Apyx Medical Corporation
Second Quarter Fiscal 2023 Earnings Conference Call
August 10, 2023

Presenters
Charlie Goodwin, President and Chief Executive Officer
Tara Semb, Chief Financial Officer

Q&A Participants
Phil -- Piper Sandler
Matt Hewitt -- Craig-Hallum
George Sellers -- Stephens
Frank Takkinen -- Lake Street Capital Markets

Operator
Hello, and welcome, ladies and gentlemen, to the Second Quarter of Fiscal 2023 Earnings Conference Call for Apyx Medical Corporation.

At this time, all participants have been placed in a listen only mode. At the end of the company's prepared remarks, we will conduct a question-and-answer session.

Please note that this conference call is being recorded and that the recording will be available on the company's website for replay, shortly.

Before we begin, I would like to remind everyone that our remarks and responses to your questions today may contain forward-looking statements that are based on the current expectations of management and involve inherent risks and uncertainties that could cause actual results to differ, materially, from those indicated, including without limitation, those identified in the Risk Factors section of our most recent annual report on Form 10-K, our most recent 10-Q filing and the company's other filings with the Securities and Exchange Commission.

Such factors may be updated from time to time in our filings with the SEC, which are available on our website. We undertake no obligation to publicly update or revise our forward-looking statements as a result of new information, future events or otherwise.

This call will also include references to certain financial measures that are not calculated in accordance with generally accepted accounting principles, or GAAP. We generally refer to these as non-GAAP financial measures. Reconciliations of these non-GAAP financial measures to the most comparable measures calculated and presented in accordance with GAAP are available in the earnings press release on the Investor Relations portion of our website.

I would now like to turn the call over to Mr. Charlie Goodwin, Apyx Medical's President and

Chief Executive Officer. Please go ahead, sir.

Charlie Goodwin
Thanks, Operator, and welcome, everyone, to our second quarter of 2023 earnings call. I'm joined on today's call by our Chief Financial Officer, Tara Semb. Let me provide you with a brief outline of what we intend to cover today.

I'll begin with a review of our Q2 revenue results and the factors that contributed to our sales performance. Then I'll walk through some of our key operational accomplishments during the quarter. Tara will discuss our financial results in detail, along with our 2023 financial guidance, which we reaffirmed in our earnings release today. I'll then provide some closing remarks, before we open the call for questions.

With that, let's begin with a review of our revenue results.

In the second quarter, we achieved total revenue growth of 32%, year-over-year, to $13.6 million. Our total revenue growth was driven by sales of our Advanced Energy products, which increased 40%, year-over-year, to $11.7 million. This growth performance was offset partially by OEM sales, which decreased 4%, year-over-year, to $1.8 million.

Relative to the range of expectations that we provided for the second quarter, which we shared on our last earnings call, our OEM sales exceeded our expectations by approximately $400,000 and our Advanced Energy sales came in approximately $1.1 million below our expectations, driven primarily by softer-than-expected demand from our OUS distributors, which we believe is due in part to timing of orders.

Looking at our Advanced Energy sales results in more detail. While our global Advanced Energy sales performance continued to be impacted by the disruption related to the medical device safety communication that was originally posted by the FDA in March of 2022, we saw improving business trends during the second quarter.

We were pleased to return to strong sales growth in the second quarter with Advanced Energy sales increasing 40% on a year-over-year basis and 21% on a quarter-over-quarter basis.

On a year-over-year basis, we were pleased to achieve growth in the global sales of our generators and handpieces, both domestically and internationally.

In terms of our Advanced Energy performance in the U.S., sales of our Advanced Energy products to U.S. customers increased 38%, year-over-year, consistent with our expectations for the quarter and represented the primary driver of our Advanced Energy sales performance.

Our performance in the U.S. was driven primarily by sales of our generators due to a combination of growth in sales to both existing and new customers with contributions from handpiece sales, as well.

Most notably, we continue to see strong demand from our existing users following the U.S. launch of our next-generation Apyx One console, at the beginning of 2023.

As a reminder, we introduced an upgrade program that enables existing users to trade in their prior generation Renuvion generator in order to receive discounted pricing for our new Apyx One console.

Importantly, we were pleased with our generator sales to new U.S. customers as well, particularly the uptick in adoption that we experienced following the updated safety communication in May.

With respect to our Advanced Energy sales outside the U.S., while sales in all markets continue to be impacted by the safety communication, we were pleased to achieve strong international generator sales growth, which was the primary driver of our international performance.

Our generator sales growth outside the U.S. was driven primarily by the distributor demand in multiple countries across Latin America and the Asia-Pacific region, which more than offset the year-over-year declines in our sales to distributors in Europe and the Middle East.

This strong generator performance was moderated somewhat by modest growth in sales of handpieces to our OUS distributors, which we believe was influenced, in part, by the timing of orders during the quarter.

In summary, the 40% growth, Advanced Energy growth we achieved in the second quarter was driven primarily by our sales performance in the U.S. Despite the headwinds we continue to experience related to the safety communication, we were pleased to see strong global sales of our Advanced Energy generators.

And ultimately, I believe we made important progress, both domestically and internationally, during the second quarter, positioning us for continued improvement as we progress through the remaining months of the year.

Moving to a discussion of our operational performance. In the second quarter, we made important progress on multiple fronts by continuing to expand the clinical indications for our Renuvion technology and address the remaining limitations of the safety communication, raise awareness of our recently secured clearances among surgeons and potential patients, advance our new product portfolio and enhance our balance sheet condition.

I'll now take a moment to walk through each of these items in further detail. First and most importantly, we made notable progress on our regulatory strategy to obtain new clinical indications to support our sales and marketing efforts and address the remaining issues outlined in the FDA's original safety communication from March of 2022.

In April, we secured a new 510(k) clearance for our Renuvion APR handpiece with an indication for the coagulation of subcutaneous soft tissues following liposuction for aesthetic body contouring.

As we shared on our last call, we believe this clearance is significant for two primary reasons. First, we believe it directly address the remaining limitations of the FDA safety communication, which initially stated that Renuvion APR handpiece had not been cleared for the use in combination with liposuction. And second, with this specific indication, our Renuvion APR handpiece is now the only device on the market with a 510(k) clearance for use following liposuction.

With this as a backdrop, on May 10, the FDA updated the safety communication. The update informed consumers and health care providers about the latest 510(k) clearance, revised the FDA's recommendations related to the use of our product, accordingly, and outlined the four new clinical indications that we have secured for our Renuvion products since the safety communication was originally posted.

It has been a little over three months since the FDA update to the safety communication was posted and we continue to believe it addressed the remaining issues set forth in the original safety communication from March 14, 2022.

Since May 10, our efforts have been squarely focused on raising awareness of these recent developments among existing and potential customers. Our team worked quickly to update our sales and marketing materials, accordingly, and educate our reps, distributors and surgeon customers to effectively communicate these developments and their significance.

We also leveraged our presence at recent medical meetings, including the Vegas Cosmetic Surgery and the aesthetic show conferences in June to raise awareness in the industry.

While it takes time to bring current and potential customers up to speed on our new 510(k) clearances and the resulting FDA updates, we believe this news is being well-received by the surgeon community, and we look forward to building on our recent progress.

In addition to commercializing our Apyx One console, which I discussed earlier, we continue to drive progress with respect to our new product pipeline. On June 14, we were pleased to announce the receipt of 510(k) clearance for our Renuvion micro handpiece with an indication for the delivery of radio frequency energy and/or helium plasma where coagulation or contraction of soft tissue, including subcutaneous tissue is needed.

The Renuvion micro handpiece features a smaller instrument shaft, which is half the width of our Renuvion APR handpiece. It's designed to complement our existing product offering by providing surgeons with a new option to achieve soft tissue contraction in cases that may benefit from the use of a smaller profile handpiece.

It's also worth noting that our Renuvion micro handpiece is designed exclusively for use with our Apyx One console, providing another compelling reason for surgeons to update to our latest generation system.

After securing 510(k) clearance, our team has been focused on preparing to commence our limited market release of the Renuvion micro handpiece, during the third quarter.

I'm pleased to announce, today, that we have commenced our limited market release at the end of July. During the limited market release phase, we look forward to gaining important feedback from a select group of our existing surgeon users to inform our full commercial launch, which we are targeting for the fourth quarter of this year.

And finally, in the second quarter, we continued to improve our operating efficiency while securing additional capital to enhance our balance sheet condition. We were pleased to deliver stronger-than-expected margin, operating leverage and cash flow from operations performance in the second quarter, despite the softer-than-expected total revenue results.

We continue to focus our investments on the highest priority areas to maximize our capital and drive improvements in our operating loss. Specifically, excluding the $2.7 million gain from our sale leaseback transaction, we delivered a $2 million reduction in operating loss, year-over-year, in Q2. We expect improvements in operating losses over the balance of 2023, as well.

May 8th, we completed the sale-leaseback transaction for our Clearwater property, which provided us net proceeds of $6.6 million.

And lastly, I'm excited to announce that actually, today, we received an $8.1 million payment from the Internal Revenue Service for the cash refunds that they had approved at the beginning of this year. This $8.1 million refund payment included $7.7 million of refunds and $400,000 of related interest.

With these cash tax refunds and potential capacity under our credit agreement and $18.5 million of cash on our balance sheet at the end of the second quarter, we remain confident that we have the adequate capital and borrowing capacity to support our near-term operations and growth initiatives as we work towards our longer-term goals of achieving sustainable profitability and strong free cash flow generation.

I'll now turn it over to Tara to review the second quarter financial results and 2023 guidance, which we updated in today's press release. Tara?

Tara Semb
Thanks, Charlie. I will begin my review of our second quarter financial performance at the gross profit line, since Charlie covered our revenue results.

Gross profit for the second quarter of 2023 increased $2.4 million, or 34% year-over-year, to $9.3 million. Gross profit margin was 68.4%, compared to 67.2% in the prior year period.

The increase in our gross margin was driven primarily by changes in the sales mix between our two segments, with our Advanced Energy segment comprising a higher percentage of total sales and within our Advanced Energy segment both by product and by geography, as compared to the second quarter of 2022.

Operating expenses increased $0.3 million, or 2.5% year-over-year. The increase in operating expenses, year-over-year, was primarily driven by an increase in SG&A expenses of $0.8 million and salaries and related costs and R&D expenses, which both increased by $0.1 million. These items were partially offset by a $0.8 million decrease in professional services expenses.

Loss from operations decreased $4.7 million, or 79% year-over-year, to $1.2 million. Included in the loss from operations is the $2.7 million gain from our sale-leaseback transaction that occurred, this period. Excluding the gain from our sale-leaseback transaction, our loss from operations decreased $2 million, or 34% year-over-year, to $3.9 million.

Total other income net was $282,000, compared to $622,000 last year. The change in total other income net was driven by an increase in net interest expense related to the outstanding debt obligations on our term loan in the second quarter of 2023, compared to no outstanding borrowing in the prior year period.

Net loss attributable to stockholders decreased $4.4 million, or 82%, year-over-year, to $1 million, or $0.03 per share, compared to $5.4 million, or $0.16 per share, for the second quarter of 2022. Excluding our nonrecurring gain, non-GAAP net loss attributable to stockholders decreased $1.7 million, or 32% year-over-year.

Adjusted EBITDA loss decreased $1.8 million, or 53%, year-over-year, to $1.6 million, compared to $3.4 million in the prior year period. As a reminder, we provided a detailed reconciliation from net loss attributable to stockholders to non-GAAP adjusted EBITDA in our earnings press release, today.

Cash used in operations for the three months ending June 30 was $4.9 million, compared to $5.9 million in the prior year period, driven by the year-over-year improvement in net loss,

offset partially by the gain on sale and higher use of cash and working capital, compared to the second quarter of 2022.

As of June 30, 2023, the company had cash and cash equivalents of $18.5 million, compared to $10.2 million as of December 31, 2022.

As Charlie mentioned, today we received an $8.1 million payment from the Internal Revenue Service for the cash tax refunds they approved at the beginning of this year. This $8.1 million refund payment includes $7.7 million of refunds and $400,000 of related interest.

Turning to a review of our 2023 financial guidance, which we reaffirmed in our earnings press release today, for the 12 months ending December 31, 2023, we continue to expect total revenue in the range of $59 million to $62 million, representing growth of approximately 33% to 39%, year-over-year.

Our total revenue guidance range continues to assume Advanced Energy revenue in the range of $51 million to $54 million and OEM revenue of approximately $8 million. In terms of our profitability guidance for the full year 2023, we continue to expect net loss attributable to stockholders of approximately $10.5 million.

Our formal financial guidance for 2023 incorporates the following considerations for modeling purposes. First, we expect gross margins of approximately 66.5% to 67.5%, up roughly 100 basis points versus our prior guidance assumptions.

Second, we now expect low to mid-single-digit growth in operating expenses, year-over-year. Third, we expect total other expense net of approximately $900,000 in 2023, compared to our prior expectation of income of approximately $1.4 million.

The change versus prior guidance is driven by the updated treatment on the gain on our sale-leaseback, which we recognized in GAAP operating loss in the second quarter, compared to our prior full year 2023 guidance, which assumed it would be recognized in total other expense net.

Note our updated guidance for total other expense net in 2023 now assumes interest expense net of approximately $1.6 million compared to $1.7 million, previously.

Fourth, we now expect non-controlling interests of approximately $180,000, compared to $150,000 previously. And lastly, our guidance for 2023 now assumes an income tax benefit of approximately $2 million, noncash depreciation and amortization of approximately $0.7 million, noncash stock-based compensation expense of $5.6 million and weighted average diluted shares outstanding of approximately 34.8 million shares.

For the third quarter of 2023, we anticipate total revenue in the range of $15 million to $16 million, up 65% to 76%, year-over year, driven by an increase in Advanced Energy sales in the

range of approximately 86% to 100%, year-over-year, offset partially by a decrease in OEM sales of approximately 7%, year-over-year.

Lastly, our formal guidance for 2023 continues to assume we end the year with approximately $20 million in cash and cash equivalents on our balance sheet, as of 12/31/2023.

With that, I'll turn the call back to Charlie for closing remarks.

Charlie Goodwin
Thanks, Tara. In conclusion, we are very pleased with our strong U.S. sales performance during the second quarter, which enabled us to deliver 40%, year-over-year, growth in our Advanced Energy business, coupled with notable year-over-year improvements in our operating loss.

From an operational standpoint, we secured a new 510(k) clearance to address the FDA safety communication and improve our positioning in the market, while continuing to raise awareness of our technologies, expand our product offering and enhance our balance sheet.

Having addressed the remaining issues in the safety communication, we have seen subsequent improvements in the U.S. sales environment for our Advanced Energy generators and we expect continued improvement, globally, over the balance of the year.

We are reaffirming our guidance today based on our recent progress and continued confidence in the ability to deliver Advanced Energy sales growth in excess of 38%, year-over-year, combined with significant reductions in our net loss in 2023.

We believe our growth in the second half of 2023 will continue to benefit from multiple tailwinds, including the four 510(k) clearances we obtained for specific clinical indications in 2022 and 2023, along with the most recent update made to the safety communication, the U.S. commercialization of our Apyx One console and our efforts to raise awareness of our technologies at both the provider and consumer levels, including our direct-to-consumer initiatives.

And in addition to driving strong growth in the second half of this year, we remain focused on delivering against our remaining strategic initiatives that we outlined at the beginning of the year, enhancing our Renuvion product portfolio by bringing new technologies to market, expanding our portfolio of clinical evidence supporting the use of our products and managing our expenses while driving progress towards profitability.

By continuing to achieve progress across all of these fronts, we are committed to positioning Apyx Medical for the future so we can continue to expand our share of the multibillion-dollar opportunity that lies ahead for our Renuvion technology in the global cosmetic surgery market.

I'd like to close by thanking our team and distributor partners for their contributions this past quarter, as well as our customers, investors and everyone on today's call for their interest and support for our mission.

With that, Operator, let's now open the call for questions.

Operator
Thank you. If you'd like to ask a question, please signal by press "*", "1" on your telephone keypad. If you are using a speaker phone, please make sure your mute function is turned off to allow your signal to reach our equipment.

We do ask that you limit yourself to one question and to one follow-up. And if you would like to ask additional questions, we invite you to add yourself to the queue again by pressing "*", "1".

And our first question will come from the line of Matthew O'Brien with Piper Sandler. Please proceed with your question.

Phil
Hey, this is Phil on for Matt. Thanks for taking our question. I guess just to start, what was the magnitude of the international softness in the quarter? Understanding the stocking dynamic you called out, but what gives you confidence international can return to a source of growth?

And just to tack on, one, you called out pockets of weakness versus strength in certain geographies. Can you speak to the differences in those individual markets that might be driving those differences?

Charlie Goodwin
Yeah, good question and thank you for it. Just let me take a step back for a minute. We saw some really positive developments in our business in Q2. So, I want to make sure that everybody understands that we feel really good about where we are.

We obtained the 510(k) clearance for Renuvion following liposuction and saw the communication update from the safety notice, as we had expected. And we also saw significant improvements in our Advanced Energy sales performance, which increased 21%, quarter-over-quarter, and 40%, year-over-year.

Our U.S. Advanced Energy sales growth and OUS generator sales growth were consistent with our expectations. So, those were right what we expected.

Our OUS handpiece sales were lower than we had expected, largely due to the timing of some distribution orders. And I'm not going to get into details other than to say that it was not a single distributor and that we expect those orders in the back half of 2023. And that's one of

the reasons why we're reaffirming our guidance today, and we feel good about our stated growth objections--or expectations for the full year and Q3.

Phil
That's helpful. And I guess just to talk a bit about the micro handpiece. What lift can you expect out of that device this year? How big of a deal is that smaller instrument shaft? And how should we think about the interest here as a lift to the Apyx One console? Thank you.

Charlie Goodwin
Yeah, so remember, as I outlined in the remarks, we have just started our soft launch in Q3. And so right now the device is in hands of some of our top surgeon customers and they're using it and we're gaining feedback where we will develop the safe and effective use guidelines. And we have all the information that we need to start to roll out of that in the fourth quarter, okay.

And the thing that is important about that, the micro handpiece and the smaller size of it is now it can go into areas where doctors wanted something smaller and didn't want to take the existing APR in there.

And so, think about places like the fine areas of the face, think about the hands, think about the knees, think about the ankles, think about smaller areas where people still want some form of skin contraction. And so, we believe this will be a nice addition to our portfolio.

And the other thing to keep in mind with this, too, is the micro handpiece if you're going to use that, it requires an upgrade to the Apyx One console. And so, we will start to see some of that benefit of the micro handpiece itself in the fourth quarter, but it's really more going to have an impact in 2024.

Phil
Makes sense, thanks so much.

Charlie Goodwin
Thank you.

Operator
Thank you. Our next question comes from the line of Matt Hewitt with Craig-Hallum. Please proceed with your question.

Matthew Hewitt
Good afternoon. Thank you for taking the questions. Maybe first up, regarding Apyx One, maybe what's the feedback been from customers? I realize it's still relatively early days, but what has been the conversion rate of your existing users, so far?

Charlie Goodwin

Yeah, the initial response that we've seen for the Apyx One launch has been positive, and it's been an important driver for us so far in Q2 of '23.

The feedback has been highlighted by the advanced features, which is the touchscreen user face, the presets for bodies and different procedures and the cloud connectivity functionality, which has really proven to be very important because a lot of the doctors were having their staff record this stuff and the amount of gas and the amount of usage and the amount of jewels, they were recording all this stuff manually on the patient's chart. And now they can just upload this and the generator will do that, automatically.

And so, that's been a really nice feature. And we're really happy with the way it's been resonating with the surgeons and we expect it to remain an important contributor for us for the second half of the year, too.

Matthew Hewitt
Got it. And then shifting a little bit here. But regarding the international handpiece sales, I understand it's a timing-related issue. If I heard you correctly, it sounds like it's more back half. So, does that imply we shouldn't anticipate that bouncing back here in Q3, it's going to take a little bit longer? Or maybe have you received some orders already here in Q3 from international, these specific international distributors? Any additional color there would be helpful.

Charlie Goodwin
Yeah, look, I think the important thing to know about that is it was just some orders, some handpieces. It wasn't one distributor, and we expect those orders in the back half of this year. And I think that's all the detail that we're going to give on that. And that's why reaffirmed our guidance for the back half of the year because we're confident that we're going to get those in the back half of the year.

Matthew Hewitt
Got it. All right, thank you.

Charlie Goodwin
Thank you.

Operator
Thank you. Our next question comes from the line of George Sellers with Stephens. Please proceed with the question.

George Sellers
Hey, good afternoon, and thanks for taking the question. Maybe to start with the quarter. I'm just curious if you could give some detail on how utilization trended with liposuction versus standalone, and if that trend changed following the FDA clearance.

Charlie Goodwin
Yeah, I don't know that I can speak to that with any trend data or anything else. I mean, remember that the FDA safety communication was just updated in the middle of May. And we basically had six weeks of time in the quarter where that was behind us. And so, in terms of monthly trends or specificity there, we did call out a notable uptick in the U.S. adoption after the safety communication in May.

So, the only thing that I can tell you is that after that was out there that we started to have a much greater rate of adoption than we did before or after that. And so that, obviously, has us very encouraged for the rest of the year.

George Sellers
Okay, that's helpful. And maybe switching to guidance here. You obviously reiterated your revenue guidance but raised the gross profit expectations. I'm just curious if you could give a little bit more detail. Is there some change maybe in the contribution you're expecting from international versus the U.S.? Or if you could just give a little bit more detail, maybe, that would be helpful.

Tara Semb
Yeah, so, I mean, really, it's primarily driven by mix assumptions and it is favorable mix within our Advanced Energy segment by geography and by product.

George Sellers
Okay, thank you for the time. I'll leave it there.

Charlie Goodwin
Thank you.

Operator
Thank you. As a reminder, if you would like to ask a question, please signal by pressing "*", "1" on your telephone keypad. Our next question comes from the line of Frank Takkinen with Lake Street Capital Markets. Please proceed with your question.

Frank Takkinen
Great, thanks for taking the questions. I was hoping to ask one on the guide, as well. I was hoping you could parse out a couple of pieces to the growth expectation. The primary question I want to ask is just how are you thinking about growth in handpieces versus console. Which do you expect to be growing faster, or is it kind of broad-based strength amongst both?

Charlie Goodwin
Yeah, look, we had growth, both in generators and in handpieces globally, right. And we had that for the quarter that we just had.

Where we had faster growth and more growth was the adoption of new generators and specifically in the U.S., but also outside the U.S. And we expect that to remain really strong in the back half of the year. And that is part of the momentum that we had. And we've got that, especially in the U.S. because of multiple tailwinds.

We've got the indications that we've talked about. We've got the reduced headwinds now that the FDA updated the safety notice. We've got the Apyx One generator which right now, remember, is only launched in the United States. So, that is a U.S. thing, in particular.

And right now, our direct-to-consumer marketing is only in the United States, too. And so, we expect the U.S. to be a bigger driver. If the U.S. is the bigger driver, that means that our gross margins go up, that there is a positive impact on our gross margins.

Frank Takkinen
And then maybe for my second one. I want to ask on Ozempic. Obviously, it's been a hot topic in all headlines, recently. Curious if you could kind of illustrate or explain how you think that could, positively or negatively, impact your business in the future?

Charlie Goodwin
Yeah, the first thing is, is that we see it as a tremendous tailwind to our business. We think it is going to be very positive for our company. The thing that I want to make sure that everybody understands is this is just playing out right now and just getting started in real time.

And we are working with some of our clinicians that are actually doing this. They're actually marketing the skinny shots and they've got a whole program for people to come in and lose the weight and then be able to take care of their lax skin, after.

And remember, for us, we've got an indication for use of liposuction, but we've also got the indication for just for soft tissue contraction. And we really don't care how the skin gets lax. What we care about is that people don't like lax skin and they want to get it treated, and Renuvion still is the best technology in the marketplace today to treat that lax skin.

And so for us, it's a tremendous benefit. It's a tremendous benefit that we think is going to continue for many years to come, quite frankly.

Frank Takkinen
Okay, maybe I'll squeak one more in here. With the FDA notice that came shortly after the liposuction 510(k), I think there was an inference in there related to the FDA enforcing on-label usage across the industry. Have you seen this play out at all in the field as it relates to your competition? Or is this something that hasn't come to fruition, yet?

Charlie Goodwin

Yeah, unfortunately, we have not seen any sign of that. There are still people that are making claims that they shouldn't make and doing things that they shouldn't be doing.

So, as of right now we really have not seen any evidence of that, even though it was--you are correct--it was stated in the safety notice that they were going to do that. But in fairness to the FDA, that safety notice did just come out on May 10. And so, we are not that far away from that still, so.

Frank Takkinen
Okay, that makes sense. Thanks for taking the questions.

Operator
Thank you. Our next question is from Matt Hewitt with Craig-Hallum. Please proceed with your question.

Matthew Hewitt
Just a follow-up regarding the OUS opportunity. I realize you have a lot on your plate at the moment, but are you still seeking other incremental OUS approvals? I believe there's been a few countries in the past that you talked about potentially going after. I'm just curious if those are still in the works. Thanks.

Charlie Goodwin
Yeah, for sure. We did not obtain any new registrations in Q2 and our guidance doesn't assume any contributions for many new countries. But as you mentioned, the two big markets that we are not in are South Korea and China. And so, we are still pursuing both of those markets.

And we look forward to the day that I can tell you that we got clearance in both of those places. So, we'll make sure that everybody knows when that happens for sure.

Matthew Hewitt
Sounds good. Thank you.

Charlie Goodwin
Thank you.

Operator
Thank you. We are currently showing no remaining questions, at this time. And with that, this does conclude our conference today. Thank you for your participation.