澳大利亚生物技术协会
澳大利亚医疗技术公司名录

公司资料

公司名称：Minomic International Ltd

关键联系人姓名：Brad Walsh 博士

关键联系人职位：首席执行官

公司网址：www.minomic.com

公司地址：Suite 2, Ground Floor, 75 Talavera Rd, Macquarie Park NSW 2113

该公司尚未上市。

关于公司

Minomic International Ltd (Minomic) 是澳洲一家私营生物标志发现公司，专门从事于前列腺癌的体外诊断 (IVD)、诊断成像和治疗。在过去的 7 年中，Minomic 开发出名为 MiCheck™ 的 MIL-38 单克隆抗体体外诊断测试，可用于发现早期前列腺癌。预计到 2017 年全球前列腺癌的诊断和筛查市场价值将达到 174 亿美元，同时前列腺癌的治疗市场价值将达到 186 亿美元，Minomic 的技术则可解决这两个市场中存在的问题。

前列腺癌筛查以及患者监控产生了价值 70 亿美元的全球前列腺特异性抗原 (PSA) 检测市场。Minomic MiCheck™ 测试快速且具有非侵入性，因而将用于标准的临床化学实验室。需要治疗的患者能更快地得到治疗，而不需要治疗的患者将免受目前常见的误报结果带来的创伤，而且还不会增加医疗体系的费用。我们完全相信使用 MiCheck™ 测试能挽救更多的生命。国际专利为 MiCheck™ 测试、MIL-38 抗体、MIL-38 抗原和相关应用提供相应保护。

研究者使用 MiCheck™ 测试的早期版本针对 125 名澳洲患者开展了概念验证临床研究，该研究表明该测试在区分恶性肿瘤患者与良性或正常患者时具有优秀的敏感性与特异性。研究者使用 MiCheck™ 测试于 2014 年末 2015 年初针对 300 名美国患者进行了试点临床研究，初步分析显示该测试能够高精度地区分前列腺癌与良性前列腺疾病。研究者正计划于 2015 年进行进一步的临床研究以确认这些初步调查结果。

MiCheck 测试的诊断性能是任何竞争产品都无法比拟的。其简单的分析架构使它能适应诊断厂商制造的多种自动分析仪。此外，MiCheck 测试简单的分析架构保证其生产成本比较适中，在与许多与其竞争的核酸检测相比时尤为如此。

MIL-38 还在高级成像和治疗应用方面拥有巨大的潜力，早期数个潜在的大型制药合作伙伴对其表现出的兴趣便证实了这一点。概念验证研究已为这些计划在 2015 年应用于动物身上和第一次应用于人体的研究奠定了基础。

最后，Minomic 持有用于膀胱癌诊断和治疗的专利单克隆抗体。这种抗体在早期研究中已显示出优异的性状，因此公司计划对其进行开发，最好是同技术兼商业伙伴进行密切合作。

关键或领先技术

MiCheck™ 测试能检测出与前列腺癌相关或脱落在患者血液中的前列腺癌细胞表面存在的蛋白质。目前用于早期发现并监控前列腺癌的最常用测试是前列腺特异性抗原 (PSA) 测试，其全球市场价值为 70 亿美元。PSA 由前列腺自然产生，并在前列腺癌细胞快速繁殖时增多。但是炎症或感染等良性状况也会使 PSA 超过正常水平。虽然 PSA 测试的敏感性很高（约 80%），却因为缺乏特异性（近似值为 40%）而广受批评。当前需要一种简单的血液检测，需要比 PSA 更具特异性并且在发现前列腺癌时能够具有高度可靠性。这就是 MiCheck MIA 所解决的未满足需求。

MiCheck MIA 测试同时具有高敏感性和高特异性，同时准确度也很高。MiCheck™ 测试是一项体外诊断测试，旨在帮助诊断并监控前列腺癌患者。它使用的是容易获得的血清或血浆标本。MiCheck™ 测试结果提供了一个临界值，可用于区分高风险的前列腺癌患者或复发前列腺癌风险性高的患者与正常患者或患有良性前列腺炎症的患者。世界各地通常使用临床化学实验室中的常规实验室分析仪进行实际的 MiCheck™ 测试。

类别

器械：泌尿科和妇科

诊断学：肿瘤诊断

关键或领先技术的研发阶段

处于临床试验阶段

所寻机遇

Minomic 目前正在筹集资金用来完成 MiCheck 测试的商业化，最有可能于 2015 年底或 2016 年初与一家大型商业合作伙伴签订许可协议来实现此目标。本公司欢迎投资，并愿为有兴趣的各方提供资料备忘录。

Minomic 也有意与能够制造、完成监管注册和在世界各地分配 MiCheck™ 测试的大型制药或诊断合作伙伴建立合作伙伴关系或展开合作。此外，Minomic 正在寻求开发和商业化合作伙伴，以协助其开发未来应用于前列腺癌和膀胱癌诊断的专利技术。

Directory of Australian medtech companies

COMPANY DETAILS

Company name: Minomic International Ltd

Key contact name: Dr Brad Walsh

Job title of key contact: CEO

Company website address: www.minomic.com

Company address: Suite 2, Ground Floor, 75 Talavera Rd, Macquarie Park NSW 2113

The company is Unlisted.

ABOUT THE COMPANY

Minomic International Ltd (Minomic) is an Australian privately owned biomarker discovery company specialising in in-vitro-diagnostics (IVD), diagnostic imaging and therapeutics for prostate cancer. Over the past seven years, Minomic has developed the MIL-38 monoclonal antibody-based IVD test called the MiCheck™ for the early detection of prostate cancer. Minomic's technology addresses the diagnostic and screening market for prostate cancer which is anticipated to reach US$ 17.4 Billion worldwide by 2017 as well as the therapeutic market for prostate cancer which is anticipated to reach US$ 18.6 Billion worldwide by 2017.

US$7 Billion dollar global PSA testing market for prostate cancer screening and also for patient monitoring. The Minomic MiCheck™ test is quick, non-invasive and will be performed in standard clinical chemistry laboratories. Those patients who need treatment will get it sooner, and those who don't need it will not suffer the trauma of false positives results commonly found at present, nor the added costs to the healthcare system. Ultimately, we believe that using the MiCheck™ test can save more lives. International patents protect the MiCheck™ test, MIL-38 antibody, MIL-38 antigen and related applications.

A proof-of-concept clinical study on 125 Australian patients of an early version of the MiCheck™ test demonstrated most encouraging sensitivity and specificity at discriminating malignant from benign or normal patients. The MiCheck™ test underwent a Pilot clinical study on 300 US patients in late 2014 / early 2015 and preliminary analysis shows the ability of the test at differentiating prostate cancer from benign prostate disease with high accuracy. Additional clinical studies are planned in 2015 to confirm these preliminary findings.

The MiCheck test level of diagnostic performance is unmatched by any competing product. Its simple assay architecture makes it adaptable onto a wide range of autoanalysers from

diagnostic manufacturers. Additionally, the simple assay architecture of the MiCheck test warrants a relatively modest cost of production, in particular when compared to many competing nucleic acid tests.

The MIL-38 also holds substantial potential for advanced imaging and therapeutic applications, as confirmed by the early interest shown by several large pharmaceutical potential partners. Proof-of-concept studies have commenced for these applications with animal and first-in-man studies planned for 2015.

Finally, Minomic holds a proprietary monoclonal antibody for bladder cancer diagnosis and therapy. This antibody has shown great performance in early studies and the company plans to develop it, ideally in close collaboration with a technical and commercial partner.

KEY OR LEAD TECHNOLOGY

The MiCheck™ test detects specific proteins associated with prostate cancer or present on the surface of prostate cancer cells that are shed into the patient's blood. The most commonly used current test for the early detection and monitoring of prostate cancer is the Prostate Specific Antigen (PSA) test which represents a global market of US$ 7 Billion. PSA is naturally produced by the prostate and raised when prostate cancer cells rapidly multiply. But benign conditions such as inflammation or infection can also raise PSA above normal levels. Although highly sensitive (about 80%), the PSA test has been widely criticised for its lack of specificity (approximate value of 40%). There is a current unmet need for a simple blood test, more specific than PSA and able to detect prostate cancer with a high reliability. This is the unmet need addressed by the MiCheck MIA.

The MiCheck MIA test offers both high sensitivity and specificity with a high level of accuracy. The MiCheck™ test is an in-vitro diagnostic test designed to help in the diagnosis and monitoring of prostate cancer patients. It uses a commonly available serum or plasma specimen. The MiCheck™ test result provides a threshold for differentiating patients at a high risk of prostate cancer or at a high risk of recurring prostate cancer from normal patients or patients suffering from benign prostatic inflammations. The actual MiCheck™ test is conducted on conventional laboratory analysers routinely used by clinical chemistry laboratories around the world.

Category

Devices: Urology and gynaecology

Diagnostics: Diagnostics oncology

Point of development of key or lead technology

In clinical trials

OPPORTUNITIES SOUGHT

Minomic is currently raising capital to complete the commercialisation of the MiCheck test, most probably through a license agreement with a large commercial partner in late 2015 or early 2016. The company welcomes investment and can provide an Information Memorandum to interested parties.

Minomic is also interested in partnership or collaboration with a larger pharmaceutical or diagnostic partner able to manufacture, complete regulatory registrations and distribute the MiCheck™ test around the world. Additionally, Minomic is seeking development and commercialization partners to assist in developing its proprietary technology for future diagnostic applications in prostate and bladder cancer.