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RTIX.OQ - Q1 2019 RTI Surgical Holdings Inc Earnings Call

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CORPORATE PARTICIPANTS

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CONFERENCE CALL PARTICIPANTS

David Louis Turkaly *JMP Securities LLC, Research Division - MD and Senior Research Analyst*

Matthew Gregory Hewitt *Craig-Hallum Capital Group LLC, Research Division - Senior Research Analyst*

PRESENTATION

Operator

Good morning. My name is Rob, and I will be your conference operator today. At this time I would like to welcome everyone to the RTI Surgical Holdings Q1 2019 Conference Call. (Operator Instructions)

Molly Poarch, Director of Investor Relations, you may begin your conference.

Molly Poarch - *RTI Surgical Holdings, Inc. - Director of Corporate Communications*

Good morning, and thank you for joining the call to discuss RTI's First Quarter 2019 Results. On the call today are Camille Farhat, our President and Chief Executive Officer; and Jonathon Singer, our Chief Financial and Administrative Officer. Camille will provide a brief strategic update and discuss the quarter. Jon will then discuss the first quarter financial results. After their comments the team will be available to take questions.

Before we start, let me make the following disclosure. The earnings and other matters we will be discussing on this conference call will involve statements that are forward looking. These statements are based on management's current expectations, but they are subject to various risks and uncertainties associated with our lines of business and with the economic environment in general. Our actual results may vary from any statements concerning our expectations about future events that are made during the call. We make no guarantees as to the accuracy of these statements. Accordingly, we urge you to consider all information about the company and not to place undue reliance on these forward-looking statements.

During this call we will also present certain financial information on a non-GAAP basis. Management believes that non-GAAP financial measures, taken in conjunction with U.S. GAAP financial measures, provide useful information for both management and investors by excluding certain noncash and other expenses that are not indicative of our core operating results. Management uses non-GAAP measures to compare our performance relative to forecast and strategic plan to benchmark our performance externally against competitors and for certain compensation decisions.

Reconciliations between U.S. GAAP and non-GAAP results are presented in tables accompanying our earnings release, which can be found in the Investor Relations section of our website.

Now I will turn the call over to Camille. Please go ahead.

Camille I. Farhat - *RTI Surgical Holdings, Inc. - CEO, President & Director*

Good morning, everyone, and thank you for joining us today. 2019 is off to a positive start. We successfully closed the acquisition of Paradigm Spine, adding the coflex device to our growing and increasingly differentiated spine portfolio.



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In the first quarter we delivered revenue approximately \$69.7 million with adjusted EBITDA of \$6.6 million or 10% of revenue. Our performance was driven by the increased strength of our spine portfolio, including \$2 million from the acquisition of Paradigm as well as a solid performance across our businesses. RTI's performance in the first quarter reflects the strategic and operational progress made towards reducing complexity, driving operational excellence and accelerating the growth of the company.

Looking ahead, we will continue to explore opportunities to simplify our channels, to further anchor our business in the areas where we can build scale and relevance and drive growth. Our operational excellence initiatives contributed to an eye-popping improvement for the quarter with a gross profit margin of 54.5% compared to 48.2% prior year. We remain on track to deliver the balance of the anticipated cost savings in 2019.

In accelerating RTI's growth, our spine franchise is a primary focus, including strengthening our portfolio and commercial structure. To that end, one of the key highlights from the quarter was the closing of Paradigm Spine. Many Paradigm team members joined RTI immediately following the close of the acquisition to drive our business forward, and collaboration between the teams has been excellent.

Integration continues to progress smoothly and in line with our expectations. Looking ahead, we'll focus on accelerating the growth of coflex through physician engagement, accelerated reimbursement and sales execution and focus. In an effort to more effectively execute on our goal to drive growth in our spine business and in conjunction with the integration of Paradigm, we have expanded our U.S. spine commercial team to focus on 2 different portfolio areas: novel and established therapies.

This approach purposefully aligns products with similar dynamics to our commercial resources and capabilities to drive growth for our spine business. Our novel therapies, including coflex and Slimmetry, require additional focus and investment in demand generation, expanded surgeon access and training, clinical evaluation and reimbursement. While our established therapies, which include Fortilink with TETRAfuse, ViBone and our portfolio of hardware interbody and orthobiologic options, require focus on channel management, distributor development programs and pricing and contracting strategies.

To drive these changes in our overall strategy in spine forward, we have welcomed Tom Popeck as the new leader of our spine franchise. Tom brings significant commercial leadership experience in the orthopedics industry. He joined us from Johnson & Johnson, where he led the commercial strategy for his DePuy Synthes business unit. And prior to J&J, Tom spent 11 years at Stryker Orthopaedics, where he led various leadership positions, including leading the Stryker foot and ankle business unit.

From a global perspective we are currently in the process of integrating the international Paradigm business. The addition of Paradigm's product offering will add approximately 35% more revenue to our international franchise and expands our commercial team. The integration supports our recent switch from direct -- I'm sorry, from distributors to direct sales in Germany, a key target market, and significantly increases our customer base there.

Turning to an update on the rest of the business. We continue to invest in predictable execution in our Sports and OEM franchises. Within the Sports franchise, we were pleased to see a return to overall growth, driven by strong demand for tendons and tissue. The team has been focused on strengthening our channel partnerships to enhance physician access, training and demand generation.

As we progress through the year, we will continue to evaluate our channel strategy to optimize the opportunity for our tissue-based products. The OEM business performed in line with expectations for first quarter 2019 with a continued focus on extending long-term customer contracts, targeting product development for product line and geographic expansions and investing in new platforms of growth that leverage our existing capabilities. The predictable revenue performance of these franchises in conjunction with operating excellence progression provide reliable EBITDA contribution to support our ongoing investment to accelerate growth. Overall, we are pleased with our strong start for the year and remain focused on executing against our key strategic and operational objectives over the balance of the year.

And with that, I will hand over to Jon to outline our financial performance.



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Jonathon M. Singer - RTI Surgical Holdings, Inc. - Chief Financial & Administrative Officer and Corporate Secretary

Thank you, Camille. Jumping right in at the top, RTI's worldwide revenue for the first quarter of 2019 were \$69.7 million compared with \$69.9 million during the same period for the prior year. Driving 2019 revenue are approximately \$0.7 million of net growth within spine and \$300,000 of growth in Sports offset by declines in OEM. The majority of the decline in OEM is due to \$1.1 million of revenue booked in the first quarter of 2018, which was shifted from the second quarter, if you recall our discussions of last year.

Spine growth represents \$1.4 million contribution from the addition of coflex. \$1.3 million net contribution from established spine growth offset by a \$2 million net decline from the suspension of map3. If adjusted for the impact of map3, established spine products grew approximately 9%.

Revenue from the Paradigm acquisition will be recognized in the spine and the international franchises, in total approximately \$2 million for the quarter as anticipated. Gross profit for the first quarter of 2019 was \$38 million, an increase of \$4.3 million or 12.8% compared to \$33.7 million for the comparable prior year period. Gross profit margins were 54.5% of revenues compared to 48.2% of revenues in the first quarter of 2018. Gross profit for the first quarter of 2018 was impacted by about \$1.3 million of charges. Excluding these nonrecurring charges, gross margins would have been 50% in 2018.

The 450 basis point improvement in margin from last year is evidence of the solid achievement of our efforts to drive operational excellence. Marketing, general and administrative expenses were \$31.9 million for the first quarter of 2019, an increase of \$3.5 million or 12.3% compared to \$28.4 million in 2018. The increase is predominantly driven by the addition of Paradigm and increased legal cost related to a patent litigation.

Research and develop expenses were \$4.3 million in the first quarter of 2019 compared to \$3.4 million, 2018. The increase in R&D is driven by the acceleration of organic growth investments, this is a good thing.

During the first quarter 2019, we incurred \$9 million of nonrecurring acquisition and integration cost to support the acquisition of Paradigm Spine. During the first quarter of 2018, the company incurred \$1.8 million of nonrecurring charges. Adjusted earnings before interest, taxes, depreciation and amortization for the first quarter of 2019 was \$6.6 million or 10% of revenue compared with \$7.8 million or 11% of revenue for the first quarter 2018. The decline in adjusted EBITDA is due to increased patent litigation cost and operating expenses focused on accelerating growth, driven primarily by incremental cost for the acquisition of Paradigm and incremental investment in R&D.

Net loss applicable to common shares was \$9.1 million or \$0.14 per fully diluted common share in the first quarter 2019 compared to net loss applicable to common shares of \$1.9 million or \$0.03 per fully diluted common share in the first quarter of 2018. As outlined in the reconciliation tables presented in our earnings release, excluding the impact of the various nonrecurring charges, adjusted net income applicable to common shares was \$0.5 million or \$0.01 per fully diluted common share in the first quarter of 2019.

Turning to guidance. Based on our current business outlook, we are reiterating financial guidance for 2019. We continue to expect full year revenues of \$325 million to \$335 million, representing approximately 15% to 19% growth over the prior period. We expect full year adjusted EBITDA to be in the range of \$36 million to \$40 million, representing approximately 7% to 19% growth over the prior year.

With regard to our capital structure, based on the anticipated growth of the spine portfolio, predictable cash generation from the Sports and OEM franchises and further efforts to reduce complexity, it is our goal to reduce debt-to-EBITDA to less than 4 by the end of 2019. I would note the following assumptions that underpin our guidance: relatively stable economic and market conditions and regulatory environment; ongoing positive impacts from efforts to reduce complexity and implement operational excellence initiatives; the successful integration of Paradigm Spine and a positive EBITDA contribution from the acquisition, which closed on March 8 of 2019; sustained favorable reimbursement from private payers; and the successful ongoing transition from map3 to ViBone.

Our guidance is intended to be for the full year. However, given that everyone develops quarterly models, I'll share some thoughts on the performance drivers in the second quarter 2019. We currently expect revenue growth will be in the range of 11% to 14%, predominantly driven by global contributions from the Paradigm acquisition.

Operator, I'd like to open the line for questions.



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QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

And your first question comes from the line of Matt Hewitt from Craig-Hallum Capital.

Matthew Gregory Hewitt - *Craig-Hallum Capital Group LLC, Research Division - Senior Research Analyst*

Congratulations on the progress.

Camille I. Farhat - *RTI Surgical Holdings, Inc. - CEO, President & Director*

Thank you.

Matthew Gregory Hewitt - *Craig-Hallum Capital Group LLC, Research Division - Senior Research Analyst*

And I apologize if you covered this, I was slow getting in on the call, but as far as Paradigm is concerned, maybe where are you from an integration standpoint? And then, secondly, maybe talk a little bit about the reimbursement landscape? How are things progressing with some of those discussions and when we might be hearing about some new coverage coming onboard?

Camille I. Farhat - *RTI Surgical Holdings, Inc. - CEO, President & Director*

Yes. Thanks, again, for joining this morning, and always the good questions coming up. Let me address these -- both of these questions. I would say that on the integration side it's progressing as expected. From a -- it really mirrors the activity that we have done with the integration of Zyga, with one exception is we have taken advantage of now Zyga and Coflex together to create that novel therapies channel that is a dedicated sales force with support around that for -- with training the -- what I would say the ordering aspect of that as well as the adoption curve, including reimbursement in clinical support for both of these therapies. So that's the additional part that we have done compared to what we had -- our playbook actually for the Zyga integration. So we anticipate that some time in Q3 we would be done with the integration and then commercially that channel has been established, the structure is in place and where we have some open positions, we're filling them right now.

Reimbursement. If you look at the season, this is usually the time of the year where insurance companies revisit their policies. So we're a little bit late to make adjustments for the previous strategies. So as an initial step, we're waiting to see the outcome of the efforts that Paradigm has put into this and they've done a lot of great work. So we'll see what comes out of that. We also are in the process of setting up a reimbursement summit, with view of the experts based on what we hear in the feedback to adjust our approach, if need be.

That said, Matt, based on the guidance that Jon has shared earlier, we're not relying and we don't need additional reimbursement coverage for the 2019 guidance numbers. We feel very good about where we are in the opportunity through the focused and the leverage of the dedicated sales force channel and the broader RTI established therapies channel to get us there, but it would be nice to have these as they would accelerate that.

Matthew Gregory Hewitt - *Craig-Hallum Capital Group LLC, Research Division - Senior Research Analyst*

That's great. And thank you for that extra color on the guidance piece there. Maybe a question -- and Jon, I think this came up a couple of times in your prepared remarks, the patent litigation, maybe just walk us through what's going on there and I guess what's being addressed?

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Jonathon M. Singer - *RTI Surgical Holdings, Inc. - Chief Financial & Administrative Officer and Corporate Secretary*

Yes. So we've got another not-for-profit tissue processor that has patents on products that look a lot like products that we've been marketing for 20 years, and these are expired patents that they felt needed to be litigated. We believe we've got multiple levels of defense. And so right now we filed IPRs on the patents because we believe that the patents themselves are not valid based on prior [art]. And so we filed the IPRs in January and then they actually got a stay of the litigation in the federal court of Florida kind of mid-March. And so pretty significant cost in the preparation of the IPRs that were in the quarter, about \$1.5 million incremental cost over prior year. With the stay, we think the spending kind of now down to a slow simmer until it's about -- they've got -- I think the litigator has 45 days to respond and then there's a set period within the IPR process.

If you look at the IPR process, which is relatively new, somewhere north of 65% of the patents that go through the process are determined to be invalid. So that's where we sat. It's kind of a -- it's unfortunate because I don't think patients or the gift of the donor are being enhanced in any way by this activity, so it's simply economics.

But again, we believe we're on the right side of the law, and we're going to continue to defend it.

Matthew Gregory Hewitt - *Craig-Hallum Capital Group LLC, Research Division - Senior Research Analyst*

Great. Thank you for those details. And then maybe last question and I'll hop off. Where does the spine sales force sit today? I think, Camille, you mentioned that you'll be looking to maybe add a couple more resources in the back half of the year. But where does that sit today, both direct versus indirect and where do you see that -- the year exiting?

Camille I. Farhat - *RTI Surgical Holdings, Inc. - CEO, President & Director*

Yes. So I just would like to clarify that we don't have at this point a direct sales force. What we -- if you go back and as I've said in my comments, the nature of novel therapies, since they're not standard of care, there is a big element of demand generation, training, clinical evaluation, reimbursement and the likes that distributors are reluctant to make the investments. So it's for us to establish that direct linkage with the surgeon and the practice, support them as they go through that. And then after a few procedures then turn it over to the distributor as that kind of moves forward. That's a little bit different than the established therapies where you're reliant more on what I'm going to call channel management distributor development programs and contracting. So both of these sales forces are within the spine franchise. They both will report -- and actually we split the marketing organization that way as well. So sales for novel therapies, marketing for novel therapies have their leaders, established therapies have their leaders in sales and marketing, and all 4 report into Tom Popeck within the spine franchise.

And yes, to the point you were making. Yes, we are making investment to expand our established therapies as well. So we feel very excited and bullish. As you know, not only did we spend last year in building differentiated pipelines, but we also got the product pipeline going and we anticipate new products to be introduced in late '19 and into 2020 in the U.S. and international.

And again, it gives us confidence when I look at the established therapies that let's just say call it the legacy business. If you take out the map3, and part of Jon's comments, that business grew 9%. So we feel very good that, that will continue to grow with more products coming, and we're happy to make the investment.

Operator

Your next question comes from the line of Dave Turkaly from JMP Securities.



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David Louis Turkaly - JPM Securities LLC, Research Division - MD and Senior Research Analyst

I apologize upfront, I've been bouncing around a little too, so I heard that you're, Jon, splitting the spine group into novel versus established. Will it carry -- I mean, you just talked about separate sales forces, but will there be any cross-selling of those devices for the folks that let's say are doing established? Can they have access to the other stuff or is it really going to be 2 separate units managed separately moving forward?

Camille I. Farhat - RTI Surgical Holdings, Inc. - CEO, President & Director

They're not 2 separate units. It's just based on what you need in order to be effective in treating patients with the right therapy. One are standard of care and everybody knows about them, right? And one requires incremental focus. But truly it's the same surgeon at the end of the day that would like to have come our way and be comfortable with RTI. We just feel that with a different level of capabilities that are required with novel therapies and effort and energy, whether it's reimbursement support, whether it's patient selection, whether it's training, that allows us to establish a more direct presence and strengthen the brand with the surgeon. And then after a few procedures turn that over to the distributor that hopefully carries also the breadth of the product portfolio with RTI.

So it's really more -- I think of the established therapies more like the conductors. And if that surgeon wants or is convinced about expanding their practice and having more choices to treat their patients, then we invite that specialist and the group that supports them from reimbursement to clinical specialists to contracting, et cetera, to support that practice in the -- along the adoption curve. Did that help a little bit, David?

David Louis Turkaly - JPM Securities LLC, Research Division - MD and Senior Research Analyst

Yes. No. Thank you for that. I guess, secondly...

Camille I. Farhat - RTI Surgical Holdings, Inc. - CEO, President & Director

I'm sorry, David, that's different than, for example, what SI-BONE is doing for that novel therapy in creating a focus and try to move the adoption curve.

David Louis Turkaly - JPM Securities LLC, Research Division - MD and Senior Research Analyst

Got it. Secondly, just on the ViBone sort of swap out with the map3, I just wanted any color there, how that's going? And then can you just remind us sort of the ASP profiles of those 2 products?

Camille I. Farhat - RTI Surgical Holdings, Inc. - CEO, President & Director

Yes. So what I will say is the ViBone progressing in line with what we have shared with you. So based on our numbers that are both in the guidance, we are on track. We continue, as we have said to you, we think that we're not going to see the full impact until we go through the year. There was quite a bit of interest right now in people trying. Some already converted, some will continue to work with the system as they put things through, and some are using this as an opportunity to reset and have a fresh look on the biologics portfolio. But we're very happy with the progress on ViBone. We're investing in that product. We will see other derivative products come out later this year and more clinical studies that will be initiated. We already have 1 under way. And just like I said last time, as we're building the -- as we built the evidence for map3, we're building the evidence around ViBone.

In terms of the pricing, David, it'd be comparable to map3, and I'll have to get back to you on the exact pricing.



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David Louis Turkaly - *JMP Securities LLC, Research Division - MD and Senior Research Analyst*

No worries. That's fine. And I guess just one housekeeping one for Jon. The -- what's your expected weighted shares outstanding for the year? I realized the first quarter had a loss due to some charges, but I'm just curious if you have a number sort of what we're going to be looking at for the fully diluted shares post-Paradigm.

Jonathon M. Singer - *RTI Surgical Holdings, Inc. - Chief Financial & Administrative Officer and Corporate Secretary*

Yes. It's about 74 million-ish is kind of the number to think about. Yes, so you've got round numbers 11 million shares that are coming in -- that came in on March 8 that had like a 0.17 weighting in the quarter. That would be fully weighted as you get there. So think around that number.

Operator

There are no further questions at this time, I'll turn the call back to management.

Camille I. Farhat - *RTI Surgical Holdings, Inc. - CEO, President & Director*

Okay. I want to thank everybody for the ongoing interest in RTI Surgical Holdings. We are confident that our strategic transformation continues to build momentum, and we are creating an organization with significant long-term value. We are focused on the execution of our plans, and we look forward to updating you on our ongoing progress.

Thanks for joining and juggling your schedule to be with us. Have a terrific day.

Operator

Ladies and gentlemen, thank you for your participation. This concludes today's conference call, and you may now disconnect.

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