UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K/A
(Amendment No. 1)

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): November 9, 2020

Shockwave Medical, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-38829**	**27-0494101**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

5403 Betsy Ross Drive, Santa Clara, California 95054
(Address of Principal Executive Offices) (Zip Code)

(510) 279-4262
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

[ ] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
[ ] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
[ ] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
[ ] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	SWAV	Nasdaq Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company [X]

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [X]

Explanatory Note

On November 9, 2020, Shockwave Medical, Inc. (the "Company") furnished a Current Report on Form 8-K (the "Original Form 8-K") with the U.S. Securities and Exchange Commission to report that on November 9, 2020, the Company issued a press release announcing financial results for the quarterly period ended September 30, 2020. In addition to issuing a press release, the Company held a conference call on the same day to discuss financial and operating results. This Amendment No. 1 to the Original Form 8-K is furnished to include a transcript of such conference call.

Item 2.02. Results of Operations and Financial Condition.

On November 9, 2020, the Company issued a press release announcing its financial results for the quarterly period ended September 30, 2020, as previously furnished. Also, on November 9, 2020, the Company held a conference call to discuss financial and operating results. A transcript of the conference call is attached hereto as Exhibit 99.2.

The information under Item 2.02 in this Amendment No. 1 to current report on Form 8-K and the related information in the exhibit attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act") or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	**Description of Exhibit**
99.2	Transcript of the Shockwave Medical, Inc. conference call held on November 9, 2020 to discuss financial and operating results for the quarterly period ended September 30, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Shockwave Medical, Inc.

Date: November 10, 2020

By: /s/ Dan Puckett
Dan Puckett
Chief Financial Officer

ShockWave Medical, Inc. NasdaqGS:SWAV
FQ3 2020 Earnings Call Transcripts
Monday, November 09, 2020 9:30 PM GMT

Corporate Participants

Daniel Puckett

CFO & Secretary

Debbie Kaster

Head of Investor Relations

Douglas E. Godshall

President, CEO & Director

Keith D. Dawkins

Chief Medical Officer

Presentation

Operator

Good afternoon, and welcome to ShockWave's Third Quarter 2020 Earnings Conference Call. [Operator Instructions] As a reminder, this conference call is being recorded for replay purposes.

I would now like to turn the call over to Debbie Kaster, Head of Investor Relations at ShockWave, for a few introductory comments.

Debbie Kaster

Head of Investor Relations

Thank you all for participating in today's call. Joining me today from ShockWave Medical are Doug Godshall, President and Chief Executive Officer; Keith Dawkins, Chief Medical Officer; and Dan Puckett, Chief Financial Officer. Earlier today, ShockWave released financial results for the quarter ended September 30, 2020. A copy of the press release is available on ShockWave'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, statements related to our sales and operating trends, future product development and approvals are based on our current estimates and various assumptions. These statements involve material risks and uncertainties, including the impact of COVID-19 pandemic 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 annual report on Form 10-K on file with the SEC and available on EDGAR and in our other reports filed periodically with the SEC. ShockWave 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.

This conference call contains time-sensitive information and is accurate only as of the live broadcast today, November 9, 2020.

And with that, I'll turn the call over to Doug.

Douglas E. Godshall

President, CEO & Director

Thanks, Debbie. Good afternoon, everyone, and thank you for taking time to join us to review ShockWave's results for the third quarter of 2020. I would like to start our discussion today with a quick snapshot of some meaningful recent achievements. We reported $19.6 million in revenue for the third quarter, representing a 73% increase from $11.3 million in revenue in the third quarter of 2019. In late August, we submitted our PMA application for FDA approval of coronary IVL. Related to that PMA, just last month, results from our DISRUPT CAD III IDE study were featured as a late-breaking presentation at the TCT Connect conference. Our DISRUPT PAD III peripheral trial results were also featured as a late-

breaking clinical trial presentation at VIVA '20 this past weekend. We continue to build our U.S. field team in anticipation of our coronary launch with a total of 100 -- over 100 people as of September 30.

To say our team has been busy would be an understatement as we have achieved significant milestones in very -- in virtually every operational area over the past month -- past several months. And having just come off both TCT and VIVA where we were honored to have data on both coronary and peripheral applications of IVL presented in late-breaking sessions at these key medical conferences, we want to begin today with a discussion of our clinical data and progress. Both conferences provided us with an opportunity to share high-quality data that confirmed the safety and effectiveness of IVL on large and challenging patient cohorts, showcasing the consistent performance of IVL.

And to provide more perspective on the clinical data, I am fortunate to have with me today Dr. Keith Dawkins, our Chief Medical Officer. Keith?

Keith D. Dawkins

Chief Medical Officer

Thank you, Doug. The team here at ShockWave has done an extraordinary job, and the results we have seen are really very impressive. At TCT, the late-breaking DISRUPT CAD III clinical trial results were well received by the clinical community. CAD III is our prospective global IDE study of coronary IVL for the treatment of de novo calcified stenotic coronary artery lesions prior to stenting. It is a single-arm study of 384 patients at 47 sites in the United States, France, Germany and the United Kingdom. The patients in CAD III had the longest, the most complex and the most calcified coronary lesions ever studied in a controlled clinical trial. We discussed the detailed results of the study during TCT, which showed that coronary IVL met both safety and the effectiveness goals. So today, I'm going to provide more perspective around what we saw and what it means for both IVL and the everyday prices of treating calcific coronary disease.

While I was a practicing interventional cardiologist, I had the good fortune of being intimately involved in patient care where most of the major innovations in PCI were introduced into clinical practice. In my view, the 3 prior transformational product introductions were balloon angioplasty, bare metal stents and drug eluting stent.

Since 2002, when the Cytosine was introduced, there's not been another disruptive innovation until ShockWave introduced IVL. As patients are living longer and suffering from diabetes in an increasing rate, more and more of the patients with coronary disease are presenting with calcified vessels, approaching an incidence of 30%. These patients are materially more challenging for clinicians to manage successfully since balloons and stents struggle to open the hard lesions adequately and atherectomy carries adverse event risk and user technique challenges that keep its use to less than 5% of PCI procedures globally.

Cases are becoming more challenging, and this is reflected in the patients treated in CAD III. The data we observed in CAD III did not just meet the A priority endpoint, they showed excellent results that the core lab adjudicated in the kinds of complex cases that are a challenge in everyday clinical practice.

Dean Kereiakes also presented data showing no significant difference in outcomes between the initial 47 rolling patients and the 384 patients in the pivotal cohort. This reinforces another aspect of IVL that has been resonating globally, ease of use. Atherectomy is a great tool for selected patients, but a large percentage of cardiologists will not use it or are not trained to use the technology, and their patients are either referred elsewhere or treated suboptimally. IVL is a tool that every interventionalist can use and use safely with minimal training. The extremely low adverse event rates reflected in the CAD III data set, combined with the simplicity of the IVL system, will make calcium intervention easily accessible and intuitive for any interventional cardiologist practicing PCI.

To close on CAD III, this study successfully demonstrated the effectiveness of coronary IVL in treating calcium with large lumen gains for facilitated stent delivery. We were pleased to submit these data as part of our PMA application to FDA in August, and we continue to anticipate FDA approval in the first quarter of 2021.

Let us now turn to DISRUPT PAD III, which was also presented as the late-breaking trial just this past weekend of VIVA 20. PAD III is the largest randomized study of severely calcified peripheral lesions ever conducted. It is not common to have a randomized core lab-adjudicated trial in the periphery in general, and there's never been one that includes calcified lesion. PAD IIII evaluated lesions that are almost always excluded from other studies. And even in this most complex population, IVL still demonstrated superiority on the primary endpoint.

The primary objective of PAD III was to demonstrate that IVL delivers improved procedural success, less need for stent and fewer complications when compared to standard balloon dilatation prior to DCB, and we won on all endpoints. PAD III demonstrated that IVL usage resulted in a significant reduction in dissection and provisional stenting versus PTA, and that IVL achieved low residual stenosis with lower pressure, less need for post validation and pure complications than PTA. PAD III confirmed the consistent safety and effectiveness of IVL from previous study in multiple vascular beds.

The data from these 2 trials help reinforce why IVL is being adopted so readily in many applications, reducing the severity of arterial dissection, minimizing the need for stents in peripheral vessels and doing so with a balloon delivery system that has almost no associated embolic risk resonates with the clinicians, particularly when procedural safety is a paramount concern. There is an interesting juxtaposition between these 2 trials. In the coronaries, the objective is to safely prepare the vessel to facilitate optimal stent deployment. In the periphery, the objective in this trial and in most peripheral intervention is to safely expand the lesion without having to place a stent. The common trait in all of the IVL applications is safety and ease of use. Both of these attributes have been well demonstrated.

I look forward to taking your questions, but for now I will turn the call back to Doug and Dan.

Douglas E. Godshall

President, CEO & Director

Thank you, Keith. ShockWave has shown a strong commitment to clinical research, and we are generating the largest collection of high-quality data in the complex calcified patient population across both peripheral and coronary applications, now having over 100 published papers on intravascular lithotripsy and data on more than 2,000 patients.

The response to our CAD III data has been extremely positive thus far. And I've had the good fortune to sit in on multiple CAD III data reviews with some of the busiest coronary interventionalists in the U.S., and the 2 most common responses I've heard after our team walks through the safety data and OCT images are: game changer and when can I have it? The PAD III data are still hot off the presses, but that, too, has been very well received thus far, and we're looking forward to sharing this unique data set with our current and prospective customers. We are so fortunate to have these 2 unusually strong core lab- adjudicated data sets to further confirm that -- what our customers already know: intravascular lithotripsy is effective, safe and easy to use.

Moving to the commercial side of the business. Average daily sales continued to build throughout the third quarter as we had predicted. U.S. peripheral cases were almost back to normal by the end of September, with most of the COVID backlog being cleared over the course of the quarter. Our large-bore strategy continues to resonate with physicians, and we are seeing IVL used in iliacs, both for access and symptomatic indications, growing fastest amongst our various above-the-knee applications.

Our S4 rollout is continuing to build in the U.S., and we are progressing well with our limited launch in Germany. What we found most encouraging about the quarter commercially was that as soon as procedures started picking up, so did the utilization of ShockWave, whether that was in the U.S. or international and whether it was coronary or peripheral. We believe the noticeable bounce back we saw during the quarter confirms that IVL has become an integral component of the treatment algorithm for both peripheral and coronary interventionalists who use our device.

Overall, it was good to see how quickly hospitals were able to recover after such a devastating second quarter and gratifying to see the ShockWave momentum build at an even faster rate than procedure recovery through the quarter. Unfortunately, as has been well documented, COVID cases are now increasing rapidly in the U.S. and at an even higher rate in Europe. September was an extremely strong month for us on an average daily sales basis, and October was similar, although down slightly, just as we witnessed last year. It was -- is normal monthly variability, particularly in the first month of a quarter.

We entered this quarter with strong momentum, so we were expecting very good sequential growth, much as we experienced last year. But given how quickly the situation with the virus is evolving and the uncertainty of the effect that could have on procedures, it is quite challenging to confidently predict where the quarter will land. We will continue working hard to serve our customers and their patients, but we will be negatively impacted if procedures drop off for a bit due to this latest COVID surge. In terms of 2021, we expect to be in a position to provide guidance earlier in the year, but we anticipate, particularly based on the recovery we witnessed last quarter, that growth will accelerate as we get past this current virus wave, and we will see further acceleration following the approval of C2.

Turning now to our sales preparations. As you know, expanding our field team in anticipation of coronary approval in the U.S. has been a key focus over the past several months, and we are impressed by the capability of the team we now have in place. We've also rounded out our sales leadership group with a full roster of 9 area directors in place, which gives us the bandwidth to effectively manage this much larger team. We are now focused on hiring clinical specialists with a goal of getting to a 1:1 ratio of territory managers and clinical specialists, which will give us the coverage and flexibility to launch C2 and maintain peripheral growth.

Our coronary training is well underway now as we prepare for the C2 approval in the U.S. In addition to our in-house training, we have enlisted several leading interventional cardiologists to help educate our team on complex coronary interventions and how IVL will fit into their practice in the overall treatment continuum. Our team will be well-trained and ready when the PMA is approved.

We believe that the best approach to the C2 launch is to progress in a deliberate way through a focused list of targeted accounts. Within this priority target list, our plan is to go account-by-account and to effectively train and install C2 to ensure that every interventional cardiologist and the key staff members at each hospital are fully educated and prepared to use IVL independently. Once complete, the team will move on to the next hospital on their priority list and repeat the same process of training and installing C2. This disciplined approach will ensure that our customers are comfortable using ShockWave independently and appropriately and will enable us to sustainably build out our coronary launch.

On the regulatory front, the team is fully committed in working through the final stages of the PMA review process. In parallel, we are pressing forward with the regulatory process in Japan. As a reminder, the coronary CE Mark and our U.S. PMA are based on 30-day follow-up, while PMDA in Japan required 12- month follow-up following our CAD IV patients. We had a very productive meeting with the PMDA a few weeks ago, during which we presented to the authority a request that we'd be able to submit with less than 12-month follow-up on patients in the study and then supplement when the 12-month data were available. We were pleased that PMDA agreed with this proposal, and we will now be able to submit a few months earlier than we had originally anticipated, which ought to then result in an earlier approval as well.

Touching quickly on reimbursement. As you are likely aware, the lower extremity endovascular basket was withdrawn from the early October CPT panel meeting by the societies. We continue to have limited visibility into what is happening behind the scenes. So right now, all we know is that the basket was withdrawn. We will, of course, stay as close to the process as we can. We had always assumed the most likely scenario was for the new basket of codes to go into effect in January of 2023, and this is something that still remains.

In terms of coronary reimbursement, we have applied for a new technology add-on payment, or NTAP, for inpatient procedures, which, if successful, would result in additional payment in October of 2021. We have applied now because the CMS inpatient group works on an annual cycle, and they permit applications prior to FDA approval. CMS outpatient programs work on a quarterly basis, and we will be able to address those opportunities after FDA approval. We are hopeful that our Breakthrough Device Designation will help for both inpatient and outpatient reimbursement programs.

And lastly, before I turn the call to Dan, we have made great strides on the production front and are poised to start work on our new cleanroom within the next month or so. COVID has dragged out the permitting and construction start, but fortunately, as is reflected in this quarter's gross margin, the operations and quality teams took advantage of the delay and made meaningful improvements to our production. We added an extra line in our existing space, lowered scrap, reduced the amount of time spent training and reduced assembly time per catheter, which collectively led to some encouraging results for the quarter and bodes well directionally for the future.

And with that, I will turn the call to Dan to review the financials.

Daniel Puckett

CFO & Secretary

Thank you, Doug. Good afternoon, everyone. ShockWave Medical's revenue for the 3 months ended September 30, 2020, was $19.6 million, a 73% increase from $11.3 million in the same period of the prior year. U.S. revenue was $11.1 million in the third quarter of 2020, representing a 77% increase from $6.3 million in the same period of last year. As we pointed out in the last call, April was a COVID low point in terms of sales, and the increase in this quarter represents a continued recovery from the impact from COVID and the growth driven by U.S. sales force expansion in the new territories. International revenue was $8.5 million in the third quarter, an increase of 67% from the $5.1 million in the same period of last year. We have seen similar recovery in the international markets as the U.S., and we are now commercially selling IVL in 49 countries outside the U.S.

Looking at our product lines, our peripheral products, M5 and S4 accounted for $12.3 million of the total revenue in the third quarter of 2020 compared to $7 million in the same period of 2019, a 77% increase. Our coronary product, C2, accounted for $7 million of the total revenue in the third quarter of this year compared to $4.2 million in the same period last year, representing a 67% increase. All of our C2 revenue is currently international. In addition, the sales of generators contributed $270,000 in revenue in the third quarter of 2020 compared to $195,000 in the same quarter last year.

Gross profit for the third quarter of 2020 was $14.3 million compared to $6.9 million in the third quarter of 2019. Gross margin for the third quarter 2020 was 73% as compared to 61% in the same period of last year. Contributors to the higher gross margin included continued manufacturing productivity and process efficiencies.

Total operating expenses for the period were $27.1 million, a 36% increase from $20 million in the same quarter last year. Sales and marketing expenses were $13.6 million in the third quarter of this year compared to $8.2 million in the same period of the prior year. The increase was driven primarily by sales force expansion.

R&D expenses in the third quarter were $7.9 million compared to $8.4 million in the same period of last year. The decrease was driven by clinical expenses as most of our major clinical studies concluded enrollment in the first half of 2020.

General and administrative expenses for the third quarter of 2020 were $5.6 million compared to $3.4 million in the same period of last year. The increase is primarily due to headcount increases to support the growth of the business.

Net loss for the third quarter of 2020 was $12.9 million compared to a net loss of $13 million in the same period of last year. Net loss per share for the period was $0.38. We ended the quarter with $215.3 million in cash and cash equivalents.

I'll now turn the call back to Doug.

Douglas E. Godshall

President, CEO & Director

Thanks, Dan. Despite the multiple challenges that we've all been facing, the ShockWave team has made great progress this quarter. With our recently published clinical data and an encouraging rebound in the use of IVL as soon as cases resumed, we continue to see mounting evidence that intravascular lithotripsy is an important disruptive therapy for patients suffering from calcified vascular disease.

I want to thank you all for joining us for the call today, and I wish you continued health as we head into what is likely to be a challenging winter season. Please wear a mask.

With that, we'll open the call for questions.

Question and Answer

Operator

[Operator Instructions] Our first question comes from the line of David Lewis with Morgan Stanley.

David Ryan Lewis

Morgan Stanley, Research Division

Just a few for me. Maybe -- Doug, maybe two for you, and then one for Keith. But Doug, just to clarify the comments in the fourth quarter, last year, you were a little more conservative in the fourth quarter just given distributor dynamics. Have you seen sort of changes in the fourth quarter as it relates to procedure cancellation outside of sort of normal international distributor activity? My just question is it just a statement around conservatism, or have you seen some changes in the channel?

And the other one for you is just thinking about coronary next year. Some of our cardiovascular companies have seen impact on launches tied to, obviously, COVID dynamics. But then again, I think about CAD III illustrating how easy this product is to use, so I would think the training dynamics here are not that dramatic. So just any thoughts you'd have on sort of new product adoption next year on coronary? And then a quick follow-up for Keith.

Douglas E. Godshall

President, CEO & Director

Yes. It's -- we really struggled with how to describe what might happen over the next 6 to 8 weeks because it's -- the business is trending reasonably well through October, very much mapping to what we saw last year, frankly, in terms of the September to October trend. And yet, it's -- you start to hear about patients getting a little bit concerned about coming into hospitals. And as Keith can attest, he's over in France right now, he has to get a permission slip to go out and go anywhere. So the -- like not too dissimilar to the way things were trending in the spring.

So it's -- we thought it would be important to be a bit cautious about guaranteeing that we're going to be growing this quarter because it seems hard to fathom that the scale of the current COVID wave wouldn't have some impact on procedures. And then sort of forecasting a virus is not something we're all that good at doing, which makes it challenging to then extrapolate what that -- what the unknown trends on COVID are going to do to our procedure volume. So luckily, great traction in the third quarter, continued very strong interest and support from both existing and pending customers, and yet, ignoring the potential COVID overhang would seem not very prudent.

The -- we're hearing of possible procedure cancellation type things, but we haven't seen a lot of it yet. But it does seem that it's -- in places like Italy, it might be happening or about to start happening.

In terms of the C2 launch, one of the beauties of our device, as Keith highlighted, is it's remarkably straightforward, ease-of-use, very little training required. We have hundreds of cardiologists who've already been trained on it in U.S. just for peripheral application, but there's very little incremental to learn when applying to the coronaries. We do however want to make sure that all the staff is well trained, et cetera. So if we have to be creative or find new ways to train, if we aren't through this COVID wave, although I think we will become first quarter, luckily, we're not a particularly labor-intensive device when it comes to training. So I don't anticipate that the actual training would be an impediment. It would be only be more of a patient volume question, is there still a real slowdown in elective procedures. And again, I would expect first -- halfway through the first quarter, it'll be more like a September than it will be like this past April was.

David Ryan Lewis

Morgan Stanley, Research Division

Okay. Very helpful. And then Keith, just a quick one for you. Obviously, the IVL has been successful in a lot of different vessel beds, but the place it's probably struggled with the most on a relative basis was the SFA, just given perceived clinical benefit and, obviously, reimbursement. I wondered just in light of PAD, that trial was majority SFA, and they're very robust results in calcified lesions. I mean does that begin to change this perception of sort of relative value in the SFA? And I'm sorry to hear about the hall pass that's required over there.

Keith D. Dawkins

Chief Medical Officer

Thank you, David, for your concern. Obviously, in terms of dividing up the lower extremity, to dig down into the different parts of the lower extremity in the results from a 306-patient study is quite challenging. But what was -- what is interesting to us is that the results really do mirror the PAD III observational study, which obviously is much larger, and will have adequately powered data sets for each part of the lower extremity.

And one of the themes that you will have seen, actually, just across vascular bed, is just a very simple mantra, ease-of-use, effectiveness, good efficacy, good safety and particularly good safety. Obviously, the lower limb, I feel as a cardiologist, is a bit like the wild west, lots of different devices and not a lot of data. So we were very encouraged to provide a randomized trial, which really confirmed what interventions, as to one sort or another, were finding in multiple vascular beds.

We're particularly interested, obviously, in below the knee. And we're now collecting a lot of below-the- knee data with S4, and that's another area which is quite challenging for interventionists.

So I think the theme is common across the vascular base, and we've shown that now with 2 late-breaking trials in quick succession.

Operator

Our next question comes from the line of Bob Hopkins with Bank of America.

Robert Adam Hopkins

BofA Merrill Lynch, Research Division

I guess, one quick follow-up here is just on the coronary side in the U.S., how long do you think it'll take to kind of get a critical mass of hospitals trained? And when would you have us be thinking about the time lines for when you'll kind of be in full launch mode?

Douglas E. Godshall

President, CEO & Director

Yes. So we're anticipating a first quarter approval. If we're on the exact 180-day clock, it'll be right around probably March 1 or so. And we will go into full launch mode right away, although what we really want to guard against is running from hospital to hospital, covering cases. That's an inefficient use of our time, and it's not the optimal way really, frankly, to even help the hospitals, we'd rather, again, sort of methodically go account by account. And fortunately, there seems to be plenty of interest from sites to come on board. You do have to still go through a back process and the like, so some who may think they're ready may take a month or 2 to get through the back process. But we anticipate that within the first week, we'll start having accounts sort of install C2.

So what we're -- what we don't -- we don't count success by numbers of hospitals, so we're not going to try to max out and try to get all 1,200 PCI sites to use ShockWave right away because then it'll probably be underutilized and we'll end up having to spend a lot of time going back and retraining and reeducating. So I fully anticipate that all 100 folks -- 100-plus folks we're going to have in the field will be working rather aggressively to both create new coronary customers while also making best use of their time to continue growing our peripheral business, which is why we think it's so important to have a good balance of sales and clinical specialist partners.

And so I don't know how you would define a full launch, Bob, but for us, full launch starts day 1, and it's methodically building out the business because we think 9 months later, that will create a much larger business than if we try to just run around and case -- chase cases.

Robert Adam Hopkins

BofA Merrill Lynch, Research Division

Yes. No, that makes sense. And -- but I'm also curious, like at this point, do you have the resources internally in terms of personnel? Because obviously, you've got a lot going on with below-the-knee launch and the new PAD data and the coronary launch. Do you have the people you need right now to make you comfortable that you can kind of maximize the opportunity over the course of the next 12 months?

Douglas E. Godshall

President, CEO & Director

Yes. Well, if we had the good fortune of getting approved today, we would launch it today. And we're not far off of our sort of a minimum target that we would like in terms of field coverage. We are -- we've been beefing up our marketing team on the coronary side, just added an excellent new team member there.

We've really revamped mid-COVID and meaningfully upgraded our training program. So we brought in a real strong training leader, which was fortuitous timing that he came on right around the time things slowed down on COVID because we had to be really creative about how to train when you're never seeing each other in person.

So none of us are sitting around saying, "Gee, I wish we had this many more people, and we can't quite -- we're not quite ready." We are continuing to hire, and we are -- we focused on territory managers in the summer, now we're focusing on clinical specialists. We're very lucky that our customers seem to say very nice things about our technology because people are hearing good things in the field, and that's helped in terms of recruiting.

Robert Adam Hopkins

BofA Merrill Lynch, Research Division

And then just real quickly, how is BTK going? Like how would you qualify the launch? And one of the important developments, I guess, over the last week has been Becton, Dickinson's announcement that seems to be almost probably permanently delayed on their end. So just kind of wanted some quick comments on how BTK is going.

Douglas E. Godshall

President, CEO & Director

Yes, it's going well. It's as Keith's implied, it's a complicated space below the knee. And like the rest of peripheral, folks have their preferred approaches. The -- some of the folks who -- in fact, we had somebody in just last week, and she always uses balloons, never ever uses atherectomy, unless absolutely necessary. And others use atherectomy whenever possible below the knee. So it's a curious space, and we don't have the kind of data that we just provided in PAD III.

On the other hand, dissections are more of a concern below-the-knee, embolization is certainly more of a concern below the knee. And I think PAD III is very extrapolatable to other peripheral vessels. Even though we can't claim it's the same vessel, I think customers will extrapolate that themselves. So I think that'll be a helpful adjunctive bit of data for us to educate our customers with.

So overall, I'd say, S4 is going well. The relaunch that really took place in the late summer, we've also been augmenting with some senior leadership engagement, and that seems to have also been bearing fruit with some of the very high-volume below-the-knee operators.

So, so far, so good. I would always take better, but it's going very well.

Operator

Our next question comes from the line of Larry Biegelsen, Wells Fargo.

Lawrence H. Biegelsen

Wells Fargo Securities, LLC, Research Division

Doug, congrats on a really nice quarter. So a couple for me. One, on Japan, I think that's coronary -- it's coronary only, right, Doug? Just correct me on that.

Douglas E. Godshall

President, CEO & Director

Yes. Yes. The timing...

Lawrence H. Biegelsen

Wells Fargo Securities, LLC, Research Division

Go ahead.

Douglas E. Godshall

President, CEO & Director

We got a note from Japan that they loved our PAD III data this morning, so that's good. So now we'll have to start up our peripheral efforts in Japan.

Lawrence H. Biegelsen

Wells Fargo Securities, LLC, Research Division

Okay. So could you be more specific, please, on the time lines there? You just said they were willing to accept less than 12 months, if I heard correctly. So I think the old timing was a 2022 launch. What's the filing there, approval and reimbursement? When -- for coronary, what's your best guess today?

Douglas E. Godshall

President, CEO & Director

So best guess. Our best guess prior to the meeting with PMDA was that we would have been submitting right at the end of June. So we think we just shaved 3 months off of that, so circa end of March, beginning of April. We always estimate about a 12-month cycle, so -- for PMDA, so assume about a year later, we would get approved, and then you start the reimbursement process. And while we will do some commercializing in advance of reimbursement, most of the efforts would take place once reimbursements are in place, and best guess would be that, that would be kind of fourth quarter of '22.

Lawrence H. Biegelsen

Wells Fargo Securities, LLC, Research Division

Got it. One big-picture question, Doug. I asked this question to Dr. Kereiakes on the TCP call. 5% penetration today in the U.S. of atherectomy in coronary. I asked it could double in the next 5 years, he said he thought it would happen faster. What can you provide us, Doug, with your -- and where you see penetration going? And we're modeling you guys capturing about half of that in 5 years. So if the market goes to 10%, you guys have half. How are you looking at this longer term?

Douglas E. Godshall

President, CEO & Director

Yes. So there's the patient population we would be applicable for and then sort of what's the realizable percentage of those patients we could achieve. Nonscientifically, and Keith can probably feel free to correct me if I'm -- if you -- or augment, Keith, but about 30% of the coronary patients have calcified coronaries. I'm encouraged how frequently that number is reinforced when we've had some of these interventionalists training our sales team. Independently, they're saying 25%, 30% that they see in their practice. Obviously, 30% are not the most severe. And so when we -- you drop down to the more severe, you're probably closer to the 10% to 15%, with somewhere between the 10% and 15% being debatable, I guess. But that's consistently what we hear from our European customers as well is that it's probably 10% to 15% could use some sort of calcium modification.

And so then it's a question of which tool you would use. We're -- at this juncture, we're not a crossing tool the way, let's say, rotablator is. But outside of the crossing for the really difficult to cross CTO kind of patients, we think we're -- which is maybe half of the current atherectomy population, we're -- we think we're applicable in the rest. So if I'm right, and it's maybe 15%, then that would suggest that 12%, 13% are sort of ShockWave target.

And what percent we will penetrate is -- in 5 years, we're obviously not -- we're not even comfortable guiding for next year, let alone guiding for 5 years out. But the enthusiasm with which the device at least is being received in Europe and the reception of the data and expectation around approval in the U.S. is about as strong as any device I've engaged with.

And Keith has some anecdotal experience. He was really instrumental in watching the product for us in India this year before COVID hit. And Keith, maybe you want to give both a epidemiologic perspective on the patient population and how much we might be equipped for it, but also your perception of what you've seen.

Keith D. Dawkins

Chief Medical Officer

Yes. Thanks, Doug. Larry, I mean the total addressable market is going up dramatically because, obviously, the population age is moving to the right. The prevalence of diabetes is going up, renal impairment is going up. And there's this general appreciation by the cardiological and peripheral community that calcified vascular disease needs treating properly. And of course, that's occurred with increasing imaging, understanding of the MOA and all the rest. And so I think -- and we don't see ShockWave IVL as an exclusive device. And so I think the whole -- the penetration of all the devices will go up. But I think the ease of use and the safety and the predictability and the ease of training will be really important.

And the other area, of course, which we don't fully understand is the threshold for using IVL. If everybody gets very comfortable with it, it's after all, only a balloon over a wire, will they begin to use it earlier and will secondary centers, not primary, centers use it?

It's interesting, in India, which, of course, there's probably more diabetes than many countries in the world, and there are some real experts dealing with calcified disease, big rota centers. They love it. And India live -- in the end of February in Delhi, lots of live cases, and I was on a call earlier today where sponsoring -- an investigator sponsored 1,000 patient study, all comer study in India of IVL, and that's just going to be very exciting. And they're very expert, and they just like -- they're just trying to work out the algorithm of what device they use where, but they just think it slots right in there.

So I think it's very difficult to put the numbers on, but an exciting prospect.

Operator

Our next question comes from the line of Adam Maeder with Piper Sandler.

Adam Carl Maeder

Piper Sandler & Co., Research Division

Congrats on the nice quarter. To start, just one clarification question. I think it was in response, Doug, to David's question just around puts and takes for Q4 and some of the commentary there. I think you said something along the lines, and hopefully, I heard you correctly here, that you didn't want to guarantee that you'd be growing in the quarter because you wanted to be conservative around COVID-19 dynamics and any potential impact that could have in your business. I wanted to make sure I understood that comment. Are you referring to Q3 levels of this year or versus the prior year? Just wanted to clarify that.

Douglas E. Godshall

President, CEO & Director

Yes. No, we'll -- it's a sequential quarterly growth question. Everything suggests to us that -- we certainly entered this quarter expecting substantial sequential growth quarter-to-quarter, and it will -- I mean, there will be some procedures that will be lost because of COVID, no doubt, as will happen to all of our peers. And so it's really just a question that is something we can't answer yet until we see what happens. Do hospitals start really shutting down on elective procedures, or do they find a better way to navigate it now than they did earlier in the year? And then what is the effect of that, plus patients electing not to get procedures? We were not commenting on year-over-year growth, which we certainly would expect year- over-year growth.

Adam Carl Maeder

Piper Sandler & Co., Research Division

Okay. Great. And then just for my follow-up, Doug, I was hoping you could talk about some of the device enhancements that are coming down the pike in coronary and peripheral. I think you're expecting to launch LX next year. And then I think you have a couple enhancements to your S4, M5 and C2 products. So maybe just talk about how the technology will evolve going forward. What we should be watching for, and how they might potentially impact the business?

Douglas E. Godshall

President, CEO & Director

Sure, yes. So the LX has sort of split into 2 projects. One is we took the original LX, which was an 8- millimeter catheter -- 8-millimeter diameter balloon, and we rolled that into an enhanced M5 product that we haven't provided all the details on that yet. We're calling it M5 plus, but that will have a larger- diameter catheter -- balloon catheter. And then we have a separate LX that is going to be rolling out not next year. So the 8-millimeter will come out next year, but the even larger sizes will be a little bit down the track. And again, details to follow, but we're very impressed by the enthusiasm physicians have using our device in larger-diameter vessel, whether that's the common femoral iliac, the desc aorta, et cetera. So a really significant unmet need, which is why we think having both an 8-millimeter and larger is going to be a real unique opportunity that ShockWave will be able to address.

And then as you saw in the past couple of years when we went from 180 pulses to 300 pulses with the M5, we'll be incorporating improvements like that where we think they're warranted and where the durability of the product, whether that's an M5 or an S4 or a C2, can absorb those kinds of additional pulses and improve sort of user satisfaction and -- customer satisfaction and procedural outcomes and economics because you don't need additional devices. So we'll look to both have mechanical improvements of the device as well as take advantage of the software element of our device to improve its performance.

And then incremental to LX and M5 plus and other enhancements, we have a sort of growing, but as yet still confidential, pipeline behind those that will -- we'll still do both of those things. We'll have some that will be softer improvements, some that will be sort of all new devices at times.

Operator

Our next question comes from the line of Bill Plovanic with Canaccord.

William John Plovanic

Canaccord Genuity Corp., Research Division

Doug, you mentioned that you started out with the territory managers, and you're adding the clinical now. How many teams do you expect to have as you hit the beginning of the year? And then as you do that onto the -- how long do you foresee it to train -- get a hospital up and trained so that you can kind of move on to the next one? I mean we heard the comments from VIVA and TCT about it's like half a case training? And then how long do you think it takes to get through the VAC at each of those facilities? And then I have a follow-up question on the PMA.

Douglas E. Godshall

President, CEO & Director

Yes. So VAC speed is highly variable. And as we put together our target list, one of the criterion for being up towards the top of the list is an understanding that this is a hospital that we'll be able to fly through the VAC committee based on the sort of political clout of the cardiology team. And so some of the sites that we get through first might be there in part because they have that sort of internal political capital versus maybe hospital down the street that one might have thought would be first on our list but it's going to take them a couple of months to get through the VAC committee. So it makes no sense for us to be actively launching a product into a site that can't use the product yet because it's not through the VAC committee.

In terms of the training, you're right, it's incredibly simple. But unlike, say, some peripheral groups where you'll sometimes have a -- have 1 or 2 major interventionalists that are doing a very high percentage of the volume in PCI, you've got -- you'll often have more operatives. You do coronary interventions and you'll often have ones who don't do a lot of atherectomy they'll want to use Shockwave. So we'll have more people to train on Shockwave than maybe we do on the peripheral side. And there's also a propensity on the peripheral interventional sort of mechanical device space where case coverage is done at a much higher rate than in the coronaries. We don't want our people to have to camp out in the lab.

It doesn't -- this device doesn't require you to be there all the time. It sort of sells itself once it's on the shelf. We see that internationally. We -- the vast majority of our coronary cases are -- they go uncovered because it's distributors who sell the product. They're not going to sit around and cover cases all day.

And so we think that bodes very well that a -- sort of once you train the staff, once you train the -- all the cardiologists on staff who do any volume of any consequence, we ought to be able to move on and still, obviously, maintain that site, but we don't have to be there handholding.

Best guess is at a busy -- in a busy lab, we'll be there for 3, 4 or maybe 5 days, and then we'll move on. It's -- part of that is how -- can we batch everybody together? So in that -- at that rate, we think you're doing kind of a lab a week. And then it's just a matter of can you stack up week after week after week VAC committees, get everybody lined up so that you can cover an account every single week. We're assuming there's going to be some lag, and we're not going to be able to go -- have a new site every single week for each territory manager. But maybe, it sort of depends on how quickly we can get through the VAC process. The demand is there, for sure.

In terms of the number of territories, your first question, I think it was your first question, we wanted to -- our bare minimum was to have 100 folks in the field come approval. We're already north of that, or we were already a north of that at the end of September, and we're further ahead than that now. So if we had circa 50 territories, that's a really good starting point for us, so if it was 50 and 50. We're not going to stop hiring now, so we'll look to be north of that.

William John Plovanic

Canaccord Genuity Corp., Research Division

Okay. And then on the PMA, it sounds like given the timing you mentioned, you're already at your 90 day, which if you haven't received or press released or 8-K-ed an MDR at this -- MDL at this point, that means you're probably in interactive review. And -- is my assumption correct? And if so, are you then at labeling discussions at this point? Or kind of where are you? I mean because if you don't get a major deficiency letter then, it sounds like this could even be a little sooner than maybe the 6 -- typical 6-month time frame.

Douglas E. Godshall

President, CEO & Director

Good knowledge of the process. We -- it's a little early for labeling. I suggested the FDA that they should call this the best device ever, and they decided that, that wasn't an acceptable label. Just kidding.

Yes, so we're -- things are tracking well. There are just so few examples of less than 180-day approvals. It's sort of you can count them on 1 hand. And when they're less than 180 day, it's not like 120 day, it's like 170. So every day to us is quite valuable. We'll take an early approval with glee, but we're not planning on anything earlier than 180 day. We're ready. If it comes now, we're ready, but we're not anticipating it.

Operator

This concludes today's question-and-answer session. I would now like to turn the call back to Doug Godshall for any further remarks.

Douglas E. Godshall

President, CEO & Director

Thanks very much. And thanks, everyone, for your time and attention. I'm hopeful that this latest COVID surge stays away from everyone who's listening and your loved ones and that things start to really blossom and return back to some form of normalcy in the very near future.

So thanks very much, really appreciate the support and attention.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for your participation. You may now disconnect.