LIPPERT HEILSHORN & ASSOCIATES - KAMADA LTD.

Moderator: Anne Marie Fields
November 12, 2014
8:30 a.m. ET

Operator: Welcome to the Kamada Limited third quarter financial results conference call.

At this time all participants are in a listen only mode. Later we will hold a Q & A session. To ask a question please press star followed by one on your touch tone phone. As a reminder, this conference is being recorded on November 12, 2014.

I would now like to turn the conference over to Anne Marie Fields with LHA. Please go ahead.

Anne Marie Fields: Thank you. Good morning. This is Anne Marie Fields with LHA. Thank you all for participating in today's call. Joining me from Kamada are David Tsur, Co-Founder and Chief Executive Officer; Gil Efron, Chief Financial Officer; and Pnina Strauss, Vice President of Clinical Development & IP.

Earlier this morning Kamada announced financial results for the three and nine months ended September 30, 2014. If you have not received this news release or if you would like to be added to the Company's distribution list, please call LHA in New York at 212-838-3777 and speak with Carolyn Curran.

Before we begin, I would like to caution that comments made during this conference call by management will contain forward-looking statements that

involve risks and uncertainties regarding the operations and future results of Kamada.

I encourage you to review the Company's filings with the Securities and Exchange Commission including, without limitation, the Company's forms 20F and 6K, which identify specific factors that may cause actual results or events to differ materially from those described in the forward-looking statements.

Furthermore, the content of this conference call contains time sensitive information that is accurate only as of the date of the live broadcast, November 12, 2014. Kamada undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this conference call.

With that said, I would like to turn the call over to David Tsur. David?

David Tsur: Thank you, Anne Marie, and my thanks to our listeners for your interest in Kamada and for participating in today's call.

Kamada made considerable progress throughout the third quarter as we continue to execute our strategy to build our core commercial business while advancing our robust clinical development programs.

Importantly, we are pleased to affirm our full-year 2014 top line guidance and are confident in our ability to achieve between $70 million to $72 million in total revenue.

Our core commercial business continued to be a tremendous asset for Kamada as it provide significant cash flow with increasing opportunity for revenue growth and expansions. It also supports our promising clinical pipeline of plasma derived therapeutics in the areas of unmet medical needs.

Before I go into the specifics of our achievements in the third quarter, let me turn the call over to Gil Efron, our CFO, for review of our third quarter and nine-month financials. Gil?

Gil Efron: Thank you, David, and good day for everyone. Our financial performance for both the quarter and year to date was strong with significant revenue increases expected in the fourth quarter. Total revenue for the third quarter of 2014 was $17.2 million compared with $17.5 million in the prior-year quarter and $15.8 million in the second quarter of 2014.

Revenue from the proprietary products segment was $9.1 million compared with $12.1 million in the 2013 third quarter and $8.7 million in the second quarter of 2014. The decline in proprietary products revenue versus last year's third quarter is due to ordering patterns and stock management of Glassia by Baxter.

The fourth quarter has historically been the strongest quarter for proprietary products revenue. As such, we expect to see a sharp increase in proprietary products revenue in the fourth quarter.

Revenue from the distribution segment increased 48 percent to $8 million in the third quarter of 2014, from $5.4 million in the prior year third quarter and increased 13 percent compared with $7.1 million in the second quarter of 2014 largely due to higher IVIG sales in Israel.

Total revenue for the first nine months of 2014 was $46.1 million compared with $46.2 million in the same period of 2013. Proprietary products revenue year to date was $25.3 million compared with $32 million for the same period of 2013, which included a $4.5 million milestone payment.

Excluding this milestone payment, revenues from proprietary products in the first nine months of 2014 decreased by 8 percent. Revenue in the distributed segment increased 46 percent to $20.8 million from $14.2 million in the year-ago period.

We remain on track to fulfill Baxter's orders for the year which included – which is included in our revenue focus. As a recap, the recent extension to our agreement with Baxter provides for minimum revenues from 2010 through 2016 of $191 million, up from $165 million in the 2013 extension and up from $110 million in the original 2010 agreement. The 2014 orders from Baxter are part of this signed commitment.

Turning to the rest of the P&L, R&D expenses for the third quarter increased to $4.2 million from $2.8 million in the third quarter last year and decreased from $5.1 million in the second quarter of 2014.

This increase was largely due to activities to support our expanding clinical programs including our Phase 2 trial in the U.S. for our inhaled AATD product; our Phase 2/3 study to treat type I diabetes patient; the initiation of the Glassia study in Graft-versus-host disease; the final analysis of our European Phase 3 study of inhaled Alpha-1; as well as to facility costs allocated to research and development use.

R&D expenses for the first nine months of 2014 of $12.6 million increased from $9.2 million in 2013 as we continued to support various clinical studies including three important clinical trials during the period, as I just mentioned.

During the third quarter of 2014, SG&A expenses increased to $2.7 million from $2.1 million in the prior year, largely due to share-based compensation expenses. SG&A expenses for the first nine months of 2014 increased to $8.1 million from $7.1 million in the first nine months of 2013, mainly due to share based compensation expenses.

Gross profit for the third quarter was $4.4 million compared with $5.9 million in the third quarter of 2013 reflecting lower revenue and product mix within the proprietary products segment as well as high revenue in the distributed product segment. This compares with gross loss of $0.7 million in the second quarter of 2014 due to an inventory write-off.

Third quarter gross margin of 26 percent compares with 34 percent a year ago and 0 percent in the second quarter of 2014. Our gross profit was affected by the level of revenue and product mix within the proprietary segments and the mix between the proprietary products revenue versus the distributed products revenue.

Gross profit for the first nine months of 2014 decreased to $7.6 million from $17.5 million in the same period of 2013 with gross margin declining to 16 percent from 39 percent. Excluding the $3 million inventory write-off in the

second quarter of 2014 and the $4.5 million milestone payment in the second quarter of 2013, gross profit for the first nine months of 2014 decreased to $10.6 million from $13 million in the prior-year period. This should improve in the fourth quarter as we expect increases in proprietary products segment revenues, which are much higher margin products.

We reported an operating loss of $2.5 million in the third quarter of 2014, compared with operating income of $1 million for the year-ago third quarter and an operating loss of $7.9 million in the second quarter of 2014. The operating loss for the first nine months of 2014 was $10.6 million compared with operating income of $0.4 million in the first nine months of 2013.

Net loss for the third quarter of 2014 of $2.9 million or $0.09 per share compared with net income in the prior-year third quarter of $0.4 million or $0.00 per diluted share. The net loss for the second quarter of 2014 was $8.4 million or $0.23 per diluted share. Adjusted net loss for the third quarter of 2014 was $1.9 million compared with the adjusted net income of $0.3 million for the same period in 2013 and adjusted net loss of $7.4 million in the second quarter of 2014.

Net loss for the first nine months of 2014 was $11.5 million or $0.32 per share compared with a net loss of $1.1 million or $0.04 per share in the same period a year ago.

Adjusted EBITDA for the first quarter of 2014 was a loss of $0.8 million compared with positive $2 million for the third quarter of 2013 and a negative $6.2 million in the second quarter of 2014. Adjusted EBITDA for the first nine months of 2014 was negative $8 million compared with positive $5.9 million for the same period last year.

Looking now to the balance sheet, we closed the quarter with cash, cash equivalents and short-term investments of $60.2 million, which compares with $74.2 million as of December 31, 2013.

During the first nine months of 2014, we used $10.6 million in cash to fund operations in R&D and $2.4 million for capital expenditures.

Moving on to our financial guidance. As reported in our press release, we're affirming guidance for total revenue for the year ending December 31, 2014, to be between $70 million and $72 million with revenue from the distribution segment to be between $25 million and $26 million and revenue from the proprietary products segment to be between $45 million to $47 million.

As I mentioned earlier and as implied from our guidance, revenues in the fourth quarter are expected to be higher than in the previous quarters of 2014.

With that overview of our financial performance, let me now turn the call back to David.

David Tsur: Thank you, Gil. We're pleased with our progress and our strong financial foundation from which to grow revenues and fund investment in our very promising clinical development program.

First, let's look at our growing core commercial business. During the quarter, we achieved a number of milestones that serve to enhance our core revenue base over the coming quarters and beyond. We're very pleased to announce the second extension to our strategic agreement with Baxter for Glassia to treat Alpha-1 deficiency in the U.S..

In addition to the significant increases to Baxter's purchase obligation, Baxter has extended the agreement throughout 2017 and the transition to royalty payment for Glassia produced by Baxter is not expected to begin before 2018. Until that time, we will continue to produce Glassia for distribution by Baxter. We are confident in our ability to support the increased demand from Baxter throughout the term of the amended agreement.

Earlier this year, we had an important commercial advancement with the FDA approval of enhancements to our manufacturing processes. These enhancements support efficiencies and provide for a nearly 50 percent increase in capacity.

Over time, this should allow us to improve profitability and provide ample supply for the growing sales of our proprietary protein plasma therapeutics and for our expanding clinical development progress.

During the second quarter, we received FDA approval of a meaningful enhancement in the infusion rate for Glassia following the study conducted by Baxter.

For an average adult patient weighing approximately 70 kilogram, the new infusion rate reduces the weekly infusion time from 70 minutes down to about 15 minutes. We expect this change to potentially drive additional revenue in the coming years, even beyond the new minimal revenues in the agreement.

This is a $750 million market that is growing at approximately 10 percent a year due to better diagnostics and non-branded disease awareness. The reduction in the infusion time along with the product's ready-to-infuse features give Glassia a significant competitive advantage and strengthens the strategic partnership between Kamada and Baxter.

In addition to expanding sales of Glassia in the U.S., we continue to increase sales of Glassia in the six other countries around the world where we market new products due to Glassia ready-to-infuse formula and enhanced infusion rate, give it a competitive edge.

Importantly, to improve infusion rate, can be used for future indications for Glassia as we know Glassia is currently in clinical trials as a treatment for Type 1 diabetes and for Graft-versus-host-disease, GVHD, which leads me to a discussion of our clinical development program.

We're advancing our comprehensive clinical development plan featuring a mix of early and late-stage programs in orphan indications with unmet medical needs. Let me begin with one of our most advanced program, which is the completed Phase 2 study of KamRAB.

Our prophylaxis against rabies is administered after exposure or contact with an animal suspected of being infected with rabies. We have a strategic agreement with Kedrion Biopharma for the clinical development and marketing of KamRAB in the U.S..

We expect to report top line data from this study by year end and to file a Biological License Application, BLA, with the FDA in the first half of 2015. In the U.S., there is approximately 40,000 post exposure prophylaxis treatment administered each year representing $100 million market opportunity.

There is only one significant provider of anti-rabies immunoglobulin in the U.S. and we believe health care providers will want to diversify their source of supply particularly if competing high-quality products were approved for use.

There are other opportunities to grow with KamRAB as the World Health Organization estimates that approximately 10 million people worldwide required a medical treatment against rabies every year after being bitten by animal suspected of rabies infection.

Turning now to another late-stage program under development, our inhaled Alpha-1 to treat Alpha-1 deficiency. In September, we reported the final data analysis from our European Phase 2/3 study of inhaled Alpha-1 to treat Alpha-1 deficiency.

Although the study didn't meet the primary and secondary end points, important lung function parameters showed concordance of a potential treatment effect in the reduction of an inflammatory injury to the lung that is known to be associated with reduced loss of respiratory function.

Based on orphan designation by our discussions with the regulator, the additional know-how we gained of this data and the persistent unmet needs in this indication would advance discussion with European Medicines Agency, EMA, with the intent of submitting for conditional approval.

We continue to prepare for discussions with our peers and the EMA regarding potential European filing and potential commercial launch with a positive regulatory review and regulatory reimbursement, we believe our inhaled Alpha-1 product faces a significant market opportunity in the hundreds of millions of dollars in Europe alone.

We look forward to having regulatory clarity from the EMA by year end and will determine our pace forward in the indication based on our exercise and interactions.

We are encouraged by the data as it demonstrate improvements in lungs function parameters that were thought not to be attainable in a study of such short duration and in so few patient studies.

In parallel, our activities for the U.S. market remain on track as we continue to enroll and treat patients in our U.S. Phase 2/3 clinical inhaled study of Alpha-1 to treat Alpha-1 deficiency. The study is testing for PK parameters in epithelial lining fluid and serum as well as for safety and tolerability.

This is an important study that the FDA requires for approval. We look forward to completing enrollment of this study by the beginning of next year and driving data in the second half of next year. We intend to use this study data along with those from the European Phase 2/3 study to discuss regulatory (inaudible) in the U.S. with FDA.

Moving to our development plan Glassia and important new indications, we have very exciting clinical and program underway with Glassia to treat newly diagnosed pediatric patients with type I diabetes, an often indication for which there are approximately 100,000 newly diagnosed cases each year according to the U.S. Centers for Disease Control and Prevention. We continue to enroll patients in our Phase 2/3 clinical trial of Glassia for this indication.

Preliminary data as well as ongoing data from the extension portion of the Phase 1/2 clinical study continues to demonstrate that approximately 20 months from diagnosis and approximately 10 months following the last Glassia infusion there are an indication of functioning better cell capacity that is considered to be higher percentage than would be expected without intervention.

The recent publication of the literature review in support of the mechanism of action of AAT in the treatment of type I diabetes in the peer reviewed Journal of Diabetes Science and Technology provide the scientific rationale that corroborates the positive clinical result achieving the Phase 1/2 clinical study

and validates our enthusiasm as we continue to enroll patients in our Phase 2/3 clinical study.

A number of recent studies support the rationale for treating type I diabetes early in the disease diagnosis or the honeymoon period during which a critical mass of functional beta cells exists, it is hypothesized that Glassia may halt pancreatic inflammation thereby allowing the survival of active and operating beta cell that secrete insulin, so a survival which may allow the patient to reduce dependence on external insulin and eventually decrease disease complications.

With this supporting mechanism of action data we remain even more encouraged with Glassia can be ground breaking treatment for newly diagnosed type I diabetes in pediatric patients as it should demonstrate the ability to halt disease progression and allow the pancreas to produce it's own insulin.

In addition, we are currently evaluating Glassia in the Phase 1/2 clinical study being conducted by Fred Hutchinson Cancer Center in collaboration with doctors. So naturally we are very pleased with the receipt of a U.S. orphan drug designation from the FDA for Glassia to treat GVHD as it is a key milestone that support our broader regulatory development strategy.

The Phase 1/2 study is evaluating 24 GVHD patients with inadequate response to steroid treatment following allogeneic bone-marrow stem cell transplant. The patients are enrolled into four dose cohort in which they receive up to eight doses of Glassia. The interim data from this study is expected by the end of this year.

Glassia is expected to decrease GVHD related symptoms including progressive tissue damage and thereby potentially increase survival rate and possible reducing the – or eliminating the need for steroid therapy. There are no drugs specific for GVHD approved by the FDA and current treatment a serious adverse event. The search for an effective, treatment continues in the area of unmet needs with a market opportunity in excess of $500 million.

In addition to GVHD, results from our Phase 1/2 study may support global clinical development activities and may serve as a platform to apply for an expansion of the AAT indications to include general organ transplantation, based on similar mechanism of action.

In conclusion, we remain focused on executing our strategy to balance continued growth from our core commercial products on advancing our clinical development programs. The expected increase in Glassia sales and the solid growth in distribution products revenue highlight the growing value of our core protein therapeutic business.

In addition, we have robust clinical development program, which includes several studies underway to support expansion of intravenous Glassia to include type I diabetes and GVHD, two areas of unmet need. Together, these strengthen our leadership position in plasma derived Alph-1 therapy to treat orphan drug indications.

We look forward to achieving several milestones during the fourth quarter and to reporting to you on our next call. And now, Operator, please open the call for questions.

Operator: OK, ladies and gentleman, if you wish to register for a question for today's question and answer session you will need to press star then the number one on your telephone keypad.

If your question has been answered and you wish to withdraw your polling request you may do so by pressing the pound key. If you are using a speaker phone please pick up your handset before entering your request. One moment for the first questions

David Tsur: While we are waiting for our first question, I would like to note that we will be participating in the upcoming Jeffries Global Healthcare Conference taking place November 19 to 20 in London. For those attending the conference and would like to meet with us, please reach out to your respective Jeffries representative or contact Anne Marie Fields from LHA.

Operator: Our first question come from the line of David Lewis with Morgan Stanley.

(James): Thanks for taking the question. This is actually James in for David. First off, I wanted to talk a bit about gross margins. Obviously, margins in the past two quarters have been a bit weak, really for the whole year frankly, have been a bit weaker than have been historically. Some of that has had to do with product mix in this quarter, but even isolating out the proprietary products GMs it does seem to be a bit softer.

So I was hoping that you could comment on now that you have the new Glassia manufacturing process in place, what are the potentials to drive efficiencies or improvements in margin for that product over time, and perhaps more broadly when you think about gross margin is this simply going to be a function of fluctuating product mix going forward or are there opportunities for structural improvements and margins?

Gil Efron: Thank you James. I agree there is a variance of between the gross margin in the different quarters and if we look on Q3 of this year compared to Q2 and then we have an improvement in gross margin, of course a significant portion of it is due to the one time write-off in Q2. But also excluding and eliminating it, it is a steady improvement compared to Q2 and even to Q1 of this year.

One of the challenges in with gross margin at this level of revenues is that it's a crucial (inaudible) the gross margins. So the more we increase our revenues and I look specifically on the proprietary products, that will then increase profitability.

If we compare that to previous year, gross margin in Q3 of this year we were at the low level that we were at the beginning of the year, for example in Q1 of 2013, and this has to do with the product mix between the product and the proprietary products, and also the product mix between the proprietary products and the distribution segment.

And then if we can look more deeper into specific quarters where there were other effects but this is I think the main picture. So going forward if we look on increasing volume of revenues that will drive an improvement in gross

margins, the approval of them improve the production and processes that David had mentioned should also help us improving our gross margins. And if we look, for example, into the fourth quarter increasing revenues and specifically revenues from Glassia should drive up our gross margins going forward.

(James): Thank you, that's very helpful. Second, I wanted to talk about rabies hyperimmunes and I think it might be helpful if you could talk a bit about what a reasonable share expectation might be in the U.S. market or more broadly why you're confident that you can take share and is there something in terms of product differentiation that as we get close to the data publication that we should be looking for in terms of things that would play out in the data?

Gil Efron: Thank you. We do hope and look forward to share with you the top line data before the end of the year. And the product is already registered and sold in different countries, and based on our experience in each of the countries where the product was launched, introduced, we gained approximately 50 percent and maybe more market share.

So it's a high quality product and if we are competitive in markets where the price is maybe 25 percent of the U.S. market, we expect that we will be extremely competitive in the U.S. market. And with a strong partner and only one competitor, we believe that with time we can gain an important market share.

(James): So should I take your comments about regional pricing differentials to suggest that your competitor strategy in the U.S. will be at least partially predicated upon favorable pricing?

Gil Efron: And not necessarily. For us, rabies is an important product, I think much more important than for the competitors. Sometimes there were problems of availability because they produce maybe limited quantities and we produce only at around and very large volumes for other countries and this is the same product that we supply to rest of the world, which really supply to U.S. market.

And we believe that quality is good, and the hospitals and the customer would like to see two players in the market. And it is basically availability, quality then I think that definitely will be not only price, we do not expect important price differentiation.

(James): Understood. Well, thanks for taking the questions. I'll let some others jump in.

Operator: Our next question comes from the line of Yigal Nochomovitz with Oppenheimer.

Yigal Nochomovitz: I just had a quick one on the Baxter agreement. You mentioned you have announced the second extension. Is there anything in the structure of the agreement with them that suggests you could have additional extensions beyond what you have already agreed to?

David Tsur: Yes, maybe. We work really closely with them. We expand our capacity to meet larger demands and the product is very well accepted in the market. If the market grow over 10 percent, our market share and number of product sold to Baxter are much higher.

So it will be discussed every year based on long-term planning. So definitely this might be the case. We can support increased demand, and Baxter and the medical community are very happy with the quality.

Yigal Nochomovitz: OK. Great and then just on AATD and your discussions with the EMA, have you had any interaction since reporting the full data with the European regulators, and is there a firm meeting schedule with them to discuss the application in the next several months?

David Tsur: As reported, we will have meetings with them before end of the year and we will be glad to update you soon after our meetings. Yes, there is a specific schedule and meetings are scheduled for December.

Yigal Nochomovitz: Great, thank you.

Operator: Our next question comes from the line of Adnan Butt with RBC Capital.

Adnan Butt: Couple of questions. First on Baxter, could you say a bit more in terms of the relationship there both in terms of the demand trend that they see for Glassia, as well as their readiness to take on the manufacturing?

David Tsur: Yes, in terms of this demand from Baxter, we reported that we see growth in the number of patients treated which is the growth is higher than the growth in the market, and this is something we discussed.

There is a improved infusion rate that we believe is very well accepted. And in terms of Baxter readiness to produce at their facilities, this is something that has to do with them – with Baxter and we cannot discuss it.

Adnan Butt: But the plan is still for them to eventually take on the manufacturing or is that to be determined?

David Tsur: Yes, I think. We don't know the specific schedule, but they have been investing in the plant and if you visit the Baxter selling both Aralast and Glassia, but if you visit exhibitions and conferences, you will see that they are promoting on the Glassia.

Their all new patients are on Glassia and Glassia is very well accepted and they take the necessary time to complete their facilities, having confidence that we can meet the increased demand in the figures mentioned are the minimal, and we expect the actual quantity and hoping that will be much bigger.

Adnan Butt: OK. Thank you that's very helpful. In terms of any discussions with the U.S. FDA for inhaled AAT, would that await the Phase 2 data that would be coming next year?

Pnina Strauss: This is Pnina. Phase 2 study is currently ongoing and we expect the result of the Phase 2 sometime late 2015. Whether the discussions with the FDA with regard to the trial, the inhaled trial, will encompass these results or not, that really depends on the timing of these discussions. But definitely the

discussions will include the considerations, the information that will arise from the Phase 2 study in the U.S..

David Tsur: And we plan to have these discussion with the FDA during the first half of next year.

Adnan Butt: OK. Thank you so much.

Operator: As a reminder, if you wish to register a question please press star then the number one on your telephone keypad. And there seem to be no further questions at this time. Please proceed with your presentation. I would like to turn the call back over to Mr. Tsur.

David Tsur: Thank you for your questions and your interest in Kamada. We look forward to updating you again when we report our fourth quarter and full-year 2014 results early in next year. Have a good day. Thank you very much.

Operator: Ladies and gentlemen, that concludes your conference call for today. We thank you for your participation and ask that you please disconnect your lines.

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