Sinovac Biotech's CEO Discusses Q3 2013 Results - Earnings Call Transcript

Executives

Dr. Weidong Yin - CEO

Nan Wang - CFO

Helen Yang - IR, Director

Chris Lee - IR

Stephanie Carrington - The Ruth Group, IR

Analysts

Isabella Zhao - Morgan Stanley

Yi Chen - Aegis Capital Corporation

John Gregory - SJ Strategic Investments

Bob Oliver - Private Investor

Sinovac Biotech, Ltd. (SVA) Q3 2013 Earnings Conference Call November 13, 2013 8:00 AM ET

Operator

Greetings and welcome to the Sinovac Biotech Limited Third Quarter 2013 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, Stephanie Carrington of The Ruth Group. Thank you. Ms. Carrington, you may begin.

Stephanie Carrington - The Ruth Group, IR

Thank you, Operator. Good day, everyone. 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 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

that are not historical (technical difficulty) statements about Sinovac's beliefs and expectations 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 any 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've Dr. Weidong Yin, CEO; Ms. Nan Wang, Sinovac's Chief Financial Officer; and Ms. Helen Yang, Investor Relations Director and Ms. Chris Lee, Investor Relations.

I'll now turn the line over to Helen Yang. Go ahead, Helen.

Helen Yang - IR, Director

Thank you, Stephanie, and hello, everyone. Thank you for joining us on this conference call. I will provide an update on the business and the financial review on behalf of our CEO, Dr. Weidong Yin; and Ms. Nan Wang, our CFO.

Let me start with the quarterly performance. We are very pleased to see another strong quarter with the sales growth of 54.5% year-over-year and a profitable bottom line with net income attributable to stockholders of $0.04 per diluted share, marking another profitable quarter following Q2.

The growth in the third quarter was mainly driven by the robust sales of Anflu, our seasonal influenza vaccine. We've continued execution of the [ph] stated sales strategy, Anflu sales was increased by 121% in this quarter compared to the same period of last year, resulting from a solid support from operations. And we're leveraging the improved efficiency and expanded capacity of our fully operational Changping site, which is conducting filling and packaging activity. We can complete the production in a timely manner comparing to the previous years. Therefore we were able to deliver majority of flu vaccines produced at the beginning of the flu season in China.

The aim of our sales strategies during 2013 to 2014 flu season is to increase the administration level, which will reduce the product return level and improve the profitability of our flu business. The promotion activities will be continued into the fourth quarter. As a reminder, flu virus strength are changed every year. Dose vaccines not being administered will be returned to the Company and will be (indiscernible) the cost to the operation.

Turning to the sales to the public market in China, we successfully want to tender in Beijing to supply Anflu and the Jiangsu province to supply Healive for its 2014 EPI program. As our sales increased, our gross profit was improved by 111.7% compared to the same period of last year. And the R&D expenses has been decreased dramatically, therefore we conclude another profitable quarter.

Elaborating the strong sales performance, we expect to generate $70 million in revenue for 12 months 2013 and we're on track to record a positive net income for the full year 2013, following three consecutive years of losses. After discussing the existing vaccine business, I'd like to turn to the near-term opportunity within our development pipeline and the [ph] latest on the new drug applications filed in May 2013.

As highlighted in our quarterly release, the CFDA issued new guidance in late October 2013, enabling applicants to apply for GMP certification for its production facilities concurrently with the production site inspection during the New Drug Application or NDA process, instead of waiting until after the new drug certificate is granted. The new guidance will accelerate the entire registration process for the vaccine products, including Sinovac's EV71 vaccine candidate.

And currently our EV71 vaccine is under the technical review by Center of Drug Evaluation, CFDA. The review on pharmaceutical data was completed and a supplementary documentation has been submitted as requested. To review on clinical data it's underway, after which an extra conference will be held for further discussion and review after which we're ready to apply for the said inspection as well as the GMP certification according to the FDA new guidance. The other pipeline products are moving forward on schedule. We will keep the public updated on any milestone progress for the pipeline.

And now I'd like to talk about the financial review on the third quarter. As introduced, the total sales increased by 54.5% to $22.1 million in the third quarter 2013 from $14.3 million in the third quarter of last year. Excluding $3.6 million of H5N1 vaccine revenue recognized in the third quarter of 2013, regular sales increased by 29.5% to $18.5 million from $14.3 million in the same quarter last year. The growth was mainly driven by the sales of Anflu as I explained earlier.

Gross profit increased by 111.7% to $15.9 million in the third quarter of 2013 from $7.5 million in the same period of last year. Gross margin was 72.1% in the third quarter of 2013, compared to 52% -- 52.6% in the same period of last year. The higher gross margin was mainly due to increased Anflu gross margin because of a lower sales return provision as well as inventory provision recorded and less excess capacity was charged to the cost of goods sold in this quarter comparing to the same period of last year.

Selling, general and administration expenses in the third quarter of 2013 were $9.9 million, compared to $7.8 million in the same period of 2012. Selling expenses as a percentage of the third quarter 2013 regular sales were 32%, compared to 28.7% in the same period of last year. The increase in selling expenses as a percentage of revenue was mainly due to the increased marketing efforts to generate Anflu sales this quarter.

G&A expenses in the third quarter of 2013 increased to $4 million from $3.7 million in the same period of 2012. The increase was mainly due to higher operating costs at the Company's Changping site as it is now fully operational. And these increases were partially offset by the decrease of bonuses due to the Board of Directors approving certain employee bonuses to be

settled from the Company's Staff Bonus and Welfare Fund, an accrued liability account, rather than charged to expense.

R&D expenses in the third quarter of 2013 decreased to $2 million from $3.8 million in the same period of last year. The lower R&D expenses in the current quarter were attributable to the completion of the Phase III study of EV71 vaccine candidate in the first quarter of 2013.

Depreciation of property, plant and equipment and amortization of licenses, permits and renovation costs for the third quarter of 2013 was $0.8 million, compared to $0.4 million in the same period of last year. Depreciation increased primarily due to more assets at the Changping facility start to be depreciated in the fourth quarter of last year, compared to the comparative period.

Net income attributable to stockholders in the third quarter of 2013 was $2.3 million or $0.04 per basic and diluted share, compared to a net loss of $3 million or $0.05 per basic and diluted share in the same period of last year. If the bonus of $0.3 million settled from the accrued liability account, was charged to operation in this quarter, the net income of the third quarter this year was approximately $2 million, or $0.04 per diluted -- per basic and diluted share.

And now let me turn to the nine months financials. The total sales of the first nine months of 2013 were $49.6 million, a 67.4% increase from $29.6 million in the same period of 2012 and exceed full year 2012 sales by $363,000. Excluding the $3.6 million, H5N1 vaccine revenue recognized, the regular sales increased by 55.3% to $46 million. The increased revenue was driven by the Anflu sales growth in the third quarter as well as the Healive growth in the first half of the year.

Gross profit for the first nine months of 2013 increased by 90.2% to $36.6 million from $19.2 million in the same period of last year. Gross margin was 73.7% compared to 46.9% in the same period of last year. The higher gross margin was primarily due to the increase of gross margin of Anflu and Healive with lower sales return provision recorded and less excess capacity charged to the cost of goods sold in the third quarter of 2013 compared to the same period of last year.

Selling, general and administrative expenses for the first nine months of 2013 were $24.6 million compared to $18.9 million in the same period of 2012. Selling expenses as a percentage of 2013 nine months regular product sales was 31.6%, compared to 33.5% of the same period of last year. The decrease in selling expense as a percentage of regular product sales was primarily due to the higher sales achieved without significantly increasing the sales team headcount and salaries.

G&A expenses in the first nine months of 2013 increased to $10 million from $8.9 million in the same period of last year. The factors affecting general and administrative expenses in the nine months of this year were the same as for the third quarter of 2013 as described above.

Research and development expenses for the first nine months of 2013 decreased to $5.9 million from $15.8 million in the same period of last year as the clinical studies of EV71 vaccine candidate was completed in early this year.

Depreciation of property, plant and equipment and amortization of licenses, permits and renovation costs in the first nine months of this year was $2.1 million compared to $1.1 million in the same period of last year. Depreciation increased because more assets at the Changping facility started to be depreciated in the last quarter of 2012.

Net income attributable to stockholders in the first nine months of 2013 was $1.6 million or $0.03 per basic and diluted share, compared to a net loss of $10.2 million or $0.19 per basic and diluted shares in the same period of last year. If the $1.7 million bonus, settled from an accrued liability account, was charged to operations for the nine months period, the net loss of the first nine months of 2013 was $0.1 million or $0.02 per basic and diluted share.

As of September 30, 2013, cash and cash equivalents totaled $89 million compared to $91.2 million as of December 31, 2012. In the first nine months of 2013, net cash used in operating activities was $14.7 million. Net cash used in investing activities was $3.4 million in the first nine months of 2013, which was mainly to acquire property, plant and equipment for the Changping facility. Net cash provided by financing activities was $15 million in the first nine months of 2013, including loan proceeds of $13.9 million. And as we introduced earlier, we would expect for the whole year 2013, we expect to generate about $70 million in revenue and we expect to making profit for this year.

And that conclude management's prepared remarks. And operator we will now take questions. Thank you.

Question-and-Answer Session

Operator

Thank you. Ladies and gentlemen, we will now be conducting a question-and-answer session. (Operator Instructions) Thank you. Our first question is coming from the line of Isabella Zhao with Morgan Stanley. Please proceed with your question.

Isabella Zhao - Morgan Stanley

Okay. Thank you. I'll transfer my question in English. My first question is the revenue outlook for the winning of the two tenders, one for the Anflu for Beijing and the other one is the hepatitis A that is seen for the Jiangsu provinces. How much revenue we expect and when will it be recognized? The next question is about the gross margin. And within the fact that the gross margin was a little high in the third Q, and I wanted to know what kind of gross margin we will expect in the fourth Q? Thank you.

Dr. Weidong Yin - CEO

To answer your question, Mr. Yin said this is a very good question, and also this is a strategy that when the company is promoting our vaccines in the private pay market we'll also have another team to focus on expanding our market share in a public pay market. And as you mentioned we won the tender of flu vaccines for the city of Beijing, and we are about to ship about 400,000 doses of Anflu in the season, about 300,000 doses has already been shipped out in the third quarter, so the revenue should already been broke in the third quarter, and another 100,000 doses will be shipped -- was shipping in fourth quarter and it was sold at about RMB25 per dose. And we think that this is a very good model that a government pays for the immunization for the citizens and each these model's can be utilizing other provinces or cities. We would think the flu market will have a better opportunity to grow.

And turning to the tender in Jiangsu; actually Jiangsu province is another territory that we're expanding the public market for Healive, the hepatitis A vaccine. So we supply Healive to the public market in Beijing and Shanghai. And in Jiangsu since the population -- the size of population is relatively bigger than the other cities. So if we won a tender normally the volume supplied will be relatively higher compared to the other cities. And in this tender we are about to ship 900,000 doses and we think that this is a very good sign to see that more and more provinces or cities recognize the value of inactivated hepatitis A vaccine and a government would like to pay for the better quality. And if this trend is expanding, we think hepatitis A vaccine market will grow or at least for the sales of our Hep A vaccines will grow even though we can't say particularly about how would be the percentage of growth, but we think the trend showing that the revenue for Hep A should grow.

And the other question about the gross margin for the fourth quarter, I can answer you that since in the fourth quarter we expect to recognize about 2 million doses of H5N1 vaccines into the revenue due to those vaccines reaching expiration date and we aim to complete the government audit activities before the end of this year. And normally dose vaccines have a, because if you know our gross margin which is about rough 50%. So we would expect in the fourth quarter our gross margin should be slightly lower comparing to the third quarter which we expect it could be around 65%. Does that answer your question?

Isabella Zhao - Morgan Stanley

Yes, thank you. [Foreign Language]?

Dr. Weidong Yin - CEO

So Mr. Yin firstly explains the new policy issued by the China Food and Drug Administration. Mr. Yin personally is very happy to see the new policy. Because normally when we apply for approval of a new product, the product, the dose here, the registration documentation needs to be revealed, technically revealed by the CFDA. And if it has, it will move to another department within CFDA to issue a certificate we call the New Drug Certificate. And this is the

evaluation of the technology itself, and there are another line for approving the production. So for the production approval based on the guidance issued by CFDA, the Company needs to apply for the onsite inspection for applying the GMP certification. And in the past the company needs to apply for the new drug certificate first, and after the new drug certificate basically itself product itself from technically it's approved and then the company can start submitting the application for the production, i.e. the GMP certification.

So moving from new drug certificate to GMP certification or onsite inspection it could either expand about three to four months or even it could go as long as two years. So right now the new policy is that while the product it's being revealed technically for the new drug certificate the company is able to make an application for the onsite inspection for the production at a GMP level. And therefore that this new policy will shorten the time spending from moving from new drug certificate to GMP certification. We think this will help generous speaking it will help to speed up the process of a product review and approval in China.

And turning to EV71 as we explained EV71 file is right now under technical review within the CFDA, and also for our production line we have already built facilities and will keep conducting the validation of our facilities in tromping. And actually once at any time if the CFDA is ready to do the onsite inspection we're able to receiving them and to cooperate for the onsite inspection. So from the management of course we will do whatever we can to moving into the GMP certification as soon as we can. However that, at this stage still it's not under our control.

So it's very hard to give you a specific time when we can finish the entire approval. But at least from the change in policy we have, we think that the government is showing a gesture of speak up the entire profit of approving products, therefore that we are more and more confident about getting the approval in a relatively short period of time. And once we reach any material milestones we will notify the public.

Isabella Zhao - Morgan Stanley

Thank you. Thank you for taking my questions.

Helen Yang - IR, Director

Thank you.

Operator

Thank you. The next question is coming from the line of Yi Chen with Aegis Capital. Please proceed with your question.

Yi Chen - Aegis Capital Corporation

Hi, thank you for taking my questions. First question, Helen did you just mention that you will recognize more revenue from H5N1 vaccine sales in this fourth quarter?

Helen Yang - IR, Director

Yes, I did.

Yi Chen - Aegis Capital Corporation

How much is that?

Helen Yang - IR, Director

Actually the revenue is about RMB44 million.

Yi Chen - Aegis Capital Corporation

RMB44 million.

Helen Yang - IR, Director

US$7 million.

Yi Chen - Aegis Capital Corporation

Okay. Second question is, could you comment the current status of H7N9 in China and whether Sinovac currently has any activity on that subject?

Helen Yang - IR, Director

So I'll translate and invite Mr. Yin to answer this question.

Dr. Weidong Yin - CEO

So, Mr. Yin's answer is that, we absolutely in China we have moved into late autumn and early winter, and we still keep seeing more cases arise. And in the past there are some cases from [ph] Zhejiang province and recently one case is identified in (indiscernible) province. And right now in China there are more than 140 cases reported. Right now we think the trend elsewhere epidemic of H5N1 it seems not being well controlled, but it's still within a limited connection. And no one actually can predict whether this virus will cause human to human transmission.

And right now Center for Disease Control is also keeping, watching about the trend of this disease development. And in Sinovac we have obtained a very strange influenza this year and starting from that we're conduction the preclinical studies and now we have almost completed

the preclinical research. However that for the approval or application of getting the vaccine commercialized whether it could go down through the case like pandemic flu like H5N1 top file by the government or it could be submitted as a regular vaccine and being approved and then commercialized regularly in the market, it's still difficult to tell at this stage.

We believe that CFDA make take different strategies based on different level of severity of the epidemic situation of H7N9, and we of course as a company will closely watch the change of the epidemic situation as well and at the same time we're, keep conducting the research. And if there is any risk to a human client in China at least we have a product to be used for that people.

Yi Chen - Aegis Capital Corporation

Thank you. Third question is, could you please comment on whether the current government's investigation of GSK China's practice has any impact on Sinovac's marketing activities?

Helen Yang - IR, Director

Sure. I'll translate the question first.

Dr. Weidong Yin - CEO

So, Mr. Yin's answer is that he don't believe there is any direct impact on our business. And we, (indiscernible) whether there is any results from these investigation. However that he wants to take this opportunity to discuss how we should make the strategy of developing a business in China. He thinks that firstly, we need to understand the real need from China, and we believe that China actually needs to have good products. Here Chinese people should be able to use good products, good vaccines. And we think that we are following this strategy in order to supply good services, good products to the Chinese population. And we were guided with these goals to conduct our research, development, production and sales and marketing.

And we believe that only through this way we're able to making a product with good quality and we will finally have our clients and users of our products to be fully benefited. And actually in China the entire competitive landscape is quite complicated, and we're facing the competition with multinational companies and local companies, they own enterprises.

But we believe that a strategy we're taking is helping us to lead the company to develop our self on a right direction. And once we keep conducting the business of supplying good vaccines to our population, we believe that the company will have a good potential and as a comparative advantage of the company will be more and more obviously as we're keep interesting of doing the right thing in China. Thanks.

Yi Chen - Aegis Capital Corporation

Okay, thank you. Final question, could you comment what the R&D expenses would look like going forward considering you have other pipeline products currently in development, and also to confirm with Helen there you just mentioned previously the revenue for 2013 would be around 70 million, correct?

Helen Yang - IR, Director

Yes.

Yi Chen - Aegis Capital Corporation

Could you talk about R&D expenses?

Helen Yang - IR, Director

Sure. Let me translate the question first.

Dr. Weidong Yin - CEO

So Mr. Yin's answer is that, actually the planning for our research and development activity is to managing the long-term growth opportunity. And if you remember that actually in 2012 the total amount of R&D expenses in the -- for the EV71 clinical studies is really high, actually the highest in our history. But we think this is worthwhile because after EV71 commercialized we will expect the revenue and such a level will be increased significantly, and at that time the company will be more capable of making a bigger investment into the R&D.

However, that right now our total revenue is still relatively small. We think that even though we still need to make investment into the research and development, and we should do so but we will not at this moment it's difficult to say that what would be the percentage, because it will go with the different status of the development project. But Mr. Yin just wants to give you a general idea about how we are looking at research and development, and how important it is for our future growth opportunities.

Yi Chen - Aegis Capital Corporation

Okay. Thank you.

Helen Yang - IR, Director

Thank you.

Operator

Thank you. The next question is coming from the line of John Gregory with SJ Investments. Please proceed with your question.

John Gregory - SJ Strategic Investments

Okay, thank you. Just a couple of questions; Helen regarding the HFMD disease which EV71 will help to prevent; is that there a certain time during the year when this disease is more prevalent is affecting children. And if that is the case, what part of the year is …

Helen Yang - IR, Director

Sure, I can answer your question. Actually the first it comes normally in April, and then it will go higher and higher starting from late March, April, May. And May is low a little bit, but when getting a little bit cold in September and there was a lower peak again. Finally, the surveillance of this disease is throughout the year. The peak is about in April and September.

John Gregory - SJ Strategic Investments

Well, it would seem like to me then I guess if it really starts in April through September, doesn't it make logical sense since you're so far along in the process with the Chinese Government that they would try to approve the vaccine before the peak season starts?

Helen Yang - IR, Director

I will translate that part for Mr. Yin.

Dr. Weidong Yin - CEO

So, from management point of view of course we would expect to see the vaccine being approved before the first peak comes. And also we conduct a survey among our clients within the center for disease control, and doctors always to use half of the vaccine available before the peak comes next year. However that as we explained is still not under our control. So we can't do that prediction whether it could be approved at the time. And actually Mr. Yin wants to explain that even if the vaccine is approved before the first peak comes, actually well we need to manufacture the vaccine batch by batch. And the use of the vaccine needs to go from one area to other areas. And Mr. Yin does not believe the timing of the approval will have a significant impact under disease epidemic situation in the first year.

John Gregory - SJ Strategic Investments

Okay. Another question; when will you know if you're a distributor in Mexico or flu vaccine has won any government business in Mexico for this year?

Helen Yang - IR, Director

Actually they are managing to conduct that. We think probably we may know the results in late January or early February.

John Gregory - SJ Strategic Investments

Okay.

Helen Yang - IR, Director

Because there are a few round of tendering process. So we need to wait for few months.

John Gregory - SJ Strategic Investments

Okay. And then, just a final question; I know the company has approved to sell it's vaccine in the Philippines and with this recent disaster in the Philippines, do you think the Government of the Philippines might be needing additional product's like hepatitis vaccine?

Helen Yang - IR, Director

Well, actually our -- the vaccine approved in Philippines is influenza vaccines whereas we're supplying flu vaccines for a few years. I think given the current disaster maybe as you know that hepatitis might be a more suitable product, but not for the flu vaccine and it will have (indiscernible) registered in for (indiscernible).

John Gregory - SJ Strategic Investments

Okay. All right. Okay. Thank you very much.

Helen Yang - IR, Director

You're welcome. Thank you.

Operator

Thank you. (Operator Instructions) Our next question is coming from the line of Bob Oliver with -- a Private Investor. Please proceed with your question.

Bob Oliver - Private Investor

Yes, thank you for sharing the information on Mexico and the potentials of Philippines. But could you spend a little more time on the specific countries that you're approaching worldwide and whether or not you expect that to be a significant part of the 2014 revenue stream (indiscernible)?

Helen Yang - IR, Director

Thank you for the question. As we explained in the past, we're currently selling our vaccines to Mongolia, Nepal and Philippines. And in next year as we just answered the previous question that we're -- we received approval of our flu vaccines in Mexico and hopefully we can sell to Mexico in 2014. And for the other countries like India and some part of South American countries, we're registering the vaccines at the moment and we don't expect any countries that we can receive any approval in next year for those countries. So in 2014 we think the sales from all of these markets is still focused on those four characters I just mentioned.

Bob Oliver - Private Investor

Thank you very much.

Helen Yang - IR, Director

You're welcome.

Operator

Thank you. It appears there are no further questions at this time. I'd like to turn the floor back over to management for any concluding comments.

Helen Yang - IR, Director

Thank you, operator. Well, thank you for everyone to participating into this call and we're looking forward to speaking to you in the next call. Thank you.

Operator

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