



AGM, Chairman's Report Roger Allen, AM

AGM Presentation, August 11th 2016 – ASX:VHT

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Breast cancer remains our focus



- 1 in 8 Western women will develop breast cancer, cases are rising across Asia with rates anticipated to double by 2030
- Volpara's mission remains the same:

To reduce the mortality and cost of breast cancer by providing clinically-validated software that underpins personalised, high quality, breast cancer screening.

Highlights of a very significant year – Board strengthened



Lyn Swinburne, AM

Founded Breast Cancer Network Australia (BCNA), and Chair of the Board of Royal Women's Hospital, Melbourne. Based in Melbourne.



John Pavlidis

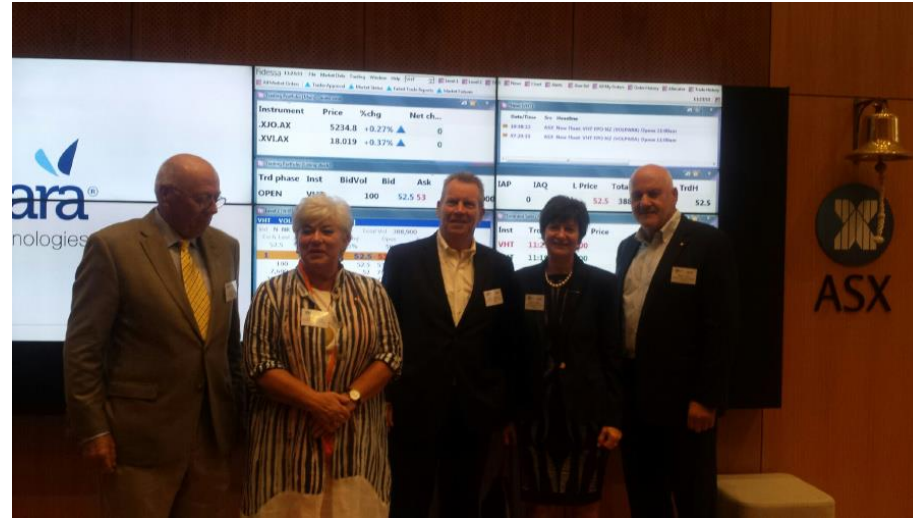
Senior sales & marketing executive based in California, former CEO of breast company acquired by Hologic, on Board of breast company acquired by GE.



John Diddams

Principal of an Australian CPA firm, extensive knowledge of Australian corporation laws, ASX listing rules, accounting standards and corporate governance. Based in Sydney.

Highlights of a very significant year – ASX listing, raising A\$10M



Listing enabled:

1. Building of a **world-class sales & marketing team**, we now have 6 additional US sales staff and VP Sales for Europe and Asia-Pacific.
2. Launching of Cloud-based, **VolparaEnterprise** product with Software as a Service pricing. Appeals to the whole breast imaging centre, not just the clinical team, and covering clinical, safety, quality and productivity, all based on our core, patented, technology.

Highlights of a very significant year – 31% product revenue growth

- Limited sales resources, increased product revenue **FY15/16 by 31%**
- Increased customer sites to now be in **35 countries**, with the latest being our first African site in Nigeria.
- **Strong platform for growth** and bringing the benefits of our world class technology to women globally.
- Board and Management have worked hard over the last year of significant achievement, and we re-iterate the commitment to grow the company and drive an **increase in shareholder value**.



Professor Sir Mike Brady

Founding Director



Sir John Hood

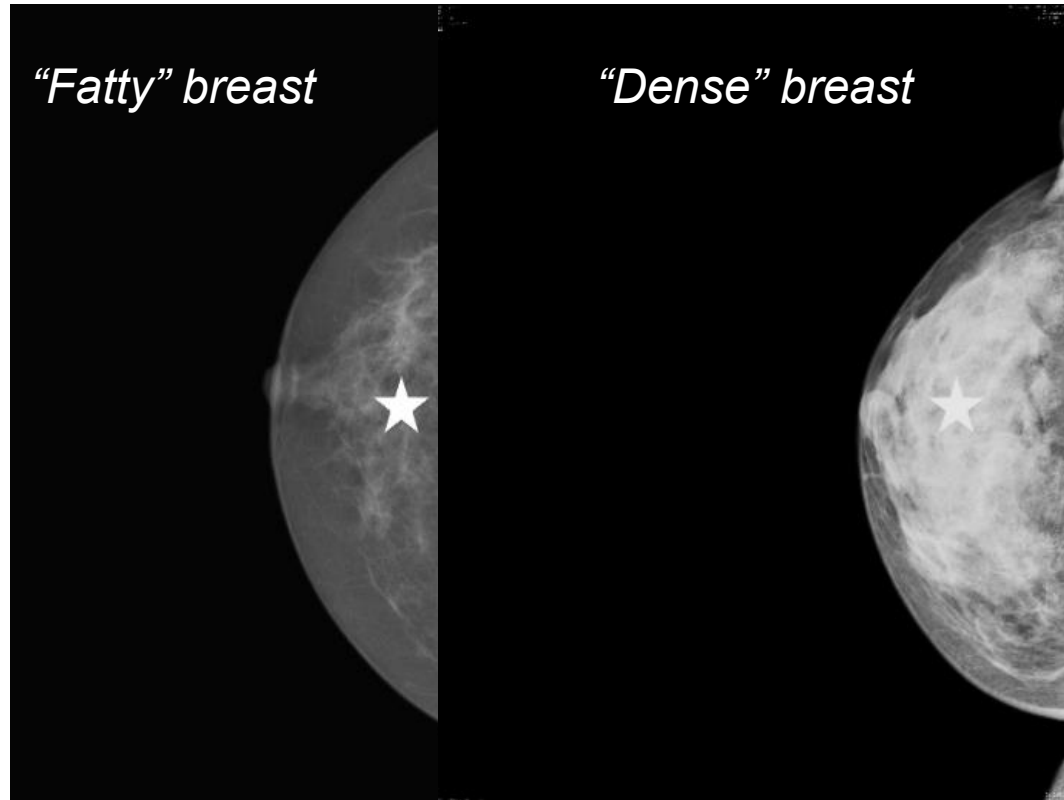
Chairman 2010–2015



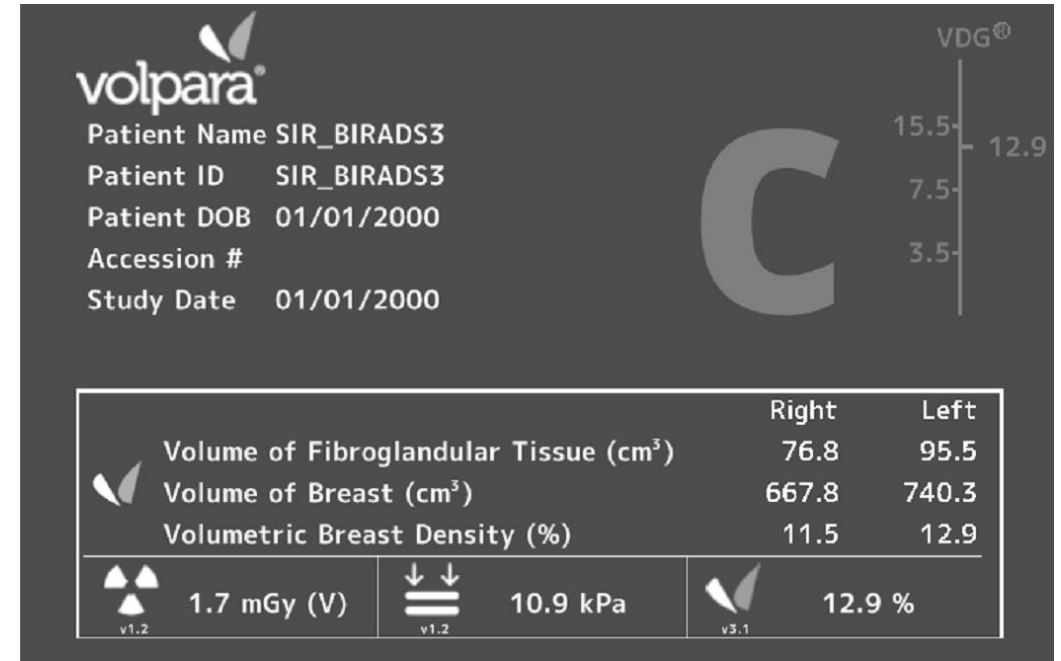
AGM, CEO's Report Ralph Highnam, PhD

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Breast density – core technology recap



1. Denser breasts make it harder to see cancer if it does develop – can you see the white star?
2. Denser breasts have higher risk of developing cancer



Volpara computes breast density and volume, and from that estimates:

- amount of radiation dose
- amount of compression applied

Intellectual property update – foundation patents in place

VHTL IP

Summary: 4 granted patents; 5 patents under examination (in 38 countries); 6 patent applications; 3 registered trade marks in 38 countries; 7 unregistered trade marks; 23 copyright works

Number	Filing date	Title	Status
PCT/GB2010/001472	03.08.09	A method and system for analysing tissue from images.	Granted: UK, USA, China Post examination EPO
PCT/GB2011/001658	30.11.10	An imaging technique and an imaging system	Granted: USA Under examination EPO
PCT/GB2014/000217	06.06.13	A method of reconstruction of an object from projection views	Under examination USA, China EPO
NZ713916	05.11.15	Focal density detection	Filed
NZ713915	05.11.15	Improved method for quantification of images	Filed
NZ721132	13.06.16	Method for the detection and quantification of breast arterial calcification	Filed
NZ721180	14.06.16	Method and system for consolidating and comparing data from databases	Filed
NZ722316	19.07.16	Method and system for positioning score	Filed
NZ722735	29.07.16	A method and system for presenting interactive acquisition and reading guidance data	Filed

Thanks to science advisory board & founders:



Professor Nico Karssemeijer

University of Nijmegen



Professor Martin Yaffe

University of Toronto

Global Frost & Sullivan award winners – breast density assessment

MAR 24, 2016, 02:41 ET

News provided by
Frost & Sullivan →



Frost & Sullivan Lauds Volpara Solutions' Quantitative Breast Imaging Tools for Driving Growth of the Breast Density Assessment Market

Volpara Solutions' Digital Health Solutions are Capable of Analyzing and Processing Large Amounts of Collected Data to Maintain Imaging Quality and Consistency



Above: Mark Koeniguer, CCO, receiving the award in July 2016.

Left: Dave Mezzoprete (VP Sales, USA), Mark and Scott McCloskey, one of our new hires.

Dr Shermis paper in *American Journal of Roentgenology*

Current Location: [DOTmed HCB News](#) > [Women's Health](#) > [This Story](#)

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Molecular breast imaging finds cancers that mammograms don't: study

August 01, 2016

by [Lisa Chamoff](#), Contributing Reporter

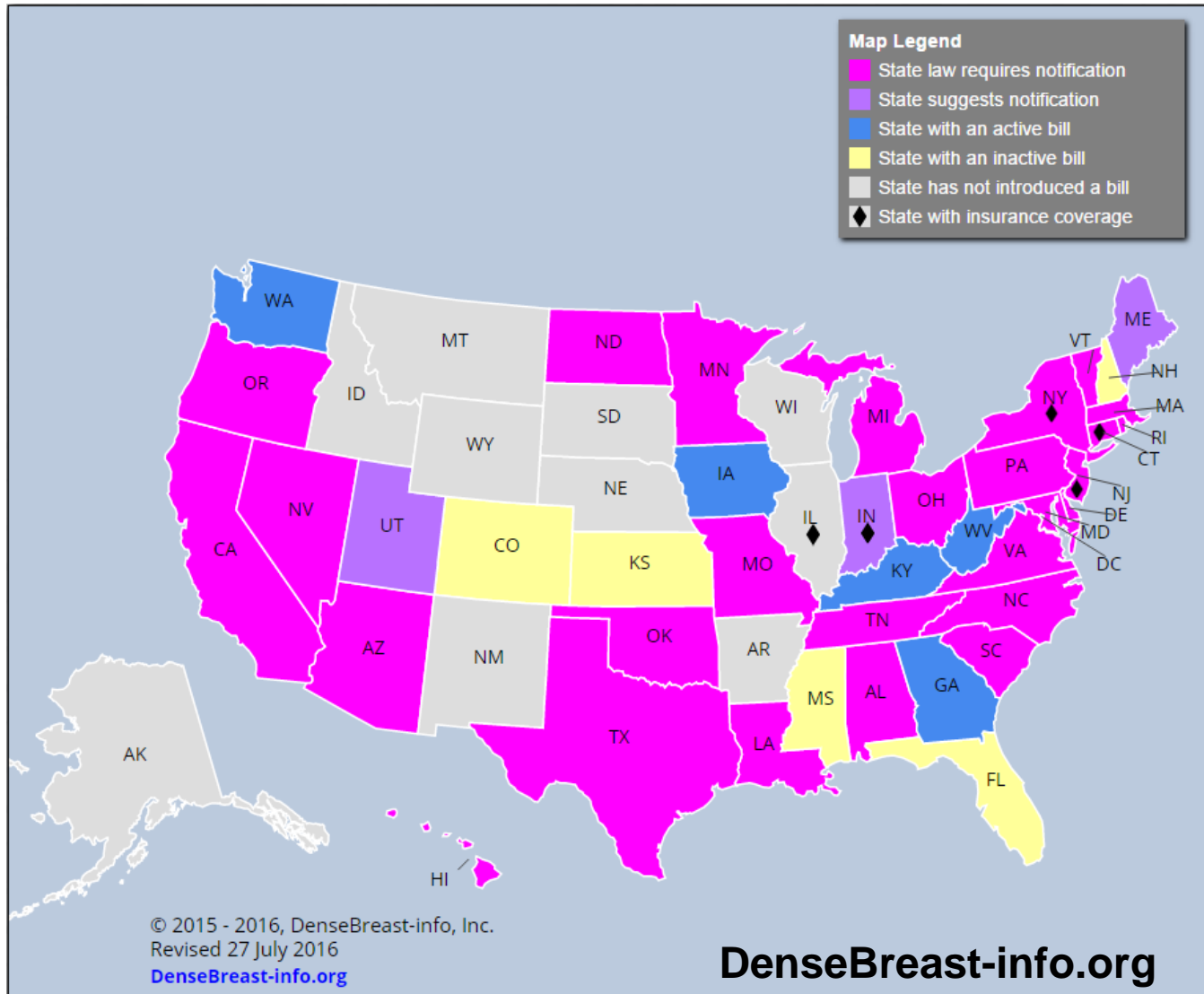
Molecular breast imaging (MBI) detected cancer in several women with dense breasts whose mammograms had been negative, with an incremental cancer detection rate of 7.7 per 1,000 screens, a study has found.



The retrospective study, published in the August issue of the *American Journal of Roentgenology*, examined data from the supplemental screening program at ProMedica Breast Care in Toledo, Ohio, from 2011 to 2014. After having a mammogram, 1,696 women with dense breast underwent supplementary screening with Gamma Medica's LumaGEM MBI system, which uses the technetium-99m sestamibi radiopharmaceutical and employs a dual-head digital detector and a special collimator. This resulted in the detection of 13 malignancies, after the mammograms read negative for cancer.

- Long term VolparaDensity user
- 1,696 women identified by VolparaDensity as having “dense breasts” – so at risk of mammography missing the cancer
- **13 more cancers detected early** by adding on additional imaging, in this case Molecular Breast Imaging.

Breast density becoming standard of care in the US



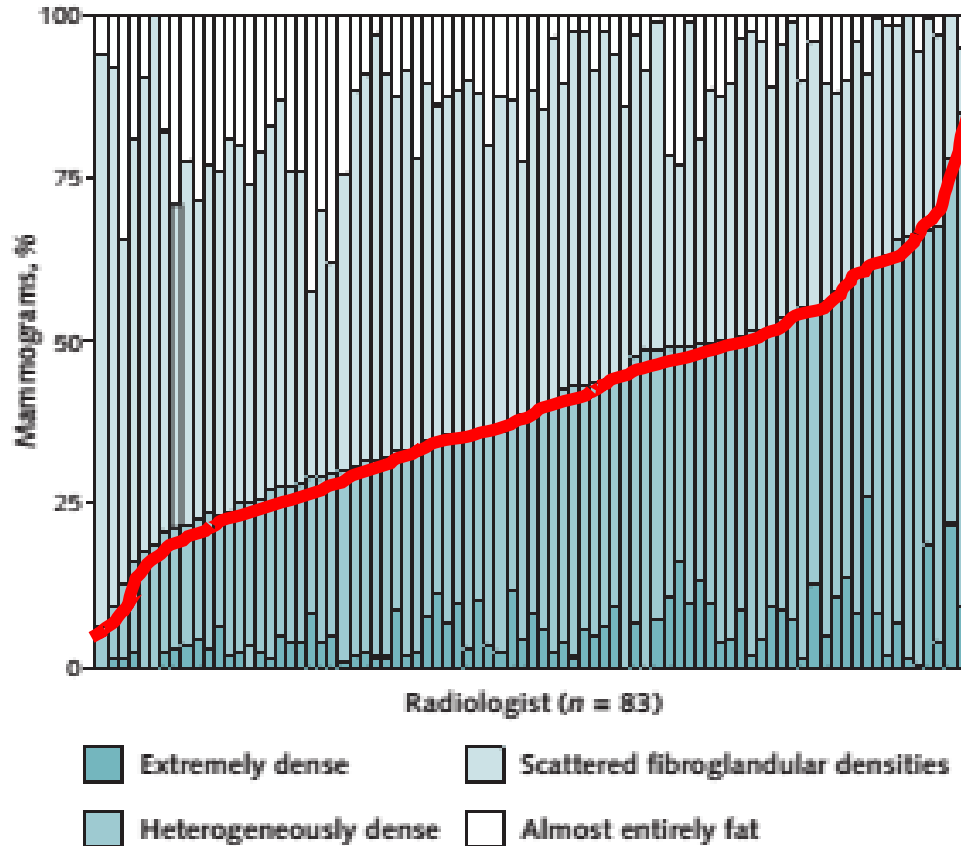
- **28 states** now require density notification (AreYouDense.org)

Federal law discussions continue.

FDA Mammography Quality meeting in mid-September 2016 will address breast density.

- Some states are now legislating for insurers to cover additional imaging for dense breasts.....

Sprague paper in *Annals of Internal Medicine*



The radiologists are arranged in ascending order of the percentage of mammograms rated as showing dense breasts (heterogeneously or extremely dense). BI-RADS = Breast Imaging Reporting and Data System.

Annals of Internal Medicine

ORIGINAL RESEARCH

Variation in Mammographic Breast Density Assessments Among Radiologists in Clinical Practice

A Multicenter Observational Study

Brian L. Sprague, PhD; Emily F. Conant, MD; Tracy Onega, PhD; Michael P. Garcia, MS; Elisabeth F. Beaber, PhD; Sally D. Herschorn, MD; Constance D. Lehman, MD, PhD; Anna N.A. Tosteson, ScD; Ronilda Lacson, MD, PhD; Mitchell D. Schnall, MD, PhD; Despina Kontos, PhD; Jennifer S. Haas, MD, MSc; Donald L. Weaver, MD; and William E. Barlow, PhD; on behalf of the PROSPR Consortium

Radiologists varied between declaring 8–86% of their populations as “dense”, leading to:

- Cancers being missed
- Unnecessary imaging being performed

Insurers are facing higher costs – the time is right for discussions with insurers around benefits of objective density.

New clinical uses of VolparaDensity – tracking surgery & drugs over time

Baseline

Post-surgery 1

Post-surgery 2

Institut Gustave Roussy
European Congress of Radiology,
Vienna 2016.

To date, we have been helping
with consistency in density
reporting – over the next 12
months there will be more papers
looking at change over time, and
we'll be involved in more & more
clinical trials.

Patient ID
Patient DOB
Accession #
Study Date 02/01/2004

	Right	Left
Volume of Fibroglandular Tissue (cm ³)	64.7	97.7
Volume of Breast (cm ³)	1060.7	1028.4
Volumetric Breast Density (%)	6.1	9.5

- mGy 5.6 kPa 7.8%

Patient ID
Patient DOB
Accession #
Study Date 11/01/2005

	Right	Left
Volume of Fibroglandular Tissue (cm ³)	49.5	58.2
Volume of Breast (cm ³)	1031.3	1039.3
Volumetric Breast Density (%)	4.8	5.6

- mGy 4.8 kPa 5.2%

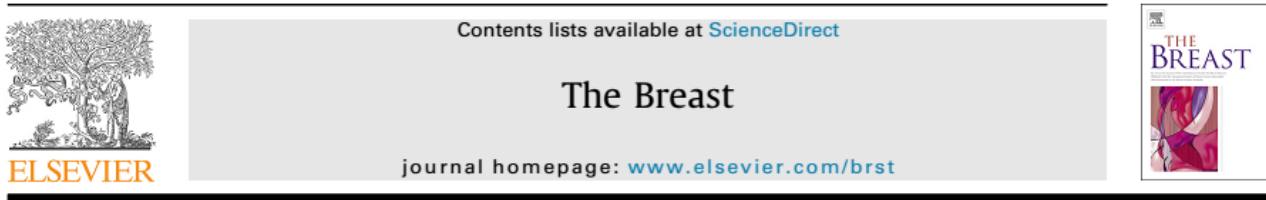
Patient ID
Patient DOB
Accession #
Study Date 12/01/2006

	Right	Left
Volume of Fibroglandular Tissue (cm ³)	45.5	47.4
Volume of Breast (cm ³)	1034.1	1053.3
Volumetric Breast Density (%)	4.4	4.5

- mGy 7.4 kPa 4.5%

Early detection of breast cancer

New clinical uses of VolparaDensity – tracking surgery & drugs over time



Original article

Consistency of breast density categories in serial screening mammograms: A comparison between automated and human assessment

Katharina Holland^{a,*}, Jan van Zelst^a, Gerard J. den Heeten^{b,c}, Mechli Imhof-Tas^a, Ritse M. Mann^a, Carla H. van Gils^d, Nico Karssemeijer^a

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^b LRCB – Dutch Reference Center for Screening, PO Box 6873, 6503 GJ Nijmegen, The Netherlands

^c Department of Radiology/Biomedical Engineering and Physics, Academic Medical Center Amsterdam, PO Box 22660, 1100 DD Amsterdam, The Netherlands

^d Julius Center for Health Sciences and Primary Care, University Medical Center Utrecht, PO Box 85500, 3508 GA Utrecht, The Netherlands

mammograms belonging to 500 pairs of subsequent screening exams were categorized into either two or four density classes. We calculated percent agreement and the percentage of women that changed from dense to non-dense and vice versa. Inter-exam agreement (IEA) was calculated with kappa statistics. Results were computed for each reader individually and for the case that each mammogram was classified by one of the four readers by random assignment (group reading).

Higher percent agreement was found with VDG (90.4%, CI 87.9–92.9%) than with readers (86.2–89.2%), while less plausible changes from non-dense to dense occur less often with VDG (2.8%, CI 1.4–4.2%) than with group reading (4.2%, CI 2.4–6.0%). We found an IEA of 0.68–0.77 for the readers using two classes and an IEA of 0.76–0.82 using four classes. IEA is significantly higher with VDG compared to group reading.

The categorization of serial mammograms in density classes is more consistent with automated software than with a mixed group of human readers. When using breast density to personalize screening protocols, assessment with software may be preferred over assessment by radiologists.

VDG = Volpara Density Grade

“When using breast density to personalize screening protocols, assessment with software may be preferred over assessment by radiologists”

New clinical uses of VolparaDensity – risk of developing cancer

Monday 11 July 2016

10:45–12:30

Symposium

Diagnosing Cancer Earlier

13 Proffered Paper: A comparison of four methods of mammographic density measurement in the UK Predicting Risk Of Cancer At Screening (PROCAS) study – on behalf of the PROCAS Study team

S. Astley¹, E. Harkness¹, J. Sergeant², P. Stavrinou³, R. Warren⁴, M. Wilson³, A. Brentnall⁵, J. Cuzick⁵, A. Howell⁶, G. Evans⁷. ¹University of Manchester, Centre for Imaging Sciences, Manchester, United Kingdom, ²University of Manchester, Arthritis Research UK Centre for Epidemiology Centre, Manchester, United Kingdom, ³University Hospital of South Manchester, Genesis Breast Cancer Prevention Centre and Nightingale Breast Screening Centre, Manchester, United Kingdom, ⁴University of Cambridge, Cambridge Breast Unit, Cambridge, United Kingdom, ⁵Queen Mary University of London, Centre for Cancer Prevention- Wolfson Institute, London, United Kingdom, ⁶The Christie NHS Foundation Trust, Breast Oncology, Manchester, United Kingdom, ⁷Central Manchester Foundation Trust, Genomic Medicine, Manchester, United Kingdom

Objectives: This study compares several methods of mammographic density estimation to determine which best predicts women subsequently diagnosed with breast cancer and which is most strongly associated with cancer in the contralateral breast at the time of screening. Such comparisons are important to enable selection of appropriate strategies for stratifying women in risk adapted breast screening programmes.

Materials and Methods: Women participating in a study of cancer risk

Conclusions: The results show that visual assessment of breast density, recorded on VAS and averaged between two mammographic readers, demonstrates the strongest relationship with cancer. This is the case for mammograms both before the detection of cancer and in the opposite breast at the time of detection. Percentage density measured by Volpara provided the strongest relationship amongst the automated measures, and provides a practical method for risk stratification.

No conflict of interest.

EACR24 Oral Presentations, Monday 11 July 2016/European Journal of Cancer 61, Suppl. 1 (2016) S5–S8

PROCAS aims to change the NHS Breast Screening Programme (BSP) by including breast cancer risk prediction for women when they attend routine breast screening.

“Percentage density measured by Volpara provided the strongest relationship amongst the automated measures, and provides a practical method for risk stratification.”

Major breast cancer risk models are expected to start including breast density.

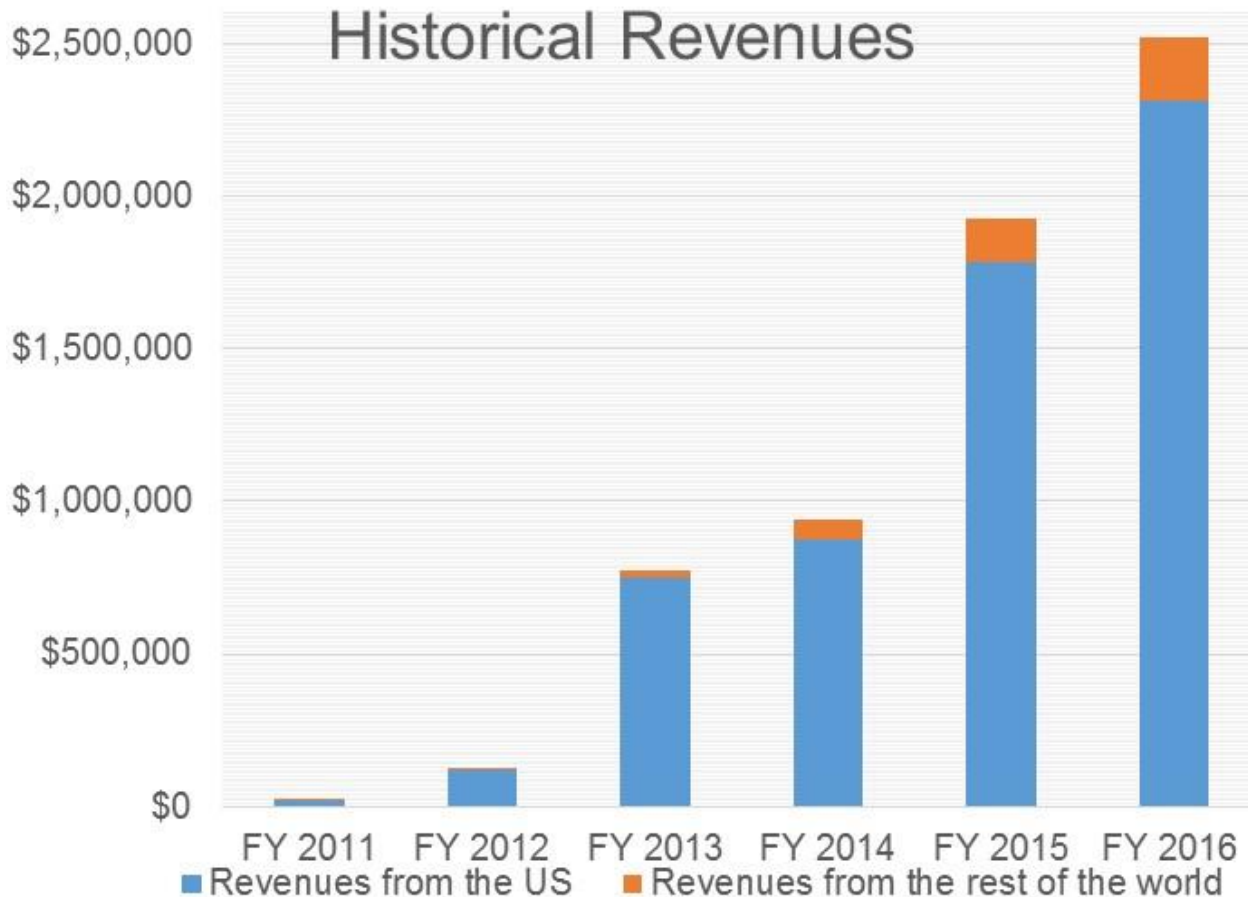
UK expected to launch project to do trial implementation of density into screening sites

FY2016 results – 31% product revenue growth, mostly VolparaDensity

US market is increasingly educated, but:

- Density appeals mostly to the radiologist
- Density is a traditional medical device, capital sale and thus subject to tight capital budgets.

Despite these points and a small US sales force, FY16 product revenue up 31% to NZ\$2.6m – we estimate we have around ~1% of US market, and we continue to work closely with distributors.



SIEMENS



Trading to end June 2016 (Q1, FY2016), 4C released, 29th July 2016

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.

Results broadly as expected, Q1 orders included VolparaDensity capital sales to:

- Multiple sites in the US, direct and via distributors
- Royal Perth Hospital
- UK, Austria, India and our 4th one into Canada
- A Clinical Research Organization (CRO)

Early 2016, new executives join & focus switches to enterprise



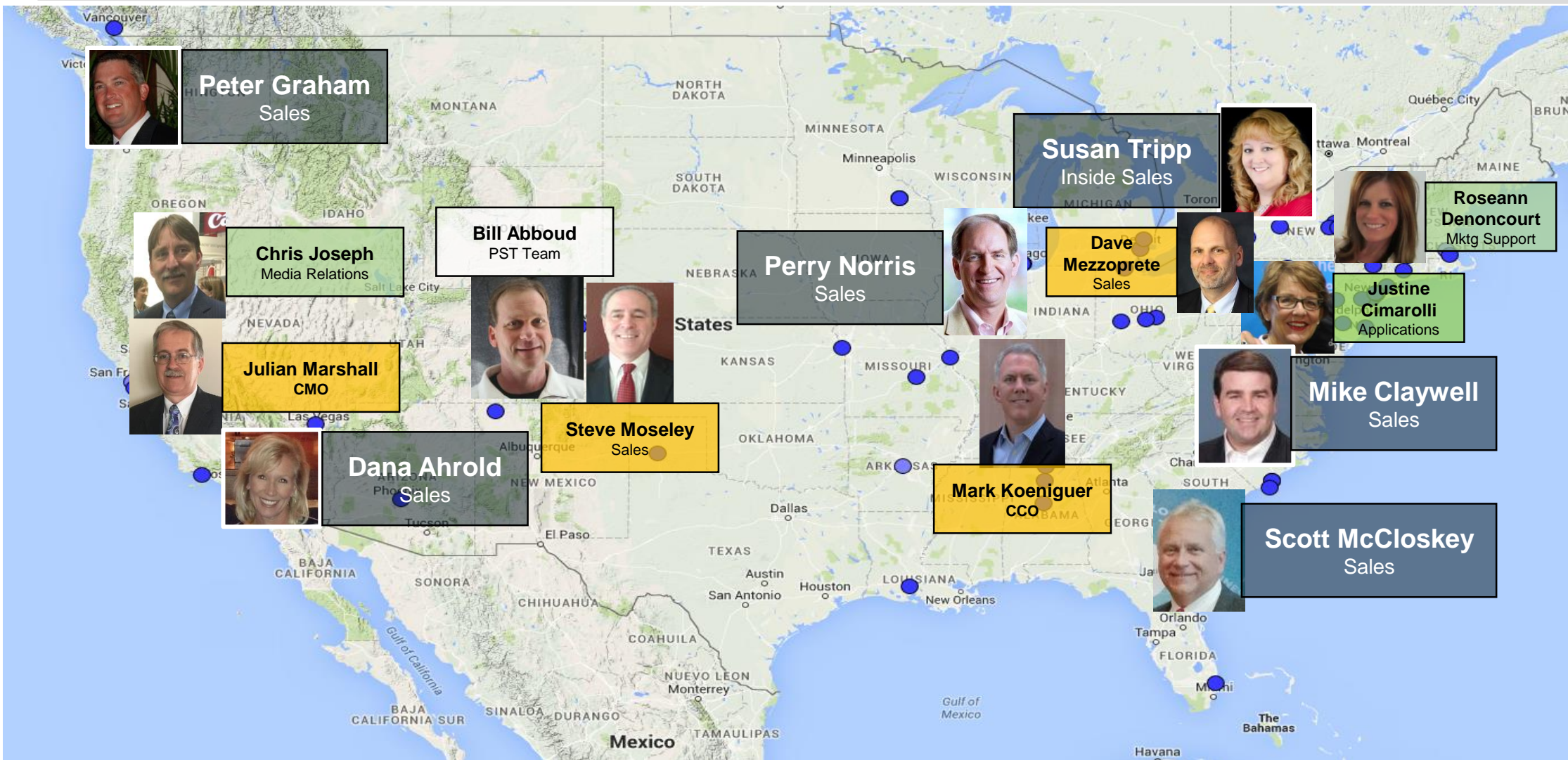
Mark Koeniguer joined as Chief Commercial Officer, based in Nashville, USA, previously with GE, and SaaS company UL.



Julian Marshall joined as Chief Marketing Officer, based in San Francisco, USA, from Hologic.

Excited about the **dynamic and leading-edge digital health company** forming around VolparaEnterprise, our new Cloud-based software for all members of the breast imaging team.

July 2016, expanded US sales team



July 2016, expanded global sales team



Anton Zerle, VP S&M, APAC
Formerly Hologic



David Lee, VP S&M, EMEA
Formerly Hologic

Driven distributors being lined up in
Europe & elsewhere



Highnam, Density Talk, Symposium Mammographicum, UK, June 2016

July 2016, VolparaEnterprise launched



Software that Saves You Time and Money



Your Finger on the Pulse
of Your Department



Understand Your
Patients Better



The Power of Objective
Quality Metrics



Ensure Your Staff is
Operating at Peak
Performance



Join VolparaEnterprise
Users Around the World

July 2016, VolparaEnterprise launched



VHT Pivoting



Density
DoseRT
Analytics
Enterprise Analytics

Timely, as reimbursement in the US is moving towards quality of service, as well as quantity (MACRA 2015 Act)

- On-site
- Capital sales model
- Clinical focussed
- Radiologist key contact
- Sales lead is density

- Predominately Cloud
- Software as a Service
- Clinical, safety, quality, productivity coverage
- **Centre Manager key contact**
- **Sales lead is cost savings & revenues**

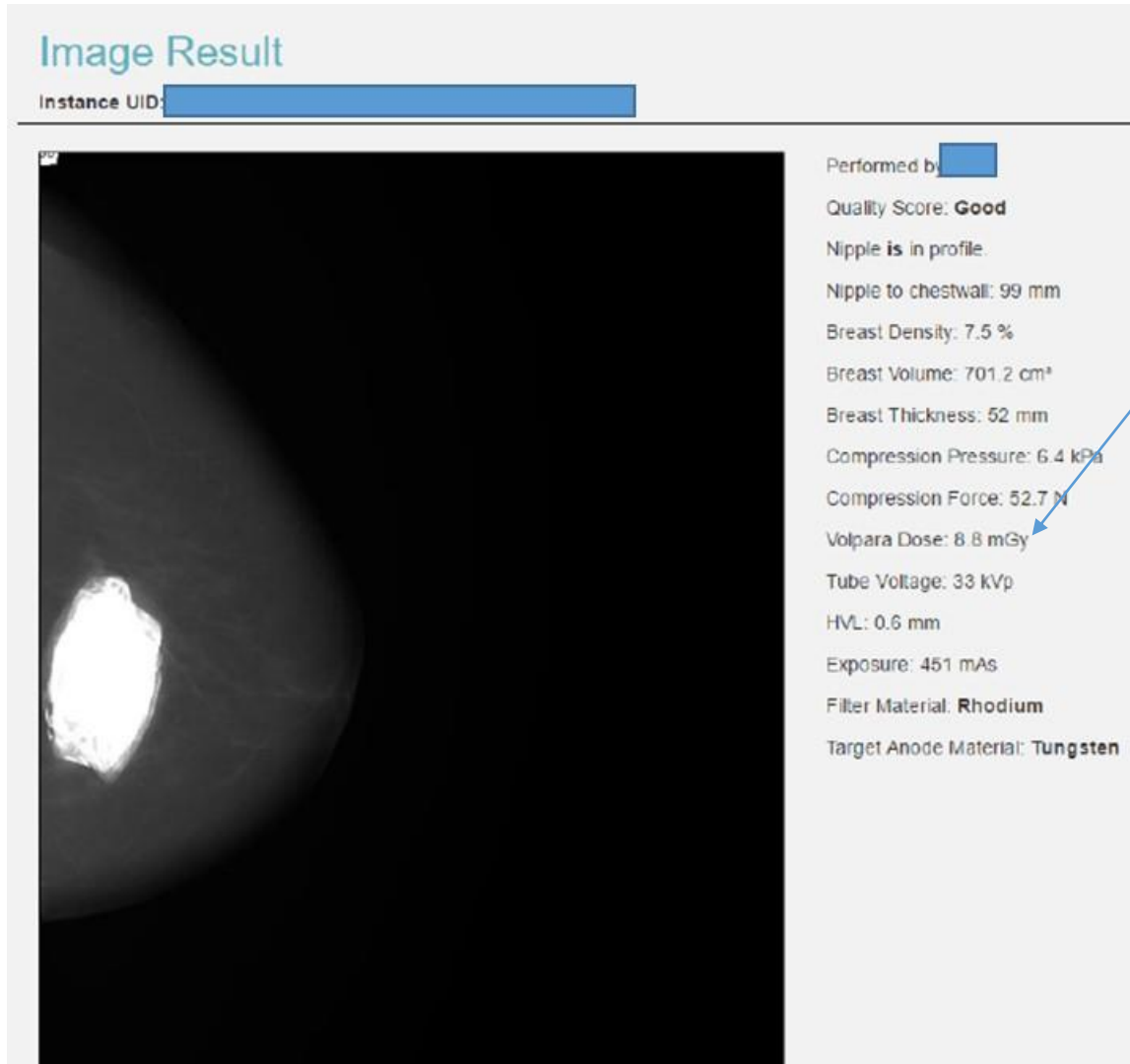
July 2016, Independent experts have validated SaaS model

- The top two preferred value metrics among respondents are:
 - 1) pricing by number of patient screens, and
 - 2) pricing by software features and functionality
- ✓ VolparaEnterprise price is the sum of **Enterprise Base + Features + Volume** components
- Transitioning from **Capital to SaaS aligns with customer interest** and optimizes both user adoption/retention and revenue
 - ✓ Modelling predicts break-even revenue compared to capital in 2-3 years, assuming retention and renewal, that would not have been captured otherwise
- **Likelihood To Buy** and **Optimal Price Band** are positively correlated across roles
 - ✓ For example, a radiologist is not only likely to buy, but demonstrated they are willing to pay the highest price
- Interesting trend to pay attention to:
 - ✓ Individual patient clinical attributes resonate strongly

July 2016, VolparaEnterprise launched



July 2016, VolparaEnterprise launched



- Very high radiation dose, 8.8mGy, ~5 times what she should have received.
- The ruptured implant has made the automatic exposure control fail – this woman should have been imaged in manual mode.

July 2016, VolparaEnterprise launched

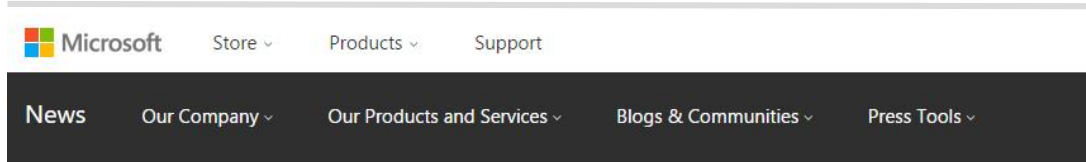
Fast start program:

- Converting existing customers over
- Targeting 50 accounts per territory via Telesales
- Mining past leads from RSNA, SBI, NCBC...
- Leveraging personal relationships

Sales funnel is rapidly expanding, with many big name accounts.

First sales of VolparaEnterprise are close

Microsoft case study on VolparaEnterprise



Using Cloud technology to improve breast cancer detection



Posted May 12, 2016 By Microsoft News Center



For successful business intelligence software developer Yellowfin, every job is important. However, the work it is doing with Volpara Solutions to better assist in the early detection of breast cancer to proving to also be incredibly satisfying.

Founded in 2009, Volpara Solutions HSSA has developed a suite of quantitative breast imaging products – VolparaDensity, VolparaDose, VolparaAnalytics, VolparaResearch and now VolparaEnterprise – which are used in 34 countries to assist in the

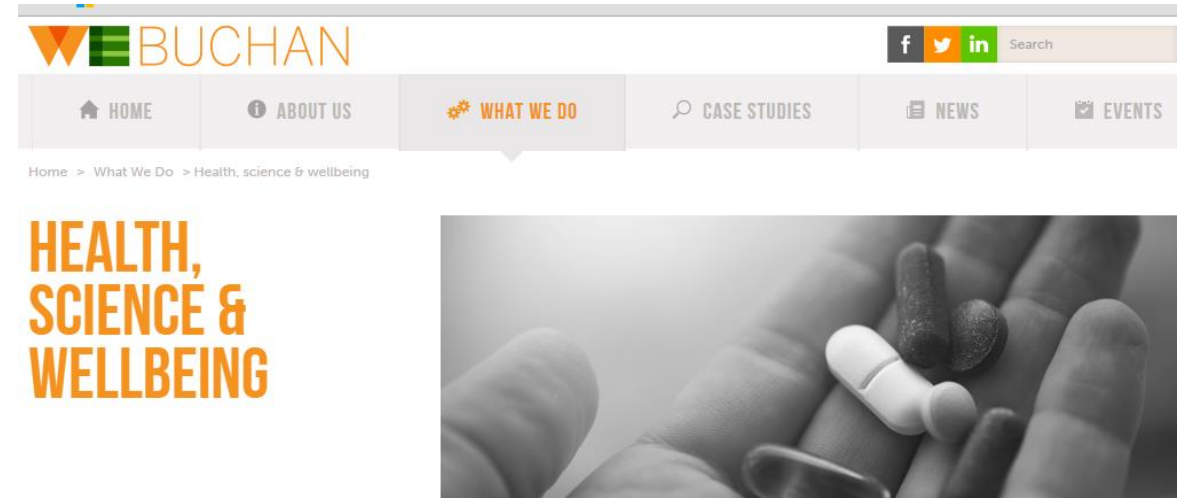
Major IT companies are entering the healthcare space as Cloud becomes more accepted, and the potential for “Big Data” becomes more widely understood.



We believe this is a major shift in healthcare and likely to see IT companies, such as VHT, not hardware manufactures, leading innovation, partnering might be one option.

Driving shareholder value – investor relations

1. Appointed Buchan as advisors, based in Melbourne, and working with multiple other biotech/digital health related companies
2. Attending multiple biotech events and meeting associated investors.
3. Increased press coverage in Australia and New Zealand.
4. Launching a quarterly newsletter to allow us to keep investors better informed.
5. Seeding a breast density awareness campaign across Australia and New Zealand.



Upcoming investor events

- Updated links on the web site under Investor Relations.
- Very welcome to come and meet us there.
- Additionally, Ralph Highnam giving invited lectures on the clinical utility of density in Kingscliff, NSW, next week:

4th International “Why Study Mammographic Density?” Meeting

Australian International Breast Density Meeting

Monday 15th – Tuesday 16th August 2016

*Peppers Salt Resort & Spa
Kingscliff, NSW, Australia*

QLD Broker Meets Biotech

8 September 2016

Stamford Plaza Brisbane

[AusBiotech](#)

WA Broker Meets Biotech

15 September 2016

Parmelia Hilton, 14 Mill Street, Perth

[AusBiotech](#)

CEO Sessions

20 September 2016

ASX Auditorium, 18 Bridge Street, Sydney

[ASX](#)

SA Broker Meets Biotech

22 September 2016

Crowne Plaza Adelaide

[AusBiotech](#)

AusBiotech 2016

24–26 October 2016

Melbourne Convention Centre

Investment summary

- **World-leading brand** operating in an important space with regulatory clearance, clinical validation and solid early sales +31% growth year on year, with new clinical utility opening up.
- **Growing market opportunity** – 39 million each year in the US are screened, increasingly in personalised ways, and we now have a good size, 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**, with pricing validated via an independent company.

It's been a remarkable year, thank you to the whole VHT team!

News flow to end FY2017 (April 2017)

Quarter (FY2017)	Approximate Month	Anticipated News Story
Q2	Aug, Sept	First sales of VolparaEnterprise
Q2	Sept	FDA panel on Mammography Quality Standards and breast density
Q2	Sept	Roadshow around Australia to meet investors
Q3	Oct, Nov, Dec	Launch of major new breast cancer risk model including density
Q3	Oct, Nov, Dec	Launch of UK project looking at implementation of density
Q3	Oct, Nov, Dec	Announcement of major new distributor
Q3	Nov	Density awareness campaign, Australia
Q3	Dec	RSNA 2016, Chicago, launch of VolparaEnterprise 2.0
Q4	Jan	Report on reimbursement potential
Q4	Jan	Increasing use of VolparaDensity in clinical trials
Q4	March	Sales of VolparaEnterprise to mix of sites, including brand names.
Q4	March	Partnership with “Big Data”/“Deep Learning” company



**Thank you for your
continuing support.**

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