

TUTOGEN MEDICAL INC

Form 425

November 16, 2007

Filed by Regeneration Technologies, Inc.
Pursuant to Rule 425 under the Securities
Act of 1933 and deemed filed pursuant to
Rule 14a-6 under the Securities Exchange
Act of 1934

Subject Company: Tutogen Medical Inc.

Commission File No.: 001-16069

Forward Looking Statements

This communication contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements include but are not limited to statements about the expected benefits of the business combination involving Regeneration Technologies, Inc. and Tutogen Medical Inc., including potential synergies and cost savings, future financial and operating results, and the combined company's plans and objectives. In addition, except for historical information, any statements made in this communication about Regeneration Technologies' anticipated financial results, growth rates, new product introductions, future operational improvements and results, regulatory approvals or changes to Regeneration Technologies' agreements with its distributors also are forward-looking statements. Forward-looking statements are subject to risks and uncertainties, including the ability of Regeneration Technologies and Tutogen to integrate their businesses successfully and to realize the expected synergies and cost savings from the merger and the risks described in Regeneration Technologies' public filings on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results reflected in these forward-looking statements. Copies of Regeneration Technologies' S.E.C. filings may be obtained by contacting the company or the S.E.C. or by visiting Regeneration Technologies' website at www.rtx.com or the S.E.C.'s website at www.sec.gov.

Important Additional Information and Where to Find It

The proposed merger will be submitted to the respective stockholders of Regeneration Technologies and Tutogen for their consideration, and Regeneration Technologies and Tutogen will file a registration statement, a joint proxy statement/prospectus and other relevant documents concerning the proposed transaction with the S.E.C. Shareholders are urged to read the registration statement and the joint proxy statement/prospectus regarding the proposed merger when it becomes available and any other relevant documents filed with the S.E.C., as well as any amendments or supplements to those documents, because they will contain important information. You will be able to obtain a free copy of the joint proxy statement/prospectus, as well as other filings containing information about Regeneration Technologies and Tutogen, at the S.E.C.'s Internet website (<http://www.sec.gov>). You will also be able to obtain these documents, free of charge, at Regeneration Technologies website (<http://www.rtx.com>) or Tutogen's website (<http://www.tutogen.com>). Copies of the joint proxy statement/prospectus and the S.E.C. filings that will be incorporated by reference in the joint proxy statement/prospectus can also be obtained, without charge, by directing a request to Thomas F. Rose, Vice President and CFO, Regeneration Technologies Inc., PO Box 2650, Alachua, FL 32616 or to L. Robert Johnston, CFO, Tutogen Medical Inc., 13709 Progress Blvd., Box 19, Alachua, FL 32615.

Regeneration Technologies and Tutogen, and their respective directors and executive officers, may be deemed to be participants in the solicitation of proxies from the stockholders of Regeneration Technologies and Tutogen in connection with the proposed merger. Information about the directors and executive officers of Regeneration Technologies and their ownership of Regeneration Technologies common stock is set forth in the proxy statement, dated March 30, 2007, for Regeneration Technologies' annual meeting of stockholders, as filed with the S.E.C. on a Schedule 14A. Information about the directors and executive officers of Tutogen and their ownership of Tutogen common stock is set forth in the proxy statement, dated February 5, 2007, for Tutogen's annual meeting of stockholders, as filed with the S.E.C. on a Schedule 14A. Additional information regarding the interests of those participants and other persons who may be deemed participants in the merger may be obtained by reading the joint proxy statement/prospectus regarding the proposed merger when it becomes available. You may obtain free copies of these documents as described in the preceding paragraph.

The following is the transcript of the Regeneration Technologies presentation at Stephens, Inc. Fall Investment Conference held on November 14, 2007.

Regeneration Technologies, Inc.

Stephens Inc. Fall Investment Conference

November 14, 2007

<<Shawn Fitz, Analyst>>

Okay. Good morning. Shawn Fitz with Stephens Incorporated here to introduce Regeneration Technologies. That's the stock that we have an over rate rating on. \$14 price target. Just briefly, Regeneration participates in the biologic market for a broad range of indications. The company's business model has been transformed from a fundamental standpoint, which, for they have a much more diversified distribution strategy with additional partners and also a significant direct presence.

The company announced yesterday that they're going to merge with Tutogen. I think this is a very compelling combination from both a strategic and financial standpoint and we view this as a smart deal, complimentary end markets. It gives an opportunity to leverage RTI's significant tissue recovery infrastructure. Expands their presence internationally and then probably more significantly, I mean as accretive from a financial standpoint. So without any additional delay, it's my pleasure to introduce Brian Hutchinson, President and CEO of Regeneration. He is also joined by Tom Rose, CFO. Brian?

<<Brian Hutchinson, Chairman, President and Chief Executive Officer>>

Thanks. Thank you Shawn. Thanks Shawn for the introduction and thanks for letting us be here today. And certainly thank Stephens, for all the Stephens employees, for all the support we've gotten over the years. I've been with the company now, almost six years and Stephens has been loyal with us from day one through good times and tough times. So we appreciate that very, very much. I'm going to try and go through a presentation and I try to also tell Shawn that we did this deal yesterday, just in time for this conference intentionally, but that wouldn't be true, but we certainly tried to tell him that.

So anyway, I'm going to run through a presentation and I actually have a couple of extra slides for the benefit of this audience to try to tell you a little bit about the company and you're going to see for a while from us by the lawyers demand, two forward-looking statements. This is the one your normal from our normal presentation which I will ultimately give to you today. And then that's the other one that's called the in summary fashion. The more information one. I don't intend to read it, but it essentially says, there'll be more information coming forth in our proxy statements regarding this merger. This and it does require shareholder approval from both companies.

So yesterday, we announced that we are going to emerge with Tutogen Medical, which happens to be in Alachua, Florida, which is a bedroom community if you will, against all Florida. So we're really connected. We're in the same industrial park. Our corporate offices are really across the parking lot from one another and in reality our bovine processing unit is actually in the same building where their processing is. We share the same rented space. So we're extremely close with one another. They have an operation based in Germany which is essentially where their company began which we think is extremely important for us to expand outside the United States.

So the terms of the deal, it is a tax free stock for stock exchange. Tutogen shareholders will receive 1.22 shares of newly issued RTI common stock when the deal is closed which sure they own. We expect this to close somewhere around the first quarter of next year. Could be as early as March 1st or as late as April 15th according to the lawyers. Certainly we've got to get regulatory approval both here in the US and in EU. So we have some work to be done. When it is over, pro forma, RTI shareholders will own 55% of the company and Tutogen shareholders about 45% of the company. And there will be about 56 million shares outstanding. I'm told that is a good thing because our both of our stocks have been nearly traded.

The leadership of the company. I will remain as Chairman and CEO. Guy Mayer will who is speaking later today in Tutogen, has a slot around three o'clock this afternoon. Guy will remain as President and he will be active in the company, very active in the company, on the sales and marketing side, both in the US and outside the US. But he will be certainly active in the company.

Tom Rose will remain the CFO of the company, and Bob Johnston who is their CFO will be a VP of Finance for the company, probably focused on Treasury and other things that are important to the company. The Directors will increase to 12. There are seven Directors in RTI today. I think there are eight total in Tutogen and I think they're going to bring on five. And that will include, the 12 will include both myself and Guy Mayer.

So this is a little bit about what the company is going to look like. If you look at the three circles on this page, this shows the RTI business. It is buying, certainly dominates 43% of the business and sports medicine 25. If you look at Tutogen there, a big dental business. 48% of their company is dental and that large international segment is extremely attractive to us in the combined company.

When you put the business together, you can see that it is a much more balanced company. We're not dependant on any one segment, the way we have been, for either company and we think this is fantastic and all of these segments have phenomenal growth and in fact all of them are in a situation where they are all spine constraint. So we feel very, very good about the spaces we're in.

This is another way to look at the information. On the combined company basis, the little red check marks show you the market segments that RTI or Tutogen plays in and then the combined. And you can see, we actually only overlap in one segment and that is in spine. They have a relationship with Zimmer spine and they have three implants. We believe that we can actually help that business private to be much, much bigger in the combined company.

So other than that we really do not overlap at all. This is another way to cut the business and this is by distributor. If you look at RTI's business we've been dominated by MSD. Even though we've worked on this a great deal in the last couple of years, they're still representing around 60%, maybe full year this year 50, but 50 to 60% of our business.

Tutogen is dominated by Zimmer at 58%, primarily dental but still a strong Zimmer hold. When you look at the combined company, that kind of drops to 37%, Zimmer 22. There's a lot more balance in this and once we get it further down the road, it will start to show you the strength of the other partners we have and this chart will show a strong mix of both products and companies that we deal with.

So that's it on the merger from my side, and Guy will have some of these same slides in front of you, and we can talk more about that as time comes on. Who is RTI? We began operations in 1998. We grew out of the University of Florida, which is why we're still in the Gainesville area. We're a leading provider of biological solutions both from allograft and xenograft and our choice for xenograft happens to be bovine. And I'll cover some of that a little bit later in this. We're currently the number two-recovery program in the United States. Even in the combined company, we'll still be number two in the United States. But internationally we'll be number one, so globally, we'll be pretty close.

We have access to the largest cultured for the bovine tissue in the United States. There are only two. One of them is locked up for pharmaceuticals. And then there is the other one that we deal with - ours is the largest and there's plenty of bovine tissue there for us to do everything we need to do for quite some time. The differentiator for RTI for years has been BioCleanse and I'll cover that a little bit. These are the markets we've played in and the sizes of the bubbles are important in that they really relate to how big the business is for us today. Not necessarily how big the market opportunity is. So for instance the big red bubble on this is spine, that's our biggest segment.

But spine is certainly not as big as reconstructive devices in total. The opportunity in reconstructed devices has been huge, we just have never had the opportunity to get into it as much as we do going forward from here. Sports medicine - a couple of years used to be a lot smaller than that. But you can see, we've done a great job in growing our sports business and I'll show you some of that on this next couple of slides. So this is the culture represented today.

Certainly we see all of these as big opportunities. This is our revenue for the first nine months of 2006, sliced by those same segments and you can see spine. It's a \$30 million segment, we're nine months growing at a rate of 14%. We think that's exactly where we think it should be, it's growing nicely. Sports medicine for us is up 80% year over year and we think that will continue through the fourth quarter and through this relationship we think we can actually fuel sports to even grow very strongly in through '08 and '09 as well.

Bone Graft Substitute, up 30%. We should never overlook that, that's actual nice growth without our Zimmer, that's not including our new pace product that we've just developed. So this is our core business, it's doing extremely well this year. That's our partnerships of Medtronic, Exactech as well as Pioneer and some other groups that we're working with and our own organization distributing that product. So it's done very, very well. General Orthopedics is very small for instance strips and stripes used in trauma surgery pretty much.

The cardio business, we've been talking about this earlier one, we're exiting it, so what you see down there is the 1.8 million in revenue. It's going to go to zero next year. And then the other represented tissue we'll recover to send to other people. This is another pie chart really looking at the biologics marketplaces. It's a huge marketplace, somewhere around two billion in size. And the blue places show you where we participate today, certainly 75% of the market is covered, we feel very good about that. We're not in the hyaluronic acid injections and we're not in platelets. But we're pretty much everywhere else.

For those of you that have followed the company for a while and used to see, I used to do five or six slides on BioCleanse and we've talked about how it works on a program a long time; at this point in time, it's undisputed, it's the leading sterilization system on the marketplace, it's safe, it's clinically proven. We've done this thing, this graph says we've implanted half a million patients. We're probably approaching getting closer to 750,000 to a million patients at this point in time. So we're really, this thing is well validated and it just flat works.

So where are we going? Where is RTI going? We changed our business model. Many of you know that late last year; we signed a non-exclusive agreement with Medtronic, which had been a constraining relationship for us. That's now changed to a non-exclusive. We went in really aggressively, went after some more donor sources and we began the development of our direct distribution model for sports medicine.

We really expanded the human area, specifically targeted around sports with Tutogen and Cryolife, two deals we did at the end of last year, swapping deals that have worked out extremely well for us. And then we've gone to optimize our just recent spine with new partners such as Orthofix, Blackstone and then there'll be others that I talk about such as Stryker, Wright Medical.

So we've done very well in changing our business model. So we have really two models. We have on the direct side we have the sports model where we have full control of the channel all the way through the customers. And then on the OEM side, if you want to use those terms, but we call it partnership side for all the other orthopedic segments we work with partners. So we have a group of partners and a portfolio of products across that segment. So this is the page that represents the Stryker agreement. And we signed it in June of last year. For those of you that follow Stryker, their spine business is up over 25% this year and growing very well. I think it's our fastest growing business segment in their company.

We just launched our first cervical graft with them earlier this year. They are blown through all of our projections and their own. This is going to be a very strong relationship and building. We feel very, very good about this. And then really now serving one of the fastest growing spine companies, and this is exactly what we're hoping to do after we changed our agreement with Medtronic.

Sports medicine. We like this graph because it shows really strong growth. If you look at the sort of the light bluish grey bars, revenues are up 80, 90% per quarter. That's directly reflective of one changing or getting those relationships with Cryolife and Tutogen to bring in more tissue that we could distribute. And two, doing some things with our own processing to get higher yields per donor.

We used to yield about 2.3 implants per donor and I think now we're over five and we've told people we think we can get to eight to nine. So we're really making some nice progress there. All internal being driven stuff. So we really have full control of this, which helps us out a great deal. We do have the direct sales force, which helps in that we are really well positioned to grow this for quite some time.

The market opportunity here is gigantic. I'll go look at the 2008 column for instance, it's about \$650 million marketplace and in there only a 150 of it is covered by allograft and that's the entire industry of allograft. And then in this space, the doctor has two choices, either allograft or autograft, that's the only choices they have and if you go and talk to a lot of docs, if you talk to a guy who does only autograft, that's because he can't get the consistent supply of allograft. That's really just the bottom line. So we think this is a huge opportunity for us to make a mark.

This doesn't show up real well on the screen but there are three examples of bone tendon and bones on this screen and up in this segment up here, this top one is a native bone tendon bone which is what people are used to seeing and then down below it, two versions of our assemble technology. That's really how we're driving yield improvements. Both these products are now on the market and doing very, very well. We've implanted hundreds of patients with adjustable and then it's going very, very well.

On the DBM side, this bone graft substitutes for us and then focused on the grey box here, it's about a \$220 million market. It is growing. This is a great opportunity for us to do quite well, and as I showed you earlier, our basic business is up 30% and we've developed a brand new product here to try to take our share back and this we signed down with Zimmer earlier this year. This is an exclusive agreement around one product. It's a single syringe product. It has great handling properties, best in class and it is the best in class performing product as well.

So we really feel strongly about this. Zimmer didn't have a bone paste product at all. So we feel really good about this. We have we're just going to be starting to ship to them this quarter. So they're really just going to start launching this very late this year and into next year but this has real strong potential. They have the largest orthopedic sales force in the world with 17,000 reps and no biologics. So we really think this is a great place. This is the beginning of a relationship with them that will cover both human and bovine tissue and now through our merger with Tutogen will be very broad and cover all their segments. This bone past product was going to go to the other segments anyway. We'll now have a bigger relationship with them to build on.

So as you know, this is really the way we see the market opportunity, \$2.3 billion marketplace. Our focus is really going to be to focus this on the synthetics and metals and the autograph places. We are not going to stop doing human tissue processing. We'll keep doing that. So we really think this is a big opportunity. We have the source of the material. We have the ability to get regulatory approvals. We have the marketing folks to develop the products and launch them. So we're well positioned. The merger here is really important. Because Tutogen already has about \$5 million bovine business. So this really helps us to accelerate our bovine numbers going forward. So we're really excited about the possibilities here.

This is how the product looks. Actually in the human body, this is a patient done in Minnesota. This is actually an ACL replacement with bovine interference screws used as fixation. This patient was out in about seven months and the you can't see it real well, but there's a CT scan there of the knee and you can see the screw in there and there is strong white lines along the edge of the screw, the doctor tells us that is new bone formation.

So he got immediate strong fixation and now he is seeing the remodeling which is exactly what we expected, that's exactly what we thought would happen. This is a great outcome for the patient and the doctor. So all is well here and this is exactly what we expected to see. So the results of our clinical work and all of our bovine products is doing extremely well. And you'll see more and more studies as we go forward. So it's really here and it's working.

This is an example of another product that we used to launch another relationship. We launched a relationship with Wright Medical. It's around foot and ankle and if any of you follow Wright, you know they're developing a segment that is focused on foot and ankle. We developed a product, not intentionally just for them, but then, that we launched it with this product and then we have subsequently developed an engineered product for them that we've now launched as well.

So they're out there really pushing this product for foot and ankle procedures. The beauty about this is you can't make this wedge out of human bone. If you do and you put it in the ankle, it will crush. It will not withstand the weight of the person when they stand up. When you make this out of bovine, it's extremely strong. You can put that in there and it can take the weight. In fact you can put it on the ground and you hit it with a hammer, you can't break it. But it does remodel. So it gives the strength they want and it remodels. We've been implanting these now for a couple of years, fantastic results. I would look for this product to by itself to be a \$1 million product line next year. Just one product.

So this is the last slide in all of this. When you look to what you see what can you expect from RTI. You'll see continued increases in revenues and that's without the merger, so just on our own for the fourth quarter and going into first quarter, continue to

see those revenue increases that we have been posting. Introducing new products to the marketplace, continue to focus on profitability and increasing our cash flow. Those have been our goals for quite some time and we expect that we will continue to do those same things. So no change in RTI through the next several months as we go through this merger. For anyone who is worried that we might lose focus. This has only been going on for a few months. It involved me, then Tom for a while, and a few others, insiders, until very recently. And as of yesterday, I said to everybody else, it's announced, now go back to work, there's nothing you can do.

So until we get approvals, no one can work on this. So we're really back working on strictly RTI's business focusing on what we need to do. So that's where we're at. I'm finishing early Shawn, so, it's all yours.

<<Shawn Fitz, Analyst>>

[Low audio]

Q&A

<Q>: [Low audio]

<A Brian Hutchinson>>: Okay, I'll start. I'll go backwards first and start with my own background. For those of you that don't know, I came from Stryker Corporation and I had many. I worked there for 12 years, I was part of the executive management team from the time it was a little company. Believe it or not, it used to be a \$200 million company at one time. It's a very big company today, but my last role there was, I was the Chief Operating Officer of the combined company when Stryker acquired Homedica. So I was the Chief Integrating Officer there. Through the entire process, I was the one that pulled that together. They've only got 4500 employees. So I know a little bit about how to do this and I also ran 17 factories for them, many of them in Europe. So I know a little bit about this process. Some of my team came to us from Stryker. Joe Condon, Roger Rose, others. And Tom Rose, our CFO has done a lot of this kind of work as well in his previous life, both as a public accountant and as a CFO. So. And then Carey Hartill. My whole management team has experience with this sort of thing. So I'm feeling very, very comfortable. I know that the Street has seen a couple of quarters of performance from us and they're saying why now. Well the timing is something you can never predict. It just happens. But the results you're seeing, they're not due to efforts from just six months. These efforts have been going on for two years. So our team is expecting to see these results and we're feeling very comfortable about that. So we feel good. In terms of timing of around, I assume, you meant timing around when the acquisition will happen.

<Q>: [Low audio]

<A Brian Hutchinson>>: Why now. Well I was approached in the late summer. As you know a year ago we signed a swap agreement with them and we've been working together in our proximity, dictate that we're together a lot. Our teams have been working

together a lot. And the more Guy looked at this, and the more I looked at this, the more it just made sense. And we started having a dialogue in the summer. I think he made the first call this time, I don't know, it's hard to say. It started very casual; it was just Guy and I. Late summer, we informed our CFO's and then the modeling started and we brought in bankers and then it took off and got momentum and we got it done as efficiently as we could and as quietly as we could and I think we did it pretty quietly. The Street reacted pretty loudly yesterday, so. So I felt like that it worked, I mean you could never predict the timing of these things. Had it been a couple of years ago, we wouldn't have done it. Had it been if we didn't change the Medtronic relationship, we wouldn't have done it. So there were certain things that had to be in place that allowed us to feel comfortable going forward to do this and we think we're there and we think our business model can sustain it and we really see it as an opportunity to grow faster than either of the two companies did previously. So we feel really good about the possibilities there. You want to add to that?

<A Thomas Rose>: I think during the the timing issue, as we worked with Tutogen in the last year on this co-operative sourcing, both companies have just seen so many opportunities where we can leverage poor sourcing as well as leveraging and maximizing the processing function in getting more units per dollar. We could not do that as separate companies. It just became very obvious and so even their opportunity [Low audio] go off forever and that certainly helped to accelerate the dialogue as Brian [Low audio].

<A>: Yes?

<Q>: [Low audio]

<A Thomas Rose>: Yes.

<A Brian Hutchinson>>: Use the microphone, Tom.

<A Thomas Rose>: Yes. A good example which pretty easy to understand, in due diligence, we looked at our production of spinal implants. There are yields per donor, is anywhere from 25 to 50% higher than the yield that Tutogen currently has. They've got a small business, our processing techniques are we've been doing spine for many, many years. They're more advanced in Tutogen. As you increase those yield, obviously there's a drug correlation between the number of units and revenues, an ASPN spine is about \$1000 per unit for us. Those incremental revenues come on with really just something from manual direct labor and packaging. So it would be highly possible for additional revenues.

<Q>: [Low audio]

<A Brian Hutchinson>>: Well in terms of the combined company, we're really not trying to say a whole lot publicly there. Yes, we've been very conservative with our numbers, including the synergy number we put out there strictly on purpose. Both of us have to run independently for a while and we don't want their work force to get scooped.

They have 108 I think employees in the lunchroom, we don't want them to go away, they don't either. So and the same thing on our side. So we're really not saying a whole lot today, but I will tell you, if you think about the way, tissue comes in and the way it's utilized, we've been competitive at the tissue recovery part of the business, even though we've been working together we're still competitors a bit. They never brought in bone or tendons from Europe. So all that will be incremental and they bring in a lot of donors in Europe. They come into their German facility. They have a substantial base over there. They've got 150 employees almost over there. So it's a big base. There's huge opportunities there, there's huge opportunities in the processing as Tom gave you an indication of. There's huge opportunities in the marketing. In that, we've got a bone phase product that gets distributed in the United States, but very little outside the United States. They've got 40 distributors outside the United States that don't have this product. So you've got an opportunity there. You have opportunities to bring other general orthopedic products to the market there. We have opportunities where we have approvals to sell bovine products in Europe that they also have. They've been implanting bovine in their spine in Europe for quite some time. We have product designs, we have material, we can supply. So there's lots of opportunities, I mean to go through the mall, we take all day. There is a punch. This is a situation where as you see that's coming together, it's incredibly compelling. It's very, very strong.

<<Shawn Fitz, Research Analyst>>

With that probably the end.

<<Brian Hutchinson, Chairman, President and Chief Executive Officer>>

Yes.

<<Shawn Fitz, Research Analyst>>

And Brian and Tom will not have time for a breakout. However they are hosting an analyst meeting in conjunction with Tutogen at 12 o'clock [Low audio].

<<Brian Hutchinson, Chairman, President and Chief Executive Officer>>

Thanks, Shawn, thanks for the opportunity.