Sinovac Biotech's (SVA) CEO Weidong Yin on Q1 2014 Results - Earnings Call Transcript

Q1 2014 Earnings Conference Call

May 22, 2014 08:00 AM ET

Executives

Weidong Yin - CEO

Nan Wang - CFO

Helen Yang - Investor Relations Director

Lee Roth - The Ruth Group

Analysts

John Gregory - SJ Strategic Investments, LLC

Isabella Zhao - Morgan Stanley

Yi Chen - Aegis Capital

Operator

Greetings and welcome to the Sinovac First Quarter 2014 Earnings Conference Call. At this time, all participants are in a listen-only mode. A brief question-and-answer session will follow the formal presentation. (Operator instructions) As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host Lee Roth of The Ruth Group. Thank you, sir. You may begin.

Lee Roth

Thanks, Christine. Good day, everyone, and thank you all for joining us for Sinovac's Q1 2014 earnings conference call. Joining me today from the Company are Dr. Weidong Yin, CEO; Ms. Nan Wang, CFO; Ms. Helen Yang, Investor Relations Director and Mr. (indiscernible), Finance Director.

Before we begin, I'd like to remind everyone that this conference call contains forward-looking statements. These statements are made under the Safe Harbor Provisions of the U.S. 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 that are not historical facts, including those about Sinovac's beliefs and expectations are forward-looking statements.

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

With that said, it's now my pleasure to turn the call over to Helen Yang, Sinovac's Investor Relations Director. Helen go ahead please.

Helen Yang

Thank you, Lee, and hello, everyone. Thank you for joining us on this conference call. I will provide an update on the business and a review of our first quarter financial results on behalf of our CEO and our CFO.

So as we announced this morning, yesterday we saw a continued momentum and profitability in the third quarter of 2014 with top line growth of more than 34% compared to the first quarter of 2013.

Our sales in the first quarter were mainly driven by Bilive, our combined hepatitis A&B vaccine and implementation of several group vaccination programs during the period cause the growth of Bilive.

Turning to our international efforts, we're excited by the progress we have made outside of China. Sinovac recently won its fourth annual public tender from Mongolia's National hepatitis A vaccination program. The 147,000 doses of our inactivated hepatitis A vaccine for this program were delivered in two batches in February and April.

Additionally, in April we obtain a five-year registration license for our inactivated hepatitis A vaccine from Chile. We're currently working on a commercialization plan for the country. In addition to our current portfolio of commercialize the vaccines, we have a robust pipeline that we believe will support the Company's future growth.

Notably we recently awarded a government grant of RMB60 million for the construction of a dedicated EV71 manufacturing plant, which provides clear evidence that the Chinese government is supportive of these programs. We expect to receive the first RMB20 million of the grant this year and the remaining RMB40 million after the vaccine is commercialized.

Also of note, just yesterday we received approval from the China Food and Drug Administration or CFDA to commence a Phase 3 clinical study on our 23-valent Pneumococcal polysaccharides vaccine or PPV. As a reminder, we independently developed the Pneumococcal polysaccharides vaccine and we will retain full commercialization rights to the vaccine upon approval.

The supply quantity of PPV has doubled in China over the past three years, demonstrating the consistent increase in market demand. PPV remains relatively expensive in China due to the limited availability of the product. The trial will evaluate the immunogenicity and safety of a single dose of the vaccine in approximately 1,200 healthy volunteers, H2 and above.

This trial is designed as a single center, randomized, double-blind and placebo control study. We're currently finalizing and confirming the trial protocol, and we expect to begin the trial in late 2014.

Additionally, we continue to expand our pipeline program. In April, we signed a technology transfer agreement related to the Sabin's stream of Inactivated Polio Vaccine or sIPV with a Dutch company called Intravacc, a research development and contract manufacturing organization specialized in vaccines.

This is a collaboration with the WHO health -- with WHO and Intravacc to develop and commercialize sIPV in line with the broader mission of securing a lasting worldwide end to all paralytic polio disease, which is the objective of the global polio eradication initiative established by the WHO.

Polio is highly infectious disease caused by a virus. One in 200 polio infections leads to irreversible paralysis. Among those paralyzed, 5% to 10% of patients died when the respiratory muscles are paralyzed, because the live attenuated vaccine virus in the Oral Polio Vaccine which is widely used can cause paralysis in extremely rare instances, resulting in cases of vaccine associated paralytic polio or circulating vaccine-derived poliovirus. The plan is to gradually replace OPV with IPV starting in 2016 with the transition expected to be completed in 2018. And this plan is driving rapid growth in global demand for IPV.

And for your information according to UNICEF 2014 OPV outlook published in February 2014. Total OPV [ph] [work] allocation increased from 1.3 billion doses to just over 1.9 billion doses. And by entering into this collaboration, Sinovac has committed to developing a capacity to supply sIPV to the public sector of countries outside of China in a quantity that will make a meaningful contribution to meeting the global demand, for example at least 20 million doses annually.

And in China the primary demand for OPV is estimated to be approximately 64 million doses annually or four doses for each of approximately 16 million children born annually. We expect a similar market size for IPV compared to OPV once it's completely replaced OPV in China due to an identical four dose immunization schedule.

OPV is currently purchased under the National Expanded Program or EPI in China. The Chinese government expected to purchase IPV under sufficient supplying to cover the target population. Currently no IPV is produced in China and since 2009 only imported IPV has been available on a private pay basis and in limited quantity.

As a result of this limited quantity, the government is developing a vaccination strategy aimed at adding at least one dose of IPV into EPI program. Our goal is to accelerate the adoption of IPV as we advance our development efforts in this area. (Indiscernible) agreement we have received a virus string from Intravacc and initiated preclinical research. And we look forward to providing further updates on our program during future calls.

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Compared to the first quarter of 2013, gross profit margin for the first quarter of 2014 increased to 75.8% from 70.2%. This increase in margin was mainly driven by lower unit costs for Healive and Bilive due to higher plant utilization, allowing the Company to better leverage economies of scale. Gross margin was

also favorably impacted by a decrease in the sales return provision compared to the same period last year.

Selling, general and administrative expenses for the first quarter of 2014 were $7.8 million, compared to $7.1 million in the same period of 2013. Selling expenses as a percentage of first quarter 2014 regular sales were down slightly from the same period of 2013 as the Company generated more revenue without significantly increasing fixed selling expenses.

G&A expenses in the first quarter of 2014 were $4 million which was consistent with $4.1 million in the same period of last year. First quarter 2014 G&A expenses include a $0.5 million foreign exchange loss due to the appreciation of the U.S. dollar against renminbi.

Excluding this foreign exchange loss, G&A expenses in the first quarter of 2014 were $3.5 million. The decrease in G&A expenses was primarily due to the fact that the Company's Changping facility commenced production, and related depreciation was recorded in production costs.

R&D expenses for the first quarter of 2014 were $1.7 million, consistent with $1.8 million in the same period of 2013. The Company's main focus in the first quarter of 2014 was process optimization of the Pneumococcal polysaccharides vaccine and varicella vaccine.

Net income attributable to common stockholders was $4,000, or $0.00 per basic and diluted share, compared to a net loss attributable to common stockholders of $2 million, or $0.04 per basic and diluted share. Cash and cash equivalents totaled $101.7 million as of March 31, 2014, compared to $107.2 million as of December 31, 2013.

And that concludes management's prepared remarks. Operator, we will now take questions. Thank you.

Question-and-Answer Session

Operator

Thank you. We will now be conducting the question-and-answer session. (Operator Instructions) Thank you. Our first question comes from the line of John Gregory with SJ Strategic Investments. Please proceed with your questions.

John Gregory - SJ Strategic Investments, LLC

Yes, good morning. In regards to your approval for hepatitis A in Chile when are you planning on to begin selling hepatitis A in Chile and do you know how much or how big the hepatitis A market is in Chile from a dollar point of view?

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Thanks John for your question. Actually by registering hepatitis A vaccine in Chile of course demonstrate our objective to expand the market, to sell the hepatitis A vaccine in the country. And as a matter of fact, we're currently working on the marketing front, but for your information right now in Chile hepatitis A vaccine is selling into the private pay market. And a targeted population mainly the babies, every -- the

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I will transfer the question to Mr. Yin. So I think once the time pass by, we're definitely getting closer to the approval date. And within the company we're currently still making preparations on the technical side as well as the production side and also the Company is keeping to keep communicating with the FDA on the technical issues for this vaccine. However, that until now we're still not able to provide an exact date for approval because these are out of our control.

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Helen Yang

I will translate the question to Mr. Yin. So I think Mr. Yin says by receiving these RMB60 million grant, definitely demonstrate governments recognition of the importance of that program. And actually right now the epidemic situation for EV71 is still very serious in China. And also the government believes that we have a world class facility for producing EV71 and by providing these grants to support us and also that showing the support to upgrade the entire standard of producing vaccines for the industry. And also we think this is a positive incentive for the vaccines to be widely received by the market or sometimes by the government, but who will provide the vaccine and who will purchase the vaccine are totally different separate entity, so that might not have a direct relationship. But we think these -- the grant will definitely provide a positive impact on this program.

John Gregory - SJ Strategic Investments, LLC

Okay. Thank you.

Operator

Our next question comes from the line of Isabella Zhao with Morgan Stanley. Please proceed with your question.

Isabella Zhao - Morgan Stanley

Hi, thank you. My first question is regarding the sales growth outlook for the whole year, and what kind of sales growth rate we are expecting. And my second question is giving the pipeline expansion for several products and especially for the PPV and sIPV, and how much investment we're looking for these two project. And regarding for that, do we kind of see increase for the R&D cost for this year and the next? Thank you.

Helen Yang

So firstly to answer your question, Mr. Yin says actually the external environment of the market is not very good. As some of you may have heard that there are some vaccination event related to the vaccination with the hepatitis B vaccine in last year which have a negative impact on the sales and on the market perception. Therefore that, we actually had these expectation, we think the market may not be good as last year, so we prepared to launch some effective implementation of our sales strategy in order to maintain the sales and even drive up the growth, that's why we had the sales growth in the first quarter. However that we think the external environment launch is still challenging especially from the competitive landscape. Actually we have seen that Merck and Sanofi all comes back to the hepatitis A vaccine market in China, and they all have hep A vaccine released into the market. So we're seeing for our hepatitis A vaccine Healive, the market will be more competitive comparing to the last two years. Therefore that we think they are challenging for us, and they may have some uncertainties for the next following quarters. However that, we are still trying to maintain a stable growth for the whole year comparing to last year. So regarding to the potential opportunity for sIPV vaccine Mr. Yin explained from three different aspects. The first one is that, this vaccine -- the polio related vaccine is mainly purchased by the government, EPI programs. So right now most of our product is supplying to the private pay. So I think having these products in our pipeline we are able to potentially to expand our market share in the public market in China. And also this is the collaboration with WHO and an organization designated by WHO, so and also as I had explained they are a big potential market in the global market, and therefore that we think this is a very key program for us to expand our international market. And the third aspect is that we're seeing future trend for the vaccine industry especially for those that who can make higher profit for the company would be the combination vaccine. Actually sIPV will be one of they key components for a really good or be a leading combo vaccine in the future. That's why we're having this vaccine in our programs. We have set up a foundation to developing a very good combo vaccine related, based on the IPV program. So actually this program is under a collaboration with WHO, and actually the technology developer is also supported by WHO. Therefore the transferring price of this vaccine is relatively lower comparing to the other commercial deals. And also right now the company has already mastered the technology of (indiscernible) vaccine. So we think the R&D expenses will be well under control. And also we will set up the facility with a reasonable budget in order to keep the cost to maintain a reasonable level of cost for IPV as well as maintaining the good quality of the vaccine.

Operator

Our next question comes from the line of Yi Chen with Aegis Capital. Please proceed with your question.

Yi Chen - Aegis Capital

Hi. Thank you for taking my question. My first question is, can you give us some color on the timeframe of the construction of PPV vaccine manufacturing facility and how much it will likely cost?

Helen Yang

Sure. So currently we are constructing the PPV plant and we would expect to complete the construction by the end of this year, and we expect the total spending of this facility around RMB60 million, about $10 million.

Yi Chen - Aegis Capital

Okay, thanks. My second question is, when do you expect to enter sIPV into clinical trial?

Helen Yang

So, we would expect to complete the preclinical studies for sIPV with the year for us to be ready to submit a clinical application to the FDA. And we will keep the progress -- we'll give updates to you.

Yi Chen - Aegis Capital

Okay. Thank you.

Helen Yang

Thank you.

Operator

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

Thank you, operator, and we thank you all for participating into the call, and we're looking forward to speaking to you in the following announcement of our second quarter results. Thank you. Have a good day.

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.

Start Time: 08:07

End Time: 08:39

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Helen Yang - Investor Relations Director

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Helen Yang - Investor Relations Director

So firstly to answer your question, Mr. Yin says actually the external environment of the market is not very good. As some of you may have heard that there are some vaccination event related to the vaccination with the hepatitis B vaccine in last year which have a negative impact on the sales and on the market perception. Therefore that, we actually had these expectation, we think the market may not be good as last year, so we prepared to launch some effective implementation of our sales strategy in order to maintain the sales and even drive up the growth, that's why we had the sales growth in the first quarter. However that we think the external environment launch is still challenging especially from the competitive landscape. Actually we have seen that Merck and Sanofi all comes back to the hepatitis A vaccine market in China, and they all have hep A vaccine released into the market. So we're seeing for our hepatitis A vaccine Healive, the market will be more competitive comparing to the last two years. Therefore that we think they are challenging for us, and they may have some uncertainties for the next following quarters. However that, we are still trying to maintain a stable growth for the whole year comparing to last year. So regarding to the potential opportunity for sIPV vaccine Mr. Yin explained from three different aspects. The first one is that, this vaccine -- the polio related vaccine is mainly purchased by the government, EPI programs. So right now most of our product is supplying to the private pay. So I think having these products in our pipeline we are able to potentially to expand our market share in the public market in China. And also this is the collaboration with WHO and an organization designated by WHO, so and also as I had explained they are a big potential market in the global market, and therefore that we think this is a very key program for us to expand our international market. And the third aspect is that we're seeing future trend for the vaccine industry especially for those that who can make higher profit for the company would be the combination vaccine. Actually sIPV will be one of they key components for a really good or be a leading combo vaccine in the future. That's why we're having this vaccine in our programs. We have set up a foundation to developing a very good combo vaccine related, based on the IPV program. So actually this program is under a collaboration with WHO, and actually the technology developer is also supported by WHO. Therefore the transferring price of this vaccine is relatively lower comparing to the other commercial deals. And also right now the company has already mastered the technology of (indiscernible) vaccine. So we think the R&D expenses will be well under

control. And also we will set up the facility with a reasonable budget in order to keep the cost to maintain a reasonable level of cost for IPV as well as maintaining the good quality of the vaccine.

Operator

Our next question comes from the line of Yi Chen with Aegis Capital. Please proceed with your question.

Yi Chen - Aegis Capital

Hi. Thank you for taking my question. My first question is, can you give us some color on the timeframe of the construction of PPV vaccine manufacturing facility and how much it will likely cost?

Helen Yang - Investor Relations Director

Sure. So currently we are constructing the PPV plant and we would expect to complete the construction by the end of this year, and we expect the total spending of this facility around RMB60 million, about $10 million.

Yi Chen - Aegis Capital

Okay, thanks. My second question is, when do you expect to enter sIPV into clinical trial?

Helen Yang - Investor Relations Director

So, we would expect to complete the preclinical studies for sIPV with the year for us to be ready to submit a clinical application to the FDA. And we will keep the progress -- we'll give updates to you.

Yi Chen - Aegis Capital

Okay. Thank you.

Helen Yang - Investor Relations Director

Thank you.

Operator

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 - Investor Relations Director

Thank you, operator, and we thank you all for participating into the call, and we're looking forward to speaking to you in the following announcement of our second quarter results. Thank you. Have a good day.

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.