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Questioning Market Leaders For Long Term Investors

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COMPANY INTERVIEW

PERCY LOMAX
ReGen Therapeutics Plc

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ReGen Therapeutics Plc (RGT.L)

PERCY LOMAX has been Executive Chairman of ReGen Therapeutics Plc since June 4, 1998. He was brought in to commercialise the intellectual property of a Polish Institute. Mr. Lomax led the Ofex float in November 1998 and more importantly the flotation on AIM, which raised £5 million in March 2000. His responsibilities, in addition to chairing the Board, have been corporate strategy, corporate governance, fundraising and investor relations. During his time as Executive Chairman the company has been spending around £2.25 million each year. Mr. Lomax has been responsible for recruitment, salary packages and the general overall welfare of the staff. From January 11, 2001 to August 31, 2002 he was Chairman at Mediwatch Plc. Mr. Lomax was brought in after the public float at the request of the then brokers to steer the company through its initial public period. This period has now expired. As a non-Executive Chairman his duties were simply those commensurate with such a post and did not include budgetary responsibility. He formed Lomax Pharmaceutical Consulting on July, 1998, to carry on the work started at Teather & Greenwood. From August 2, 1995, to January 31, 1999, Mr. Lomax was co- Founder and Director of Polymasc Pharmaceuticals Plc, developed to commercialise the intellectual property of a department of the Royal Free Hospital School of Medicine. This company was quoted on the AIM market in December 1995, and in summer 1999 was taken over by Valentis Incorporated. He was principally responsible for corporate governance, fundraising and investor relations. From January 1, 1995 to June 30, 1998 he was Corporate Healthcare Broker for Teather & Greenwood. During this time he was a leading person in the flotation of PolyMASC and Oxford Biomedica and the rescue rights issue of Proteus. His experience over the previous 10 years led him to believe he could do better on his own. From January 1, 1992, to December 31, 1994, he joined Robert Fleming Securities as Executive in charge of European pharmaceutical research, appointed Manager in April 1993. The work involved investment analysis and corporate broking. From January 6, 1990 to December 31, 1991 he was working in European and UK Pharmaceutical Sales and Research for Sheppards. His work involved all aspects of research and selling. From January 4, 1989, to May 31, 1990, he was a European Healthcare Analyst at Prudential Bache. From January 1987 to December 31, 1989, he was head of team researching and selling health care and chemicals at T.C. Coombs. He was promoted to become head of UK and European Sales and Research. He was in charge of a team of 10 with a budget of around £0.5 million. During this time he floated Medirace which subsequently became Medeva in August 1987, now part of the largest UK biotech company, Celltech. From October 1976 to September 1986 he was a Pharmaceutical and Chemical Analyst for Vivian Gray & Co. and became a General Partner and Head of Research. During this time he studied for the Stock Exchange exams, which he passed. From November 1973 to October 1976 he joined the firm of Hart Morris as a Pharmaceutical and Chemical Analyst directly from Fisons. From January 1970 to October 1973 he was a Corporate Planning Executive for Fisons. He co-wrote two major papers on the future of the agrochemical industry and Fisons' place in it and on the Holmes Chapel Plant (the major UK pharmaceutical plant). The conclusions of both, which were to get out of agrochemical and put more money into pharmaceuticals were rejected. From June 1967 to December 1969 he was Assistant to Commercial Intelligence Manager at Glaxo. This was primarily a market research department. During his period there he worked on the launch of Ventolin, at one time one of the 10 best selling drugs in the world and still a very important medicine. Mr. Lomax has a BSc Econ and is a Fellow of the Securities Institute.

SECTOR: BIOTECHNOLOGY

(SAT103) TWST: Shall we start with a brief introduction to ReGen Therapeutics, perhaps including an historical overview and then bringing us to date with how you are positioned today?

Mr. Lomax: ReGen was founded in February 1998, went to the OFEX market which is an unlisted market, in December 1998 raising £1.45 million. We then went to the Alternative Investment Market (AIM) of the London Stock Exchange in March 2000, which is a publicly listed market, raising £5 million. That's how we evolved into the public arena. We have remained on the AIM market and completed some additional fund raising since then.

With regard to the business, the crucial point is that we have finished our clinical trial

ReGen Therapeutics Plc

Ticker (exchange)	**RGT (LONDON)**
Price close 5/05/03	**1.00**
12 Months Price Range	**0.50 - 5.00**

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Strategy

Since it was founded in 1998 to develop a treatment for Alzheimer's disease from ovine colostrum ReGen has achieved a number of significant milestones, which are fully spelt out in the History section. The key one, however, was the ending of the Polish Clinical Trials in the summer of 2002. Originally these trials had been designed to take the product onto the Polish market. Although we were advised by three different sources in Poland that a positive result from these trials would allow us to market the product there it was clear well before the end of the trials that this would not be so. The outcome of the trials was positive and we therefore looked to ways in which we could carry the project forward, although within a longer time frame.

The resulting review of strategy has led us to the following decisions:

- The first was to significantly reduce our administrative costs and to this end three directors have left the Board and our Polish office has been closed.
- We are carrying out further development work on Colostrinin™ and will look into increasing the dosage in view of the relatively safe profile of the drug.
- We have now been granted a patent on the neutraceutical uses of Colostrinin™ and are actively pursuing a neutraceutical development route.

Neither of the above immediately address the cash requirements of the Company and we are looking to acquire private companies which are profitable. Because of the dearth of Initial Public Offerings there are a number of attractive businesses around with which we are in discussion.

We also believe that adding further legs to the Company makes it a safer and more attractive investment for shareholders.

ReGen has come a long way in the four years since its IPO in December 1998. Our vision is that by December 2006 we will have a profitable and fully listed UK based drug company.

History

ReGen Therapeutics Plc was formed in February 1998 and in October 1998, through the acquisition of The Georgiades Foundation Ltd and its subsidiaries, Georgiades Biotech Ltd and ReGen Biotech Ltd, acquired the intellectual property rights to develop Colostrinin, a new and novel therapy for a number of human conditions including, primarily, Alzheimer's disease.

Tests using Colostrinin, dating back to 1995 and performed by the Ludwik Hirszfeld Institute of Immunology & Experimental Therapy in Poland, had indicated a potential benefit to Alzheimer's disease sufferers. ReGen therefore embarked on an extensive project to expand on the earlier indications and develop the therapy, with the intention to pursue the registration of Colostrinin as a pharmaceutical drug and bring it to market as quickly as possible.

ReGen's shares were admitted to trading on the London OFEX market in November 1998, following a successful £1.45 million fundraising. An additional £0.3 million of interim funding was raised following a share placing a year later and in March 2000 another £5.0 million was raised through a further issue of stock and the Company's shares moved up to a listing on the AIM market of the London Stock Exchange.

During 1998 the Company embarked on a long term programme of clinical development and a formal placebo-controlled clinical study commenced in Poland at the end of 1999 and ended in May 2002, and it reached the statistical endpoint which showed there was a 98% chance that it improved cognitive function as measured by ADAS COG which is the normal measure. Then there were no safety issues or concerns. One of the problems with existing registered drug treatments for Alzheimer's disease are their unpleasant side-effects. Some patients using Colostrinin have experienced very mild side-effects, insomnia for instance, but even these appear only at the very beginning of treatment and are generally short-lived.

In addition to pursuing the clinical development programme, an extensive manufacturing development project has been carried out, most recently in collaboration with AEA Technology, now called Accentus plc, in Oxford, who worked on a scaled-up version of the original laboratory method of manufacture, enabling Colostrinin to be produced in sufficient quantities to facilitate further testing and supply tablets for future clinical trials.

A number of key professionals with pharma-industry experience have been recruited by the Company since its formation, including Mike Harvey, CEO, who joined ReGen in February 2000 from the Medeva group. The Board of Directors is chaired by Percy Lomax, with many years experience in biotech financing and general corporate development, supported by some other well-known "names" from the pharmaceutical industry.

'ReGen's continuing activities in Poland resulted in the formation of a Polish subsidiary, ReGen Polska Sp. z o.o., in 2000. The then level of corporate activity in Poland warranted a corporate presence, but following the ending of the trials and no likelihood of an immediate launch in Poland, ReGen decided that it no longer warranted a corporate presence there.'.

In addition to the continued development being carried out in the UK and Poland, the Company has a number of collaborators worldwide, including long term relationships with the University of Texas Medical Branch in Galveston, Texas, USA and with Rentschler Biotechnologie of Laupheim, Germany, the latter of whom maintains a substantial shareholding in ReGen.

'The lifeblood of a Company of ReGen's type, size and ambitions is it's intellectual property portfolio. To these ends a substantial number of patent applications have already been made and are being added to in order to protect the Company's scientific discoveries. Many of these patents are particularly targeted at protecting discoveries in the field of the treatment of Alzheimer's disease, but many have potentially much wider applications and should, if granted, allow the Company's expansion into the development of other therapies as it progresses into the future. Three UK patents have already been granted and the Company expects further patent grants in other territories during the next year.'

(RG010) in Poland and it reached the statistical end point which showed there was a 98% chance that it improved cognitive function as measured by ADAS COG which is the normal measure. The clinical trial, while conducted in Poland, was conducted under the aegis of a German clinical research organization and the statistical data was evaluated by a professor at the University of Ulm. So while it was not done according to the same box-ticking requirements of FDA or the European Medicine Evaluation Agency standard, we do have a scientifically valid trial which showed the product had efficacy in Alzheimer's Disease.

The tablets used in the trial were a very low dose and there were no toxicity or safety issues, which of course is not true of any of the Alzheimer's drugs on the market. Therefore, since the trial, which ended in May 2002, we have been looking at whether we may in fact have a use in areas such as mild cognitive impairment and even a nutraceutical type usage for a slightly differently produced product. We are carrying out all the other scientific bits and pieces, the tick boxes, which the Western agencies require. This had not been done prior to this for the simple reason that I think the then Chief Executive and the Chief Scientific Officer were concentrating on the trial. They left us in the summer of last year, and I have concentrated since then on doing the further development work and tidying up.

"The crucial point is that we have finished our clinical trial (RG010) in Poland and it reached the statistical end point which showed there was a 98% chance that it improved cognitive function as measured by ADAS COG which is the normal measure."

When we have completed full scale manufacturing scale up, we shall then examine the dosage again because with no toxicity or safety issues in theory we should be able to expand the dosage to increase efficacy. Finally, because we can see there is a problem with funding what you might call blue sky biotech, we have decided on an acquisitive route whereby for paper we will take over small companies with revenue streams which are not in drug discovery but in health care. This would provide a revenue base and make our investors more comfortable, who are still looking at a 2006 launch for the product and we are not going to get any deals done until I suspect 2004.

"The tablets used in the trial were a very low dose and there were no toxicity or safety issues, which of course is not true of any of the Alzheimer's drugs on the market. Therefore, since the trial, which ended in June 2002, we have been looking at whether we may in fact have a use in areas such as mild cognitive impairment."

On the management side we reorganized last summer; the Chief Scientist and the Chief Executive left; we shut our Polish office; we halved the size of the London office; and overheads on an MAT basis came down from £1.5 million to £800,000. The managers are now targeted on financial lines to achieve certain objectives.

We have also been doing a considerable amount of work with the University of Texas Medical Branch and interesting results have been coming out of there. In particular, the mode of action study which was published at a conference in Barcelona in the autumn. That was Marian Kruzel and the team at the UTMB. There is other scientific work that is coming out of UTMB which is not yet in the public domain but which we believe will make an important contribution when we can finally release it. There is obviously further work that needs to be done there, but we are still proceeding with that, and of course we are proceeding with our patenting work worldwide.

So all in all, we have achieved what we set out to do, although somewhat more slowly than we thought we would. And if I had been asked five years ago whether I would settle for where I am now, I would have probably said yes.

TWST: What's the next step? If I ask a similar question, but bringing it down to two years, what key objectives would you like to have accomplished by then?

Mr. Lomax: The key objectives now are firstly to get our manufacturing up to commercial scale. Secondly, to attract a partner for Phase IIB/III trials that can take the product into significant clinical trials in Europe certainly, and possibly in the United States, during which period of time, we would have had a stage payment or possibly two stage payments paid to us from the said partner. The third objective is to have a further healthcare business which is achieving significant profitability — I mean significant in terms of a small biotech; I don't mean challenging Hoffman-LaRoche — which would be a stream of revenue to defray some of our research costs.

"Because we can see there is a problem with funding what you might call blue sky biotech, we have decided on an acquisitive route whereby for paper we will take over small companies with revenue streams which are not in drug discovery but in health care."

TWST: Can you elaborate? What areas of health care would you be interested in acquiring?

Mr. Lomax: It would be non-invasive; so, diagnostics, clinical research tools and allied areas. We believe, and this is early stage, that there are other potential uses for Colostrinin. So we don't need, as yet, to get into buying a further pipeline. Our aim is to have a balanced company. I don't know what the situation is like in the United States, but certainly in the UK there is concern about people pouring money into biotechs and never seeing a return. In the UK in particular, there have been a number of very significant failures in the biotech front, which I am sure you are aware of. That has blunted investor confidence. We have identified four areas which we would like to explore for further uses of Colostrinin, but at the moment we don't have the time, financial resources and people to do that. So it is slightly on the back burner while we are getting our product to a stage where we can get a partner to take it into Phase IIB. Quite clearly, we don't have the resources to do a Phase IIB/III trial ourselves.

"We have also been doing a considerable amount of work with the University of Texas Medical Branch and interesting results have been coming out of there."

TWST: Can you paint a quick picture of your financial position?

Mr. Lomax: Like all biotechs, we are always looking for money. But we have cash and we have a significant current asset position. I have said I will always use odd sorts of funding mechanisms, but one thing I'm not terribly interested in is doing a huge funding round where everyone goes charging all over the place. Our spending is about £1 million a year, you see. So we don't need huge amounts of money to keep going. What we're doing is not high cost. The clinical trials are finished. We spent a lot of money last year, but in the current year we are basically ticking science boxes. In 2001, we spent £2.5 million; and in 2002, we spent £1.9 million, which reflects the ending of the clinical trials. So our spending went down after June 2002.

This year, we are still doing our science at the University of Texas Medical Branch, and they are being very useful. We also have an alliance

with Roswell Park as well where they are doing some work for us. We are still keeping patients in Poland on the product, and this helps in an ongoing review of how people are doing on the drug. So if we've had people on it for three or four years, while that's not something that you can put in the main body of your submission to EMEA, it is still quite useful to know that there have not been any adverse side affects. Since patients first went on the product in 1995 no adverse side effects have been reported and that is over eight years ago.

So my point is that we are active, but we are not a company which requires vast amounts of money at the moment. Of course, to do a phase IIB/III trial, we would have to gear up enormously and that is not something we are going to do; I am very much of the organic growth school. You know, when we've got some sales revenue and we are a bigger company, it may well be we could do a IIB trial ourselves in two or three years down the road.

"The key objectives now are firstly to get our manufacturing up to commercial scale. Secondly, to attract a partner for phase IIB/III trials that can take the product into significant clinical trials in Europe certainly, and possibly in the United States."

TWST: Let's just go back to the Colostrinin and the Alzheimer's market, which evidently is a substantial and growing area. Can you quantify that market opportunity for your product?

Mr. Lomax: Let's put it this way, for a small British biotech the market is simply staggering. If our product worked completely, at its peak it would be one of the biggest products the world's ever seen. The Pfizer Aricept drug is a $1 billion drug and it only works for a limited period of time with a significant side effect profile. It is, of course, better than what was there before. But if you had a product that worked for five or six years with no side effect, quite clearly you would have something that was immensely bigger than a $1 billion product. There haven't been that many $1 billion products. You could be looking at a product the size of the Zantac or Lozec products.

"We believe, and this is early stage, that there are other potential uses for Colostrinin. So we don't need, as yet, to get into buying a further pipeline. Our aim is to have a balanced company."

The demographics are of course going our way, because, as you probably realize the incidence rises with age. The opinions vary, it depends which statistician and which country you are looking at and how people quantify it, but there is some indication that it is of the order of 10 times more likely at 80 than 70. Some statisticians suggest that you are looking at 3% incidence at 70 and some people say 30% incidence at 80. Whatever one you take, you are seeing a gigantic rise. And, of course, as people age, the demographics work our way.

The other thing of course, is that people with Alzheimer's in the earlier stages are still physically quite well. To use myself as an example, I am about 14 stone 10. If I had Alzheimer's, it would be difficult to control me, to say the least. You know, dealing with men who have Alzheimer's who are in their seventies, who can be weighing anywhere between 12 and 16 stone, is not too easy for an 8 or 9 stone nurse. So in that sense, the health economics for a drug that works are sensational. There are some figures in the US which suggests it costs about $180,000 a year to care for an Alzheimer's patient. Well, if we sell the drug for $2,000 a year, the health economics are in our favour.

TWST: Is there anyone else working along the same track you are taking to address Alzheimer's?

Mr. Lomax: As far as we see, no one has been working on the areas we have been working in. Briefly, what we appear to be able to do is stop brain cell death. So if we keep the brain cells alive, while you may not actually make anyone better, you can stop them from deteriorating.

TWST: So if you catch it soon enough?

Mr. Lomax: That's the point about it being safe in mild cognitive impairment. That's where we get even more excited. The diagnosis is getting so much better, and our theory is if we can catch it when people are let's say just vaguely confused, and we can actually get a drug into people at that stage, then we might be able to actually stop the transition into Alzheimer's. We don't know if we can yet because we haven't had enough time, but this could be an enormous opportunity.

"This year, we are still doing our science at the University of Texas Medical Branch, and they are being very useful. We also have an alliance with Roswell Park as well where they are doing some work for us. We are still keeping patients in Poland on the product, and this helps in an ongoing review of how people are doing on the drug."

TWST: What are your thoughts on genomic-related regeneration approaches? Is that to be construed as competition in a sense?

Mr. Lomax: Having been in the industry for 36 years, I would never say there is no competition. What I would say is we have finished Phase IIA trials with no toxicity and no safety issues with a product that has reached the statistical end point. As far as I am aware, there is no product even in Phase I that has such a profile. Given the length of time you have to do trials in an Alzheimer's drug, we have a very substantial time lead. That's the point I'd make. If someone came out with the same therapy now, they would still have to do at least three years of trials just to get to where we are now and that does not include the setting up time. That's the difference. You know, with an anti-bacterial or a cancer drug you can tell if it has any effect in a very short period of time. With Alzheimer's, because of the nature of the disease we have to test it for a period of time.

"for a small British biotech the market is simply staggering. If our product worked completely, at its peak it would be one of the biggest products the world's ever seen."

TWST: In terms of your evolvement, what is the thread that ties together your research arm in Texas, your trials in Poland and your UK listing?

Mr. Lomax: It is very simple. Our Research and Development Director was a naturalized Polish-American. The science was developed in Wroclaw, Poland, but it is probably better known as Breslau and is now in Poland, not Germany. Strangely enough, that is where Dr. Alzheimer is from. It's one of those odd quirks of fate. The trials were done there because the Poles believed the product worked. One of the leading Alzheimer's specialists in Poland was very bullish about it and wanted to do the trials there.

The Chief Scientific Officer is not with us anymore and his number two has taken over, but he also lives in Houston. Well, of course UTMB has a great medical reputation, so we saw no point in not using UTMB. It was as simple as that. We have an excellent relationship with UTMB. I think it's a fine institution and they have come up with some very good work for us. The reason we listed

in London was because the AIM market was a very good route in. I happen to work in London and was approached by the original Founders as to whether I could float it. The answer was, yes I could. And that's why the head office is in London.

"Given the length of time you have to do trials in an Alzheimer's drug, we have a very substantial time lead. If someone came out with the same therapy now, they would still have to do at least three years of trials just to get to where we are now and that does not include the setting up time."

TWST: Can you tell us more about your experience and background?

Mr. Lomax: I started at Glaxo in 1967, which I think was one of the best decisions I ever took in my life because I've remained either as an employee, an advisor, a Director or a Chairman in that industry for the rest of my life. I started when Glaxo was promoting Betnovate and Ventolin. I then went to Fisons when Intal was in it's growth stage. I then came to the City where I was an investment analyst in health care. I never got the top ranking, but I was a ranked analyst for a long time. I went into corporate broking, corporate finance, and I was involved in the floats of Medirace, which became Medeva and has now gone into Celltech, PolyMasc, Oxford BioMedica, the rights issues for Proteus, ReGen obviously, and so on.

TWST: Do you find that balance between financial and industry experience is a useful skill set in the biotech space?

Mr. Lomax: I think so. I did six years to start off in the industry and then I was in the City for about 22 years full time until 1996. Then I was part City, part industry for a while and now I have been back in the industry for the last five years.

TWST: It seems the financial credentials for biotech leaders have become as important, at least to investors, as the scientific background.

Mr. Lomax: I think that's absolutely right. I remember going to a presentation on the biotechnology industry by one of the really top American brokers in about 1978/1979 and at that time it looked absolutely fantastic. You liberate all these scientists and wait to see what they produce. Well, AmGen produced and Genentech produced but in the UK there has not been a corresponding success. It's a slight exaggeration, but the failures have been greater than the successes and there have been an awful lot of people basically saying, "We've been pouring millions into biotech and we are not seeing anything." So the financial skills have come in more. We don't pay ourselves large sums of money, and of course that makes the investors feel better. They know they are not just paying to keep me alive and I think that's important.

"The product had a clinical trial in Poland in which it reached statistical significance and it is potentially a blockbuster product. I would also point out that we are actively, and I do mean actively, pursuing revenue generation."

TWST: Just drawing on your experience as an analyst, what is your sense of investment community sentiment at this stage and what sort of reaction are you receiving in light of your clinical trials progress?

Mr. Lomax: The first point is that no one has confidence in the sector. It's quite extraordinary. I have finished trials which show that I've got a product that has efficacy in Alzheimer's, has no safety and no toxicity issues, and is waiting to go to phase IIB/III, and yet most New York millionaires could buy it outright. I think some people

do understand the sector. But in general, there has been a vast de-rating of the biotech sector. If I were an immensely rich drug company, what I would do is go and buy 20 biotechs and see what I can get out of them, because quite frankly if they are all sitting around saying their research budgets are not coming up with much, there are an awful lot of biotechs with a very considerable number of products in early clinical trial, which don't need a great deal more than cash and development spend.

TWST: As a quick recap, what should investors be looking for from ReGen in the next year or so?

Mr. Lomax: Manufacturing scale-up, a partnership and entry into Phase IIB/III clinical trials in Alzheimer's and revenue generation from the non-drug discovery part, i.e. profits.

TWST: What do you see as the major obstacles to achieving these objectives?

Mr. Lomax: On the revenue generating side, just actually acquiring the companies and chunking through the process, really. On the other side, convincing a major healthcare company that I really have got a major product.

TWST: On the acquisition side, is there a geographic criterion?

Mr. Lomax: Yes, it's called England. I think it would be silly of us to look outside the United Kingdom because there are a lot of deals to do here. Our culture is very similar to the American culture and we can do deals. But if we go blundering around in France it won't work.

TWST: Can you leave us with three or four compelling reasons why investors should take a look at ReGen?

Mr. Lomax: We have been around five years. Clearly, the longer you're around, the longer you are likely to stay around, which I think is important. The management team has been together for some time, so you have a coordinated company. The product had a clinical trial in Poland in which it reached statistical significance and it is potentially a blockbuster product. I would also point out that we are actively, and I do mean actively, pursuing revenue generation.

TWST: Thank you. (DG)

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