

Latest News from Sienna Cancer Diagnostics

December 2015

Successful Completion of Johns Hopkins Hospital Clinical Study

One of the world's most prestigious clinical and academic institutions, Johns Hopkins Hospital (Baltimore, United States) has completed a study which highlights the clinical benefits of using the Sienna Anti-hTERT antibody (SCD-A7) as an adjunct to routine cytopathology testing in the assessment of cancer.

Researchers from Johns Hopkins will present the abstract at the annual gathering of leading Northern American pathologists in March 2016.

Lead study investigator, Assistant Professor of Pathology, Christopher VandenBussche, M.D., Ph.D. says his work "focuses on translational research that combines traditional cytomorphology with novel molecular and immunological techniques in order to enhance the diagnostic and clinical value of cytologic specimens".

As a result of the positive outcomes of this initial telomerase immunocytochemistry study, a follow-on study using a larger number of patients is now being planned for commencement in early 2016.



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IVD Product Development Update

Key to the commercial growth of the company is the development, registration and launch of an IVD-registered version of Sienna's core telomerase detection technology.

Development of this product has progressed significantly throughout 2015, with testing and analysis of various production methods resulting in the best product format for Sienna to bring to market, both from both a clinical performance as well as manufacturing efficiency standpoint.

Manufacturing of several batches of the new antibody format, which will be used for product verification and validation testing (both critical to the FDA and European IVD registration process) will begin within the next month.

Also important in the process of IVD product registration is certification of Sienna's Quality Management System to the ISO13485 standards. At the end of November, Sienna underwent a preliminary assessment by a Notified Body to determine what additional work needs to be done in order to achieve certification. The assessment was extremely positive and we anticipate achieving final certification in the first quarter of 2016.

"The most important use of funds from the upcoming capital raising, is the completion of development, followed by the registration and commercialisation of Sienna's IVD product format"

– COO, Matthew Hoskin



If you've not yet noticed our new website, take a look at:

www.siennadiagnostics.com.au



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Growing Clinical Collaborations

One of Sienna's many strengths is its strong network of partners and collaborators. Academic and clinical research & development performed in external pathology laboratories is invaluable to Sienna. The past few months has seen exciting new studies commenced at highly credible and capable institutions.

UCLA (University of California, Los Angeles) commenced a study into the clinical application of Sienna's SCD-A7 antibody as an adjunct to cytopathology in the examination of urine samples, and Princess Alexandra Hospital (Pathology Queensland) began a study to investigate the clinical application of the antibody in various other cytopathology specimens in which cancerous cells are likely to exhibit

telomerase. The Sienna team will work closely with these pathology laboratories to help unlock the clinical potential of Sienna's unique reagent (SCD-A7) for detection of this important cancer related biomarker (telomerase) and establish new commercial opportunities.



Patent Portfolio Strengthened

2015 has seen some significant milestones achieved with respect to advancement of Sienna's intellectual property portfolio.

Whilst holding the global license to intellectual property protecting the use of telomerase detection for clinical diagnostic purposes, Sienna has sought to bolster that position through the filing of additional patent applications based on intellectual property developed internally. Early in the year Sienna progressed its provisional application directed towards the use of telomerase detection to resolve atypical urine cytology findings by filing a complete application. A complete application takes advantage of the Patent Corporation Treaty (PCT), leading to a more cost-efficient patent registration process. Sienna will now pursue patent protection in strategically targeted countries, with the PCT providing additional time for those countries to be confirmed. In August, two additional provisional patent applications directed towards methods-of-use were filed.



Annual General Meeting

In November Sienna held its Annual General Meeting at Graduate House in Carlton, where shareholders voted in the adoption of a new company constitution.

Following the AGM, Sienna's CEO Dr Cliff Holloway presented plans for further commercialisation and growth of the company. Dr Holloway, who has since been appointed to the Sienna board, presented a detailed program of short, medium and long term strategies and plans for Sienna. These were well received by shareholders who provided the board and management team with positive feedback and encouraged the implementation of those plans. With the board, management team, and shareholders well aligned behind the Sienna strategic plan, the focus now is on raising capital to accelerate its execution.



"Sienna is now ideally placed for commercial growth through a combination of market penetration, geographical expansion, and product expansion strategies. We will be adding resources over the coming year to facilitate and drive that growth."

– CEO, Dr Cliff Holloway