Integra LifeSciences Holdings Corporation (IART)
2023 Piper Sandler Healthcare conference fireside chat
November 28, 2023 4:00pm

Matt: All right. Afternoon, everybody. Thanks so much for joining us. Matt O'Brien, I cover medical technology here at Piper Sandler. I'm very fortunate to have Integra with us here. From the company is Jan, who's the CEO, and then a couple of folks from IR are out in the audience. So thanks so much for coming out. Really do appreciate it.

Jan: Great to be here, Matt.

Matt: Excellent. So, maybe start a little bit with Q3. You know, it was a little bit better than you expected, a little more stable than I think a lot of folks, I guess, generally, were expecting for med tech. So, what did you see in Q3 and then your early days of Q4, you know, that, you know, prior to the earnings call, you know, what were you seeing from your end markets?

Jan: Yes. Well, one, we're happy with the markets that we see. [?But then?] that's both in our neural parts as well as our tissue technologies, including international. So, yeah, market is there. We get confirmation our product portfolio is as distinctive as we like to think it is. We are winning where we wanna win. And we've got our commercial team focused on getting the most out of the market potential. So, it has led in the third quarter, if you exclude for a minute the impact of Boston to growth numbers, five or above, which we see as a benchmark and an indicator for where we wanna be with our long-range planning. Of course, Boston is keeping us as busy as obscuring some of those numbers. But we remain laser-focused on executing the remediation, staying on track there. While in parallel, we continue to focus also on the several new product initiatives and growth initiatives that we have, and that really are strong pillars under the business for the next LRP period to come.

Matt: Okay. And then, you know, the Boston recall did take some folks by surprise in Q3. It seemed like it had a bigger impact than expected. There was more of a, you know, return provision than I think that anyone of us were expecting. Can you just talk a little bit about, you know, what dynamic hit you there as you weren't expecting, and then just the customer attrition and your ability to hold onto those customers eventually?

Jan: Yeah. So, two questions. First on the recall, you know, which in the essence was a misestimate based on the limited information in the month of June, July, when, you know, we called a recall, yeah, had to give guidance. I wanted to give guidance on what we assumed would be called back. At that point in time, we did have pretty much no visibility to what do our customers have on the shelf in their books. And so we made a number of assumptions that, based on some of the bigger customers, where we do have access, made sense. It's only in the month of August, September, October when our sales force started to work with customers to call the products back and document what's there, that we started to see that, specifically on the smaller customers, they had more inventory in months of supply than what we had assumed. And that's where the $7 million surprise pretty much came from. It's the smaller, where we misestimated what they had on their shelves.

Matt: And you're still comfortable with that $7 million? That's the number, that there's not gonna creep higher? You had those...

Jan: Yes, because that number was made with pretty much full insight now on what's on the shelf. This is based on the touches that our sales reps had with the customers.

Matt: Okay. And then, you know, how have the customers responded to -- you know, to the recall? I mean, recalls happen in med tech. This isn't surprising. Have they been reasonable as far as their frustration levels, or is that something that could be, you know, a headwind for you guys as you head into next year?

Jan: I would say reasonable as it comes with frustration level. And I would say it's credit to our sales force, the relationships that they've built, the credibility that the Integra brand has in the market. And like you said, customers know that this will happen now and then. The fewer, the better. We've put our effort in making sure that, with our customers, we help them through this tough period but put them in as smooth as we can.

What we've done internally to accomplish that is, one, make sure that we protect our sales force. Our sales force is a major relationship linked to the customers. We've matured in their compensation, how we incentivize them that, you know, we gave them some protection, at the same time incentivizing them for working the substitution products. Integra, we have the benefit

of not being a one-trick pony; we have a broad portfolio, you know, both for SurgiMend as well as for PriMatrix. There's other Integra products that could be good substitutes. So our sales force has worked with customers to -- where we could to substitute, and we're confirming that 10% to 50% of sales revenue which will come back to other products.

The other parts where we can't substitute is going to other players. When I talked about sales force and the more information they get as they continue working with customers is that they feel good about getting that business back. And pretty much for the same reasons that we got the business in the first place, which is the products SurgiMend and PriMatrix are really exceptional in what it brings to the patients from a perspective of strength, uniformity, conformity, ability to deliver bigger sizes, and at price points which are competitive to the alternatives.

And so as we recall the product, the discussions with our customers became interesting because they told us why they wanted to keep that product. They essentially made a sales pitch for us, which we're gonna be using as we get back into the market, why they like SurgiMend, why they like PriMatrix. And so today okay, we plan based on those insight from the moment where we get back into the market to when we get our revenue level back where we were before. It's gonna be about 12 months to get back to that. And that's, again, based on what we learn from customers and based also on what we learned from some cases in the past.

Matt: Okay. How confident are you in the progress you're making on the Boston manufacturing side and getting back to the point where, you know, you were able to manufacture as much as you need?

Jan: Yeah. It's a tough question because I can tell you what's behind my confidence. There's -- [?you know?yeah?], what definitely has made me confident is that along the path at several points in time, we brought in external auditors to assess the progress we're making, both from a perspective of, are we forgetting anything? And second, what we're doing, does it meet the standard that the FDA or any other auditor will hold us against? And so that for me is the major factor of I feel good with the progress we make, but I also feel good with the quality of the process we're making.

As some of you may remember, when we had the earnings call in October, we put a couple of milestones down, okay, to measure or

to communicate our progress. The first one was this first phase from June, July till October, where, you know, we made a holistic plan, leveraged all the inputs, feedbacks we've gotten from FDA. And other auditors and internal, made a plan, progressed well on that plan, and kicked our own tires along the way to make sure we made it.

So, then we said, okay, the next big step is to turn the factory back on. Very important, because remediating your quality management system, there's a lot of paperwork. It's upgrading your process description, upgrading your design history files, and so on. A lot of paperwork, but then reality still has to happen. So turning on the factory is important for fine-tuning, for validating processes, validating product, and starting to train or retrain our operators in the factory. Okay. So we said we wanna do that before the end of the year. In essence, we turned on the factory a bit more than two weeks ago already. Okay. So I'm happy with the fact that we're creating additional time for us to iterate, to drive improvement, to double-check, triple-check, you know, on the different changes we make, and creating more time to ramp up our operators back in the factory that hasn't been running for pretty much nine months now.

But then the next phase is gonna be in the first quarter, okay, where as part of the plan and agreed with the FDA, we will have an external auditor do an end-to-end audit for us, commissioned by us. Okay. On a positive outcome, which we drive for; we communicate that to the FDA. At that point in time, we can go commercial, which would mean we start first building inventory -- enough inventory to have a smooth commercial [?house?ounce?]. Yeah, be back in market mid-second quarter and second quarter.

So that's another important milestone, say, end of Q1. Part of what we're doing in the beginning of Q1, probably in January, early Feb, is a bit of a dress rehearsal. So we're bringing in another auditor to do an end-to-end audit, you know, of the facility. Okay. A last time to kick all tires, just make sure that there's nothing that we may have forgotten. And so it is that process that gives me comfort is that we're not making only progress with checking; we're checking the quality of the process from perspective of, does it meet the standard that external regulators will put on us?

Matt: Okay. So it sounds like everything's in pretty good shape as those things go then. I mean, fingers crossed…

Jan: Well, this is where...

Matt: …[?that comes?] whatever you wanna call it.

Jan: I'll be paranoid until, you know, we get the product in the market.

Matt: Got it. Okay. Okay. I mean, where can your customers go, you know, from a competitive perspective for a SurgiMend or a PriMatrix, and why are you confident you can get those folks back?

Jan: Yeah, so for SurgiMend's -- the biggest part of that business is in the breast reconstruction market. It's a $600-million-dollar -- big market, attractive market, but dominated by one player who has more than 90% share in that market. Now, we were growing faster than the market before the recall, so we were taking share. That share that we've taken in many cases goes back to the incumbent. Our sales force feels confident that the volume will come back for the same reason that customers came to us in the first place, which is the qualities of the product, the strength, the size, conformity, and step-change lower price level. So that's a clear area on where to focus.

PriMatrix, which is about room reconstruction, that's a more fragmented competitive space. You know, so volume is going to different players. One thing that we have learned during the recall is that the product is probably better than we ourselves thought based on why customers really didn't wanna give it up. And so that insight will help us to further dimension how and where we planned the relaunch of PriMatrix.

Matt: Let's move on to other areas of the business that are, you know, perking up nicely, although I do want to talk about China for a minute, but Starlink, that has relaunched in certain international markets. Just love to hear about how that's going there and then the domestic relaunch and thoughts there.

Jan: So Starlink relaunched in first international countries, end of September it was. Over the fourth quarter, you know, one country after another based on their regulatory pathway, we get in the back. We should be, by the end of the fourth quarter, be back in all international markets where, you know, we had Starlink. Good experience with the customers.

You may remember when we had the recall, we had the insight that, for the surgeon, it was important to be able to maintain working with the Microsensor. The feel, the rigidity, I mean, remember the Microsensor is what the surgeon will put in your

brain. So they want something that they know how it's gonna bend them and react.

And so as part of the recall, we ensured that we brought the earlier product, ICP EXPRESS, off the shelf and made that available again to our customers. So we solved their issue. They could continue to work the way they wanted to work. Today we see, as we're back in the market, that customers have been waiting for Starlink to come back. We have seen very little return sale of Starlink. So customers like the product and have given it the time to wait for Starlink, which is a step change, better product than anything else in the market.

So that's the dynamic we see in international with existing customers. We start to see competitive wins, again, where we take out competitive sockets in international. We expect the same to happen in the U.S. there. The 510K got submitted end of the third quarter. It's a normal 510K, not a special, so we fall into the normal timelines, which point us to getting back in the market somewhere in the first quarter next year.

Matt: Okay. Excellent. Best of luck with that. And then, on the, you know, China anti-corruption topic of conversation right now, can you just maybe remind us your percentage of sales that comes out of China, and then how impactful is everything that's going on over there to your business?

Jan: So, China, volume is about 6% of our top line. China growth is more important than that 6%. So China is an important opportunity for us. From a government action in anti-corruption, I think like everybody, in the month of August, they were, like, a certain freeze because nobody knew what was happening. So nobody is there to do anything. The government in September took more time to explain what they were trying to accomplish. That created a bit of normality back.

We've seen September relatively little impacts, no material impact then in October and after. Now, part of that is explained by the type of business we're in. Okay, we're essentially -- it's a neurosurgery business in China, which are very much procedure-driven. As a doctor, the judgment calls in what technology going to use are kind of limited. There's also limited opportunity for overuse or abuse [UNINTELLIGIBLE], right? You're only gonna use one sensor, not two. And so that makes it a kind of a more predictable type of area where the risk for doctors to make choices is lower than in other parts of healthcare where there's bigger money at stake. So that has

helped us in not seeing too much of an impact. In addition, we are building out China with U.S.-based standards.

So from a perspective of how we set up our education events, how we remunerate [?KOLs?] that come in and speak and educate, that's all following processes that we have here. It's all the right ones, and essentially that's what China wants to have. But we don't need to change our own process there. I'm not disrupting my own sales force in China because I got them where they need to be from the compliance perspective.

Matt: Okay. Okay. Good to hear. As far as the breast recon PMA goes, I'm trying to remember off the top of my head, which is not good, but just where that stands, especially with the Boston facility, and then, you c- -- can -- you can't progress ahead with that PMA until the manufacturing facility is back up and running? Is that right?

Jan: That's right. So there's two parts to the PMA, right? There's the clinical part, clinical study, and then there's the manufacturing certification to declare your manufacturing is certified for PMA products. On the clinical side, we submitted in July the last pieces of data that the FDA wanted to have. So that's kind of -- that data is in. The critical path is now getting the certification of the Boston plant. Before that, to happen, the Boston plant needs to be up and running, needs to be back in the market. Then we will probably invite the FDA to come and audit, hopefully in the fourth quarter of 2024, if not in the first quarter of 2025, for that PMA audit. To then get this PMA, we aim for the first half of '25.

Matt: Okay. How big a deal do you think the PMA is gonna be in terms of transitioning market share to SurgiMend because you have that big provider that's been there for a long time and people have used forever?

Jan: Tough to see what kind of further acceleration it would give. So today with SurgiMend, you know, which is, doctors make the choice based on the capabilities for soft tissue reinforcement. We can't commercialize specifically for breasts, but that alone resulted already in growing faster than the market. When we will have the PMA, we will be ahead of competition. Okay. The question is how much is it, one year, two years, more? So we can actually really educate customers on the benefits of SurgiMend as compared to alternatives.

So, yes, we expect a significant impact. At the same time, we're also going for PMA with our DuraSorb, resorbable synthetic,

which I would say is one year behind SurgiMend. So we're aiming for a position where, during a certain time, we are the only one with two PMA products in the market that have complementarity. And that, for our sales force, will be a fantastic situation to offer that choice and capability with a PMA label to SurgiMend. So we're really focused [?that?] time, and whatever advance we have, we aim to make the most out of that advance.

Matt: Got it. Okay. All right. Well, fingers crossed there as well. What about on the top-line side of things? You know, again, things were steady in Q3. I think the Street's modeling it at, like, kind of 4%, 5% top-line growth next year. That's kind of in line with the LRP that you laid out at the analyst day; is that we should continue to expect on the top line from Integra?

Jan: So, this year, if [?we?you?] look, year to date, apart from Boston, you know, we're above the 5%. So our core starts to show numbers that start to point towards those LRP expectations. Now, with Boston coming back next year, there's gonna be some year over year that make -- probably make the number look a bit higher than that. But overall, that's what we keep communicating around our core. We started to see the 5% to 7% growth expectation from the core of our products. And so we'll definitely make our plans [?in function?] of what we see the market and our capability to deliver to that market.

Matt: Okay. Is there gonna be a scenario where the -- [?the?I said?] 5% to 7% over the LRP period, but, you know, when you get SurgiMend and the PMA approval, and there's DuraSorb as well, I mean, could there be a structure where you're at the high end of that range or even higher for a little bit, just given the opportunity for that product?

Jan: Yeah. It's too early to give, kind of, further guidance on LRP, right? I think at this point in time, we try to get beyond the disruption that Boston gets in every number, every protection. Yeah. At that point in time, you know, we'll -- both on growth, but also on our margin evolution, you know, start updating that trajectory, and those [?end point?].

Matt: Well, that was the next question. Because of -- I'm assuming those are higher margin products; we're just talking about the mixed shift that you should see from th- -- from those products as well as Starlink and then Aurora, etc., going forward, how can [?mix?] benefit you guys going forward?

Jan: Well, most of the, whether you talk Starlink, whether you talk [inaudible 00:22:16], all of them is [?mix?] accretive. There's other NPIs, you know, new product introductions that are coming -- Aurora, we'll get full commercial now with Aurora. There's -- probably end of next year, there's the [?combo-catheter?], new products that come. So all of these should be products that are margin accretive and growth accretive to the business. That's where we pointed them and why we prioritized them before.

Matt: Got it. Okay. And then, just lastly, last couple of minutes here, just on the M&A side of things, I think you ended Q3 at about three times levered. You know, that's the bottom end of the range you typically operate in. Are you open for business as far as M&A goes or, hey, let's get through Boston first and then hope we'll revisit this?

It's a mix of those two answers, right? One, we have a strong balance sheet, and we have a good financial rigor. And M&A remains a key lever of our strategy, both in tissue tag as well as in CSS. Tissue tag. Okay. There we made a decision until we got Boston back. Yeah, we got a lot in our hands. Yeah, leadership focus on Boston. On the CSS side, the common side, looking at opportunities, we may be at this point a bit less aggressive than we typically would be if Boston would be back. Yeah. At the same time, you know, we know the strategic targets that we would like to have in the portfolio. Sometimes we can't control the timing. So, between now and Boston, if something happens, it would be on the CSS side with deals that are clear, strategic adjacencies or [?tokens?].

Matt: Okay. Still smaller though, most likely, than something a little more bulky or -- And then does the interest rate environment kind of change your view as far as what you'd be interested in?

Jan: Not too much impact of the interest rates. Yeah. There's definitely -- I mean, this is not the time to do something that really big transformational.

Matt: Are there areas of CSS that are growthy areas? Because I know, you know, tissue tech is a faster growth area for you guys.

Jan: So the answer is yes, right? And, you know, part of how we filter in our game board is what are the growth accretive segments, okay -- and, which at the same time has synergistic

capabilities, technology, or channel. So we can drive value and adjust growth acceleration.

Matt: Okay. [INAUDIBLE] Well, as I look at the clock here, we're out of time, so I'll have to go ahead and end it there. Jan, thanks so much for all the feedback. Appreciate it.

Jan: Thanks for the opportunity --

[END OF Integra LifeSciences Holdings Corporation (IART).mp3]