

KING PHARMACEUTICALS INC

Form DFAN14A

October 23, 2002

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**SCHEDULE 14A
(Rule 14a-101)**

INFORMATION REQUIRED IN PROXY STATEMENT

SCHEDULE 14A INFORMATION

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MERIDIAN MEDICAL TECHNOLOGIES, INC.

(Name of Registrant as Specified in Its Charter)

KING PHARMACEUTICALS, INC.

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**KING PHARMACEUTICALS, INC.
Conference Call
Question and Answer Session
October 21, 2002
9:00 am E.D.T.**

- Operator: Very good. At this time we will now begin the question and answer session. We will take our first question from the site of Mr. Greg Gilbert of Merrill Lynch.
- Greg Gilbert: Thanks. Good morning. I have a three-part question. Could you quantify the commercial versus government revenue, first? Second, can you give us any color on quantifying the level of synergies and/or the timing of those synergies, given that it may take a while to get the manufacturing integrated? And finally, what is the timing for the filings of the migraine product and the nerve gas antidote for the commercial market?
- Jefferson Gregory: Okay Greg, let's see. We have got first to try to quantify a percentage of the commercial versus government revenue. Jim, do you think you can do that?
- James Lattanzi: Sure. The commercial revenues are roughly half of the revenues. They were approximately \$40 million in 2002. The government revenues were approximately \$37 million in 2002.
- Jefferson Gregory: Okay. Timeline for synergies I think that the company should be able to begin to realize synergies next year, pretty quickly, I think because of their facility that they are in, and that we have a facility that is available near them in St. Louis. That is the previous Jones facility. And we intend to move the Meridian operations into that facility.

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Right now Meridian is currently in a number of I guess they are best categorized as cabana buildings or something, around about a four or five block area in one of the business parks in St. Louis. And we think that presents a pretty inefficient operation.

And also, since we already have the (Jones) facility, I think it is about 150,000 square foot facility, all under one roof, with a CGMP approval from the FDA. It seems to us to make sense to move all their operations in there.

We think that is going to improve the efficiency of their operations, also, be able to improve the overall capacity of what they can produce out of their operations, and also decrease some of the costs, because we won't have to carry the lease overhead that they currently have in the business park.

There are other synergies that can be created too. But I think we will begin to see some of those in 2003. What was the third question Kyle?

Kyle Macione: The filing of the nerve gas.

Jefferson Gregory: The filing of the nerve gas NDA you mean, and the migraine product? I think the migraine product looks like it is some time in about 2004. And the nerve gas filing I think is a 2003 type of thing. But we are going to be meeting with the FDA to talk to them about it.

Currently the product is the nerve gas antidote product is not approved under an FDA filing, under an NDA in the United States. So the public generally cannot buy it. Only governments can buy it. And we believe that it might be important to talk to the FDA. And in fact we know that the FDA would consider such a filing from the company.

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How much work they would require on that, we are not certain at this point, since the product has been generally used for some time. I don't think that they are going to require any clinicals. But we will have to see.

We have yet to schedule a meeting with them. But I would expect that we would get a meeting with the FDA before the end of the year, because I believe that they think this is an important issue.

We also would like to try to bring forward a pediatric dose for the product. That will require a filing as well. And it is our understanding that the FDA would well receive such a filing. Okay? Other questions?

Operator: Yes. Our next question comes from the site of Cory Davis of JP Morgan.

Cory Davis: Good morning. Just I am having trouble getting to your accretion of two cents in '03 before synergies. Maybe you can help us out a little bit more with what your revenue assumptions are for that, or at least how long you are going to amortize the purchase price over.

James Lattanzi: Well the purchase price is going to be amortized on average over 20 years. But there is an element of in process R&D, and an element of good will that needs to be factored in Cory. So I think the amortization per year is roughly going to be around \$5 million.

Cory Davis: Okay. Well that's a lot lower than I thought it was going to be. So that two cents of accretion is really on an as reported basis, not a cash EPS type of thing.

James Lattanzi: That is correct.

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- Cory Davis: Okay. And then my next question is, just in thinking about where the revenue is going to go, I would imagine that the stuff going to the government is not being used, but just being stockpiled. So how sustainable is that growth into the government sales?
- Jefferson Gregory: It is very steady. It is steady on an annual basis. I think I mean it has little spurts associated with it, because they will put in an order. But I think what you are seeing is a pretty steady purchase on an annual basis. And it has also been growing a little bit, because of the purchase of some foreign governments that they are now selling to.
- And we are really not putting much in there right now in our calculations for homeland defense, which actually could be quite significant.
- Cory Davis: Okay. And on the commercial side, for the EpiPen®, is there any chance to restructure your deal with Dey? Or are they going to continue to sell it? And maybe you can just break down the financials on what the profit split on that one looks like.
- Jefferson Gregory: I think that Dey has done a real good job on it. I think that they get a royalty that is pretty sizeable for the product. And Dey currently has about 200 sales reps in the pediatric marketplace that are aggressively promoting the product in a primary position.
- So while there might be an opportunity to talk about restructuring the transaction or approaching Dey about the product, I think Dey has just done an excellent job with the product, in creating a preeminent position. And they continue to do so on a regular basis. And Meridian gets the benefit on it. It is a pretty sizeable royalty that they get for the production on the product.

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Cory Davis: So you actually book all of the revenues for EpiPen® and then just pay them out through the cost of goods line?

Jefferson Gregory: No. They book the revenues, and pay us a royalty.

Cory Davis: Okay. So is there any cost of goods associated with the EpiPen®?

Jefferson Gregory: Yes there are.

Cory Davis: Because you do the manufacturing.

Jefferson Gregory: Yes. And the revenues for EpiPen®, roughly 36 million, margins roughly 50%

Cory Davis: And last question is Meridian doesn't have any field sales reps right now. Is that correct?

Jefferson Gregory: Right.

Cory Davis: Okay. Thanks guys.

Jefferson Gregory: Mmm-hmm.

Operator: Our next question comes from the site of Michael Tong of Wachovia Securities.

Michael Tong: Hi. Just a little bit of a longer-term question. As you wait for the approval of the DiaJect® product, first of all what can you give us a little bit more clarity as to when that might be in '03? And how do you see that product being positioned in your current sales force, when that approval becomes real?

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Jefferson Gregory: Yeah. I think that we would hope to see that approval in the first half of '03. The filing was in the very early part of '02 on that product. And we would position it in with a sub-group we would section off about 100 reps who would not only promote our other products, but also promote the DiaJect® product, and try to hit into the epileptic marketplace, as a product to help to prevent seizures for epileptics to carry in their pockets.

Michael Tong: If I can just quickly follow that. I mean if I looked at Altace®, Levoxyl®, Ortho-Prefest® and DiaJet®, how do you see that being positioned within the various compartments of your sales force, so to speak?

Jefferson Gregory: Well I would see it positioned with a split off group of reps that we would be getting. We do intend to continue to grow our sales force at King. And I would consider that to be a product that we position with part of that growth unit that we are going to have.

Michael Tong: Great. Thank you.

Operator: Our next question comes from David Maris of Credit Suisse First Boston.

David Maris: Good morning. Just if I could step back for a second, if you could talk a little bit about your Jones Pharma acquisition and the timing of how long it took for you to go in and really figure out what the cost synergies were; how long it took to realize those and where you are in the process with Meridian on that as well?

And how long you saw or you anticipate seeing the benefits of lowering margins from that acquisition and if that is translatable into this acquisition as well?

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Jefferson Gregory: Any of you guys want any of that?

James Lattanzi: In terms of the Jones integration, David, that transaction was closed in October of 2000. And by July 1st of 2001, that transaction was fully integrated into King. And we realized the synergies, although the Jones acquisition was not about synergies but no more synergies that were realized.

Kyle Macione: It's right. The Jones acquisition, in terms of cost saving synergies, there has been some realized over time. But as you know, David, the primary addition of the Jones transaction related to products with good growth potential. But there were there have been synergies realized over time, in a rather short time frame as Jim described.

David Maris: In other words, then you would see this as a slightly more abbreviated process and possibly greater cost savings from a percentage of operations?

Jefferson Gregory: Yeah. I'd say that's a good characterization. I think that there are better synergies in this transaction than were presented in the Jones transaction.

And I think that Meridian, which has kind of come from a contract manufacturing background, has really positioned itself over time to really sort of take the next step into getting to be able to market their own products, achieve certain growth as a result of homeland security markets, not just as a result of the good relationships that they've developed with the Department of Defense and that part of the business.

And I think that this is a natural transformation for their assets at this point, to bring them into King and allow our additional infrastructure to be able to help

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them grow and to be able to help the growth of their capacity to be able to produce more products which is also a little bit of a constraint on them.

David Maris: Great. Well, thank you very much and congratulations.

Jefferson Gregory: Sure thing.

Operator: We'll take our next question from Maria Phillips of BOA Securities.

Maria Phillips: Hi. Thank you. Regarding EpiPen®, can you give us a sense of what that market has grown? How that market has grown over the last couple of years? And also the government market, how it's grown over the last couple of years and what you anticipate going forward? And also back to EpiPen® for a moment, what is its patent or exclusivity position? Thank you.

Jefferson Gregory: Yeah. Well, first of all, EpiPen® doesn't have a patent on it. They own the NDA on it. The trademark is owned by Dey. There is no patent on it. But I believe the overall market is a little over \$100 million right now in total revenue. It has been growing at close to about 10% a year. So it's a nice little market, a nice little niche market. And I think Dey's done a real good job with it.

There is a I think well, one of the concerns in the transaction is there is a near-term competitor that we believe will be coming out, that's a device from Hollister-Stier. We believe that they could get approved before too long. But it will not be an ANDA-type of product, a knock-off of EpiPen®. They'll have to do their own marketing on the product and try to grow it.

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So it's not substitutable really for EpiPen®. In other words, if somebody writes EpiPen®, you just can't give somebody a Twin their product called TwinJect®. You'd have to actually get the doctor to rewrite the prescription.

So I think that EpiPen® still has a pretty exclusive market. They've dominated the marketplace for, you know, 20-25 years; I think they're going to continue to do that pretty well. The product is pretty unique from that perspective. And because of the Dey marketing, I think that they've done a really good job of getting into the pediatric market to getting people to start on the product pretty early.

I think I missed one of your questions

Kyle Macione: I think the other question was the government sales and the growth going forward.

James Green: Yeah.

Jefferson Gregory: The government sales have been fairly steady over the last few years. In 2001, revenues were roughly \$25 million. In 2002, they increased to \$32 million. There was a one-time pick-up in revenues, a few million dollars because of some 9/11 issues. But we expect the government business to be stable and have some growth going forward.

Maria Phillips: Great. Thank you.

Jefferson Gregory: That's if we all don't end up going to war. And then, of course, if we all end up going to war, I would think that business would probably pick up some. But I think the other issue that we like in this marketplace is the concept of going after an NDA and going to our homeland security. We're

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really not putting any of those numbers into our projections right now because we don't have an NDA and we're not currently really servicing that market except through government contracts.

And so that's part of the our intentions is to meet with the FDA, see if we can't get a formal application on their new dual chambered auto-injector that they just got that's got some patents on it to give exclusivity until about 2010. And we think we can get additional patents on it so it would be extended beyond that and go after some of that marketplace. We think that that could be a pretty good potential upside for growth.

Operator: We'll take our next question from Tim Coan of US Bancorp Piper Jaffray.

Tim Coan: Hi. Good morning. I was wondering if you could give me just a couple of details on the DiaJect® ANDA? Specifically, why was the referenced product discontinued?

Jefferson Gregory: What you're saying that I'm sorry; you caught me off guard here. The referenced product was discontinued? You're saying that valium injection was discontinued?

Tim Coan: Yeah, the diazepam auto-injector. I'm looking at the (system) petition that Meridian sent to the FDA talking about how they believe that this is useful for an ANDA application despite the fact that the diazepam auto-injector's NDA was, as I'm shown, discontinued list.

Jefferson Gregory: I would imagine that that's just due to the fact that it's not due to a prejudicial issue. It just deals with the fact that they didn't have a sizable market at that time. So it was discontinued due to non-use. So that's a typical

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type of filing that you would see where you're trying to establish that the product was not discontinued for prejudice.

Tim Coan: And so what does the FDA's guideline where are the FDA's guidelines then in terms of getting an equivalent product to a discontinued product?

Jefferson Gregory: Well, I think what you're going to be able to establish is that you're doing an equivalent product with improved valium, not auto-injector, but valium inter-muscular injection. And that's really what you're establishing your product against. This is an inter-muscular injection.

Tim Coan: Right.

Jefferson Gregory: Okay? So is valium which is the referenced product in 10 milligram per mil injection. And so what you're comparing yourself to is those is that product. And since it's a solution, then what you would basically say is we're qualitatively/quantitatively the same. But by equivalence, it's a given on inter-muscular aqueous injection if you can just prove Q and Q.

Tim Coan: Could you all just give a little more details on the DHE product and what is the development print plan for that? Is that another ANDA or are you going to do a clinical trial on that?

Jefferson Gregory: Well, I think it's going to be basically an ANDA concept. But, you know, I think we're going to be taking a look at it ourselves to see whether or not we can do something a little bit better.

Tim Coan: Okay. And the last thing is what's the shelf life on the government products?

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Jefferson Gregory: On the separate injector, which is what they're moving away from, there's currently, it's sold in like a little case of atropine auto-injector and pralidoxine auto-injector in two separate auto-injectors in a case. And you're suppose to take the auto-injectors and inject them into two separate sites. Those two injectors have about a five-year expiration date.

The new one that they've just finished developing with the government right now is they're dual chambered called the ATNAA auto-injector and it's a single auto-injector with atropine in one chamber and pralidoxine in the other.

The engineering process was quite unique for this because one of the problems that you run into with atropine and pralidoxine is that they do have to be injected into two separate sites. So the fact that you can keep them separated by a dual chamber auto-injector isn't enough. You actually have to get them to inject at two different places in the body and being injected by a single needle in an inter-muscular injector kind of presents a conundrum to that problem.

But Meridian actually came forward with a very novel concept on how to be able to do that in a sequential manner. And that's what their patents are actually on and I think that they are, you know, should be quite exclusive in that marketplace. That product has a two-year exclusivity. I'm sorry, two-year expiration on it. And that's the product that the military is moving towards starting next year.

Tim Coan: Thanks.

Jefferson Gregory: Sure.

Operator: Our next question comes from Jon Moran of SG Cowen.

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Jon Moran: Yes, hi. Just on the EpiPen®, I'm wondering why no generic company has pursued a generic? Is there is it difficult to show bio-equivalency or anything unique there? Also, how do you expect to differentiate versus the new entrant specifically? And also, on the government contracts, I know they were renegotiated in 2003, when should we expect those will come up for renegotiation next?

Jefferson Gregory: Okay. Somebody help me out here. What was question one?

Kyle Macione: Generic competition

Jefferson Gregory: Why there is no generic? I couldn't tell you other than to tell you that EpiPen® has been such a dominant product in the marketplace and these technologies are not easy to duplicate in neither delivery device technologies. And there just aren't that many people that are doing them.

And so all I can tell you is that nobody has done a generic. As far as we're aware, nobody is working on a generic. So and I imagine if somebody came out with a generic, it wouldn't be all that much cheaper than an EpiPen® would be. So I think that it's a pretty good marketplace for that product.

The what was question two?

Kyle Macione: Differentiate with the new product.

Jefferson Gregory: Oh, how do you differentiate it? I think that the other guys' job is to try to differentiate themselves from EpiPen®. I mean when you're the, you know, the gold standard in the industry, they have to try to differentiate themselves.

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I know that the way in which they're trying to do it is to say that their product has a manual injector that you can get out of the screw top and that so their product is actually an auto-injector with a follow-up manual injector and that that's better in the overall marketplace because you get two instead of one.

Their project, there are two injections; TwinJect® of auto-injector and a manual injector is more expensive than a single EpiPen®. So but I think that's what they're going to say is two is better than one.

Then what was the third question?

Jon Moran: The just the timing of renegotiation for the government contracts?

Jefferson Gregory: The government contract, as you mentioned, was just signed last month and that there's two one-year options so it extends respectively for three years.

Jon Moran: Thank you.

Jefferson Gregory: Yep.

Jefferson Gregory: But I do want to tell you that, you know, the government has just worked with Meridian to develop the ATNAA dual chamber syringe for nerve gas anecdote and that was the result of a ten-year project and, you know, millions of dollars of investment by the government. So I don't think that contract is going to go away. Oh, and Meridian owns the patents on that product until 2010.

So, you know, the government wants that product, they've invested a lot to get that product, and so I think that that agreement is pretty stable there for at least until 2010 anyway.

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Operator: Our next question comes from Mr. Marc Goodman of Morgan Stanley.

Marc Goodman: Yeah. Just first of all, this new competitor, Hollister, have they launched this product? Are they about to launch this product? You mentioned that it was more expensive. Is that do you think it will be? Or have they already set pricing? Second of all, you mentioned something about additional formulations, pediatric and adult; could you just repeat that one more time? I think it was using the EpiPen®.

And then the third question I have is just about gross margins. You mentioned 50%. Was that just on the EpiPen®? I know it's a public company so I can get the numbers. I haven't seen them yet. But what are the gross margins for the total company and where do you think they can go as you leverage, you know, the infrastructure, the synergies, and all that kind of stuff?

Jefferson Gregory: Yeah. I think the answer to your first question which is the potential competitor in the epinephrine marketplace, you know, we mention it because, you know, market researchers tell us that they're out there and, you know, they could get approved. They are launching, they're not currently approved as far as we're aware of. But they could get an approval. We're anticipating that they will but potentially, they might not.

At any rate, that's about all I can tell you about it is that we know that they're out there and we know that they've been working on the thing. And their concept is this auto-injector that has one auto-injector and then a manual injector in the inside chamber.

Marc Goodman: Uh-huh.

Jefferson Gregory: What was the other question, adult versus pediatrics?

Marc Goodman: Yeah. The

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Jefferson Gregory: Yeah. I wasn't referring to epinephrine. There currently is an adult and pediatric EpiPen®. There's EpiPen® Junior and Regular EpiPen®. I was referring to the nerve gas anecdote product. Right now, because most of the production has been for the military, there's not really a big need to produce a pediatric product.

But if you're going to go into homeland security, you know, the issue is that kids live in the homeland just like adults do. And so if you're going to protect or produce an auto-injector that delivers a set amount of product, you need to be considering the fact that children don't need that much. And so you have to come forward with, in essence, a pediatric version as well. And I think that this would be well received by the FDA.

I don't know if you saw that expose that was done by yeah, was it CNN or

James Green: CNN.

Jefferson Gregory: ...CNN that Connie Chung did on this issue in which, you know, they took like 10 or 15 minutes, they had a big expose on it talking about how if somebody let off the nerve gas in the United States that basically, you'd have all these children that would get exposed but they wouldn't have nerve gas anecdotes for children, they would just have to start injecting them with adult nerve gas anecdotes and just see what happens.

Marc Goodman: Uh-huh.

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- Jefferson Gregory: And so it was sort of an alarmist kind of piece but it didn't go without our notice. And it didn't go without the FDA's notice either. So we think that that product will be well received. And then there was a third question
- James Lattanzi: The last question dealt with the margins. The margins historically have been in the high 40s. We think we can move those margins to the mid-50s, maybe even higher as we introduce DiaJect® and other products.
- Marc Goodman: Thanks.
Operator: We'll take our next question from Steve Valiquette of UBS Warburg.
- Steve Valiquette: Hi. Thanks. One question I still have, I'm actually curious how you came across this company as an acquisition target? Was this company on the block? Was it based on an old relationship; any comments there?
- Jefferson Gregory: No. The company was not on the block. The company was not shopped at all. I think that Meridian is just a company that we became aware of almost two years ago and we've sort of been watching and talking with their CEO, Jim Miller, off and on for a couple of years now. And we felt that the timing was right.
- You know, previously, either the timing wasn't right for them or the timing wasn't right for us. And the valuations didn't quite fit. And I think that it's just one of those things at this point where all the timing elements sort of fit out and the transaction could now they're at a point where they want to take the next step and King can help them to get there.

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And King knew taking a look at the transaction, the numbers worked very, very well for King and provided a certain opportunity for our company. So it's just something that the timing finally came around to a correct point.

Steve Valiquette: Okay. All right. Thanks and congratulations.

Jefferson Gregory: Oh, thanks.

Operator: There are no further questions at this time. I'd like to turn it back over to our hosts.

James Green: I want to thank you for joining our conference call today. We appreciate your interest in King Pharmaceuticals and we look forward to speaking with you again next week on Monday, October 28th, following the day's that day's planned release of King's third quarter 2002 results. Thank you.

Operator: This does conclude our conference call for today. You may now disconnect your lines and thank you for participating.

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Meridian will be filing a proxy statement and other relevant documents concerning the transaction with the Securities and Exchange Commission (the SEC). STOCKHOLDERS AND INVESTORS ARE URGED TO READ THE PROXY STATEMENT AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC BECAUSE THEY CONTAIN IMPORTANT INFORMATION. Investors will be able to obtain the documents free of charge at the SEC's website, www.sec.gov. In addition, documents filed with the SEC by Meridian will be available free of charge from Meridian's Manager, Investor Relations & Corporate Communications, Lenny Santiago, 10240 Old Columbia Road, Columbia, MD 21046 (tel. no. (443) 259-7842). READ THE PROXY STATEMENT CAREFULLY BEFORE MAKING A DECISION CONCERNING THE MERGER.

Information regarding the identity of the persons who may, under SEC rules, be deemed to be participants in the solicitation of stockholders of Meridian in connection with the transaction, and their interests in the solicitation, is set forth in a filing made by Meridian with the SEC on October 21, 2002.