

THOMSON REUTERS STRETEVENTS

# EDITED TRANSCRIPT

RVA.AX - Q4 2017 REVA Medical Inc Earnings Call

EVENT DATE/TIME: MARCH 07, 2018 / 9:30PM GMT



MARCH 07, 2018 / 9:30PM, RVA.AX - Q4 2017 REVA Medical Inc Earnings Call

## CORPORATE PARTICIPANTS

**Brandi L. Roberts** *REVA Medical, Inc. - CFO, Company Secretary & Senior VP*

**Cheryl Liberatore** *REVA Medical, Inc. - Director of Communications*

**Regina E. Groves** *REVA Medical, Inc. - CEO & Director*

## PRESENTATION

### Operator

Ladies and gentlemen, thank you for standing by. Welcome to REVA Medical's 2017 Fourth Quarter and Full Year Financial Update Call. (Operator Instructions) As a reminder, this conference is being recorded. And I would now like to turn the call over to the company's Chief Executive Officer, Reggie Groves. Ma'am?

---

**Regina E. Groves** - *REVA Medical, Inc. - CEO & Director*

Thank you, James. Before we get started, Cheryl Liberatore, our Director of Communications, will read the safe harbor statement.

---

**Cheryl Liberatore** - *REVA Medical, Inc. - Director of Communications*

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 as statements regarding the projections and timing surrounding our plans to commence commercial operations and sell products; conduct clinical trials; develop pipeline products; incur losses from operations; list our securities for sale on a U.S. stock exchange; and assess and obtain future financings for operating and capital requirements.

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, 2017, filed with the United States Securities and Exchange Commission, today, March 7, 2018.

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 statement, whether as a result of new information, future events or otherwise.

I would now like to turn the call over to Reggie.

---

**Regina E. Groves** - *REVA Medical, Inc. - CEO & Director*

Thank you, Cheryl. Hello, everyone, and thank you for joining us today to discuss REVA's recently announced financial results for the fourth quarter and full year of 2017. We will also provide a business update. With me today are Brandi Roberts, our CFO; and Rick Kimes, our SVP of Operations.

Following my update, we will open the phones for your questions. Our top 3 priorities remain: one, ensuring Fantom's commercial success; two, expanding our business; and three, managing our cash position.

I will provide a detailed update on progress against our priorities in just a moment, but first, I would like to discuss our stock price. Our stock has significantly underperformed the market, despite the many positive milestones REVA has achieved. We believe this underperformance is driven



## MARCH 07, 2018 / 9:30PM, RVA.AX - Q4 2017 REVA Medical Inc Earnings Call

primarily by factors outside of our control. These factors include lack of liquidity, the actions of select investors, and performance of Absorb, a competitive bioresorbable scaffold.

In terms of liquidity, our stock volume averages about 50,000 CDIs, or 5,000 shares of trading per day. As a consequence of this low volume, any purchase or sale can have a significant impact on our share price.

In terms of investor actions, we have seen both the collapse of some of the funds holding our security as well as the closure of specific funds that have passed their extension windows due to the duration of their investment in REVA. In these cases, selling may occur regardless of price.

Finally, the worldwide withdrawal of Absorb from the market generated a headwind that was not anticipated. We believe REVA is undervalued at this time and are optimistic that our continued progress will result in positive momentum for our stock.

Now I'd like to focus on the items we can control, our corporate priorities. Our first priority is the commercial success of Fantom. 2017 was an extraordinary year for REVA as we secured CE Mark for our Fantom bioresorbable scaffold, Presented 12- and 24-month data from our FANTOM II clinical study, and began commercial sales. 2017 was also marked by dramatic changes in the competitive marketplace after Abbott withdrew their bioresorbable scaffold Absorb in September. The withdrawal of Absorb has had both negative and positive impacts on Fantom. Negatively, physicians have a concern about scaffold safety, based on adverse events reported in the Absorb clinical studies. Last September, EuroIntervention published the ESC-/EAPCI task force recommendations on the use and evaluation of bioresorbable scaffolds. Notably, in this document is their recommendation that drug-eluting stents should be preferred to bioresorbable scaffolds in routine clinical practice until the benefit of bioresorbable scaffolds is clearly demonstrated relative to drug-eluting stents. These recommendations were generated on an analysis of published clinical results, which were primarily studies of the Absorb scaffold. Unfortunately for REVA, this task force generated its recommendations without considering clinical evidence from the FANTOM II clinical study presented live in May last year. Our 6-month results have been published in a journal, but that occurred after these recommendations were made.

Fortunately, there are many positive aspects from Absorb. The first is that competitive bioresorbable scaffolds that were made using the same polymer as Absorb seem to be fading away. Their commercial presence appears to be nearly non-existent.

Second, Abbott established reimbursement for Absorb that is separate from drug-eluting metal stents, which helps support a price premium for Fantom relative to drug-eluting stents.

Most importantly, physicians continue to believe that bioresorbable scaffolds are the transformation in the treatment of coronary artery disease. They are very interested in supporting a truly differentiated product and remain interested in Fantom, specifically.

We continue to believe that Fantom, made from our proprietary Tyrocore polymer, will be the platform that lives up to the full promise of bioresorbable scaffolds. That said, we recognize that we are now in a position of leadership and we will need to rebuild confidence in bioresorbable scaffolds and the market.

In 2017, we reported 12- and 24-month results from the FANTOM II clinical study. 12-month results presented at the PCR Congress in May showed a low 4.2% rate of Major Adverse Cardiac Events in 240 patients. Analysis of intravascular imaging results was also presented at May, and demonstrated excellent healing at 6 and 9 months.

In October, we presented 24-month results on an interim data set of 125 patients. In this subset of patients, we reported a low 5.6% rate of Major Adverse Cardiac Events. This compares favorably to the 24-month event rate of 7.9% for Xience and very favorably to the 11% rate for Absorb in the Absorb III trial. We plan to present 24-month results on the full FANTOM II patient data set at the PCR Congress in May of this year.

We've also made excellent progress in hiring our commercial team. We took the time to find the right people. 2 sales managers joined us in November, 2 in January and 1 in February. Today, our European sales team includes our European Sales Leader and 5 sales managers located in our initial target countries of Germany, Austria and Switzerland.



## MARCH 07, 2018 / 9:30PM, RVA.AX - Q4 2017 REVA Medical Inc Earnings Call

In the third quarter of 2017, we had billings of \$105,000, and in the fourth quarter, we had billings of \$98,000. Our units sold were just about the same. We did expect December to be a little slow due to the holidays. Our recognized revenue grew from \$17,000 in the third quarter to \$28,000 in the fourth quarter, as we more than tripled the number of customers reordering in the fourth quarter compared to the third quarter. We believe that reorders are one of the most important metrics of Fantom's commercial success.

In the first 2 months of this year, we have continued to see momentum. As of the end of February, our average monthly billings increased 50% over prior quarters and we have 4x the number of customers than we did in the third quarter of 2017. We are starting to see our sales manager make an impact on the top line.

While I'm pleased with the progress we have made in the 8 months since we received our first commercial order, I am more excited about our outlook for 2018. As mentioned earlier, we have our full sales team in place for our first phase of launch. As we move into the second quarter of 2018, this team will be fully past their training stage and ready to execute our plans in Germany, Switzerland and Austria.

I appreciate that many people may have expected us to have higher revenues and billings by now. Our strategy remains to commercialize in a prudent manner, by gaining acceptance in the accounts we are in versus growing as rapidly as possible. Also, we have been thoughtful as we brought on our sales force, and just now, have the full complement onboard and in the final stages of the training. Of course, the third factor is the withdrawal of Absorb. The selling cycle is a little longer because we are not only having to have the physician interested, we must also gain acceptance from department chiefs and purchasing departments. We are committed to Fantom and Fantom Encore and we believe that our product will be the transformation for the market.

Regarding our second business priority, we have several efforts underway to expand our business. These include geographic expansion, extending our technological lead in bioresorbable scaffolds and moving beyond the coronary arteries. Our geographic expansion is now in progress. On January 24, 2018, we announced the first implant of Fantom in Italy. We are now evaluating distributor partnerships for Italy and select other countries such as Turkey. We are also seeking regulatory approval in Brazil in partnership with a distributor.

In terms of extending our technological lead in scaffolds, we are extremely excited about the recent CE Mark of our 2.5-millimeter Fantom Encore. The new Fantom Encore family represents a significant advancement for REVA, as we have reached a much smaller strut thickness, without a compromise in scaffold strength or x-ray visibility. The 2.5-millimeter Fantom Encore is nearly 25% thinner than Fantom. This reduction in thickness brings our 2.5-millimeter Encore closer to the strut thickness of state-of-the-art drug-eluting metal stents. Thinner struts are associated with reduced risk for adverse events like stent thrombosis. Later this year, we will seek approval for our 3.0 and 3.5 millimeter sizes and fully launch the Fantom Encore product line.

In addition to the FANTOM II study previously discussed, we continue to build clinical evidence for use of Fantom in a broader patient population. Our long lesion, multi-vessel trial in Germany has enrolled 20 patients. We expect to complete enrollment of 30 patients later this year. Our pilot study of 10 patients in STEMI continues and we expect enrollment to be complete in that study by the end of this year.

Importantly, we are progressing with our European post-market study, which targets enrollment of 1,500 patients. The principal investigators of the study have been selected and the protocol is in the final stages of completion. We expect to file for the first ethics committee approval within the next 60 days and initiate enrollment shortly thereafter.

We also continue to make progress with the FDA regarding our potential path for a clinical study in the U.S. We are in discussions with the FDA on key questions they have asked regarding our bench and animal data. We anticipate additional meetings with the FDA in the coming months and continue to expect conditional approval in 2018.

Moving beyond the coronary arteries, we plan to secure CE Mark in 2018 for a bioresorbable scaffold to treat below-the-knee peripheral artery disease. Resorbable technology is attractive in this patient population because of the frequent need for retreatment. We also continue to work on a novel polymer formulation designed to accommodate important features for treating above-the-knee peripheral artery disease, such as crush recoverability.



## MARCH 07, 2018 / 9:30PM, RVA.AX - Q4 2017 REVA Medical Inc Earnings Call

Regarding our third corporate priority of cash management, I will let Brandi talk in detail, but I will summarize by saying, we have a plan to address our capital needs, which includes both pursuing sales expansion and executing on business development and strategic opportunities. Our current cash position is anticipated to last us through the end of the first quarter of 2019, and we are actively managing our corporate spend.

Now I will turn the discussion over to Brandi.

---

### **Brandi L. Roberts** - REVA Medical, Inc. - CFO, Company Secretary & Senior VP

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 U.S. dollars.

Our results through December 31, 2017, have just been reported with both the SEC and ASX, and will be available on our website. Our fourth quarter and full year 2017 financial results press release was also issued earlier today in both the United States and Australia. We ended 2017 with approximately \$20 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 fourth quarter, total billings for shipped product were \$98,000. We recognized revenue of \$28,000. As a reminder, revenue can be recognized only when we have met all 4 of the following criteria: one, persuasive evidence if an arrangement exists; two, delivery has occurred; three, the fee is fixed or determinable; and four, collectability is reasonably assured. Due to our previous 6-month shelf life and accompanying offer for product exchange, we have been recognizing revenue only when we believe that exchange rates no longer exist. We recently received approval for our 9-month shelf life and are working towards 12 months later this year. With our extended shelf life, we plan to discontinue the exchange program.

Gross profit for the fourth quarter of 2017 was negative \$7,000. The negative margin was related to an \$18,000 expense that we recorded for potential excess inventory. Excluding this expense, gross profit would have been 39%. Our gross profit is lower than we plan in the future, primarily due to low manufacturing volumes.

Research and development expenses decreased by \$1.4 million to \$2.6 million for the fourth quarter of 2017, compared to \$4 million for the same period in 2016. The decrease is due primarily to net decreases in material cost and testing services of \$700,000 and personnel cost of \$600,000, both related to our transition from a research stage to commercial-stage company.

Selling, general and administrative expenses increased \$700,000 to \$2.8 million for the fourth quarter of 2017, compared to \$2.1 million for the same period in 2016. The increase is due primarily to increases in personnel costs of \$300,000, audit fees of \$200,000 and sales and marketing expenses of \$200,000. These increases are related to the initiation of commercial activity in 2017.

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

We recorded a gain of \$7.1 million on the change in fair values of convertible notes and warrant liability for the fourth quarter of 2017, as compared to a gain of \$21.8 million for the same period in 2016. The gain 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 \$200,000 for the fourth quarter of 2017 versus net income of \$15.2 million for the same period in 2016.

To highlight some of our full year results, total billings for shipped product were \$203,000. This reflects shipments from July through December 2017. Revenue recognized was \$45,000.



## MARCH 07, 2018 / 9:30PM, RVA.AX - Q4 2017 REVA Medical Inc Earnings Call

Research and development expenses decreased by \$5.4 million to \$12.8 million for the full year 2017, compared to \$18.2 million for 2016. The decrease is due primarily to net decreases in material costs of \$1.7 million, stock-based compensation of \$1.3 million, clinical costs of \$1.2 million, personnel costs of \$600,000, and testing and validation costs of \$500,000. Decreases were related to our reduction in force in July 2017 and decreased activity as enrollment was completed in 2016 for the FANTOM II study and we prepared for commercialization.

Selling and general and administrative expenses of \$8.6 million for the full year 2017 were consistent with 2016. Although SG&A expenses were consistent, stock-based compensation decreased by \$1.4 million. This was offset by increases in personnel expenses of \$500,000, sales and marketing expenses of \$400,000, audit and tax expenses of \$400,000 and consulting expenses of \$100,000. The decrease in stock-based compensation was related to executive retirements that occurred in July 2017. The increases were related to increased activity for commercialization as well as accounting for convertible notes issued in 2017.

We recorded a gain of \$35.7 million on the change in fair values of convertible notes and warrant liability for 2017, as compared to a loss of \$25.2 million for 2016. Accordingly, we recorded net income of \$7.1 million for the full year 2017, versus a net loss of \$54.1 million for 2016.

Now that I've highlighted the results of our operations for the fourth quarter and full year 2017, I'd like to discuss cash management in some detail. As I mentioned previously, we ended 2017 with about \$20 million of cash, cash equivalents and investment securities. That cash would last us through the first quarter of 2019, assuming we can meet our sales forecast and manage our expenditures accordingly. We are managing our spend by: one, limiting our sales and marketing activities to only those that are imperative; two, focusing our R&D efforts on Fantom Encore and advancing our polymer science; and three, managing our inventory levels and controlling our cost of revenue through smart builds and sensible ordering of raw materials.

We are also executing on our plan to bring in additional funding to the company, which includes pursuing sales expansion and executing business development and strategic opportunities. We are very excited about Tyrocore, Fantom, Fantom Encore and how we may work with others to bring in additional capital and add value for our shareholders.

Now I'd like to open up the lines to take your questions.

---

## QUESTIONS AND ANSWERS

### Operator

(Operator Instructions) I'm not showing any questions in queue.

---

### Regina E. Groves - REVA Medical, Inc. - CEO & Director

Okay. Then, I'll go ahead and close by saying, in summary, I am extremely pleased with our progress against our 3 corporate priorities. Our commercial launch of Fantom is progressing well. We are expanding our business rapidly with Fantom Encore and additional clinical evidence as well as advancing into peripheral artery disease, and we are focused on managing our cash position. We look forward to providing you with updates on our progress throughout the year. Thank you for joining us today.

---

### Operator

Thank you. Ladies and gentlemen, that concludes today's conference. Thank you very much for your participation. You may all disconnect. Have a wonderful day.

---



## MARCH 07, 2018 / 9:30PM, RVA.AX - Q4 2017 REVA Medical Inc Earnings Call

**DISCLAIMER**

Thomson Reuters reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES THOMSON REUTERS OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2018, Thomson Reuters. All Rights Reserved.

