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Silk Road Medical, Inc (SILK) CEO Erica Rogers on Q4 2021 Results - Earnings Call Transcript

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EPS of -$0.42 misses by $0.07 | Revenue of $28.27M (33.75% Y/Y) beats by $2.36M

Silk Road Medical, Inc (NASDAQ:SILK) Q4 2021 Earnings Conference Call February 24, 2022 4:30 PM ET

Company Participants

Marissa Bych - Investor Relations

Erica Rogers - Chief Executive Officer

Lucas Buchanan - Chief Financial Officer and Chief Operating Officer

Conference Call Participants

Joanne Wuensch - Citibank

Robbie Marcus - JPMorgan

Danielle Antalffy - SVB Leerink

Operator

Good day, ladies and gentlemen and welcome to the Silk Road Medical's 2021 Fourth Quarter Earnings. [Operator Instructions] As a reminder, this conference call is being recorded. I would now like to turn the conference over to your host Marissa Bych, Investor Relations. Thank you. Please go ahead.

Marissa Bych

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 of Silk Road Medical. Earlier today, Silk Road Medical released financial results for the 3 and 12 months ended December 31, 2021. A copy of the press release is available on the company's website.

Before we begin, I'd like to remind you that management will make statements during this call that include forward-looking statements within the meaning of 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, the impact of COVID-19 on our business and prospects for recovery, expense management, expectations for hiring, physician training and adoption, growth in our organization and reimbursement, market opportunity, commercial and international expansion, regulatory approvals and product development are based upon 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 or 10-K filed with the Securities and Exchange Commission on November 9, 2021.

This conference call contains time-sensitive information and is accurate only as of the live broadcast today, February 24, 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.

And with that, I will turn the call over to Erica Rogers, Chief Executive Officer.

Erica Rogers

Thank you, Marissa. Good afternoon and thank you all for joining us. I would like to start by acknowledging the meaningful impact our teams and physicians had in 2021. We treated nearly 14,000 patients and surpassed $100 million in total revenue. We drove measurable progress on regulatory and reimbursement fronts in anticipation and support of standard surgical risk label expansion in the U.S. and our planned entry into Japan and China while further developing our long-term pipeline. And we did all of this despite the significant headwinds faced by the U.S. health care system. Our end goal hasn't changed: to establish TCAR as the standard of care in what is now a $1.2 billion market in the United States alone.

Highlighting our top line growth, I am pleased to announce that achieved $101.5 million in full year 2021 revenue, representing 35% year-over-year growth. We continued to take meaningful share from carotid endarterectomy while becoming the number one company in the U.S. carotid stent market by a wide margin. We are encouraged by this success and believe we have many years of sustainable, strong growth ahead of us to reach full market penetration.

Reviewing our regulatory and clinical achievements, early in the year, we submitted a PMA supplement for standard surgical risk label expansion of our ENROUTE stent, laying the foundation to unlock a 50% expansion of our U.S. total addressable market. At the Vascular Annual Meeting in August of 2021, an independent analysis was presented illustrating equivalent risk of perioperative stroke, death or MI plus ipsilateral stroke in a head-to-head comparison of CEA versus TCAR, with cranial nerve injury risk significantly reduced with TCAR. The study affirmed the benefits of TCAR in the standard surgical risk patient population, building on our long-standing clinical evidence base and generating significant positive enthusiasm in the physician community. We continue expect the FDA to complete its review process within the first half of this year.

On the international front, we filed our Shonin applications with PMDA in Japan for both the ENROUTE neuroprotection system and the ENROUTE stent last year. And we submitted NMPA in China for the stent with the NPS system already under review. Preliminary commercial steps are underway in both countries, and we look forward to providing more detail as these initiatives progress. Of course, this year was not without challenges, and I want to recognize the immense efforts of our team, our physicians and their tireless staff for continuing to put patients first throughout the peaks and valleys of COVID-19.

After a gradual improvement over the first half of the year, the third and fourth quarters were impacted by first Delta, then Omicron. Dynamics exiting the year were characterized by hospital staffing shortages, policies pausing elective procedures and limited bed capacity. Challenges have persisted through mid-February, again, with regional variability and nuance, pressuring hospital-based procedure volumes, including TCAR. That said we have now begun to see early favorable signs of recovery through improving daily TCAR counts in areas where procedures and restrictions have lifted and the spread of COVID-19 has slowed. These dynamics in mind, we are initiating guidance of $126 million to $132 million in full year 2022 revenue.

Our approach to guidance takes into account the scale of our U.S. sales territories and hospital accounts, the increasing experience of our trained physicians and the power of our continuously growing clinical evidence base, all supporting the strength of TCAR's fundamental value proposition. At the same time, our approach considers the challenges, regional variability and uncertainty associated with the current environment. Lucas will provide greater detail regarding our financials and forecast shortly.

I would now like to turn to our 2022 strategy. Our single most important objective this year is driving U.S. TCAR adoption. We are laser focused on continuing to increase our penetration into the large and still untapped pool of carotid procedure volume, which we estimate included 169,000 procedures in 2021, of which 13,900 were TCARs, representing approximately 8% of the market. We finished 2021 with a presence in nearly 1,000 hospital accounts, covering the majority of the carotid procedures in America. Within this concentrated hospital base, we have a critical mass of over 2,000 trained physicians served by 58 active sales territories, setting us up to drive deeper penetration in the years ahead.

We plan to continue adding to our commercial team in 2022 with the goal of increasing the amount of time our sales professional spend with each trained physician to drive greater adoption. Our experience and our data show that the more experience a physician has with TCAR and the more touch points he or she has with our team, the greater the impact is on his or her adoption curve. By segmenting our physician data into quartiles and measuring physicians' adoption curve from the quarter during which they were initially trained, we see steady growing adoption in each quartile over time. Our goal is to continue to accelerate the adoption curve of each physician cohort.

Let me take you through a few examples. Currently, we are working with our physicians to address the pipeline of carotid disease patients whose care has been deferred or delayed. Job one is preventing every possible stroke by driving patients back into the health care system. We have seen firsthand the devastating effects of rationing care in this critical disease, and the message of not waiting is one that our team has been actively sharing to a strong response among our physicians and their patients.

Recently, a leading physician in New York worked with our team to disseminate referring physician and patient education materials after 3 patients in their health system had devastating strokes while awaiting their TCAR procedures, 2 of which had been deferred multiple times due to COVID procedure cancellations. In Louisiana, our team is educating physicians in the emergency room, where patients often first present with a stroke from carotid origin, leading to direct referrals from the ER to TCAR physicians. These are just two examples of how we are turning over every stone to continue driving awareness.

In addition, this year more than ever before, we are promoting the obvious patient benefits and satisfaction of this minimally invasive approach because we know that when given a balanced choice, patients choose TCAR over CEA nearly every time. For example, Delray Medical Center in Florida, where physicians have performed over 200 TCAR procedures, routinely offers TCAR and CEA to patients, with patients embracing TCAR most often due to the option for a faster and easier recovery and a return to full and active life.

In 2022 and beyond, we will measure our success with the simple metric of TCAR's share of all carotid interventions. And we are excited to drive this therapy from 8% penetration to a future where the vast majority of patients are served with the minimally invasive standard in stroke prevention, TCAR. Key to this strategy is leveling the playing field against carotid endarterectomy. And in 2022, we look forward to expanded TCAR labeling and reimbursement coverage to include standard surgical risk patients. This will allow all patients at risk for a devastating stroke from carotid artery stenosis to have the opportunity for a safe, less invasive procedure.

As I mentioned earlier, we are on track for standard surgical risk label expansion within the first half of this year. Our dialogue with the FDA remains productive, and we are keeping CMS and the Society of Vascular Surgery abreast of the progress. Our sales force is incredibly enthusiastic about this opportunity, and we continue to prepare for commercial launch and the potential initiation of a post-approval study to collect prospective data in the standard surgical risk patient population.

As a reminder, this indication would increase our total addressable market by roughly 50%. But as we've indicated in the past, we do not expect an expanded label to be an immediate revenue driver. Rather, we expect the indication to firmly establish TCAR on a level playing field with CEA for all patients, adding to the many powerful reasons for physicians to adopt and perform TCAR. We believe we are most likely to recognize a gradual layering effect to our growth profile beginning in 2023 and beyond.

For this year, our focus will be on the Medicare coverage process, awareness and education in the referring and treating physician community, initiation of a post-approval study and the continued support of physicians gaining their experience and confidence in TCAR across a variety of patient presentations. In addition to our label expansion efforts on the regulatory side, we remain hard at work developing new and improved products to extend our leadership in the TCAR category. Over the next 12 to 24 months, our pipeline of products includes new stent sizes and configurations, improvements to our neuroprotection system and a dedicated balloon catheter purpose-built for TCAR. We look forward to providing more detail as these initiatives progress.

Looking further ahead, we continue to see meaningful potential in additional growth drivers to expand our impact on the market. In 2021, we made progress on our NITE-1 IDE feasibility study and invested in additional pipeline development initiatives. Core to these efforts, we created an innovation team in Minnesota and augmented our capabilities substantially. Our new innovation center has simulated operating room environments, which enable us to have routine robust physician involvement early in our product development processes as well as shortened cycle time on product iterations. We firmly believe that transcarotid technologies hold the potential to solve difficult clinical problems in the treatment of complex neurovascular and cardiac disorders and will become an important part of the treatment paradigm in the future.

To summarize, we are making meaningful progress on our many endeavors to drive near-term procedure growth and invest in long-term opportunities. I will now turn the call over to Lucas Buchanan, our Chief Financial Officer and Chief Operating Officer.

Lucas Buchanan

Thank you, Erica. Revenue for the 3 months ended December 31, 2021, was $28.3 million, a 34% increase from $21.1 million in the same period of the prior year. Growth was driven primarily by increased procedures per trained physician sequentially and year-over-year as well as an expanding base of hospital accounts, trained physicians and active sales territories, partially offset by ongoing regional headwinds related to COVID-19. The number of TCAR procedures in the fourth quarter was just shy of 3,900, a 35% increase from the same period of the prior year.

Similar to the regional variability seen in our third quarter 2021 results, our fourth quarter performance across regions varied with a clear tie to COVID hospitalizations in any given region. As an example, in regions where COVID patients as a percentage of all inpatients were relatively high in Q4 versus Q3, procedures per physician were flat to down sequentially. Whereas in regions showing lower COVID patients as a percentage of all inpatients, procedures per physician grew sequentially by an average of 7%.

Gross margin for the fourth quarter of 2021 was 74% compared to 75% in the fourth quarter of the prior year. The decline was driven by initial costs associated with the start-up and expansion of our manufacturing activities at our new facility in Minnesota. We expect gross margins to be slightly lower for the full year 2022 as compared to 2021 as we bring on this important new capacity to support our long-term growth.

Total operating expenses for the fourth quarter of 2021 were $35.1 million, a 14% increase from $30.9 million in the fourth quarter of 2020. R&D expenses for the fourth quarter of 2021 were $7.5 million compared to $10 million in the fourth quarter of 2020. The decrease was primarily driven by a reduction in clinical expenses as compared to the fourth quarter of 2020, partially offset by an increase in personnel and product development and program costs.

Sales, general and administrative expenses for the fourth quarter of 2021 were $27.6 million compared to $20.9 million in the fourth quarter of 2020. The increase was primarily attributable to continued expansion of our sales team and commercial efforts in general and other corporate costs. We expect continued growth in operating expenses in 2022 as we invest further in our pipeline and our sales team. Net loss for the fourth quarter was $14.7 million or a loss of $0.42 per share as compared to a net loss of $16.8 million or a loss of $0.49 per share for the same period of the prior year. We ended 2021 with $110.2 million of cash and cash equivalents.

Turning to our 2022 outlook and commercial strategy, we remain focused on driving the adoption curve in our significant trained physician base as well as preparing for a potential standard surgical risk indication. We ended 2021 with a commercial presence in 975 hospitals and just shy of 2,100 trained physicians served by 58 active sales territories, and we expect to end 2022 with 70 to 75 active sales territories. While driving adoption in our trained physician base is our primary focus, we also expect to train 200 to 300 new physicians in 2022. And we expect our physician base to perform over 17,500 procedures for the year.

As Erica mentioned, we expect full year revenue to be in the range of $126 million to $132 million, representing growth of 27% at the midpoint over 2021 revenue of $101.5 million. This includes an expectation for our first quarter revenues to be sequentially slightly lower than our fourth quarter 2021 revenues, considering ongoing Omicron-related pressures. That said, we are encouraged by gradually improving daily TCAR case counts, and we remain optimistic that we will see recovery continue into March and the second quarter.

As always, our guidance philosophy considers several variables, including a gradually improving health care operating environment as well as the potential for ongoing regional variability, as Erica mentioned in her earlier commentary. Most importantly, our physician engagement remains high, which is a testament to the established value of TCAR and an improving procedure outlook with the lifting of COVID-related restrictions and constraints.

At this point, I would like to turn the call back to Erica for closing comments.

Erica Rogers

Thank you, Lucas. Looking back, we introduced TCAR into the U.S. market just over a handful of years ago. And today, leading physicians around the country consider TCAR as first-line therapy, an incredible achievement for a brand-new category and paradigm-shifting procedure. TCAR is now available in nearly every hospital in the country treating meaningful quantities of carotid disease, and over 40,000 patients have been treated as of today.

We have built the infrastructure to move from ushering in to executing on TCAR as a new standard of care in minimally invasive treatment of carotid artery disease. We have the pieces, the focus and the scale to move to double-digit market penetration this year and make a difference in the lives of tens of thousands of additional patients and their loved ones. We have concretely established an entirely new market with a robust untapped opportunity ahead and we have entered the next era of transcarotid therapies.

We will now open the line up to questions. Operator?

Question-and-Answer Session

Operator

[Operator Instructions] Your first question comes from the line of Joanne Wuensch from Citibank. Your line is open.

Joanne Wuensch

Hi. Can you hear me okay?

Erica Rogers

Hi, Joanne.

Joanne Wuensch

Hi. How are you?

Erica Rogers

Good.

Joanne Wuensch

Excellent. That is a lot. Thank you for that. What's interesting to me is how much – or how many physicians you plan on training over the coming year. And I would be curious to see what you are seeing in terms of procedural utilization, for maybe the lack of a better term, for those that had been trained in the last year versus those that were trained maybe pre-pandemic or 2 years ago?

Erica Rogers

Sure. Well, let me take some of that, and Lucas will take some of that. So, first and foremost, we have said before and we are committed to training as a part of this company probably for many years to come. And so we view training physicians as a sort of an and to driving deeper adoption, not an or. And so it's critical that we continue to build the pipeline of newly trained physicians. And of course, as we talked about also, training fellows, graduating vascular fellows remains an important part also of our training paradigm. And so we intend to train roughly 200 to 300 new physicians in 2022. And we ended up training about 644 physicians in sort of what we would consider pandemic times. And so job one is getting those 644 physicians up and through that early part of their adoption curve, gaining their comfort level with the procedure.

Joanne Wuensch

Excellent. If I can get a follow-up in, when do you think your two targeted OUS countries, Japan and China, start to contribute revenue?

Lucas Buchanan

I will take that, Joanne. Since we are still in the regulatory process, and that will be followed by a reimbursement process and some market preparation activities, it's not included in the guidance we have given this year.

Joanne Wuensch

Okay. Thank you very much. I will get back in queue.

Erica Rogers

Thanks Joanne.

Operator

Your next question is from Adam Maeder from Piper Sandler. Your line is open.

Unidentified Analyst

Hi everyone. This is Simran on for Adam. Thank you for taking the question. I guess I just want to start off with your latest trends on asymptomatic and symptomatic volumes. Curious to know where that is today and how you think about that going forward?

Erica Rogers

Absolutely. Hi Simran, good to have you. So, it's an interesting question because for most of normal times, the asymptomatic patient population is really the majority of the kinds of patients that get treated, representing about 70% typically of our procedural volume. And why is that, well, it's because ideally, you want to get at treating this ticking time bomb before it goes off and creates a stroke. We did see in periods in this pandemic fluctuations in that mix, that sort of 70-30 mix. And when elective procedures were put on hold, we would sometimes see an increase on a percentage basis of symptomatic patients being treated. But by and large, as the pandemic wanes in terms of hospitalizations, we go back to our typical 70-30 split with asymptomatic representing about 70%.

Unidentified Analyst

Okay. Perfect. Thank you. And then as we think about utilization trends in our models for 2022, can you help us think or provide a bit more color on what's embedded in the guidance there?

Lucas Buchanan

Sure. I am happy to take that. So, as we said, our guidance relative to new physicians trained is 200 to 300, and we trained roughly 290 in 2021. So, that brings us up to the just shy of 2,100 as of the end of last year. So, if we just take the midpoint of that 200 to 300 for 2022, we would be roughly 2,350 or just shy. And so if you also triangulate that against our revenue guidance and kind of in excess of 17,500 procedures, that's kind of the combination of things that gets us to the modeling aspects of your questions.

Unidentified Analyst

Got it. Thank you.

Lucas Buchanan

And I will just add, the revenue per procedure, if you haven't done the math based on the full year results, was roughly $7,300. That will probably come down a little bit in the future for reasons we have addressed in the past, but that's the math.

Operator

Your next question is from Robbie Marcus from JPMorgan. Your line is open.

Robbie Marcus

Great. Thanks for taking the questions. Just a quick clarification. I feel like on the third quarter call, the timing for standard risk was by second quarter. And I heard by the end of second quarter now. Did I mishear on the third quarter call, or did it move back a little bit?

Erica Rogers

Yes. I think you misheard on the second quarter call, Robbie. It's always been by the end of the second quarter.

Robbie Marcus

Okay. So that's an easy one. The second question, as we think about standard risk, maybe just walk us through why it's going to be, in your view, a gradual ramp in revenue. I would imagine with the 50% greater TAM, no real difference in training at all, it's the same procedure, same docs, what would hold it back from being a rapid adoption?

Erica Rogers

Yes. I like that question, Robbie, and good to have you, by the way. So look, our expectations remain consistent, which is hearing back from the FDA and hopeful label expansion in the first half of this year. And following that is some effort with CMS, as we have talked about before, to obtain the coverage. We don't expect that to be protracted. But nonetheless, there is time involved. And then we launch into an awareness and an education phase to make sure that all of our physicians understand that TCAR can then be indicated for the standard surgical risk patient and also educating referring physicians. This is an important piece of that as well. And we will sort of start-up that engine on what we presume will be a post-market – post-approval study in the standard surgical risk patient population. So, there is a lot of activity there. But I think it's safe to say that, that's not going to create an immediate spike. What's important here is leveling the playing field and changing the way that we talk about TCAR in the context of all carotid patients. And so over time, I think we are going to see a gradual layering, which is going to lead to ultimately becoming the standard of care in our belief.

Robbie Marcus

Got it. Thank you. And maybe just to sneak a quick one in. Lucas, how do we think about expense growth in 2022 with all of the launch activity and post-approval study going on? Thanks.

Lucas Buchanan

Sure. So, we touched on the sales headcount growing from 58 active territories at the end of last year with a couple additional reps in training to ending this year roughly 70 to 75. So, there is increased investment in the sales team headcount. As well, there are a number of R&D initiatives, including the one you just mentioned, the potential initiation of a post-approval study if we are able to get the standard surgical risk label expansion by the end of Q2. That will start up all of those activities in the second half of this year. And we continue to invest in both products and regulatory – international regulatory processes for TCAR as well as for other Transcarotid therapies, as Erica mentioned, with our new pipeline and innovation team and infrastructure in Minnesota, complemented by our team in California. So, there is a lot of exciting things going on to invest in on the R&D side, both for kind of short, mid and long-term growth drivers.

Robbie Marcus

Great. Thanks a lot.

Operator

Your next question is from Rick Wise from Stifel. Your line is open.

Unidentified Analyst

Hi Erica. Hi Lucas. This is actually John on for Rick. Congrats on the quarter. You mentioned that one of your main priorities for 2022 is increasing penetration in TCAR adoption. I just want to drill into that a little more. Could you tell me what exactly you think needs to happen to get there? Is it just continuing to execute on existing principles, or do you need to add more salespeople or have them alter kind of where their priorities are? So, any color there would be helpful.

Erica Rogers

Absolutely, John. Thanks very much for joining us, and please send our regards to Rick. And so one thing – way to think about this is sort of the infrastructure that we have been building all along, which is to get to what we consider critical mass. And it's critical mass in the sales territories ending the year with 58, heading to 70 or 75, in nearly 1,000 hospitals that account for the majority of carotid disease, well over 2,000 physicians trained and a sizable cohort of those physicians already having surpassed their kind of early adoption curve or getting to that 10-plus procedure mark where they really gain their confidence. And so this is becoming a critical mass story versus a drilling down in the procedures per physician per quarter kind of metric. That said, I think I am going to ask Lucas to give a little more color on how we have been looking at procedures per physician to understand that what we are doing is working to drive physicians up the adoption curve.

Lucas Buchanan

Yes. We have touched in the past on our kind of top quartile analysis and measuring physicians regardless of what calendar year they were trained, kind of what their adoption curve looks like from that first quarter of training. And that top quartile and top half, if you combined the top one and two quartiles, continue to show really strong growth over time. Time and experience is our friend. And collectively, the top half is doing three to four procedures per quarter. As you move out, and we said in the past, the top half of that group is in the four, five and six range. So we have – and that translates on a full year basis to still a lot of headroom to go in terms of further penetration, right. We are nowhere near maxed out there. And then there is a lot in the bottom half of newly trained physicians, and physicians train in a pandemic and earlier on in their time. And so we have tools and programs and tactics to focus on all those different quartiles and segments and behavior attributes, as we have talked about in the past. One simple thing we are doing is just expanding the sales team, which by definition, narrows the geography because we are already in most of the hospitals we want to be in. We are just trying to narrow the size of these territories so that we increase the touch points. And we know that physicians' time and experience with the procedure plus the higher energy of applying our tools and tactics and programs to our sales force has a direct effect on the adoption curve. So, some of this falls in the kind of good old-fashioned commercial execution category so that we can achieve our growth profile.

Unidentified Analyst

Thanks. That's helpful. And just one more for me. You mentioned the innovation team and getting that started up and potentially even shortening product development cycles. Could you kind of, on one hand, quantify that for me and then just get into a little of what your expectations are for this team? And have you seen any positives there far?

Erica Rogers

Yes. Absolutely, so we have not only been expanding our capabilities right here in our Sunnyvale headquarters in California in R&D, but we took advantage of this new build-out in Minnesota to put in a kind of simulated operating room environment and physician training center. So, what that allows us to do is bring physicians in and have real hands-on experience with our devices as they are iterating. Putting versions of these new devices in the hands of physicians early in these simulated environments so that we can get immediate and real-time feedback, which shortens the cycle time of iteration. It's really that simple. And not only that, but it gives us an opportunity to reinforce the benefits of TCAR and help to drive adoption at the same time. So, in terms of the immediate impacts, we talked about some products coming down the pipeline, which we will ultimately reveal more details on. But we have really put a focus on making TCAR easier and even more simple for physicians. And one example of that is this bespoke balloon, which will be designed for use in TCAR procedures, which we are making very good progress on. And furthermore, changes to the Neuroprotection system, while although working extraordinarily well, and it's hard to imagine that you could improve upon it, there are some things that we are doing based on physician feedback. And we are turning those changes quite swiftly. And then, of course, there is the long-term growth potential. And those are really the fascinating and interesting pipeline products that are transcarotid in nature and address really complex clinical problems in both neuro and cardiac.

Unidentified Analyst

Thanks for taking my questions.

Erica Rogers

Thank you.

Operator

Your next question is from Danielle Antalffy from SVB Leerink. Your line is open.

Danielle Antalffy

Yes. Good afternoon everyone. Thanks so much for taking the question. Erica, I was curious about the fact that there is a potential incremental market expansion opportunity here in that it feels like over the last decade or so, the asymptomatic patient population, carotid interventions have had – there has been a higher bar to intervene. I think – I don't know the exact number, you might know, but maybe it varies by center. But is there an opportunity now with TCAR to move that bar back lower and intervene earlier in these asymptomatic patients? If so, what do you think it's going to take? Is the standard risk approval enough, or is it going to be more real-world data? Any thoughts there? And then just one follow-up for Lucas.

Erica Rogers

Sure. Hi Danielle. Thanks very much for joining us. Well, firstly, the good news is the procedural volume has gone up moderately. We reported 169,000 is roughly the treated patient population now in the United States, which is an increase just in the treated patient population. And your question is really about all of those patients who are diagnosed with critical carotid stenosis, but for whom they are not being treated. And your point is a good one. We have seen this in every other open to endovascular conversion story that has gone before us in coronary or peripheral or neuro, where there is a market expansion effect. And that is really driven by demonstrating a reduction in the morbidity and the mortality associated with the index procedure. And so it's a combination of all the things that you mentioned. It's a continued accumulation of the strong evidence base that we have already built, more accumulation in patients who are considered at standard risk, which have potentially fewer comorbidities and continuing to drive awareness among referring physicians. But for sure, we know that when the only tool in the toolbox is a big invasive procedure, that, that procedure is used extraordinarily conservatively. And so while we are not turning our attention there just yet as we march through this very large untapped opportunity in the treated population, eventually, we will turn our attention to expanding this market.

Lucas Buchanan

And Danielle, if I might just quickly add. There is a lot discussion in the medical community about the downstream cardiovascular effects post-COVID infection as well as the kind of deferral of routine healthcare that allowed chronic conditions like carotid artery disease to become more progressive. And so we may be headed into an era where there is just more kind of screening and diagnosis of cardiovascular disease writ large, which could filter to carotid artery disease as well. And as Erica mentioned, just to put a finer point, the 169,000 procedures as an update for 2021, that's relative to 166,000, which was in our investor deck in 2019. And arguably, 2021 was a real COVID-impacted year. And so one could ask the question, should there have been even more diagnoses and procedures, so we like the overall kind of demographic trends in this market.

Danielle Antalffy

Got it. Okay. Thank you for that. And then Lucas, a question for you, the last few years have been years of heavy investment here, and I appreciate the commentary on 2022. Looking forward, at what point can we start to really see you guys generate positive operating leverage and grow expenses at a significantly slower rate? Thanks so much.

Lucas Buchanan

Well, we are seeing it right now. Our investments in new territories are quite productive very quickly. And so again, when you have got the coverage model you need in terms of the number of hospitals and the number of sales territories to cover the treating physicians, you can then drive operating leverage going from 8% penetration to something much bigger. And so that is the key to our operating leverage. We are going start to see it. Even though we are still building out the sales team in 2022, we are seeing it, and we will see it more as a function of our penetration in the years ahead against that kind of fixed installed base and that critical mass we talk a lot about. And that will give us fuel to drive the path to profitability while investing in the R&D line along the way.

Danielle Antalffy

Thanks so much.

Operator

I am showing no further questions at this time. I would now like to turn the conference back to Erica Rogers.

Erica Rogers

Thank you very much all of you for joining us at what is a very interesting time. We appreciate your time and attention. Thank you.

Operator

Ladies and gentlemen, this concludes today's conference. Thank you for your participation. Have a wonderful day. You may all disconnect.

Comments

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