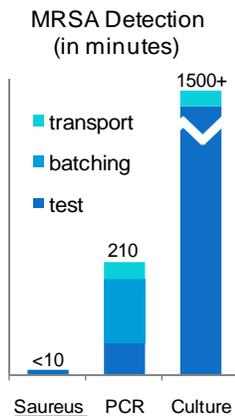




A Platform for Rapid and Cost-Effective Detection of MRSA and Other Dangerous Pathogens™

## Overview

Saureus, Inc. is developing a patented platform technology for rapid detection of dangerous disease causing organisms such as methicillin resistant *Staphylococcus aureus* (**MRSA**).



The key performance features of Saureus' technology are:

- The test is 20x faster than any available diagnostic technology. Total time from sample acquisition to signal is less than ten minutes.
- Does not require use of complex laboratory equipment, processing procedures or highly trained personnel so tests can be performed at the point-of-care and for a much lower cost than any other rapid detection technology.
- Detection sensitivity is very high, enabling detection of infection carriers directly from non-invasive clinical samples (nasal swabs).

The company will initially target the hospital market and eventually other health care facilities (doctors' office and nursing homes) for MRSA screening, but the technology's significant performance advantages over existing diagnostic methods, combined with a broad array of applicable target diseases in global markets, provides multiple opportunities for commercial success.

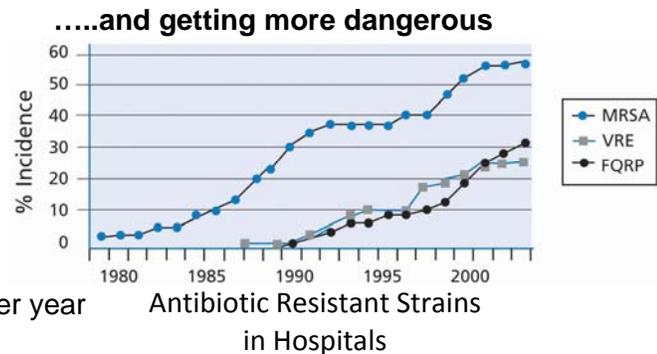
## Hospitals are very dangerous places....

Every year hospital acquired infections (HAIs) sicken millions and kill thousands in the US alone. Some of the most dangerous of these infections are caused by methicillin resistant *Staphylococcus aureus* or MRSA. In US hospitals alone, MRSA is responsible for:

- 278,000 infections (>100,000 of which are serious) per year
- 19,000 deaths/year (more than AIDS)
- Over \$4 Billion in incremental healthcare expense per year

## Most MRSA prevention strategies leave the doors wide open

The most widely used strategies against MRSA are designed to keep it from spreading around once it is already inside a hospital through enhanced cleaning and contact precautions. The growing consensus finds that true prevention efforts keep MRSA from entering (or re-entering) the patient flows of the hospital in the first place. This is accomplished by challenging health care providers to identify MRSA carriers as quickly as possible and routing them away from other patients and into isolation wards before the carrier has a chance to spread the infection. The problem with this strategy is that all currently available MRSA diagnostic tests require at least a few hours (if not overnight) to determine if someone is a carrier. This delay allows carriers to spread the



### MRSA Trojan Horses

2% of the U.S. population carries MRSA in their nasal passage.

Carriers do not display any outward symptoms of the infection, but are very effective at carrying the bug into the hospital and spreading it around to surfaces, equipment and other people in the hospital.

disease until test results are available and it forces hospital admissions staff to initiate isolation protocols on patients based solely on risk factors such as age, living situation, and other non-health specific characteristics. Unfortunately, studies show that these risk-based screening protocols miss ~80% of actual MRSA carriers.

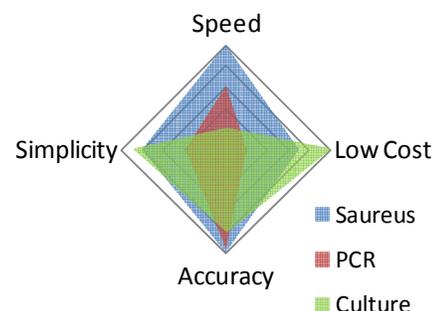
**Saureus' rapid detection technology will enable all hospitals to screen for and keep MRSA from entering hospitals, reducing infections by more than 70%.**

*Speed* – Studies have shown that speeding up the detection time by switching from overnight cultures to 4-hour PCR can help reduce infection rates significantly, as much as 70%. No comparable test exists to test the hypothesis, but the ability to screen patients on-demand in less than 10 minutes (i.e., before they're admitted to a hospital), will provide an even greater reduction in infection rates.

*Simplicity* – Designed without complex equipment or processes, the test will allow the 80% of U.S. hospitals which do not have the money or skilled technicians necessary to operate molecular diagnostics equipment (PCR) to perform rapid MRSA screening.

*Accuracy* – The high sensitivity and specificity of the test will provide physicians a strong basis for clinical decisions which, combined with the rapid results, will enable physicians to forgo broad spectrum (empiric) antibiotic therapies and target the specific biologic threat.

*Low Cost* – With no capital equipment or specially credentialed operators required, fast adoption of the technology will be enabled.



### **The Secret Sauce**

Immunoassays based on agglutination reactions are a common tool in clinical and research laboratories to confirm the identity of cultured samples. Although they are very rapid, the reason for their low penetration in the point-of-care testing market (e.g., MRSA screening) is that they do not have the sensitivity and specificity to reliably produce a detection signal from the antigen produced from a clinical sample such as a nasal swab.

Saureus has solved both the sensitivity and the specificity problems by combining two innovative (patented) techniques for processing the sample. Rapid and specific cell lysis to allow access to intracellular material (e.g., antigens) provides speed and required specificity while design of the agglutinin (clumping platform) provides the sensitivity. Rapid access is enabled by the use of an enzyme reagent that is highly specific to each target pathogen (e.g., MRSA) and works almost instantly to cleave open the cell wall of the target, without hampering the subsequent work of the antibodies. Design of the agglutinin to significantly increase sensitivity of the assay is driven by our ability to control the number, density and orientation of antibodies on the agglutination platform. By creating a platform with huge numbers of antibodies correctly oriented to capture antigens, the test will be able to detect the presence of antigen at a sensitivity level at least fifty times better than the current immunoassays.

**Market size** The US market for rapid MRSA screening is large, but currently limited. Due to the high cost and centralized nature of molecular diagnostics, most rapid MRSA screening efforts take place in well-funded academic medical centers and are focused on high-risk patients such as in Intensive Care Units (ICUs). These represent an important but small fraction of the total opportunity. With the introduction of Saureus' better, faster, and less expensive technology, the market will grow to include all hospitals, not just big AMCs, and, instead of conserving screening resources to focus only on the

most fragile patients, those hospitals will be able to extend screening to all patients and healthcare workers, changing the nature of the war on MRSA. There are also a number of legislative and financial (Medicare) forces that are driving the adoption universal screening from MRSA, and the introduction of a very rapid, less expensive method to fulfill that need will hasten adoption even further.

#### MRSA Hospital Testing US Market

19 M Outpatient Surgeries  
5 M ICU Patients  
12 M Skin & Soft Tissue Infections  
+ 37 M Hospital Admissions

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= 73 M Testing Opportunities

@ \$50/test → **>\$3.65 Billion TAM**

MRSA impacts hospitals all over the developed world. Many European nations have already or are in the process of moving hospitals to universal screening, so this technology, fully deployed, will have a potential hospital market of over 180 million testing opportunities annually, a \$9 Billion opportunity.

### The test kits will be simple to operate and relatively inexpensive to manufacture

The product, or test kit, will be comprised of a sterile test tube, an enzyme for rapid, MRSA-specific cell lysis, and multiple monoclonal antibodies attached to the surface matrix that captures antibodies much better than conventional sensitized latex beads. The user, a physician, a nurse or lab technician, will place a sample (nasal swab) of body fluids or tissues from the patient into the receptacle, add the enzymatic lysing agent for the suspected species (MRSA), then add the matrix



pre-loaded with specific antibodies to bind to the specific antigen of interest. Presence of the suspected pathogen will be confirmed by the “clumping” of the heat-killed bacteria with species-specific antigen present in the targeted bacteria, forming a lattice that falls out of solution and becomes easily visible. When several possible bacterial contagions are suspected, panels of tests can easily be performed simultaneously to narrow a specific diagnosis.

### Delivering the Opportunity

The company has identified future areas of expertise that will be required to bring the test kit to market and has begun initial conversations with potential partners with complementary skill sets in regulatory, reimbursement, medical device manufacturing and quality systems, as well as experienced IVD sales executives. As the development program advances, we are prepared to make decisions that will maximize the value of the company and its future opportunities.

### Progress and Next Steps

The development of this technology is underway and Saureus, Inc. is seeking five-hundred thousand dollars in seed capital to fund the development of the test kit. Several important observations have been made already and management has determined this seed capital will provide sufficient resources to reach a critical proof-of-concept milestone, in which the company can reproducibly create the components of the test kit and be able to detect the presence of MRSA, with sensitivity greater than twice that of current agglutination methods, within ten minutes of sample acquisition. Once this hurdle is cleared (9-12 months) the company plans to raise additional funds to optimize the test kit, scale the organization and complete FDA clinical trials prior to launch.

### Team

George Newcomb is a co-founder and the CEO of Saureus, Inc. Mr. Newcomb has experience in new product development and launch execution across a broad range of sectors in the healthcare industry. He was a co-founder and COO for a successful managed healthcare company that was sold

in 1999. Since then, he has served in senior management positions with start-ups and in multinational Fortune 500 companies (Abbott Labs). He is a graduate of Connecticut College and the Tuck School of Business at Dartmouth.

Dr. Ambrose Cheung, Professor of Microbiology & Immunology at Dartmouth Medical School (<http://dms.dartmouth.edu/mcb/faculty/cheung.php>) and co-founder in this enterprise, is the Chief Scientific Officer. His research interests include *Staphylococcus aureus* pathogenesis, virulence and antibiotic resistance. He holds multiple patents related to virulence genes and autolysis regulators and has authored over 100 peer-reviewed publications in addition to four textbook chapters. He has a graduate of Colby College and received his MD at Northwestern University.

## Financial Pro-Forma

<b>Assumptions</b>						
	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015</u>
Sales price per unit				\$ 50	\$ 50	\$ 50
Gross Margin per unit (%)				70%	75%	75%
COGS per unit				\$ 15.00	\$ 12.50	\$ 12.50
SGA as a % of Sales				NA	20%	20%
R&D as a % of Sales				NA	25%	25%
Number of hospital accounts				50	500	1,000
Units sold per hospital account				1,000	1,000	1,000
Total Unit Sales				50,000	500,000	1,000,000

<b>Pro-forma Financial Projections</b>						
	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013</u>	<u>2014</u>	<u>2015</u>
Sales Revenue	\$0	\$0	\$0	\$ 2,500,000	\$ 25,000,000	\$ 50,000,000
COGS	\$0	\$0	\$0	\$ 750,000	\$ 6,250,000	\$ 12,500,000
<i>Gross Margin</i>	NA	NA	NA	70%	75%	75%
R&D Expenditures	\$ 300,000	\$ 366,000	\$ 1,411,000	\$ 1,527,000	\$ 6,250,000	\$ 12,500,000
SGA Expenditures	\$0	\$ 146,000	\$ 633,000	\$ 1,640,000	\$ 5,000,000	\$ 10,000,000
Total Operating Expenditures	\$ 300,000	\$ 512,000	\$ 2,044,000	\$ 3,167,000	\$ 11,250,000	\$ 22,500,000
<i>Operating Margin</i>		NA	NA	-57%	30%	30%
EDITDA	\$ (300,000)	\$ (512,000)	\$ (2,044,000)	\$ (1,417,000)	\$ 7,500,000	\$ 15,000,000
Financing Raised*	\$ 500,000	\$ 5,000,000				
Cash Balance	\$ 200,000	\$ 4,688,000	\$ 2,644,000	\$ 1,227,000	\$ 8,727,000	\$ 23,727,000

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