

#### **ASX RELEASE**

#### **Volpara March Newsletter**

**Wellington, NZ, 16 March 2020:** Volpara Health Technologies ("Volpara; ASX: VHT), a SaaS medical technology company whose artificial intelligence (AI) imaging algorithms assist the early detection of breast cancer, is pleased to provide investors with its March Investor Newsletter.

This eNewsletter edition outlines Volpara's recent activities and upcoming events, including:

- Message from Volpara CEO Dr Ralph Highnam
- FDA clearance for ScreenPoint's Transpara software
- Information on lung cancer screening
- Data privacy expert Karin Lindgren joins Volpara's Board
- Q&A with Karin Lindgren and Prof. Sir Mike Brady

The Investor Newsletter can be viewed at the end of this cover note and is also available on Volpara's website.

#### **ENDS**

#### **Authorisation and Additional Information**

This announcement was authorised by Volpara CEO Dr Ralph Highnam and Volpara Company Secretary Craig Hadfield.

#### 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 3 9866 1215

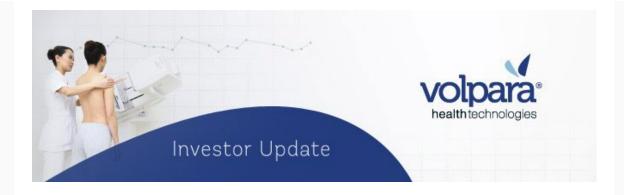
#### About Volpara Health Technologies Limited (ASX: VHT)

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\$95 million, including A\$55 million in June 2019. VHT is based in Wellington, New Zealand.

At the end of June 2019, VHT acquired MRS, 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 <u>www.volparasolutions.com</u>



### **Message from the CEO**

Dear Investor,

It's been a turbulent few weeks on stock markets around the world, but I'm pleased to inform you that Volpara is having a good Q4. Subject to the closure of one or two major deals, we are currently on track to meet the upgraded annual recurring revenue (ARR) guidance that we announced at the end of Q3, namely NZ\$17.8 million.



Fourth-quarter sales to date have featured some excellent combination sales of products—a mix of traditional Volpara products and the products that we acquired last year from MRS, including the Aspen breast information system. These sales are validating the rationale for the acquisition of MRS. As more of the bigger deals close, we will continue to see our ARPU (average revenue per user or price per patient) rise.

Increasing ARPU and sales productivity was also the rationale behind licensing the Transpara computer-aided detection product from ScreenPoint Medical last year. We're delighted to inform you that as of 9 March 2020, the Transpara software is now cleared by the US Food and Drug Administration for the processing of 3D breast images—the predominant imaging modality used in the United States.

Over the last nine months, Volpara has been building a solid pipeline of leads and interest in Transpara. Trials for the 2D version are in process outside the United States, but most US leads have been waiting for the 3D clearance from the FDA. Our sales team is excited to now have the opportunity to close sales of the 3D software. We have already closed our first deal, a trial of Transpara, following the FDA approval.

Further news of interest about our total available market recently came in the form of

market research by Signify Research in the UK. Signify Research has concluded that the number of women screened for breast cancer each year has risen from 75 million to 92 million. Much of that growth is in Asia where, sadly, the incidence of breast cancer continues to rise.

Much of the world's current focus is on containing COVID-19. Volpara believes that many more lung CTs (computed tomography) will be used to screen patients to understand the extent of COVID-19. Through our acquisition of MRS, Volpara has entered the lung cancer screening business, and we currently have about eight percent of the US market. Most lung cancers are found incidentally when people are screened for other diseases or conditions, such as pneumonia and now COVID-19. Consequently, we are prioritising product development to get our lung product, Aspen Lung, to utilise the Fleischner Society recommendations for dealing with incidentally detected lung nodules. That software should be ready by the middle of the 2020 calendar year.

Whilst on the subject of lung screening, we're also pleased to announce that we're assisting Sydney start-up DetectEDx to push out its free on-line teaching tool for radiologists on how to spot COVID-19. Please watch our social media feeds for the full details.

In relation to COVID-19, I can tell you that the Board is closely monitoring the situation. Fortunately, we have a strong bank balance, and because we are an IT company based partly in New Zealand, partly in the United States, we have a strong culture of working remotely and working at home. In addition, many sales leads can be followed up remotely with online demonstrations, we do almost all contract negotiations remotely, and installation and most of our training take place remotely. Nonetheless, things are changing frequently and we're carefully plotting out different paths forward depending on how things eventuate over the next few months. We'll be updating you in detail at the end of Q4 on this.

Below you'll find more detail on some of the stories above. We also have some farewell words from Professor Sir Mike Brady as he leaves the Volpara Board, and some introductory words from Karin Lindgren, a data privacy expert, as she joins the Board.

In other developments, Volpara has been included in the S&P/ASX All Technology Index, which launched in February. The new tech index captures ASX-listed companies in the fast-growing tech sector and is expected to help boost the interest of institutional and retail investors in this area.

We at Volpara continue to believe in our mission to save families from cancer.

We also believe that the Company is in good shape financially and operationally. We are well placed to continue to grow our market in both breast screening and lung screening and deliver value for shareholders.

Very best regards,

# ScreenPoint receives FDA clearance for Transpara

ScreenPoint Medical announced on 9
March 2020 that it has received clearance
from the US Food and Drug
Administration for its Transpara 1.6.0
software for 3D breast images.

The Transpara software significantly reduces 3D reading time to about 35 seconds per exam, which is very close to the typical reading time for 2D mammograms.



"This clearance is significant for Volpara as the Transpara product plays a role in the intelligent breast cancer screening platform that we've been promoting to great success across the US since RSNA (Radiological Society of North America) 2019," said Volpara's Chief Commercial Officer, Mark Koeniguer.

Volpara CEO Ralph Highnam said Volpara is having a good Q4, and he is pleased that ScreenPoint Medical has followed on the clinical performance of Transpara 2D with the FDA clearance of the 3D software.

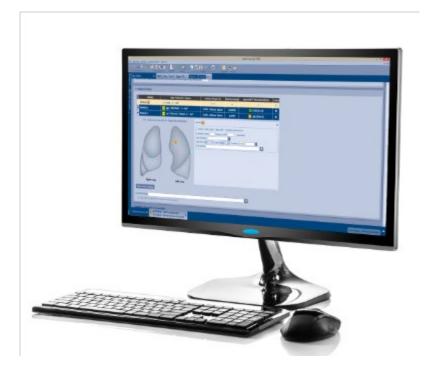
"I congratulate Professor Nico Karssemeijer and the whole ScreenPoint team on this accomplishment," said Dr Highnam. "ScreenPoint has already delivered, with multiple independent, peer-reviewed publications demonstrating that Transpara significantly improves accuracy in 2D mammography. Now the same applies for 3D."

Unlike earlier computer-aided detection systems that acted as a second reader, Transpara results are viewed while the radiologist is reading the study.

Volpara's Chief Medical Officer, Dr Monica Saini, said she knows firsthand the pressure faced by clinicians to read results very quickly but not miss anything.

"Tomosynthesis certainly made interpretation slower, so it's great to now have a tool like Transpara to improve accuracy and speed," said. Dr Saini. "Radiologists like myself are seeking tools like Transpara to improve the efficiency of our workflow and augment our busy practices."

### Lung cancer screening: the numbers



The United States is the biggest market for lung cancer screening. About one in every 14 people will develop lung cancer, and nearly 25 percent of all cancer deaths is a result of lung cancer.

About 8,000,000 people in the United States are estimated to be eligible for lung cancer screening based upon their history—Did you smoke for many years? Did you used to work down the mines? Did you have prolonged exposure to asbestos?

Of those people eligible for screening, only 14 percent actually get screened today using low-dose lung CT. That is despite recent results showing a near 40 percent drop in mortality from lung cancer if a patient is at high risk and does get screened.

In the United States, lung cancer screening takes place at about 2,000 sites. Volpara, via its acquisition of MRS, covers 8.2 percent of the market.

The next release of Aspen Lung will include the recommendations from various clinical groups relating on how to deal with lung nodules found by imaging the lung for other reasons, such as looking for COVID-19. Given the current outbreak, this work has been prioritized for release in mid-2020.

US-based healthcare technology lawyer and senior IT executive Karin Lindgren joined the Volpara Board at the end of January as an independent director. Karin brings to the Board an in-depth knowledge of data privacy and US healthcare and has extensive personal networks across the IT landscape.

Volpara receives a huge amount of data collected from patients who are screened for breast cancer. Volpara Chair Paul Reid says Karin has wide knowledge of healthcare IT, especially around patient data, where rules and regulations are still evolving.

Karin is based in Boulder, Colorado in the United States.

Karin replaced Prof. Sir Mike Brady, one of Volpara's founders, who retired after 10 years' service on the Board. Sir Mike will continue to be available to assist Volpara where required.

**READ** the ASX release here

# Karin Lindgren explains what she expects to contribute to Volpara



"Transparency in how businesses such as Volpara request consent, abide by their privacy policies, and manage the data they collect is vital to building trust and accountability with patients, customers, and other stakeholders who expect privacy."

What attracted you to the Volpara Board and what is your view of the company's current trajectory?

"Last year, Volpara acquired MRS Systems, Inc., and since I had served for more than 10 years as an outside lawyer to MRS and advisor to the CEO, I was already familiar with the breast health technology space. Soon after the acquisition, I was introduced to Volpara's executive management team. I was impressed with the depth and strength of the team and their thoughtful strategic vision, roadmap of technology opportunities, and plans to expand past breast health.

"I'm excited about Volpara's current business and technology trajectory, and enthusiastic that I have this opportunity to support that trajectory as a new member of the Board."

# What can you bring to the Volpara Board to assist the development of the company and help add value for shareholders?

"I expect to bring to the Board a wealth of experience gained from having practised law as a healthcare technology lawyer in various roles for the past 35 years. Those roles included law firm partner; general counsel/chief legal officer; independent digital board director; university professor; senior technology executive; and chief compliance, IT audit, privacy, and risk officer at several US health technology and informatics companies. I also bring my work as an early legal counsel on health informatics and data governance, HIPAA (Health Insurance Portability and Accountability Act of 1996) privacy and security, and SaaS to support Volpara's continued growth in those areas.

"Volpara has a thoughtful approach to enterprise business risk. As Chair of Volpara's new Risk Committee, I will work with the team to add value for shareholders by providing enhanced oversight of the special risks and compliance requirements inherent in a medical technology business—in particular, risks regarding data governance, information security, and privacy."

#### How did you develop your expertise in data privacy?

"I have been in the right place at the right time over my 35-year professional career. I began practising law in California in the mid-1980s, when the concept of managed healthcare was in its infancy in the US and health organisations started collecting masses of new data on patients and providers. In the absence of legislative direction at that time, I guided clients on their legal and ethical obligations to protect and secure that data. I also litigated several lawsuits among managed-care organisations regarding the use and sharing of data.

"As managed care expanded and data privacy and security became a high public priority, I wrote and spoke extensively on data-related legal issues, especially data privacy. Working as chief compliance officer and chief privacy officer at several health informatics companies, one of which covered over 90 percent of US academic medical centres, I gained firsthand knowledge of the many challenges arising from data privacy. Some of that experience included successfully managing several government investigations relating to data privacy concerns and successfully defending the effectiveness of compliance programs built to manage risk and protect clinical data warehouses and databases.

"In the early 1990s, I began moonlighting as a professor teaching health and technology law and ethics in schools of business, law, medicine and nursing across the US. At Northwestern University and at the University of Colorado, I built a new curriculum and taught several new courses covering data privacy, data governance and ethics for health informaticists. By 2000, I had also built a solo law practice, LindgrenLaw Group LLC, where I focused on advising founders of young, high-growth health technology companies on how to keep health data private and secure. I also have served on the advisory boards of numerous medical technology startups.

"By 2005–2006, I was general counsel and chief privacy officer for a health informatics technology company in Chicago when then-Senator Barack Obama created a task force to look into improving the HIPAA data privacy and security regulations. I consulted on that task force, and that group's body of work ultimately became part of the Health Information Technology for Economic & Clinical Health Act (HITECH Act) of 2009 which removed multiple loopholes in HIPAA, thereby strengthening health data privacy rules.

"Since then, I served as senior vice president and chief privacy officer of a medical clearing house and data platform company which handles the data of over 60 percent of patients in the US. My teams built a robust, EHNAC-accredited, HITRUST-certified data protection program and created a world-class compliance program to oversee and manage multiple regulatory mandates, especially relating to data privacy."

## How important is the issue of data privacy in the United States and Australia and how does that pertain to Volpara?

"Data privacy has become one of the defining social and cultural issues of this era. Transparency in how businesses such as Volpara request consent, abide by their privacy policies, and manage the data that they collect is vital to building trust and accountability with patients, customers, and other stakeholders who expect privacy."

#### Why is helping women deal with breast cancer important to you?

"Like so many people worldwide, my family has been sadly touched by breast cancer, and other kinds of cancer, and I have long been active in cancer support organisations over the years.

"Volpara's cutting-edge work on breast density, and its goal of helping patients identify breast cancer sooner, getting them to treatment faster, are game-changers. This is work I am proud to be supporting both as a woman and as a member of the Volpara Board."

# Prof. Mike Brady reflects on his service to Volpara and women with breast cancer



"Volpara always has been, and will continue to be, focused on the women who are being assessed for possible breast cancer and breast cancer risk. By putting breast imaging on a firm, scientific footing, Volpara makes a major contribution to early detection, which means better prognosis."

One of Volpara's founders, Professor Sir Mike Brady, has retired from the Board after 10 years' service. Volpara chair Paul Reid says that Volpara is sad to see Sir Mike retire and thanks him for his many contributions in helping make Volpara a major player in breast cancer screening. Sir Mike agreed to answer a few questions:

#### Why have you decided to call it a day?

"The main reason is that I had been on the Board for 10 years, which is four more than is the norm for a UK plc. I believe that there should be regular turnover on any Board of any company, listed or privately held.

"Also, having Board meetings start at 2200hrs, or midnight in France where I am over the summer, became increasingly tiring. For this same reason, I have almost never participated in the science meetings, which I have found frustrating since I would love to have done so"

#### How has Volpara changed since you founded the Company?

"Volpara has grown, but not just in size. First, listing on the ASX; second, building the superb US sales force around Mark Koeniguer; and third, acquiring MRS. These advances have transformed Volpara from a science-led startup to a professional, commercial company which nevertheless maintains a strong science base. Volpara's current <a href="Enterprise">Enterprise</a> product was miles from our imagination when we founded the Company, and it is thrilling to see."

#### What is your view of Volpara's current trajectory?

"Volpara is THE company that best assures a quality experience for a mammography imaging centre—for women, for technologists, for reporting physicians, and for the 'C Suite'. The Volpara/MRS combination is a uniquely strong basis from which to dominate the US mammography market. Add to this capabilities such as risk and decision support; triage to further, more detailed examinations such as MRI and ABUS; and monitoring therapies—the future burns very brightly."

# What have been the highlights and/or challenges during your association with Volpara?

"The main challenge to any small, growing company is balancing the need for growth, particularly of revenues, and controlling expenditure and cash. To this end, having supportive and critically constructive shareholders is crucial, and Roger Allen (Non-Executive Director) has been a key ingredient of Volpara's success. The second challenge is to appoint the right team. Ralph (Highnam) and Mark (Koeniguer) have done a brilliant job in this respect."

What difference do you think Volpara has made for women who may have breast

#### cancer and what is there still to do?

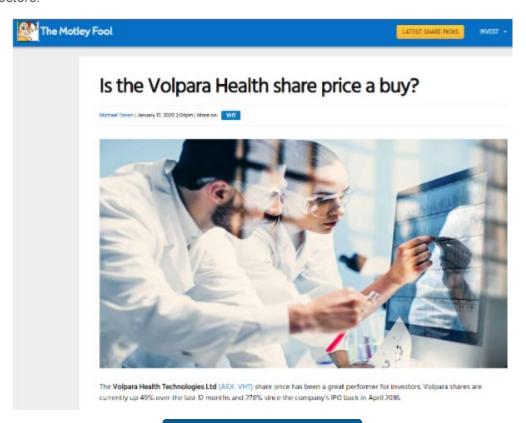
"The variability in the quality of imaging centres, particularly in the USA, and the consequent variability in the experiences of women being imaged in those centres, have always been a major challenge and concern. Volpara's *Enterprise*—based as it is on the solid foundation of estimating breast density, radiation dose, compression, and positioning—is a major step towards improving both.

"Volpara always has been, and will continue to be, focused on the women who are being assessed for possible breast cancer and breast cancer risk. By putting breast imaging on a firm, scientific footing, Volpara makes a major contribution to early detection, which means better prognosis."

### **Media Coverage**

Volpara recently received positive coverage in *The Motley Fool*.

"The Volpara Health Technologies Ltd share price has been a great performer for investors."



**READ** the article here

Volpara also appeared in The Market Herald.

"Medical technology company Volpara (VHT) has experienced another strong quarter of growth."



Volpara's story is one of the many fascinating entrepreneurial journeys that have been shared to an ever-growing audience on *Morgo Podcasts*.

Since the podcasts' launch in July last year, it has had more than 1,500 podcast downloads and 250 people tuning in via the Morgo website.

**LISTEN to Volpara's story at Morgo Podcasts** 

Diagnostic Imaging Europe Feb/March 2020 includes many articles featuring Volpara, including a full report on the Dutch DENSE study (p. 39), risk-based screening (p.46), and an article about breast density from A/Prof. Jennifer Stone from the University of Western



**READ** the articles here

## On the Blog



29 January 2020
Understanding the Use of Competing Mortality in Risk Assessment
By Kristy Manning, PhD, Senior Research Scientist

To understand the risk of developing a disease such as breast cancer, studies test the predictive value of risk factors. However, what if some of the study participants don't live long enough to complete the study? And, what if they would have developed the disease if they hadn't died from something else?

How does this get accounted for so that the risk of developing breast cancer isn't overestimated? To answer these questions, it is important to understand the concept of competing mortality and how it impacts lifetime risk scores in disease risk assessment models.

**READ** the full article here

## **Upcoming events (subject to change)**



Coffee Microcaps Conference 26 March 2020 Online presentation

Coffee Microcaps

MSRT Annual Conference 2–4 April 2020 Leominster, MA

Massachusetts Society of Radiologic Technologists

Breast Screening Forum 2020 3–5 April 2020 Vancouver, Canada

BC Cancer Breast Screening Program

NCoBC 2020 3–8 April 2020 Las Vegas, NV National Consortium of Breast Centers 2020 SBI/ACR Breast Imaging Symposium 16–19 April 2020 Denver, CO

Society of Breast Imaging

American Society of Breast Surgeons Annual Meeting (ASBrS 2020) 29 April–3 May 2020 Las Vegas, NV

The American Society of Breast Surgeons



#### The Volpara team led by CEO Dr Ralph Highnam.

#### **Contact:**

Ralph Highnam, CEO Volpara Health Technologies

ralph.highnam@volparasolutions.com

t: +64 21 149 0541

Kyahn Williamson

WE Communications

kwilliamson@we-worldwide.com

t: +61 3 9866 4722









Copyright © 2020 Volpara Health Technologies, All rights reserved.

Want to change how you receive these emails? You can <u>update your preferences</u> or <u>unsubscribe from this list</u>.

