HD **Q2 2022 Silk Road Medical Inc Earnings Call - Final**

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Presentation

OPERATOR: Ladies and gentlemen, thank you for standing by, and welcome to Silk Road Medical's 2022 Second Quarter Earnings Conference Call. (Operator Instructions) I would now like to hand the conference over to Marissa Bych, with Investor Relations.

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MARISSA BYCH: Hi. Thank you, and thank you all for joining today's call. Joining me are Erica Rogers, Chief Executive Officer; and Lucas Buchanan, Chief Financial Officer and Chief Operating Officer. Earlier today, Silk Road Medical released financial results for the 3 months ended June 30, 2022. A copy of the press release is available on the company's website.

Before we begin, I would like to remind you that management will make statements during this call that include forward-looking statements within the meaning of the federal securities laws, which are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Any statements contained in this call that relate to expectations or predictions of future events, results or performance are forward-looking statements.

All forward-looking statements, including, without limitation, those relating to our operating trends and future financial performance, expense management, expectations for hiring and growth in our organization, physician training and adoption, market opportunity and penetration, commercial and international expansion, regulatory approvals, reimbursement, competition and product development are based upon our current estimates and various assumptions. These statements involve material risks and uncertainties that could cause actual results or events to materially differ from those anticipated or implied by these forward-looking statements.

Accordingly, you should not place undue reliance on these statements. For a list and description of the risks and uncertainties associated with our business, please refer to the Risk Factors section of our quarterly report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2022.

This conference call contains time-sensitive information and is accurate only as of the live broadcast today, July 26, 2022. Silk Road Medical disclaims any intention or obligation, except as required by law, to update or revise any financial projections or forward-looking statements, whether because of new information, future events or otherwise.

Now I will turn the call over to Erica Rogers, Chief Executive Officer.

ERICA J. ROGERS, PRESIDENT, CEO & DIRECTOR, **SILK ROAD MEDICAL**, **INC**: Thank you, Marissa. Good afternoon, and thank you all for joining us. We are pleased to share our recent performance with you today and highlight a series of significant achievements at Silk Road Medical in the second quarter of the year.

First and foremost, we drove strong TCAR adoption marked by $33.2 million in revenues and 4,700 procedures for the quarter, reflecting 25% and 29% year-over-year growth, respectively. Before reviewing our results in greater detail, let me expand upon our successful efforts to widen the reach and impact of minimally invasive TCAR across all eligible patients.

Early in the second quarter, we received FDA approval for the expanded indication of our ENROUTE Transcarotid Stent System, to include patients as standard risk for adverse events from carotid endarterectomy or standard surgical risk. This approval opens our currently addressable market opportunity to the entire U.S. carotid artery procedure market of approximately 170,000 annual procedures.

More importantly, this expansion levels the playing field between TCAR and CEA as physicians now have the discretion to treat any eligible patient with a TCAR procedure. As captured in a recent press release by the Society for Vascular Surgery, the data supporting TCAR use in standard surgical risk patients offers compelling reason for clinicians to more widely adopt TCAR technology as it has demonstrated both safety and efficacy and present an excellent alternative to CEA.

Within weeks of FDA approval, we also received expanded Medicare coverage for TCAR in standard surgical risk patients under the national coverage determination within the TCAR Surveillance Project, ensuring that all carotid patients who require treatment have the opportunity to benefit from a minimally invasive approach.

We're grateful to the teams at FDA, CMS and the Society for Vascular Surgery for their valuable contribution and partnership in recognizing the weight of real-world evidence supporting TCAR use in this expanded patient population and the significance of preventing the debilitating impacts of stroke on individuals, their families and the health system as a whole.

Lastly, we formally announced ROADSTER 3 in June, our post-approval study designed to assess the real-world treatment of standard surgical risk patients with TCAR. This prospective single-arm study will enroll a maximum of 400 patients across roughly 60 leading clinical research sites. And the primary endpoint is a composite of major adverse events, including death, stroke or myocardial infarction through 30 days post-procedure, plus ipsilateral stroke from day 31 to 365 post-procedure.

We are excited to add prospective data to the already compelling real-world clinical evidence for TCAR in standard surgical risk patients, and we look forward to updating you as the study progresses.

We are now investing substantial time and resources in marketing efforts specific to standard surgical risk label expansion, with a focus on incorporating our patient-first mentality, including updated sales and marketing material, direct print and digital communications, and patient stories and testimonials, all as part of our broader primary strategic priority of U.S. commercial execution. On that note, I am pleased to review our commercial progress in the second quarter in greater detail.

As evidenced through our Q2 results, we are making steady progress toward penetrating the large and still untapped pool of carotid procedure volume. Exiting the second quarter, we are well on our way toward reaching our year-end goals of 70 to 75 active territories and 200 to 300 new physicians trained. Our efforts to drive more frequent and deeper customer engagement are yielding strong results, meaningfully increasing procedures per trained physician across our sales territories.

Based on our strong first half U.S. TCAR procedure growth and our outlook over the remainder of the year, we are pleased to raise our 2022 revenue guidance to $128 million to $133 million, reflecting year-over-year growth of 29% at the midpoint of the range. We continue to expect the vast majority of our 2022 revenue to come from TCAR procedures in the legacy high surgical risk patient population, with a gradual layering effect from standard surgical risk expansion into 2023 and beyond.

That said, we view our opportunity holistically and do not intend to distinguish our expectations by patient subpopulation in the future. As we like to say, 100% of these patients are at risk for stroke from their disease process and 100% are at risk of complication from invasive surgery, and we expect to continue to take share from CEA. Lucas will provide greater detail regarding our financial outlook shortly.

In summary, TCAR is finding a prominent place in the carotid treatment continuum. In fact, we're excited to share that we recently celebrated our 50,000th TCAR procedure performed to date, an incredible testament to our impact on the lives of patients and their families. We know that stroke risk does not stop and patients need to be protected from its devastating consequences, regardless of the broader health care operating environment.

We are executing well against the substantial opportunity ahead of us as we continue to progress initiatives to expand our business over the longer term, looking at both complementary and tangential opportunities. We're looking forward to providing updates on these longer-term initiatives over the next several quarters.

With that, I will now turn the call over to Lucas Buchanan, our Chief Financial Officer and Chief Operating Officer.

LUCAS W. BUCHANAN, CFO & COO, **SILK ROAD MEDICAL**, **INC**: Thank you, Erica. Revenue for the 3 months ended June 30, 2022 was $33.2 million, a 25% increase from $26.5 million in the same period of the prior year. Growth was driven primarily by growing TCAR adoption. The number of TCAR procedures in the quarter was 4,700, representing a 29% increase from the same period of the prior year.

For the past 3 consecutive quarters, we have seen sequential growth in procedures per trained physician despite the dilutive effect of adding newly trained physicians to the denominator of that metric each quarter, and we expect this trend to continue to be the primary driver of our growth in periods ahead. Our business continues to benefit from the increasing tenure and experience of our physicians, demonstrated by our physician base with 3 and 4 years of TCAR experience, whose procedure rates continue to increase.

Gross margin for the second quarter of 2022 was 73% compared to 75% in the second quarter of the prior year. As a reminder, we are incurring manufacturing expansion costs in our new Minnesota facility as we invest in our business. Validation activities at this facility are nearing completion, which should lead to commercial unit production starting later this year. We continue to expect a slightly lower full year 2022 gross margin as compared to 2021.

Total operating expenses for the second quarter of 2022 were $38.4 million, a 29% increase from $29.8 million in the second quarter of 2021. R&D expenses for the second quarter of 2022 were $10.7 million compared to $7.3 million in the second quarter of 2021. The increase in R&D spending was driven by growth in personnel and stock-based compensation as well as continued investments in new and ongoing R&D programs.

Sales, general and administrative expenses for the second quarter of 2022 were $27.7 million compared to $22.5 million in the second quarter of 2021. The increase in SG&A spending was driven by growth in personnel, stock-based compensation and a modest year-over-year increase in physician training and travel expenses. We continue to expect modest sequential increases in total operating expenses into Q3 and Q4.

Net loss for the second quarter was $15.4 million or a loss of $0.44 per share as compared to a net loss of $10.5 million or a loss of $0.31 per share for the same period of the prior year. We ended the quarter with $108.9 million of cash, cash equivalents and short-term investments, bolstered by our debt financing in late May, which provided us with access to up to $250 million in additional capital on very favorable terms, $75 million of which we have drawn down. The loan facility provides substantial flexibility as we invest for continued short- and long-term growth along our path to profitability.

Turning to our commercial progress. As Erica mentioned earlier, we are proud to share that we recently eclipsed 50,000 TCAR procedures globally. We are on track toward our goal of 70 to 75 territories by the end of the year, and coupled with an improved operating environment, we expect deeper and more frequent engagement with our trained physician base. We exited 2021 with roughly 2,100 trained physicians and are on track toward our goal of training 200 to 300 new physicians in 2022.

With a continued drumbeat of compelling clinical evidence, broad FDA labeling and Medicare coverage, a compelling economic value proposition and increasingly tenured, trained physician base and a world-class commercial organization, we are well equipped and laser-focused on driving procedures per physician growth as we establish TCAR as the standard of care.

I would also like to highlight our operational initiatives and progress. With the addition of our Minnesota facility to augment our California activities, our manufacturing and distribution capacity is well positioned to meet TCAR demand over the foreseeable future and achieve our quality, cost and risk mitigation objectives.

We are fortunate to have not experienced major disruptions in our supply chain this year despite the macro environment, save for longer lead times from some of our vendors. Our ops teams are working hard to manage through the turbulent environment with solid results thus far. We are also pleased that we continue to attract talented people to help us deliver on our near- and long-term operational goals.

Closing with our 2022 revenue guidance, as Erica mentioned, we now anticipate revenue to be in the range of $128 million to $133 million, representing year-over-year growth of 29% at the midpoint of the range.

Understanding the potential for some vacation seasonality, we continue to expect an acceleration into the back half of the year. We remain confident that our physician base will perform over 17,500 procedures by year-end, implying double-digit penetration into the total U.S. carotid procedure market.

With that, I will hand it back to Erica for her closing comments.

ERICA J. ROGERS: Thank you, Lucas. We are pleased by our team's accomplishments in the second quarter, which reflect a culmination of years of efforts, to establish an unmatched physician partnership through rigorous training engagement and engagement with them in the management of carotid artery disease. Our diverse employee base is renowned for their carotid clinical acumen and their deep commitment to driving better outcomes for patients and providers.

To this end, we are excited to highlight that Silk Road Medical was recently certified as a Great Place to Work for the second year in a row via the Great Place to Work global engagement survey. Results show that 92% of employees at Silk Road Medical say it's a great place to work compared to 57% of employees at a typical U.S.-based company.

We are particularly pleased, in conjunction, to be listed by Fortune Magazine in the Top 30 Best Workplaces in the Bay Area in 2022 in the small and medium workplace category. We are incredibly proud of the team we have built and the high quality of talent that continues to come through the doors.

With that, we will open the line to questions. Operator?

Questions and Answers

OPERATOR: (Operator Instructions) And our first question comes from the line of Robbie Marcus with JPMorgan.

LILIA-CELINE BRETON LOZADA, RESEARCH ANALYST, JPMORGAN CHASE & CO, RESEARCH DIVISION: This is actually Lilly on for Robbie. First, could you talk a bit about how you're thinking about standard risk ramping over the course of the year and what sort of time frame we should be keeping in mind for more meaningful revenue contribution?

ERICA J. ROGERS: Yes. Hi, Lilly. Thanks so much for joining us. I'll take that one, or the first part of that, at least, which is, look, the near-term focus for us is on training and education around standard surgical risk. It's building awareness among our customers, our physician community, that the label exists and that coverage has been broadened to include standard surgical risk.

And as we've said before, influencing the hearts and minds of our customers takes time and is one physician at a time. We continue to believe that with time and experience, that translates into higher adoption and probably more rapid adoption into the standard surgical risk patient population. And so for all of those reasons, we continue to believe that there's a kind of gradual layering effect of increased utilization across all patients, that we'll start to see in the latter half of this year, but more importantly, into 2023.

LILIA-CELINE BRETON LOZADA: Got it. That's really helpful. And then on guidance, so you beat by $2 million in the quarter, though raised by just $1 million. So is there any change to your expectations for the back half of the year? And why not raise by the size of the beat?

LUCAS W. BUCHANAN: Thanks for the question, Lilly. This is a combination of factors that inform our guidance. Obviously, we look at kind of the pace of inputs in terms of sales territory expansion and physician training. And it's always been a back half-loaded year in that context. And obviously, we had kind of Omicron still around in Q1, in January and February. We always factor in Q3 seasonality, which takes the form of vacations in kind of the front half of Q3 typically and then Thanksgiving and the holiday season in Q4.

And look, we've got some great anecdotes and a little bit of data points around the impact of standard surgical risk, not just for that patient population, but for kind of leading into TCAR more broadly, whether you're a new physician or kind of middle of the road in your experience or deeply adopted at this point.

So we're confident, but it's too soon to extrapolate the pace of that until we get a few more quarters under our belt. So those are all the things we think about. Obviously, the business is performing well in the hospital environment we're in, which is on the path to normalization. There's still friction in the system of varying degrees regionally, but we're pushing through that as we have been.

OPERATOR: And our next question comes from the line of Rick Wise, Stifel.

FREDERICK ALLEN WISE, MD & SENIOR EQUITY RESEARCH ANALYST, STIFEL, NICOLAUS & COMPANY, INCORPORATED, RESEARCH DIVISION: I also would like to focus on guidance a little bit. I mean hey, it's great to see a good quarter, better-than-expected quarter. And like the previous questioner, I'm also sort of fascinated by your beat by $2 million, raise by $1 million at the midpoint kind of mindset. And maybe that's -- Lucas, you take us through just thinking about it from another angle. I was thinking about the 4,700 procedures. And if we assume 100 more in the third quarter, 100 more in the fourth quarter, I mean, that seems fairly modest to me.

And I apologize for pushing you on this a little bit, but when we've done our doc survey work and ongoing conversations, the experienced TCAR doctors we talk to frankly talk about the -- how can I say it, taking a more meaningful step-up in their procedure volume with standard risk and reimbursement in hand. How am I not thinking about it correctly? I mean I appreciate your conservatism and your careful approach to guiding us. But I don't know. That sounds cautious based on what we're hearing and what you've just done.

LUCAS W. BUCHANAN: I certainly appreciate the question, Rick. I'm not sure I have much more to add. I mean we're all trying to predict human behavior and an adoption curve fundamentally. ASPs remain stable and strong. So it's all about procedures per physician, and it's also about kind of the ordering patterns of hospitals. And we think there's probably a little bit of conservatism on how many units they're ordering just in the kind of macro environment. That all gets reflected in kind of our revenue, divided by procedures, metric.

So all of that is going in. We obviously are hearing the same very positive anecdotes that you're hearing. We want to see the talk translated into action. And if things change, we'll update our guidance accordingly. But we think it appropriately accounts for the risk and opportunities ahead as we sit here today, with not a lot of data yet, obviously, for the trends that will drive that metric, influenced by the recent news on standard risk.

ERICA J. ROGERS: And Rick, I'll just jump in and say, look, I've been out talking to customers as I always do. And the enthusiasm is high. You're absolutely right. And I think what we're hearing is this approval and the expansion of coverage really legitimizes TCAR as a therapy that can stand against carotid endarterectomy.

And so what you're seeing in the guidance is just it's early days here. We're just a few weeks in, for all practical purposes, on coverage. And so we want a little more time to go by to make sure that this rising tide effect will -- that we'll actually observe that.

FREDERICK ALLEN WISE: Got you. No, that all makes sense. And I know it's early. A couple of other things I wanted to make sure I understood a little better. Did I miss it, and I may have, did you mention the number of docs trained in this quarter? And just to get a sense of maybe, as you answer that, you can tell us just is it more challenging? Is it getting easier to train people, given the complicated environment we're living in?

And maybe just last for me, I'll just go ahead and jump ahead. Help us better understand, just maybe give us a little more color on the territory expansion. And remind us what you're doing and how long it takes and when you -- how long it takes to get those territories productive and when you think that will also be more of an accelerant for Silk Road and for TCAR adoption.

LUCAS W. BUCHANAN: Thanks, Rick. I'll take the front end of that question. No, we did not mention the number of physicians trained. We don't typically talk about that on a quarterly basis. We exited last year with roughly 2,100 trained. We -- our guide is 200 to 300. We said we're on track. I would say, physician training demand has always been strong and continues to be and probably even more so with the recent news. So we are servicing that demand.

ERICA J. ROGERS: Yes. And just rounding out some color on that. I would say, overall, Rick, it's easier, just in the sense that the COVID sand in the gears on getting people together in person to train, that has gotten better. We are taking full advantage of our brand-new gorgeous innovation center in Minneapolis. We're bringing physicians together in that facility for the didactic and the hands-on. Those training sessions are going extraordinarily well. The feedback from physicians has been just terrific on the models and the facility itself.

Now the second part of your question was on territory expansions. That's going as planned. We're on track to get to the 70 to 75 active territories. You asked how long does it take for these reps to become effective. And the good news is we're not really opening de novo ground anymore. These are territories that have had a Silk Road sales professional. And by splitting these territories, we are increasing the touch points. We're going deeper and more frequent into these hospital accounts and with our physician customers. We continue to invest in world-class training and our sales professionals, and we take our time to make sure they are fully prepared.

As you heard, Rick, in my remarks, my prepared remarks, we are renowned for our clinical acumen and expertise in the field. We are considered unmatched clinical partners in the treatment of carotid artery disease. And so we're not going to let up on the quality of the training of our sales professionals.

And we hand them the keys to the territory when we believe they are ready to participate as a sales professional at that level. So this is all to say that all of these things are known to us. They are factored into our guidance. They're factored into how we think about accelerating in the back half of the year.

OPERATOR: And our next question comes from the line of Michael Polark with Wolfe Research.

MICHAEL K. POLARK, DIRECTOR & SENIOR ANALYST, WOLFE RESEARCH, LLC: I was hoping for a quick reminder on the physicians that have been using TCAR for, say, 3 or 4 years. Where are those levels of productivity today? I'm just kind of interested in that and the updated view on that North Star.

LUCAS W. BUCHANAN: Mike, I'll take part of that question. Good to hear from you. So we -- if you look all the way back to kind of pre-pandemic, the end of 2019, we had roughly just shy of 1,500 docs trained back then. So that's kind of starting to get real tenure from the docs trained in 2019, 2018, 2017. And the point of my comments in the prepared remarks are that there's no kind of saturation. There's no -- they don't hit a wall. They continue as a cohort, kind of climbing up the adoption curve.

And they've gone through a lot of noise over the last couple of years. Obviously, all of that experience has been solely in the high surgical risk patient population. But even with all of that, it's steady progress. And as just a function of time, there are more and more physicians that are reaching 1, 2, 3 and 4 years from their initial training.

We've always said training a new physician is not an immediate driver of the business, it's an investment in the long term. And I think the point is we're starting to yield the fruits of some of those investments we've made 2, 3 and 4 years ago in physician training. And so we like the trends we see is the main takeaway.

MICHAEL K. POLARK: Appreciate that color, Lucas. Maybe one follow-up down the P&L. I just hear the comment about the gross margin and expectation down a little bit this year as you ramp the Minnesota facility and get that site to commercial production volumes by the end of the year.

I guess where -- just remind me, is the expectation that, that facility scales, that we're headed back to the prior high watermark on gross margin and potentially beyond? Just can you frame up where we're headed and over kind of what sort of glide path in the next 2 to, say, 6 quarters?

LUCAS W. BUCHANAN: Yes. So it all starts with pricing, obviously, and our commercial team continues to do just an excellent job at the kind of product pricing level. And then with Minnesota, it's both making sure that we have augmented capacity, but also risk mitigation, in order to build -- be able to build the same product in 2 locations. And so even though we've got significant capacity in California, we wanted to augment that with Minnesota.

But as I said, that facility, second facility, is about to come online and then we'll benefit from volume over time against the fixed overhead across 2 sites. And we've got the hard-working teams looking at cost reduction through design and through other efforts over the long term. But we're happy with the investments we've made on kind of the quality and capacity side of the house.

OPERATOR: And our next question comes from the line of Joanne Wuensch with Citi.

ANTHONY OCCHIOGROSSO: This is Anthony on for Joanne. And congrats on a good quarter. My first is I just want to zoom out for a second and maybe focus on macro impacts. Are you seeing any headwinds still sort of from hospital resource shortages, staffing nursing shortages, contrast dye shortages, sort of any of those headwinds?

ERICA J. ROGERS: Yes. I appreciate the question, and thanks so much for joining us. And yes, we're super excited about the quarter, for sure. So to answer the question, look, there continue to be staffing shortages. There continue to be -- that continues to be exacerbated by the Omicron BA.5 variant, which takes people out-of-pocket and they can't go to work when they're infected, obviously. But I think it's safe to say that we're seeing normalization return in pockets, and we like the trends that we're seeing.

As it relates to contrast shortage, there were some of that in the quarter. But luckily, with our procedure, it was not only prioritized, is the severity of carotid disease, but there are ways to kind of get around using a whole lot of contrast anyway. And that does feel like an issue that is largely behind us. And so while I think it's too soon

to say we're back to a fully normalized operating environment in health care, with the labor shortage still persisting, we like the trends.

ANTHONY OCCHIOGROSSO: Great. And then my second, just a few updates. First, on the regulatory processes in China and Japan. And then I don't think I heard an update this quarter on the NITE-1 Study, so if there's anything there to call out, that would be helpful.

ERICA J. ROGERS: Yes, good observation. Look, I think the short answer is the real meaningful meat of the second quarter was the commercial performance, which we're incredibly proud of. We did make progress on both NITE-1 and Japan and China regulatory. And we're pleased with the progress we've made in both, and we look forward to more substantive updates in the quarters to come.

OPERATOR: And our next question comes from the line of Adam Maeder with Piper Sandler.

ADAM CARL MAEDER, VP & SENIOR RESEARCH ANALYST, PIPER SANDLER & CO., RESEARCH DIVISION: Congrats on the quarter. Maybe to start, Lucas, just one on the P&L and OpEx spend. I think I heard the commentary, where you expect a continued ramp in the back half of the year. But if we were to look out a little bit further, how should investors think about pathway to profitability? And how are you planning to prioritize top line growth versus leverage? And then I had a follow-up.

LUCAS W. BUCHANAN: Thanks, Adam, for the question. So top line growth is the path to profitability because of the operating leverage potential we have, and I've talked about this on prior quarters. We are largely built out kind of functionally in a lot of the commercial infrastructure to support growth from physician training, to med affairs, to marketing. Obviously, still a little bit of work to do, as Erica mentioned, to build out the sales team.

Same thing on the G&A side, we've been investing across the board to support HR, IT, finance, et cetera, and we've touched on the manufacturing side. So a lot of those investments are behind us, and we expect kind of the overall OpEx to be more modest sequentially, whether it's quarters or years going ahead.

There's always variability on the R&D line, but that team is also well built out now in terms of the number of people and programs to do the multiple things we want to do across short-, mid- and long-term drivers.

And so we're really set up for operating leverage and continuing to be able to grow revenue at durably high rates, but significantly modulating the cost growth. So we're kind of at that position as we sit here today. Our OpEx as a percentage of sales has been ticking down over the last couple of quarters, and we're focused on that. We're focused on contribution margin per territory, et cetera, et cetera.

ADAM CARL MAEDER: Got it. That's very helpful color, Lucas. Appreciate that. And then maybe for the follow-up, I just wanted to switch over to the clinical data side. This is a little bit of a 2-part question. But the first is there was a Kaiser paper that was published a few weeks ago looking at medical therapy for stroke prevention in patients with asymptomatic disease. Just curious if you had any thoughts on that particular paper.

And then as we look ahead, CREST-2, I think, clinicaltrials.gov has a primary completion date of December '22. So what are your expectations for that study? Is this a study that can inform clinical practice? Or do you see it not being particularly impactful?

ERICA J. ROGERS: Sure, Adam. Thanks so much for being on the call. I'll start with the Kaiser paper. I think you're referring to Chang, et al, from JAMA. And the first thing to say about this paper is that this is a very old topic. The debate about whether or not to treat asymptomatic disease versus best medical therapy has been ongoing since the dawn of time.

There have been multiple randomized controlled trials on this topic. Of course, it was the topic of CREST-1. And there have been even broader, larger, more comprehensive publications beyond this one that you're referencing and even in the last 12 months that had very different conclusions than what Chang, et al, are concluding.

So we have great respect for the authors here, but I think there's some fundamental flaws in the design. I mean first of all, it's a very contained patient population across Kaiser. But the real flaw is that the paper kind of reflects clinical decision-making. The patients who got carotid intervention deserve them and needed them. And the patients who did not and were observed over medical therapy were deemed to have not needed an intervention in the first place.

And so that is a fundamental flaw in this retrospective analysis across patients in Kaiser. And the utilization of a carotid intervention is about at the same rate as it is across all of the United States. In other words, when we

look at our 170,000 patients per year treated against the patients diagnosed with carotid artery disease, the percentages are about the same.

And there are a number of other flaws in the paper. And so for all of those reasons, the short answer really is this will be minimal to 0 impact on our business and will hardly be noticed, quite frankly. So that's the Kaiser paper.

On CREST-2, we've been talking about CREST-2 for 8 years. This study has been enrolling for a very long time at a very slow rate. And the reason for that, Adam, is that there are real challenges in this study design. As you know, it's 2 RCTs embedded in 1, comparing CEA, the best medical therapy, and transfemoral cath, the best medical therapy.

And the real challenge in enrolling is that you have to first believe that there's equipoise in those 2 things before you can randomize a patient, which means, again, as we talked about in Chang, et al, if you firmly believe, as a clinician, the patient needs to be treated based on the progression of disease or severity of disease, you're not going to randomize them.

And so what that really means is the patients that are getting randomized are the patients in whom -- whom will do well on optical -- optimal medical therapy to begin with. And so I think it's going to be highly criticized for that reason, when all is said and done. And of course, the technology around carotid artery stenting, namely TCAR, has massively evolved in the 8 years since the beginning of this trial.

While the website is suggesting a closure date at the end of December, our estimates put it out much longer than that, based on the current kind of enrollment rates. And I do want to remind, Adam, that the follow-up period is 4 years. And the reason for that is if you're trying to discern a difference between medical therapy and treatment, you have to run it out 4 years.

And so that's 4 years from the last patient enrolled before there will be a definitive answer on this question. There may be some interim, short-term data, on the 30-day outcome, but that's utterly meaningless in the medical therapy arm.

OPERATOR: Thank you. I'm showing no further questions. So with that, I'll turn the call back over to CEO, Erica Rogers, for any closing remarks.

ERICA J. ROGERS: Thank you very much. And again, I want to reiterate how proud we are of our team at Silk Road Medical. Thanks very much.

OPERATOR: Ladies and gentlemen, this concludes today's conference call. Thank you for participating, and you may now disconnect.

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