IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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FEDERAL TRADE COMMISSION, **CV No. 1:25-cv-02569-RC**

Plaintiff,

v. **Washington, D.C.**
Thursday, November 20, 2025
EDWARDS LIFESCIENCES CORPORATION **10:00 a.m.**
and JENAVALVE TECHNOLOGY, INC.,

Defendants.
- x

TRANSCRIPT OF EVIDENTIARY HEARING - DAY 3
***** MORNING SESSION *****
HELD BEFORE THE HONORABLE RUDOLPH CONTRERAS
UNITED STATES DISTRICT JUDGE

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P R O C E E D I N G S

MS. HALL: Your Honor, we sent over an updated witness list last night, but we are already changing it slightly. We talked to Dr. McCabe last night and, given we got a lot of the things that he was going to cover yesterday, we don't want -- intend to call him by Zoom tomorrow. We're going to look and see if there's a few designations to put in, but otherwise we'll take that off the schedule.

MR. SHORES: And with respect to the schedule, Your Honor, we went back and did discuss about next Tuesday after Thanksgiving. We're really trying to slim things down to be done before, but I would respectfully request if the Court could hold that time -- and, again, we're going to do everything to not have to use that time.

THE COURT: All right. And I -- previously, I had ordered the FTC to read their designations into the record. If we take that out, will it -- will we get finished by Tuesday?

MS. HALL: We will take a look and do the math, Your Honor.

THE COURT: Okay.

MS. HALL: And we will need to know, of course, who they may be removing to see if that's going to make the difference, but we will take a look.

THE COURT: Okay.

MR. SHORES: We'll look at that on our side, too, Your Honor, and come back to you.

THE COURT: Okay. Thank you.

MR. LIPTON: Good morning, Your Honor.

CROSS-EXAMINATION

BY MR. LIPTON:

Q. Good morning, Mr. Bobo.

A. Good morning.

THE COURT: I remind you you're still under oath.

THE WITNESS: Thank you.

MR. LIPTON: So Mr. Bobo, we're going to -- and, Your Honor, we're going to hand out some binders we're planning to use.

BY MR. LIPTON:

Q. And, Mr. Bobo, this is an open court session. It's open to the public. So be careful in talking about confidential information. Where there is confidential information in one of the exhibits we talk about, I'll ask you to look at the paper copy and I'll ask you to -- at particular points, to not refer to particular numbers and things of that nature. So when there's an exhibit that's fully available to the public, we can see it on the screen, but I may direct you to the binder for certain exhibits. Is that okay?

A. Yes. Thank you.

Q. Okay. So good morning, Mr. Bobo.

Can you please remind us of your title?

A. Corporate vice president strategy and corporate development, Edwards Lifesciences.

Q. And how long have you been with Edwards?

A. I've been with Edwards since 1995, I believe, the fall.

Q. And can you please describe your role for us at Edwards?

A. Sure. I have responsibility for enterprise-wide strategy. So as we think about the areas that we prioritize to invest in and therapies that could be meaningful to patients, I spent a lot of my time with the business units and the corporate team thinking about that and setting strategy. In addition, I have responsibility for our corporate development activity, which is any investment, any M&A, any joint venture we might consider as part of our strategy.

Q. And what was your role in particular in connection with the acquisitions of JenaValve and JC Medical?

A. I was principal in the original strategic discussions around aortic regurgitation and the impact that could have on patients and the attractiveness to Edwards's strategy. In addition, I had principal responsibility for the transactions approaching the companies, or being approached in the case of JC, and talking about what their -- what they were interested in, what could be interesting to us, and

ended up point on the transactions, both of them.

Q. And how does merger and acquisition activity fit with the strategic priorities of Edwards?

A. We historically have been a company that, first of all, is very focused in structural heart, so we don't do a lot of things in med-tech health care. We're very focused on a particular set of diseases. And we have a very robust internal set of engineers in R&D. But traditionally -- I can only go back 25 years -- every one of our meaningful platforms that is making a difference today with patients ended up having early stage acquisitions of technology, in some cases IP, that ended up being an integral part of that. And so M&A is important to our strategy because it oftentimes is how we source combination of ideas that end up becoming meaningful therapies to patients.

Q. And are there particular types of companies that you are looking to acquire or invest in?

A. There are. We are a little unique because we tend to spend our time in earlier stage companies. So we'll go into companies or technologies that are early stage, oftentimes early ideas, some intellectual property, maybe, some early testing on the bench, maybe, some early testing in animals, all the way through companies that are in clinical trials or just completed clinical trials. But all of these, if you look at the life cycle of these therapies, they're early

stage. So we tend to like getting involved early because we're able to bring our expertise, some of our judgment, some of our experiences, alongside those ideas.

In addition, in just about every one of our major platforms, there are a combination of contributions from technology, from R&D, from intellectual property that end up coming together to make that product successful. So the early-stage company ends up being a particular focus for us.

Q. And when you acquire one of these companies -- one of these early-stage companies, do you expect to invest in the company after you've acquired it?

A. We do, and significantly, and in some cases for 10 or 15 years. These therapies often take a long time to incubate and develop and reach a point where you're ready to have it touch thousands of patients, and so they end up representing significant and sustained investment.

Q. And how do you define success in terms of your investments and your acquisitions?

A. We think a lot about that, and I think there's two elements that are meaningful. One is you like to believe that it's going to advance our strategy to bring life-saving therapies to patients. Secondly, there's a long-term reality to this. So we look at, longer-term, what is this product on a path to deliver clinically in terms of safety and efficacy? So in our business, many of our measurements

are -- we have to look back 10 years and say, that was a good technology; that was a good acquisition. And so our definition of success ultimately is the impact we're able to have on patients. Most of the patients we treat and have brought therapies to don't have options today. They suffer from the disease. Most of them die from the disease. If we're able to bring a therapy in that actually bends that curve, gives them a much better life, and/or saves lives, that, ultimately, quite frankly, motivates the whole company and that's our best definition of success.

Q. And how do -- how does what you just described fit with the company's objectives for growth and shareholder returns?

A. They're integral. One of the things we have at the end of our credo is -- that we wrote 25 years ago, really elevating the role of the patient, is when we're able to solve things for the patient in a way that really moves the needle for the patient, what we've learned is our employees get motivated, our regulators are great partners to us, the payers, shareholders. So the beautiful thing about a patient focus, if you're able to practically express that every day, every week, every month, is it not only moves the needle for the patient, but we end up with a great company. We end up with a company that grows. We end up with a company that has great jobs, delivers profits to shareholders. And so for us, it's a connected system.

Q. Are your acquisitions and investments always successful?
A. No. I have many examples of technologies and therapies we thought had promise and were unable to make it through a clinical trial, were unable to get FDA approval. In some cases, we looked at it and said, This is just not a good answer for the patient. There's a better answer. In a couple of examples I can think of, we invested in a technology for 10 or 12 years. We had a self-expanding valve called CENTERA that is in this category. By the time it got through its European trial, our balloon-expandable product had advanced so far and had such amazing clinical outcomes that to take patients from that product to this newer product, quote-unquote, would have been taking patients back. So we made the tough decision to say, even after all that investment, it's not a product we're going to commercialize; we're going to continue to advance the SAPIEN platform. So there are many cases where they don't work, and that's part of the business.
Q. We've heard questions from the FTC throughout this case about Edwards trying not to spend -- overspend on R&D to avoid negatively impacting the company's earnings per share. How do you square those objectives with the approach to M&A and investments that you've just described to us?
A. Yeah. It's important to, kind of, understand a little bit of the journey that Edwards has been on. We're, I

think, this year, about 18 percent of our sales, we spend in R&D. That's the highest number in med-tech in our peer group. I think the next closest is 13, 14 percent. So there's some people out there that say we spend way too much on R&D. We historically have been very supportive of that because it's been absolutely the center of our ability to invest in these early-stage technologies that take significant investment.

Two years ago, we spun out part of our company, we sold it to Becton Dickinson, a company called -- a critical care business. It was about $1 billion in revenue. When you take that revenue out, it has the mathematical effect of inflating your R&D percentage to, I think, in the case, 19 percent. So over the last couple of years, and we talk about it today, we're not trying to cut R&D; every year R&D goes up. But to sit at 19 percent is probably too high for any of our peer groups. And so what we've seen over the last couple -- three years, and we expect this to continue, is with modest growth in R&D and more growth in sales, we expect that ratio to go 19 last year, 18 this year, maybe, 17 next year, and settle in, kind of, in the mid teens, which is what we think our business needs to execute our strategy of early-stage R&D, early-stage M&A, and these projects where you have to invest for long periods of time to get them through the FDA.

Q. Do you go through a process of prioritizing your R&D investments across different projects?

A. We do. And it's actually an intentional and rigorous part of our annual planning process. Starts in March where the teams begin putting together the strategic plan. We have a very important review in June. We continue to work it through the summer. And culminating in an operating plan that we write in November. And the primary output of those plans, and, I think, the best implementation of strategy is when you're able to prioritize your resources. And we spend a lot of time talking about what therapies are a priority, are we investing in them? You know, if you say they're a priority and you don't put money in them, they're not a priority. And so we have a very intentional process involving the executive team to make sure we come out of our planning process with clear priorities, with funding aligned to those priorities.

Q. And where does aortic regurgitation fit into the strategic priorities of Edwards?

A. In the last -- probably since 2024, it's at or near the top. It's a therapy area that we think is dramatic for patients. These are patients that largely don't have a solution today. We saw in the JenaValve trial that they were successful at running an FDA clinical trial and actually producing pretty amazing results. We also saw

that, as that trial went on, more and more patients were referred to the trial. So we saw a very important demand signal. So for Edwards, aortic regurgitation is one of our top strategic priorities, which is why it motivated us to look hard at how to get in and how to begin advancing the trials and the efforts.

Q. So let's look at a document.

MR. LIPTON: Let's pull up D-X-251, please, Mr. McCloud.

BY MR. LIPTON:

Q. And, Mr. Bobo, this is one where, I think, it would be helpful to turn to your binder and the tabs. You'll see the D-Xs. If you can please open up D-X-251?

THE DEPUTY CLERK: Should this be displayed for the public?

MR. LIPTON: I'm sorry? Yes, this is fine to display. It will have redactions for the public version. Thank you.

BY MR. LIPTON:

Q. And, Mr. Bobo, please look at the cover email and then the first page of the PowerPoint, please.

A. I see the cover email. Yeah.

Q. And do you -- please take a look at the first page of the PowerPoint. And then my first question is, do you recognize this document?

A. I do.
Q. And what is this?
A. This is a strategy and portfolio overview that my team creates, and it's typically something that I take my CEO, CFO, and our key members of our leadership team through, kind of, synthesizing the strategy work that has been done as of this date.
Q. Okay. And can you please turn to Page 11, and I'm using its page numbers at the bottom center of the document so they sync up with the -- what we're showing on the screen. And, Mr. Bobo, without getting into the specific numbers on here, can you please tell us what this slide is showing us?
A. This slide, kind of, describes the R&D spending by major area within the company, that -- our plan from 2025 through 2031, including the mix and the growth rate of those specific R&D projects.
Q. And are these numbers part of your strategic plan at Edwards for the next six years?
A. They are.
Q. Okay. What does this show us about TAVR-AR which, I believe, is the pink bar in the middle of the chart?
A. Well, it shows -- without getting into numbers, it shows consistent growth. As we looked at this opportunity, we believed -- at the time, we believed that Jena would have been relatively close to FDA approval. JC would have been

in the very earliest days of R&D. There would be a follow-on trial with Jena, so you see continued escalating spending in R&D for TAVR-AR. The other thing, I think, that's noteworthy is it is the highest percent growth R&D project in our strat plan as reflected in the number, fourth down, under R&D CAGR percent.

Q. Thank you, Mr. Bobo. We can set that document aside.

Let's talk about your proposed acquisition of JenaValve. When did you first consider an acquisition of JenaValve?

A. The first time was back in 2019.

Q. And what did you conclude about JenaValve at that time?

A. We were able to engage with the company and had a framework that both sides thought could work. We entered significant diligence with -- across our teams, looking at JenaValve. And we ultimately decided not to move forward with the investment and a potential acquisition at that time because of some very specific areas of the company that we were concerned were meaningfully immature, or perhaps they really -- we weren't confident they could execute the plans that they were hoping to execute. Too early. So we said, Look, wish you guys the best. There's two or three areas that are -- just don't feel right to us, but we're happy to stay in touch and see how you do.

Q. And did that view of JenaValve change at some point?

A. It did.
Q. And what changed and when?
A. In the fall of 2023, they were able to present the results of their U.S. pivotal trial -- and pivotal is, maybe, an odd word to some people in the room, but the it's the trial that the FDA approved for them to run for the purpose of getting this product approved in the U.S. to be sold. And they shared those data at a conference called TCT. And it was my practice once or twice a year to meet with John and his chief medical officer, Duane, just to stay updated on the company. And in that particular meeting they walked me through the results of the clinical trial. And two things struck me as changed from 2019. One, they actually finished the trial. In 2019, we weren't exactly convinced they could do that. And, two, the results were pretty remarkable in terms of the improvement it gave patients. And also, the fact that a lot of patients had come to the trial, and still wanted the therapy, that were in line. There was a line of people that still wanted the therapy. Those three things caused me to step back saying, this feels like it's more real and could be a very meaningful part of our strategy.
Q. And that last point that you mentioned about the patients wanting the therapy, how did that fit into your thinking about the business perspective there?

A. Yeah. It's an important one, because whenever you are trying to innovate a therapy for a group of patients with a disease where there's no alternative today, you spend a lot of time trying to figure out, are there a lot of patients? Are there a few patients? And because there's no therapy, most of these patients get parked in Middle-earth. They're with their GP, they're with their cardiologist, and there isn't an active process to bring them to a therapy because there isn't one. So one of the benefits of a clinical trial is you're able to assess, one, does the technology provide a safe and effective therapy? But it also gives you very early insight that, if there's a therapy, can you validate that there's a sizable population of patients who could benefit? And their trial did that.

Q. All right. So before you invest hundreds of millions or billions of dollars into a therapy, is it important to know or -- is it important to have a picture of the potential market opportunity there?

A. It is.

Q. Okay. And so at -- after that point, did you enter into talks with JenaValve about a potential acquisition?

A. We did. In that fall, as I recall, we had conversations with John and his chairman about, what do they want to do with the company? Did they want to try to continue to raise money? Were they interested in a transaction? Expressed

interest in a transaction. We then started talking about the framework and what a transaction could look like, what their board thought, what they wanted. And we continued those conversations through January. And then about that time, we actually stepped back, because they had some failures in their testing, and we said, You need to go understand those failures so we know how to do diligence and to see if now's the right time to continue a conversation. And then, as I recall, in early spring, late winter, we actually re-engaged in a negotiation.

MR. LIPTON: Can we pull up, Mr. McCloud, D-X-72, please?

And this one's fine. We can just look at this on the screen, if that's easier.

BY MR. LIPTON:

Q. So please take a look at the first page of the PowerPoint, Mr. Bobo. And first question is, do you recognize this document?

A. I do.

Q. And what is this?

A. I believe this is the title sheet to a set of slides we prepared for our board that I presented to our board in January of 2024.

Q. Okay.

MR. LIPTON: Let's turn to Slide -- Page 3,

please, of the document.

BY MR. LIPTON:

Q. And under JenaValve, this says, "EW declined transaction in 2019. U.S. trial results motivated a re-look."

Do you see that, Mr. Bobo?

A. I do.

Q. And is that consistent with what you just described to us?

A. It is.

Q. And up in the top right portion of the slide, it says, "JenaValve FDA approval EOY 2024."

Do you see that?

A. I do.

Q. And what did you mean by that?

A. At the time, we believed and were -- and the company communicated to us they expected FDA approval by the end of year 2024.

Q. And did they hit that target?

A. They did not.

Q. And is there any mention of JC Medical on this slide?

A. No.

Q. And you can -- you have the document in front of you. If you'd like, you can look and see if there's any mention in the rest of the document. But were you considering an acquisition of JC Medical at this time in January of 2024?

A. I don't believe we were. What tab is this document?
Q. D-X-72.
(Brief pause.)
A. No, this deck and this conversation -- at this point in time, JC wasn't even a thought in our mind. We were solely focused on JenaValve or the Jupiter transaction.
Q. Okay. Thank you.
MR. LIPTON: And, Mr. McCloud, can we turn to Page 6 of that document, please.
BY MR. LIPTON:
Q. And, Mr. Bobo, briefly, please tell us what you're showing on this slide.
A. Page 6 is -- allowed me to illustrate some of the strategic thinking we had behind this potential transaction. It's titled, "Strategic Considerations."
Q. And can you briefly describe for us the strategic considerations that you presented to the board?
A. Sure. We started with, kind of, re-expressing the success of the trial that JenaValve had run. Not only produced very attractive data for the patients, but also validated a clinical need which, for the first time, we were able to put an estimate on what we thought the addressable market could be. And, again, this isn't -- group of patients that had no options. And so getting validation that if you had a therapy that was successful, patients were

moving to it, helped us validate this important point.

In addition, they had a continued access arm. They call it a CAP on this particular slide. And after you finish enrolling for the pivotal trial, the FDA lets you continue to enroll because it's an urgent need and a solution. And we were watching the interest in the CAP arm of the trial be significant and sustained.

Q. Thank you.

And under the third major bullet, the first sub-bullet there that starts with the words "Leeds U.K.," it says, "Leeds U.K., valve manufacturing has improved but will need significant investment to address yields, 50 percent, and capacity constraints, 58 valves per month."

Do you see that?

A. I do.

Q. And what were you trying to convey by pointing to those figures regarding yields and capacity constraints?

A. It's, maybe, helpful just for me to provide context. This is in light of the work we'd done in 2019 which, believe it or not, were much worse than this. They were much lower than 50 percent and couldn't do anywhere close to 58,000 a month. So on one hand, we were saying, good job; you guys made progress since 2019 addressing some of your issues. But this is still far from the mark you'd want if you were going to commercialize something. So typically, we

come in and say, Great. Nice job. Good progress. But we'd come in with a significant investment and a significant pool of resources to try to take yields from 50 to 90, to try to take valves per month from 58 to whatever we thought the first couple of years of commercial demand would be. And so this ended up being one of our early focuses coming out of diligence: Look, we're going to have put significant time and money here.

Q. And did you form a view as to whether Edwards would be able to fix JenaValve's manufacturing problems?

A. We did.

Q. And what was that view?

A. So the view was anchored in our experience. We've actually brought in a number of early-stage technology -- valve technologies, CardiAQ, Innovalve -- I could go down a long list -- PVT, and typically small companies focus on enough to do a trial and not much more, and yet we're very skilled and experienced at how tissue gets processed, how you sew leaflets, how you form frames, how you attach cloth to frames. And we just learned in our own journey what it takes to go from a few per month to hundreds to thousands. And we would bring that experience and those processes. And many times in many cases, you'd bring fixtures in, you'd bring different training programs. And we just had a track record of being able to take people from this kind of

starting point to something that would support a commercial business. It takes time. It takes money. But we have specific people in the organizations that are masters at tissue, at sewing, at processes, at metals, and we would bring them -- those individuals in to this project to do the same thing.

Q. And on this slide, it mentions that it will need significant investment to address those issues. Were you prepared to make the investment required to fix JenaValve's manufacturing problems and provide the resources necessary to commercialize Trilogy at scale?

A. Absolutely, including upgrades to the facility. Typically, one of the improvements -- one of the ways to improvement is you bring very different equipment and instrumentation in. So that would have also been part of our plan, not just our expertise and our people, but we would have invested in the facility.

Q. And today, if you're able to close the -- if you're able to -- strike that.

Today, do you have money allocated to fix JenaValve's manufacturing problems if you're able to close this acquisition?

A. We do.

Q. And was that -- can you briefly describe it? Is it OpEx -- without saying the numbers, is it OpEx? CapEx?

What do you have allocated?
A. Both. So it's an important distinction. We have operating money that we would allocate to invest in JenaValve. In addition, we have historically brought significant capital spending, which is a different budget item. And we're not a very capital-intensive business, so we bring whatever capital we need to. And the capital investments pay for things like upgrading the facilities, new tables, new instrumentations, new microscopes, new computers, new displays, some of the IT software that is needed to accelerate a manufacturing footprint. And we're fully prepared to bring not just the operating expense, but also capital expense needed to allow this footprint to support a commercial business.
Q. And you mentioned a moment ago -- you mentioned the people who you have, the talent that you have. Do you have specific people identified who would lead this project if you're able to close the acquisition?
A. We do. We have specific people, and I could name names, but we have people that have been part of the diligence team, and their job is, when we have these kinds of acquisitions, they actually pull together a team, they assess, they find the gaps, and they deploy resources.
Q. Yesterday, the FTC asked you some questions about whether you will continue to -- continue manufacturing of

Trilogy in JenaValve's facilities. Do you recall those questions from the FTC?

A. I do.

Q. And in the near term, is your plan to keep manufacturing for Trilogy in JenaValve's facilities?

A. It is, both Leeds and Irvine, and it's an important distinction as to why. When you go through an FDA PMA process, part of the process actually validates not just the designs, but also the manufacturing. And the validation includes a location -- Leeds or Irvine. And those validations also, in addition to being reviewed by FDA, the FDA actually goes and audits those sites. So when you come through a PMA approval, you have -- you've had sites that are audited, you've had all the validations that have been reviewed by FDA and commented on. And so you don't have the ability to just flip a light switch, turn off those sites and go somewhere else. You have to go through a whole process of a new site and then the validations and then the FDA audit of that site.

So our typical practice -- and we've done this many times -- you come into the facilities that you acquire, you strengthen them, you invest in them, you let them support the commercial business, and then, over some period of time, you will bring up oftentimes a second site in one of our footprint factories where you duplicate what you're

doing in the original site. Sometimes you'll bring up an improved design in your own footprint that builds on their footprint, but because of the FDA PMA process, you really need to stay in place, invest, strengthen, fortify those sites, support the commercial business, and then, over a period of years, bring up, validate, and get FDA approval for incremental sites. So that's why we would -- it's highly valuable to the transaction to stay in those sites and to make sure they can support the business.

Q. And is that a process you've done in the past with other transactions?

A. We have done that in the past multiple times and, in fact, we're in the process of doing that now with a transaction that we closed in the middle of 2024. So we're very experienced. We know what it takes. And it's part of our process.

Q. Okay. We'll come back to JenaValve in a few minutes, but I'd like to talk about your acquisition of JC Medical.

How did you become interested in acquiring JC Medical?

A. The CEO, Mark Turco, who's a friend -- I've known him for many years; he's been in the med-tech business for a while -- he approached me in, call it, February of 2024, if I recall the dates right. We were talking in a meeting and he said, "Hey, can we get some time?" I said, "Sure." We

sat down and talked. And he said, "Look, I'm running JC Medical. We have completed" -- I think at the time -- "15 patients in an early feasibility trial." And he said, "Look, the parent company, Genesis, cannot afford to continue this effort so they're going to shut us down." I said, "Well, what's changed?" He said, "Look, they've had real pressures in the Hong Kong stock market. They're pressured on how much they can spend. And while they think this is an interesting space, they just don't have the capital means to continue prosecuting a U.S. pivotal trial and FDA approval."

I said, "What are you going to do?" He said, "Well, I've gone out and talked to everybody, and I don't think there's anybody that I can raise money from or who will buy this." And I said, "Well, interesting." I said, "Look, the way we typically think about this is I need to look at the clinical data." Because what qualifies our interest most is if we're able to see a signal in clinical results that would be validating of your platform being an ultimate solution for these patients. He said, "No problem. I'll send you the data. You can take a look it."

So we looked at his data, and that was the initial process that we started to engage in to see if this is something we could be interested in.

Q. Okay. Thank you.

MR. LIPTON: And let's pull up, if we could, Mr. McCloud, D-X-78.

And this is one that's fine for us to look at on the public screens.

BY MR. LIPTON:

Q. And the top email on the page is dated February 9, 2024. Mr. Bobo, is this an email that you sent to Mr. Zovighian?

A. It is.

Q. And the subject line of the email is, "JC Medical J-Valve." Do you see that?

A. I do.

Q. And you wrote to Mr. Zovighian, "Per our conversation last evening on a second AR valve that could be in play."

Do you see that?

A. I do.

Q. And what was the conversation you were referring to?

A. I believe I probably mentioned to -- mentioned it to him in passing the night before when we were probably together at a meeting or a dinner. And I probably gave him a brief thumbnail on -- Mark Turco approached me and here's the situation they think is -- their company is in.

Q. Okay. And let's look down at the -- at -- toward the bottom of that page. There's a -- the bottom email is from Mark Turco to Larry Wood --

MR. LIPTON: And then let's scroll up, if we

could, please. Can we see the email above that, please, Mr. McCloud, also. Thank you. And both, if we could. Could we see both emails.

BY MR. LIPTON:

Q. So there's an email from Mark Turco to Larry Wood, and then it looks like Larry Wood forwarded that to you. Do you see that, Mr. Bobo?

A. I do.

MR. LIPTON: And then let's look, please, Mr. McCloud -- I apologize; you had it up a moment ago. The email from Mark Turco to Larry Wood.

BY MR. LIPTON:

Q. And at the bottom of that email, Mark says, "Please let me know what Don and Bernard have to say. Our cases have gone well, both in compassionate use and special access, as well as in our EFS."

Do you see that?

A. I do.

Q. And do you have an understanding of what Dr. Turco is saying there?

A. I do.

Q. And what was that?

A. So he sent an email to Larry, kind of, thumbnailing the data. And our typical process is Larry, who was running the business at this time -- we would typically interact with

myself, Bernard our CEO, and Larry around this potential opportunity. It's important in my role to -- for the business leaders to be involved early because they oftentimes have important perspective on the need, the clinical data, and the progress that the companies have made.

Q. Thank you.

MR. LIPTON: And we can take that down, Mr. McCloud.

BY MR. LIPTON:

Q. After the initial outreach from Dr. Turco, did you undertake diligence of JC Medical?

A. We did. As I recall, we entered a confidentiality agreement so that we were able to get access to the clinical data in particular, but also we wanted to understand, kind of, the nature of the company. It was a bit different, because they had a U.S. operating group doing the trial but all the manufacturing and much of the development was being done in China. And for us, it was a bit different. So we wanted to spend some time understanding the nature of that relationship, where the technology was, where the manufacturing was, and where the clinical data were.

Q. And did you ultimately get comfortable with the fact that their valve was manufactured in China and the other work that you said that was done in China? Did you get

comfortable with that?

A. We did. We actually sent a team over there that spent, I think, about a week in the plant. And we went deep. We looked at their lines, we looked at their documentation, their validations, their source data. And these guys had done an exemplary job of building a line and building test data like we would have done, and that was a pleasant surprise.

Q. And as a result of this diligence, did you become interested in JC Medical as a potential acquisition candidate?

A. We did. In particular, the -- part of the diligence that was most noteworthy to me was, when we looked at the clinical data -- now, keep in mind, we also had a team looking at JenaValve and we were deep on their clinical data. One of the features, and this is not uncommon of early generational technology, is they go out and they can treat some of the patients, but not all of the patients. You find in these patients, and this is true in most structural heart patients, there's a wide range of variability between patients. In this room, there's a wide range of variability in how valves are expressed and how they're positioned and sit and all of that.

And so in the JenaValve trial, we saw that they were able to treat -- make it up -- three or four out of ten

patients that presented, because their technology was appropriate and optimized for that group. In the JC Medical, the surprising part was they were able to treat about 30 percent more patients than JenaValve. Now, neither side knew that. We knew it because we looked at it. And that was really the tipping point. We said, Okay. There's something in this JC technology that's able to expand the number of patients that we could treat. We're early-stage guys. We buy stuff early frequently. We think that could be valuable to a broader AR strategy because, instead of treating -- I'll make it up -- three out of ten patients, wouldn't it be great to be able to treat six out of ten patients?

And that was the earliest conversation strategically that we had with Bernard, with Larry. And it's really what caused the three of us to say, Of course; if it's possible to do that, these two technologies together will have a much more consequential impact on the disease than any one. And that's what motivated us.

Q. Was it the difference in valve sizes between the two companies that enabled JC Medical to treat more patients?

A. Two things -- and I'm not the engineering expert -- although I was an engineer by training, I'm still -- I'm recovering now. The height of the frame, it's a short frame, and you can see that picture here -- it's a shorter

frame which, for some anatomies, is preferred versus the taller frame. And they're able -- they were able to express a larger valve diameter which, in these patients in particular, their disease actually expands the annulus that the valve needs to sit in. So the ability to go into larger diameter annulus with a valve that doesn't fail was, kind of, an interesting intersection. Many had tried and had not been able to end up with a design that could do that.

Q. And maybe you answered my next question. I was going to ask, if larger valve sizes are desirable and can allow you to treat more patients, why not just build larger valve sizes with JenaValve's valve?

A. It has turned out broadly in the field large valves are problematic. When you end up with a large valves, you end up with very different stresses on the metal frame. You end up with very different stresses on the leaflets and on the geometry of the leaflets. And even in Edwards, there's a limit to how big of valves we've been able to build. And in this particular case, the fact that JC, early on, first 15 patients, were able to treat, call it, 30 percent more patients with larger anatomies was very meaningful. We've looked at a lot of different platforms that were unable to do that.

Q. So if JenaValve has plans to build larger valve sizes, does that mean they're necessarily going to be able to do

it?

A. It means they have plans. I think it's -- it's a very difficult engineering problem to solve.

Q. So I'd like to talk about your objectives with -- with two acquisitions. At some point, you got comfortable with the plan to seek to acquire both of these companies; is that correct?

A. It is.

Q. Why were you interested in acquiring two companies in this space instead of just one?

A. Two things, I think, were probably prominent. One was the real promise that, together, we could end up with a couple of platforms that would more broadly satisfy the patient need. And as I said before, in, you know -- this is unusual for a business, but our strategy is substantially driven by how big a solution do you have for a particular disease. The wider the solution, the more interested we get. It's better for patients and it's better for business. So that was number one.

The other -- number two, and, maybe, almost equally important, is in every one of our leading platforms, curiously, they have DNA from multiple developments, multiple technologies, and in many cases multiple acquisitions of early-stage technology. And what we've learned is that to fully satisfy -- to bring a range of

products to a disease -- a portfolio of products to a disease -- it's true on our aortic business, our mitral business, our tricuspid business, our surgical business: I can look at the DNA of every one of those products, many of whom have multiple products targeting the same valve, because the patients are that heterogeneous, they have multiple strains of technology that ultimately came together to make that a viable solution. So it's very, you know -- it may seem odd from a distance or to an outside observer, but for us, it's been our journey. We've ended up with technologies we've acquired or licensed in tissue or metal or the valve design or a delivery system, and we often put those together to end up with the most compelling therapy for patients.

And so for this one, we said, Look, AR has been hard to crack. JenaValve has been trying for 20 years. These are very tough problems. And so to have the incremental improvements JC demonstrated in early trial plus the broader set of data that JenaValve has, we said, These technologies together, in concert, have a very good odd of giving us a successful product for patients and a broader product. And that -- that thinking is natural to us and it came to bear in this particular case.

Q. So fair to say -- are there advantages in terms of the innovation process and having two platforms to work from?

A. There is. Part of what we've learned is no one engineer has a monopoly on all the great ideas, and sometimes you get two or three great ideas to come together to end up with the most impactful therapy.

Q. And can you give us some examples where Edwards has combined two developmental platforms as part of the new product development process?

A. I can. If I go back to our surgical business, we have had an evolution of technologies both on frame and tissue. We started using porcine tissue in the early days. We moved to bovine pericardial tissue. We've had evolution in the frame designs of the surgical platform. So in our surgical business today, I think we have three aortic valves, because the patients are different enough that all three are needed. In our transcatheter aortic valve business, we bought a company in late 2003 called PVT. I was actually -- I had the chance of being point on that transaction. We had an internal program called Patriot that had been trying for four or five years to develop a transcatheter aortic valve. When we bought PVT and brought it in house, they had some remarkable engineering that we had not thought of. We had probably the advantage on the delivery system and the tissue. That all came together and ended up being what we now call our SAPIEN platform.

I could tell the same story in our transcatheter

mitral valve. There's four different pieces of DNA in that, including an acquisition of CardiAQ. I can tell you the same story in our transcatheter self-expanding EVOQUE valve, which is today the only valve that's available for tricuspid patients. The patients, prior to this valve, would suffer and die from their disease. That valve has DNA from CardiAQ, from our FORTIS mitral valve, and from our RESILIA tissue that came from the surgical business.

So it's just a common pattern where we try to bring the best technologies together so that we can bring a therapy that's going to be safe, it's going to be effective. And in our experience, it almost always involves a combination of brilliant insights and engineering and technology.

Q. And can you think of any examples where Edwards has developed two platforms in parallel for the same product area or same disease area?

A. I can. We have -- there's a contemporary example going on right now. We have a transcatheter mitral valve called SAPIEN M3. It recently was approved in Europe, and we expect approval soon in -- in the U.S. At the same time, in parallel, we had a product called Eos in development. A year-and-a-half ago we bought a company called Innovalve out of Israel. And that platform, the Innovalve platform, is currently under development. And we -- there are anatomical

and patient reasons why we fully expect to have the M3 platform in the market and to have the Eos Innovalve platform in the market. They touch different patients, different parts of the disease and, in concert, we believe we'll be able to treat a majority of patients with severe, symptomatic mitral regurgitation.

And so what drives us to do that isn't we want a more complex business that's more expensive because you're managing two platforms. It's what the patients need because there's so much diversity across the disease.

Q. Do you know exactly what the future holds in terms of innovation, future generation products, the course of these platforms for aortic regurgitation? Do you know exactly what the future holds?

A. We don't. It's the most humbling part of being in this business. You innovate, you have ideas, you bring technologies together, and it could turn out to be three platforms that go to a valve; it could be one. Look, we might find something in 15 or 18 months that's another piece of technology that we're going to want to bring in because it will address some of the problems we're seeing in our clinical trials. So we don't know -- it's not until you get deep clinical experience that you really can answer the -- answer fully how broadly applicable is it and is it going to provide the safety and efficacy that you and I -- you or I

as a patient would want?
Q. Are you aware that the FTC has asked, during its review of this matter, if Edwards would be willing to divest JC Medical to resolve the FTC's concerns?
A. Yes, I am.
Q. In fact, one of the FTC commissioners asked you directly, Mr. Bobo, at a meeting, if Edwards would be willing to divest JC Medical to convince the FTC to clear the JenaValve transaction. Do you recall that?
A. I do.
Q. What was your response to that question?
A. I think my response was a hard no.
Q. Okay. And why?
A. Look, when we acquired JC Medical, we immediately started working on 1.1, 1.2, 1.5 of the design. In part of that journey, we bring our tissue, we bring our trade secrets, we bring some of our IP, we bring our delivery system insights. And so when I was asked that question, I wasn't trying to be difficult, but I don't have a pure JC Medical product that existed when I bought it. I have a JC Medical product today that's fully intertwined with the Edwards DNA, trade secrets, and intellectual property. And it's just impossible for us to take that set of inventions and progress and give it to a third-party outside company when it involves so much of Edwards's DNA. And that's the

principal reason where -- it's so conflated today, there's not a separable piece you could sell that wouldn't compromise Edwards as a company.

Q. Did the benefits of owning two platforms that you just described to us, did that also play into your consideration of that question?

A. In addition, and I think I went on to explain this, the ability for us to have two platforms to treat a broader set of patients is just core to the strategy and it -- quite frankly, it's core to who we are. And for us to say, Look, we're going to not serve half the patients for the sake of convenience is just a very difficult thing for us to think about doing.

Q. So now, I'd like to talk a bit about your plans to integrate the two businesses, Mr. Bobo. Are you involved in the integration planning process for these transactions?

A. I am at a high level, yes.

Q. Okay. And you've been able to close the JC Medical transaction, but you haven't been able to close the JenaValve transaction; correct?

A. Correct.

Q. Okay. So let's start with JC Medical. At a very high level, what have you done to integrate that business after you closed the transaction?

A. So we -- just to back up, as part of the transaction

process, we had a team do diligence and we were able to go very deep in the diligence, and that actually is a very helpful effort because that frames how we integrate. What you learn in diligence actually informs how we integrate. So once we were able to close, at close, we were able to identify -- we had already identified an integration team, an integration team leader, a project management office resource, and the functional resources across manufacturing with Nate and Andrew, across quality, across clinical with Jamie, across regulatory with Scott, across R&D with Laksen. I mean, I can go down the list. And we put together a full plan to do two things -- do several things. One, transition the trial. So Jamie's team came in and took over the trial and actually moved that product into a pivotal trial in amazing speed. Scott took over the regulatory interaction with the FDA and advanced that at amazing speed, much faster than the small company could have done. We had a team go into China for an extended period of time and develop a transfer plan that allowed them to supply product for the clinical trial, and then for us to have a transfer-out plan where -- we call it "they pitch, we catch" -- so that we can begin to get this technology into Irvine, into our R&D teams and into our manufacturing teams.

And the way these integrations work is these teams meet. We have regular report-outs. And, in fact, in this

particular case, once a month, they came to the ELT and reported on their progress: Here's our plan. Here's where we're at. Here's where we have issues. Here's where we need help. And it was an enterprise-wide priority and the integration actually went remarkably well in my assessment.

Q. And have you been able to do the same level of integration or integration planning with respect to the JenaValve business?

A. Our efforts to do the integration planning got aborted. We did diligence with JenaValve, so we got a reasonable picture of where they were and what the gaps were. But because of this process, we were unable to go deep on any additional confidential information with a broader team. And so while we've had some high-level discussions, including with John Kilcoyne, on what do you think you need for integration, how are we thinking about it, it's at a very high, non-confidential level. And so we've been able to, kind of, bucket things, but have not been able to go to the same level of depth.

But, look, we've done this a lot. We know how to engage. The moment we get a green light, we'll have the same thing. We'll have a leader. We'll have a full team. We'll parachute in. We'll be able to quickly take this apart and understand where we need to put resources, where we need to put spending, and how we need to put this

together in an integrated plan. And I can also assure you that this will be reviewed and tracked at the very top of the company as part of our monthly leadership team meetings, because it's that important a strategic priority for us.

Q. Could you do more planning for the integration by forming a clean team and having a clean team environment do that planning work?

A. Look, we historically have, on and off, used clean teams. In this particular case, we think it's very impractical for this reason. Right now, we have a team that's prosecuting the JC Medical program. And as you know, we've had a couple of challenges in the clinical trial. When we have those challenges, we surge resources. In fact, in this year, 2025, we're probably going to spend 8 to 10 more on that program than we thought and we budgeted, because they had challenges and that's what it takes to get through those challenges. If we were to encircle a clean team to start to go look at JenaValve, it ends up taking a lot of my best talent out of circulation. So then, when I have a JC problem, I'm not able to send those people in to go fix it. And we thought that would have been bad for the business, bad for the company to artificially isolate teams on a transaction that was still not certain. So we made the hard decision to say, I'm not going to contaminate a bunch of people, put them in a clean team, and not be able to use

them if we had issues in JC Medical.

Now, look, a year ago, I didn't know we were going to have issues. We weren't that prescient. I didn't know that. But they have had issues. We've had to put the trial on hold twice. We've had to bring in a significant amount of resources to understand root cause and to bring fixes, and I would have been impaired in my ability to do that if a number of those people would have been walled off in a clean team.

Q. And I apologize. I should have asked some basic questions to make sure we're clear to everybody on the terminology. When we talk about an acquisition of a company like JenaValve, dealing with technology, R&D, confidential competitively sensitive data, do they -- what -- in what sort of circumstances would they make that data and information available to you, as an acquirer, before closing the transaction?

A. Speaking of JenaValve in particular?

Q. Yes, and if you can put your -- I'm trying to get to the basics of, what is a clean team? Why would you need that here?

A. Yeah, let me back up. That's a fair point, because that's, kind of, a term of art. When you have a clean team, you'll get some of your best people and you'll say, Look, we're going to actually dedicate you to a confidential

project and process that's confidential in two ways, both directions. You're going to learn a bunch of information from the company that you'll need to bring your expertise to this plan to how we need to spend money, how we need to resource it. In addition, though, anything you learn with that engagement, you cannot use in Edwards. So you cannot share it with anybody else in Edwards. You can't use it on an Edwards project. Because it's their confidential information, whether it's trade secret or just their confidential information. So if you're on a clean team, the good news is you get close to that secret information and you get to bring your expertise and create -- help create a plan that we will go execute. The downside is you're now disqualified to be put on anything that is the same subject or the same topic because we're very disciplined on not misusing somebody's confidential information, and you wouldn't want that to end up in one of your products that's solving the same kind of problem. So if I had a clean team for JenaValve and we were not able to close the transaction, that team would be unable to work on any of our aortic regurgitation projects for years. And that's just a tradeoff we couldn't make.

Q. I see. And so just to get back into your previous answer, during the -- in the last few months, there have been issues with the Sojourn valve and some issues that have

caused the JOURNEY trial to be paused; correct?
A. Yes.
Q. And what have you done to try to tackle that -- those problems when they arose?
A. We had brought in significant additional resources from research and development, from manufacturing and quality, to, kind of, swarm the problem. And it's important we do that because we have clinical sites out there that had patients queued up to be treated, and now we had to go and say, hold -- time out; we can't treat you. So we brought in significant more resources, people -- I think I mentioned, probably, spending another 8 to 10 million on top of the 30 we budgeted this year to try to get this resolved. And many of those people -- we couldn't have done that if we would have put them in a clean team. We would have had to limp along with less resources.
Q. Okay. Thank you.
And, Mr. Bobo, did you meet with Mr. Kilcoyne earlier this year to talk about integration planning for JenaValve?
A. We did.
Q. Okay.
MR. LIPTON: Can we please pull up D-X-235, Mr. McCloud.
BY MR. LIPTON:

Q. And, Mr. Bobo, this is one that's probably easier to look at in the hard copy in front of you because of redacted material. So please take a look at the cover email and the first page of the PowerPoint, Mr. Bobo.

A. I'm sorry. Is it 235?

Q. Yes, 235.

A. Okay. I see it.

Q. Yeah, this one will be easier probably in the binder. My first question will be: Are you familiar with this document?

A. Yes, I am.

Q. And what is it?

A. This is an email and attachment from John to me with their high-level initial thoughts on how we would approach integration.

Q. And, first of all, why were you talking with Mr. Kilcoyne about integration planning in May of this year?

A. We, you know -- this is probably one of several conversations where we would ask ourself, Hey, do we have enough additional information or certainty on the transaction to start integration? Because core to a great acquisition is a great integration, and so it's on our mind. And one of those conversations, we were both going to be at a meeting in Europe and I said, "Look, why don't we get together and I'd welcome your thoughts on how you think of

it at a high level, knowing we can't get into the confidential information yet."

Q. Okay. And did Mr. Kilcoyne talk through this presentation with you?

A. He did.

Q. Okay. Let's turn to Page 4 of the document. And, again, I'm using the small numbers in the bottom center of the page to sync up with the screens.

On Page 4, about two-thirds of the way down the page, there's a bold-faced bullet. It says, "Significant talent infusion necessary ASAP as JVT very short-staffed in all functional areas to support U.S. launch."

Do you see that?

A. I do.

Q. What was your reaction to that?

A. So broadly, on, kind of -- as John was thinking his way through it, I wasn't surprised. It's not uncommon for small companies that are very focused on a clinical trial to be less mature in a lot of the functions that are needed to support commercialization. It was very clear to me, in talking with John, that he felt they had significant shortfalls in key functional areas that would be needed when they went to commercialize the valve.

Q. Okay. So let's flip to Page 10 of the document, again, using the small numbers in the bottom center. And we'll get

into some of the details. But at a high level, what -- what's your understanding of what's presented here on this slide?

A. We're talking about Page 10?

Q. Yes, Page 10.

A. He went through, kind of, his integration thoughts, high level, by department or by functional area, including operations and quality, research and development, the valves, the delivery systems. He goes on, commercial, clinical, medical, regulatory. So he's, kind of, going through each part of his organization reflecting on where they were from a staffing and a talent perspective.

Q. Okay. Thank you.

And so the first section is ops. What is ops?

A. Operations. Think manufacturing and quality.

Q. Okay. So there's a bold-faced bullet there that says, "Significant talent infusion is necessary," like the earlier one we looked at. And then the next bullet says, "New and/or materially expanded manufacturing facility needed ASAP," and then there's a parenthetical that's redacted there.

What was your reaction to that bullet?

A. Again, not surprised. They had -- these companies typically build enough capacity to supply clinical demand. And when you're going to go to commercial, there's a scale

phase you go through where you actually try to bring up additional capacity. And just to be specific, because it's a bit nuanced in our business, capacity doesn't necessarily just mean a building. A lot of the capacity is gated by training sewers. Every one of these valves are hand-sewn. And many of these sewing operations in a valve, these individuals -- they are amazingly talented individuals -- they'll sew for 10 or 12 hours. So you could imagine part of the scaling is: How do you hire sewers? How do you get them trained? How do you add lines? How do you make your lines more efficient so the product flows through in an accelerated way and doesn't get -- move through in a more chaotic way?

So those these are all the kinds of things that we would typically invest in when we're trying to scale capacity.

Q. I see. And so if JenaValve, for example, has a certain nameplate capacity for its facility, the most valves they could potentially manufacture there, does that mean they're going to be able to achieve that capacity?

A. By "nameplate capacity," you mean, hypothetically, if you've got 20,000 square foot and you've got tables two foot apart and all of that, it's -- it's one of the calculations, but, no, what gates them is your ability to set up the lines, hire and train the people. And another important

part we learned from diligence is significantly improve the way they processed certain steps of the manufacturing to take the friction out of that manufacturing. So it's really a multi-pronged effort that you go through in addition to just physical space.

Q. Thank you.

And then, if we look down at the next section on that slide, the section that's headed, "R&D" -- do you see that, Mr. Bobo?

A. I do.

Q. Under "valves," the first sub-bullet says, "Continuity important. Retain and augment with EW production personnel." And then the second bullet says, "Valve R&D team possesses material, technical and black art awareness of valve." And the third bullet says, "Additional talent infusion necessary as very short-staffed."

Do you see those bullets?

A. I do.

Q. And have you been planning to keep on staff the JenaValve R&D technicians who are skilled in the -- with knowledge of their product?

A. We were, and I'll go farther to say if you look at any of our recent transactions, we want the people. The people that actually created these innovations turned out to be -- end up, in our mind, to be a big -- an important and

valuable part of the acquisition. So yes, we wanted the R&D people.

Q. And are you planning to provide the additional talent infusion that Mr. Kilcoyne described as necessary because they're very short-staffed?

A. Yes.

Q. Okay. Let's look down at Page 11, the next slide, under the section "Commercial." Do you see that, Mr. Bobo?

A. I do.

Q. And so there are some references to the size of their team that will -- we won't say the numbers out loud. But the third bullet says they have a certain number of people in their U.S. field team and a certain number of people in marketing. Do you see that?

A. I do.

Q. And what do you understand field team to mean in this context?

A. Field team loosely refers to people that are deployed in the field. They're hospital-facing. They're usually across the country. They're organized by regions. They can be sales professionals. They can be clinical specialists that are needed to support each of the cases. Most of these procedures, you need a clinical specialist in with the cardiologist, actually helping implement the procedure, get the device ready, get it prepped, support the physician

during the procedure. Those are all in the field. So we call them field-based.

Q. Let me pause there and make sure I understand something. You have an Edwards clinical support employee attending every TAVR implantation; is that correct?

A. Yes, we do.

Q. And is that true with TAVR-AS where you've implanted hundreds of -- of thousands of valves?

A. Yes, it is, and it's true from day one and it's still true today.

Q. And is that your plan, to have that support for the clinicians in the TAVR-AR space, as well?

A. It is. It's turned out to be one of the most effective way to make sure every patient gets the best outcome. So that's how we do it.

Q. Can JenaValve do that for a wide-scale launch with the number of employees that you see listed on this slide that Mr. Kilcoyne provided to you?

A. No.

Q. Do you have the team that can do that?

A. We have the team.

Q. What is that -- you have -- you currently have the team?

A. We have the team.

Q. What team is that? What do they do today?

A. So we have a team -- a fairly substantial team. I'm not

going to tell you the numbers since it's open. Very substantial team in the U.S., sales team, clinical specialists, that actually support all of our TAVR cases. And this team would be trained with some of the expertise that the JenaValve team has developed with their product, because it's nuanced to their product. We would run that training through our entire U.S. team, and that team would also support all of the cases for aortic regurgitation.

Q. So you'll take your fully-fledged TAVR-AS nationwide field team and apply that team to the TAVR-AR business; is that correct?

A. Yes.

Q. Okay.

MR. LIPTON: Let's look down lower on that page, please.

BY MR. LIPTON:

Q. In the -- under clinical and medical -- do you see that? There's another bold-faced bullet that says, "Significant talent infusion necessary as very short-staffed to support ongoing clinical trials," and then it lists the number of people that work in that aspect of the business.

Do you see that, Mr. Bobo?

A. I do.

Q. And what is your reaction to that bullet?

A. Not surprised, but this is an area where we bring

tremendous capability. We've got a very large clinical, regulatory, and medical affairs team that's able to pick up trials and drive them. We've been very successful at that. And our full intention would be to leverage that team for AR.

Q. And does Edwards have the resources and the personnel to solve the shortcomings that were identified by Mr. Kilcoyne in that meeting?

A. Yes.

Q. I'd like to talk a little bit about the resources that you have allocated to integrate and run the JenaValve business, if you're able to close the transaction. What have you done at Edwards to make sure you're ready to integrate the JenaValve business if you get the green light to close this deal?

A. So coming off the diligence that we had concluded in mid-2024, as I've previously discussed, that really gives us a very helpful roadmap of what we should prioritize in integration and where they need teams. So while we haven't been able to get updated on all that confidential information, we've done this enough to have a pretty good idea of what we -- where we're going to be directly connecting to our organization. Clinical and regulatory, that's an easy connection to our TAVR clinical and regulatory team. They have the ARTIST trial that's

underway. We think it's a very interesting trial. We would come alongside, bring resources to it to make sure that got supported and accelerated.

On the R&D front, we've got an established R&D team, a very large R&D team we've already identified, and would target resources that we have today to come alongside JenaValve and make sure that any of the R&D work that needed to be completed to get FDA approval, for example, that we brought those resources to bear.

As it relates to commercial, they don't have a big team. We have a big team. We would go through a planning exercise to get the team trained and in a position to commercialize.

As it relates to manufacturing and quality, we do have a team that we've identified with leaders and with individuals that are subject matter experts that we would immediately bring in to Leeds and Irvine. We would update our understanding of their -- the progress they have made, plus or minus, and we would immediately deploy a prioritized set of investments to begin strengthening and scaling those plants, Leeds and Irvine, to be able to support a commercial organization. We would have a leader -- integration leader. This would be something we would look at every month. And this is something that we'd have high expectations that the team brings up and is executing on very quickly, with the

goal of getting this therapy to patients.

Q. Now, the -- you mentioned the word "investments" in there and it sounds like all of these things take money. Is there money set aside for the JenaValve project for when you're able to close the transaction?

A. There is.

MR. LIPTON: Let's introduce D-X-252, please, if we could, Mr. McCloud. Thank you.

BY MR. LIPTON:

Q. And this is one it may help to look at the binder because a lot of this is redacted. So 252. It should be toward the back. And please take a look at the cover email and then the first page of the PowerPoint, Mr. Bobo. And my first question will be: Do you recognize this document?

A. I do.

Q. And what is this?

A. This is a memo. The first one is from Robert Cook who's in our FP&A team, to Bernard, Scott, myself, and Mark Wilterding, with some thoughts around strategic plan wrap-up and financials, with an attachment. And then a follow-up meeting -- memo from Bernard, our CEO, wanting us to summarize our strategy work in June with, kind of, a few bullet points highlighting the outcome of that strategy work in June as it relates to the broader Edwards.

Q. And this document, the PowerPoint, is this created as

part of your strategic planning process?
A. Yes.
Q. And if we look at Page 6 of the -- using the numbers in the bottom center of the page, and without talking about the specific numbers on here, what is this page showing, Mr. Bobo?
A. This page shows spending considerations. And, look, when you go through any planning process in a company, you, you know, it ends up being a little bit of a learning process. You've got, how are we doing in 2025 from a -- against our 2025 plans? What do each of the programs need -- the strategic priorities need for '26? What's changed? Our business is dynamic enough where we get changes. Sometimes timelines move out. Sometimes they move in. Sometime regulatory approvals come early; sometimes they come late. So we spend time looking at all of that. And this lays out on this particular slide spending considerations by each of the major areas of what did the original submission input for numbers, what's the growth rate, how do we think those should be sharpened or fine-tuned? Leading to what we call a second submission.
Q. And, ultimately, does a budget for the company come out of this process?
A. It does. These numbers and this process in June, we continue to refine, and then in early November we actually

finalize the budget for 2026. And in my experience at Edwards, our 2026 budget in November that's set faithfully follows the priorities on this page, although some of the numbers move up or down a little bit, depending on the specifics at that point in time.

Q. Okay. So actually, at Edwards, the money that you spend on your business unit comes -- is based on the budgeting that you do through this process; is that correct?

A. Yes.

Q. Okay. At the top -- let me ask also, the numbers that come in on this slide, do they come -- is there input from the business units and the business areas that comes into these numbers? Or how to these numbers --

A. These are -- these come in from the business units, the functions, and the regions. These are their numbers.

Q. Okay. So they request the money that they'll need to run -- to run the projects; correct?

A. Right. They say, for me to execute this strategy, here's the money I think I need.

Q. Okay. Thank you. So at the top of this on the second line, we see TAVR aortic regurgitation, OpEx, JC Medical. Without telling me the numbers, what does that line represent?

A. That represents the dollars that we would pencil in for JC Medical in 2026.

Q. Okay. And so if we look over at the -- to the right in that row, without telling me the number, what does that number represent?

A. That represents the operating expense, OpEx, so CapEx would be in addition. We don't spend a lot of time on CapEx because we have a lot of that bandwidth. But this is the operating spending that would be used for JC Medical in 2026 to fund R&D, the clinical trial, any manufacturing, quality, regulatory activities needed to support those objectives.

Q. Okay. And if we look down at the bottom of the page, the second to last row says, "AR initiative."

What does that line represent?

A. That line represents a placeholder for JenaValve, assuming we close.

Q. Okay. And in that row, there are three numbers. There's a number on the cell furthest to the left; then there's a number in parentheses; and then there's a number to the right. I don't want you to say the numbers out loud. But what do those numbers represent?

A. So the number on the left in this particular case was, kind of, an initial approximation from our finance planning, FP&A team. The number in the middle is an adjustment that we applied. And the number on the right is the number that's in the strategic plan. And, in fact, it's the number that's in the operating plan, having come out of that

process a couple of weeks ago for 2026.
Q. Okay. And is that money today actually allocated -- is that money actually given over to the business today?
A. It's not. We keep it at corporate. I think -- some people have accused me of holding it. So somewhere, I've got $100 million. We keep it at corporate. And when we close, that money would, then, be allocated and given to the business to start to apply against -- to the integration plan and all the goals that we've set for that business.
Q. Okay. So it's set aside and reserved.
A. Set aside and reserved.
Q. Okay. Thank you. And what happens if the costs to run the JenaValve business exceeds what's budgeted here?
A. In -- we have pool spending that is actually in our 2026 budget. This is money that's also held at corporate, unallocated. And as projects end up with surprises or needing more investment, they come to our executive team, make the case, and we release additional money. And so the way to think about that magnitude is it's -- 30 to 40 percent of the number on the right is the kind of pool money that would be available to deal with surprises, not too dissimilar to what we did this year with JC. Budgeted, call it, 25, 30. We got surprised. We're probably going to spend another 10. It went through the same process. And we would do the same thing.

Q. Okay. And I'm not asking you to rehash everything you've told us, but broadly speaking, what will Edwards do with the money you've set aside for JenaValve if you're able to close the transaction?

A. We fully expect to spend every penny.

MR. LIPTON: Okay. Thank you, Mr. Bobo. I have nothing further.

REDIRECT EXAMINATION

BY MS. HALL:

Q. Hi, Mr. Bobo. I just wanted to go back to something you said a few minutes ago, and I'm just going to make sure I get it correctly here. I believe you were talking about the TAVR-AS sales team, and you said you would run the TAVR-AR training through the entire U.S. team, and that team would also support all the cases for aortic regurgitation; is that right?

A. Yes.

Q. So is your testimony that all of the current TAVR-AS sales team will be used -- sorry. Will all of the TAVR-AS training team, then, be used to train on TAVR-AR?

A. Yes, and, maybe, just a little more specific. We've got clinical specialists and sales teams, and the clinical specialists are the ones in particular that would need trained [sic] on the specifics of the JenaValve AR platform. Our plans over time would be to train that team so we're

able to service accounts across the country.
Q. So your testimony is that all TAVR-AS trainers will become TAVR-AR trainers?
A. Eventually, over time, yes.
Q. Do you recall in your deposition on October 9th, 2025 -- well, let me ask it this way. How is the training team incentivized to spend their time on TAVR-AR as opposed to TAVR-AS?
A. The training team is, first of all, not commission-based, so they don't get paid on how many get sold. They get paid on delivering high-quality outcomes. Acute; right? You do the procedure. We want the device to be successfully implanted, for the patient to come out and successfully go home within a day or two. So the clinical specialist team, that is what they get measured on. That is what they run to. And so whether it's a patient that has AS or a patient with AR, they're in the hospital. Many of these clinical specialists are actually dedicated to one or two hospitals. So they're there every day. And the cases that are teed up to be done, they're there to support. And so there isn't this false dichotomy between I've got to do an AS or an AR. These cases get scheduled and they're there to support those teams.
MS. HALL: Mr. Nguyen, can you please call up Mr. Bobo's deposition from October 9th, 2025, Page 111,

starting at Line 6.

THE DEPUTY CLERK: This is to be displayed; correct?

MS. HALL: Yes.

BY MS. HALL:

Q. And, Mr. Bobo, you were under oath during your deposition?

A. Yes.

Q. You attempted to testify accurately?

A. I did.

MS. HALL: You don't have it? Well, I'll just read it, then.

BY MS. HALL:

Q. "How is the training team incentivized to spend their time on TAVR-AR as opposed to TAVR-AS?

"Typically, we're -- we will actually dedicate people to focus on AR.

"And this is an important distinction at Edwards?

"We've got this track record. You look at other companies develop -- when we bought up -- brought up a mitral tricuspid business, we didn't leverage the aortic stenosis team. We just stood up a very focused separate team because the needs were different, the patients were different, the screening was different, the imaging was different. And so as we look at the AR opportunity, this --

within TAVR, we will begin to select and specify and focus team members to go drive and implement centers to successfully do AR, so that some team, continuing to do AS -- although you can imagine, with 850 centers, we've largely -- we've largely trained -- and we've got that bolus of accounts up and successful. The patient that -- the people that are focused on AR will be sized to the ramp we expect to drive, the number of sites per month, per quarter, per year that need to be done, that will be adequately resourced, and then we'll be incentivized to bring centers so that they're certified. If we pick on Cedars-Sinai, they're certified between the two physicians. They've done enough cases to be proctored and now independent. They've got the imaging flow. So they know how to pick a patient and get the right patient into the right procedure. And now you've got a site that's up and running. When you walk away from that, whether they do five a week or two a week or ten a week, that's not part of the formula. We want them to be fully capable and trained and deliver perfect outcomes to patients, and then they move on and get the next site framed and up and running."

Do you remember that testimony?

A. I do.

Q. Okay. And, Mr. Bobo, you testified a little about a valve called CENTERA?

A. Yes.
Q. And, I believe, you -- was CENTERA in development for about eight years?
A. I'd have to go back and refresh my memory. It was in development for quite a while. Eight years feels right. Maybe longer.
Q. And that was a TAVR-AS device?
A. It was a TAVR self-expanding AS device.
Q. And the SAPIEN devices are balloon-expandable; right?
A. Yes.
Q. And you would describe CENTERA as a best-in-class product?
A. The data that was generated for CENTERA was very competitive for self-expanding valves. So by best-in-class, I presume you mean self-expanding versus balloon-expandable. That's how we use it.
Q. And some cardiologists prefer self-expanding valves for aortic stenosis patients with heavily calcified tissue because the greater force of balloon-expandable valves can cause annular rupture?
A. Some do -- some physicians do say that and do prefer it.
Q. You were asked earlier about changes that Edwards has made to the J-Valve device. The J-Valve device is manufactured in China by Genesis MedTech?
A. Currently, yes.

Q. And no changes have been made to the J-Valve valve itself that is manufactured in China by Genesis MedTech?

A. As manufactured in China, I don't believe so.

Q. Okay.

MS. HALL: I believe the other questions I have will require a sealed session, Your Honor.

THE COURT: All right. Let's seal the courtroom and we'll take a 10-minute break.

(Brief recess taken.)

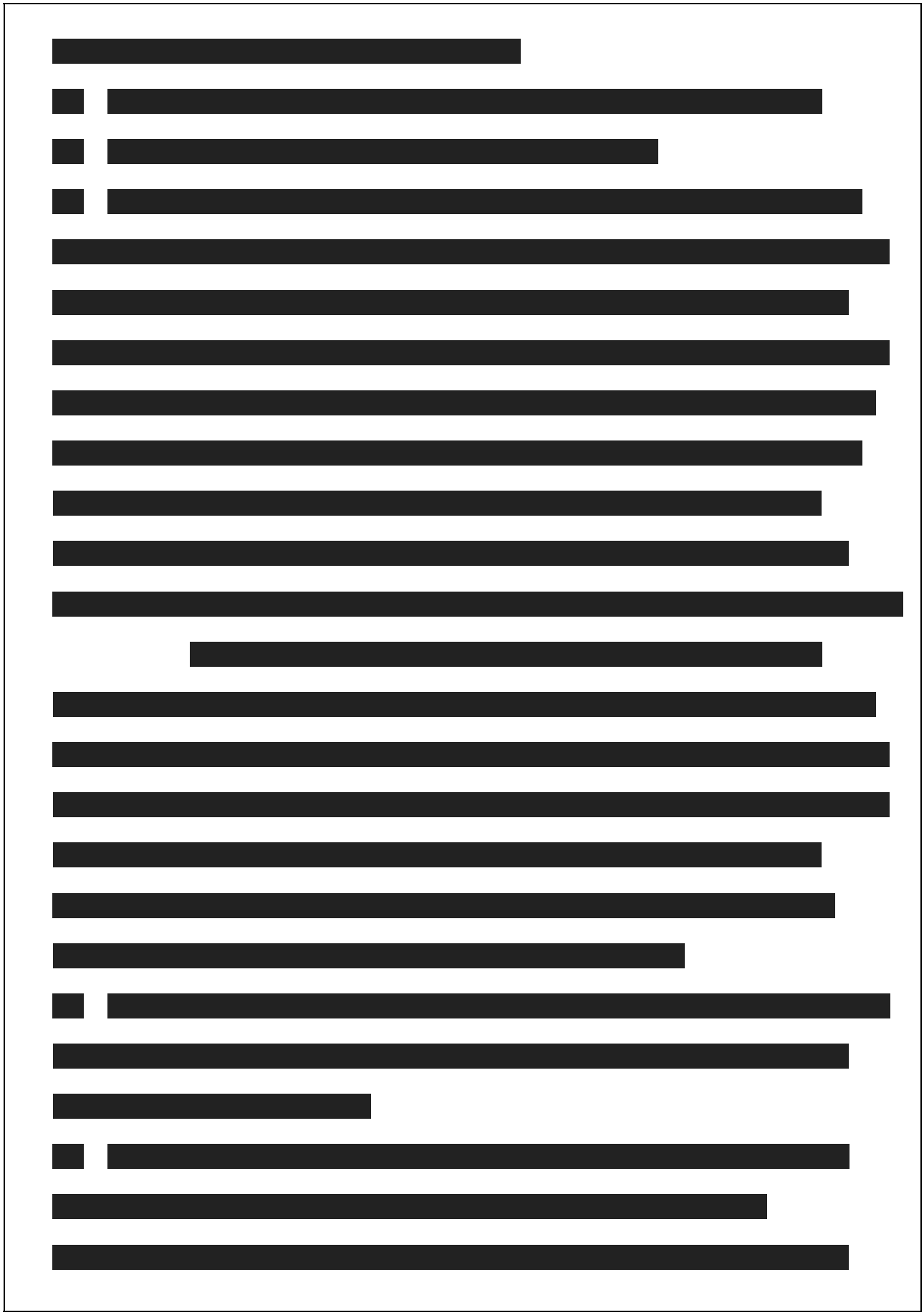
(Following proceedings under seal:)

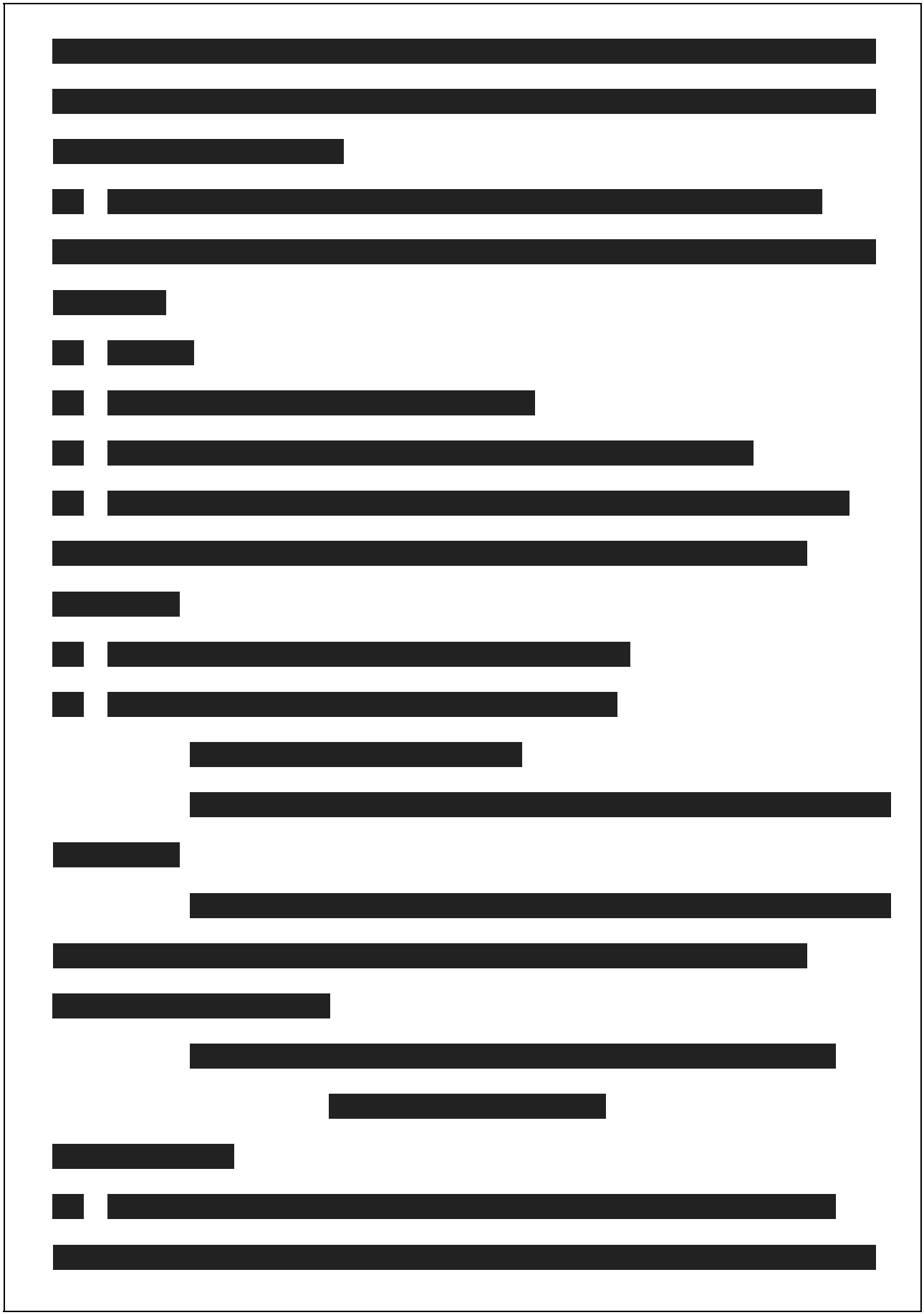
[redacted]

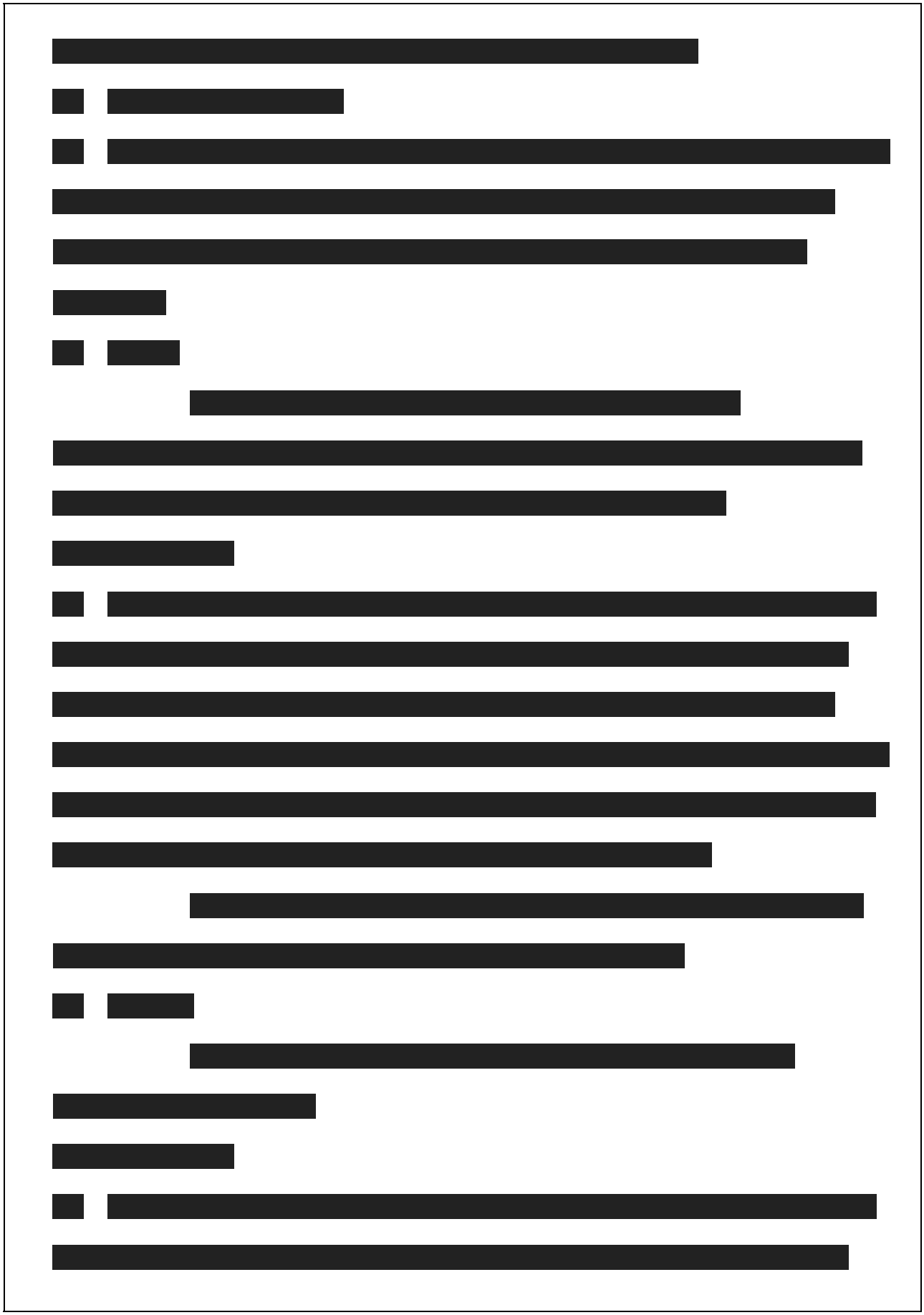














[redacted]

(Following proceedings in open court:)

MS. MCNEIL: Good morning, Your Honor. Jean McNeil for the FTC. The FTC calls Jeremy Bierman of Edwards Lifesciences.

THE COURT: Ms. McNeil, are you the same person as Betty McNeil?

MS. MCNEIL: Yes, Your Honor. Betty Jean McNeil.

THE COURT: Okay.

(Brief pause.)

JEREMY BIERMAN, WITNESS FOR THE GOVERNMENT, SWORN

DIRECT EXAMINATION

BY MS. MCNEIL:

Q. Good afternoon, Mr. Bierman. My name is Jean McNeil. I'm an attorney with the FTC. Could you please state your full name for the record.

A. Jeremy Bierman.

Q. You're employed by Edwards Lifesciences; right?

A. That's correct.

Q. You are the VP of strategy and analytics at Edwards's transcatheter heart valve business unit; correct?

A. That is correct.

Q. You advise on the price of Edwards TAVR products; right?

A. Yes.

MS. MCNEIL: Let's take a look at P-X-1394, if

Mr. Nguyen could please display it.

BY MS. MCNEIL:

Q. You sent P-X-1394 to several members of the Edwards leadership team on July 27th, 2024; right?

A. Yes.

Q. And this email is dated a few days after Edwards acquired JC Medical; right?

A. Yes.

Q. This email is also dated a few days after Edwards proposed to acquire JenaValve; correct?

A. Yes.

Q. I'd like to turn to you -- the next slide, P-X-1394. The next slide reads, "Market growth opportunity with an expansion into aortic regurgitation"; right?

A. Yes.

Q. And beginning on the left side of the slide, the slide estimates the size of the total addressable market for AR in the U.S.; right?

A. Yes.

Q. This slide estimates that there are approximately 118,000 patients in the U.S. with AR; right?

A. Yeah, that's our estimate.

Q. Okay. And I want to take a look at the right side of the slide. This slide describes JenaValve as Gen 1; right?

A. Yes.

Q. It also describes J-Valve as Gen 2; right?
A. Yes.
Q. I want to move to P-X-1394-021. This slide begins, "The due diligence readout for Project Dragon"; right?
A. Yes.
Q. And Project Dragon refers to the JC Medical transaction; right?
A. It does.
Q. I want to move to the commercial diligence summary which is at P-X-1394-035. In the upper right-hand corner, you are listed as one of the JC Medical commercial diligence team leaders; right?
A. That is correct.
Q. I want to move to the bottom row which is entitled, "Global launch strategy pricing." Do you see that?
A. I do.
Q. And this slide reads, "Opportunities: U.S. market is the priority to establish with target premium pricing for dedicated ADR TAVR product."

Do you see that?

A. I do.
Q. Okay. And because we're in a public session, I won't read the figures, but I'll direct you to your binder to P-X-1394, Page 035.
A. It was 13 what?

Q. P-X-1394.
A. And what page are we looking at?
THE COURT: 35.
BY MS. MCNEIL:
Q. Page 35.
A. Okay.
Q. Okay. And the first bullet also reflects a list ASP and a net ASP for JC Medical's TAVR-AR device; right?
A. Yes.
Q. And ASP here refers to the average sales price; right?
A. That is correct.
Q. Mr. Bierman, Edwards's commercial diligence team projected a go-to-market premium list price for JC Medical's TAVR-AR device; right?
A. Can you repeat that?
Q. Sure. The commercial diligence team that you are a part of projected a go-to-market premium list price for JC Medical's TAVR-AR device; right?
A. Well, it's not really a projection as much as it is a placeholder.
Q. Is it fair to say that at the time of the commercial diligence summary, the diligence team projected an average sales price for the JC Medical TAVR-AR device?
A. No, we modeled market size based off of a 37-5 ASP.
Q. Okay. Is your testimony that you did not project a

target premium price for JC Medical's TAVR-AR device?
A. At this moment, when this was created, we had not defined what the go-to-market list price would be.
Q. Okay. Mr. Bierman, you testified in a deposition on October 1st, 2025; right?
A. Sounds right.
Q. You were under oath during that testimony?
A. Yes.
Q. You were represented by counsel during that testimony?
A. Yes.
Q. I'd like to point you to your deposition at Page 207, Lines 14 through 17. During your deposition, you were asked, "And what does target premium pricing refer to?"
Answer: "It refers to the price that we would be setting our list price at, go-to-market price at."
Did I read that right?
A. Which line is it?
Q. Lines 14 through 17.
A. Yeah, that's how it reads.
Q. Okay. Edwards's commercial diligence team also projected a net ASP for JC Medical's TAVR-AR device; right?
A. Yes.
Q. And the net ASP refers to the projected average sales price after rebates are applied; right?
A. That is correct.

Q. I want to move to P-X-1394-053 which is the Project Jupiter diligence readout. Project Jupiter refers to Edwards's proposed acquisition of JenaValve; right?
A. That is correct.
Q. And I want to take a look at the commercial diligence summary for JenaValve which is at P-X-1394-072. In the upper right-hand corner, you are listed as one of the JenaValve commercial diligence leaders; right?
A. That is correct.
Q. Okay. And, again, I want to take a look at the bottom row titled, "Global launch strategy pricing." The first bullet here also reads, "Opportunities: Establish TAVR therapy for AR in the U.S. with target premium pricing for dedicated AR TAVR product"; right?
A. Yes.
Q. And the bullet also goes on to reflect a list ASP and a net ASP; right?
A. Correct.
Q. Edwards's commercial diligence team projected a go-to-market premium list price for JenaValve's TAVR-AR device; right?
A. Yeah, we modeled a list price shown there.
Q. Okay. And Edwards's commercial diligence team also projected a net ASP for JenaValve's TAVR-AR device; right?
A. Correct.

Q. Okay. And the go-to-market premium list price for JenaValve's TAVR-AR device price is the same go-to-market premium list price for JC Medical; right?

A. Correct.

Q. I want to take a look at another document, which is P-X-1391. You sent P-X-1391 to your boss, Pooja Sharma. Do you see that?

A. Yes.

Q. And I want to begin with the first talking point. You write, "Announced acquisition of JC Medical and intent to acquire JenaValve."

Did I read that right?

A. Yes.

Q. And in the second talking point, you write, "Both companies have technology focused on AR that are key to Edwards being first to market within the U.S. and lead the space well into the future with revolutionary next gen platforms."

Do you see that?

A. I do.

Q. "Both companies" refers to JC Medical and JenaValve; right?

A. Correct.

Q. And your talking points anticipate JenaValve would be key to Edwards being first to market within the U.S.; right?

A. Yeah, at that time, that's what we believed.
Q. Okay. I want to take a look at another document which is marked P-X-1390. You also sent P-X-1390 to your boss, Mrs. Sharma; right?
A. Correct.
Q. And I want to begin with the email dated July 20th, 2024, and I want to take a look at the second U.S. sale FAQ. Do you see that?
A. Yes.
Q. The question is, "When will we launch our AR platform?" Right?
A. Yes.
Q. Okay. And I want to take a look at specifically at the third line down in your answer. You write, "Our primary focus is getting the platform approved for commercial use in the U.S., targeting Q1 2026"; right?
A. Yes.
Q. And that refers to the JenaValve platform, right?
A. Correct.
Q. And then the next sentence you write, "The JC Medical platform is a future generation technology with some really promising IP"; right?
A. Correct.
Q. In July 2024, the expectation was that the JC Medical platform was the future generation AR technology; right?

A. It was intended to be a part of our future generation platforms.
Q. Okay. But this sentence specifically refers to JC Medical's platform as the future generation technology; right?
A. Yeah.
Q. I want to move down to the next FAQ. The question is, "What has the feedback been from customers on both platforms"? Right?
A. Yes.
Q. And "both platforms" here refers to JC Medical and JenaValve; right?
A. That is correct.
Q. I want to move down to the answer. You write, "We're in a situation where we are feeding the starving, so to speak"; right?
A. Right.
Q. And "we're" here refers to Edwards; is that right?
A. That's correct.
Q. And the phrase "feeding the starving" means there are a lack of treatment alternatives for AR patients; right?
A. That is correct.
Q. And your message goes on, "There is no alternative to surgery for these patients. So relative to that, it's amazing"; right?

A. Correct.
Q. Mr. Bierman, if JenaValve commercialized Trilogy, Edwards's Sojourn would compete with Trilogy in the TAVR-AR space; right?
A. Assuming that this acquisition doesn't go through?
Q. Yes. If the acquisition does not close and JenaValve commercializes Trilogy, Edwards's Sojourn would compete with Trilogy in the TAVR-AR space; right?
A. Yeah, if JenaValve was able to successfully achieve FDA approval, which is a big question mark, then we would be competing with JenaValve if this doesn't go through.
Q. Okay. So by owning JenaValve and JC Medical, Edwards anticipates being the only TAVR-AR provider in the U.S. for a period of time; right?
A. If Edwards -- if this transaction goes through and Edwards is first to market, by definition, there will be a period of time, whether it's a day or measured in years, where we will be the only player in this space.
Q. Okay. And by owning JenaValve and JC Medical, Edwards anticipates not having to deal with a low-cost TAVR-AR alternative in the market; right?
A. Not indefinitely.
Q. During the period in which Edwards owns both JC and JenaValve and there's not another alternative, Edwards would not be dealing with a low-cost alternative; right?

A. We wouldn't be dealing with any alternative if we were the only player in this space.
Q. Let's take a look at another document, which is P-X-1016. This is an email from you to Mrs. Sharma on November 4th, 2024. In the email, you listed several topics for an Edwards December 2024 strategic off-site. Do you see that?
A. I do.
Q. And in addition to the specific topics, you listed the strategic focus and questions for each topic in that middle column. Do you see that?
A. I do.
Q. I'm going to move down to the last row in the chart where you listed AR as a top topic for the December off-site. Do you see that?
A. I do.
Q. And here, you proposed three strategic focus questions for AR. Do you see that?
A. I do.
Q. And the second strategic focus says "If JV acquisition success, what is our commercial strategy?"
Do you see that?
A. Yes.
Q. And JV here refers to JenaValve; right?
A. That's correct.

Q. The third question posed reads, "If JV acquisition fails, how do we accelerate JC commercialization?"

Do you see that?

A. I do.

Q. And JC refers to JC Medical, right?

A. Correct.

Q. If the JenaValve transaction fails to close, Edwards will be asking itself how best to accelerate JC Medical; right?

A. Correct.

Q. And if the transaction fails to close, Edwards will be moving as quickly as possible to commercialize an AR TAVR device; right?

A. We are moving as quickly as possible to commercialize an AR device. Anytime something changes -- and this would be a significant change -- we're going to evaluate all of our programs and ask ourselves, is there something that we can do to accelerate or close the gap on any time lost?

Q. But specifically, if the acquisition fails, Edwards will be moving as quickly as possible to commercialize its own AR TAVR device; right?

A. We're moving as quickly as we can today.

Q. Let's take a look at P-X-1389. And I want to begin with the email in the center of the page that's dated August 11th, 2025. And I want to specifically take a look

at the fourth bullet where you write, "I added a placeholder slide after JOURNEY and Sojourn overview to address how we are looking to accelerate Sojourn post FTC decision."

Do you see that?

A. I do.

Q. And post FTC decision refers to the FTC's complaint to stop Edwards's proposed acquisition of JenaValve; right?

A. Correct.

Q. Mr. Bierman, Edwards does not have access to JenaValve's current business plan; right?

A. Correct.

Q. Edwards does not know what it will take to properly resource the JenaValve TAVR-AR device from a commercial standpoint; right?

A. Correct.

Q. Edwards does not know how many commercial employees are needed to launch Trilogy in the U.S.; right?

A. Correct.

Q. Edwards does not have access to JenaValve's current information that it would need to combine that technology with JC Medical; right?

A. Correct.

Q. And, to your knowledge, it will -- it is undetermined whether Edwards will continue to work on Trilogy's large valve program; right?

A. That hasn't been determined yet.
Q. Okay.
MS. MCNEIL: Your Honor, no other questions.
THE COURT: Thank you.
MR. COATE: May I proceed, Your Honor?
THE COURT: You may.
CROSS-EXAMINATION
BY MR. COATE:
Q. Good morning -- or almost afternoon now, Mr. Bierman. How are you feeling?
A. I'm doing well. Thanks.
Q. I appreciate you being here. Where are you from?
A. Southern California.
Q. And where did you go to school?
A. I went to the University of San Diego for undergrad and I went Concordia University for my master's.
Q. And when did you start working at Edwards?
A. I started working at Edwards in 2012.
Q. And what was your first role there?
A. Yeah, I started in our surgical valve division in an upstream marketing capacity; then transitioned over to our transcatheter heart valve division where I led our U.S. business operations for about seven years, and in the last year-and-a-half, I've led strategy and analytics.
Q. And as the leader for strategy and analytics, just for

the Court at a high level, what are your responsibilities?

A. Yeah. Breaks into three pillars. First pillar focuses more on long-term portfolio strategy and strategic communication, which includes communications for our Board of Directors, our executive team, the investor community.

Second pillar focuses more on near-term commercial strategy.

And the third pillar focuses more on business analytics, market-level insights.

Q. Okay. I'm going to go ahead and shift topics now, Mr. Bierman. The FTC just finished asking you some questions about integration efforts. Do you remember that?

A. I do.

Q. We'll move through these quickly. But just to clarify, does Edwards have access to JenaValve's current clinical data right now?

A. No.

Q. Do you have access to their current plans for future commercialization?

A. No.

Q. What about their current manufacturing data?

A. No.

Q. Does JenaValve have FDA approval today to sell Trilogy commercially in the United States?

A. No.

Q. Do you know why JenaValve does not yet have FDA approval?
A. No idea.
Q. Do you know when JenaValve's going to get FDA approval?
A. No idea.
Q. Are you sure that JenaValve is going to get FDA approval?
A. No idea.
Q. And so how does that uncertainty impact Edwards's ability to engage in fulsome integration planning right now?
A. We can't. It's impossible to do it without key pieces of information that we would get visibility to once the transaction closed.
Q. If the transaction closed, what would be the, kind of, first steps for integration if it went through?
A. I mean, it would be an all-hands-on-deck, sort of, exercise where we would be quickly trying to unpack what the current state of the company is in. I think one of the higher priorities would be to understand where they're at in the FDA approval process and understand, you know, what questions remain unanswered by the FDA. Could include things around manufacturing, quality, could be additional data that they need to see. We really don't know. So we'd be trying to understand what the nature of that is.
Q. Uncertainty aside, do you believe that Edwards would be

able to successfully integrate JenaValve and to improve upon Trilogy?

A. Yes. Absolutely.

Q. Why?

A. There isn't another TAVR manufacturer that exists today that has as much experience as we do. We've both manufactured, innovated a number of different generations, more than any other TAVR manufacturer in the world. If you look at the amount of data and evidence that has been generated since we've been in market, there is no other manufacturer that has come close to the same amount of evidence. And if you look at the number of patients that have been treated with our platform, we're at over a million patients treated globally today with our transcatheter aortic valve replacement platform.

Q. And so do you believe that that experience in TAVR-AS, which is a term the Court's heard a lot about so far, would assist Edwards in innovating on Trilogy as a TAVR-AR product?

A. Yes.

Q. Let's talk about Edwards's experience with TAVR-AS. I'd like to pull up D-X-0191. Okay. And looking at the second -- you have a binder in front of you, but I think everything should be on the screen and we're not going to get into anything confidential. So you can probably just

look at that, Mr. Bierman.

A. Perfect.

Q. Looking down at the second email, this is an email from Meredith Zia sent on January 27th, 2025, to you, on the CC line, with the subject "SLT presentations." Do you see that?

A. I do.

Q. Okay. And let's go ahead and turn to Page 2. This is the cover page of that attachment. It's entitled, "Senior leadership team meeting, January 28th, 2025." Do you see that?

A. I do.

Q. Are you familiar with this document?

A. I am.

Q. Were you involved in preparing this document?

A. Yeah, my team was.

Q. Okay. Would you have set eyes on it at some point?

A. I would have. Yes.

Q. All right. Let's go ahead and turn to Page 21. This slide is entitled, "Our investments in evidence and technology leadership have enabled TAVR growth in symptomatic severe AS to date."

Do you see that?

A. I do.

Q. There's a box at the top called "Technology evolution"?

A. Yeah.
Q. What's that depicting?
A. It's showing the five different TAVR-AS generations that we've commercialized within the U.S. and outside the U.S., as well.
Q. And without getting into any confidential information, are there additional generations that Edwards is working on right now?
A. Yeah, we're working on a couple.
Q. And do each of these generations represent a major innovation in the TAVR-AS platform?
A. Oftentimes, it represents more than one additional innovation. There's usually multiple that are involved in each generation.
Q. And why is Edwards committed to innovation in this space?
A. Our north star here is to get to zero at the end of the day.
Q. And just to explain to the Court, what do you mean by get to zero?
A. We feel that until we get to zero percent mortality, zero percent stroke, zero percent on other complications, that our job isn't done. There's more that can be done through innovation to ensure that patients get the best outcomes possible with this therapy.

Q. When Edwards first began working on a TAVR-AS device, approximately what was the mortality rate then?
A. Yeah, in some of the early human use studies, in the first handful of cases, we saw a mortality rate that was around 50 percent.
Q. Let's go ahead and turn to the next slide. The title of this is, "The Edwards TAVR platform remains highly differentiated as the best-suited technology for patients with aortic stenosis."
I had noted at the top 1 million patients treated, which, I think, you said earlier, Mr. Bierman. Looking at this chart, what is the mortality rate for TAVR-AS -- for Edwards's TAVR-AS product today?
A. Yeah, these numbers represent the results from our PARTNER 3 trial where we looked at the low-risk, severe, symptomatic aortic stenosis patient population. And at one year, you had a 99 percent survival rate.
Q. And what about at five years?
A. At five years, it was a 90 percent survival rate.
Q. And let's go back to the past slide that we were just looking at. Has the innovation that we were talking about in this top box -- has that been the cause of this dramatic reducing in mortality rate from 50 percent at the beginning to now approximately 1 percent now?
A. Yes.

Q. And looking at the bottom chart, it says, "17 years of partner trials." What's this showing?
A. This is showing all of the different clinical trials that we've ran, focused on different patient populations, and it's stratified by surgical risk. And it's just showing which trials were conducted over the years that focused on which patient population.
Q. And through these clinical trials, has Edwards been able to expand the patient populations that it can treat?
A. Absolutely.
Q. And looking at the title of this slide again, it notes that "Investments in evidence and technology leadership have enabled TAVR growth."
What's TAVR growth referring to?
A. The growth of the TAVR market.
Q. And how does the innovation and this expansion in patient indications play into growing the TAVR market?
A. Well, the trials themselves allowed us to generate the evidence in order to get the indications needed in order to make this therapy available to more patients, and the results that came out of those trials wouldn't have been possible without the outcomes that were made possible by the innovations in our later generation valves.
Q. Okay. Thank you, Mr. Bierman.
MR. COATE: You can take that slide down -- or

that document down.

BY MR. COATE:

Q. I'd like to pull up P-X-1390 which is a document that the FTC just asked you about.

A. Okay.

Q. All right. And counsel asked you about this U.S. field FAQ. Do you remember that?

A. Yes.

Q. And let's go down to the second set of Q&A that you drafted. Do you see that?

A. Yes.

Q. And was this the final version or was this a draft?

A. This was a draft.

Q. Okay. Let's take a look at the language that counsel asked you about, because I just want to make sure we have a clean record. The sentence reads, "Our primary focus" -- after the redacted portion, the sentence reads, "Our primary focus is getting the platform approved for commercial use in the U.S., targeting Q1 2026." And the next sentence reads, "The JC Medical platform is a future generation technology with some really promising IP."

Do you see that?

A. I do.

Q. It reads, "A future generation technology," right, Mr. Bierman?

A. It does.
Q. It doesn't say the future generation technology?
A. Correct.
Q. When you prepared this, were you indicating that you had already decided that JC Medical would be the future generation technology?
A. No, there's no way to anticipate what the scope of a future generation device is going to be without learning from previous generation devices.
Q. And looking at this FAQ and the other documents that you were shown, is Edwards's plan to proceed with both of these technologies if the acquisition goes through?
A. That's correct.
Q. You can set that one aside.
MR. COATE: Let's pull up P-X-1453. The cover email is an email from Meredith Zia sent on June 25th, 2024 to Pooja Sharma and Jeremy Bierman.
BY MR. COATE:
Q. Do you see that?
A. Yes.
Q. That's you?
A. Yes.
Q. The subject is, "Diligence summary for review, Friday a.m. read-out." Do you see that?
A. I do.

Q. Suggesting maybe this went through some versions?
A. Say that again.
Q. This, maybe, went through some different versions?
A. Yeah. Yeah, it did.
Q. The attachments are Project Dragon diligence report. Do you see that?
A. I do.
Q. What does Project Dragon refer to?
A. Project Dragon refers to the diligence that was done on the JC Medical company.
Q. And the next attachment is Project Jupiter P-2 diligence report. Do you see that?
A. I do.
Q. And what does Project Jupiter refer to?
A. Project Jupiter refers to the JenaValve company acquisition project.
Q. Let's go to the second sentence in the email. It reads, "Since these are separate for Jupiter and Dragon, I've been given guidance to share strengths versus weaknesses instead of an H2H comparison."

Do you see that?

A. I do.
Q. And how do you understand a strengths-versus-weaknesses comparison to differ from an H2H comparison in this context?
A. Yeah, in this example in the sentence, what we're doing

is we're making sure that we are assessing both projects on their own merits. So we're going to look at them individually. We're going to look at the pros and cons, where there's risks, where there are opportunities that we've identified within each. The purpose of the exercise wasn't to compare one versus the other and try to come up with which one might be better.

Q. And so your team assessed each of these transactions independently in preparing the due diligence?

A. That's correct.

Q. Now, Mr. Bierman, during opening arguments, the FTC suggested that, maybe, this email had been prepared and, maybe, the diligence had been prepared in anticipation of an FTC investigation. Looking at the date of this of June 25th, 2024, can you speak to that?

A. At this moment in time -- right? -- first half of 2024, I didn't even know what the FTC was.

Q. Okay.

MR. COATE: We can go ahead and turn to Page 7.

BY MR. COATE:

Q. This is an attachment to the email. It's entitled, "Project Jupiter P-2 diligence read-out, June 28th, 2024." Do you see that?

A. I do.

Q. And let's take a look at Page 9. And you'll recall,

Mr. Bierman, that you were asked about a version of this slide during the FTC's examination. Do you remember that?
A. Correct.
Q. The title of this is, "Commercial diligence summary." Is this a read-out for the Jupiter, or JenaValve, transaction?
A. It is.
Q. Let's look at the bottom row which is global launch strategy and pricing. And then in the key issues and findings, there's a set of opportunities and a set of challenges. Do you see that?
A. I see it.
Q. And one of the opportunities identified is to establish TAVR therapy for AR in the U.S., with target premium pricing for dedicated AR TAVR product, 37.5,000 list ASP. Do you see that?
A. I do.
Q. You were asked about that during the FTC's examination?
A. Yes.
Q. At this time, in June 2024, had your team conducted a comprehensive pricing analysis to determine what the price of Trilogy should actually be?
A. No.
Q. What would a comprehensive pricing analysis by your team look like?

A. Yeah. It would be quite extensive. I mean, it would involve knowing what the commercialized product is so that we can understand the features and the benefits to both patients as well as hospitals. It would have involved a pricing elasticity study. And it would have involved extensive voice-of-customer research in order to understand what we would go to market with in terms of a list price.

Q. And was your team able to do that here?

A. No, we wouldn't have done that here.

Q. So how did you arrive at 37,500?

A. It was rather unsophisticated. We basically chose the middle point between what our list price for the latest generation TAVR-AS device was, which was at $34,000, and what our pulmonic platform device was going for, which was $41,000.

Q. And so 37.5 was just in the middle of those two numbers?

A. It's smack dab in the middle of those two numbers.

Q. Fair to say this is a placeholder?

A. Yeah, for modeling purposes only.

Q. I want to turn away from this document for just a moment and pull up your deposition transcript just to clarify something that happened during examination.

MR. COATE: Can we go to page 207?

BY MR. COATE:

Q. Do you recall that counsel asked you about this page of

your deposition during the examination?
A. Yes.
Q. And it was on the topic of this list price?
A. It was.
Q. Counsel asked you about page 207, but she didn't ask you about page 208. Let's go to 208.
The question was "Let's begin with the list price."
And you answered "It was more of an assumption."
Do you see that?
A. I do.
Q. And is that what you were just testifying to here, is that this was an assumed price picked as a middle number between two others?
A. That's correct.
Q. Okay. Let's go back to the exhibit we were looking at. All right. So we've talked about the opportunities. There's also a set of challenges. Do you see that?
A. I do.
Q. And going to the second clause past the semicolon, one of the challenges your team identified is a COGS reduction. What does "COGS" stand for?
A. Cost of goods sold.
Q. Why was your team noting that one of the challenges would be reducing the cost of goods sold for JenaValve?

A. Because at the time that we did the diligence, their cost of goods sold were astronomical.

Q. And moving to the next part of that phrase, it says, "And optimization to scale needed."

Do you see that?

A. Yes.

Q. And what was this referring to?

A. Their ability to scale and more specifically -- their ability to manufacture enough devices to meet demand forecasts that they had set out. I believe at the time they had a yield, which is the percent of total product manufactured that can actually be used that was somewhere around 50 percent.

Q. And is that low, Mr. Bierman?

A. It's a poor yield.

Q. At this time, while you were doing due diligence, did JenaValve provide you with forecasts about how it was going to perform in the future?

A. Yes, they provided -- we requested a number of documents. In addition to that, we had multiple conversations with their chief commercial officer.

Q. Did you believe that their forecasts were realistic considering the cost of goods issue and the scalability issue?

A. No, that was one of the big gaps that we couldn't

reconcile, even after they provided all the documentation that they had and we had all the conversations that we had. There was a significant gap between how much they were forecasting that they were going to sell and what their ability to actually manufacture was, and we couldn't explain how that gap was going to be filled, and neither could they.

Q. And how would you describe JenaValve's forecasts for the rate at which its sales were going to grow?

A. They were steep. They were ambitious in their sales forecasts into the future.

Q. Did that surprise you?

A. Not really.

Q. Why not?

A. It's something that you typically see when you're working with startups. They want to make sure that their company that they're selling is going to be valued as high as possible, and one way to do that is to paint a very rosy picture on what your future sales are going to be.

Q. And have you worked on other acquisitions of startups at Edwards?

A. Yes.

Q. Okay. I want to shift to a new topic. Does your team -- well, to begin, do you remember that the FTC asked you some questions about who might end up in the market, and at what point in time, for TAVR-AR?

A. Yes.
Q. Does your team track the competitive landscape for TAVR-AR?
A. Yes.
Q. How does your team go about doing that?
A. There's a number of ways that we do it. Mostly, we learn -- we learn quite a bit from medical conferences that we're attending. You'll have different companies that will present on early human use or early feasibility studies that they're conducting and what the results of those studies are. We'll also take a look at what clinical trials have been started, which are published on government websites. And then another thing that you can look at are patents that are being filed as a way of getting clues of what types of technologies different companies are looking to develop.
Q. And does your team create reports or presentations about these -- this competitive landscape?
A. Yes.
Q. Does it do that periodically?
A. Very regularly.
MR. COATE: Let's pull up D-X-0197.
BY MR. COATE:
Q. At the top, this is an email from Meredith Zia sent on February 14th, 2025, to you, among others. Do you see that?
A. Yes.

Q. The subject is regarding strategic portfolio and program review. Do you see that?
A. Yes.
Q. Let's turn to Page 2. This is the title of the attachment. It's SPPR portfolio packet, February 12th, 2025. Mr. Bierman, what does "SPPR" stand for?
A. Strategic portfolio and program review.
Q. All right. And are you familiar with this document?
A. I am.
Q. Is your team involved in preparing it?
A. They are.
Q. And updating it from time to time?
A. Yes.
Q. Let's turn to Page 15. The title of this slide is, "Competitive landscape: TAVR aortic regurgitation." Do you see that?
A. Yes.
Q. What's this competitive landscape showing?
A. It's showing a number of different TAVR aortic regurgitation devices that are in process of being commercialized, or are commercial, in various markets by various manufacturers.
Q. Is this an exhaustive list of every company in the world potentially working on a TAVR-AR device?
A. No, that's not possible.

Q. Could companies be working on TAVR-AR devices without you knowing?
A. Absolutely.
Q. Without getting into any confidential information, is Edwards working on devices that the public doesn't yet know about?
A. Yes.
Q. Let's look at the third column which refers to a company called Jenscare. Where is Jenscare located?
A. China.
Q. And they're working on a device called Ken-Valve?
A. Yes.
Q. Let's go down to the third row which refers to the China region. It says, "Approval estimated," and it has a picture of a device. Do you see that?
A. I do.
Q. Does Jenscare have a commercially approved TAVR-AR device in China?
A. They do.
Q. Did that happen earlier this year?
A. It did.
Q. And if we go up to the top row, still in the Jenscare column, this refers to the U.S. region, and it says, "Entry anticipated: TBD."
Do you see that?

A. I do.
Q. Why did your team anticipate that Jenscare was going to enter the United States with a TAVR-AR device at some point?
A. Because they've already shown that they can enter the U.S. market with a transcatheter valve replacement device.
Q. Okay. Well, let's explain that for the Court. So Jenscare currently has a transcatheter valve replacement device; is that what you're saying?
A. Yes.
Q. And is that for the aortic valve?
A. No, it's for the tricuspid valve.
Q. Okay. So it's a transcatheter device, but it's for a different valve on the heart?
A. That's correct.
Q. But it still is a valve replacement device?
A. That is correct.
Q. And you were saying that they already are engaged in an early feasibility study in the U.S.?
A. Yeah, they've announced that they've completed enrollment of their early feasibility study in the U.S. and that they have received reimbursement from Center of Medicare and Medicaid Services for those procedures.
Q. Why is it important to your team that Jenscare has been able to secure reimbursement from CMS?
A. It shows that they're very serious about entering into

the United States market because they have gone through the effort of figuring out how to navigate the regulatory and reimbursement policy landscape or environment so that they can bring a device to market.

Q. And so your team is anticipating their entry into the United States with a TAVR-AR device?

A. Yeah, I don't know why you wouldn't bring a device into the market if you know how to get through all of the regulatory hurdles that you would need to get through in order to bring a device to the U.S. market.

Q. Let's move over to the next device indicated in the U.S. row. Are you familiar with Laguna Tech?

A. Yes.

Q. Where are they located?

A. In the United States.

Q. And are they working on a TAVR-AR device?

A. They are.

Q. And your team is noting that they have planned for an early feasibility study in the U.S.?

A. That is correct.

Q. Okay. Let's take a look at the last company identified in the U.S. row. It's a company called Cuspa, C-U-S-P-A, and it has a device called Cusper. Do you see that?

A. I do.

Q. Now, it notes here that this device is a valve repair

device. Do you see that?
A. I do.
Q. What does that mean?
A. So with all devices that are on this slide, the vast majority of them are valve replacement devices. So this is where you're taking a bio-prosthetic valve and you're replacing the native valve in order to restore heart function. With this valve repair device, what it does is it is used to modify the native valve and restore functionality to the native valve in order to restore heart function.
Q. Would Cusper be a transcatheter device?
A. It would.
Q. And would it treat aortic regurgitation?
A. That's the plan, yes.
Q. And your team is noting that they have a planned pivotal study in the United States. Do you see that?
A. That's correct.
Q. Why is your team reporting that out?
A. Because Cuspa had announced that at medical conventions that we've been at.
Q. And what's the most up-to-date intel that you have on the status of that?
A. My understanding is that they are delayed, but they still intend on doing that. That was as of EuroPCR in May of this year.

Q. Okay.

MR. COATE: Let's go ahead and zoom out here.

BY MR. COATE:

Q. Taking a look at the competitive landscape, does your team only track devices in the United States?

A. No.

Q. Does your team only track devices that are already in a pivotal trial?

A. No.

Q. Does your team only track devices that are already in an early feasibility study?

A. No.

Q. And why is it important for your team to track everyone in the competitive landscape?

A. Yeah -- at the end of the day, we can't rest on our laurels. We've got to be up to speed on everything that's being worked on in the spaces that we're looking to have an impact. And it's important that we're not surprised by anything.

Q. And if Edwards is successful in commercializing a TAVR-AR device in the United States, are you and your team anticipating competitors?

A. Absolutely.

Q. Looking at this slide, are Edwards and JenaValve the only companies working on a TAVR-AR device?

A. No.

MR. COATE: No further questions. Thank you, Mr. Bierman.

REDIRECT EXAMINATION

BY MS. MCNEIL:

Q. Mr. Bierman, I want to return to -- I'm going to try to work my way backwards with the questions. So I'm going to return to the last document you were taking a look at, which is Defense Exhibit-0197. You took a look at Page 15 that depicts the competitive landscape. Do you remember that?

A. Yes.

Q. And, first, this slide deck was prepared in February of 2025; right?

A. Is there -- yep, looks like it was updated February 6th, 2025.

Q. And that was during the pendency of the FTC's investigation; right?

A. Say that again.

Q. That was during the pendency of the FTC's investigation; right?

A. I don't know what that means, the appendice [sic].

Q. That was during the FTC's investigation of Edwards's proposed acquisition of JenaValve; right?

A. Okay. Sounds right.

Q. Okay. And I want to start with the competitive

landscape. And I want to focus specifically on the U.S. row. Do you see that row?

A. I do.

Q. Okay. And you discussed Jenscare; is that right?

A. Yes.

Q. And it says, "Entry anticipated: TBD"; right?

A. That's right.

Q. It does not outline a pivotal study; right?

A. It doesn't.

Q. It does not outline an EFS study; right?

A. It doesn't.

Q. Okay. And I want to move over to Cuspa. Do you see that?

A. I do.

Q. And that is a valve replace system; right?

A. It's a valve repair system.

Q. Valve repair. And that differs from TAVR; right?

A. It does.

Q. Okay. And then I believe you were asked specifically about scaling JenaValve; right?

A. Yes.

Q. I want to turn to P-X-1394-006. We took a look at the document at the beginning of the testimony today. And I want to move to P-X-1394-006. And this slide is titled, "Our strategy is to be first to market in the U.S. and lead

therapy for AR patients globally through a robust future portfolio." Do you see that?

A. I do.

Q. And there's discussion on this slide of the JenaValve device. Do you see that?

A. Yes.

Q. Okay. And there's discussion of the J-Valve device. Do you see that?

A. I do.

Q. But I want to specifically focus on the key risks. Do you see that? On the --

A. Yes.

Q. -- right side of the slide. And one of key risks was Edwards's inability to scale manufacturing; right?

A. It says inability to scale manufacturing. But I don't know if it was in reference to Edwards.

Q. This is an Edwards slide presentation; right?

A. It is. Can you pull down the blow-up?

Q. Sure.

(Brief pause.)

A. Yeah, what I don't know is if we're highlighting risks that have been identified through the diligence process at this point.

Q. Okay. Is it fair to say that one of the key risks identified on this slide is the inability to scale

manufacturing?

A. That is highlighted as a key risk.

Q. Okay. And I believe you also discussed the assumptions around the pricing of the JenaValve and the JC Medical TAVR-AR device; right?

A. Correct.

Q. And you called it just an assumption; is that right?

A. Correct.

Q. I want to move to P-X-1390-009. And I want to take a look at the second Q&A. The question is, "What will the pricing strategy for the AR platform be?"

Do you see that?

A. I do.

Q. And it says, "We are still figuring out those details. I would anticipate the list price to be" -- and then there's a redaction portion. But it goes on, "We are first to market and we have one shot at setting the bar on commercial price. We know that once the bar is set, it is really hard to raise it."

Do you see that?

A. I do.

Q. And it goes on, "But similar to when we launched SAPIEN in the U.S., we are going to have a period of time where it is only Edwards playing in this space and we aren't going to have to deal with low-cost alternatives."

Do you see that?

A. I do.

Q. You also stated during your testimony that you believe Edwards could successfully bring JenaValve to market because of its AS experience; is that right?

A. Correct.

Q. Edwards is not the only U.S. company with AS experience; right?

A. That is correct.

Q. Medtronic has AS experience; right?

A. They do.

Q. Abbott has AS experience; right?

A. They do.

Q. Okay. And then, I believe, you also talked about the results from starting clinical trials; is that right?

A. Yes.

Q. Okay. Mr. Bierman, you are not on the R&D team, are you?

A. I am not.

Q. You are not on the regulatory team; right?

A. Correct.

Q. Okay.

MS. MCNEIL: No further questions, Your Honor.

THE COURT: Thank you.

MR. COATE: Two very brief clarifications, Your

Honor.

RECROSS-EXAMINATION

BY MR. COATE:

Q. Hello again, Mr. Bierman.

A. Hi.

Q. Can we pull up P-X-1390 which counsel was just asking you about?

And this is the page that counsel was asking you about, which is 009. Do you see that?

A. I do.

Q. Let's go to Page 2. And let's go to the same, sort of, Q&A that you had teed up. This is the -- about middle of the page that begins with, "What will the pricing strategy be for the AR platform?"

The first sentence reads, "We are still figuring out those details, and if you recall, our approach to pricing/discounting strategy on S3 UR, we likely won't have an answer for you until after we launch."

Do you see that?

A. I do.

Q. And so is it impossible at this time to set the price for a TAVR-AR device that isn't [sic] received FDA approval yet even?

A. It would be very premature.

Q. Let's take a look at D-X-0197. Let's go to the last

page where you were. Counsel asked you if the FTC had already began investigating the deal at the time that this was prepared. Do you remember that?

A. Yes.

Q. Did your team prepare this slide for the FTC?

A. No.

Q. Did you prepare it because you knew the FTC was investigating?

A. No.

MR. COATE: No further questions.

MS. MCNEIL: Nothing further, Your Honor.

THE COURT: Thank you. Thank you, Mr. Bierman.

THE WITNESS: Thank you.

(Witness steps down.)

THE COURT: Probably makes sense to break for lunch now. So come back at 1:50.

MR. SHORES: Thank you.

(Luncheon recess taken at 12:50 p.m.)

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CERTIFICATE OF OFFICIAL COURT REPORTER

I, TIMOTHY R. MILLER, RPR, CRR, NJ-CCR, do hereby certify that the above and foregoing constitutes a true and accurate transcript of my stenographic notes and is a full, true and complete transcript of the proceedings to the best of my ability, dated this 20th day of November 2025.

/s/Timothy R. Miller, RPR, CRR, NJ-CCR
Official Court Reporter
United States Courthouse
Room 6722
333 Constitution Avenue, NW
Washington, DC 20001

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