ASX RELEASE

Investor Presentation: US Screening Market Reopens Amid COVID-19

Wellington, NZ, 15 June 2020: Volpara Health Technologies ("Volpara," ASX: VHT), a medical technology company whose cancer screening software platform assists in the delivery of personalized patient care in the areas of breast and lung cancer, has released an updated investor presentation.

The presentation includes an update on the recovery in the US market, as restrictions put in place due to COVID-19 are eased.

Seventy-eight percent of Volpara®Enterprise™ software customers have resumed screening, as of the end of May 2020; this figure has continued to increase throughout June. Volumes have returned to within 10 percent of previous levels. As imaging facilities open their doors and deal with a customer backlog, 5 percent of customers are even recording image volumes greater than pre-pandemic levels.

ENDS.

For further information, please contact:

Ralph Highnam, CEO
Volpara Health Technologies
ralph.highnam@volparasolutions.com
t: +64 21 149 0541

Trevor Chappell
WE Communications
WE-AUVolpara@we-worldwide.com
t: +61 407 933 437

About Volpara Health Technologies Limited (ASX: VHT)

VHT is a MedTech SaaS company founded in 2009 on research originally conducted at Oxford University. VHT's clinical functions for screening clinics provide feedback on breast density, compression, dose, and quality, while its enterprise-wide practice software management helps with productivity, compliance, reimbursement, and patient tracking.

VHT's technology and services have been used by customers and/or research projects in 38 countries and are supported by numerous patents, trademarks, and regulatory clearances, including FDA clearance and CE marking. Since its listing on the ASX in April 2016, VHT has raised A$32 million, including A$37 million in April/May 2020. VHT is based in Wellington, New Zealand.

At the end of June 2019, VHT acquired MRS Systems, Inc., a company based in Seattle, WA. MRS provides mammography reporting systems to over 1,600 breast clinics and hospitals, and to VHT a much stronger US presence, experienced local headquarters, and accelerated sales through cross-selling opportunities.

For more information, visit www.volparasolutions.com

Important Notice & Disclaimer

This presentation is date 15thJune2020 has been prepared solely for the purpose of providing potential investors with information about Volpara Health Technologies Limited (**"Volpara", "VHT" or the "Company"**). The information contained in this presentation is of a general background nature, is in summary form, and does not purport to contain all of the information that a potential investor may need or desire. Potential investors should conduct their own investigation and analysis of Volpara and of the information contained in this presentation and should rely solely on their own judgment, review and analysis in deciding whether or not to invest in Volpara. The information in this presentation has been prepared in conjunction with an oral presentation and should not be taken out of context. The content of this presentation is provided as at the date of this presentation (unless otherwise stated) and the information in this presentation is subject to change without notice.

Forward-looking statements
This presentation may include forward-looking statements. Such statements can generally be identified by the use of words such as 'may', 'will', 'expect', 'intend', 'plan', 'estimate', 'anticipate', 'believe', 'continue', 'objectives', 'outlook', 'guidance', 'forecast' and similar expressions. Indications of plans, strategies, management objectives, sales and financial performance are also forward-looking statements. Such statements are based on assumptions and contingencies which are subject to change without notice and are not guarantees of future performance. Such statements involve known and unknown risks, uncertainties, assumptions, contingencies and other factors, many of which are outside the control of Volpara. No representation is made or will be made that any forward-looking statement will be achieved or will prove to be correct. Actual results, performance, operations or achievements may vary materially from any forward-looking statements. Circumstances may change and the content of this presentation may become outdated as a result. Readers are cautioned not to place undue reliance on forward-looking statements and Volpara assumes no obligation to update such statements except as required by law. No representation or warranty, expressed or implied, is made as to the accuracy, reliability, adequacy or completeness of the information contained in this presentation.

Past performance
Past performance information given in this presentation is given for illustrative purposes only and should not be relied upon as (and is not) an indication of future performance.

Information is not financial or product advice or offer of securities
This presentation is not, and is not intended to constitute, financial or product advice, or an offer invitation, solicitation or recommendation to acquire or sell Volpara shares or any other financial products in any jurisdiction and is not a prospectus, product disclosure statement, disclosure document or other offering document under Australian law or any other law. This presentation also does not form the basis of any contract or commitment to sell or apply for securities in Volpara or any of its subsidiaries. It is for information purposes only. Volpara does not warrant or represent that the information in this presentation is free from errors, omissions or misrepresentations or is suitable for any intended use. The information contained in this presentation has been prepared without taking account of any person's investment objectives, financial situation or particular needs and nothing contained in this presentation constitutes investment, legal, tax or other advice. The information provided in this presentation may not be suitable for a potential investor's specific needs and should not be relied upon in substitution obtaining independent advice. Subject to any terms implied by law and which cannot be excluded, Volpara accepts no responsibility for any loss, damage, cost or expense (whether direct, or indirect, consequential, exceptional or special damages including but not limited to loss of revenue, profits, time, goodwill, data, anticipated savings, opportunity, business reputation, future reputation, production or profit, any delay costs, economic loss or damage) incurred by any person as a result of any error, omission or misrepresentation in this presentation.

Preparation of information
All financial information has been prepared and reviewed in accordance with Generally Accepted Accounting Practice in New Zealand, New Zealand Equivalents to International Financial Reporting Standards and International Financial Reporting Standards. Certain financial data included in this presentation is 'non-IFRS financial information'. The Company believes that this non-IFRS financial information provides useful insight in measuring the financial performance and condition of Volpara. Readers are cautioned not to place undue reliance on any non-IFRS financial information including ratios included in this presentation.

Third party information and market data
The views expressed in this presentation contain information that has been derived from publicly available sources that have not been independently verified. No representation or warranty is made as to the accuracy, completeness or reliability of the information. This presentation should not be relied upon as a recommendation or forecast by Volpara. Market share information is based on management estimates except where explicitly identified.

No liability or responsibility
The information in this presentation is general in nature and is provided in summary form and is therefore does not purport to be complete. No other party than Volpara has authorised, permitted or caused the issue or lodgement, submission, dispatch or provision of this presentation and there is no statement in this presentation which is based on any statement made by any of them or by any party other than Volpara. To the maximum extent permitted by law, each Volpara and each of its affiliates, directors, employees, officers, partners, agents and advisers expressly disclaim all liabilities in respect of, and make no representations regarding, and take no responsibility for, any part of this presentation and make no representation or warranty as to the currency, accuracy, reliability or completeness of this presentation.

To the maximum extent permitted by law, Volpara and each of its affiliates, directors, employees, officers, partners, agents and advisers and any other person involved in the preparation of this presentation disclaim all liability and responsibility (including without limitation, any liability arising from fault or negligence) for any direct or indirect loss or damage which may arise or be suffered through use or reliance on anything contained in, or omitted from, this presentation. Volpara accepts no responsibility or obligation to provide an update in respect of any matter arising or coming to their attention after the date of this presentation which may affect any matter referred to in this presentation.
Each recipient of this presentation represents and warrants to Volpara that it is able to receive this presentation without contravention of any applicable law or legal restriction in the jurisdiction in which the recipient resides, conducts business or receives this document.

This presentation should be read in conjunction with Volpara's other periodic and continuous disclosure announcements lodged with ASX.

- **Volpara is a Software-As-A-Service ("SaaS") company that utilizes AI to improve the early detection of breast cancer by analysing breast images ("mammograms") and associated patient data to provide:**
  - Clinical Decision Support and Practice Management tools
  - Cost effective reduction of breast cancer deaths (500,000 deaths globally each year)

- **Breast cancer screening is a ~US$750M Annual Recurring Revenue (ARR) opportunity for Volpara:**
  - ~92m women are screened per annum globally
  - Volpara's product suite will sell for up to US$10 per screen (potential ARPU)
  - Genuine first mover advantage and established users in 38 countries
  - Competitive moat – intellectual property, papers, product suite, regulatory, scale
  - Data and images from sites go to the Cloud for use in future product development

- **Volpara's software is experiencing rapid uptake in the US market (39M screenings p.a.):**
  - 27.1% of US screenings (end March) are using at least one of our products
  - NZ$18.0M ARR at end of FY20, growth of 172% (from strong organic & inorganic)
  - Negligible churn & increasing ARPU
  - Gross margins of above 86% and rising

- **Positive outlook for FY21 despite COVID-19 uncertainty due to industry, company & business resilience:**
  - Whilst screening did stop, it is a critical service which has now mostly restarted
  - Volpara team very used to working remotely and working from home & on Cloud
  - Business model is resilient with recurring revenue & annual payments up-front
  - Experienced SaaS direct sales team in the US and ANZ with networks and leads well-established

- **Volpara raised A$38M in April/May 2020, the funds are being used to:**
  - Strengthen the balance sheet, ~NZ$69M post-raise
  - Pursue several identified M&A opportunities that have the potential to increase US market share and/or ARPU

Volpara exceeded already upgraded FY20 forecasts with

~NZ$18,000,000ARR

~27.1% footprint in US breast imaging clinics

volpara® health technologies

Delivering Strong Growth in All Key Metrics Year-on-Year
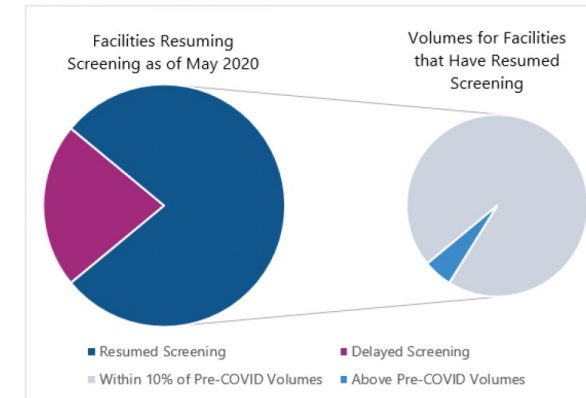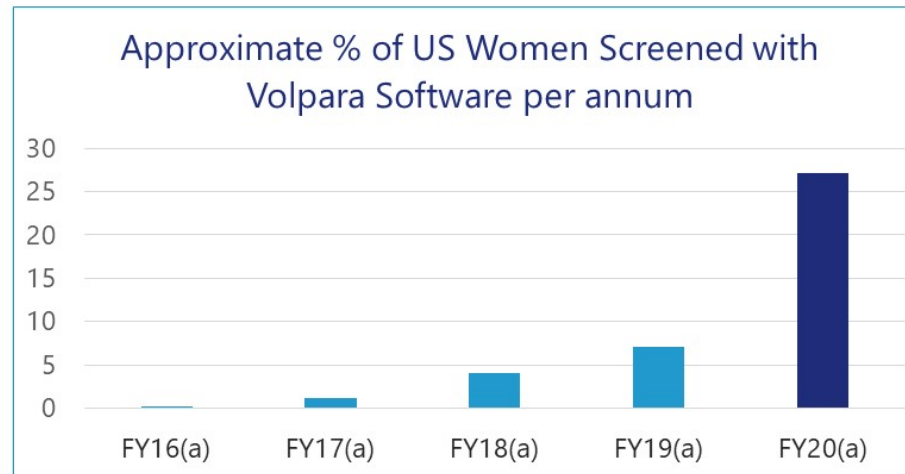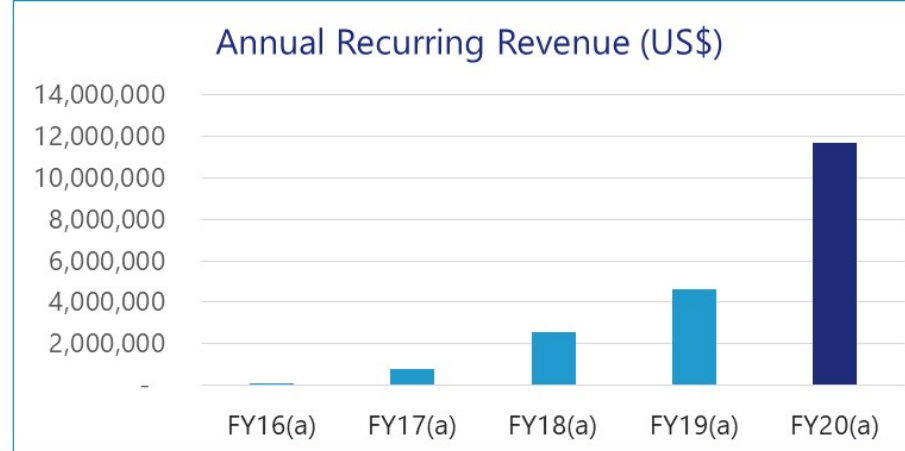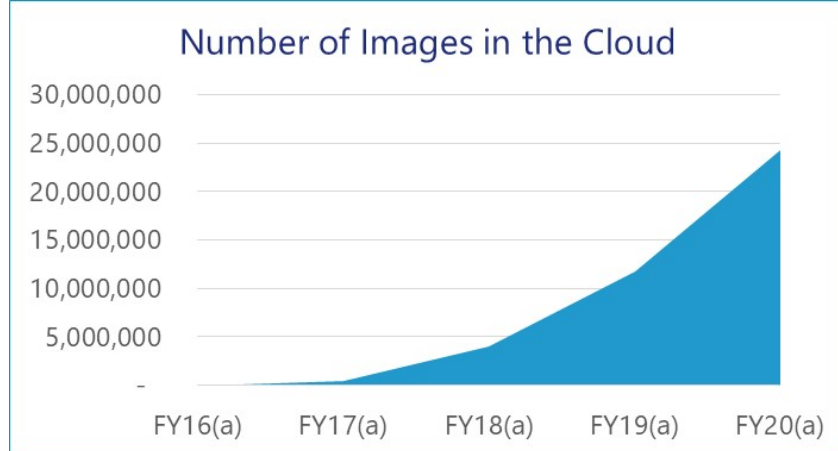
- ~80% of US sites were screening again June 2nd

- Most are close to pre-COVID levels, 10% are doing more.
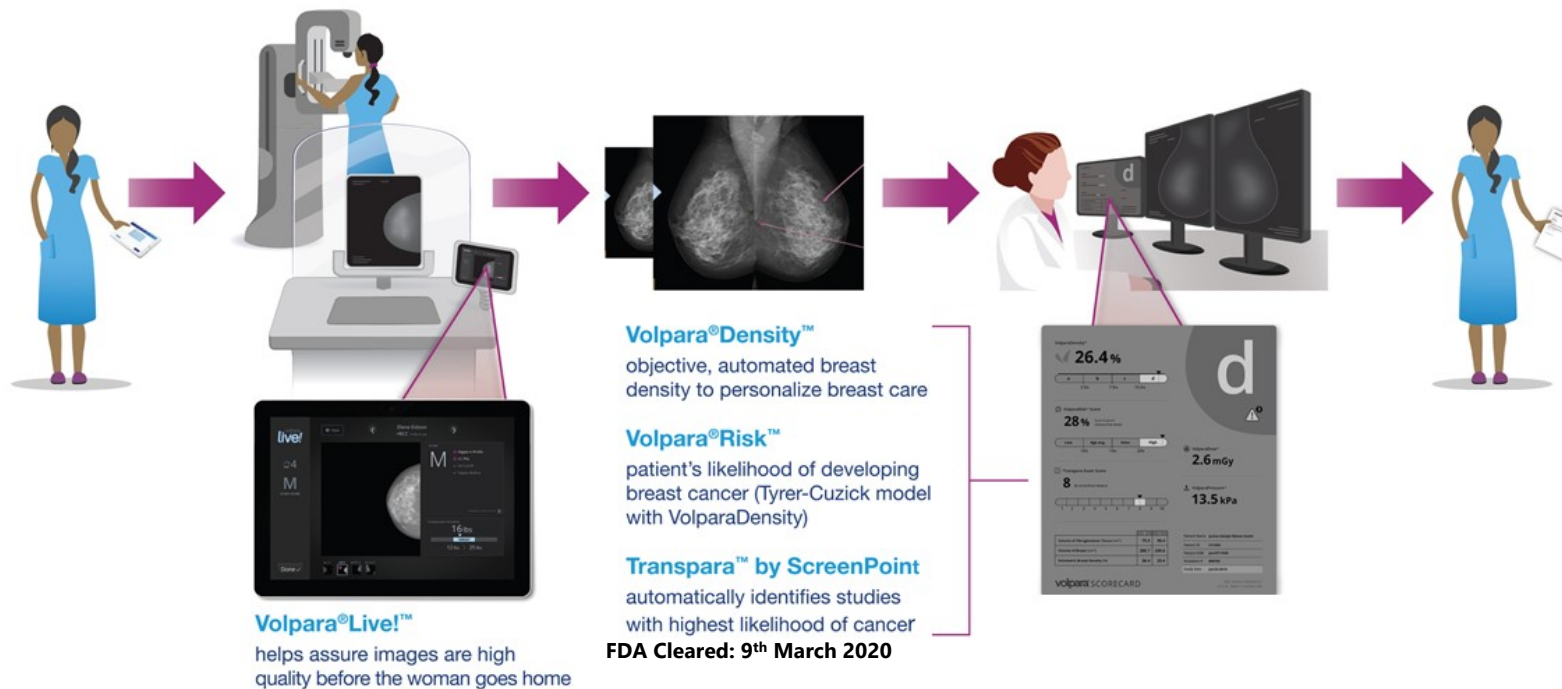
Saving Families from Breast Cancer

- Earlier detection improves survival & reduces treatment costs, and ~92M women are screened globally each year

- "One size fits all" breast cancer screening using breast x-rays (mammograms) is proven to save lives, but room to improve:
  - 25-40% of cancers are missed by the radiologist
  - 2- 3% of women get recalled due to bad imaging

- US payers reimburse ~US$150 or so per woman per year for screening, giving a total spend of ~US$4.5Bn

- Volpara uses AI algorithms to provide objective measures of the breast from the data & mammograms from any mammography machine to help with clinical decision support and practice management

- With over 300+ publications and granted patents and trademarks our technology is world-leading
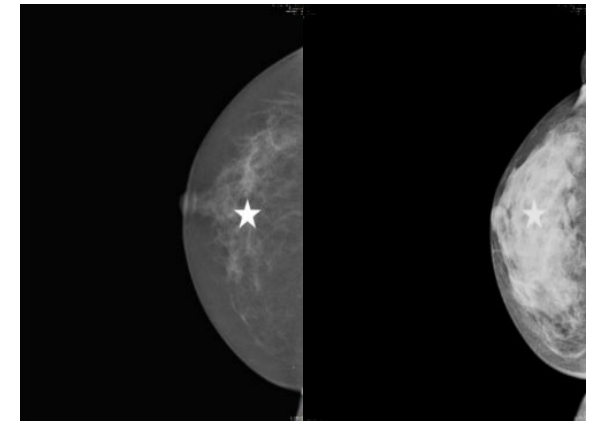
The whiter breast is "denser" – more likely to develop cancer and more likely to have cancer missed – can you see the star?

Clinical Decision Support
Powered by AI

Volpara®Live!™
helps assure images are high quality before the woman goes home

Volpara®Density™
objective, automated breast density to personalize breast care

Volpara®Risk™
patient's likelihood of developing breast cancer (Tyrer-Cuzick model with VolparaDensity)

Transpara™ by ScreenPoint
automatically identifies studies with highest likelihood of cancer
FDA Cleared: 9th March 2020

Ambry Genetics®
A Konica Minolta Company

Collaboration signed April 2020 for electronic referrals to genetics testing, if the risk score is high

Practice and Enterprise Management

Aspen Breast
patient analytics, tracking and reporting, acquired June 2019

Data + Images

Volpara®Enterprise™
imaging analytics, quality and productivity issues, and easier FDA audits

volpara health technologies

Note: Final product names subject to change
Software due for final release in FY2021

Attractive Recurring Revenue Model

- Volpara provides Software-as-a-Service (SaaS), with pricing based on the product used and number of women screened at each site

- Most Volpara contracts signed are 5-year annual rolling contracts with effectively fixed amounts paid annually upfront

- Average Revenue Per User (ARPU) is the average revenue achieved per woman screened per year at a site – currently, our ARPU over the entire installed base is US$1.04, it's at that level because most users have only the Aspen product currently which was historically sold as capital with a small service & maintenance contract, not as SaaS

- **Since 1st November 2019, all new quotes/proposals are SaaS contracts**, **and most new deals are significantly above US$1.04 ARPU comprising multiple products – in Q4, ARPU on <u>new</u> deals was US$1.45 – US$3.10**

VOLPARA'S AIM IS TO GET TO

~US$10 ARPU per screen

VolparaEnterprise

VolparaDensity

VolparaLive!

Risk Assessment[1]

Computer-Aided Detection[2]

VolparaAspen[3]

Genetics Testing[4]

1&3 – these were MRS products prior to acquisition
2   - Transpara, licensed from ScreenPoint Medical BV
4   - Fee we receive from Ambry Genetics as part of April 2020 deal

US Market – ~39M Women a Year, Volpara has ~27.1% Footprint

- ~8,700 sites all regulated by the FDA, who are pushing quality & likely to mandate breast density reporting

- Volpara sells direct with (now) 17 experienced SaaS sales people, and a collaborative working relationship with GE

- The acquisition of MRS has created major cross-selling opportunities, especially around personalized healthcare, 27.1% of US sites now have at least one Volpara product

- Volpara's unique products have created a first mover advantage, built competitive defences, and provide outcomes being requested of sites by the FDA and other groups

THE UNIVERSITY OF TEXAS
MD Anderson
Cancer Center

Memorial Sloan Kettering
Cancer Center

KAISER PERMANENTE®

Walter Reed
National Military
Medical Center

Expected before Oct 2020

FDA NEWS RELEASE

FDA advances landmark policy changes to modernize mammography services and improve their quality

Proposed rule would require breast density reporting, enhance the FDA's ability to enforce mammography facilities' compliance with standards

THE AMERICAN SOCIETY OF
Breast Surgeons - Official Statement -

Position Statement on Screening Mammography

ASBrS Breast Cancer Screening Guidelines Recommendations

volpara
health technologies

The customer trade marks (above) are the property of the Customer and are used for illustrative purposes only. No rights in or to the trade marks, no association, and no endorsement of our products on the part of the customer is intended or implied. Some sites might still be in the installation phase.

Outside the US – 38 Countries Using Volpara Software
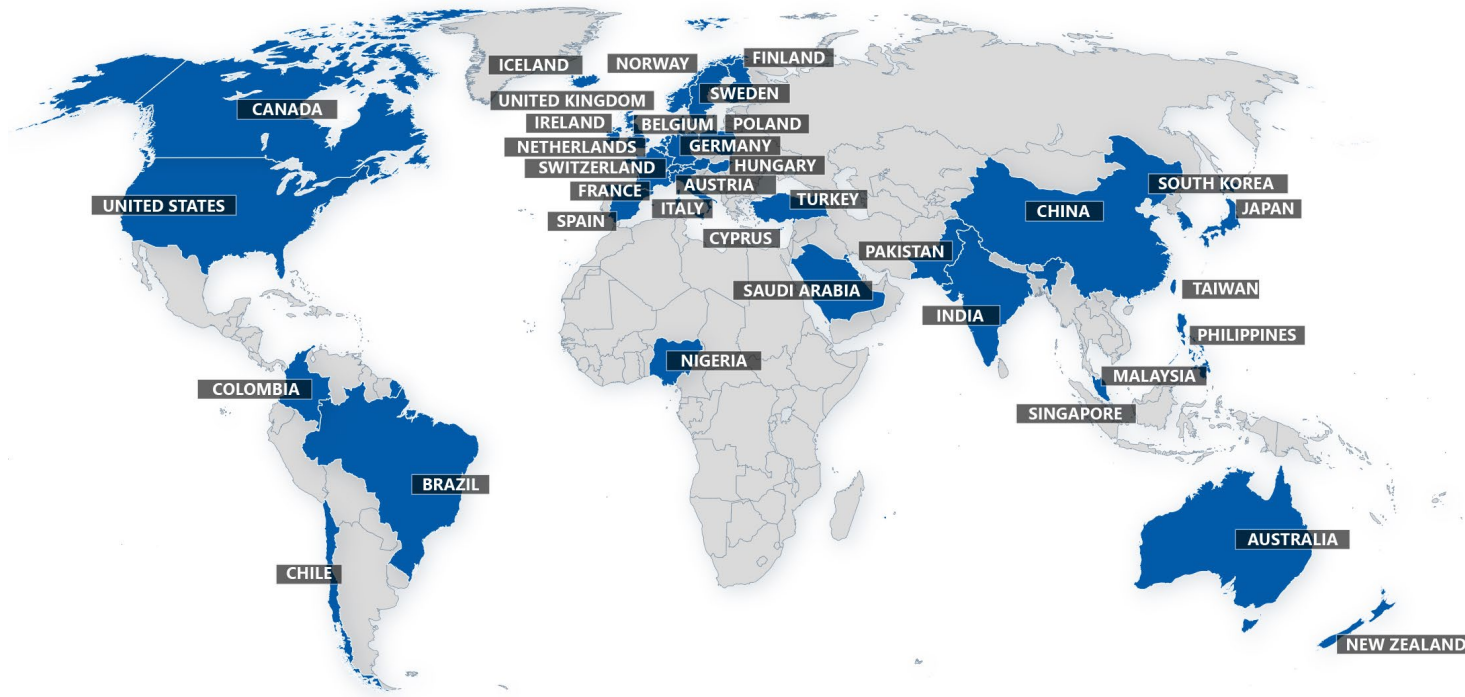
- Major trials underway with public sector run programs, **DENSE announced in Dec 2019 from Netherlands showing major drop in interval cancers:**

  > MR Imaging as an Additional Screening Modality for the Detection of Breast Cancer in Women Aged 50–75 Years with Extremely Dense Breasts: The DENSE Trial Study Design[1]

- Key luminaries signed-up across Asia and Europe

- Mix of direct and distributor sales

- Australia & NZ have seen strong private uptake over last year

- **First major public screening program signed up to Enterprise in Dec 2019 – going live in CY2020**

The customer trade marks (above) are the property of the Customer and are used for illustrative purposes only. No rights in or to the trade marks, no association, and no endorsement of our products on the part of the customer is intended or implied. Some sites might still be in the installation phase.

9

FY2021 Outlook and Strategy

1. **Recognize world has changed with COVID-19 but breast screening remains a critical service**
   - No governments/regulators want to restrict screening long-term and risk more late stage cancers, increased costs and avoidable deaths
   - We will continue to have a US (private-led, Govt paid) & Australia/NZ (Coronavirus under control) focus
   - We recognize Europe/Asia will take longer to recover due to porous borders and Govt led screening programs

2. **We continue to innovate**
   - The data we have is valuable, and we need to continue extracting value for women from it
   - World class engineering team with a strong R&D pipeline

3. **Focus on long-term SaaS contracts which appear resilient even with COVID-19**
   - Majority of our Volpara contracts are 5-year annual rolling contracts, paid annually in advance
   - Contracts are priced on products chosen, seat-licenses and volumes of screens
   - Sites have restarted screening and most expect to catch-up on volumes
   - Cash collection continues to be strong & currently no obvious signs of any significant churn risks

4. **We can change how we operate and reduce customer acquisition costs**
   - We have a strong US team that are actively working on closing a large outstanding sales pipeline
   - Focus of Q1/Q2 is on closing outstanding deals & increasing the ARPU from the existing customer base
   - We are transforming to digital & remote sales & marketing with increased sales productivity
   - We are also partnering to scale – Ambry Genetics is the first example

5. **We want to be ready for opportunities that will emerge in FY2021 from COVID-19**
   - We are positioned strongly vs other companies due to balance sheet capacity and access to capital
   - We have been tracking M&A opportunities for many years that would add to US market share or increase ARPU
   - We have identified several M&A opportunities that are at various stages

volpara
health technologies

Appendix

# Strong Investor Base – 12,000+ Retail Shareholders & International Institutions

Key Corporate Data 30th April 2020

Share price	A$1.33
52 week low / high	A$0.79-A$2.17
Shares on issue	218,479,977
Market Cap.	A$319.2m
Cash (Post Raise)	~NZ$67.0m / ~A$64.0m
Debt	No debt
Enterprise value	A$255.2m

Share Register Breakdown:

- Institutions / Brokers
- Retail & Other
- Founders / Management / Board

23%
59%
18%
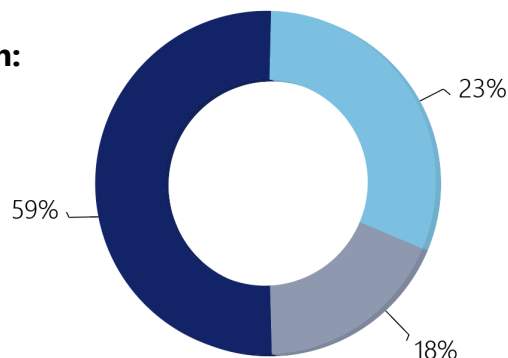
Top Investors	Balance as at 30 April 2020	%
J P MORGAN NOMINEES AUSTRALIA	21,470,149	8.95%
PATAGORANG PTY LTD	18,467,848	7.69%
RALPH HIGHNAM	16,190,485	6.75%
CITICORP NOMINEES PTY LIMITED	12,841,164	5.35%
CUSTODIAL SERVICES LIMITED <BENEFICIARIES HOLDING A/C>	8,693,152	3.62%
NATIONAL NOMINEES LIMITED	7,340,000	3.06%
PROF SIR MICHAEL BRADY	6,619,075	2.76%
MR MARCUS SARNER	5,980,404	2.49%
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED	5,246,524	2.19%
BNP PARIBAS NOMS (NZ) LTD <DRP>	3,360,002	1.40%
SIR MARTIN FRANCIS WOOD	3,004,655	1.25%
LADY KATHLEEN AUDREY WOOD	3,004,654	1.25%
PROF MARTIN YAFFE	2,785,850	1.16%
PROF NICO KARSSEMEIJER	2,556,806	1.07%
CS THIRD NOMINEES PTY LIMITED <HSBC CUST NOM AU LTD 13 A/C>	2,246,664	0.94%
MR JEREMY PALMER	1,966,317	0.82%
HSBC CUSTODY NOMINEES (AUSTRALIA) LIMITED-GSI EDA	1,485,001	0.62%
WHITFIELD INVESTMENTS PTY LTD	1,430,767	0.60%
SIR MARTIN GREGORY SMITH	1,366,977	0.57%
BNP PARIBAS NOMINEES PTY LTD <IB AU NOMS RETAILCLIENT DRP>	1,201,712	0.50%
Total Securities of Top 20 Holdings	**127,258,206**	**53.02%**
Total of Securities	**240,018,439**	

Research coverage by:

BELL POTTER   morgans   ORD MINNETT

volpara health technologies

12

Strong & Experienced Board

Paul Reid — *Chair*

- Joined the Board in 2018, based in Wellington.
- Former CEO of MetService, Figured, and Executive at AirNZ, Carter Holt Harvey.
- Chairman of Figured, Pukeko Pictures and Director for NZ listed Comvita and Christchurch Airport.

Dr Monica Saini — *Executive Director*

- Joined the Board in 2017, based in Wellington
- Former Chief of Breast Imaging, Santa Fe, USA
- Former Chief of Breast Imaging, Christus St. Vincent, USA
- Former Medical Director of Breast Ultrasound, GE Medical
- Breast Radiologist, New Zealand Breast Screening

Karin Lindgren — *Non-Executive Director*

- Joined the Board in January 2020, based in USA
- Experience Board member
- Healthcare technology lawyer
- Expert in data governance and privacy
- Extensive US healthcare & IT networks

John Diddams — *Non-Executive Director*

- Joined the Board in 2015, based in Australia
- Principal of Australia CPA firm, focusing on ASX
- Currently non-executive director of Aroa Biosurgery
- 25 years raising capital, performing due diligence

Ralph Highnam, PhD — *Managing Director*

- PhD, AI and Breast Imaging, University of Oxford
- Former CEO of successful Mirada Solutions
- Co-founded Volpara (VHT) 2009 to exploit concepts from PhD work

John Pavlidis — *Non-Executive Director*

- Joined the Board in 2015, based in USA
- Over 25 years' medical device experience
- CEO of VytronUS, former president and CEO of R2 Technology (AI for Breast Imaging)

Roger Allen, AM — *Non-Executive Director*

- Joined the Board in 2010, Chairman from Oct 2015-Feb 2019, based in Australia
- Successful tech entrepreneur, and established VC
- Served on 2 Australian PMs' Science & Tech Councils Advisories

volpara
health technologies

Strong & Experienced Executive Team

Mark Koeniguer — *Chief Commercial Officer*

- Joined 1st January 2016, based in Nashville
- Highly experienced in medical imaging software sales
- 25 years of leading sales teams
- Worked across radiology

Craig Hadfield — *Chief Financial Officer*

- Appointed full-time CFO, 1st March 2017
- Over 8 years' experience in senior and managerial auditing roles around the world, ex Deloitte and EY

Simon Francis — *Chief Operating Officer*

- Joined 1st August 2019, based in Wellington
- Director in Technology Consulting at PwC for 8 years
- Highly experienced with regulatory & compliance
- Run large international delivery teams
- Extensive background in process and optimization

Dr Monica Saini — *Chief Medical Officer*

- Joined 1st November 2017
- Former Chief of Breast Imaging, Santa Fe, USA
- Former Chief of Breast Imaging, Christus St. Vincent, USA
- Former Medical Director of Breast Ultrasound, GE Medical
- Breast Radiologist, New Zealand Breast Screening

Mark Morris — *Executive VP, Customer Success*

- Joined June 2019, based in Seattle
- Former CEO of MRS Systems, Inc, 2007-2019

Kathryn Greene — *Chief People Officer*

- Joined 1st August 2019
- BCom, Management & Employment Relations
- Previously at Orion Healthcare with global responsibility

volpara health technologies

Volpara's Unique Technology

Volpara is unique in measuring and reporting on the four key metrics at the point of screening: volumetric breast density, positioning, radiation dose & breast compression

Camera unit

X-ray beam

Breast compression:
Too hard, exam is painful but usually good images & low dose. Too soft, tissue is not spread enough, high dose, but no pain.

Radiation dose:
Needs be high enough for a good quality image, but low enough so as to not induce a cancer.

Breast density:
The more white tissue, the "denser" the breast which is a risk factor for developing and hiding cancer. Assessment by eye is subjective.

Breast positioning:
All the tissue needs to be imaged, otherwise a cancer might be missed.

Overview of VolparaDensity
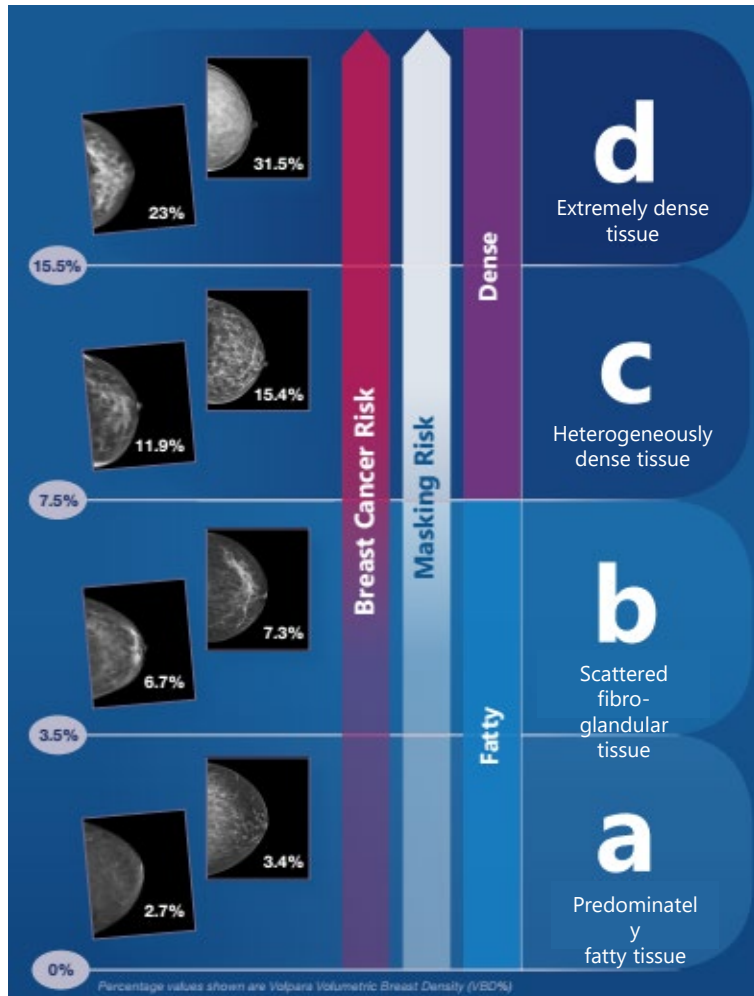
FDA 510(k) cleared

VolparaDensity

- Automated, <u>objective</u>, density scoring for each patient
- VolparaDensity is the only commercial density tool included in leading risk model Tyrer-Cuzick
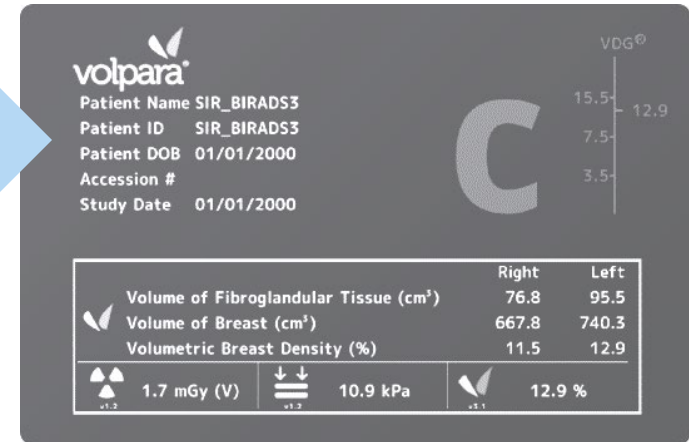
>300 publications

Annals of Internal Medicine   ORIGINAL RESEARCH

Automated and Clinical Breast Imaging Reporting and Data System Density Measures Predict Risk of Screen-Detected and Interval Cancers

Karla Kerlikowske, MD; Christopher G. Scott, MS; Amir P. Mahmoudzadeh, MScEng; Lin Ma, MS; Stacey Winham, PhD; Matthew R. Jensen, BS; Fang Fang Wu, BS; Serghei Malkov, PhD; V. Shane Pankratz, PhD; Steven R. Cummings, MD; John A. Shepherd, PhD; Kathleen R. Brandt, MD; Diana L. Miglioretti, PhD; and Celine M. Vachon, PhD

- **Most US women are routinely told their breast density**
- FDA is planning to ensure all are told

Nancy Cappello drove the idea of density notification. Sadly, she succumbed to complications of breast cancer, 15th Nov 2018.

'Fatty' breast   'Dense' breast
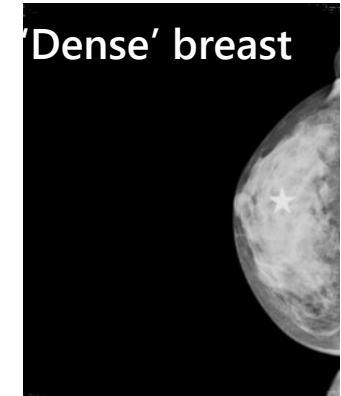
The white star mimics a cancer – easy to see in a fatty breast, much harder on a dense breast.

volpara health technologies

Overview of VolparaLive!
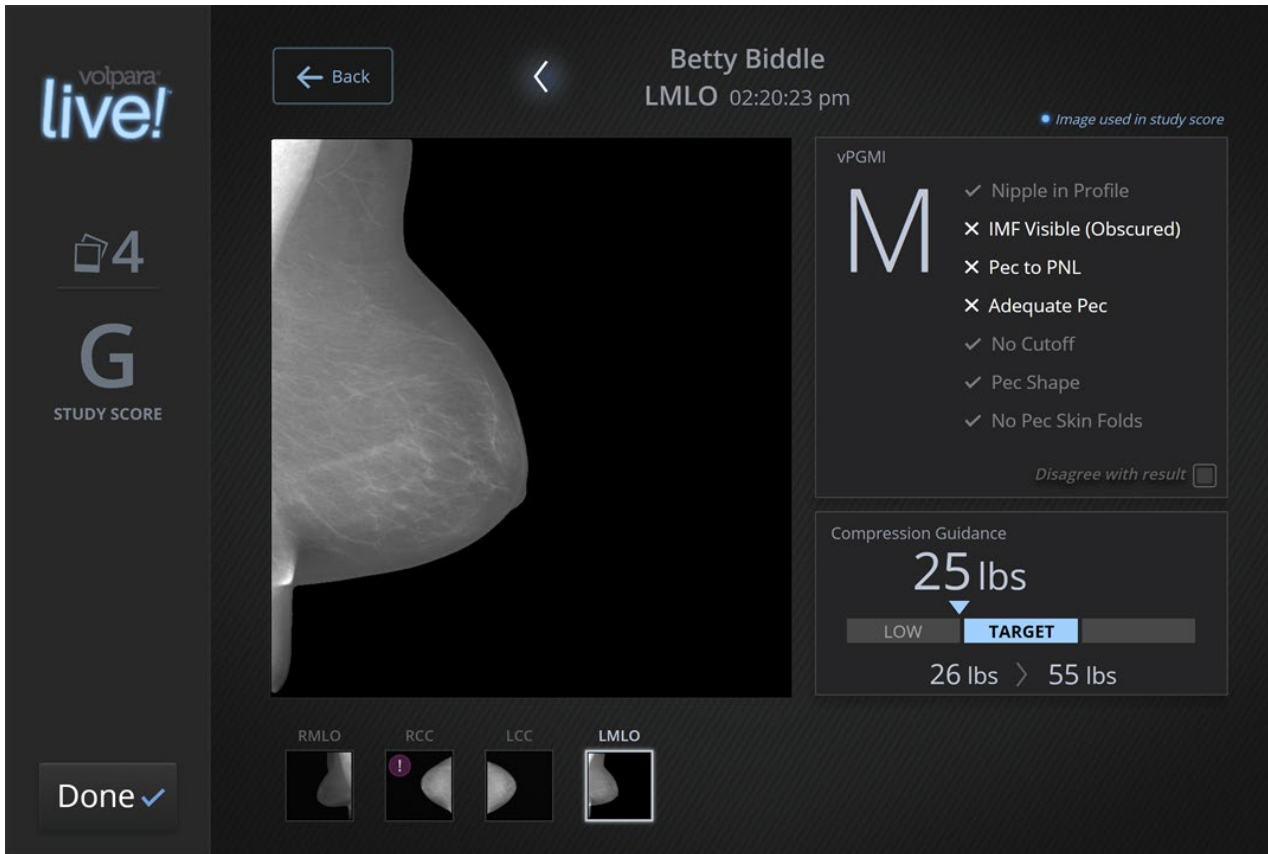
- **VolparaLive! makes patients happier and clinics more profitable**
  - By ensuring that high quality images are taken the first time, fewer women are recalled for a repeat image
  - When patients are recalled for repeat images, the clinic is not reimbursed

Overview of VolparaEnterprise

Volpara Cloud on Microsoft Azure
Powered by Volpara Artificial Intelligence

Volpara proprietary software aggregates data

Secure access to Volpara AI Analytics in the Cloud via browser

Each uses Volpara dashboards to better manage staff, equipment utilisation, compliance and drive profitability

Lead Technologist accessing VolparaEnterprise

Breast Imaging Manager accessing VolparaEnterprise
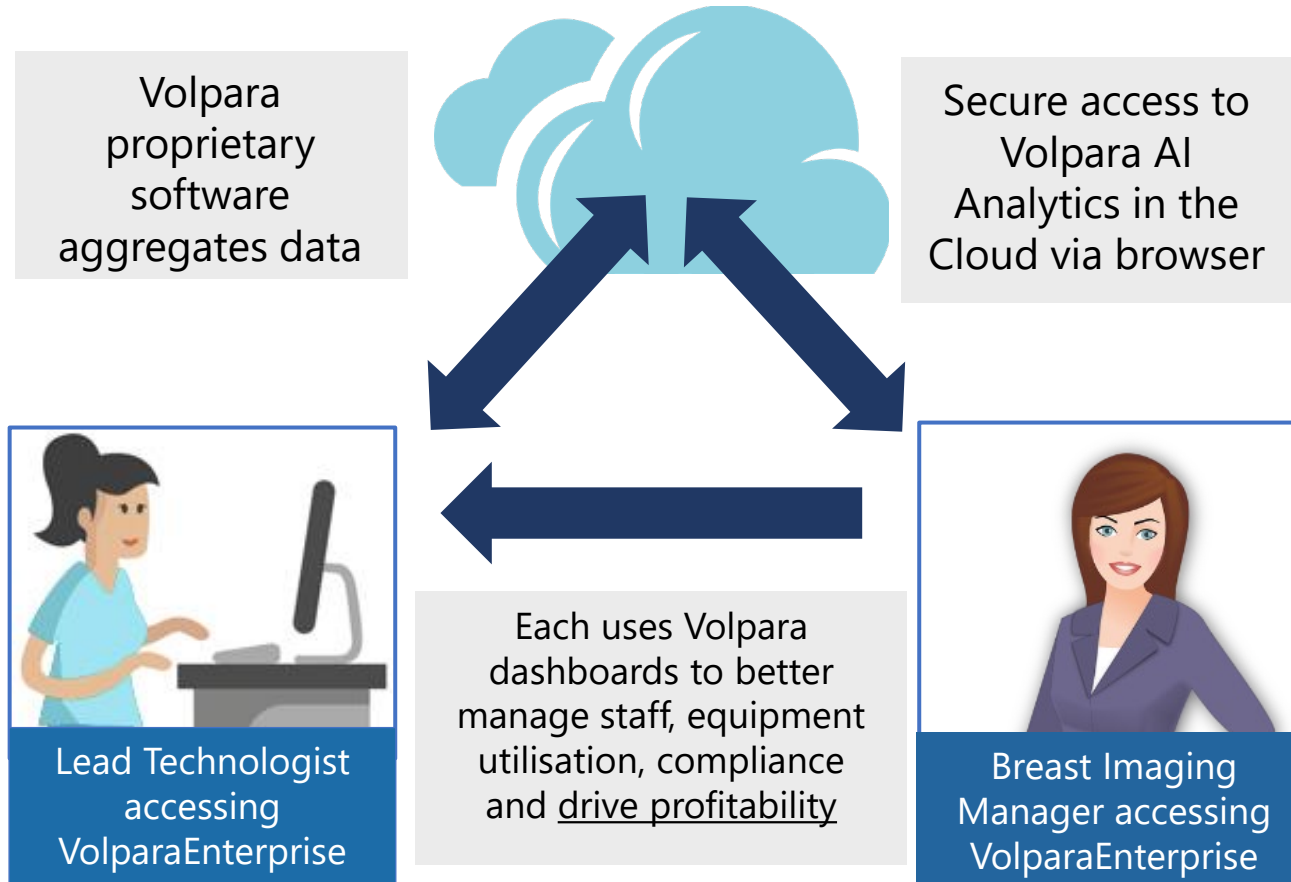
VolparaEnterprise Dashboard
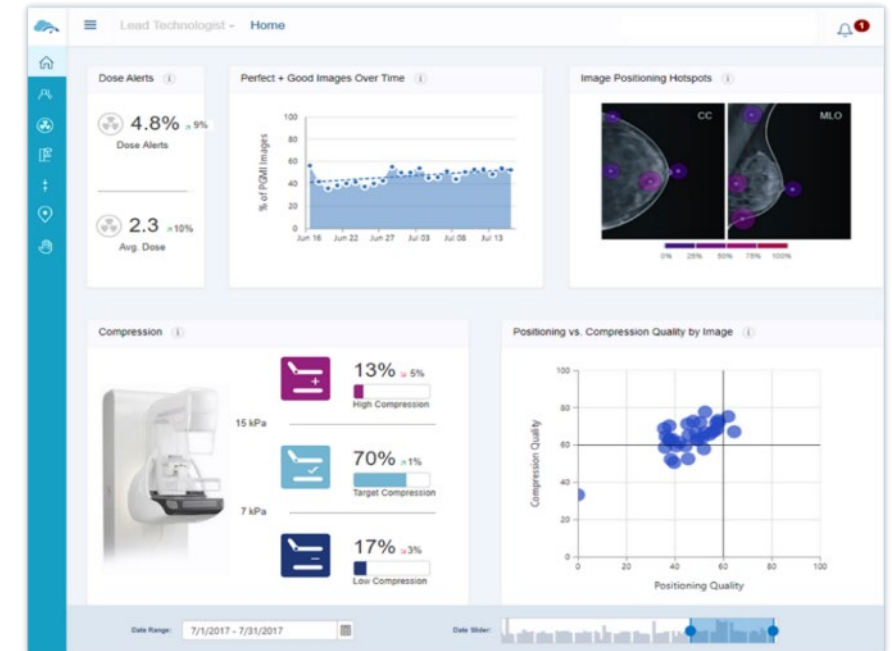
Overview of Aspen Breast – Patient Management Software

- Tracking and reporting breast procedures

- Enables structured reporting, and easy compliance with regulations.

- Fully integrated into clinical IT networks.

Volpara acquired this from MRS Systems Inc, June 2019

volpara
health technologies

Overview of Aspen Lung – Patient Management Software

- Tracking and reporting lung procedures

- Enables structured reporting, and easy compliance with regulations.

- Fully integrated into clinical IT networks.

- Lung cancer kills 2M a year, 144K in the US. Screening significant reduces mortality.

Volpara acquired this from MRS Systems Inc, June 2019

volpara health technologies

Proven to Improve Patient Care & Profitability

Clinical Decision Support

Using **VolparaDensity** to help judge who should have additional imaging:

- ProMedica reported 7.7 more cancers per 1,000 women using molecular breast imaging[1]

- EWBC reported 3.3 more cancers per 1,000 women using ultrasound[2]

1 – Shermis et al, AJR, 2017
2 – Destounis et al, J Ultrasound in Medicine, 2017

Practice Management

"I can't see how a large and busy practice in breast imaging can meaningfully meet quality assurance without VolparaEnterprise" [ProMedica, Ohio]

"[VolparaEnterprise is…] A tremendous tool in both our quality improvement and operational efficiency efforts." [Swedish, Seattle]

volpara
health technologies

Major Tailwinds in the US – Regulatory, Legal & Society Guidelines

The Washington Post
Democracy Dies in Darkness

Health

FDA wants women to get breast-density information along with their mammograms

Agency proposal would update mammography regulations for the first time in two decades.

- Breast density advocates have forced 38 US states to legislate that radiologists notify women screened about breast density (when mammography is less effective)

- FDA has announced (March 2019) new draft regulations:
  - All women must be informed of their breast density
  - This is additional to their push for higher quality, EQUIP

THE AMERICAN SOCIETY OF Breast Surgeons - Official Statement -

Position Statement on Screening Mammography

ASBrS Breast Cancer Screening Guidelines Recommendations

May 3, 2019 ASBrS recommends risk-based screening, where risk is assessed using a model such as Tyrer-Cuzick including breast density

VolparaDensity is the only commercial density product approved for use in Tyrer-Cuzick.

MRS has a full risk product already built.

volpara health technologies

Significant Barriers to Entry

Unlike some SaaS businesses there are significant barriers to entry for anyone trying to replicate our software:

- Years of lead time developing the software (we have invested 10+ years)

- Embedded and sticky nature of the software

- FDA clearance under 510(k) as a medical device, and global regulatory clearances

- Hundreds of clinical publications including global, multi-year clinical trials

- Only commercial density tool in the leading risk model, Tyrer-Cuzick

- 101 granted national patents, 9 international applications, 4 in progress

- Registered trademarks in 39 countries

- Copyright works (software, graphics and text)

- Trade Secrets (which protect the key part of the code)

- High level of data security – ISO27001 certified

In addition our first mover advantage and installations at Marquee Customers in the US leaves us better positioned to win new business than a new entrant

volpara health technologies

Landmark for Women – Tyrer-Cuzick Version 8 Risk Model

VolparaDensity is the only commercial density measure in Tyrer-Cuzick, one of the most used breast cancer risk models globally

Subscription-Based Business Model

The customer pays Volpara for a service provided by the software, rather than buys a perpetual license with a once off, up-front fee (a capital sales model).

Although the customer might pay for the service a year in advance, under accounting standards the majority of revenue can only be recognised once the service has been provided (i.e. over time).

The model is attractive to companies & investors as it is a recurring revenue model (less lumpy), but there are different metrics people use to judge progress, the definitions VHT currently focuses on are:

- **Total Contract Value (TCV)** - this is the value of contracts signed in the current financial year, the revenue from these deals might be recognised over one or many years and the customer might, or might not have a cancellation clause of some kind

- **Annual Recurring Revenue (ARR)** - this is the normalized amount of cash reasonably expected to be booked for the next 12 months on the basis of the contracts signed previously, and assuming installation upon order

- **Churn** - is the percentage of revenue from customers that either discontinue or reduce their subscription in a given 12-month period

- **Average Revenue Per User (ARPU)** – this is the expected revenue each year from each woman screened using Volpara software