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SVA - Q3 2015 Sinovac Biotech Ltd Earnings Call

EVENT DATE/TIME: NOVEMBER 12, 2015 / 1:00PM GMT



CORPORATE PARTICIPANTS

Helen Yang *Sinovac Biotech Ltd. - IR Director*

Weidong Yin *Sinovac Biotech Ltd. - CEO*

CONFERENCE CALL PARTICIPANTS

Bill Zima *ICR - Moderator*

Christina Yao *Morgan Stanley - Analyst*

Peter Halesworth *Heng Ren - Analyst*

PRESENTATION

Operator

Greetings and welcome to the Sinovac Biotech third quarter 2015 earnings conference call. (Operator Instructions). As a reminder, the conference is being recorded.

It is now my pleasure to introduce your host, Bill Zima of ICR. Thank you. You may begin.

Bill Zima - *ICR - Moderator*

Thank you, operator. Good day, everyone. Before we begin, I would like to remind everyone that this conference call contains forward-looking statements. These statements are made under the Safe Harbor provisions of the US Private Securities Litigation Reform Act of 1995.

These forward-looking statements can be identified by words or phrases such as will, expect, anticipate, future, intends, plans, believes, estimates, and similar statements. These statements are not historical facts, including statements about Sinovac's beliefs and expectations that are forward-looking statements.

Forward-looking statements involve inherent risks and uncertainties. A number of important factors could cause actual results to differ materially from those contained in forward-looking statements. Sinovac does not undertake any obligation to update any forward-looking statements, except as required under applicable laws.

On the call today, we have Mr. Weidong Yin, CEO; Ms. Nan Wang, Chief Financial Officer; Ms. Helen Yang, Investor Relations Director; and Mr. Shuo He, Finance Director.

I will now turn the call over to Helen Yang. Helen, please begin.

Helen Yang - *Sinovac Biotech Ltd. - IR Director*

Thank you, Bill. Hello, everyone, and thank you for joining us today. On today's conference call, I will provide an update on Sinovac's business and operations during the third quarter of 2015. Then, I will review our financial results for the third quarter and first nine months of this year, on behalf of our CEO and CFO.

In the third quarter, we recorded sales of \$16.8 million, a slight decrease from our sales in the third quarter last year, primarily due to a depreciation of the renminbi against US dollar. If we look at our sales in terms of renminbi, the numbers are actually very close, which is in line with our strategy to maintain the sales of our core products, while we prepare for the launch of our new EV71 vaccine, which we expect to serve as a catalyst for the future growth.



The broader vaccine market in China has remained stable over the past few quarters, which we expect to continue. However, over the longer term, we expect China's recent relaxation of the one-child policy to be a distinct driver for the growth in the market in the coming years.

Some estimates we have seen indicate that there will likely be around 8 million additional births per year, or an increase of 7%, as a result of this policy. As more families apply to have second children, the market for pediatric vaccines will expand, creating meaningful growth potential for Sinovac, as children are targeted population for our vaccine portfolio.

Now, I would like turning to our research and development milestones in this quarter.

For EV71, the site inspection and GMP inspection of our production facility have been completed, and the vaccine samples have passed the required testing by the CFDA. We expect to receive final approval by early 2016, at which point we will be able to begin commercial production of our vaccine. It will take up to approximately four months to complete the production and get product released to the market.

As we have discussed previously, we estimate the target market in China for EV71 to be about 80 million children, with each child requiring two doses. Thus, we expect this vaccine to be a meaningful growth driver for the Company, once it's brought to the market.

As we announced last month, our subsidiary, Sinovac Dalian, obtained approval from the CFDA to begin human clinical trials on our varicella vaccine candidate. We are currently preparing for the clinical trials, which we expect to be able to complete by 2017.

We anticipate being able to commercialize our varicella vaccine in 2019. In addition, we are planning to use the varicella vaccine as a component in the a measles, mumps, rubella and varicella, or MMRV, combination vaccination, which is currently in our development pipeline.

As for the other component vaccines, we have licensed a [mumps] vaccine for sales in China. We have already obtained clinical trial approval for our internally developed rubella vaccine, and we plan to begin developing a measles vaccine.

We will also plan to develop MMR combination vaccine to address significant demand in the public pay market in China while, at the same time, both the varicella vaccine and the MMRV combo will be supplied to the private pay market in China, which is continuing to grow.

With that, I would now like to review our unaudited financial results for the third quarter and first nine months of 2015.

As I mentioned, total sales in the third quarter were \$16.8 million, a decrease of 2% compared to \$17.1 million in the same period of last year. The slight decrease is attributable to the depreciation of Chinese renminbi against the US dollar.

Gross profit was \$11.2 million in the third quarter, compared to \$12.2 million in the prior year period. Gross margin decreased to 66.4% from 70.9% in the prior year period. The decrease is primarily due to a lower utilization rate of our production facility, as compared to the third quarter last year.

Additionally, in the third quarter of 2015, we delivered more Healive to the public pay market, as opposed to the private pay market, which resulted in a lower average selling price for the quarter compared to the prior year period.

Selling, general and administrative expenses in the third quarter of 2015 were \$10.1 million, compared to \$8.5 million in the same period of last year. The increase was mainly due to the increased G&A expenses associated with the trial production of the EV71 vaccine for the site inspection.

R&D expenses in the third quarter of 2015 were \$2.2 million, compared to \$2.5 million in the same period of 2014.

Net loss attributable to common shareholders for the third quarter of 2015 was \$1.6 million or \$0.03 per basic and diluted share, compared to a net income attributable to common shareholders of \$89,000 or \$0.00 per basic and diluted share in the same period last year.

And now, turning to our results for the first nine months. Total sales in the first nine months of 2015 were \$44.6 million, an increase of 4.2% from \$42.8 million in the same period of 2014. The increase is primarily due to increase of sales of Healive into the public market, and increased the sales of Bilive into the private pay market.

Gross profit was \$33.1 million, an increase of 5.1% from \$31.5 million in the same period of 2014. Gross margin was 74.2%, compared to 73.6% in the same period of 2014.

Selling, general and administrative expenses in the first nine months were \$26.2 million, compared to \$24.9 million in the same period of 2014. The increase was primarily due to increased G&A expenses associated with the trial production of the EV71 vaccine, as I mentioned.

R&D expenses were \$6.6 million, compared to \$7.5 million in the same period of 2014.

Net loss attributable to common shareholders in the first nine months of 2015 was \$1.6 million, or \$0.03 per basic and diluted share, compared to a net loss of \$2.2 million, or \$0.04 per basic and diluted share, in the same period of 2014.

As of September 30, 2015 cash and cash equivalent totaled \$54.4 million, compared to \$91.5 million as of December 31, 2014. In the first nine months of 2015, net cash used in operating activity was \$11 million. Net cash used in investing activities was \$3.4 million, which was for the payment of property, plant and equipment.

Net cash used in the financing activities was \$21.9 million, including loan proceeds of \$14.4 million and loan repayments of \$37.2 million. As of September 30, 2015 Sinovac had \$24.9 million of bank loans due within one year. We expect that our current cash position will be able to support our operations for the next 12 months. We will seek new commercial bank loans to finance the operation and commercialization of our pipeline products.

With that, I would like to turn the call back to the operator for questions. Operator.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions). [Christina Yao, Morgan Stanley].

Christina Yao - Morgan Stanley - Analyst

I may ask you some questions on behalf of my analyst, Isabella Zhao. My first question is, what is the business outlook for 2016 in terms of sales and profit growth?

My second question is, if EV71 gets approval in early 2016, when do we expect to contribute to top line and how much revenue contribution in 2016 and 2017?

Okay, I will translate it into Chinese (spoken in Chinese).

Weidong Yin - Sinovac Biotech Ltd. - CEO

(interpreted) This is a very good question, and actually one we are looking at 2016. As you asked, EV71 is very important for us and as you know that EV71 vaccine approval is right now at a final stage.



CFDA is currently reviewing some clinical data and now we're getting closer to the obtaining of the NDA production lines then, after that, there will be a GMP license. And as we explained in the script that we're looking into next year for commercializing EV71 and it's very difficult to predict what time we can actually receive the approval.

In order to receive the CFDA inspection for the production facility, we conduct a trial production of over 1 million doses, and all these inspections have been conducted pretty well. Vaccine samples have been taken by CFDA, and our vaccine candidate passed all the tests.

Therefore, that we're confident for the stable of our vaccine production processes and, as you may know, that the production of these vaccines may take about three months, plus the [lot] release processes. So once we obtain the new drug certificate, and GMP license, it will be easier to predict when the vaccine can be commercialized on the market.

We would expect that the gross margin of EV71 will be higher than the gross margin of our existing vaccines.

Right now, the sales team are still conducting their final preparation for commercializing these vaccines, including team training, organizational restructuring, customer interactions. However, at this moment, the pricing of this vaccine is not finalized, and also the timing of receiving the approval is still pending; therefore, at this moment, we're not able to give a revenue projection.

Is that okay?

Christina Yao - Morgan Stanley - Analyst

Yes. Thank you.

Operator

(Operator Instructions). [Peter Halesworth, Heng Ren].

Peter Halesworth - Heng Ren - Analyst

Congratulations on being on the verge of the final approval of EV71; it's been a long wait and we are hoping for the best. I just wanted to ask very quickly about the G&A expenses associated with the trial production.

You just stated that there were about 1 million doses made during the trial production, and I saw in the press release that the G&A costs in the quarter were up about \$1.5 million. So is it fair to say that the cost per dose is about \$1.50 each? And then I have another question.

Helen Yang - Sinovac Biotech Ltd. - IR Director

Peter, we are translating your question.

Peter Halesworth - Heng Ren - Analyst

Thank you.

Weidong Yin - *Sinovac Biotech Ltd. - CEO*

(interpreted) Actually, it is not reasonable to predict the costs of EV71 through this kind of calculation because for the G&A the Company policy are different from the cost of sales. Therefore, that this is not accurate calculation for EV71. And also I believe that for the trial production, the cost level will be different from that we do the official commercial production.

Peter Halesworth - *Heng Ren - Analyst*

Okay. Is there any estimate on the cost of production per dose?

Weidong Yin - *Sinovac Biotech Ltd. - CEO*

(interpreted) Right now, we think that for EV71 it will be depending on the size of scale of production that we are going to do for next year, that will have a direct impact on the level of cost.

Therefore, I want to everyone understand that no matter what our production quantity we're going to make for next year, overall we believe that the gross margin will be improved for the Company after EV71 is commercialized.

Peter Halesworth - *Heng Ren - Analyst*

Okay. And just a quick follow-up question. I understand that the timing is difficult to predict in terms of the commercial production, but how long would it take you, do you believe, to get to the 20 million dose production capacity that you currently have? How many months would that take?

Helen Yang - *Sinovac Biotech Ltd. - IR Director*

So for 20 million doses, that is an estimated production capacity, I believe that on the first day of production that we will start from conservative approach, I believe at a mature level we will definitely meet the 20 million doses, but definitely not for the first year. Plans for the first year, next year is not going to be a full year sales.

Peter Halesworth - *Heng Ren - Analyst*

Okay. And then just two quick follow-ups. One is on the discussions with the CFDA; has pricing been a consideration in your discussions with them, and is there any range available in terms of the possible pricing on EV71, even just a range?

Helen Yang - *Sinovac Biotech Ltd. - IR Director*

Actually, the CFDA is a national authority for reviewing and approving new products. They are not relate to the decision of pricing because our expectation is that EV71 will be provided to private pay market. Based on the existing policy the manufacturer has the right to fix the final price, and [make a calling] with the related government.

Peter Halesworth - *Heng Ren - Analyst*

Okay. And then lastly, I'd just like to re-extend a long-standing invitation to Chairman Yin to visit the States and maybe meet with US investors. I think it would be an opportune time, especially if, and when, the final approval comes through for EV71. I think investors would very much appreciate meeting the Chairman and hearing his perspective.

Helen Yang - *Sinovac Biotech Ltd. - IR Director*

Thank you.

Operator

Thank you. We have no further questions at this time. I would now like to turn the floor back over to management for closing comments.

Helen Yang - *Sinovac Biotech Ltd. - IR Director*

Thank you. Once again, we want to thank you all to joining us on the call, and we're looking forward to meeting you and talking to you in the next few months, and hope we are all together to celebrating the commercialization of EV71 vaccine. Thank you.

Operator

Ladies and gentlemen, this does conclude today's teleconference. You may disconnect your lines at this time. Thank you for your participation and have a wonderful day.

Editor

Portions of this transcript that are marked (interpreted) were spoken by an interpreter present on the live call. The interpreter was provided by the Company sponsoring this Event.

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