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Alkermes 2Q03 Financial Results
Conference Call Script
Moderator: Rebecca Peterson
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8:30 am Eastern Time

Operator: Ladies and gentlemen, thank you for standing by. Welcome to the Alkermes Second Quarter 2003 Financial Results conference call. At this time, all participants are in a listen-only mode. There will be a question-and-answer session to follow. Please be advised that this call is being taped at Alkermes request. At this time, I would like to introduce your host for today s call, Ms. Rebecca Peterson, Director of Corporate Communications at Alkermes. Please go ahead.

REBECCA: Good morning and welcome to Alkermes conference call to discuss our financial results for the second quarter of fiscal 2003. I m Rebecca Peterson, Director of Corporate Communications of Alkermes and with me this morning is Richard Pops, our CEO and Jim Frates, our CFO. During this call, Richard Pops will provide some introductory comments, then Jim Frates will review our financial results for the quarter and

discuss our financial guidance for the remainder of fiscal 2003. Richard Pops will then review the recent highlights of the quarter. We will then take your questions.

Some of the statements that we will make during this conference call contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. While we believe that our expectations in making these statements are reasonable, actual results could vary materially from expectations as a result of a number of factors, including, but not limited to, whether the issues raised in the non-approvable letter for Risperdal Consta can be resolved in a timely manner, if at all; actions by our partners with regard to marketing and regulatory filings; whether sales of Risperdal Consta will reach the expected levels; whether the exchange offer we announced this morning will be successful and achieve its intended results; decisions by the FDA or foreign regulatory authorities regarding our product candidates; the outcome of clinical and preclinical work we are pursuing; whether product candidates that seem promising now will result in approved, marketable products; potential changes in cost, scope and duration of clinical trials; and decisions we make about the timing and scope of proprietary product development. For a more detailed list and description of some of these risks and uncertainties, please see the reports filed by Alkermes with the Securities and Exchange Commission. Alkermes disclaims any intention or obligation to update or revise any forward-looking statements.

Now I d like to turn the call over to Richard Pops.

RICHARD: Thanks Rebecca. I wanted to make a couple of remarks prior to turning the call over to Jim in order to give you a sense of the intensity of the activity here at the company. There is a tremendous amount of energy at Alkermes now as we turn the corner from what was a surprising occurrence this summer with the receipt of a non-approvable letter from the FDA for Risperdal Consta and get back on plan.

We are actively managing this business, and you are beginning to see some of the results. We feel very strongly that we are emerging from this period a stronger company. Why? Because we have taken this opportunity to evaluate our business from top to bottom, to focus in on our most important opportunities and to manage towards profitability. I will cover specific projects in a bit more detail later, but in quick summary, here are the three key things that you should be aware of that we have been focusing on and acting on in the past four months:

1. Risperdal Consta: An incredibly important product for us. Obviously from an economic point of view, but what gets lost sometimes in the focus on economics is the importance of the product from a medical point of view. As the product launches in markets around the world

and begins to be used by patients and physicians, we are being reminded of the need for this product and of its significant medical value. Now approved in 8 countries and launched in 3, with more on the way. Johnson & Johnson has great expectations for this product and we are getting our first indications of the interest in the product from the marketplace. J & J is very determined to gain approval for this product in the United States. A tremendous amount of work has been done since July 1, and we are very encouraged by the data, the feedback from outside consultants, the commitment of the project teams and J & J management. At Alkermes large-scale production facility in Ohio, we are manufacturing commercial quantities and are preparing expanded facilities and personnel to support this brand at significant projected sales levels on a global basis.

2. Other partnerships. This summer, we took a look at every one of our partnerships with the idea of focusing our resources on those with the highest expected net present value. That analysis, and the resulting series of discussions with our partners, is drawing to a close. We expect to move forward with J & J, obviously, with Risperdal Consta. We are conducting a Phase III clinical trial of Nutropin Depot in adult growth hormone deficiency in collaboration with Genentech. We have been generating exciting data with Eli Lilly in both of our pulmonary programs: insulin and human growth hormone, and we are excited by our opportunities there. AC2993, in collaboration with Amylin, is an

important program. We are moving ahead with Serono on the development of ProLease rh-FSH. An area of concern is GlaxoSmithKline. We have a collaboration with them that covers four areas in the field of respiratory products. This collaboration is not moving at a pace that we are satisfied with. Based on the diligence provisions of the contract that were negotiated to provide for this circumstance, we have the opportunity to reclaim two of those fields from GSK at the end of this month, and we plan to do so. The other two fields also have diligence provisions but remain under the control of GSK. Because we have developed encouraging data in this program, we are looking forward to having the freedom to operate again in these fields.

3. Balance Sheet. We ended the September quarter with $80.9 million of cash. Notwithstanding the fact that we have significant additional assets that do not show up in that number, namely approximately $150 million of guaranteed payments from J & J, Risperdal Consta coming on stream around the world, $123 million of plant and equipment assets on the balance sheet and the $100 million investment we made in Reliant Pharmaceuticals at the end of last year, we want to strengthen the balance sheet. For this reason, we announced today an innovative transaction that takes advantage of the current market conditions. If completed, the exchange offer announced today will enable us to exchange our $200 million of outstanding convertible

notes for $115 million of new 7 year notes. In addition, it provides us with the flexibility to raise up to another $50 million if we choose to. Importantly, the structure is designed to enable us to be debt free once our stock price trades above a set price for 20 of 30 trading days. That price, along with other specific parameters, will be set based on market pricing at the time of the completion of the exchange, but if it were to happen today, the price would be approximately $20 per share. We are taking advantage of the confluence of our confidence in Risperdal Consta, the current pricing of our bonds and the increasing strength of our common stock, and we believe that the timing is right for this type of exchange now. Our goal is to exchange the existing convertible notes for new ones that provide us with the opportunity to emerge debt free and well capitalized long before maturity. So, there has been a flurry of activity since July 1, and we are quite energized. We continue to face significant risks and uncertainties, as always, and I do not want to suggest otherwise. But I did want to let you know that we are making good progress and that there have been significant positive developments since the end of the June quarter. With that as a preamble, I will turn it over to Jim Frates.

JIM: Thanks Richard. We believe with our restructuring and our focus on our key products we are on track, focused on our goals of profitability. So, first I will review the financials for the quarter and then discuss our financial guidance for fiscal 2003.

Research and development revenue under collaborative arrangements was $9.5 million for the three months ended September 30, 2002 compared with $14.5 million for the same period last year.

The net loss attributable to common shareholders was $67.8 million or $1.05 basic and diluted loss per common share compared with $12.6 million or $0.20 basic and diluted loss per common share for the second quarter of last year. We do include a portion of Reliant s losses in our income statement and we had two non-recurring charges in the second quarter, so the net loss for the quarter excluding the $35.3 million noncash charge related to our share of Reliant s losses, the write off of $2.7 million in deferred merger costs related to the termination of the our proposed merger with Reliant and a $3.7 million restructuring charge was $26.2 million or $0.41 basic and diluted loss per common share. The increase in the net loss was primarily a result of an increase in R&D, combined with a decrease in revenues as the Risperdal Consta program evolves from a development stage project into a commercial program.

At September 30, 2002, we had total cash and investments of $80.9 million versus $118.7 million on June 30, 2002. The decrease is a result of our quarterly operating loss, our nonrecurring charges such as severance associated with our restructuring and an investment in $10 million in capital expenditures in the quarter. As Rich mentioned, we also have a number of assets which we can monetize over time, if necessary.

These include our 19.6% ownership interest in Reliant as well as $123 million of fixed assets and the stream of minimum revenues our partnership with Janssen insures now that Risperdal Consta has been approved in Germany and the U.K.

We are also taking proactive steps to deal with our capital structure. Earlier today, we announced the filing of registration statements with the SEC for a proposed exchange offer of $115 million of face amount of 6.52% convertible senior subordinated notes due in 2009 for our $200 million face amount of our currently outstanding 3.75% Convertible Subordinated Notes due in 2007 and are offering to our exchanging note holders the ability to purchase up to an additional $50 million of new notes for cash. As Rich mentioned, if the exchange offer and the cash offer are consummated, fully subscribed and achieve the results we intend, this transaction will lower our debt obligations while making the conversion into equity much more likely in the near term given our view of Alkermes prospects. In addition to this exchange we are offering to exchanging note holders the ability to purchase up to $50 million of additional new notes for cash. So when we close this transaction, if all goes according to plan, we will have $165 million in debt and an additional $50 million in cash on the balance sheet. If we are not reviewed by the SEC, this transaction could close as early as mid-December.

At the time the exchange offer is commenced, we will file a Tender Offer Statement with the SEC. The Tender Offer Statement, including the related prospectus and other documents, will contain important information about the exchange offer and the cash offer. We will make the prospectus and related documents available to all holders of our existing convertible notes at no expense to them. The Tender Offer Statement, the prospectus and all related documents filed with the SEC will also be available for free at the SEC s web site at www.sec.gov.

Guidance

Let me move on and provide you with financial guidance for Alkermes for fiscal 2003. As you know, we have not updated guidance since July when we learned of the delay in Risperdal Consta in the United States. Now that we have a better understanding of the timeline for Risperdal Consta, we can give you updated guidance.

Revenue. Our revenue projection for Alkermes for the full fiscal year 2003 ranges from $45-50 million (down from our previous guidance of $70 to $75 million). The decrease in research and development funding is as a result of an expected decrease in funding from partners as well as the delay in Risperdal Consta in the United States. As Rich stated, we have engaged in an overall strategic review of our pipeline and partnerships to make sure that those expected revenue sources are as solid as we can predict.

We project that our research and development expenses for fiscal 2003 will be approximately $100-105 million (down from previous guidance of $105-115).

The decrease is primarily attributable to the review of our pipeline, and also includes some costs related to the expansion of our commercial facilities both in Massachusetts and in Ohio.

G & A. We project that general and administrative expenses for fiscal 2003 will be about $25 million on an operating basis and roughly $28 million when we include the one time fees and expenses associated with our previously announced termination of our merger with Reliant.

Projected Net Operating Loss. Thus prior to any noncash charges associated with Reliant and our restructuring charges, we anticipate recording a net operating loss of between $80-85 million in fiscal 2003.

While we do not typically give guidance beyond our current fiscal year, due to all the variables that can affect our business, our best estimate for fiscal year 2004 is an operating loss ranging from $35 to $40 million below this year s projections.

Finally, as our pipeline continues to expand and mature and as we begin to receive revenue from sales of Risperdal Consta, we continue to aim for break-even to profitability in calendar year 2005, though I will reiterate that that guidance is highly dependent upon the timing and nature of the launch of Risperdal Consta in the US.

With that, I will turn the call back to Rich.

RICHARD: Thanks, Jim. We will finish with an update on our pipeline.

Risperdal Consta

The key events of this quarter were the first approvals and launches of Risperdal Consta and J & J s receipt of the non-approvable letter in the US.

As most of you know, Risperdal Consta is our long-acting formulation of Johnson & Johnson s atypical antipsychotic Risperdal and is intended to improve compliance and reduce relapse among schizophrenic patients. The long-acting formulation is made possible by use of Alkermes Medisorb® drug-delivery technology.

In August of this year, Risperdal Consta was approved and launched in Germany, the United Kingdom and Austria. It has been approved in Switzerland, New Zealand, Mexico, and the Netherlands and we learned yesterday of its approval in Iceland. So far both we and J & J have been pleased with the results, though the data are limited. When we asked J & J to give us a way to characterize the early data, the response was that the product is exceeding their expectations in the markets where it is being sold.

Both we and J & J are optimistic about the commercial prospects for Risperdal Consta. With respect to timing of potential approval in the US, J & J has requested that we not give specific guidance at this time. We have told anyone who has asked that we are actively encouraging J & J to provide such guidance and we expect them to be willing to do so at some time. Please do not confuse J & J s reluctance to disclose their plans with the intensity with which they are pursuing the various alternatives.

In the meantime, separate from the regulatory activity, we are manufacturing commercial quantities of Risperdal Consta and expanding our facilities in Wilmington Ohio to accommodate J & J s projected worldwide demand. This expansion is well underway. When we are done next year, we will have manufacturing capacity to supply J & J with Risperdal Consta sufficient to generate peak revenues to Alkermes well in excess of $100 million per year.

Now let me move on to some important points regarding other aspects of our pipeline.

As you know, a key element of our strategy is to develop a pipeline of proprietary products products we develop on our own, based on our drug delivery technologies and whose increased therapeutic value we can capture for our own account.

The most mature product in our proprietary pipeline is Vivitrex , our extended-release formulation of naltrexone, used for the treatment of alcohol and opioid dependence that is currently available in daily oral dosage form. We designed Vivitrex to provide therapeutic concentrations of naltrexone over a one-month period, and have tested it in Phase I and Phase II clinical trials. The product candidate is based on the same delivery system as Risperdal Consta, and leverages our extensive formulation and manufacturing experience with that dosage form. Vivitrex is currently in Phase III trials. Enrollment is proceeding very

well and we plan to enroll the full complement of 600 patients. We expect that this enrollment will be complete in the first quarter of calendar 2003. With a six-month endpoint to this study, we would therefore expect to announce results in the second half of 2003.

As you may know, we have other proprietary programs underway which we have not announced. Yesterday we disclosed for the first time the existence of one of these products, an inhaled formulation of epinephrine that we are quite excited about. In the press release, we announced the successful completion of a Phase I study of the product candidate, which we call AIR Epinephrine. The inhaled formulation offers an alternative drug delivery method for epinephrine, which is currently self-administered by injection for the treatment of anaphylaxis, a sudden, potentially life-threatening allergic reaction. AIR Epinephrine was developed using our novel AIR technology for the pulmonary delivery of dry powder aerosols composed of large porous particles. We believe that this product could offer important therapeutic advantages over the current widely used injectable form of epinephrine. We have completed two studies of AIR Epinephrine and have met with regulatory authorities in the US and in Europe with respect to its continuing development. We intend to continue to develop this product for our own account. Given our projections as to the ultimate commercial opportunity for this product candidate, we will consider co-development and marketing opportunities with companies that could enhance the value of the brand.

I think I will stop here. We continue to make progress in our other programs, but instead of taking you through every product candidate, I will stop here and open it up for questions. In closing, we are deeply committed to building this company leveraging a superb capability in advanced formulations into a portfolio of important products. In collaboration with pharmaceutical company partners, and, importantly, for our own account as well.

Operator?

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