

# HARRINGTONGROUP

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## Harrington Group Limited (HGR)

Our core business is Sun Biomedical Laboratories Inc (SBL) which researches, develops and manufactures illicit drug screening devices.



VisuaLine multi-drug urine test

SBL has a portfolio of screening devices including urine tests and the Company's unique saliva screening device OraLine.

## Mission

Our goal is to build a sustainable world class organisation in the field of invitro diagnostics. We will achieve this through the commercialisation of existing Sun Biomedical IP, strategic alliances and the acquisition of complimentary technologies.

## HGR Corporate Snapshot

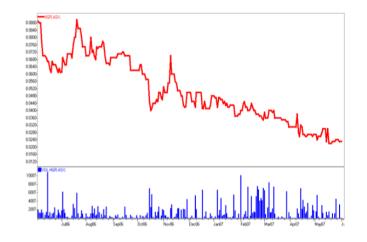
Total Shares on issue (ASX:HGR) 184,000,000

Market Capitalisation@ 2.3 cents \$4.2 million

Cash at Bank 31 December 2006 AUD \$400K

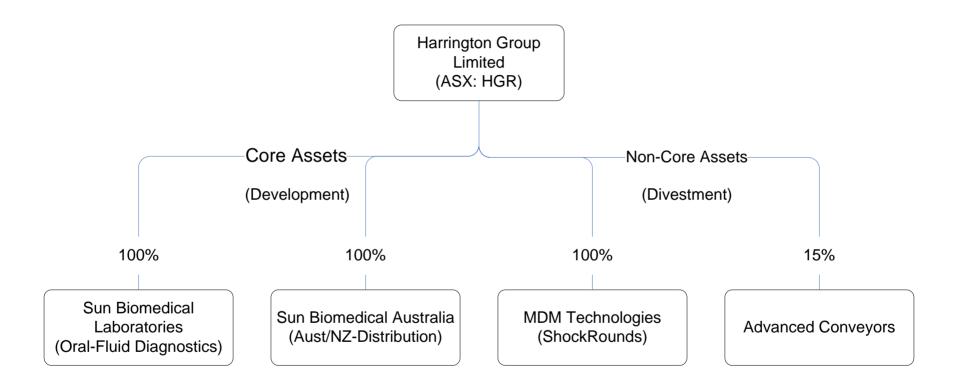
Major shareholders:

- MDM Group Inc (USA) (ShockRounds Vendor)
- Log Creek Pty Ltd (June '06 placement)
- Ming & Alice Sun (USA) (SBL Inc Vendor)
- Top 50 shareholders hold:



34%
12%
7%
85%

### **HGR Group Structure**



### **Board and Management**

Peter King Chairman	Mr. King has a long and distinguished professional and public career. He is a Rhodes Scholar and a practicing barrister specialising primarily in commercial and public law at Queen's Square Chambers Sydney, Australia.
Peter Bartleet Non Executive Director	Mr. Bartleet has corporate experience including over 15 years as a senior executive of an international consulting group. He has been involved in the management and development of a number of companies, including several ASX listed entities
Peter Boonen Non Exec. Director	Mr. Boonen is President and founder of MDM Group Inc., Harrington's largest shareholder. He has over 30 years of extensive business experience in the property, investment banking and equity markets in Australia, the U.S, and Canada
Brian Andrews Managing Director	Mr. Andrews has over twenty years experience in the medical devices arena having successfully marketed a broad range of technologies ranging from invitro diagnostics to high tech medical optical devices used for minimally invasive surgery. He has an MBA from Monash University and, during his career has lived and worked in both the U.S. and the U.K
Andrew Paice CFO Exec. Director	Mr. Paice is a successful and competent financial executive who has operated in a variety of senior finance roles across a broad spectrum of industries. Amongst his achievements Mr. Paice has lived and worked in Turkey managing the finances for a global pharmaceutical Bristol-Myers Squibb
Dr. Ming Sun General Manager SBL USA	Dr. Sun is personally responsible for the development of the companies core IP and the benchmark product OraLine IV. He has successfully built and managed SBL for 14 years and now looks forward to the opportunity to refocus is energies toward the development of the next generation oral fluids immunoassay device

## Objectives

### Commercialisation of SBL diagnostic technologies

- First saliva drug screening device to receive U.S. FDA 510(k) clearance.
- Effective distribution coverage in the U.S. and major European markets by end of 2008.
- The Company is budgeting for SBL operations to arrive at a breakeven point by the end of calendar year 2007.
- Realisation of formal rolling quarterly order for OraLine in China by Q4/07.

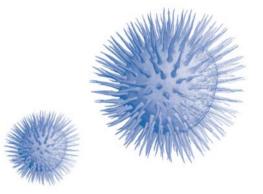
#### Divestment of non-core assets

- ShockRounds IP
- Advanced Conveyors

## **Oral-fluid Based Diagnostics**

# New York Academy of Sciences meeting October 2006

"Oral-based diagnostics have the potential to detect systemic disease and evidence of exposure to various harmful substances, as well as provide biomarkers of health and disease status. Integration of novel approaches to oralbased diagnostics is expanding to include genomics, proteomics, bioinformatics and nanotechnology".



#### Applications

- Illicit drug screening
- Infectious disease screening
- Disease management

#### **Diagnostic Indications**

- Early detection of cancers
- Therapeutic drug management
- Diabetic glucose management

## **Oral-fluid Based Diagnostics**

### The Advantages

- Non invasive
- Difficult to adulterate
- No special facilities required
- Minimal training requirements
- Correlation with plasma and/or blood

### The Challenges

- Some medical conditions/use of drugs produce a dry mouth effective
- Variability in sample viscosity and continuity
- Vested interests in urine, blood and laboratory based testing



## Oral-fluid Illicit Drug Screening

### The industry position

- Low sensitivity levels
- Predominantly converted urine tests detecting metabolites often not found in saliva
- Viscosity challenges dealt with through sample collection pads and dilution

### The SBL competitive advantage

- Detection of parent drug/active agent relevant to recent use and potential impairment
- Assays based on liquefaction of whole saliva samples, no sample dilution
- Industry benchmark sensitivity levels for THC [active hallucinogen found in marijuana/cannabis]
- 20 years of research into the use of oral-fluids as a diagnostic medium for a broad range of disease states

### Immediate Revenue Opportunities

### US workplace drug screening legislated since 1988

- Estimated 133 million US workplace tests p.a.
- Total market value estimated at \$1.3 billion p.a.
- Predominantly urine
- Trend toward saliva, no products with 510(k) clearance

#### Over the counter market

• 27,000 pharmacies selling average 12 units pcm p.a.

#### Teen drug use

- Legislation enabling schools to implement drug screening programs
- Increasing direct to consumer demand driven by parents concern over teenager drug use

### **Immediate Revenue Opportunities**

### Certification by China Ministry for Public Security

- Successful evaluation of OraLine
- Rolling quarterly order with China government under negotiation
- Expected annual volume 1 million units 2007

### Ketamine test submitted for certification

- Largest illicit drug of abuse in China
- Detection sensitivity of 150ng/ml as compared to 1,000ng/ml for existing urine tests
- Saliva based platform more practical for policing programs
- Use of Ketamine is wide spread throughout Asia

### **Recent Success**

### US distribution partners

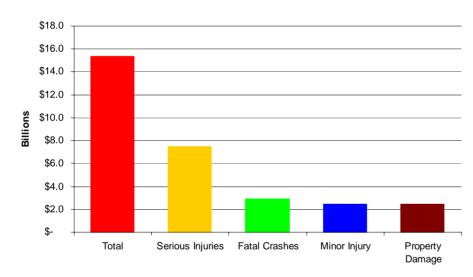
- Bioscreens
  - Drug test wholesaler with direct marketing business conducting 100 million mailings per annum
    - direct marketing campaigns to temp labour agencies, correctional institutions and construction companies
    - pre-marketing sales increase from 2,000 units to 5,000 units pcm
- Noble Medical
  - Drug test wholesaler to workplace testing service providers
    - direct marketing and field sales campaign to point of care testing agencies
    - pre-marketing sales increase from 1,000 units to 2,000 units pcm

### **Recent Success**

#### US distribution partners

- Express Diagnostics
  - Drug test manufacturer (urine) and wholesaler to workplace testing service providers
    - negotiations in progress to switch 15,000 units pcm from competitor saliva product to OraLine
    - representation in Latin America, commenced shipping Chile
    - negotiations in progress to supply E.D with membranes for their urine cups, present volume 120,000 pcm
    - negotiations in progress for licensing manufacturing agreement for SBL urine products

#### Roadside Testing: The extend of problem (Australia)



#### Annual Cost of Road Accidents

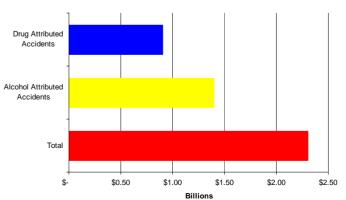
#### Victorian Police - the first 12 months

13,176 screened

Only **2.2%** tested positive for Cannabis and/or Methamphetamines

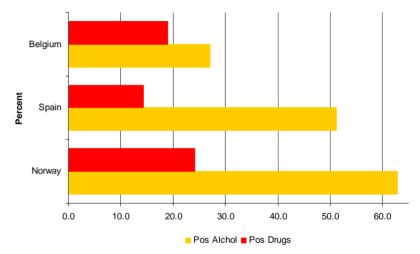
Alcohol & drugs deathly driver				
1990-1999 NSW, VIC, WA				
Alcohol	29.1%			
Alcohol & Drugs	10.0%			
Drugs	23.5%			
Cannabis		13.5%		
Opiates		4.9%		
Benzodiazepines		4.1%		
Amphetamines		4.1%		
Other		2.7%		

#### Substance Abuse Attributable Cost



#### Roadside Testing: The extend of problem (Europe)

- Netherlands
  - of 293 drivers screened, 12.3% tested positive for alcohol and 8.2% tested positive for drugs
- Germany
  - of 2,234 drivers screened, 5.5% tested positive for alcohol and 2.6% tested positive for drugs
- Norway
  - 4:1 ratio of drug affected drivers versus inebriated drivers [Lopianecki 2001]



Accident Victim Analysis

Cannabis accounts for **59%** of positive drug affected drivers

### **Roadside Testing**

- Enabling legislation
  - US, Australia, New Zealand, UK, Ireland, France, Finland, Norway, Switzerland, Belgium, Spain, Germany
- Government funded research
  - Netherlands, Ireland, Belgium, Finland, Norway, Switzerland, Spain, Germany
- Existing roadside testing programs
  - VIC, NSW, WA, QLD

- No perfect mouse trap!
  - Rosita-2 roadside testing project
    - "Government officials should carefully weigh the pros (deterrent effect) and the cons (risk that drivers will realise that they often test negative after having used drugs due to the limited sensitivity of the test) of introducing random drug testing with the currently available devices".

### The perfect mouse trap

- Strategic Development Alliance
  - Biosensia
    - VC funded Irish development group
    - core competencies, micro fluidics and Molecularly Imprinted Polymer "MIP" assays
    - functional MIP's array, having difficulties with sample acquisition and transportation
    - Manufacturing alliance with Lion Laboratories (leading supplier of police B.A.C tests)
  - SBL
    - Expertise in the acquisition and transportation of whole saliva samples

## Key Growth Drivers

- Attainment of US 510K clearance for OraLine IV
- Maximise potential penetration of the U.S. workplace screening market
- Efficient low cost manufacturing capabilities
- Strong marketing and distribution partnerships
- Continual innovation and rapid introduction of new saliva testing platforms
- Realisation of an effective roadside screening tool

## The Immediate Challenges

### FDA 510(k) clearance

- 510(k) clearance is a prerequisite for many employers to switch from urine to oral fluid tests
- P.O.C 510(k) is a necessary precedent to OTC clearance

#### Structure

- No redundancy in key U.S. management and operations roles
- Limited operational experience at a board level

#### Revenue

• SBL operations operating below breakeven point

## **HGR Capital Requirements**

Additional \$2.4 million required for:

- SBL promissory note:
- Regulatory studies:
- Working capital to support:
  - manufacturing upgrades
  - SBL operations headcount
  - Product commercialisation
  - Research & Development
- Cost of issue:

circa \$510 circa \$350

circa \$1,240

circa \$300

### New issue

Underwritten Renounceable Rights Issue:

• 1:1 issue @ 1.3 cents to raise circa \$2.4 million

Secured Interim Working Capital Loan provided by Underwriter

- \$480,000 20% of underwritten amount.
- Loan set off against any shortfall commitments balance (if any) placed up to HGR's then placement capacity.
- Lenders receive 12 options for each \$1.00 lent plus 2% commitment fee

### Summary

#### Strong Product and IP suite

- Unique proprietary oral fluid diagnostic platform
- Specific expertise in the detection of THC in oral fluids
- Only approved oral fluid diagnostic for illicit drug detection in China
- Lean structure readily adaptable to the application of new technologies

#### **Substantial Market Opportunities**

- Ideally positioned within the lead market for roadside drug testing
- Opportunity to leverage oral fluid IP for integration into diagnostics for additional disease states

#### **Advanced Sales Prospects**

• OraLine prospects in US and Chinese markets are advanced and close to realisation.

#### **Adequate Funding**

• Rights Issue to deliver adequate funding to achieve near term objectives and position the Company for profitability



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