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In accordance with our obligation as a 12g3-2(b) filer, number 82-5135, to file home country announcements, please find the following announcement which was released through the Australian Stock Exchange today –

1. Newsletter to Shareholders dated September, 2002.

Yours sincerely

T M Fenton

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Newsletter

September 2002

Dear Shareholder

BresaGen has experienced some turbulent times in the market of late. We have put out a number of announcements but it is not possible to really explain what is behind the moves in the documents we are obliged to file under continuous disclosure rules. This newsletter seeks to fill you in more thoroughly on recent events.

Board Composition

Let's turn to the recent Board changes. We have recognised for some time the need to restructure our Board to reflect the evolutionary changes that have been occurring in the Company as we become more involved in clinical products and the American scene. The recent resignations are the first stage of this process. Unfortunately individual requirements meant that we had to announce the departures before being in a position to announce replacements. However I should point out that all of the Directors concerned had indicated their intention to retire from our Board before we knew that British Biotech were to withdraw from our E21R program.

I am working closely with our new Chairman Peter Hart to build a Board that will work more closely with management in line with contemporary practice and meet the mooted guidelines for independent Directors on both sides of the Pacific. We have identified the skills that we need to recruit to our Board and in fact have individuals identified who we expect to join us.

While it would be unfair to name them prematurely, I can tell you the skills we are seeking. We expect to recruit a US based patent attorney who is a partner in one of the leading US intellectual property firms specialising in the biotechnology sector. These skills are going to be important at the Board level as intellectual property development, trading and licensing become key elements of our product development programs. We have some 140 issued or pending patents in key countries around the world. Using them to gain freedom to operate in key markets, especially the USA, and to gain licensing income or as part of strategic sales will add shareholder value.

We also plan to recruit a seasoned US based biotechnology executive with significant experience at Board level in strategic planning and fund raising. Australian membership of our Board will be strengthened by the addition of a Director with a formal financial background.

Peter Hart as Chairman brings the benefit of a long association with the Company. He is proving to be an "involved" Chairman and has instituted a strategic steering committee for the Company which consists of himself, myself, non executive Director Rudy Mazzocchi and executive Director Chris Juttner. This committee will serve as a sounding board for new ideas and a bridge between management and the Board. Our regular phone meetings contribute to the best possible integration of the Australian and American operations. Our new model is much closer to the American one for technology growth companies which utilises people with a working knowledge of the industry and specialist skills.

Politics

BresaGen has become intimately involved in what may be loosely referred to as "Stem Cell Politics". Shareholders on both sides of the Pacific would be well aware of the ethical controversies surrounding aspects of stem cells and particularly those sourced from embryos. Participating in the debate and trying to ensure a workable outcome in both countries has absorbed a significant amount of management time largely working behind the scenes directly with

politicians or supplying information to lobby groups. Our position paper on this topic has been posted on our website and is periodically updated.

A key issue for us is the ability to be able to derive new cell lines for product development as opposed to research purposes. Quite properly regulatory authorities impose much stricter requirements upon materials destined for implant into human patients. It is our judgement that derivation of new embryonic stem cell lines under strictly controlled and documented conditions is required for product development. In particular the cells destined for "commercial" cell lines need to be derived without ever contacting cells from species other than human. We have invented certain techniques pertinent to this requirement and filed patent claims.

It is critical that the development of commercial cell lines be permitted in at least one of the countries in which we operate. Hence our commitment and contribution to the political process in this area. The situation in Australia is still unclear until new legislation is voted on later this year. The big unknown for us is whether or not the existing frozen surplus embryos likely to become available with informed consent can meet current Good Manufacturing Practice (cGMP) requirements.

Approval of the Australian Bill is not critical to our product development plans. A recent clarification by the US National Institutes of Health (NIH) means we can produce new commercial cell lines to cGMP requirements at our American laboratories while fully meeting all legal and ethical requirements.

BresaGen is not affected by any ban on therapeutic cloning as our product plans do not involve therapeutic cloning at all.

Technical Progress

There are some commercial restraints upon us with regard to keeping shareholders completely up to date on what we have discovered in the laboratory. Before revealing our progress to competitors we need to file patent applications where appropriate. These filings remain hidden for up to 18 months. In addition it is to our advantage to publish our key findings in quality peer reviewed scientific journals to give credibility to our findings. Journals will not publish work that has been previously reported in newspapers for example. This also causes delays.

Working within the above restrictions I can report that we have made exciting progress in both our cell therapy program and protein production technology.

If we look back a year, President Bush was just announcing substantial US government support for cell lines which existed on August 9th 2001. Following this announcement we were allowed to bring our cell lines into our laboratories on the University of Georgia campus. Until then work on embryonic stem cell lines within US government supported facilities such as the University of Georgia risked withdrawal of all Federal funds from the institution.

Since bringing our cell lines on campus we have learned how to grow them reliably and, as announced recently, shown that our cellular differentiation technology works with human cells. The importance of this announcement should not be underestimated. We can now produce the type of human cell that is ultimately required by patients suffering from Parkinson's Disease. Other specific cell types required for other central nervous system diseases can be produced but our first product focus is on Parkinson's Disease.

Having proven an ability to produce potentially useful cells we are now turning our attention to product development. This means the production of commercial cell lines in parallel with animal testing of our cells in disease models. Experiments in rats have started and the next step will be safety studies in primates. We have started to put cells into the hands of collaborators whom we expect to be among the first to undertake human trials even though these trials will ultimately use commercial cell lines and are at least two years away.

The American Food and Drug Administration (FDA) has approved section 510K marketing of our catheter device designed to deliver cells deep in the human brain using real time imaging to guide the surgeon making the implant. This development was announced on August 8th. BresaGen will be able to use this device in the validation process leading to human therapies.

In the past year our cell therapy program has progressed dramatically.

In August 2001 most experiments were being done on mice and our four human cell lines had just been acknowledged as eligible for US Federal NIH funding. Today we have transferred our techniques from mice to human cells and developed product concepts for treatment of neurological disease with an early focus on Parkinson's Disease. Testing of our product concept in animal models has commenced using human cells and we have addressed issues such as scaling cell production and making "clean" commercial cell lines suited for the production of cells destined for human transplantation. Significant intellectual property filings have been made as the work has progressed. During the year we have maintained an important dialogue with the FDA so that our prospective products will meet their requirements when human trials begin. I think this progress is remarkable and we are emerging as a leader in this important new area of medicine.

Protein Pharmaceuticals

This technology platform is a long established part of our business. Over some 12 years we have developed a capability to manufacture certain classes of proteins very efficiently in the bacterium Eschericia Coli (*E.coli*). Our lead product E21R was aimed at several applications including acute myeloid leukemia (AML). We recently suffered a severe disappointment when some pre-clinical laboratory results could not be repeated in the UK. While we are still investigating why this happened, the bottom line is that E21R as a treatment for acute myeloid leukemia has been abandoned.

Following a review we have decided to reinstate a pilot Phase 2 study in rheumatoid arthritis patients where the pre-clinical results continue to suggest the drug may be effective. A pre-clinical study where the drug is used in conjunction with the chronic myeloid leukemia drug Glivec is also likely to continue as our investigators have made some interesting observations in preliminary studies.

The cessation of the AML studies with British Biotech has necessitated some cuts in our headcount as announced, as we were intending to supply all the E21R protein required for the clinical trials. We are also redirecting our resources to accelerate human growth hormone (hGH) being registered as an Active Pharmaceutical Ingredient (API). Availability of a high quality hGH from our new FDA compliant plant will be the first step in the development of a generic biologicals industry around the world. This has been a contentious issue with regulatory agencies but it is our judgement that high and increasing drug costs - particularly of biological drugs - is generating pressures where a biological generic sector is going to emerge rapidly. With our protein production expertise we have the opportunity to become a key supplier in this field.

Our protein group has also proven successful in developing a "fusion" technology where quite small proteins or even smaller peptides can be produced by attaching them to a larger one and then specifically separating them. We are carrying out contract work for others who have small protein or peptide products at an advanced stage of development but need a cost effective production process for them to become viable products. Our strategy is to use our process development skills to add value to such emerging products.

Finally, a word about our new headquarters and production facility. This building is well underway in Thebarton SA just a few hundred metres from our current location. The SA Government is providing finance and we will purchase the building over 10 years. It will be the most sophisticated

protein manufacturing plant of its type in Australia and is designed to meet American Food and Drug Administration requirements for the production of biologicals for human use. A facility of this type is essential if the Australian biotechnology industry is to meet its potential and take products into clinical trials and ultimately local manufacture rather than selling them off at an early stage to foreign partners.

Construction is progressing well with the main shell of the building complete and internal fitout commenced. We expect to start moving in around the end of this year. The decision to build this facility was a difficult one. We wanted surety that it was required. E21R was a driving force for the decision to go ahead as we needed to produce significant quantities to world regulatory standards. Given that this requirement has significantly diminished our challenge now is to fill our new facility with contract work where our process development skills are attractive to others. Our recent workforce changes are designed to put our best efforts behind this challenge and inquiries and contracts to date are encouraging. Work in the cell therapy group is also identifying cellular control molecules that could become products within their own right and utilise the manufacturing skills in the protein pharmaceutical group.

Going Forward

BresaGen has always faced a dilemma. Are we nicely diversified or insufficiently focused having two core technology platforms within the Company? We do face pressures to effectively split the Company through divestiture or consolidation with others of one of the platforms. On the other hand there is a good case for persevering with both and taking advantage of the potential synergies as our cellular research throws up new opportunities for protein or peptide products which can be developed and made in our new facility.

There is no clear answer but management and the Board will continue to review this issue as we strive to build shareholder value in what are very difficult times for companies trying to invent the great opportunities of the future without a profitable base today. Investing in the future has always been risky but I am confident our team will deliver rewards for patient shareholders just as Christopher Columbus showed the value of venture investment by Queen Isabella in 1492.

Yours sincerely,

Dr John Smeaton
President & CEO

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