

FREE ARTICLE

[Join Over 1 Million Premium Members And Get More In-Depth Stock Guidance and Research](#)

SILK ROAD MEDICAL INC (SILK) Q4 2020 Earnings Call Transcript

By [Motley Fool Transcribers](#) – Mar 2, 2021 at 10:00AM

You're reading a free article with opinions that may differ from The Motley Fool's Premium Investing Services. Become a Motley Fool member today to **get instant access to our top analyst recommendations, in-depth research, investing resources**, and more. [Learn More](#)

SILK earnings call for the period ending December 31, 2020.

SILK ROAD MEDICAL INC (SILK -1.56%)

Q4 2020 Earnings Call

Mar 1, 2021, 4:30 p.m. ET

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

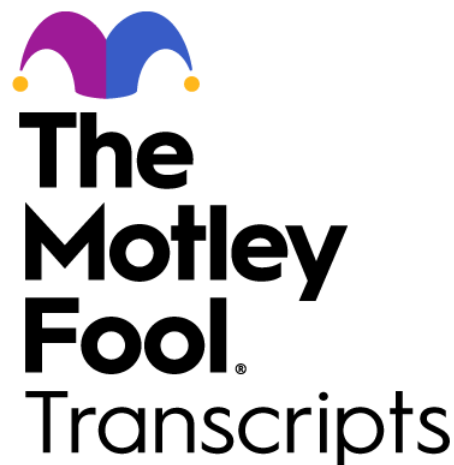


IMAGE SOURCE: THE MOTLEY FOOL.

marks:

Ladies and gentlemen, thank you for standing by, and welcome to the Silk Road Medical's 2020 Fourth Quarter Earnings Call. [Operator Instructions] After the speakers' presentation, there will be a question-and-answer session. [Operator Instructions]

I would now like to hand the conference over to your speaker today, Ms. Caroline Paul of Investor Relations. Thank you. Please go ahead, madam.

MOTLEY FOOL RETURNS



Market-beating stocks from our award-winning analyst team.

STOCK ADVISOR RETURNS

311%

S&P 500 RETURNS

102%

Calculated by average return of all stock recommendations since inception of the Stock Advisor service in February of 2002. Returns as of 10/12/2022.

Discounted offers are only available to new members. Stock Advisor list price is \$199 per year.

Join Stock Advisor

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

er than Silk Road Medical Inc

ng analyst team has a stock tip, it can pay to listen. After all, ve run for over a decade, *Motley Fool Stock Advisor*, has tripled

They just revealed what they believe are the **ten best stocks** for investors to buy right now... and Silk Road Medical Inc wasn't one of them! That's right -- they think these 10 stocks are even better buys.

[See the 10 stocks](#)

**Stock Advisor returns as of September 30, 2022*

Caroline Paul -- *Investor Relations*

Thank you, and thank you all for participating in 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 full year ended December 31, 2020 [Phonetic]. A copy of the press release is available on the company's website.

INVEST SMARTER WITH THE MOTLEY FOOL

Join Over 1 Million Premium Members Receiving...



- New Stock Picks Each Month

f Companies

ing Market Hours

[Get Started Now](#)

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

[Got it](#)

[Cookie Settings](#)

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 such statements -- 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, label expansion and product and pipeline 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 November 16, 2020.

This conference call contains time sensitive information and is accurate only as of the

March 1, 2021. Silk Road Medical disclaims any intention or
required by law to update or revise any financial projections or
statements whether because of new information, future events or

the call over to Erica.

President and Chief Executive Officer

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

Thanks, Caroline. Good afternoon, and thank you for joining our fourth quarter and year end 2020 earnings call. Joining me is Lucas Buchanan, our Chief Financial Officer and Chief Operating Officer. While 2020 was marked by unprecedented challenges, we would prefer to reflect on the strength and tenacity of our team here at Silk Road Medical and the accomplishments that have paved the way for growth in 2021 and beyond.

Throughout the year, we continued our momentum in the United States, expanding our sales team, training new physicians in innovative ways and meaningfully moving physicians up their adoption curve. These efforts were reinforced by tremendous strides in published clinical evidence. With over 7,000 TCAR procedures worth of data in peer-reviewed publications. Exiting 2020, physicians performed more than 26,500 TCAR procedures worldwide with over 10,000 in 2020 alone. We also made meaningful progress on multiple long-term growth and market expanding initiatives.

As part of these endeavors, we recently submitted our PMA Supplement for the ENROUTE Transcarotid Stent System intended to expand indications for use to include the treatment of patients at standard risk for adverse events from carotid endarterectomy, in other words, standard surgical risk. Coming into this year, we are well positioned with a solid commercial, clinical and financial foundation to focus on the opportunities within our \$5 billion addressable market.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

results. As we indicated in January, we entered the fourth of the potential for a resurgence in the pandemic and that came t of the quarter. With hospital resources pressured specifically ls, we started to see constraints on elective procedures. That severe carotid artery disease, stroke prevention can only be this translated into solid fourth quarter results in spite of the t.

2020 revenues were \$75 million, up 19% year-over-year with fourth quarter results of \$21 million and year-over-year growth of 13%. Through the year, we expanded our active sales territories from 33 to 40 by year-end and began the first quarter of 2021 with 43 territories. Despite the significant dip in physician training efforts in the second quarter, we were able to train over 350 new physicians in 2020 to reach approximately 1,800 total physicians trained. We also expanded our hospital account base from roughly 640 in the beginning of the year to just over 800 by year end. As a result of our commercial efforts, our growing physician base performed just shy of 2,900 procedures in the fourth quarter and over 10,000 TCAR procedures for the full year.

Over the course of 2021, we expect to see continued momentum as the healthcare operating environment normalizes. The key factors governing a return to normal growth are of course hospital resources and patient behavior. These are in turn impacted by the pace of virus transmission, the impact of variants and vaccination efforts. We're cautiously optimistic that normalization will begin in the second quarter, although there are clearly several unknowns. With these caveats in mind, our expectation is for 2021 revenues to be in the range of \$102 million to \$108 million.

As we usher in the Transcarotid era, we continue to be focused on US commercial execution with an increasing bias toward driving deeper adoption within our trained physician base. As always, this entails a relentless focus on patient outcomes as we

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

toward the standard of care. Over the past five years, we have markets only dedicated carotid commercial infrastructure, clinical evidence base and trained a large cohort of physicians. leveraging this collective infrastructure as we exit 2020 with just estimated US treated patient population and only 2% of the population.

Strategic priorities for 2021 are, number one, continued focus on on and driving the adoption curve. And number two, preparation of surgical risk, label expansion for the ENROUTE stent. At th

same time, we are also investing in our long-term growth drivers, which encompass new indications, new products, new therapies, including acute ischemic stroke and international expansion.

With respect to our first priority, 2021 marks the third year in a row with US commercial execution as our number one priority, and this is unlikely to change for years to come. We have proven that we can compete and win where so many others have failed in the past, against what is now an almost 70-year-old standard of care in carotid endarterectomy. In fact, in a study just published in JAMA Network Open, the authors found the availability of TCAR in a hospital is associated with a significant decrease and the likelihood of major adverse cardiovascular events at 30 days after carotid revascularization whether TCAR or carotid endarterectomy.

In other words, having a less invasive option like TCAR allows for better patient care. Regarding our opportunity to continue moving physicians up the adoption curve, over half of the physicians we've trained through 2020, were trained within the prior eight quarters. As of the fourth quarter of 2020, when we normalize time from training and we look at our top quartile, we are moving physicians from about 1.4 procedures per quarter up to 5.2. We are encouraged by the meaningful progress we've made over a short period of time and the future is very bright as we look to leverage the foundation we have built. We remain the only TCAR company in the market as we execute toward a billion dollar opportunity.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

second priority, we have been focused on architecting a regulatory standard surgical-risk patient population and ensuring we meet the needs of our patients. While there is still plenty of opportunity within the high-risk patient population, we have previously discussed our desire to unlock the remaining untapped US patient population. After careful consideration, we are pleased to have recently submitted our PMA Supplement intended to expand our indications for use to the standard

surgical risk patient population. This is an important first step on our journey to address the full patient population with severe carotid artery disease.

From physician training to commercialization efforts to a likely post market study, if the PMA supplement is approved, we will be prepared to enter an era where TCAR is on an even playing field with carotid endarterectomy in terms of an addressable patient population. With our two top priorities in mind, we enter 2021 with a desire to further accelerate investment in our commercial organization. Going forward, we expect to shift more of our hiring emphasis toward a new sales professionals or area managers who will continue to leverage our strong base of therapy development specialists. In a few moments, Lucas will share more details on our commercial strategies designed to best serve the ongoing interest in TCAR.

Turning now to our other long-term growth drivers. With respect to our markets outside the US, we recently highlighted a conservative international market opportunity of \$2.3 billion, which together with the \$2.8 billion US market derives a global opportunity of over \$5 billion. To put that in perspective, the US is only 10% of the global stroke burden. International expansion remains on the horizon as we make regulatory progress in geographies such as China and Japan and as we evaluate go-to-market strategies. We are excited about the opportunity to bring TCAR to other corners of the globe, where there is both awareness and demand in the physician community.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

development of our pipeline, we remain committed to expanding our technologies, most notably to address the neurovascular. We see opportunity for improved clinical outcomes. We are making progress we are making in acute ischemic stroke and other areas, and providing more details in the future.

We provide a brief update on our voluntary recall of certain loss of carotid Stent System, which are manufactured by our partner. And previously, our team reacted swiftly to mitigate risk by

recalling the impacted units and launching a comprehensive investigation and testing effort to identify the root cause. At this point, there have been no reported strokes, deaths or long term patient sequelae associated with these units and we have not received any new complaints related to this issue. Cordis is ramping up its production to replenish our inventories.

So, in summary, we remain focused and excited about our potential to drive the US TCAR market forward as the sole player while we continue to progress our other long-term growth initiatives.

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

Lucas Buchanan -- *Chief Financial Officer and Chief Operating Officer*

Thank you, Erica. Revenue for the three months ended December 31, 2020 was \$21.1 million, a 13% increase from \$18.6 million in the same period of the prior year. Growth was again driven by increased adoption of TCAR across an expanding base of hospital accounts, trained physicians and active sales territories, partially offset by regional headwinds related to COVID-19.

Gross margin for the fourth quarter of 2020 was 75% roughly flat compared to the prior year as improvements in productivity were slightly offset by costs to manufacturing, engineering and infrastructure projects. Sales for the fourth quarter of 2020 were \$30.9 million, a 44% increase from \$21.4 million in the fourth quarter of 2019.

Operating expenses for the fourth quarter of 2020 were \$10.0 million compared to \$3.3 million in the fourth quarter of 2019. The increase was primarily driven by the timing of product development initiatives. Sales, general and administrative expenses for the fourth quarter of 2020 were \$20.9 million compared to \$18.2 million in the fourth quarter of 2019.

This website uses cookies to deliver our services and to analyze site usage. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

quarter of 2019. The increase was primarily attributable to expenses related to growth in our commercial team as well as personnel related expenses.

Expense growth was partially offset by the continued reduction in travel trade show and other expenses due to COVID-19. We expect continued growth in operating expenses in 2021 as we expand our commercial team and invest in a number of continued and new R&D initiatives. Net loss for the fourth quarter was \$16.8 million or a loss of \$0.49 per share as compared to a net loss of \$8.3 million or a loss of \$0.27 per share for the same period of the prior year. We ended 2020 with \$147.5 million of cash, cash equivalents and short-term investments.

Regarding the balance sheet impact of the voluntary recall of certain lots of our ENROUTE Transcatheter Stent Systems in the first quarter of 2021, the obligation to customers was recorded as an accrued liability, whereas the replacement product from Cordis is considered receivables.

Turning to our commercial strategy that Erica mentioned earlier, and our outlook for 2021 we are focused on accelerating the adoption curve and are now significant trained physician base as well as being prepared for a potential standard surgical risk indication. With this in mind over roughly the next two years, we expect to adjust our historical 1:2 ratio of area managers to therapy development specialists to almost a 1:1 coverage ratio without significant change to our overall goals for commercial team

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

be investing in more sales expertise with more focused
ent our excellent clinical support. We expect to end 2021 with
ritories, and we are committed to growing our footprint with
ion in 2022. While driving adoption in our trained physician base
e also expect to train approximately 200 new physicians in
ysician base to perform in excess of 14,500 procedures for the

As a result of our commercial efforts, we expect full-year revenue to be in the range of \$102 million to \$108 million, representing growth of 36% to 44% over 2020 revenue of \$75.2 million. We are cautiously optimistic with our expectations. Recognizing that trends of COVID-19 which are persisting in the first quarter can alter the timeline to a normalized healthcare operating environment.

One final update that I wanted to provide is on our rebranded website that also includes our environmental social and governance policies. Our inaugural Corporate Sustainability Report, which we were up -- which we published in the fourth quarter highlights our dedication to patient safety, as well as our commitment to diversity and equal opportunity. Fundamentally we are in this business to transform and improve lives. We are looking forward to further progress on our status as a socially responsible organization.

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

Erica J. Rogers -- *President and Chief Executive Officer*

Thank you, Lucas. As we reflect on 2020 and the current environment, we are reminded about how far we have come as a company over a relatively short period of time. Just a few years ago, there was no such thing as TCAR and now we stand well in excess of 25,000 procedures performed to-date. We have developed an entirely new market, and

hered in an entirely new era of transcatheter therapies.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

rewards 2020 behind us, I look forward to building upon Silk of employees, engineering competencies and deep intellectual supporting transcatheter innovations. This solid foundation positions transforming the way we treat patients in order to deliver more healthcare system, and of course our shareholders.

open it up to questions. Operator?

Questions and Answers:

Operator

Ladies and gentlemen, we will open it up for question-and-answer session. [Operator Instructions] Your first question comes from the line of Bob Hopkins from Bank of America. Your line is now open.

Bob Hopkins -- *Bank of America -- Analyst*

Okay. Thanks for taking the question and good afternoon.

Erica J. Rogers -- *President and Chief Executive Officer*

Hi, Bob.

Bob Hopkins -- *Bank of America -- Analyst*

Hey, Erica. How are you?

Erica J. Rogers -- *President and Chief Executive Officer*

Good.

This website uses cookies to deliver our services and to analyze our website traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

Bob Hopkins -- *Bank of America -- Analyst*

What I want to ask you guys about the PMA, which you released. And I am just curious could you give us a sense for what's included in that filing and whether or not that big uptick in R&D is related to that filing and data collection? Thank you.

Erica J. Rogers -- *President and Chief Executive Officer*

Yeah. Sure, Bob. Thank you for the question. And yeah, we are really pleased to have announced the submission of the PMA supplement for standard risk. And I think it's obvious that we did not do a prospective clinical trial specifically for this indication. But with that, we are really not going to talk about the contents of the submission itself. We feel it's not prudent to talk about at this point in the review process by the FDA. And relative to the R&D expense, I will let Lucas take that question.

Lucas Buchanan -- *Chief Financial Officer and Chief Operating Officer*

Yeah. I mean, ultimately, Bob, we hope to shed some light on the front part of your question. In terms of the uptick in R&D in Q4, that's part of it. There are other puts and takes related to the timing of R&D broadly defined including clinical regulatory and quality.

Bob Hopkins -- *Bank of America -- Analyst*

Thanks. Thanks for that. The two other things I just wanted to get a quick comment on are, you mentioned OUS markets and I know reimbursement in Europe is something that, there's obviously a pathway associated with that. So I'm just curious on OUS is there any kind of preliminary sense you can give for when you think you will be commercial outside the United States? And then it also, Erica, if you don't mind, just here we are to March 1. Things sounded pretty weak in December and January. Have

in terms of surgical procedure volumes and start to get better sense would be great?

Erica -- *President and Chief Executive Officer*

in reverse order, Bob. So here's what's interesting is, our mix of asymptomatic treatment, right, procedures is kind of an interesting interesting lens to look through for kind of hospital based procedures as a relatively accurate barometer throughout the pandemic, that mix of asymptomatic and symptomatic change.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

And so while we saw in January, as you can expect, coming out of the fourth quarter, a mix where the symptomatic urgent patient population was being treated quite aggressively. We are pleased that as we have moved through the quarter we are starting to see what we would consider are more normal mix of asymptomatic and symptomatic. So I think that, that's a reassuring sign in the healthcare infrastructure just in general to address that.

On the first part of your question, on international, for the first time, Bob, we have kind of put a number, albeit a conservative number on international, which we have done a roll up kind of bottoms up across the major markets in which we might consider launching TCAR and that roll up is about \$2.3 billion in the treated patient population alone.

And of course, we look at Europe and Japan and China, and the first step for us really is to knock down the regulatory barriers in China and Japan, which we continue to work on and we are pleased with the progress. Meanwhile, we have hired a Vice President of International Market Development who is working closely with Andy Davis, Chief Commercial Officer, to develop the strategies to go forward in some of these markets.

Bob Hopkins -- *Bank of America -- Analyst*

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

elines though?

dent and Chief Executive Officer

meline update specifically yet, Bob.

Bank of America -- Analyst

Erica J. Rogers -- *President and Chief Executive Officer*

Thank you.

Operator

Your next question comes from the line of Robbie Marcus from JP Morgan. Your line is now open.

Robbie Marcus -- *JP Morgan -- Analyst*

Great. Thanks for taking the questions. Maybe to follow-up on some of those, for the standard risk submission, was that at the behest of the FDA, did you have discussions with them. Maybe you could help us understand what changed from, let's say, JP Morgan or the third quarter earnings call to today that that prompted it, and you mentioned, it would likely require a post approval study. What should we be expecting in terms of size and cost or something like that?

Erica J. Rogers -- *President and Chief Executive Officer*

Sure. Well, let me sort of take those in reverse order, which is that typically a carotid stent PMA would have kind of a requisite post-approval study. And what we saw in our first PMA approval of the ENROUTE stent in high surgical risk, Robbie, was a

what looked like a more real world study in the post-market course, that was ROADSTER 2, ROADSTER 2 with those incredible events. And so it wouldn't be unusual for the FDA to require a study on any carotid stent and so we are kind of preparing for that

any of the specifics on what we might think would be the scope of that is done in conversation with FDA as you probably know so we are not ready to reveal the details yet. In terms of wh

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

changed between JP Morgan and now, really is the submission itself. And while we are not getting specific on exactly when that PMA went in, suffice to say, it was after JP Morgan, which is why we continue to say we were working on it in discussions with FDA and the other key constituents.

Our strategy all along from the beginning, from the dawn of time, Robbie, was to be in conversations with FDA, with CMS, with the Society of Vascular Surgery and to settle on not only the best approach from a regulatory standpoint, but also to drive adoption and to drive toward a reasonable coverage environment. And so I think without getting into the details since we are in the review process now, suffice to say that, we reached what we felt was a reasonable agreement among the parties.

Robbie Marcus -- *JP Morgan -- Analyst*

Okay. And I'm guessing, we are not going to learn more about what the agreement is until approval.

Erica J. Rogers -- *President and Chief Executive Officer*

Yeah. I think that's a fair assumption, Robbie. I think it's -- it would be atypical for any company to kind of reveal the contents of a PMA in advance of approval. And so I think those details certainly will come into the public light on their own postal approval.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

organ -- Analyst

one on reimbursement upon hopeful approval, do you think you mbursement for standard risk right away or do you think it t required time after approval?

dent and Chief Executive Officer

Yeah. Well, the first step in any coverage environment is approval, right? So we have to -- we certainly have to knock down the PMA approval first. But I think it's safe to say, we have been in discussions all along with the parties around the table and so we will continue to work toward an optimized coverage environment as we seek to get FDA approval.

Robbie Marcus -- *JP Morgan -- Analyst*

Got it. And then last from me, you trained around 350 or so docs during 2020, guidance for 2021 it's only for 200 doctors. I imagine part of this is probably due to the soft environment in first quarter. But I was hoping you could help us understand the 200 number and where that's coming from? And Lucas, if you want to put out a first quarter range for the street, I imagine that's probably a big part of the delta between guidance and what street number set just thought it would be a good opportunity? Thanks.

Erica J. Rogers -- *President and Chief Executive Officer*

Yeah. I can take the first one on training, Robbie. We have said all along that we have been working to kind of lay down the infrastructure of territories, hospitals open, physicians trained. At the end of the day, what we are trying to get at are procedures and to get at procedures you need to train physicians. And so coming out of 2020 with roughly 1,800 physicians trained, that's a lot of access to a lot of procedures.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

prepared remarks, our commercial focus is very much about their adoption curve and this is reflected in the remarks that the sales infrastructure, really making sure that we guide and one of those physicians trained up their adoption curve. And of trained in the pandemic environment potentially need some you can imagine.

more physicians yet to be trained in terms of getting at kind the volume in the United States, our bias is increasingly more

toward moving the existing physicians up the adoption curve, which is why you are -- part of why the number is around 200 for 2021 guidance.

Lucas Buchanan -- *Chief Financial Officer and Chief Operating Officer*

Yeah. And just to zoom out a little bit on that and then I will get to your guidance question, Robbie. At a high level, when you are going against such an established standard of care in CEA, really we have spent the last many years establishing TCAR, which requires not only opening accounts and training docs and taking them carefully through their learning curve, but really establishing a published clinical evidence base from which to market with. And so our past has really been about establishing TCAR and establishing this market. And our future is really, we know the therapy works. It delivers incredible outcomes and so it's more of a commercial focus and driving that adoption curve in this infrastructure that's built with outcomes always as the number one goal.

With respect to your guidance question, yes, like the rest of the industry, Q1 is COVID affected. As a reminder, we are an inpatient procedure. There's an urgent part of the business and there's an elective part of the business in the symptomatic versus asymptomatic. And our assumptions starting in Q2, we start to see a much more normalized operating environment. So if there are further COVID trends that play out to the downside that's not necessarily in our guidance. We are assuming a more normal starting in Q2 and getting incrementally better.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

to do with just kind of the overall engine of medicine and getting treatment funnel, back diagnosis funnel, getting hospitals of COVID and that's a little bit unpredictable. I think we believe big seasonality impact as everybody wants to go visit their and whether you are a patient or a provider, we have had in Q1, of course. But really, we continue to focus on the setup and feel -- feeling really bullish about the business of TCAR a

our long-term growth drivers, especially on the heels of this most recent announcement of a PMA supplement submission, which is really amazing news.

Robbie Marcus -- *JP Morgan -- Analyst*

Great. Thanks a lot.

Operator

Your next question comes from the line of Rick Wise from Stifel. Your line is now open.

Rick Wise -- *Stifel -- Analyst*

Good afternoon to you both. Erica, you were kind enough to highlight the progress you have made on the recall and it was great that the patient comments and that you had no new complaints. Is it basically resolved now in your mind? And just to amplify a couple of things, you indicated Cordis is ramping production to replenish your inventories. Maybe you can give us some color about when you -- how soon you think your inventory will be replenished? And last on that topic, was there an impact on -- in the fourth quarter, again, remind me, but has there been an impact on January, February volumes from your lack of -- from a lack of inventory, I am just not clear about some of those nuances? Thank you.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

dent and Chief Executive Officer

to address those questions and thanks very much. So as it course, nobody wants to have a recall. But I am proud of the very quickly and we were very proactive in that response and e. And so as a result, in many cases our relationships have as a result of our conservatism around patient care.

To get at the question of whether or not the recall itself impacted procedural volumes or for that matter or kind of how the fourth quarter ended, I think we can emphatically say, no. There was there was no impact on procedural volumes. Our field team and our customers were able to continue to execute the cases that were on the schedule and we have been very swiftly replacing the inventory at the hospital level, as well as our own inventories.

Luckily, as a company, we were pretty conservative about the on-hand inventory we carry which put us in a pretty good spot. And so that's the inventory that we are working to replace swiftly with Cordis and they have been a terrific partner not only in getting to resolution of the matter, but in really ramping production to bring us our kind of stock levels back up to where we want them.

So, in terms of whether or not the issue has been resolved. I think it's fair to say we have isolated the root cause, and so what that means, Rick, is now we are in the process of the corrective actions component here, which is highly documented process of making sure the corrective actions are in place and that those corrective actions are effective and so we are in the process of doing all of that which I consider to be on track.

Lucas Buchanan -- *Chief Financial Officer and Chief Operating Officer*

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

let me just quickly add on the financial aspects of your
ed remarks. It's really a balance sheet effect in terms of liability
place those products in a receivable on the Corids side as we
Cordis and so there's no P&L impact either in Q4 or likely in Q1.
main focus is on servicing demand and not going on back
d. So it's really more a question of building up our safety stock.

alyst

Lucas Buchanan -- *Chief Financial Officer and Chief Operating Officer*

Most of that are in inventories.

Rick Wise -- *Stifel -- Analyst*

Sure. And apologies for coming back to the standard risk filing. The good news is you don't have to say when you are going to do something, but now we are moving onto Phase 2 of how long is it going to take? And I know it's impossible to know but I feel like I have to ask. Maybe blame it on your outside consultants. What are your outside consultants saying about the PMA supplement at the current time, are we thinking it could average is it a six-month kind of process, a 12-month kind of process? Can you give us any incremental color just so that we could roughly frame a reasonable expectation?

Erica J. Rogers -- *President and Chief Executive Officer*

Yeah. Rick, I think, it's a fair question, which is the PMA supplement kind of falls under the PMA general category, which is six -- typically a six-month review process. That said, we have not baked in any assumptions around standard surgical risk lift in our guidance for the year. So the \$102 million to \$108 million does not contemplate standard surgical risk commercial activity this calendar year.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

analyst

me, you called up the JAMA study. I wanted to ask you about lly well for TCAR and I realize it's -- I mean it's just part of a es and data that you have. But is it that so much where -- is that tion more aggressively or is that over dreaming or hoping for ific study? Thank you.

President and Chief Executive Officer

Sure, Rick. And I'm glad that you caught that paper in JAMA last week and we felt it was significant enough, obviously, to put a press release around it. It is very big news. And in terms of the light switch phenomenon, we have said this before that becoming the standard-of-care is a methodical and careful march with both our physicians and hospitals. We do see this as a unique tailwind, because it's really about overall outcomes.

It's about hospital efficiencies and better patient care and so I think it will have a unique impact. It's probably too soon to measure or to tell you exactly what that impact is. Although, I assure you our marketing and sales teams are armed and are having those conversations right now. But I think it's safe to say that this business is probably not going to be as a light switch phenomenon. It's moving physicians, moving hospitals up the adoption curve methodically.

Rick Wise -- *Stifel -- Analyst*

Thank you very much.

Lucas Buchanan -- *Chief Financial Officer and Chief Operating Officer*

Hey, Rick, I just want to add some additional color to Erica's PMA comment. I think it's at minimum a six month review cycle, these -- as you know, these PMAs can take

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

on that. This is a novel strategy given that we did not do a
to it's fair to say it's hard to predict. And I think, as Erika
dance is a function of a lot of different puts and takes, focus
e of medicine overall coming out of COVID hopefully than any
and standard surgical risk. There's a lot of preparation regardless
ed. It's not a light switch type of thing. It's something that will
with and talk to physicians about.

Analyst

Thanks again.

Operator

Your next question comes from the line of Joanne Wuensch from Citibank. Your line is now open.

Joanne Wuensch -- *Citibank -- Analyst*

Good afternoon, everybody, and thank you for taking my questions. I want to get to a previous question that sort of focuses on the first quarter, because I think the way when I look at the model you are sequentially improving throughout the year second half stronger than the first half, but it all gets sort of based on that first quarter. Street consensus is around \$24 million. Could you please give us sort of a range of thought on how we are starting the year?

Lucas Buchanan -- *Chief Financial Officer and Chief Operating Officer*

Yeah. I think we have discussed some of the monthly trends in Q4 and alluded to Q1. And I think that argues for more conservatism on Q1 overall in terms of sequential experience off of Q4. And I think as we look toward the year where we are really looking at kind of a three quarter with the second quarter being the path to the

tion. Third quarter typically has some seasonality. We think the be bigger this year just given what's behind us as a society and Q2 to Q4 with a fair amount of conservatism on Q1. Obviously go to see how it fully plays out.

bank -- Analyst

le bit further it sounds like what you are saying given the trends th quarter. I am trying not to put words in your mouth. But I set this up right.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

Lucas Buchanan -- *Chief Financial Officer and Chief Operating Officer*

I think that's on the conservative side of conservative, Joanne.

Joanne Wuensch -- *Citibank -- Analyst*

Okay. Conservative side of conservative. I got it. Can you help us think about how you prepare for standard risk? Is it different? Is it, I mean, different training, different physicians, different sales people. Help us understand that?

Erica J. Rogers -- *President and Chief Executive Officer*

Yeah. Sure, Joanne. Hi and thanks for joining us. And so, in terms of how we have been telling the story up till now, it's really been working with our physicians to identify the high surgical risk criteria that qualify a patient for treatment. If and when we obtain the standard surgical risk PMA approval, it will be the first time where a therapy has been on a level playing field with carotid endarterectomy.

And so that's -- that inherently is going to change the way we talk to our physician customers where the focus will really be on reasons not to do TCAR versus finding those high surgical risk to patients in the high surgical risk criteria. And so, we will be working on additional marketing materials, additional training materials for our own

re labels that get change that flow through the marketing
are all of the things that we are doing in the background.

bank -- Analyst

last question is, what other milestones you are in a position to
mic stroke?

dent and Chief Executive Officer

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

Joanne, we continue to be excited by the opportunity. It's a very fast growing market as you know. It's highly competitive as you also know. And so as a result, we were saving the details until such time that we really kind of have to talk about them. But we are pleased with the progress that we are making and the progress is really on the clinical and regulatory fronts within R&D at the moment.

Joanne Wuensch -- *Citibank -- Analyst*

Terrific. Thank you so much, and have a great night.

Erica J. Rogers -- *President and Chief Executive Officer*

Thanks, Joanne.

Operator

Your next question comes from the line of Danielle Antalffy from SVB Leerink. Your line is now open.

Danielle Antalffy -- *SVB Leerink -- Analyst*

Thank you so much. Good afternoon, everyone. Thanks for taking the questions. Just to follow up on Joanne's question regarding standard risk, and Erica, you alluded to

you do have standard risk you are going to -- it's kind of like the R -- why not TCAR versus who can get a TCAR versus who has serious about how you are thinking of the sort of halo effect on standard risk could bring once you have it and how much of an just in the existing high risk indication. That's the first part of the follow-up.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

President and Chief Executive Officer

Yeah. I think overall, Danielle, it's certainly positive news, and again, this submission is really the first part of a journey toward standard surgical risk. So we don't want to get too far ahead of ourselves. But I think we have said this all along, Danielle, which is vascular surgeons don't really divide up the world in high surgical risk and standard risk. That's a vernacular that is born out of regulatory and reimbursement policies. And so what we find ourselves doing now is really having a conversation that is kind of not natural around high surgical risk and standard risk. So this will be for the first time putting us on a level playing field.

Whether or not that has a halo effect for the overall market opportunity, the number of patients treated, etc. I think it's too soon to tell. So I don't want to get ahead of ourselves. I do think there is a tailwind in this JAMA paper that we just talked about, which is the presence of TCAR in an institution improves the outcomes overall and that coupled with our entry ultimately into standard surgical risk. These are the kinds of tailwinds that will begin to move us toward the standard-of-care and potentially begin to expand the market.

Danielle Antalffy -- *SVB Leerink -- Analyst*

Yeah. That's -- Okay. That makes sense and that's helpful. And I guess just to get my follow up, I mean you kind of answered it already. I will ask it anyway to see if there's any more color to be gleaned here. But is if you get a little bit more granular there and looking at the centers that are already doing TCAR for example, I think that by treating those patients, they are already trained on the device, and that's the rationale in continuing to treat a patient that they are going forward with the carotid endarterectomy once you have the standard of care. It just seems like there is no rationale, but maybe I am being

This website uses cookies to deliver our services and to analyze our website traffic. We also share information about your use of our site with our advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

President and Chief Executive Officer

Danielle, this is the question that we ask ourselves every day, right? What is the continued rationale? And it really comes down to inertia. We are up against a 70-year old procedure and physicians who have been doing that procedure for multiple decades many of them. And we have talked about this inertia before by saying a mid-career vascular surgeons done 400, 500 carotid endarterectomies compared to maybe 50 or 60 TCARs, which is a lot but it pales in comparison. And so it's really about physicians in their own hands, the predictability of TCAR. I think this JAMA paper furthers the evidence on the predictability of TCAR. It's baked into that whole improving of the overall outcomes. And so each and every month that goes by and every publication that is presented in a peer reviewed journal begins to chip away at that inertia.

Danielle Antalffy -- *SVB Leerink -- Analyst*

All right. Thanks so much.

Operator

Your next question comes from the line of Adam Maeder from Piper Sandler. Your line is now open.

Adam Maeder -- *Piper Sandler -- Analyst*

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

I thanks for taking the questions. I had just one quick question Erica and Lucas. And I know you acted out of an abundance of did a thorough investigation in it. It sounds like you have the issue and that's behind you. So, I guess, I was hoping if you understand what the root cause was up to the detachment -up too. Thanks.

President and Chief Executive Officer

Yeah. Sure. Happy to talk about the root cause and thanks for joining us, Adam. As we talked about before, the root cause is really human error centered, having to do with a particular part of the manufacturing process. And we consider it very good news that a root cause could be identified. Often in these recall scenarios, you are looking for a kind of a needle in a haystack, you are trying to find some commonality among the lots that have been recalled. But thanks to the excellent work of our engineering team and our quality team we very quickly zeroed in on in particular human aspect of the process.

Adam Maeder -- *Piper Sandler -- Analyst*

Okay. Thanks for the color there, Erica, and that's great to hear. And for the follow ups, I guess, the next question is on just the growth outlook for 2021. It feels like the focus has really started to shift more toward increasing utilization in the existing customer base versus training more and more physicians. So the question is, qualitatively how should we think about the growth of the business in terms of the contribution from increased utilization with existing docs versus new doc ads? And I know you gave that 200 new doc number, but what does that mix look like and then maybe you could level set us on those dynamics in past years in terms of their contributions to growth?

Lucas Buchanan -- *Chief Financial Officer and Chief Operating Officer*

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

will take that one and Erica can add any color. We have always new physicians is kind of investment in the future not necessarily mess in the near-term. And going back to 2019, we trained quite than we had planned to. So our bias has been even throughout and more focus on the trained physician base. We are exiting 2020 n overall and so there's just a lot of room to run by applying that ws is that this is already a concentrated group of docs and so n to benefit from all those prior year training activities.

And the fact that we have gotten a lot of physicians now through their first cases and early part of their experience curve. And as the data and the experience in individual hands accrue that's where we can constantly kind of revisit and remind about all the benefits of TCAR against CEA, which they still hold in high regard. And so that's where we have been increasingly applying the focus and that continues even more so in 2021, as well as planning for hopefully positive news with FDA on the standard risk medication.

Adam Maeder -- *Piper Sandler -- Analyst*

Thanks for the color there. And then just one last one if I can sneak it in just on the P&L. Opex in Q4 was a little bit above what we are modeling and I think that was due to the R&D step up. It sounds like you expect continued growth in opex in 2021. So just trying to, I guess, dial that in a little bit better for our models. So just any quantitative or qualitative color you can give on opex spend in 2021 would be great? Thanks so much.

Lucas Buchanan -- *Chief Financial Officer and Chief Operating Officer*

Yeah. As I said in my prepared remarks, there were some timing related effects in Q4. That being said, if you annualize that number, you can look at a run rate and not only are we continuing to invest in certain product and clinical and regulatory activities, but we have got some new ones this year. We are also investing, as we said, in the the next two years to a slightly different mix. And so all of those incrementally take up opex in the '21 quarters and drive long-term

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

Piper Sandler -- *Analyst*

OU.

There are no questions from participants online. I will turn the call back over to Ms. Erica Rogers for the closing remarks. Please go ahead.

Erica J. Rogers -- *President and Chief Executive Officer*

Thank you all very much for tuning in to the Silk Road earnings call and we hope you have a terrific 2021.

Operator

[Operator Closing Remarks]

Duration: 58 minutes

Call participants:

Caroline Paul -- *Investor Relations*

Erica J. Rogers -- *President and Chief Executive Officer*

Lucas Buchanan -- *Chief Financial Officer and Chief Operating Officer*

Bob Hopkins -- *Bank of America -- Analyst*

organ -- *Analyst*

alyst

bank -- *Analyst*

Leerink -- *Analyst*

Sandler -- *Analyst*

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

[More SILK analysis](#)[All earnings call transcripts](#)

This article is a transcript of this conference call produced for The Motley Fool. While we strive for our Foolish Best, there may be errors, omissions, or inaccuracies in this transcript. As with all our articles, The Motley Fool does not assume any responsibility for your use of this content, and we strongly encourage you to do your own research, including listening to the call yourself and reading the company's SEC filings. Please see our [Terms and Conditions](#) for additional details, including our Obligatory Capitalized Disclaimers of Liability.

Motley Fool Transcribers has no position in any of the stocks mentioned. The Motley Fool has no position in any of the stocks mentioned. The Motley Fool has a [disclosure policy](#).

5 Stocks Under \$49

We hear it over and over from investors, "I wish I had bought Amazon or Netflix when they were first recommended by the Motley Fool. I'd be sitting on a gold mine!" And it's true.

And while Amazon and Netflix have had a good run, we think these 5 **other** stocks are screaming buys. And you can buy them now for less than \$49 a share!

You can grab a copy of "5 Growth Stocks Under \$49" for FREE for a limited time only.

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

SILK

\$42.28 (-1.56%) \$0.67



Motley Fool Stock Advisor's Latest Pick?

[Get Access](#)
311% Avg Return*

**Average returns of all recommendations since inception. Cost basis and return based on previous market day close.*

RELATED ARTICLES



Silk Road Medical, inc (SILK) Q3 2021 Earnings Call Transcript



Silk Road Medical, inc (SILK) Q2 2021 Earnings Call Transcript



SILK ROAD MEDICAL INC (SILK) Q1 2021 Earnings Call Transcript



SILK ROAD MEDICAL INC (SILK) Q3 2020 Earnings Call Transcript



SILK ROAD MEDICAL INC (SILK) Q2 2020 Earnings Call Transcript

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)

Articles



2 Pieces of Good News for Retirees on Social Security and Medicare

Tomorrow's a Big Day for Social Security Beneficiaries. Here's Why

**Soc
Wha**



Premium Investing Services

Invest better with The Motley Fool. Get stock recommendations, portfolio guidance, and more from The Motley Fool's premium services.

View Premium Services

This website uses cookies to deliver our services and to analyze traffic. We also share information about your use of our site with advertising and other partners. [Privacy Policy](#)

Got it

[Cookie Settings](#)