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Bionomics Limited (ASX code: BNO) announced recently that it has signed a development and licensing agreement with Merck Serono, a division of Merck KGaA. The agreement is in relation to a new treatment for multiple sclerosis and other autoimmune conditions and is based on Bionomics' Kv1.3 compounds. Why have you decided to license out the program at this stage?

CEO & MD, Dr. Deborah Rathjen

The agreement with Merck Serono is a significant milestone for us. It validates our discovery approach, which has allowed us to successfully develop the program to its current pre-clinical stage. Securing a commercial partner for our Kv1.3 program has been a priority for us this year as it will allow us to focus our resources on our lead clinical programs, anti-cancer agent BNC105 and BNC210 for the treatment of anxiety.

Merck Serono is a very strong partner for the Kv1.3 program as they're a world leader and pioneer in treating multiple sclerosis (MS). One of their products, Rebif® (interferon beta-1a), which is a disease-modifying drug used to treat relapsing forms of MS, is registered in more than 80 countries worldwide.

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Can you provide background to the Kv1.3 program and detail on how the agreement with Merck Serono will work?

CEO & MD, Dr. Deborah Rathjen

MS is an inflammatory disease caused by the autoimmune destruction of the sheath of fatty material (myelin) that surrounds certain nerve cells and influences the rate at which nerve signals travel. MS is estimated to affect over two million people worldwide. In 2001, the National Health Survey indicated that there are approximately 15,000 Australians living with MS. There's a clear need for a safe, effective, oral drug as the current treatments for MS are systemically administered (subcutaneous (SC), intramuscular (IM) or intravenous (IV)) and only partly effective and can be associated with major side-effects. Kv1.3 inhibition represents an innovative approach for the discovery of oral compounds in the field of MS.

The agreement with Merck Serono covers the development and commercialisation of a novel series of our Kv1.3 blockers. These active compounds target the voltage-gated potassium ion channel Kv1.3 that has been shown to inhibit the proliferation and differentiation of immune cells, which are associated with nerve cell damage in patients with MS.

Together with Merck Serono, we will seek to identify new Kv1.3 inhibitor compounds for clinical development through our screening platform during the initial phase of the collaboration. This R&D collaboration brings together our expertise in Kv1.3 biology and Merck Serono's expertise in MS pharmacology in a combination that has the potential to accelerate progress in the identification of novel drug candidates for the treatment of MS. We look forward to working with Merck Serono to develop the program further and to ultimately bring innovative treatment options for patients with MS to the clinic.

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Can you describe the financial terms of the license agreement?

CEO & MD, Dr. Deborah Rathjen

Under the agreement, Bionomics will receive an upfront payment of US\$2 million and has committed research funding for the initial phase of the collaboration. Merck Serono will fund all development activities including clinical development and will select a number of compounds for further development. For each compound, we have the potential to receive milestone payments of up to US\$47 million based on successful development and commercialisation. We will also be eligible to receive undisclosed royalties on the sales of the licensed products.

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What is the timeline for the development of the Kv1.3 compounds for multiple sclerosis and the potential market for a successful multiple sclerosis drug?

CEO & MD, Dr. Deborah Rathjen

The global MS market is currently estimated at US\$2 billion per annum. There are strong reasons to suggest that the Kv1.3 inhibitors can match the market needs for a safe and effective oral drug to treat MS. In April, Merck Serono announced that the first quarter 2008 worldwide sales of Rebif[®] for the treatment of relapsing forms of MS increased by 11 percent to €313 million. This is an indicator as to the market potential for a successful MS product.

With regards to timeline, any selected Kv1.3 inhibitor must go through the required development process from Phase I to Phase III of clinical development. Under the agreement, this will be fully funded by Merck Serono and will take place over several years.

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You recently presented new data on your developmental anti-cancer agent BNC105 at the American Association for Cancer Research Annual Meeting showing evidence of almost complete disruption of tumour blood vessels in animal models of lung, brain, neck, breast, colon and prostate tumours. Can you provide an update on the current clinical trial and your future plans for the development of BNC105?

CEO & MD, Dr. Deborah Rathjen

Our research on BNC105 continues to provide supporting evidence for the unique attributes of BNC105 and the action of BNC105 suggests that it may be effective against solid tumours arising from a range of tissues.

BNC105 is highly selective and potent in disrupting blood vessels which support the growth of solid tumours. This makes it a potential candidate with an improved therapeutic index. The action of BNC105 exhibits a dual mode where, in addition to anti-vascular effects, it also exhibits potent direct anti-proliferative effects on cancer cells. The mechanism of action results in a tumour “lock-in” effect, with BNC105 persisting inside the tumour mass longer than normal tissues. BNC105 also has a combinatorial capacity with other anti-cancer therapies. For example, BNC105 combined with existing gold standard treatment Avastin[®] shuts down tumour blood vessels for prolonged periods.

The first clinical trial of BNC105 in patients with advanced cancer commenced in February under a successful US FDA Investigational New Drug (IND) application. The aims of the trial are to evaluate the safety of BNC105 and to establish a starting dose for subsequent trials. The dose-ranging trial will also gather data related to the vascular disrupting activity of BNC105 through extensive use of tumour imaging techniques and evaluation of biomarkers.

To date, the trial has progressed well with the enrolment of patients with a variety of different cancers proceeding as projected. We’ve chosen the Royal Melbourne Hospital, the Peter MacCallum Cancer Centre and the Western Hospital as initial clinical trial sites, and other trial sites are expected to open later this year.

Based on the strong progress of BNC105 to date, we’re already planning for the next series of clinical trials with the aim that these will get underway in 2009.

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Sai Advantium was awarded the contract to manufacture your anxiety drug candidate BNC210 in April. What impact does this contract have on your cash burn?

CEO & MD, Dr. Deborah Rathjen

We've awarded the Good Manufacturing Practice (GMP) contract of BNC210 to Indian company, Sai Advantium following a competitive bidding process. Sai Advantium is an experienced contract manufacturing service provider for the pharmaceutical industry. In the process of awarding Sai Advantium the contract, we had their GMP facility audited and are satisfied that BNC210 is being manufactured within FDA requirements by Sai Advantium.

As at 31 March, our cash position was \$7.5 million. The contract with Sai Advantium is within budget for the overall BNC210 development program.

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Previously Bionomics had targeted an IND submission in relation to BNC210 by the end of this calendar year. Are you still on track to meet this target?

CEO & MD, Dr. Deborah Rathjen

In addition to the GMP manufacture of BNC210, we've also advanced the formal safety and tolerability evaluation program of BNC210, required for the IND submission. These studies are being conducted by WIL Research Laboratories, LLC, in Ashland, Ohio (USA), a contract research organisation recognised worldwide for conducting quality Good Laboratory Practice (GLP) studies.

In April, we submitted a pre-IND package to the FDA and the program currently remains on track to meet its target of submitting the IND by the end of 2008.

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What other potential milestones are expected this calendar year?

CEO & MD, Dr. Deborah Rathjen

We've delivered on a number of key milestones this year including this latest significant milestone, the deal on our MS program with Merck Serono. Our other achievements include initiation of the BNC105 clinical trial, payment of US\$1 million preclinical milestone by Genmab A/S under our license agreement and initiation of manufacturing and safety studies towards a successful BNC210 IND submission.

Other potential milestones for this year include completion of enrolment in the current BNC105 trial, completion of the manufacture of BNC210 clinical trial material and the required safety studies, and the IND submission for BNC210.

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Thank you Deborah.

For more information about Bionomics Limited, please visit www.bionomics.com.au or call Dr Deborah Rathjen on (08) 8354 6101.

For previous Open Briefings with Bionomics Limited, or to receive future Open Briefings by e-mail, please visit www.corporatefile.com.au.

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Factors Affecting Future Performance

This announcement contains "forward-looking" statements within the meaning of the United States' Private Securities Litigation Reform Act of 1995. Any statements contained in this press release that relate to prospective events or developments, including, without limitation, statements made regarding BNC105 and its' drug development programs are deemed to be forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "projects," "forecasts," "will" and similar expressions are intended to identify forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by these forward looking statements, including risks related to our available funds or existing funding arrangements, a further downturn in our customers' markets, our failure to introduce new products or technologies in a timely manner, regulatory changes, risks related to our international operations, our inability to integrate acquired businesses and technologies into our existing business and to our competitive advantages, as well as other factors. Subject to the requirements of any applicable legislation or the listing rules of any stock exchange on which our securities are quoted, we disclaim any intention or obligation to update any forward-looking statements as a result of developments occurring after the date of this announcement.