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Teleflex Incorporated (TFX) CEO Liam Kelly on Q3 2019 Results - Earnings Call Transcript

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Q3: 10-31-19 Earnings Summary

Press Release *10-Q* *Slides*

EPS of $2.97 beats by $0.22 | Revenue of $648.32M (6.34% Y/Y) beats by $5.16M

Earning Call Audio

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Teleflex Incorporated (NYSE:TFX) Q3 2019 Earnings Conference Call October 31, 2019 8:00 AM ET

Company Participants

Jake Elguicze – Treasurer and Vice President-Investor Relations

Liam Kelly – President and Chief Executive Officer

Thomas Powell – Executive Vice President and Chief Financial Officer

Conference Call Participants

David Lewis – Morgan Stanley

Larry Keusch – Raymond James

Richard Newitter – SVB Leerink

Shagun Singh – Wells Fargo

Matt Taylor – UBS

Anthony Petrone – Jefferies

Brian Weinstein – William Blair

Adam Maeder – Piper Jaffray

Dave Turkaly – JMP Securities

Mike Matson – Needham & Company

Matthew Mishan – KeyBanc

Kristen Stewart – Barclays

Operator

Ladies and gentlemen, thank you for standing by, and welcome to the Q3 2019 Teleflex Incorporated Earnings Conference Call. [Operator Instructions].

I would now like to hand the conference over to your speaker today, Jake Elguicze, Treasurer and Vice President of Investor Relations. Please go ahead, sir.

Jake Elguicze

Thank you and good morning everyone, and welcome to the Teleflex Incorporated Third Quarter 2019 Earnings Conference Call. The press release and slides to accompany this call are available on our website at www.teleflex.com.

As a reminder, this call will be available on our website and a replay will be available by dialing 855-859-2056 or for international calls 404-537-3406, passcode 1185417. Participating on today's call are Liam Kelly, President and Chief Executive Officer; and Thomas Powell, Executive Vice President and Chief Financial Officer. Liam and Tom will provide prepared remarks, and then we'll open up the call to Q&A.

Before we begin, I'd like to remind you that some of the matters discussed in the conference call will contain forward-looking statements regarding future events as outlined in our slides. We wish to caution you that such statements are, in fact, forward-looking in nature and are subject to risks and uncertainties and actual events or results may differ materially.

The factors that could cause actual results or events to differ materially include, but are not limited to, factors referenced in our press release today as well as our filings with the SEC, including our Form 10-K, which can be accessed on our website. With that said, I'd like to now turn the call over to Liam.

Liam Kelly

Thank you, Jake, and good morning everyone. It's a real pleasure to speak with you again. I am very pleased with Teleflex's performance during the third quarter, as we continue the positive momentum in our business, delivering 6.3% revenue growth on an as reported basis and 8% growth on a constant currency basis.

Like the first half of the year, during Q3, the strength in our top-line performance was once again broad-based, driven by improvements across nearly every global product category. This included 50.4% growth in Interventional Urology, 8.2% growth in Interventional Access, 6.1% growth in Vascular Access, and 5% growth in Surgical.

While from a geographic perspective, we achieved particularly strong growth within the Americas where constant currency revenue growth was 10.7%. We saw a rebound in EMEA where constant currency growth improved to 5.1% and we drove continued steady performance within Asia, where currency-neutral revenues grew 5%.

Turning to some other key metrics. In addition to delivering robust constant currency revenue growth, which we were able to achieve even when faced with a difficult prior-year comparable, I was also pleased to see the year-over-year and sequential expansion in both our adjusted gross and operating margins.

And, during the quarter, our adjusted gross margin reached 58.6%, which was an increase of 160 basis points as compared to the prior year and 90 basis points sequentially. While our adjusted operating margin totaled 27%, which was an increase of 100 basis points as compared to the prior year and 180 basis points sequentially.

Turning to the bottom line. Thanks to stronger-than-expected revenue and margin performance, coupled with additional benefits from a further reduced tax rate, our adjusted earnings per share during Q3 was $2.97, which represents an increase of 17.9% over the third quarter of 2018.

When normalizing for the impact of FX, Q3 adjusted earnings per share grew approximately 19%. In summary, we are very happy with our better than expected revenue performance as during the third quarter, our global Vascular Access, Interventional Access and Interventional Urology businesses outperformed as compared to our prior expectations.

The strong year-to-date results, coupled with our outlook for the fourth quarter has led us to once again increase our full-year 2019 guidance for constant currency revenue growth from a range of between 7.5% and 8% to a new range of between 8% and 8.25%. This updated guidance takes into consideration the better than expected performance from our Vascular and Interventional Access product line.

However, this is largely offset by an issue that recently arose relating to the suspension of operations at a third party in Georgia. This sterilization issue is causing a disruption of selected Teleflex products, mostly within our surgical and OEM businesses. We are working diligently to resolve this issue to ensure patients and their healthcare providers have access to effective products.

Importantly, the UroLift product is not one of the Teleflex products that is impacted by the sterilization disruption issue. Additionally, our increased constant currency revenue growth guidance range also assumes an improvement in full year UroLift revenue growth, as we now expect UroLift revenue to increase 40% as compared to our prior expectation, which called for full-year revenue growth of approximately 35%.

Today, we are also reaffirming our full-year 2019 adjusted growth and operating margin guidance ranges as well as narrowing our adjusted earnings per share guidance from a range of between $10.90 and $11.10 to a new range of between $11.05 and $11.10.

Our updated revenue and adjusted earnings per share guidance takes into consideration the sterilization issue I just mentioned, as well as worsening FX environment since we last reported earnings. Indeed, if we reported our full year adjusted EPS on a currency-neutral basis, our year-over-year EPS growth assuming the midpoint of our updated range would equate to a growth of approximately 16%.

With that as an overview, let's now review Q3 revenue in more detail. I will begin with a review of our reportable segment revenues and unless otherwise noted, the growth rates I would refer to are on a constant currency basis. The Americas delivered revenues of $374.5 million, which is an increase of 10.7%. This was driven by our Interventional Urology, Interventional Access and Vascular Access product category.

Moving to EMEA, it reported revenues of $140.5 million which represents an increase of 5.1%. On our last earnings call, we stated that we expected to see an improvement in the performance of our EMEA business and that is what occurred, as during the quarter, the growth in this part of the world was led by our Interventional Access, Vascular access and urology products.

Turning to Asia, revenues totaled $77.9 million, which is an increase of 5% as compared as compared to the prior year period. From a product standpoint, growth was strongest within our Surgical and Vascular Access categories, while from a geographic perspective, our business in China grew 11.5%. This was somewhat offset by weakness in Australia and New Zealand.

And lastly, our OEM business reported revenues of $55.4 million, which represents an increase of 1.9%. You may recall, on our last earnings call, we said that we expected our OEM business to show flattish growth within the quarter due to a difficult comparable as well as timing of certain orders and that is what occurred. In fact, during the third quarter, this business did a little bit better than we previously expected.

Now let me move to a discussion on our revenues by global product category. Like my comments regarding our reportable segments, my comments regarding our global product category growth will also be on a constant currency basis unless otherwise noted. Starting with Vascular Access, third quarter revenues increased 6.1% to $148.7 million. This was driven by strong growth in PICCs and visual navigation products as well as growth in sales of CVCs.

Moving to interventional access, third quarter revenue was $106.9 million, which is an increase of approximately 8.2%. Like the results we delivered in the first half of the year, the strength in this business during Q3 was broad based with growth in complex catheters, biologics, on-controls, intra-aortic balloon and closure products.

Now to Anesthesia, quarter three revenue was $87.1 million, which is an increase of 1.5%. The increase here is primarily driven by sales in endotracheal tubes, atomization and laryngoscope products.

Shifting to our Surgical business, revenue increased 5% to $92.6 million driven by sales of ligation clips and surgical instruments. Moving to Interventional Urology, revenue increased a robust 50.4% to $73.6 million.

While the growth rate this quarter is somewhat inflated due to the easier comparable because of the voluntary product withdrawal we had last year, our sales force continues to make excellent progress driving physician adoption of the UroLift system, and we remain on track to trade a total of over 450 new urologists during 2019.

Transitioning to UroLift 2, we continue to expect to begin the rollout of the UL 2 during the fourth quarter with a full conversion of the U.S. physician base from UL 1 to UL 2 expected in 2021.

And finally since OEM was covered in our segment review, let me summarize third quarter revenue for the businesses within our other category, which consists of our respiratory and urology care products. Revenues here were down 0.4% on a constant currency basis, totaling $83.9 million. This was driven by declines in sales of our respiratory products, somewhat offset by an increase in sales of our bladder management products.

That completes my comments on quarter three revenue performance. Next, I would like to briefly discuss some important clinical publications and awards concerning UroLift. First during the month of August, the UroLift System won the 2019 James & Wells Medical Technology Association of New Zealand Award.

This award recognizes products that significantly contribute to improving patient outcomes by enhancing their quality of life, as well as exhibiting technical excellence and innovation across the medical device sector. This achievement is yet another example of the UroLift System superiority as compared to alternative methods to treat BPH and it should help us as we continue to try to expand the adoption of the UroLift product within the New Zealand market.

Lastly, during September, the Urology Times showcased the effectiveness and benefits of the UroLift System, noting that due to shortcomings in TURP and medications, the advancement of the minimally invasive surgical technologies categories remains imperative for men seeking an effective treatment option for BPH.

In the article, UroLift scores favorably, with patients reporting rapid recovery and symptom relief, preserved sexual function, low catheterization rates and low complications. That completes my comments on UroLift.

Let me now provide a brief update on another product we are enthusiastic about, MANTA. For those who may not be aware, MANTA is the first commercially available biomechanical vascular closure device designed specifically for large bore femoral arterial access site closure. It helps reduce time to hemostasis without pre-closure, delivering reproducible results that help clinicians achieve successful closure.

During TCT, there were several presentations regarding MANTA, as enthusiasm continues to grow for this device. Our initial limited market release and price discovery activities remain very much on-track; while account penetration, reorder rates and initial adoption in the U.S. have been strong. Full market release for this product in the U.S. will occur in January of the new year, and we fully expect MANTA to be a nice contributor to our revenue growth rates in 2020 and beyond.

In closing, I would like to reiterate how pleased we are with our performance during both the third quarter, and first nine months of the year. Revenue growth continues to exceed our expectations, driven by a broad spectrum of products and geographies, which led us to increase our full year revenue guidance for the second consecutive quarter. In addition to continued top-line strength, during the quarter we achieved significant year-over-year, and sequential, gross and operating margin improvements, and we expect that to continue during the fourth quarter. And as such, we are narrowing our full year adjusted earnings per share guidance to a range of between $11.05 and $11.10.

Before, I turn the call over to Tom, I'd like to take a moment to reflect on our long-range plan. We are currently nine months into a three-year journey. Our revenue growth has exceeded our initial expectations and our margin targets remain very-much on-track. We feel more confident than ever in our abilities to achieve the goals laid out in May of 2018. I would like to thank our employees and management teams for their excellent execution in the first nine months of our LRP, and for their continued focus on reaching our goals.

That completes my prepared remarks. I would now like to turn the call over to Tom for a more detailed review of our third quarter financial results and full year 2019 financial guidance. Tom?

Thomas Powell

Thanks Liam and good morning everyone. Given the previous discussion of the Company's revenue performance, I'll begin at the gross profit line. For the quarter, adjusted gross profit was $380 million versus $347.3 million in the prior year quarter, or an increase of approximately 9.4%. Adjusted gross margin increased 160 basis points versus the prior year period, reaching an all-time high of 58.6%.

The expansion in adjusted gross margin primarily reflects increased sales volumes, a favorable sales mix of higher margin products and benefits from cost improvement programs. Partially offsetting these gains were negative impacts from incremental tariffs. Adjusted operating profit was $175.3 million as compared to $158.7 million in the prior year, or an increase of approximately 10.5%.

Adjusted operating margin increased 100 basis points versus the prior year period, reaching 27%, also an all-time high. As the year has progressed we've realized robust sequential expansion of adjusted operating margin. The first quarter adjusted operating margin was 23.7%, followed by 25.2% in the second quarter and now 27% in the third quarter.

And we expect further sequential expansion in the upcoming fourth quarter. The trend of strengthening operating margin is largely the result of expansion in the gross margin, timing of investment spending and volume leverage.

Continuing down the income statement, net interest expense decreased to $19.1 million, and this compares to $26.9 million in the prior year quarter. The decrease in interest expense primarily reflects the impact of our cross-currency swap agreements.

Moving to taxes. For the third quarter, our GAAP effective tax rate was negative 132.3% and reflects a discrete tax benefit of $129 million resulting from a non-U. S. legal entity restructuring that eliminated the requirement to provide for foreign withholding taxes on the future repatriation of certain non-permanently reinvested earnings.

On an adjusted basis, our third quarter tax rate was 10.3%, as compared to 10.7% in the prior year period. That takes me to our third quarter 2019 adjusted earnings per share, which was $2.97, or an increase of 17.9% as compared to prior year. We are encouraged by the strong earnings generation, stemming from upper-single digit constant currency revenue growth combined with margin expansion.

Turning now to select balance sheet and cash flow highlights. During the first nine months of 2019, cash flow from operations totaled $289.2 million, compared to $302.9 million in the comparable prior year period. The decrease in cash flow from operations is primarily attributable to contingent consideration payments of $26.1 million and the net unfavorable impact from changes in working capital, driven primarily by increases in inventory. The increase in inventory was in part a tactical move designed to enhance customer service by increasing safety stock levels on select products.

Turning now to debt and leverage, during the third quarter we reduced debt outstanding by approximately $132 million resulting in quarter ending net leverage of approximately 2.45 times. Finally, today the Company issued a notice of redemption to holders of outstanding 250 million, 5.25% senior notes due in 2024. Pursuant to the notice of redemption, the 2024 notes will be redeemed on November 15th at a redemption price equal to 102.625% of the principal amount outstanding plus accrued and unpaid interest, and this completes my comments on third quarter results.

Now I'll move to 2019 guidance updates. Given our performance for the first nine months of the year, and our expectation for the fourth quarter, we are increasing our full year constant currency revenue growth guidance from a range of between 7.5% and 8%, to a revised range of between 8% and 8.25%. As a result of prevailing foreign exchange conditions, we now expect that foreign exchange will result in a 225-basis point headwind to full year revenue, as compared to our previous expectation of a 150-basis point headwind. As such, we are lowering our as-reported revenue growth guidance from a range of between 6% and 6.5%, to a revised range of between 5.75% and 6%.

We are reaffirming our previously provided adjusted gross and operating margin guidance ranges and given the favorable trend in Libor rates versus expectations and a modest fourth quarter benefit from the redemption of our 2024 notes, we are reducing our estimate for full year net interest expense to approximately $80 million.

Turning to taxes, we now anticipate that our full year adjusted tax rate will fall within a range of 12.25% and 12.5%. This is down from our prior expectation of being on the lower end of the 14% to 14.8% previously provided guidance range. From a share count perspective, we continue to expect full year weighted average shares to be approximately 47.1 million.

That takes me to our GAAP and adjusted earnings per share ranges. On a GAAP basis, given the third quarter discrete tax benefit and strong financial results, we are increasing our full year guidance from a range of between $6.82 and $6.94, to a new range of between $9.85 and $9.90. On an adjusted earnings per share basis, we are raising and narrowing our guidance from a previous range of between $10.90 and $11.10, to a revised range of between $11.05 and $11.10.

Included in the updated adjusted EPS guidance range is a $0.07 estimated earnings impact stemming from the closure of a third party sterilization facility. Also included in the adjusted EPS guidance range is our current foreign exchange assumption of a $0.41 full-year headwind versus our previous expectation of a $0.35 foreign exchange headwind.

If we reported our full year adjusted EPS on a currency neutral basis, our year-over-year EPS growth, assuming the mid-point of our updated guidance range, would equate to approximately 16% growth, which serves to reinforce the strength of our 2019 financial leverage.

In closing, we are very pleased with the financial performance achieved in the first nine months of 2019. The acceleration in revenue growth is broad based, both from a geographic and a product standpoint. And despite a less favorable currency environment, we have increased our earnings estimate by also funding incremental investment.

And that concludes my prepared remarks. At this time, I would like to turn the call back over to the operator for question and answers.

Question-and-Answer Session

Operator

Thank you. [Operator Instructions] Our first question comes from David Lewis with Morgan Stanley. You may proceed with your question.

David Lewis

Good morning, thanks for taking the question. Just – maybe just two for me here. First, Liam, just kind of a broad commentary on the LRP and then maybe, Tom, a couple questions to you on the fourth quarter. So, Liam, look 6% to 7% was the LRP guidance perspective you offered, you are delivering kind of a point above the high end of the range here, closer to 8%, and I think about next year, you've got Manta, you've got some RePlas as well. So, as I think about next year, is the right way to think about 2020, you're going to deliver the LRP around 6% to 7% or given those product launches you can do a little better? And I have a couple of follow-ups for Liam, I'm sorry, for Tom.

Liam Kelly

Yes. Sure David. So based on the LRP, obviously, we will get the 2020 guidance when we report our Q4 earnings in February, but I will comment, as I said in my prepared remarks on the LRP, we couldn't be happier with the progress we're making. We are only nine months in but within the first nine months of the year, our revenue growth has been incredibly solid.

So, year-to-date through the nine months, we've grown at 8.4% and we've been able to take up our revenue guidance twice within the year. So we feel really confident. We've got, obviously Manta will come into play in 2020 and we also in 2021, we'll have the UroLift in Japan that wasn't in our previous guidance.

So regarding the revenue line for our LRP, we feel extremely confident in the goals that we set out in May of 2018 and it's not just on the revenue line, as we've gone through the year, we've been able to demonstrate the external community that our margin expansion to the point where in this quarter, we've hit an all-time gross margin high for the company and an all time op margin high for the company showing significant leverage in the income statement, while at the same time, being able to invest in some of our businesses, in particular the UroLift product, as we continue to invest behind the sales force there and we will continue to do that also in Q4.

David Lewis

Okay, very helpful Liam, and Tom just two for you, just first on growth into the fourth quarter, guidance implies about a point or two momentum acceleration sort of what drives the confidence to finish the year that strong? And then on earnings, just wonder if you could help us with the reconciliation, it looks like a conservative earnings number implied in the guide for the fourth quarter and there's a lot of moving pieces between tax, interest, sterilization and margin improvement. Could you just bridge us a little bit on sort of the components that drive positive or negative tailwinds into the fourth quarter, because as I said, it looks a little conservative? Thanks so much.

Liam Kelly

So, Dave, we will get Tom to cover the EPS and I'll cover the revenue. So, on the revenue side, so first of all, you have the impact of the stabilization issues. First of all, let me just start by saying that with the sterilization capacity issue, it is contemplated in our updated guidance and contemplated it is contemplated in our updated guidance and contemplated in our raise in our revenue. We do think it's going to have an impact in the fourth quarter of about $8.7 million, and Tom will cover the EPS impact.

But as he said in his prepared remarks is about $0.07, that's about a 40 basis points full year headwinds based on that sterilization issue. Regarding your question, David, on headwinds and tailwinds, obviously, we have an extra billing day in the fourth quarter. So the way I think you should look at it is the impact from the sterilization issue is pretty much washed with the billing day in the fourth quarter.

Now if you take the midpoint of our guidance range in the fourth quarter, it would imply that we're planning to grow in the mid-sevens in Q4 in order to get to the midpoint of our updated guidance – at the midpoint of our guidance and we feel really confident on that and that's again against a tough comp. What I really like about the set up for Teleflex is that we are able to put forward a growth rate in the mid-sevens up against the top – a tough comp of 7.7% in the prior year. And also in this quarter, if we do a pro forma on the prior year, the growth was 8.2% and we were able to grow 8% on that. So those are really the headwinds and tailwinds, FX can go either way, and I'll let Tom now address the EPS question.

Thomas Powell

Sure. So if we look at our fourth quarter EPS, I'd say that given the midpoint of our guidance, we're looking at 15% to 16% EPS growth. So, we look to put up another very solid quarter. Now in terms of just the third quarter performance, we came in favorable versus our internal expectations, favorable versus consensus by $0.22, and as an outcome, we raised our guidance at the midpoint, by $0.075. Now in addition to that $0.075 guidance range, we've also included in our guidance $0.06 associated with a stronger headwind from foreign exchange and a $0.07 adverse impact from the closure of the sterilization facility. So as we look into fourth quarter, we've got a couple of items that

are impacting us negatively. But overall, we are pretty excited about the strength of the performance as we finish out the year, as mentioned, we're expecting earnings growth kind of in the 15% to 16% range.

Liam Kelly

And Dave, I just wanted to add one comment on that from what Tom said. We are also investing behind UroLift in the fourth quarter, a little bit heavier than we had anticipated. We had anticipated some new sales hires that would come in Q1, we're actually going to bring in those additional headcount in Q4, so that we hit the ground running in Q1 of next year. And we're also anticipating doing additional DTC in Q4. So what I – again, what I really like about the setup is we are able to call up our earnings. We are able to call up our earnings guidance, invest behind the growth drivers in the business and offset some bad guys which the sterilization is. So I think all in all, we couldn't be happier with the performance of the business for the first nine months and our guidance would reflect that.

David Lewis

All right, thanks for the clarity guys. Great quarter.

Liam Kelly

Thanks, David.

Thomas Powell

Thanks, David.

Operator

Thank you. Our next question comes from Larry Keusch from Raymond James. You may proceed with your question.

Larry Keusch

Perfect. Good morning, everyone. One for Liam, and then one for Tom. Liam, maybe on UroLift obviously the product continues to be strong and is outpacing the expectations that you have set through the year and perhaps you could talk a little bit as we're again moving

into this phase into the fast followers, how you're kind of thinking about average procedures per physician and how that's trending and sort of where the sales force is really, really focused on making sure this continues to gain traction?

Liam Kelly

Thanks, Larry. And we had a resounding quarter for UroLift, it grew at 50.4%, through the first nine months of the year, it's growing at around 45%. So that, you're right, the product is exceeding all of our internal expectations. This third quarter had a slightly easier comp because we had the voluntary withdrawal of the product in Q3 last year. So that has definitely helped this quarter but notwithstanding that we're incredibly focused on making this product a standard of care.

Regarding the physicians, the business is incredibly stable. The average physician continues to do about four procedures a month. We continue to develop champions and we continue to make this product the standard of care. I think the number of publications obviously will help, the DTC helps and I think having a sales force Larry that wakes up everyday and only thinks about one product is an obvious advantage as we continue to drive accelerated performance.

And so, as I said in my prepared remarks, I think we will definitely achieve, if not, modestly exceed the 450 clinicians we have targeted to train this year and as we move from the early adopter to the fast follower, what has been very encouraging for me in particular is that the growth has not slowed as we move to that second phase of clinician and right now we are moving into the fast follower.

Our thought has always been that it will take a little bit longer to bring that clinician on board, that clinician really requires, there appears to be using the product, they require very strong clinical data. They will require real world data that is very aligned to the clinical data and they need broad coverage to ensure that they're going to get paid for the procedure and I think as we sit here right now moving to the fast follower, all four of those boxes are ticked for Teleflex Larry.

Larry Keusch

Okay, perfect. That was helpful, Liam. And then, I guess, the question here is just want to take your temperature on your confidence in the margin expansion actually through the LRP, not for 2019, so kind of what gets you there? And how do we think about the gating in 2020 and 2021 for that operating margin expansion, just wanted to think about how we are calibrating for that LRP? And, I guess, lastly, just on that, given that your sterilization is bit of a headwind, what sort of feedback are you getting from your sterilization provider as to kind of when they think they might be able to resolve some of these issues?

Liam Kelly

Okay. So let me take it in chunks, Larry. Let me start with the cadence of margin in our LRP, and let me begin by saying, and as I said in our prepared remarks, I'm more confident than ever in our margin expansion within our LRP. As I said, we hit an all-time high on both growth and operating margin. And where is the margin going to come from, while about 60% of it is going to come from mix, our philosophy in Teleflex that not all growth is equal and where we're growing our businesses is in Interventional Urology, Interventional Access, Asia and within our Vascular business in particular PICCs and Vidacare. All of those are accretive to our margins, and if you look at where our investment goes, Larry, it goes behind those businesses and you can see for the first nine months of the LRP, those are the businesses that are performing exceptionally well and then add-in OEM, which has had a great performance.

With regard to the cadence – so that answers your question on our confidence, Larry. With regard to the cadence, what I would expect and I don't want to get into 2020 guidance as you can appreciate, but what I would expect, Larry, is that we would see more margin expansion in 2020 than we've seen in 2019. So you would expect to see further margin expansion to 2020, and then another uptick in 2021, but rest assured, there would be an uptick in both years in our margin expansion in 2020 and 2021, that would be our expectation.

And then onto your question on the sterilization, we began a number of weeks ago, when this issue arose in the Atlanta area, Larry to begin to re-qualify other sterilization cycles in other areas and our partner has been working very much with us to help us to do that. They don't have clear line of sight as to when that facility may be reactivated. I think that

they are working with the county officials. I think that they are I think that they are working with the EPA and, but right now we don't have line of sight. Our expectation is that we will have other cycles revalidated by quarter one and we would envisage that that would allow us to continue to supply product into the marketplace at that time.

And I think what has been helpful in some of the FDA statements that have come out and the FDA put out a note last week stating that more than 20 billion devices sold in the U.S., so that is $1 billion Larry, are sterilized with ethylene oxide, accounting for almost half of all medical devices. And I think they also said, it's important to note that there is no readily available process at our facilities that can serve as a viable alternative especially when you're dealing with plastic products.

So, I think that was also incredibly helpful and our associations, in particular, AdvaMed and MDMA continue to work with these local government authorities to educate them on the importance of having sterile product in the marketplace because it could have a much bigger patient risk than the ETO environmental issue, which from what I can see are very complying to the Clean Air Act.

Lawrence Keusch

Okay, perfect. Thanks for the very detailed answers earlier. Appreciate it.

Thomas Powell

And I just – just to add on to that, Larry, as we look at 2019 margin expansion, we believe that the business is performing incredibly well. So is the business creating financial leverage? Absolutely. However, there are kind of three factors that limit kind of the printed result on margin expansion and those are FX, that's been about a 40-basis point headwind in the year, tariffs is another 30 basis points.

And then, we've made a number of investments for the future, which we believe will benefit us in the longer term, but this year, we've got expense with no real benefit and those include the market development in Japan for UroLift, the pre-launch U.S. investment from MANTA, we've got an acceleration of the UroLift sales hires through the fourth quarter now.

And so that's another 65 basis points. So, if you think about it, we've got about 140 basis points factors that are kind of impacting this year that we believe will provide benefit for the future or perhaps go away in the future. So, the underlying operating performance of the business is very solid this year being masked somewhat by FX tariffs and some of the investments we've chosen to make.

Lawrence Keusch

Great. Thanks for that color.

Thomas Powell

Yes.

Operator

Thank you. Our next question comes from Richard Newitter with SVB Leerink. You may proceed with your question.

Richard Newitter

Hi, thanks. I have two, and congrats on the quarter. First on sterilization, I just want to ask, could you quantify or give us a sense as to what your expectation is for expenses or impact to carry over into 2020, I mean, should we be dialing in as a placeholder an impact in the first half of next year, $0.07 is a – it's a pretty big impact, I know these things take some time. Thanks for the color earlier, but that's my first question, how do we think about this impacting 2020?

Liam Kelly

So, Rich, I wouldn't expect a material expense in 2020 in relation to this. What we are doing is working with our partner to validate another sterilization cycle either in another geography or in another size. So I wouldn't anticipate a significant uptake. The $0.07 quite frankly, Rich, is a little bit less than I would normally expect if you get $8.7 million, I would expect $0.08 to $0.09 of an impact normally.

Because of the margin profile in particular of the products in the other category that helps us minimize the EPS impact, that's what gets it down to that $0.07. And obviously, we have been working to substitute products as well in order to minimize the impact. And as I said in my earlier comment, we anticipate having cycles being validated early in 2020. So, and we are working towards that.

Richard Newitter

Okay, thanks. And, Liam, I appreciate that, the cadence of achieving the margin expansion over the long-range plan. It's more margin expansion in 2020 versus what we saw in 2019. And then more in 2021 versus what you'll see in 2020, but just if I could, maybe just kind of throw out what the consensus range for 2020 is it's between 100 to 200 basis points of margin expansion anticipated for next year and then something north of 200 implicitly baked in to get to your long range plan.

I guess, could you just give directional color, is that an okay place to be for the street, do you feel comfortable generally as a framework for thinking about the cadence with where the current Street is? Thanks.

Liam Kelly

Thanks, Rich. As you can probably appreciate, I can't comment on 2020 guidance at this stage. So, I think that as we look at it, I reiterate what I said. There will be a pickup in margin expansion in 2020 and there will be a further pick up on op margin. I would expect – let me try to help you here. I expect more op margin than gross margin expansion in 2020, maybe that would help you frame and in line with what you said, but it's hard for me to comment on 2020 and 2021 until I get to our Q4 and 2020 guidance, Rich, is I'm sure you're going to appreciate. But we're very confident in getting to 60% to 61% by 2021 and we're very confident on getting to 30% to 31% by 2021. I hope that will give you some flavor.

Thomas Powell

And just to throw in a couple of factors that we've got out there happening in 2021, why they step up or why they hear steps up so much more than 2020. First is the conversion of the UroLift 2 we expect to complete by 2021, and that's going to drive actually a pretty significant amount of margin expansion. Then, also just on the cadence of our footprint projects, we will have meaningfully more savings in 2021 than we will in 2020. So those are two factors that serve to really drive that 2021 margin expansion, up more than the other years.

Richard Newitter

Okay, thanks a lot.

Thomas Powell

Obviously, the reduction in some of the investments that we put in this year helps 2020.

Liam Kelly

Thanks, Rich.

Operator

Thank you. Our next question comes from Shagun Singh with Wells Fargo. You may proceed with your question.

Shagun Singh

Hey, guys. Thank you so much for taking the questions, and congratulations on a great quarter.

Liam Kelly

Thank you, Shagun.

Shagun Singh

Liam, the Street appears to be modeling about 50 to 150 bps contribution from MANTA, which is on top of the LRP, is that reasonable? Are you expecting pent-up demand, if you can give us your take on 2020? And then also year-to-date core is tracking to about 5.4% and UroLift – core ex-UroLift is tracking to 5.4% and then UroLift is tracking to about 3.5%. How should we think about these two buckets in 2020? And then I have a follow-up.

Liam Kelly

Yes, so let me deal with the latter half of your point – your question first. So if you take the midpoint of our updated guidance, it is about 8.125%. Our expectation is that ex – that UroLift will add around 3% and the rest of the business will add around 8% – pardon, will add around 5%. So that will get us to that 8.125% at the midpoint of our range.

To address your question with regards to MANTA, as I said in my prepared remarks, we continue to make excellent progress with the U.S. LMR in the quarter. We're getting very positive feedback and we've got a very high reorder rate from the testing sites. That to me is a real positive. We will continue with the LMR in Q3. And as I sit here today, I can tell you, we are pretty much finalized on our pricing strategy and we will go to full market release on January 1, 2020.

With regard to its impact on the revenue in 2020, obviously expected to be positive, but again like my comments to many of your colleagues, unfortunately, I can't start to give guidance for 2020. I will do that when we announce our quarter four results and our guidance for the year, but I can tell you, Shagun that it's gone better than expectations and again it all comes back to patient outcomes and clinical data.

This product has robust clinical data showing 70% reduction in major vascular complications and meantime to hemostasis going from 6 to 10 minutes, down to 23 seconds and the surety of closure is what we're discovering is really important to the sites that they know that they'll close it first time, every time. So it's very positive. It's going well. And it will be a driver in 2020.

Shagun Singh

Thank you so much for that color. And then just as a follow-up. I wanted to focus on UroLift in Japan where you are – you're waiting for reimbursement, how are you preparing for the launch in 2020 and how quickly are you able to commercialize once reimbursement becomes effective, which is likely on April 1? Thank you so much.

Liam Kelly

So, yes, so we expect to reimbursement in the latter half of 2020 and we expect to be generating revenue in 2021. So you're absolutely correct there. What we are doing in preparation of that, and this was part of the investments that we pulled forward into 2019, we have got market development specialists on the ground, working with the key opinion leaders and urologists in order to ensure that they are aware of the product. And that they are assisting in communicating with the authorities that the need for this product is in the marketplace and that is an ongoing process, and will continue during 2020 until we get the reimbursement in the latter half of 2020 and generate revenue in 2021.

And I would reiterate again Shagun that the revenue for UroLift was not initially in our LRP because we didn't anticipate having approval in Japan in 2021, which now we expect. So, we do expect revenue in 2021, which wasn't in our original plan.

Shagun Singh

Thank you.

Liam Kelly

Thank you very much.

Operator

Thank you. Our next question comes from Matt Taylor with UBS. You may proceed with your question.

Matt Taylor

Hi, thanks for taking the question. I was hoping you might give us some color on the UroLift patients if you have any view on whether the TAM is changing here? Are you still seeing mostly drug dropout patients be treated or is that actually expanding into other patients. And can you comment on the competitive environment, are you seeing other MIS treatments also pickup and what's happening with surgery? Maybe just comment on all of those dynamics.

Liam Kelly

Yes. So the TAM, we don't believe has changed. We still believe that the U.S. market is a $6 billion market, if you take the drug dropout category. The best data we had was during the L.I.F.T. study which showed that almost 70% of our patients came from the drug dropout category. And anecdotally, we don't think that has changed at all, that's where the majority of our patients come from. With regard to do we see a drop off in surgical procedures? No, and I wouldn't expect too much because as we promote the UroLift product and as doctors move more and more patients into treatment for BPH with the UroLift product, they will also draw from patients that would traditionally have had a TURP or had a surgery.

But also we're adding to that pool of patients because as they examine the patient, they may find that patient has got an ongoing disease of the bladder or they may have a prostate, in 5% of cases the prostate is too large for UroLift and those patients will be added to the surgical pool.

So, as we draw off from the surgical pool, we are also adding to the surgical pool, so therefore we've never expected that TURPs would go down for example as UroLift goes up. The third part of your question, Matt, I think was on the competitive landscape, we haven't seen any new technologies come to the marketplace and the technology that we see out there are the traditional ones, a TURP more or less is done with steam rather than with just a different form of ablation.

And we continue to focus on the patient outcomes, because we believe that a patient will opt for a procedure that they can go in on a Friday, have the procedure done, won't wear a catheter, no sexual dysfunction, immediate relief and you could be back sitting at your desk on Monday morning rather than an invasive surgical procedure that gives you a risk

of sexual dysfunction, almost guarantees you are wearing a catheter and in some instances that catheter placement is for a period of time. And I still believe that the real world data on UroLift is so compelling compared to the real world data on any other technology out there because our real world data is showing better results than the clinical data, whereas with other technologies, we've seen worse results in the real world as compared to the clinical data.

Matt Taylor

Thanks Liam. That's good color. I just had one follow-up, which is, looking probably a couple of years out at China, what do you think the reimbursement in the addressable market could look like there?

Liam Kelly

So, as the Chinese market is a significant market from the population standpoint, we are currently working on sizing that and we'll be able to give some more details as we enter that market space. I do think that we have an advantage in China insofar as that we have a very robust call point in China into the urologist. And the reimbursement world in China – Chinese market, Matt, is a paper plate. So it's an out-of-pocket and always has been, not just for this procedure but for every procedure, it is an out-of-pocket experience for the person that has the procedure.

We will – are building our dossier for the submission of registration of the product to the Chinese authorities and we would anticipate at this stage sometime late in 2021, we would be in a position to get reimbursement, if they don't require clinical study, if they do, that would push that into 2022, Matt.

Matt Taylor

Okay, great. Thank you.

Operator

Thank you. Our next question comes from Raj Denhoy with Jefferies. You may proceed with your question.

Anthony Petrone

Hey, this is Anthony in for Raj. Congratulations on the quarter. I actually have a couple on MANTA, and then one just on the balance sheet and M&A. On MANTA, can you maybe just recap how you're looking at the market, there is trending now obviously, the TAVR market is proving to be more expensive with the low risk indication. And I think this year, we're looking at 90,000 procedures. The technology is also using EVARs. And so in the limited market release, how are you seeing MANTA being used in those two-end markets? How are you seeing pricing shake out versus the competitor? And then ultimately, what do you think your penetration can be in these two-end markets? And then I'll have a follow-up. Thanks.

Liam Kelly

So what we're seeing in the limited, so first of all, let me size the market. We size the market as $200 million to $300 million that is before the expansion into lower TAVR procedures, that could probably add another $20 million or $30 million to our TAM potentially. What we're seeing in the limited market release is the majority of the procedures that it's being used in is in TAVR. We are focused on the TAVR centers and because it has, they are larger, they are faster growing and – but obviously that intervention is if it does the TAVR, it does the EVARs as well.

So obviously, we're picking up EVAR procedures and even it's also being used with the Impella in a number of cases. From a pricing perspective, we have now got a much better understanding of the relationship between price and volume for the bigger centers versus the smaller centers. We have our pricing strategy pretty much complete in preparation for January 1 full launch of the product and we feel confident that we have pricing nailed down in order to ensure that pricing won't be a barrier to adoption based on volume.

You'll have to excuse me, Anthony, if I don't go into details on the pricing, I'm sure our competitors listen to the call the same as anyone else. So, I don't want to share that from competitive reasons, but I can tell you, Anthony, that we feel incredibly confident in our pricing strategy. And we believe that it will not be a barrier to adoption. And even at the

lower end of the pricing strategy that we have for a significant volume, it is up, still accretive to Teleflex and this product will be an accretive product to Teleflex gross margin and a driver for growth over the long-term.

Anthony Petrone

Fair enough. And actually the follow-up will be, instead of M&A actually intra-aortic balloon pumps. So your competitor had a recall last quarter, it looks like the business over at Teleflex benefited from that. It seems that that was the case this quarter, so just an update on intra-aortic balloon pumps and how that dynamic is playing out? Thanks again and congratulations.

Liam Kelly

Yes, thank you very much. So the intra-aortic balloon pump recall by the competitor, we won't see a benefit to that, Anthony, in all fairness, what customers will tend to do because it's capital equipment, they'll postpone the purchase for a period of time. Our growth is purely down to taking share from that same competitor. Now, the longer the recall goes on, you would expect that in Q4, but still hangs out there, if you won't, we will get a benefit then. But our growth has been driven by us taking share from that competitor and our balloon pump business is growing in the very, very high teens rate in that area.

So we're very confident in our business. I will tell you that we are taking share with new pump on the market, it's doing exceptionally well and we're very happy with that business. We will see – start to see the benefit, I believe of the recall, the longer it goes on and in particular as we get into this quarter we are in now and into the coming quarters.

Anthony Petrone

Thanks again.

Liam Kelly

Thanks, Anthony.

Operator

Thank you. Our next question comes from Brian Weinstein with William Blair. You may proceed with your question.

Brian Weinstein

Hey guys, thanks for taking the questions. The U.S. number or the Americas numbers was obviously very good. We have seen though in the past, sometimes you get hit by distribution patterns, where things get a little bit ramped up and then have to get pulled back in the channel. Question is are you seeing anything that suggests or maybe any overstocking somewhere we may need to think about that going forward. And, in particular, we're hearing about flu-related products at distribution seeing a bigger bump than usual heading into the season. So can you talk about any impact that you saw in any of that? Thanks.

Liam Kelly

Absolutely, Brian, I think that we are looking at it. First of all, we saw a modest destocking by distributors within the third quarter. So, and that's in line with our expectation, you normally expect to see that, but more encouraging for me, in the key North American market is the revenue I recognize is the revenue I sell into the distributor.

But if I look at my tracings and if I look at the end customer demand, my end customer demand is actually greater than what I'm selling in and recognizing through the distributors. So that gives me a certain level of confidence that there is not an issue with regard to the stocking that I should be worried about, in particular, since I've seen modest destocking in the third quarter. Having said that it's, I don't have the best visibility into it, but I think the portfolio we've built, Brian, is one that has protected us against this.

In the past, half of our business would have gone through these box-moving distributors, whereas now only a third of our business and the happiest moment for me, I have got to tell you was when we had some destocking in Q1 and restocking in Q2 and the investment community hardly even noticed it. And that's the type of portfolio we're trying to build in Teleflex, and that's the level of execution that we're trying to deliver in Teleflex and I have got to say the other bit that has happened is that I feel is that this is the fifth quarter

back to back that we have been absolutely consistent in our delivery on almost every line on our income statement; revenue, margins and earnings. So the level of performance by our teams out there is at a very high level.

Brian Weinstein

Great, thanks for taking the question guys.

Liam Kelly

Sure, Brian.

Operator

Thank you. Our next question comes from Matthew O'Brien with Piper Jaffray. You may proceed with your question.

Adam Maeder

Hi, it's Adam on for Matt, congrats on the quarter and thanks for taking the questions.

Liam Kelly

Thank you.

Adam Maeder

I wanted to ask about capital allocation over the next 12 months for the company or so just including the potential for M&A, are you seeing attractive assets or multiples still to speak at this point? And I had a follow-up.

Liam Kelly

Okay, Adam. So, first of all, let me start with our leverage. Our leverage is about 2.45x at the end of this quarter. So we definitely have capacity. Multiples have not been the issue for us in the assets we look at, the assets that we have traditionally focused on were

always high quality assets. The multiple expansion, at least what I'm seeing out there, has come in lower quality assets, which were never the assets that Teleflex had been interested in.

Our preferred use of capital is to continue to do M&A and we are very active in the marketplace looking at assets. I guess, the easiest way to tell you, I'm spending more of my time on M&A in the last number of months than I have in any time since I took over as CEO. We continue to see attractive assets in the space that we look and I think what gives us an advantage in this area is that we're looking pretty broadly.

So, we're looking in men's health, we're looking in vascular area, vascular area, we're looking in the surgical area, we're looking in the OEM area. We're looking in the Anesthesia and Emergency Medicine area, and of course we never stop looking in the Interventional, Cardiology, and Radiology area. So we're looking at a broad spectrum and the assets that we look at, we think we'd be able to carve out value even in the current environment, but rest assured we are active and busy.

Adam Maeder

That's very clear. Thanks. And then if I can squeeze one more in on the surgical side. Can you update us on the rollout of Percuvance, I know that's been in a limited launch space, can you just talk about the clinical feedback from clinicians and when we should expect that to progress to a more full launch? Thanks for taking the questions.

Liam Kelly

Yes, thanks, Adam. So we're continuing with the limited market launch. As I said a couple of times, Percuvance is really a show me product. We want to finish the limited launch. We have some clinical work that we want to finish as well before we get too excited about the product, but rest assured, once we get to 2020 guidance, we'll give a further update.

Adam Maeder

Appreciate it. Thank you.

Liam Kelly

Thank you.

Operator

Thank you. Our next question comes from Dave Turkaly with JMP Securities. You may proceed with your question.

Dave Turkaly

Hey, great, thanks. You may have mentioned this, I apologize if you did, but that sterilization plant, when exactly did that occur and what was the cause of it going offline or closing?

Liam Kelly

Yes. So Dave, this has been pretty well documented within the media. The initial concerns were in relation to ETO emissions in the Atlanta area. Then it became, I believe, an issue for the local Cobb County with regard to permits. The company is working with the local Cobb County, the environmental group, the last I saw had put out a notice that the company was compliant to all the relative standards and they are working now with Cobb County trying to reopen the facility. As I said earlier, they don't have any line of sight as to when they will be able to reopen the facility, but we have transitioned products to other qualified sterilization cycles to minimize the impact down to that $8.7 million in revenue and $0.07 in EPS.

Dave Turkaly

Got it, thanks. And then the last one, just quickly the $130 million tax benefit, is that or you said something about O-U.S., I think restructuring, but is that, I'm sure it's a one-time, but are there other opportunities for things like that, is that just sort of something we shouldn’t expect to see again?

Liam Kelly

That is a one-time benefit that will occur this quarter, in this quarter only. I wouldn't count on that in the future. There may be some other restructurings out there that could bring on a similar benefit. However, I wouldn't count on that. There is no line of sight right now

currently doing anything else along those lines.

Dave Turkaly

Great, thanks.

Operator

Thank you. Our next question comes from Mike Matson with Needham & Company. You may proceed with your question.

Mike Matson

Yes, thanks. So just back to the sterilization issue, I understand you're trying to address the problems with the current products that are exposed. But just from a risk mitigation perspective, is there anything you could do with other products and other facilities to try to prevent this type of impact in the future or is that just not possible?

Liam Kelly

Good question, Mike, one thing that we have done is we have looked at comparable cycles, validated additional cycles in a risk mitigation stance. And also we have on our major codes, as Tom mentioned in his discussion around our increase in inventory, part of the tactical increase in inventory is around risk mitigation against any other sterilization issues.

I think, Mike, it really comes back to the fact that there are 20 billion medical devices that are sterilized in the United States using ETO. And it is a requirement because other types of sterilization processes do not work on products with deep crevices, products made of certain materials. So, I think we've got to have a balanced approach here. Obviously, we all want to protect the environment, we all want to have a safe environment to live in, but if you're living in LA, you have as much exposure because of pollution than you would in any other area. So, I think, common sense is starting to prevail. It is my observation and I was particularly encouraged by the FDA statement that they made last week.

Mike Matson

Okay, thanks. And then just one follow-up, just on MANTA, is there any economic data as part of the SAFE MANTA trial or any other trials or is anything – efforts underway to collect any economic data that could help drive adoption and maybe get this thing through VAC committees? Thanks.

Liam Kelly

Yes, there is a JAMA study that was published that I believe stated that a major complication would cost a hospital $18,000 to treat. That study was done in 2017. And the clinical data for the product is compelling in this area where it shows over 70% reduction in those major complications from 7.5% to 2%. So, if you combine that with the JAMA study, Mike, that that would be a compelling argument for any VAC committee.

Mike Matson

Thank you.

Operator

Thank you. Our next question comes from Matthew Mishan with KeyBanc. You may proceed with your question.

Matthew Mishan

Great. And thank you for squeezing me in, I just have one. Can you guys update your free cash flow expectations for the year? And I'm sure there are some annual increases throughout the LRP. But I think free cash flow was supposed to be somewhere between $500 million and $550 million per year through that LRP and there seems to be a delta between where you are today and those expectations? Can you kind of bridge those?

Thomas Powell

Sure. So to your point when we put together the LRP and guided at Analyst Day, we had said that free cash flow would average between $500 million and $550 million over the period 2019 to 2021 and inherent in that guidance was the assumption that free cash flow would in fact build to your point. So in 2019, we thought it would be less than that three-year average, 2020 kind of in line, and 2021 well in excess. Now since putting the LRP

together, we've experienced improving results from the NeoTract business and we've made other business decisions aimed at improving our operations and some of these decisions will have an impact on the near-term free cash flow.

So for 2019, I'd now expect cash flow from operations around $435 million and CapEx of approximately $100 million. Now let me give you some kind of the key deltas from when we put the LRP out there, why we're not seeing free cash flow at the same level that we initially expected. The first is that NeoTract is performing better and as a result, we are paying a higher level of contingent consideration than what was originally contemplated in purchase accounting and those additional payments in excess of what was initially booked actually go through cash flow from operations.

Then, in addition, we put in an additional restructuring program in 2019. And that program doesn't generate savings until 2021 and there's also cash outflows that we have to invest in the project in 2019. And there's also CapEx associated with it. And then in another action that we've taken in an effort to really enhance customer service, we have reevaluated our safety stock levels and as a result we've increased our strategic inventory balances this year.

Now we believe that this is part of the reason why we're seeing improved customer service results including improved on-time delivery. And we think will ultimately benefit the company over the longer term, but each of these have served to reduce the free cash flow from our previous expectations, but again we're pretty happy that NeoTract is over-performing. We think the increased inventory will actually help the business as well as the restructuring programs will help us in the longer term.

Matthew Mishan

And just a follow-up to that Tom, is the contingent – changes in contingent consideration, is that a one-time payment that's impacting 2019 or is that something else that would potentially impact 2020 and 2021 as well?

Thomas Powell

It could potentially impact 2021 – 2020.

Liam Kelly

2020. So the bulk of the contingent consideration runs through to the end of 2020 and it is paid in 2021 for NeoTract.

Matthew Mishan

All right, thank you guys.

Liam Kelly

Thank you.

Operator

Thank you. Our next question comes from Kristen Stewart with Barclays. You may proceed with your question.

Kristen Stewart

Hey guys, congrats on a great quarter and Happy Halloween.

Thomas Powell

Thanks, Kristen.

Liam Kelly

Thank you, Kristen.

Kristen Stewart

Just a couple of follow-ups for me. Just wanted to circle back on, I guess, David's first question. He had mentioned RePlas, which I guess now is called EZPlas as being something to expect in 2020. I just want to make sure I didn't miss something on that. Is there an update on that product as my understanding was that that was still something that you're trying to figure out the filing timeline on that, could you provide an update on that? And then I have a follow-up as well.

Liam Kelly

Yes, absolutely. I think David asked about MANTA but happy to discuss EZPlas. As we said on our last call, we would give an update once we had a clear line of sight to BLA submission. But I can tell you that our collaboration with the FDA continues to be very constructive and obviously the FDA, Teleflex, and the military, we're all excited about the product as we know it can have a positive impact on humanity.

As we continue this journey, we have done a significant amount of testing and we submitted that to the FDA. We have ongoing testing that we are doing that we will continue for the next few months. Again, working with the FDA, we have agreed the pediatric study plan, which was a big step forward. And I think that for us is a positive development. So we've covered that obstacle and of course, we are sailing unchartered waters with the FDA, but we are working hand and glove with them, making progress, and as soon as we have a clear line of sight to the testing being done, submitted to the FDA, and a clear timeline for the BLA, we will update the investment community.

I would just remind you that we had about $7 million for this product in our LRP by 2021. And we believe that it is $100 million market opportunity, $25 million in the military and $75 million in the civilian market. So continue to work on it and making progress.

Kristen Stewart

Perfect. So, then the other question I have is just on UroLift manufacturing. I believe you guys produce that in Pleasanton, is that at all impacted by some of the rolling kind of blackouts with what's going on with the fires in California or any level of risk there, I am not sure if you guys have any alternative manufacturing in Mexico or anything, just anything to think about there. I'm sure you guys have safety stock and everything else, probably generators too, but just wondering how you guys are thinking about that as a risk level?

Liam Kelly

We have a hamster on wheel, Kristen…

Kristen Stewart

That's good to hear.

Liam Kelly

We are actually, we…

Kristen Stewart

Perfect, thank you.

Liam Kelly

We're in good shape there. When we bought the NeoTract company, we identified this as a risk. And in the first 12 months, we opened up an alternative manufacturing site in one of our existing facilities, so we can manufacture this product in dual sites and we haven't had any impact of the power outs that I'm aware of. So, no impact of the power outs and dual manufacturing already established as a company.

Kristen Stewart

Perfect. Those hamsters are doing well then. Glad to hear.

Liam Kelly

They're going around in circles.

Kristen Stewart

All right. I feel like that too, so. All right, thanks very much guys. Congrats again on the quarter.

Liam Kelly

Thank you.

Operator

Thank you. I'm not showing any further questions at this time, I would now like to turn the call back over to Jake Elguicze for any further remarks.

Jake Elguicze

Thanks, operator and thanks everyone for joining us on the call today. This concludes the Teleflex Incorporated third quarter 2019 earnings conference call.

Operator

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