Sinovac Biotech's CEO Discusses Q1 2013 Results - Earnings Call Transcript

Executives

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John Gregory – SJ Strategic

Sinovac Biotech, Ltd. (SVA) Q1 2013 Earnings Call May 28, 2013 8:00 AM ET

Operator

Greetings, and welcome to the Sinovac Biotech Q1 2013 Earnings Conference Call. (Operator instructions.) As a reminder, this conference is being recorded. It is now my pleasure to introduce your host, Stephanie Carrington of The Ruth Group. Thank you, you may begin.

Stephanie Carrington

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, and including statements about Sinovac's beliefs and expectations are forward-looking statements.

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On the call today we have Dr. Weidong Yin, CEO; Mr. Danny Chung, Sinovac's CFO; and Ms. Helen Yang, Investor Relations Director. I will now turn the line over to Helen Yang. Go ahead, Helen.

Helen Yang

Thank you, Stephanie, and hello everyone. Thank you for joining us on this conference call. I will provide you an update on the business on behalf of our CEO Mr. Yin, and Danny Chung, our CFO, will then provide the financial review.

So firstly, let me start with the sales performance of this quarter. We believe that we were doing well on the sales activity. In Q1 2013 we reported a total of $10 million revenues just now which is about 58% growth year-over-year. The sales growth was primarily driven by the sales of Healive, our inactivated hepatitis A vaccine which increased over 280% year-over-year.

In Q1, the demand of our hepatitis A vaccine was very strong and the [competition] landscape for the inactivated hepatitis A vaccine was developed to our favor. We are pleased with the high recognition of our inactivated hepatitis A vaccine for its good quality by the user when desired to replace the free live attenuated hep A vaccine with ours.

In addition to the growth with Healive our mumps vaccine manufactured by the Dalian site was commercially launched to the market in this quarter, which also contributed to the sales growth in this quarter. The growth was partly offset by the decrease of Bilive sales comparing to the same period last year, which was impacted by the measles vaccination [Contain] implemented by the government in Q1 which is conflicting to the sales of Bilive because of that activity taking a majority of the time and manpower of the vaccine introducing panel, which is the Centers for Disease Control.

As our sales increased our gross profit margin was improved and spending on R&D was largely reduced, which resulted in a lower loss position in this quarter comparing to the same period of last year. Our CFO will discuss the financials in detail. I just want to highlight that in Q1 2013, net loss attributable to stockholders in Q1 2013 was $2.0 million or $0.04 per basic and diluted share, compared to a net loss of $5.6 million or $0.10 per basic and diluted share for the same quarter of last year.

After discussing the existing vaccine business I would like to turn over to the near-term opportunities. As you may now we have completed a Phase III clinical trial on our proprietary EV71 vaccine candidate which concludes with an approximately a 95% efficacy rate against hand, foot and mouth disease caused by EV71. The trial was conducted among 10,000 healthy volunteers aged from 6 months to 35 months old. The safety results showed no significant differences between the vaccine group and the control group and there is no rare, severe adverse reactions reported in the trial.

[Imposed] GMP level and zero conversion rates showed the vaccine can effectively induce the immune response or immunization on the vaccine group. Our next step is to file the new drug application to the China Food and Drug Administration to apply for the new drug certificate and the production license for this vaccine. The enterovirus 71 or EV71 vaccine remains to be meet significant unmet medical needs across China and Asia based on the widespread outbreaks of hand, foot and mouth disease caused by EV71.

And there's also a significant pediatric mortality rate. In 2012 over 2 million cases were reported in China and over 500 fatal cases were published by the China National Health and Family Planning Commission which is previously named Chinese Ministry of Health. Most of the severe cases were caused by EV71 infection and usually spring is a peak outbreak season in China for hand, foot and mouth disease caused by EV71. In the first four months in China there are a total of over 350,000 total reported cases of head, foot and mouth disease with 57 fatalities.

We also recently learned from the public information that there are outbreaks of head, foot and mouth disease at a secondary school in Hong Kong affecting students aged between 13 and 16 which shows an outbreak trend which is expanded in the population age. And in China one cohort represents about 15 million to 17 million population, and it was studied previously in the epidemic situation that the majority of the cases reported are among the group under 5 years old; and most of the severe cases were reported under 3 years old.

As we indicated previously, the EV71 vaccine production facility at our Changping site is ready for GMP inspection. Once the new drug certificate and production license are granted we can apply for the GMP certification in order to commercialize the products, which we expect to complete all these regulatory approvals in the year of 2014. Sinovac is also committed to advance our other vaccine pipeline development programs.

In January we filed an IND which is a clinical trial application for our varicella vaccine and as a reminder, we previously filed an IND for our pneumococcal vaccine as well as a rubella vaccine. We recently received a notice from CFDA to submit supplementary documents for the pneumococcal vaccine and we are now in the process of preparing and submitting required information to the central government.

On the manufacturing aspect, based on China's new GMP regulations in order to be able to carry out vaccine production every vaccine manufacturer has to pass the GMP certification under the new guidelines. And we are very happy to announce that after a whole year of preparation and validation by our quality and production team on a commercial production plan we successfully passed the on-site inspection at all commercial production facilities in Beijing at one time; and officially received the GMP certificate covering all of our commercial production plants in Beijing on April 18, 2013.

And finally, I would like to turn over to the newly emerged H7NI influenza in China. Influenza A or H7NI is one of a subgroup of influenza viruses that normally circulate among birds. This virus had not been seen in people until recently. However, human infection has now been detected in China since April this year. According to the publicly available data, as of May 24, 2013, there are a total of 131 reported H7NI infectious cases which included 36 deaths.

Currently Sinovac is paying close attention to epidemic situation of H7NI influenza and meanwhile preparing for the development of an H7NI vaccine candidate. Currently we are expecting the H7NI [therapy] provided for the potential manufacturing of the vaccine. And now I would like to turn over the call to Danny to review the financial results for Q1 2013. Danny, please.

Danny Chung

Thanks, Helen. This is a great opportunity for me to introduce the financial highlights and summary for Q1 2013. The sales analyses are in the attached table and you can refer to the figures inside the table.

The total sales for Q1 2013 increased by 66% to $10.1 million from $6.0 million in Q1 in the prior year. The total sales growth was primarily driven by a sales increase in Healive which was due to the favorable competition landscape. The mumps vaccine manufactured by our Dalian site was firstly commercialized in the current Q1 and also contributed to the total sales growth. The total sales growth was partly offset by the decrease of Bilive sales.

Our gross profit for Q1 2013 increased by 90% to $7.1 million from $3.7 million in the same period of 2012. Gross profit margin percentage increased to 70% from 62% in 2012 with Healive sales representing 61% of the current quarter's sales compared to 27% in the same period of last year. The main reasons for the increase in gross profit margin in Q1 2013 was the lower unit cost of Healive resulting from higher production volumes in response to increased sales; and also the higher sales of the Healive vaccine in [streams] sold at premium price.

Selling and G&A expenses for Q1 this year were $6.4 million compared to $4.3 million in the same period of last year. SG&A expenses as a percentage of sales in Q1 were 63% compared to 72% for the same quarter of last year. The increase in selling and G&A expenses was mainly due to increased selling activities and costs that resulted in sales increases in hepatitis A and new mumps vaccines.

And also we had material and labor costs for the ongoing validation activities to prepare ourselves for the GMP certification for the EV71 manufacturing facility at our Changping site. And also we have higher operating, amortization and [security] costs generally in the current quarter for the Changping site because the site was not under renovation in the same period in the prior year.

R&D expenses in Q1 this year were $1.8 million, a significant decrease from $7.3 million in the same period of last year because the EV71 vaccine Phase III trial was approaching the end stage in the current quarter but it was just started in the same period of last year. Also since most of the vaccine was commercialized in this quarter we did not have any research and development expenses in the current quarter, but the vaccine was under development in the same quarter of last year.

Depreciation of property and equipment and amortization of licenses and permits for this quarter was $0.8 million compared to $0.3 million for the same period of last year. Depreciation expenses decreased because more assets were put into service at the Changping facility since Q4 last year.

Net loss attributable to stockholders in Q1 was $2.0 million or $0.04 per basic and diluted share compared to a net loss of $5.6 million or $0.10 per basic and diluted share for the same quarter of last year.

Now I'll turn to the cash position. As of the quarter end in March, our total cash and cash equivalents totaled $91.6 million compared to $91.2 million as of December last year. Net cash used in operation activities was $5.6 million in Q1. Net cash of $2.1 million was used in investment activities, mainly in payment and prepayment for acquiring the property and buying equipment for the Changping site.

Net cash provided by financing activities was $8 million in Q1 including loan proceeds of $7.5 million to run under a credit facility already in place supporting our EV71 vaccine commercialization and daily operations. When appropriate the company will seek new sources of financing to commercialize other pipeline products. That ends the financial highlights and summary, so I'll turn it back to Helen and the Operator.

Helen Yang

Yeah, that actually concludes management's prepared remarks. Operator, we are now taking questions.

Question-and-Answer Session

Operator

Thank you. We will now be conducting a question-and-answer session. (Operator instructions.) Thank you. Our first question comes from the line of Isabella Zhao with Morgan Stanley. Please proceed with your question.

Isabella Zhao - Morgan Stanley

Hi, good evening, this is Isabella on behalf of Bin Li from Morgan Stanley. My first question is regarding the process of the EV71 vaccine application. Can management give us more color? When do you expect to file the new drug application and when should we look at the sales beginning to contribute? And also how much is the sales we should look at in 2014 if it's a successful launch? And my other question is regarding the other vaccine sales expectations for this year – do we have a similar sales cycle for the next quarter as compared to Q1? That's my first question, thank you.

Helen Yang

Thank you, Ms. Zhao. I will firstly translate your question and then I will invite Mr. Yin to answer your question.

To answer your first question, management is actively working on the new drug certification, and actually as we mentioned several times we're actually preparing in parallel for our commercial [climb] for the EV71 vaccine. Mr. Yin described that there are two uncertainties that may impact the entire reviewing timing for the EV71 regulatory approval process. The first one is that actually it's under the control of the CFDA – that is how much time they're going to spend on reviewing the entire file. And on the other hand we believe that the outbreak situation, the epidemic situation if it's quite serious we think that might be helpful to speed up the process for getting the approval. And the management will do whatever we can to submit a new drug application as soon as we can.

Regarding the commercial sales of the vaccine, our Sales and Marketing Team has already made a [field] version of pricing and the targeted territory for commercializing these vaccines. And we think that generally speaking, all these terms are not fixed yet but we think that because we're starting from the private pay market so we think the sales volume may start from a low level and it will go up step by step.

And also from the pricing point of view we think we will start at a relatively high price and we will start with the private pay market first and then after a [series] we may consider to provide it to the public pay market. So we think maybe at first we'll focus on those territories that have high epidemic situations with this disease.

Actually we have seen very good results from the sales growth for the hepatitis A vaccine when the sales team is executing the sales strategy and focusing on the private pay market. And management of course expects to maintain a similar level of growth for the next quarter and management has provided guidance for the forward-looking four quarters to the public. So we are just hoping that we are expecting to provide resources and trying to maintain the similar level of growth.

Isabella Zhao - Morgan Stanley

Okay, thank you. And my next question is regarding for the gross margin. I know that in this quarter gross margin was helped with higher (inaudible) sales. What are we going to look at in the gross margin for next quarter and for the whole year?

Danny Chung

Well, I think that depends on how we're going to execute the sales strategy. But at this point in time if the sales team is keeping this kind of level obviously we expect to be continuously strong in the gross margin.

Isabella Zhao - Morgan Stanley

Okay.

Helen Yang

In addition to that, I think what Danny described for the next quarter is absolutely correct. But I think you are aware that normally the flu vaccine gross margin is relatively lower comparing to the hepatitis vaccine, and since sales normally will be reported in the second half of the year. So generally speaking we expect the gross margin of the company in the second half will be lower when comparing to the first half.

Isabella Zhao - Morgan Stanley

Okay. That's all my questions, thank you.

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 comments as to why the sales of Bilive has been sequentially decreasing for the last few quarters?

Helen Yang

Normally when we are considering about the sales growth we are looking at the Bilive and Healive as a group of products sharing the same hepatitis A vaccine, and we think that combining the two, we think the total sales of Bilive and Healive still show strong growth comparing the same period last year. And we believe that the success of Healive has been a very good execution on the replacement strategy that we implemented in this Q1, which is to take our Healive vaccine in the private pay market to replace the live attenuated vaccine in the EPI market.

Yi Chen - Aegis Capital

Okay, thanks. My second question is do you expect the SG&A expense as a percentage of sales to remain at roughly the same level going forward for the rest of the year?

Danny Chung

Well basically in terms of the amount we definitely will have increased SG&A. In terms of the depreciation expenses there'll be increases and also the facility costs in Changping will be also added to the ongoing increase in the SG&A. So in terms of the amount I can see the [imbalance] happening.

Yi Chen - Aegis Capital

Okay, thank you.

Operator

(Operator instructions.) Our next question comes from the line of John Gregory with SJ Strategic. Please proceed with your question.

John Gregory - SJ Strategic

Thank you. I wonder if you could answer this question. Here in the US several financial writers have tried to say they think EV71 vaccine will not be that big of a revenue generating product but obviously you all think otherwise, and it might have something to do with the fact that there really isn't any hand, foot and mouth disease in the US. But how does hand, foot and mouth disease affect China, the country of China? I mean obviously this must be of great concern so how does it affect the daily life when this disease is becoming a problem?

Helen Yang

Sure, thanks John. I will translate the question to Mr. Yin.

So firstly Mr. Yin thinks this is a very good question, because when we are looking at the epidemiology of these hand, foot and mouth disease in US and China we saw it was significantly different. In China there are a great number of young children aged 1 or 2 years old who develop hand, foot and mouth disease; and most of the severe cases develop symptoms like meningitis.

And normally when a lot of children get infected, the parents try to take the kids to the [treating hospital] but right now in China normally there are cases that the children may not be able to have the opportunity to see a doctor and get a good treatment due to the lack of resources to cover the whole group who are getting infected in China. That's why we have such a high level of reported cases and also the fatalities.

And also right now in China the parents have a very great concern about their children who are doing a lot of socializing in the kindergarten or in the school age that may be infected, so this is a description on the real situation in China.

And in addition to that, based on the clinical study and epidemiology studies done in China on these hand, foot and mouth disease outbreaks, over 80% to 90% of the severe cases were actually caused by EV71 infection. And many of these kids were infected and developed very serious symptoms like high fever and meningitis. And also there is a number which is calculated by the experts showing that the median of the number of days from when the kids get infected until the kids died is only 3.5 days. That's how it causes a lot of concern among parents.

And also in recent years it's always the case that if the previous cases were found in preschool and kindergarten, and some of the times the school has been closed down for a period of time. So it is kind of a passive way of stopping the transmission, and this kind of situation happens regularly in every city every year. And also you know that in China there is a one child policy; that's why the parents, governments and schools are trying to provide good healthcare and living conditions for the kids. That's why to control the disease outbreak of hand, foot and mouth disease has become a very big issue among the civil society.

And before we commenced our Phase I clinical studies on EV71 vaccine we had a conference call with the experts from the US FDA to discuss about the trial and the epidemic situation of head, foot and mouth disease in China. And also we held a similar type of discussion with big pharma especially in the US and Europe. However, there are also comments similar to what you

said, that in the US the symptoms only develop in kind of mild symptoms, not very serious; and there is no [find out] of a group of children that developed the severe symptoms.

However, we think that there is no evidence showing that this virus will not be transmitted among different countries or among different types of populations. And we believe that the China demand is the primary focus for now but potentially we think there will be opportunities for using this vaccine abroad, outside of China.

John Gregory - SJ Strategic

And it would just seem to me that when you would have several schools close down because somebody got infected or somebody died, that the demand just in the private sector would be overwhelming. I know that if that happened in the US it would be overwhelming, the doctors that would want the vaccines. And one of the things that I don't totally understand is with this type of infection going on and with children being killed, why wouldn't the China FDA fast track this thing especially after the fantastic Phase III results you got?

Helen Yang

So Mr. Yin said just as what you expected, actually Sinovac as the vaccine developer, we of course want to move to advance the development as soon as we can to control the disease epidemic. And at the same time, the previous MOH, the Ministry of Public Health was also very supportive on the vaccine development as well as the CFDA. And also the Ministry of Science and Technology even provided the funding to support the vaccine development. That's why we can complete three phases of clinical studies within a relatively short period of time. So this is what you said – no matter from us or from the regulators, everyone's putting a lot of support in trying to have a vaccine to be available as soon as we can.

John Gregory - SJ Strategic

Okay, just one more question and that's in regards to the new bird flu epidemic, is there some magic number of cases like 200 or some magic number of deaths like 50 that's going to trigger you working on this whether the government gives you an order or not for the private pay sector? I mean what will be the decision that is the turn on process to make this bird flu vaccine?

Helen Yang

Regarding the bird flu, actually the company has already initiated the planning for the possible development of an H7NI vaccine and we're also having close communications with the government organizations in the science and technology and health industries. And we think that the research and development of the vaccine could be similar to the technology that we use for H5N1 – the avian flu vaccine for humans. We could possibly try a split-viral technology or whole virus technology either to add the (inaudible) or without (inaudible).

And right now we are seeing that the total number of infections with H7NI is over 100 cases within a few months which is already more than the H5N1 infection within years in the past time. So we think the concern on H7NI seems to be more serious or bigger than the H5N1, but right now as a matter of fact there is no order being placed by government yet. And we didn't make a final decision whether we are going to be commercially manufacturing this vaccine, but we think the company can make a big effort firstly on the development of this vaccine. Nut we think the development won't cost too much investment because the company itself has the technology platform and our teams are trained to develop a similar type of vaccine.

So we actually analyzed a different type of scenario for the possible epidemic situation of H7NI. It could be developed as serious as the H1N1 bacteria in 2009 and it's also possible that it could suddenly disappear like SARS ten years ago, or like H5N1 with a few number of infections among people but no human-to-human transmissions being confirmed. However, no matter which type of scenario happens we believe that right now Sinovac is more mature comparing to how we worked when we were facing the previous types of developments on H1, SARS and H5; and we believe that we have more experience of getting benefit from these types of opportunities.

John Gregory - SJ Strategic

Okay, this last question – the mumps vaccine where you did $0.5 million in the quarter, is that what you were expecting to do in Q1 or were you surprised by that good number?

Helen Yang

So actually for the mumps vaccine, the scale of a potential level of sales is relatively small compared to our other vaccine types. And in China this vaccine was used to immunize the people living in the area where they were having the outbreak. And because this is the first year for us to do the commercial launch of this vaccine we think we are more focused to stabilize the commercial production on a large scale and also of trying to test the water of expanding the sales.

Therefore we don’t have a very aggressive expectation of the revenue generated in mumps for this year; that’s why we didn’t have a projection on mumps as well.

John Gregory - SJ Strategic

Okay, thank you.

Operator

Thank you. It appears 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. Once again, we thank you for everyone’s participation and we would like to report good development progress made by the company in the next following weeks. 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.