Reva Medical Inc.(2017 Q3 Update)

November 7, 2017

Corporate Speakers:

- Reggie Groves; REVA Medical, Inc.; CEO, Director
- Brandi Roberts; REVA Medical, Inc.; SVP, CFO, Company Secretary

Participants:

- Tanu Jain; Bell Potter Securities; Analyst

PRESENTATION

Operator: Welcome to the REVA Medical 2017 Third Quarter Financial Update call.

(Operator Instructions)

I would now like to introduce your host for today's conference, Reggie Groves, CEO. Please go ahead.

Regina Groves: Before we get started, Cheryl Liberatore, our Director of Communications, will read the Safe Harbor statement.

Cheryl Liberatore: This conference call may include forward-looking statements that involve risks, uncertainties and assumptions. All statements that are not statements of historical fact, including those that address future operating performance and events or developments that we expect or anticipate will occur in the future are forward-looking statements, such statements regarding the projections and timing surrounding commercial operations and sales; clinical trials; pipeline product development; and future financing.

We caution listeners that forward-looking statements are not guarantees of future performance and actual results and the timing of events could differ materially from those anticipated by forward-looking statements as a result of many factors, including those discussed under risk factors in our Form 10-K for the year ended December 31, 2016, filed with the United States Securities and Exchange Commission on February 28, 2017.

Listeners are cautioned that many of the assumptions on which our forward-looking statements are based are likely to change after our statements are made. Further, we may make changes to our business plans that could affect our results.

Any forward-looking statements in this conference call speak only as of today. REVA does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. I would now like to turn the call over to Reggie.

Regina Groves: Thank you, Cheryl. Hello, everyone, and thank you for joining us today to discuss REVA's recently announced financial results for Quarter 3, our first quarter of revenue and a general discussion of the progress we are making against our priorities.

Also with me today are: Brandi Roberts, our CFO; Jeff Anderson, our SVP of Clinical and Regulatory Affairs; Rick Kimes, our SVP of Operations; and Joann Yao, Senior Director of Global Marketing. Following my updates, we'll open the phone for your questions.

The third quarter of 2017 was an extraordinary quarter for REVA as we accepted the first orders for our Fantom scaffolds and recognized our first revenue. I will review the progress against our corporate priorities in just a moment. But first, I would like to discuss the market conditions into which we have entered, as I believe the opportunity for REVA is very promising.

During the third quarter, Abbott officially withdrew their Absorb bioresorbable scaffold from the market worldwide. In addition, Boston Scientific and Medtronic made announcements about redirecting their R&D efforts away from stents. While at first blush, these changes may appear to present headwinds for REVA, I believe they represent significant opportunity.

Abbott launched Absorb in 2012, creating tremendous excitement about the potential for bioresorbable scaffolds. Due to Abbott's efforts, physicians understand the limitations of metal stents and the promise of bioresorbable scaffolds. The withdrawal of Absorb has created an unmet demand in the market. Fantom is uniquely positioned to fill the void left by Absorb, as REVA has approached prospective customers, all have expressed their desire for a successful second-generation scaffold to fulfill this promise.

We view Boston Scientific and Medtronic's announcement as reassurance that the 3 big players see the metal stent market has having achieved the plateau on the S-curve of innovation. That is, they see no further investment in a metal stent that will drive significant advancement or change in competitive position.

Bioresorbable is the only disruption on the horizon. Yet PLLA has proven that it is not the polymer to achieve results. REVA's Tyrocore polymer is the only proprietary polymer and Fantom is uniquely positioned to capitalize on this opportunity.

Now let me turn to our corporate priorities. With CE Mark secured, our priorities have shifted from preparation to execution. Today, our top priorities are: one, ensuring Fantom's commercial success; two, expanding our business; and three, managing our cash position.

So, let me turn to our commercial progress. As previously announced, we secured our first commercial contract in June and the first commercial order of our product in early July. On August 1st our Vice President of Europe became a full-time employee. Since launch we have approached more than 3 dozen potential customers and in the third

quarter we had billings of $105,000, which included initial orders from new customers as well as some reorders.

These billings were achieved with only our VP of Europe on the ground, who was also focused on training new accounts and hiring our first sales managers, the first two of which started on November 1st. We are hiring experienced sales managers and believe that they will be able to add to our billing in a meaningful way. We have another sales manager committed to starting on January 1, and two more in final discussions to start in the first quarter of 2018.

Regarding our second business priority, we have several efforts underway to expand our business. These include geographic expansion, expanding our lead in bioresorbable scaffolds and moving beyond coronary arteries. Geographically, we are executing our Phase I launch in the markets of Germany, Austria and Switzerland and will be adding the Benelux region and Denmark in early 2018.

In addition, we are now actively developing our plans for our Phase II launch, including additional countries in Europe as well as in the Middle East and Brazil. Extending our lead in coronary bioresorbable scaffolds includes building clinical evidence and launching the next generation of Fantom.

Regarding building clinical evidence, at TCT, we saw the first promising data from Absorb II which showed 0 scaffold thrombosis between three and four years for Absorb, thus providing the first evidence of the potential benefit from bioresorption.

Also at TCT, REVA released preliminary two-year data on a subset of patients that showed a 5.6% major adverse cardiac event rate. This compares favorably to the 2-year event rate of 7.9% for Xience, and very favorably to the 11% rate for Absorb in the Absorb III trial.

REVA is continuing to invest in expanding clinical evidence. Our long lesion/multi-vessel trial in Germany is actively enrolling, and our pilot trial in acute MI is now moving forward. We are continuing to develop our plans for a post-market registry in Europe and expect that trial to be underway in early 2018.

In the third quarter, we completed our second meeting with the FDA regarding our potential path for a clinical study in the U.S. As is customary, the FDA has asked a number of questions, and we are in the process of responding to them. We anticipate a couple of additional meetings with the FDA and continue to expect conditional approval in the first half of 2018.

Our plans for expanding our lead in bioresorbable scaffolds are made complete with our efforts from the next generation of Fantom, the Fantom Encore. The 2.5 mm size will have a market-leading strut thickness of 95 microns, and is expected to receive CE marking in the first half of 2018. The 3.0 mm and 3.5 mm sizes will follow later in 2018. Moving beyond the coronary arteries, we plan to secure CE Marking in 2018 on our first-

generation scaffold for below-the-knee peripheral artery disease. We also continue to work on potential changes to our polymer to accommodate important features for above-the-knee applications like crush recoverability.

Regarding our third corporate priority of cash management, I will let Brandi talk in detail, but will summarize by saying we are pleased with our initial billings of $105,000 and continue to manage our cash position to take us into 2019 with a target of reaching cash flow breakeven, excluding the cost of the U.S. trial. Now I will turn the discussion over to Brandi.

Brandi Roberts: Thank you, Reggie. A quick reminder before I get started. Our financial statements are prepared in accordance with U.S. generally accepted accounting principles and are presented in US dollars.

Our results through September 30 have been reported with both the SEC and ASX, and are available on our website. Our third quarter financial results press release was also issued earlier today in both the United States and Australia. We ended the third quarter with approximately $24.1 million in cash, cash equivalents and investment securities. As Reggie mentioned, cash management is a priority for us, and I will discuss this in more detail in just a bit.

In the third quarter, we recognized our first revenue, $17,000. Revenue can be recognized only when we have met all of the 4 following criteria: one, persuasive evidence of an arrangement exists; two, delivery has occurred; three, the fee or price is fixed or determinable; and four, collectability is reasonably assured. We also have to take into consideration any return or exchange rate in our assessment. We analyze our product reorder rates to evaluate and determine whether exchange rates exist and are likely to be exercised.

The revenue recognized in the third quarter represents units that have subsequently been reordered and we believe will not be subject to exchange. The variance between our billings of $105,000 and revenue recognized as $17,000 was recorded as deferred revenue of $88,000 in the third quarter. Gross profit for the third quarter 2017 was $10,000 or approximately 59%.

Gross profit this quarter was higher than expected due to a portion of manufacturing costs being allocated to R&D expenses, as they were incurred prior to CE Mark in April 2017. We anticipate that future gross profit will be lower than our third quarter results and industry standards until we reach higher sales and manufacturing volume.

Research and development expenses decreased by $1.1 million to $3.1 million for the third quarter of 2017 compared to $4.2 million for the same period in 2016. The decrease is due primarily to net decreases in personnel costs of $400,000, material cost and testing services of $400,000, both related to our transition from research and development to commercialization, and overhead allocations of $300,000 as we continue to assess our overhead rates during this initial period of commercial activity.

Selling, general and administrative expenses decreased $200,000 to $1.7 million for the third quarter of 2017 compared to $1.9 million for the same period in 2016. The decrease is due primarily to decreases in personnel cost of $700,000, of which a significant portion is related to the forfeiture of performance-based stock awards in connection with the executive retirements and the reduction of force that occurred in the third quarter of 2017. This decrease was offset by increases of $300,000 in audit-related and legal fees, attributed to the accounting for our 2017 convertible notes payable and warrants and $200,000 in sales and marketing expenses.

Interest expense increased by $1 million to $1.5 million for the third quarter of 2017 compared to $500,000 for the same period in 2016. The increase is due to a full quarter of interest on both the 2014 and 2017 convertible notes in the third quarter of 2017 as compared to a full quarter of interest on only the 2014 convertible notes in the third quarter of 2016.

We recorded a gain of $12.3 million on the change in fair values of convertible notes and warrant liability for the third quarter of 2017 as compared to a loss of $17.3 million for the same period in 2016. The gain or loss on change in fair values of convertible notes is impacted by the number of convertible notes outstanding for each period as well as other factors that drive fair value, most significantly, the market trading price of our stock.

As a result of this activity, we recorded net income of $6.1 million for the third quarter of 2017 versus a net loss of $23.9 million for the same period in 2016.

Now that I've highlighted the results of our operations for the third quarter, I'll like to discuss cash management in some detail. As I mentioned previously, we ended the third quarter with about $24.1 million of cash, cash equivalent and investment securities. We want to ensure that we can make that cash last into 2019, with a target of getting to breakeven excluding a U.S. clinical study.

We are doing that in 3 ways: one, we are implementing our commercial launch in a prudent manner. We have targeted Phase I countries and are hiring experienced sales managers who will target hospitals with 1,000 or more procedures per year; two, we are managing our spend in-house. We are limiting our R&D focus to our new thin strut program and advancing our polymer science; three, we are actively managing our inventory levels and controlling our cost of revenue through smart bills and sensible ordering of raw material.

In conclusion, it was a busy quarter for REVA with the launch of commercial operations. I'm glad to be here and excited about our opportunities. Now I'd like to open up the line to take your questions.

QUESTIONS AND ANSWERS

Operator: (Operator Instructions)

Tanu Jain of Bell Potter Securities.

Tanu Jain: Reggie, I just wanted to get a little bit more clarity on the number of accounts that you've managed to lock in this last quarter? And also, could you just go over the only European countries that we are in at the moment? And what's going to come on line in the next two to three months?

Reggie Groves: Okay. I'll try to answer your questions as best as I can Tanu. Yes, what we're saying about our status is that we've approached more than three dozen accounts that nearly all, about 90% plus of those accounts are either existing customers at this point or are committed to becoming customers and are somewhere in the process of trying to move through the contracting stage.

What we're not releasing at this time is exactly how many are at which stage of that process. We are right now, only in Germany and Switzerland. We will be moving into Austria very quickly. And our move to the Benelux regions and Denmark will follow probably the first quarter of 2018.

Tanu Jain: Right. And then the other countries that you mentioned, Brazil and Middle East and the rest of Europe, when does that second phase of your launch in terms of timing, when does that comes online?

Reggie Groves: Yes, we haven't set an exact start date for Phase II launch at this point. We're in the planning stages. We're understanding each of those markets, which markets we might go direct, which markets we might go with a distributor, we're evaluating distributors for those markets where we would be inclined to go with a distributor. We are, obviously, focused first on the Phase I markets and getting our hiring taken care of there before we step on a gas pedal for Phase II.

Tanu Jain: Right. And in terms of your sales growth, I think you're planning to have about 5 by the end of first quarter '18. You think that's going to be enough for the foreseeable future? Or how do you see the sales force growing beyond that?

Reggie Groves: Yes. So, for our Phase I countries, we're absolutely comfortable that our initial launch with the 5 sales personnel is more than adequate to achieve the plans that we have in place. We will be evaluating adding additional folks as it makes sense to add them, both in the geographies we're already in, Phase I, and as we move into the Phase II accounts. But we don't have exact timing for the addition of those staff at this point.

Tanu Jain: Right. And just on the accounts that you are in, would you be able to give some kind of color on your market share there? Or how you're seeing adoption? Or any trend that you've seen so far in the reordering rates and stuff?

Reggie Groves: It is just too early, Tanu, to have any sort of trend that has any meaning, which is why I didn't touch on that in my prepared remarks.

Tanu Jain: Right. But have you seen anything in terms of your early customers in terms of market share there?

Reggie Groves: It's just too early, right? I mean the accounts have been coming on board; every month we're adding accounts. Each one gets started in a little bit different way. It's just too early to call it.

If you look at our corporate presentation that's on our website, you can see some information there about what market share positions might look like. I have discussed in the past that our goal in this initial set of accounts is to move quickly to that 2% to 3% market share position and to move up from there as we get more clinical evidence.

As Fantom Encore comes online, we believe we can move to the 5% share position, up to the 10% share position and beyond with time. What I can tell you right now is the physicians that we have approached in Europe, every single physician we've approached, wants to buy a resorbable product. A very small minority of them, less than 10% have said, we want it, but we're going to sit and wait for a little bit while additional clinical evidence emerges.

But everybody else has said, we want it, and those that have come over and gotten through the entire contracting process and are using the product have expressed enormous satisfaction with Fantom.

Operator: Thank you. I'm showing no further questions at this time. I'd like to turn the call back over to Reggie Groves for any further remarks.

Reggie Groves: In summary, I'm extremely pleased with our progress against our three corporate priorities. Our commercial launch of Fantom is progressing on plan. We are expanding our business rapidly with clinical evidence, next-generation thin strut coronary scaffold, and moving into peripheral artery disease, and we are successfully managing our cash position. Thanks again for joining us today.

Operator: Ladies and gentlemen, thank you for participating in today's conference. This does conclude today's program. You may all disconnect. Everyone have a great day.