more capacity reservation as opposed to a very fixed volume per product. In other words, you can play your entire volume on a number of products, and you can pull out those products, do a technical transfer of basically bring in… so you can pull out Product A, you can replace it with Product C. That's what you can do is you can plug and play with those products.

That's the beauty about capacity reservation. You're not confined to one product per se. It's a little bit like the Airbnb but applied to vials, applied to pharmaceutical large molecules. That's almost the same principle of this. It's a good concept as opposed to having very defined, strict guidelines on a single product. That's what you're going to see, people thinking outside the nine dots. COVID-19, quite frankly, could be part of that when you think about it. It could be, imagine if you had capacity reservation, you could dislodge certain products, plug in COVID-19 by doing a tech transfer, and then when the volume comes down, then you re-plug the other products. People had to think outside the nine dots. At the site level, sometimes it's difficult to get that.

[00:46:04]

Q: Can you quantify the extent to which fill finish pricing for COVID-19 vaccines is lower than the standard?

JL: I would say maybe about 50% of that. Remember what I had said, the gross margin on this could be as high as 85%. You have some room to play with this given the level of urgency on this. There's room to play.

[00:46:56]

Q: What implications does the spare capacity for vaccine demand have for other product forms?

JL: I think you're going to see more and more specialisation of CDMOs. Some CDMOs are going to become more OSD-oriented. PII is one. In fact, I was talking to the President there. They see that they could be a specialist in OSD. Recro Gainesville in Georgia, they could be an OSD specialist as opposed to… I think what you're going to see, in my opinion, you're going to see those larger CDMOs may become more and more specialised in either very specific technologies for OSD and sterile fill finish, whereas other CDMOs may take more the oral solid dose. The same way in the topical business. When you look at the topical business, you can count the CDMOs. Other than Tergus, you have DPT, you have MedPharm in the UK. DPT, which is part of Mylan. Basically, these three are the top three CDMOs in the topical business. In my opinion, you're going to see more and more specialisation this way, going forward.

[00:49:05]

Q: Which players have stood out to you as winning COVID-19 vaccine share, having mentioned Emergent?

JL: I know Patheon is. I know Catalent is. I know Lonza is. Those are the players that basically are freeing up or making sure that they have models in place. I know for sure that Patheon had at least three lines where they had already placed the orders, not that they knew anything was coming. It's just that they were in discussions with other customers for vaccines. They may utilise some of this because they had capacity. They're all going to benefit from this. The key question which I don't have the answer to is what is the future going to be? Is the future going to go down to a very slim portion of this, or is there going to be a continuous demand? Right now,

from where I stand, I'm not an expert, is, this is going to go away to very slim demand. In other words, it's a one-time, then goes away. It's not going to be like the flu vaccine or other vaccines that you've seen. Again, I'm not a scientist, I'm not an expert, but what I'm told is the degree of changes is very small. Once you have immunity, then you don't need to get this every year. How long does that last? That's the other key question. Does it last one year, 10 years? How long does it last?

[00:51:16]

Q: Have there been significant changes in contract length and pricing amid the COVID-19 work and shift towards large molecules and smaller batches? What exactly is being included in contracts as well as pricing?

JL: Number one is, in a lot of companies, you have one contract per product. The thinking, especially because of the fact that you can switch so you have multiple products per contract, so that's number one. Same thing with the quality agreements that are attached to that. In other words, you can have quality agreements attached to a master manufacturing agreement that has multiple products. When you have that, the forecasting is very important. Price increases per year, or price decreases, extremely important. All the logistics assigned to this, who is responsible for API, who gets billed for API, what about the rest of the materials? The storage condition for this is really important. The thinking originally was that logistics footprint was going to expand. Now I'm seeing a stop because the focus is we need to look at supplying the demand and not necessarily thinking of expanding our footprint in terms of logistics, at least for now.

Then, obviously, anything that has to do with failure, failure to deliver, who is responsible for what? The term gross negligence as opposed to negligence or just following a process is going to be really key because those batches are very expensive. The liability limit for these contracts, especially for vaccines, is really key. We were talking about CAPEX. You can imagine, if there is a failure on a batch and you're responsible for it, then it's going to cost a lot of money, especially if the API is there, which is probably 80% of the cost. If you recall the conversation at the beginning, the CDMOs don't pay for this. This is the client. If you have a batch failure, you are responsible for replenishing that API. That liability is going to be really key. Those are the areas that you are going to see process improvement. That's another thing. You need to have a defined process improvement and who benefits from what. A lot of the contracts didn't have that, didn't have the right language to address that. Those are all areas that only the top tier have good contracts, in my opinion, decent contracts, that they can change.

[00:55:32]

Q: What pace are you forecasting for M&A through 2021, and which particular capabilities do you expect to be targeted as potential acquisitions?

JL: I could be wrong. I think that the focus is so much on COVID-19 right now that there are some discussions, but I think you're going to be seeing a resurgence. Those two trends that we talked about, so in other words, specialising the CDMOs in certain categories, I think you're going to see some acquisitions of… Patheon is a perfect example. They acquire a lot more than Catalent right now. They seem to be expanding, but you're going to see post-COVID-19, in my opinion, people thinking about the footprint of their capabilities and looking for acquisition that matches that footprint. If you're in OSD, you're going to look for this. If you're in topicals, you're going to look for mergers and acquisitions in the topical business. If you're in the large molecule high volume, you're going to look for this as opposed to large molecule in cell and gene therapy and smaller volume close to the patient. You're going to look for different footprint, so on. You're going to start seeing some specialisation as opposed to just merging sites for dollars and efficiency. People are going to start looking at supply chain-based M&A, in my opinion, could be wrong, not an expert. If I would have to do it, that's the way I would do it.

[00:57:40]

Q: Can we conclude with any further key components we should be considering relating to potential industry M&A and core CDMO capabilities?

JL: What I would do is I would take the top, let's say, 30 CDMOs, look at the dosage form footprint, look at the regional footprint, look at the profit margin by dosage form footprint, and then ask yourself, regardless of, you just ask yourself, who would benefit from merging these organisations, given that dosage form footprint and margin footprint and regional footprint? That's what I would do. The other thing too is that a lot of people are starting to think about is, the packaging, and that's why Catalent got rid of their packaging for oral solid dose, they sold this to PCI, bulk manufacturing and distribution is something that more and more people are going to be doing. Then, you could do the inspection, the packaging, the distribution almost as a separate business. Just ask yourself, is bulk manufacturing in the CDMO business, even in the pharma business, because you know that 70% of their products are made by pharmaceutical companies, not by CDMOs. Then you ask yourself a question. Will the future separate these two? Bulk manufacturing vs inspection, packaging, distribution, logistics.

[00:59:48]

AA: On that note, we will conclude today's Interview. Let me close by saying thank you, John, for your input today, and thank you, clients, for joining Third Bridge Forum's Interview. If you would like to speak to John in a private call or meeting, please let your relationship manager know. Thanks so much, everyone.

JL: Thank you. Bye.

Transcription ends at 01:00:02 of the recorded material