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Focused on Improving the Effectiveness of Drug Discovery Screening, Biocroi Ltd has developed their Advance Microplates which are the Standardized Containers in which Human Cells are Grown and their Happy Cell low-viscosity Suspension Medium for Cell Culture use for Studying Tumor Formation

Healthcare
Assays

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Peadar Mac Gabhann
Managing Director

BIO:
Graduated from the National University of Ireland, University College Dublin in 1978 with M.Sc. degree in Industrial Microbiology. Carried out research in Holland, Switzerland and Japan. Joined Schering Plough in 1983 and was a key member of staff in the start-up of their world-class Biotechnology facility in Cork for the production of Interferon. As Director and board member of Schering Plough Japan, led the company's research and Asian business development operations.

Has more than 25 years experience at the forefront of the international Pharmaceutical industry. Extensive expertise in R&D, Manufacturing and QA/QC. Specialised in Regulatory Compliance, Pharmaceutical Computer Systems, Advanced Factory Automation Systems. Participated in the concept, design, commissioning, validation, start-up and approval of several multi-national pharmaceutical plants in Ireland and Europe.

Company Profile:
Biocroí Ltd, established 2009, is a tool-based SME developing a range of proprietary, IP protected, advanced multi-well microplates and HAPPY Cell Advanced Suspension Medium (ASM) for the growth of cells in 3-D for use in: High Content Analysis and Cell Based Assays.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Mac Gabhann, what is the focus of the company today?
Mr. Mac Gabhann: Biocroí Ltd's mission is to develop and sell technologies to improve the effectiveness of the drug discovery process; to decrease failure rates and in parallel reduce costs in pharmaceutical drug development. We operate in an area called Drug Discovery Screening, where pharmaceutical companies screen 1,000's of different compounds for potential new drugs. Therefore, we are developing disruptive tools to make that process more effective and more efficient.

CEOCFO: How does the process work today? What have you figured out that is going to make it go more smoothly and more efficiently?
Mr. Mac Gabhann: Biocroí has developed two innovative products/technologies: (i) Advanced Microplates, and (ii) Cell Culture Medium. Microplates are in every pharmaceutical drug discovery laboratory in the world. More than $500 million worth are consumed annually. They are standardized containers in which human cells are grown and assayed against new chemical and biological entities. They are the modern day equivalent of the test tube. One version is the "96 well plate" and the other is the "384 well plate. You can Google these and see many examples of them. Typical volumes in the 96-well would be one hundred micro liters and in the 384-well about fifty micro liters. Miniaturization is a key driver in pharmaceutical R&D…Less is More. One of the big issues when you miniaturize is that the contents of these reaction vessels get more subjected to the environmental conditions. And as any microplate procedures involve multiple steps wherein the microplate is removed from the temperature controlled incubator to a lab bench and then back again. This results in: Rapid decrease in plate temperature, evaporation from the plate wells and results in erroneous data. Biocroí's Advanced Microplates contain a patented gel technology surrounding the wells which prevents evaporation; buffers temperature effects; improves cell growth and provides better cell based assays. So that the readouts from these assays are much more consistent throughout.

Our other product, Happy Cell, is a unique, low-viscosity suspension medium for cell culture and very useful for studying tumor formation and treatment. Recent research has shown that cells cultured in-vitro in 3D are more physiologically relevant than cells cultured conventionally on flat surfaces of tissue culture plates. As a consequence therapies that show promise with 2D cells often fail in later stage development because cells

grown in typical 2D environments do not mimic the 3D cell environment of living things. By screening drug candidates in our 3D environment, the researcher will detect ineffective therapies early in the process. If a drug candidate looks promising in a 3D environment, it has a greater probability of working in the living environment. See our website for further details:
www.advancedmicroplates.com.

CEOCFO: Has the drug community or the medical development community been looking for better tools?
Mr. Mac Gabhann: Absolutely! 92% of drugs fail clinical trials! There is a realization that we need to rapidly change the way we currently develop new drugs. We need to develop new tools and technologies if we want to improve the success rate. Improving by just 1% could reduce cost by 1$ billion a year. Industry wants to improve the quality, increase the speed of development, increase throughput while reducing the costs.

CEOCFO: How are you able to achieve the results you are getting with each that has not been done before?
Mr. Mac Gabhann: Biocroí's Advanced Microplates: Significantly improve the quality & accuracy of cell based assays; Provide more uniform results with fewer repeats; Enable a substantial decrease in reagent & cell usage thereby resulting in a significant cost saving. Biocroí's unique, low viscosity cell culture medium, Happy Cell ASM: Improves drug development success analysis; is cost effective, simple to use, requires minimal human Intervention and is readily scalable.

CEOCFO: Is that product in the market today?
Mr. Mac Gabhann: Yes. We launched Happy Cell ASM at the American Association of Cancer Research (AACR 2012) in Chicago in April this year. We are currently selling the product throughout Europe & Asia. We will soon break into the US market.

CEOCFO: What has been the reaction so far?
Mr. Mac Gabhann: Very positive. People who said they would never change now are realizing that Happy Cell is just what they needed. Of course, the big challenge is to try and change the overall buying behavior in the target market…..trying to break through all the noise and get to the innovators. And, unfortunately the innovators are in the minority, 2.5% of the population. If "Johnny Whoever" has a job to get "X" compounds screened by the end of the year he is going to do it the way he has always done it. Not a new way that will give better outcomes. His primary goal is to satisfy the boss and the boss's boss. Just because they are involved in research and discovery activities in their day-to-day job does not make researchers innovators, in the context of adopting new technology, despite what they might claim.

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CEOCFO: How do you break through?
Mr. Mac Gabhann: What we need is a targeted effort to find the true innovators within the population, understand their situation and more importantly why they might be motivated to change approach. Provide them with a "FIX". We also need to jump on the social media band wagon create a message that has the potential to go viral. We are currently seeding product into the market and placing it with many kinds of disparate research groups. We are hoping that one of these groups generates something very novel so that we can create a headline that we can send around the world.

CEOCFO: Would you tell us more about your second product?
Mr. Mac Gabhann: Biocroí has two patent applications covering advanced microplates filed in US, Canada, EU, Australia and Japan. The major claims in the first patent are accepted by US examiner and so we expect that to be granted before year end. In addition, Biocroí has developed valuable know-how on the design and manufacture of theses Advance96, Advance384 plates and in particular in assay miniaturisation. The unique gel technology surrounding the wells, which we will own, when the patent is granted has many potential future uses. It can turn the microplate into a miniature bioreactor and can be used to create specific micro environments within the plate that mimic the human environment e.g. for studying hypoxia. It can also act as a feeder layer for cells or as a way of removing waste product from the cells.

CEOCFO: What is it that causes that to happen? What is it that you are doing that is making that difference?
Mr. Mac Gabhann: High Content Analysis (HCA) commands a major place in drug discovery. According to a recent report in July 2012 revenues in the global market for HCA are estimated to exceed US$3.0 Billion in the next 6 years. HCA uses living cells, image analysis and robotics to measure changes in properties of cells caused by external treatment. We now have the capability to stain 100's of different pathways within the cell with a variety of different colors. So we can take a color snap-shot of the inside of the cell that is fixed in time based on a certain treatment. It's like high quality photography. Labs have sophisticated automation and robotics that can analyze those images and with complex algorithms can deduce conclusions about the effects of a particular compound on the cell. If you are getting blurred or inconsistent images from the outside wells of the microplates that are improperly pixilated then this is reflected in a poor result. If you cannot read the

results properly this contributes to the background noise and reduces the overall accuracy of the test. Therefore, what researchers do now to overcome this noise is to remove those outside wells from the equation and do their computational analysis using the other wells. With the result, their overall throughput efficiency is reduced by 24%. In a large pharmaceutical company where they often use 1,000's of plates and millions of wells in a large drug screening experiment. Twenty four percent reduction in highly inefficient..that's difficult to live with in an age of high technology.

CEOCFO: What is the science and technology?
Mr. Mac Gabhann: Environmental conditions result in fluctuations in thermal conditions, variations in dissolved CO2, alterations in water media hydration and mechanical disturbances. All of these conditions can; retard cell growth, result in abnormal gene expression, induce cellular stress and increased heterogeneity in cell populations. Our patented gel that surrounds the well provides thermal buffering so that the plates cool slower when taken out of the incubator and counteracts many of the above interactions. It also prevents evaporation which results in improved cell growth and reproducibility with less edge-effects and better research outcomes.

CEOCFO: Where are you in commercialization process for this area?
Mr. Mac Gabhann: We are currently seeding our products in the market with key customers so that they will incorporate them into their work flows. We are fortunate in that our Chief Scientific Officer and inventor of the technology is a frequent key-note speaker on the world-wide lecture circuit so he is actively promoting the technology among his peers. However, getting new technology incorporated is easier said than done. People have very set way of doing things. If something new arrives they say "great, fantastic." However, the boss still wants them to produce what they signed up for. Frequently, they just do not have the time to innovate.

CEOCFO: Are you funded to get through the next steps or will you be looking for funding?
Mr. Mac Gabhann: We are currently looking for funding right now to take us through next year. We have about 40% of that funding already lined up and are out there looking for the remaining part.

CEOCFO: How do you, as an individual and from the company perspective, deal with the frustration of knowing that you have a product that is a potential gamechanger and yet it is so difficult to reach people?
Mr. Mac Gabhann: You live and you learn! You certainly don't realize it when you start up and initially make business plans. You convince yourself to believe your unique, innovative products will be easy to sell. If you didn't believe you would never write the plan and wouldn't go into the business it in the first place. This is so much a part of life. And life's experience teaches you to manage your expectations and frustrations. Everyone can't be a at #1. It a bit of a lottery getting there. Perseverance, determination and a little bit of luck along the way. You just have to accept it as it is and keep trying to breakthrough.

CEOCFO: Why should investors and people in the business community pay attention to Biocroi today?
Mr. Mac Gabhann: Having worked at a senior level within the multinational pharmaceutical industry for many years I realize that it is almost impossible for these large multi-national companies to innovate within the confines of their existing structures. It's like trying to force a large oil tanker to change course at sea. It can… but it is afraid where it might end up. However, the industry has to change if it is to progress. The only way it can do that well is by in-licensing technology developed by small companies on the outside and incorporating these new technologies into their workflows. The products that Biocroí have now are the first of many fixes developed by industry experts who have worked within the industry for many years. Our current products dramatically improve the efficiency of drug discovery screening and will help reduce that horrible FDA 92% failure statistic. Moving on from here, once we have these out-licensed, we have a whole range of ideas for tools and technologies that we can bring along quickly. So, we are not just a one or two hit wonder.

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