

**ASX:VHT** 

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Chief Executive Officer

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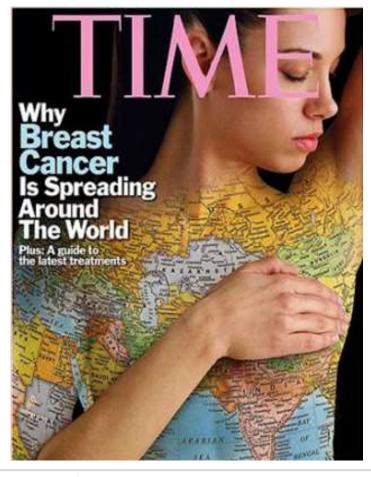


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# Company overview: reducing mortality & cost of breast cancer



- Formed in 2009, by world-leading breast cancer scientists, to deliver software to identify high risk women using patented quantitative analysis of breast x-rays
- First product, *VolparaDensity*™, measures breast density
- FDA and other regulatory clearances
- High level of clinical validation, forming high barrier to entry
- Solid early sales: FY16 revenue NZ\$2.5m, up 31% pcp, with small sales team and capital sales model, ~90% of sales are in the US.
- Listed ASX, April 2016, raised A\$10M to ramp up:
  - ✓ management & sales force
  - ✓ expanded product offerings to offer advanced data analytics, pay per patient (SaaS)



# Company overview: highly experienced Board & Management team



Roger Allen, AM Chairman Australia



Ralph Highnam, PhD **CEO & Executive Director** NΖ



**Prof Sir Mike Brady Director** UK



**John Pavlidis Director** USA



Lyn Swinburne, AM **Director** Australia



**John Diddams Director** Australia





**Brian Leighs** ΝZ



**Dave Murray Chief Financial Officer Chief Technology Officer** ΝZ



**Mark Koeniguer Chief Commercial Officer Chief Marketing Officer** USA

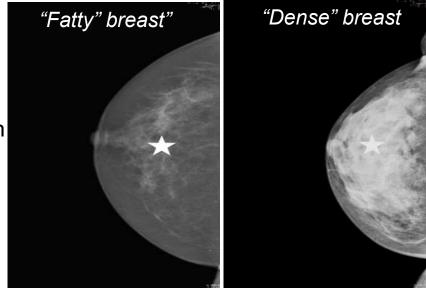


**Julian Marshall** USA



# Breast cancer screening saves lives, but can be optimised knowing risk

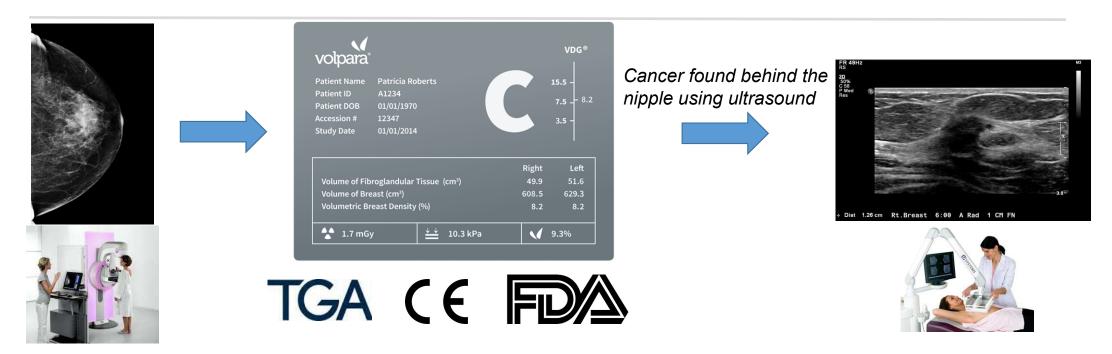
- Mammogram is the current gold standard, 39m screened per year in the US, costing ~US\$7.8B pa.
- 20–30% of cancers are missed mostly due to high breast density, which also increases risk of developing cancer.
- 40–50% of women in the US have dense breasts.
- 28 states in the US have now passed laws to ensure women are told their density.
- Additional imaging of women with dense breasts helps, but drives up costs and false positives.
- Interpreting density wrongly can lead to both insufficient or excessive imaging – radiologists' subjective reading of mammograms sees disagreement rates of 35%+.



Breast density ≈ percentage of breast that is glandular tissue.



# VolparaDensity provides a rapid, objective measure for decision-making



- Competitors lack clinical validation and/or are specific to certain x-ray hardware
- VolparaDensity is vendor neutral and has over 140 publications behind it
- Frost & Sullivan Global Award winners for Breast Density Assessment 2016

Opportunity to grow breast screening in a consistent, objectively justified manner & catch cancer early



# Personalised screening is a significant, growing market opportunity

Total addressable market for VHT's <u>current</u> product line is over A\$1 billion based on numbers of screening sites, average numbers of x-ray systems and typical sales prices.

2016 VHT estimates	Number of screening sites	X-ray systems	Current women screened per year
US	8,700	15,500	38,577,000
EMEA	1,300	13,000	28,350,000
APAC	456	4,700	6,556,000

The incidence of breast cancer is expected to double by 2030, driving trend towards earlier and wider-reaching screening programs.



# Solid early sales performance from VolparaDensity

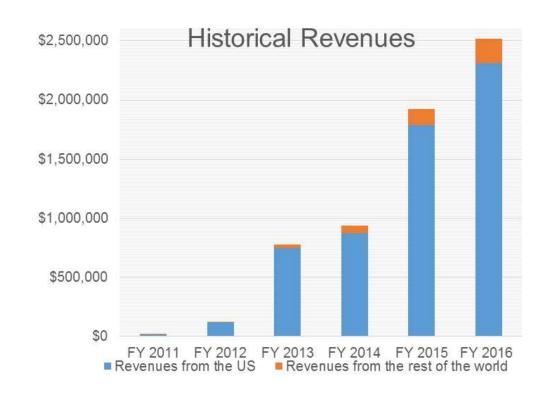
 Strategy has been balanced distribution model using small direct sales force & distributors:





- Over 100 sales across the US, based on capital sales model
- FY16 revenue up 31% to NZ\$2.5m

Only ~1% of US breast centres now have VolparaDensity





# ASX, 27 April 2016 – A\$10M to accelerate & transition

#### Aim A - Sales team fully on board Achieved 1st July 2016





Anton Zerle VP S&M, APAC



David Lee VP S&M, EMEA

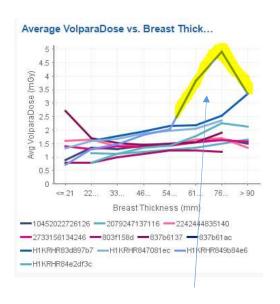
# Aim B - Expanded products with data analytics Achieved mid-July 2016



- Quality control dashboards with breast imaging metrics
- Pay per patient, so recurring revenue (SaaS)
- Appeals to managers, radiologists and whole team



# VolparaEnterprise – cloud-based data analytics, case study



This site has 11 x-ray machines, one of them an outlier and giving out twice the radiation dose for women with larger breasts, increasing the risk of inducing a cancer.







Return on investment based on productivity, quality, safety, comfort



# Latest financials & top shareholders

#### As at end June 2016, 4C Statement (Q1 FY2017)

Cash at the end of the quarter was NZ\$8.392 million including NZ\$6 million in bank term deposits exceeding 90 days.

Receipts from customers were NZ\$764,000.

#### As at end, Monday 5<sup>th</sup> September:



<u>Top 20</u>	Shareholding %
Mr Roger W Allen	16.47%
Dr Ralph Highnam	12.58%
Ms Tina Jennings	9.29%
Professor Sir J Mike Brady	6.37%
Mr Marcus Sarner	4.81%
K1W1 (Sir Stephen R Tindall)	4.78%
Private Clients of Craigs Investment Partners	4.17%
Professor Martin Yaffe	3.30%
Professor Nico Karssemeijer	2.86%
Harbour Asset Mgt	2.68%
Hood Family Trust (Sir John Hood)	2.62%
Sir Martin Francis Wood	2.05%
Lady Kathleen A Wood	2.05%
Mr Martin Smith	1.58%
Mr Jeremy Palmer	1.58%
Craigs Investment Partners	1.54%
Milford Asset Mgt	1.53%
Mr Robert N Smith	0.96%
Mr John F Diddams	0.89%
Mr & Mrs Anthony N Wales	0.81%



# Anticipated news flow to end FY2017 (April 2017)

Approximate timing	Event	
Sept	First sales of VolparaEnterprise	QLD Broker Meets Biotech 8 September 2016
Sept 15 <sup>th</sup>	FDA panel on Mammography Quality Standards and breast density	Stamford Plaza Brisbane
Sept	Roadshow around Australia to meet investors	AusBiotech
Oct, Nov, Dec	Launch of major new breast cancer risk model including density	WA Broker Meets Biotech 15 September 2016
Oct, Nov, Dec	Launch of UK project looking at implementation of density	Parmelia Hilton, 14 Mill Street, Perth
Oct, Nov, Dec	Announcement of major new distributor	AusBiotech
Nov	Density awareness campaign, Australia	CEO Sessions 20 September 2016
Dec	RSNA 2016, Chicago, launch of VolparaEnterprise 2.0	ASX Auditorium, 18 Bridge Street, Sydney
Jan	Report on reimbursement potential	ASX
Jan	Increasing use of VolparaDensity in clinical trials	SA Broker Meets Biotech 22 September 2016
March	Sales of VolparaEnterprise to mix of sites, including brand names	Crowne Plaza Adelaide
March	Partnership with "Big Data"/"Deep Learning" company	



### Investment summary

- World-leading brand operating in an important space with regulatory clearance, clinical validation and solid early sales +31% growth year on year.
- Growing market opportunity 39 million each year in the US are screened, increasingly in personalised ways, and we now have a good-sized, direct, high-quality US sales team.
- Products do not just cover clinical, but also safety, quality, comfort and productivity aimed at the budget holders and priced to speed market adoption.

Thank you for your time.

Ralph Highnam, PhD (Oxford)
Chief Executive Officer

ralph.highnam@volparasolutions.com +64 21 149 0541





Broker Meets Biotech, September 2016



# **Additional Information**

# Who are we? A reputable, influential Board



#### Roger Allen, AM

Chairman

- Joined the Board in 2010, appointed Chairman in Oct 2015
- Built CPG, co-founded Allen & Buckeridge (VC fund)
- Served on 2 PMs' Science & Tech Councils, Advisory Boards



#### Lyn Swinburne, AM

Non-Executive Director

- · Joined the Board in 2015
- Founder of Breast Cancer Network Australia
- Chair of the Board of Royal Women's Hospital in Melbourne



#### **Prof Sir Mike Brady**

*Non-Executive Director* 

- Founding Director of VHT and Perspectum Diagnostics
- Author of over 750 articles and 26 patents
- · Current professor of Oncological Imaging at Oxford



#### John Pavlidis

Non-Executive Director

- · Joined the Board in 2015
- Over 25 years' medical device experience
- CEO of VytronUS, former president and CEO of R2 Technology



#### John Diddams

Non-Executive Director

- Principal of Australia CPA firm providing corporate advisory service
- · Currently NED of Skydive and House with No Steps
- 25 years' experience raising capital, performing due diligence, IPOs



# Who are we? An experienced, qualified management team



#### Ralph Highnam, PhD

Chief Executive Officer

- PhD, Breast Imaging, University of Oxford 1992
- Former CEO of Mirada Solutions: medical imaging software sold in US
- Co-founded Volpara (VHT) 2009, time right to exploit concepts from PhD



#### Julian Marshall

Chief Marketing Officer

- Joined 1<sup>st</sup> March 2016, based in San Francisco, USA
- 30 years' experience in breast imaging software product management
- Former Senior Director of Global Product Management at Hologic



#### Mark Koeniguer

Chief Commercial Officer

- Highly experienced in medical imaging software sales, including SaaS
- Based in Nashville, USA, with over 25 years of leading sales teams
- Worked across radiology, with long tenures in breast imaging specifically



#### **David Murray**

Chief Technology Officer

- 25 years experience in medical device companies
- Director of Product Develop for TomoTherapy (acquired by Accuray)
- 10 years as chair of DICOM Working Group 7 (Radiation Therapy)



**Brian Leighs** 

Chief Financial Officer

- Member of VHT management since 2010
- 40 years' experience in senior financial management
- Holds directorships on 2 other health technology companies



### Intellectual property and regulatory position

#### **Intellectual Property**

- Since 2009, Volpara has built a portfolio of intellectual property rights which complements and facilitates the VHT business objectives.
- The portfolio now comprises three granted patents, seven patent applications (proceeding in 40 countries) and three trademarks registered in 38 countries, unregistered trademarks, copyright works (including software, graphical and text) and trade secrets (which protect the key part of the code).
- A "foundation" patent describes *VolparaDensity*, and subsequent applications which relate to imaging systems and supplementary image properties cite the foundation patent. Provisional patent applications are filed regularly, reflecting VHT's ongoing innovation, research and product development.
- A full independent report on VHT's intellectual property portfolio is included in the Prospectus.

#### **Regulatory Position**

- *VolparaDensity* is considered in most jurisdictions to be a medical "device" since it measures and estimates specific information about the patient.
- Regulatory bodies in each market dictate that medical devices must be manufactured to the highest standards and cleared before they can be marketed in that country. This presents significant barriers to entry for new market participants.
- In the US, Volpara has achieved three FDA clearances so far covering *VolparaDensity*. *VolparaDoseRT* and *VolparaAnalytics* are both covered as Class 1 quality control devices, which requires that they are manufactured to FDA standard and registered.
- VHT has CE marking to sell all its products in Europe, and regulatory clearance to sell clinical systems in Australia, Canada, South Korea, Thailand and New Zealand.



# VolparaEnterprise - revenue model



- Move to "Software as a Service" model provides lower entry costs and volume based, user pay model appealing to purchasing decision makers
- Recurring revenue stream with annual license based on number of users + additional volume based payments for each breast screen
- Independent pricing survey completed 1<sup>st</sup> July 2016, validated appeal of model & pricing.



# VolparaEnterprise - benefits patients, physicians, and centres



**Patient** 

Cancer detected earlier
More comfortable
Lower radiation dose
Rapid results



**Physician** 

Referrer, radiologist, surgeon
Lowered liability
Provides Quality Assurance metrics
Reduced human-error
Triage high-risk patients
Consistency of care



#### **Screening centre**

Budget controllers
Improved patient care
Enhanced profitability
Key metrics around network of
breast imaging systems
centre comparison

