



TomoSwiss.AI

Confidential Information Memorandum

August 2024

Strictly private and confidential

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Executive Summary (1/2)

Investment opportunity:

Dr Kit Vaughan, the owner of Project **TomoSwiss.AI**, has been mandated by the Industrial Development Corporation of South Africa (IDC) to locate a financing partner to acquire 100% of the intellectual property assets ("IP") of CapeRay Medical (Pty) Ltd ("CapeRay"), a global leader in the development of cutting-edge, breast imaging technology. By so doing, this will allow the financing partner to take an equity position in a new Swiss-based company to be called **TomoSwiss.AI**.

TomoSwiss.AI represents an attractive early investment opportunity for strategic investors, providing an ownership share in next-generation breast imaging technology at a significantly discounted, pre-money valuation of \$3.0M (\$3.54M post 1st round).

Key Facts

CapeRay was established by Dr Kit Vaughan and Professor Tania Douglas in 2010.

Best of industry knowledge – Dr Kit Vaughan is recognized globally as a creative medical engineer and thought leader in his field. He has exceptional capabilities with a healthy combination of management, financial, operational and industry-specific expertise.

Dr Vaughan has created a unique and compelling diagnostic platform that is easy to use and combines the power of ultrasound and artificial intelligence (AI) for the early detection of breast cancer.

The global market for breast imaging *technology* is forecast to reach \$6bn in 2024 and, with CAGR of 8.6%, will double in size over the next 7 to 10 years. The global market for breast imaging *services* is currently worth \$50bn with exponential growth potential. Project **TomoSwiss.AI** will be targeting both these markets.

The AI in Healthcare Market is projected to grow at a CAGR of 48%, from \$15bn in 2023, to \$103bn by 2028.

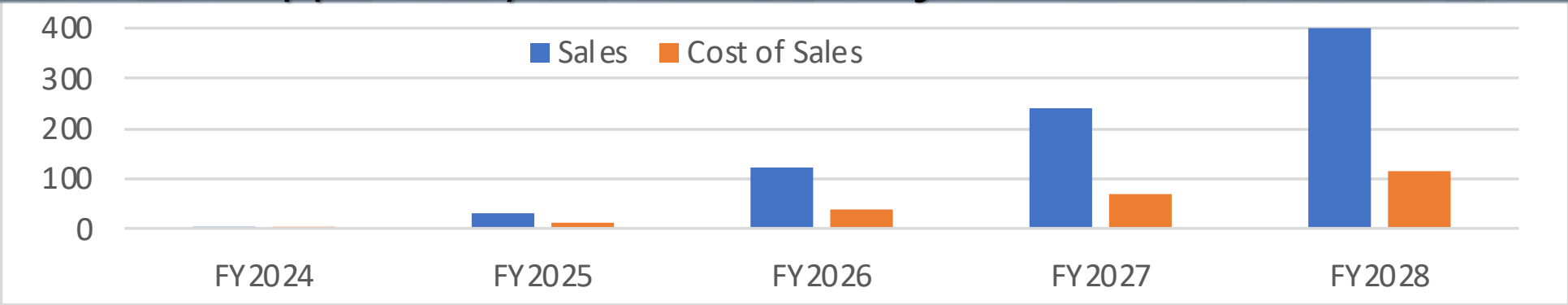
Acquisition Opportunity

The majority owner (80%) of CapeRay Medical (Pty) Ltd ("CapeRay") is the Industrial Development Corporation of South Africa ("IDC") which is willing to sell all CapeRay's IP assets, including its international patents, to an international investor. These IP assets may be acquired for less than 10% of the pre-money enterprise valuation of **TomoSwiss.AI**.

We are seeking an initial investment of \$600,000 (less 10% expenses) that will be used: (1) to acquire the tangible and intangible IP assets for an agreed price of ZAR 5.4m (~ \$300,000), plus a commitment to make future royalty payments based on a portion of revenue generated by products developed exclusively with the IP assets; and (2) to transfer the balance of \$240,000 to **TomoSwiss.AI** as working capital.

The first product from **TomoSwiss.AI** has a rapid path to market and will generate significant revenue within the first few years (as seen in the chart below) and as detailed in slides 10 and 11.

Growth Opportunity at a Glance - Projected Sales (USD millions)



Executive Summary (2/2)

Growing Market

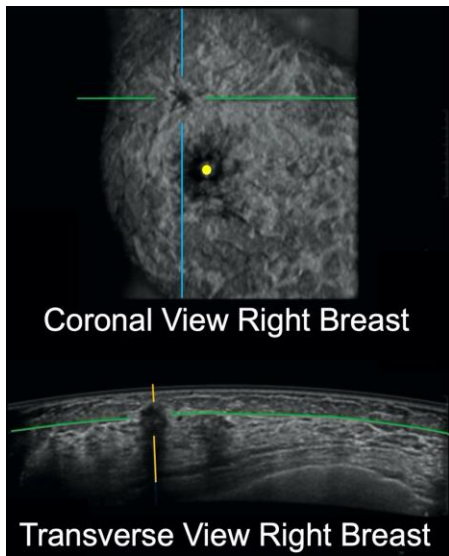
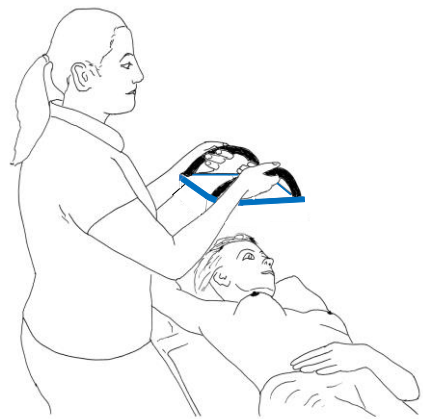
- There are two separate but linked markets that **TomoSwiss.AI** will target: global breast imaging *technology* (<http://bit.ly/4ow5V3b>) and global breast imaging *services* (<http://bit.ly/3JlEfa5>). Between 2024 and 2030, technology will grow from \$6bn to \$9bn, while services will grow from approximately \$50bn to \$62bn.
- With massive growth potential in the affordable hand-held devices segment of the imaging market, **TomoSwiss.AI** will exploit this gap by bringing portable ultrasound devices to market in both developing and developed countries, using its proprietary breast imaging platform combined with artificial intelligence (AI).

Background

- Under Dr Kit Vaughan's leadership, CapeRay successfully developed, manufactured, clinically tested, published internationally, and secured the CE Mark for a novel patented system that combined full-field digital mammography and automated breast platform (ABUS) in a single device as described in slide 6.
- The company has built on its ABUS technology to develop a prototype portable system that combines ultrasound imaging and artificial intelligence (AI). The AI applications, which include both image enhancement and the diagnosis of lesions, have been developed in conjunction with FirstStep.ai (<https://firststep.ai/>).

Product Pipeline

- The IASO system is illustrated at right.
- As seen, the proprietary system is based on a flat-panel ultrasound device that captures 3D images as input for a diagnostic AI algorithm.
- The IASO transducer has been based on next generation capacitive micro-machined ultrasonic transducer (CMUT) technology that will facilitate volume manufacture at reduced cost (<https://bit.ly/3RzgrDr>).



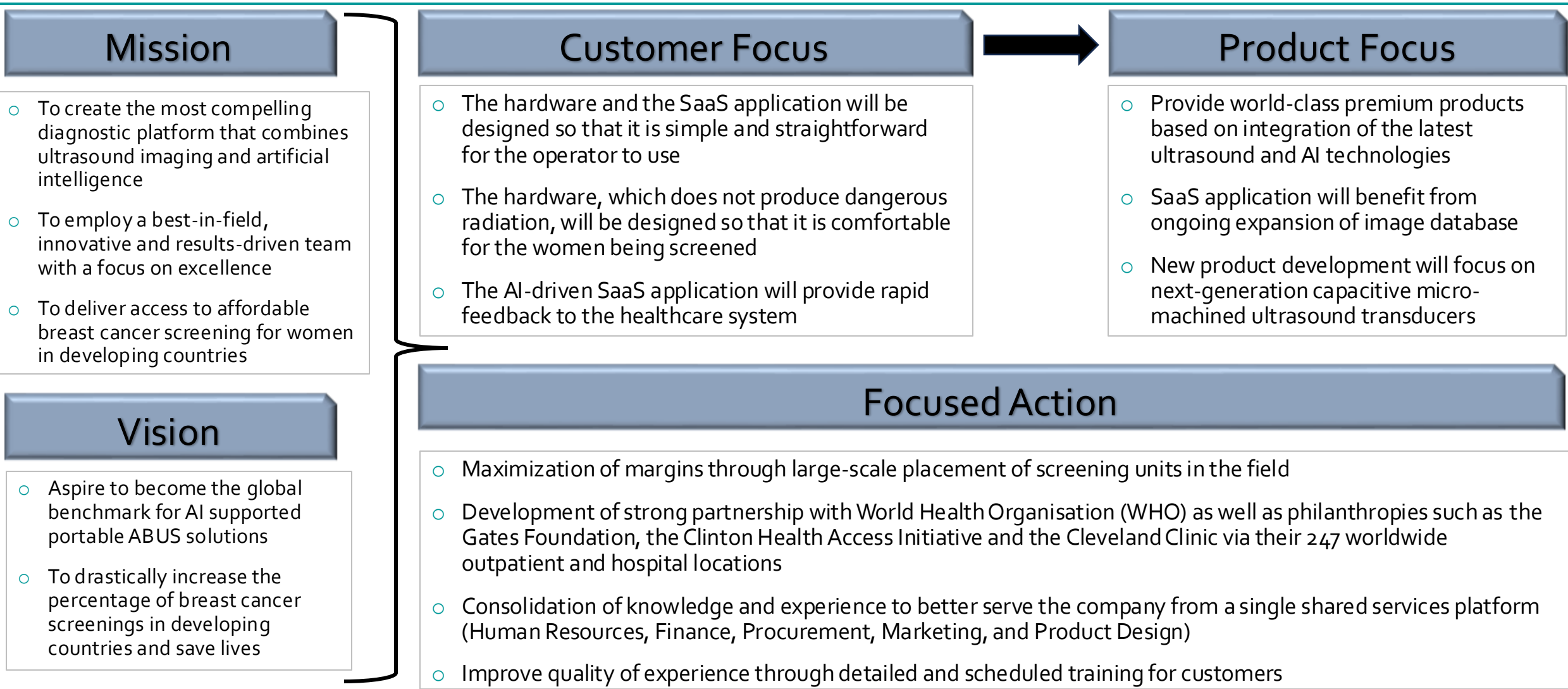
Customer Profile

- The customers in developed countries will be general practitioners and small clinics.
- The customers in developing countries will be government healthcare systems working with the WHO and other global philanthropic organizations (see below).

Growth Opportunities

- The WHO, in their Global Breast Cancer Initiative that was launched in 2023, identified timely diagnosis and comprehensive treatment as key pillars to breast cancer survival (<http://bit.ly/3lupJEo>). This initiative will open up significant growth opportunities in developing countries that lack breast screening services.
- Global philanthropies such as the Gates Foundation (<https://bit.ly/4erLNGt>), Pivotal Ventures (<https://bit.ly/4exS3MO>), and the Clinton Health Access Initiative which has a special focus on women's health (<http://bit.ly/3lexRJ3>) offer further growth opportunities in developing markets.

Mission, Vision and Strategy for TomoSwiss.AI Strong, Sustainable & Profitable Growth

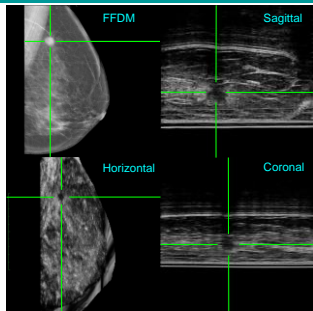


CapeRay History: Products, Publications, Patents and Certification



Products

- There were three separate products developed over the past 14 years, the most successful of which was the **ACESO** system, the first product in the world to combine full-field digital mammography and automated breast ultrasound in one device. See the publications, patents and certification listed below.



Publications

- Vaughan CL, Douglas TS, Said-Hartley Q, Baasch RV, Boonzaier JA, Goemans BC, Harverson J, Mingay MW, Omar S, Smith RV, Venter NC, Wilson HS, "Testing a dual-modality system that combines full-field digital mammography and automated breast ultrasound", *Clinical Imaging*, 40(3): 498-505, 2016.
- Padia K, Douglas TS, Cairncross LL, Baasch RV, Vaughan CL, "Detecting breast cancer with a dual-modality device", *Diagnostics*, 7(1): 17, 2017.
- Vaughan CL, "Detecting early breast cancer by integrating full-field digital mammography and automated breast ultrasound", *Diagnostic Imaging Europe*, 33(5): 62-64, 2017.
- Vaughan CL, "Novel imaging approaches to screen for breast cancer: recent advances and future prospects", *Medical Engineering & Physics*, 72: 27-37, 2019.

Patents

- Evans MD, Smith RV, Vaughan CL "Dual-modality mammography", *United States Patent and Trademark Office*, Patent Number 9,636,073, 2 May 2017.
- Smith RV, "Method of assembling a housing for a scanning assembly", *United States Patent and Trademark Office*, Patent Number 10,220,574, 5 Mar 2019.
- Vaughan CL, Baasch RV, "Multi-modal imaging system and method", *United Kingdom Patent Office*, Patent Number GB 2,566,942, Issued 3 June 2020.
- Long J, Smith RV, Vaughan CL, Baasch RV "Imaging system housing", *United States Patent and Trademark Office*, Patent Number 11,304,672, Issued 19 April 2022.
- Vaughan CL, "Portable medical imaging device", *United States Patent and Trademark Office*, Patent Application 2024/0197289, Published 20 June 2024.

Certification

- On 8 November 2017, CapeRay was awarded the CE Mark by Underwriters Laboratory (UL) for the **ACESO** system, a "Combined X-ray and ultrasound medical device for breast imaging."
- Between 2015 and 2019, Dr Kit Vaughan had three in-person and online pre-submission meetings with the FDA.

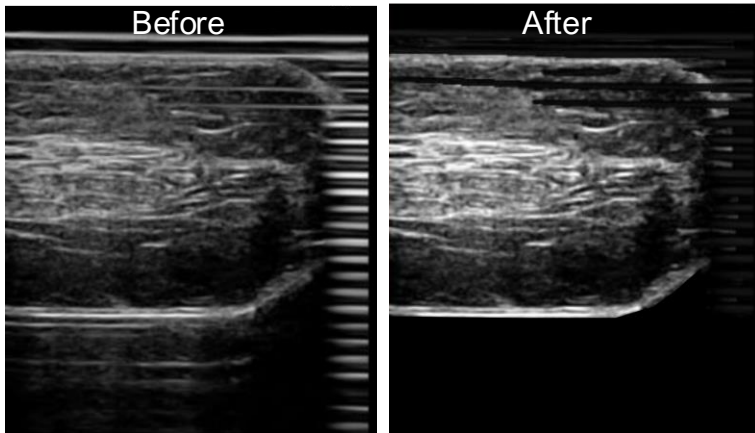


Artificial Intelligence (AI) Integrated within the IASO Portable ABUS Device

Project with FirstStep.ai

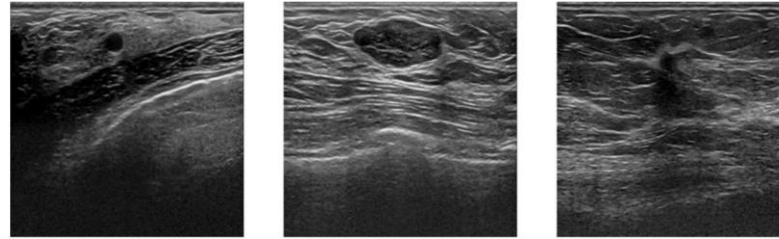
For the past 24 months, Dr Kit Vaughan has been collaborating with Dr Leen Remmelzwaal of FirstStep.ai (<https://bit.ly/3mtZAFU>) who has developed proprietary AI technology based on convolutional neural networks (CNN). The company's Designer tool incorporates image modification, object detection, object segmentation, pose estimation, 3D reconstruction and time series forecasting (<https://bit.ly/482VUht>).

Their first successful project was to remove artefacts that sometimes appear in ABUS images. Seen below left is a sagittal plane image of the breast before the AI algorithm has been applied, while on the right is the image after it has been filtered to remove artefacts.



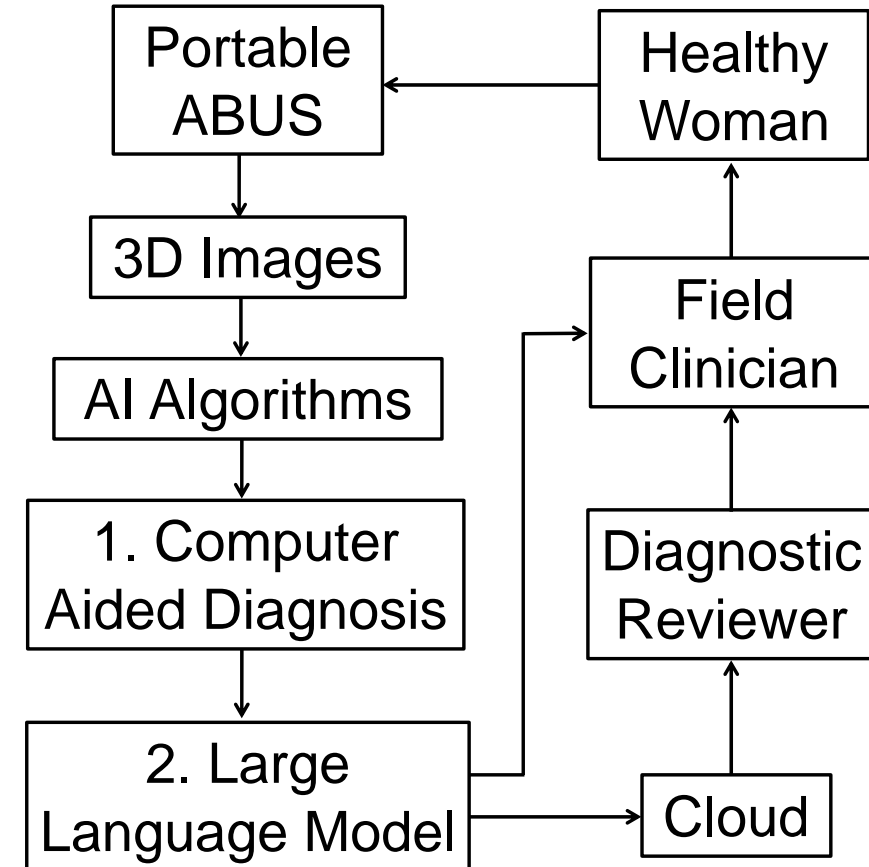
AI Detects Breast Cancer

An AI algorithm based on CNN has been used to distinguish benign (below left and centre) from malignant (below right) lesions in ABUS images (<http://bit.ly/3ZnB6Nm>). An AI algorithm based on CNN has also been used to classify breast tumours seen in ABUS images and demonstrated 94% accuracy (<https://bit.ly/3dcjb5Q>).



The flow diagram at right demonstrates how the IASO system will be applied in the field. A field clinician will engage with a healthy woman volunteer using the portable ABUS device which generates 3D images of each breast. There are two places in the data flow where AI plays an important role after acquisition of the 3D images and artefacts have been removed: (1) an algorithm based on FirstStep.ai's CNN technology is applied to detect breast lesions; and (2) a large language model (LLM) interacts with both the diagnostic reviewer (i.e. radiologist) and the field clinician. If a malignant lesion is detected, the woman will be referred for further testing and treatment.

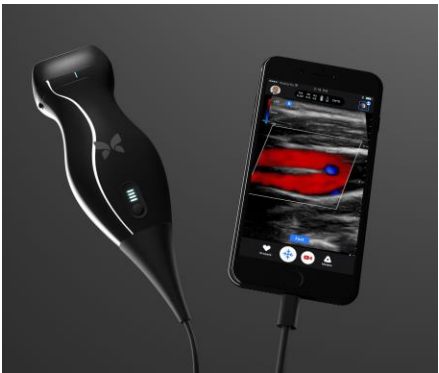
Field Application of IASO



Comparison of IASO with Existing Products

Hand-Held Ultrasound (HHUS)

Parameter	HHUS	IASO
Cost	\$5,000	\$15,000
Probe area	50mm slice	256mm x 192mm
Time to scan	30 minutes	< 10 minutes
Dimensions	2D	3D
Operator	Skilled	Unskilled



Butterfly Network

<https://bit.ly/31ml2kU>



Healcerion

<https://bit.ly/3dcM9T8>



Chison

<https://bit.ly/3oIPMw8>

Automated Breast Ultrasound (ABUS)

Parameter	ABUS	IASO
Cost	\$150,000	\$15,000
Probe area	250mm x 152mm	256mm x 192mm
Time to scan	20 minutes	< 10 minutes
Dimensions	3D	3D
Operator	Skilled	Unskilled



GE Invenia

<http://bit.ly/2SfxyLb>



Siemens Acuson ABVS

<https://bit.ly/3Dk3AM0>



SIUI IBUS 60

<https://bit.ly/3ryiA6D>

Global Breast Imaging Market Size: Technology and Services (in US\$ billion)

Two Target Markets:

The global breast imaging *technology* market was worth USD 5 billion in 2023 and, at a compound annual growth rate of 8.6%, is projected to reach USD 9 billion by 2030 (<http://bit.ly/4ow5V3b>).

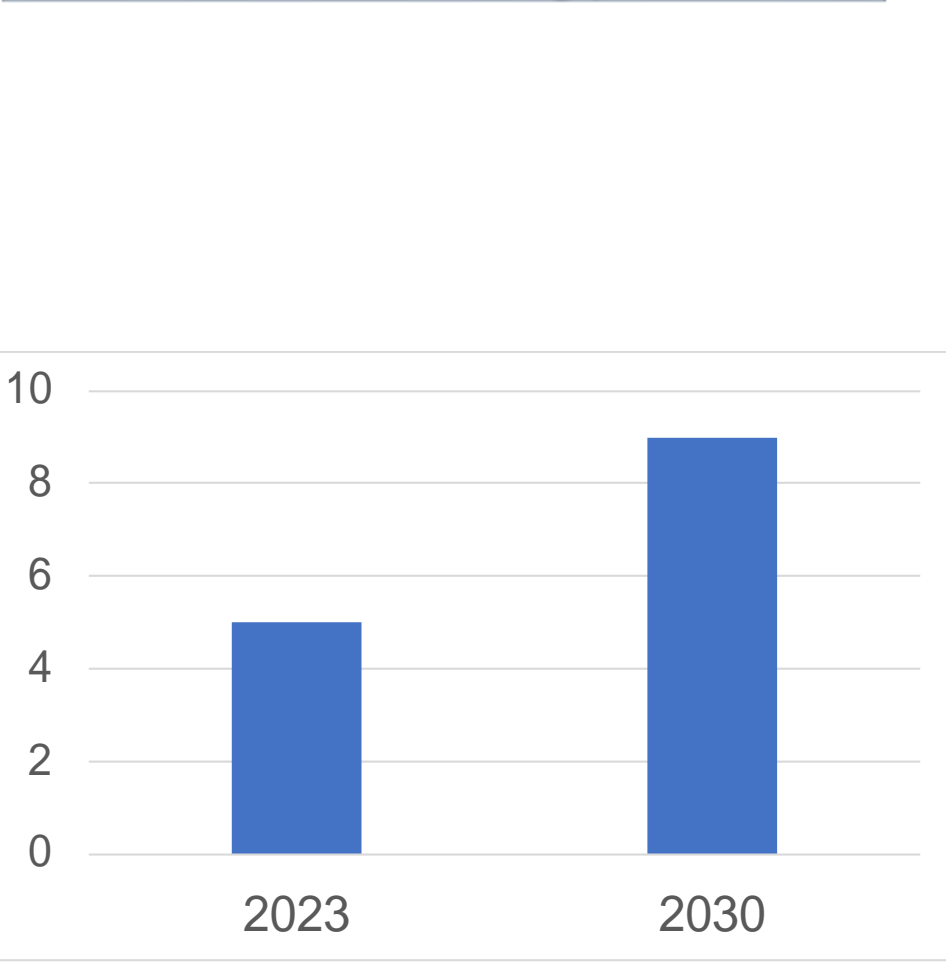
The global breast imaging *services* market, which consists of mammography and ultrasound, was worth USD 50 billion in 2023 and, at a compound annual growth rate of 5.1%, is projected to reach USD 62 billion by 2030 (<http://bit.ly/3J1efa5>).

While the technology and services markets are both significant in size, the services market is clearly an order of magnitude larger than the technology market.

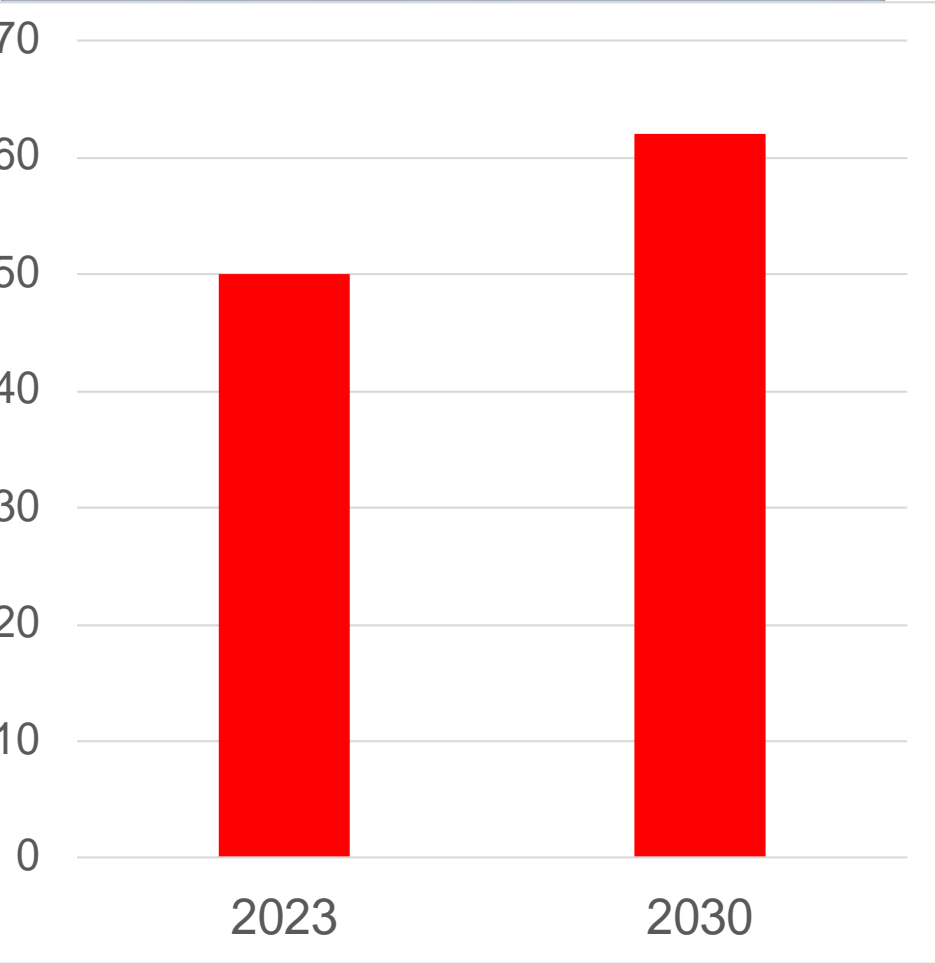
TomoSwiss.AI will target both markets and, with its AI-driven revenue model, will benefit significantly through its SaaS diagnostic service.

In addition, **TomoSwiss.AI** will continuously build its image library, thus increasing the value of its data base exponentially.

Technology



Services



Forecasts and Assumptions

US Dollars (USD)	FY2025	FY2026	FY2027	FY2028	FY2029
Iaso Systems: Units sold annually	0	250	500	1,500	2,000
Price per unit	\$15,000	\$15,450	\$15,914	\$16,391	\$16,883
Iaso SaaS: Number of scans conducted annually	-	500,000	1,500,000	4,500,000	8,500,000
Price per scan	\$20	\$21	\$21	\$22	\$23
Total Revenue	\$0	\$14,162,500	\$39,783,750	\$122,931,788	\$225,101,762
Cost of Sales Iaso Systems: Cost per unit	\$10,000	\$10,300	\$10,609	\$10,927	\$11,255
Iaso SaaS: Cost per scan	\$5	\$5	\$5	\$5	\$6
Total	\$0	\$5,150,000	\$13,261,250	\$40,977,263	\$70,344,301
Operating Costs					
On-Going Payment to IDC, Commission to Distributor	\$0	\$3,540,625	\$9,945,938	\$30,732,947	\$56,275,441
Sales & Marketing	\$0	\$1,133,000	\$3,182,700	\$9,834,543	\$18,008,141
Salaries and Wages	\$350,000	\$437,500	\$546,875	\$683,594	\$854,492
Overheads	\$50,000	\$58,000	\$67,280	\$78,045	\$90,532
Depreciation of Property, Plant & Equipment (PP&E)	\$13,661	\$10,929	\$8,743	\$6,995	\$5,596
Amortization of Capitalized R&D	\$41,866	\$250,171	\$285,861	\$415,526	\$883,015
Maintenance, repair, and after sales service	\$0	\$424,875	\$1,193,513	\$3,687,954	\$6,753,053
Clinical trials	\$50,000	\$500,000	\$1,000,000	\$1,200,000	\$1,200,000
Regulatory approvals	\$50,000	\$200,000	\$300,000	\$300,000	\$350,000
Total Operating Costs	\$555,528	\$6,555,100	\$16,530,909	\$46,939,602	\$84,420,269
Assumptions		Assumptions			
Annual increase in sales price and cost of sales	3%				
On-Going Payment to IDC (5%), Commission to Distributor (20%)	25%	Tax rate			22%
Sales & Marketing as a % of sales	8%	Number of scans per system per annum			2,000
Annual Growth Rate of Number of Staff	25%	R&D as a % of sales			3%
Maintenance and after sales service as a % of sales	3%	Capex as a % of sales			3%
Overheads - Annual Growth Rate	16%	Purchase price of all assets (in USD)			\$295,082

Projected Income Statement

US Dollars (USD)	FY2025	FY2026	FY2027	FY2028	FY2029
Sales	\$0	\$14,162,500	\$39,783,750	\$122,931,788	\$225,101,762
Cost of sales	\$0	\$5,150,000	\$13,261,250	\$40,977,263	\$70,344,301
Gross profit	\$0	\$9,012,500	\$26,522,500	\$81,954,525	\$154,757,461
Operating expenses	\$555,528	\$6,555,100	\$16,530,909	\$46,939,602	\$84,420,269
EBITDA	-\$500,000	\$2,718,500	\$10,286,195	\$35,437,443	\$71,225,803
Depreciation and amortization	\$55,528	\$261,100	\$294,604	\$422,520	\$888,611
Operating profit	-\$555,528	\$2,457,400	\$9,991,591	\$35,014,923	\$70,337,192
Net Finance costs received/ (paid)	\$61,071	\$160,777	\$178,069	\$346,163	\$1,030,999
Profit before tax	-\$494,457	\$2,618,176	\$10,169,659	\$35,361,086	\$71,368,192
Taxation on accounting profit	\$0	\$467,218	\$2,704,543	\$7,779,439	\$15,701,002
Profit after tax	-\$494,457	\$2,150,958	\$7,465,116	\$27,581,647	\$55,667,189
Dividends	\$0	\$0	\$0	\$0	\$0
Retained income for the period	-\$494,457	\$2,150,958	\$7,465,116	\$27,581,647	\$55,667,189
As a % of sales					
Gross profit	0%	64%	67%	67%	69%
EBITDA	0%	19%	26%	29%	32%
Profit after tax	0%	15%	19%	22%	25%

Founders and Joint Venture Partners of **TomoSwiss.AI**

Dr Kit Vaughan



<https://bit.ly/3JJVxz5>

Kit is a Fellow of the International Academy for Medical and Biological Engineering and is the holder of multiple United States patents in the field of biomedical engineering, with a focus on breast imaging. He was the founder and CEO of CapeRay Medical that developed, clinically tested and secured the CE mark for a novel system that combined mammography and ultrasound. Kit will serve as CEO and executive director of **TomoSwiss.AI**.

Robert Kaufmann



<https://bit.ly/3RIID7t>

Prior to his return to Switzerland in 2016, Robert built up and managed a group of companies with over twenty global leading firms from various industries in Dubai, UAE. The company was co-chaired and in partnership with a family office of the Dubai Royal Family. Since then, he founded Ivest Consulting GmbH in Zürich and is focusing on projects in international finance in mainly MedTech, ESG and Renewable Energy industries. Robert will serve as CFO of **TomoSwiss.AI**.

Alois Suppiger



<https://bit.ly/45GSgcZ>

Alois is the owner and CEO of Swissray Technologies AG, based in Hochdorf, Switzerland, a company that offers a range of innovative X-ray systems and services for clinics, medical imaging institutes, and hospitals. His company has committed to serve as a joint venture (JV) partner with **TomoSwiss.AI**. Prior to his current position, Alois spent 22 years as Senior Vice President for global sales and marketing at Swissray Medical AG.

Martin Darms



<https://bit.ly/4bdoZoc>

Martin, who earned an MSc in electrical engineering and information technology at ETH Zürich, has served as the CTO of Swissray Technologies AG for the past 5 years. Prior to this he spent 19 years as Vice President for R&D at Swissray Medical AG, during which period he brought multiple novel products to market. Martin will serve as CTO and executive director of **TomoSwiss.AI**.

Role of Joint Venture Partner Swissray Technologies AG

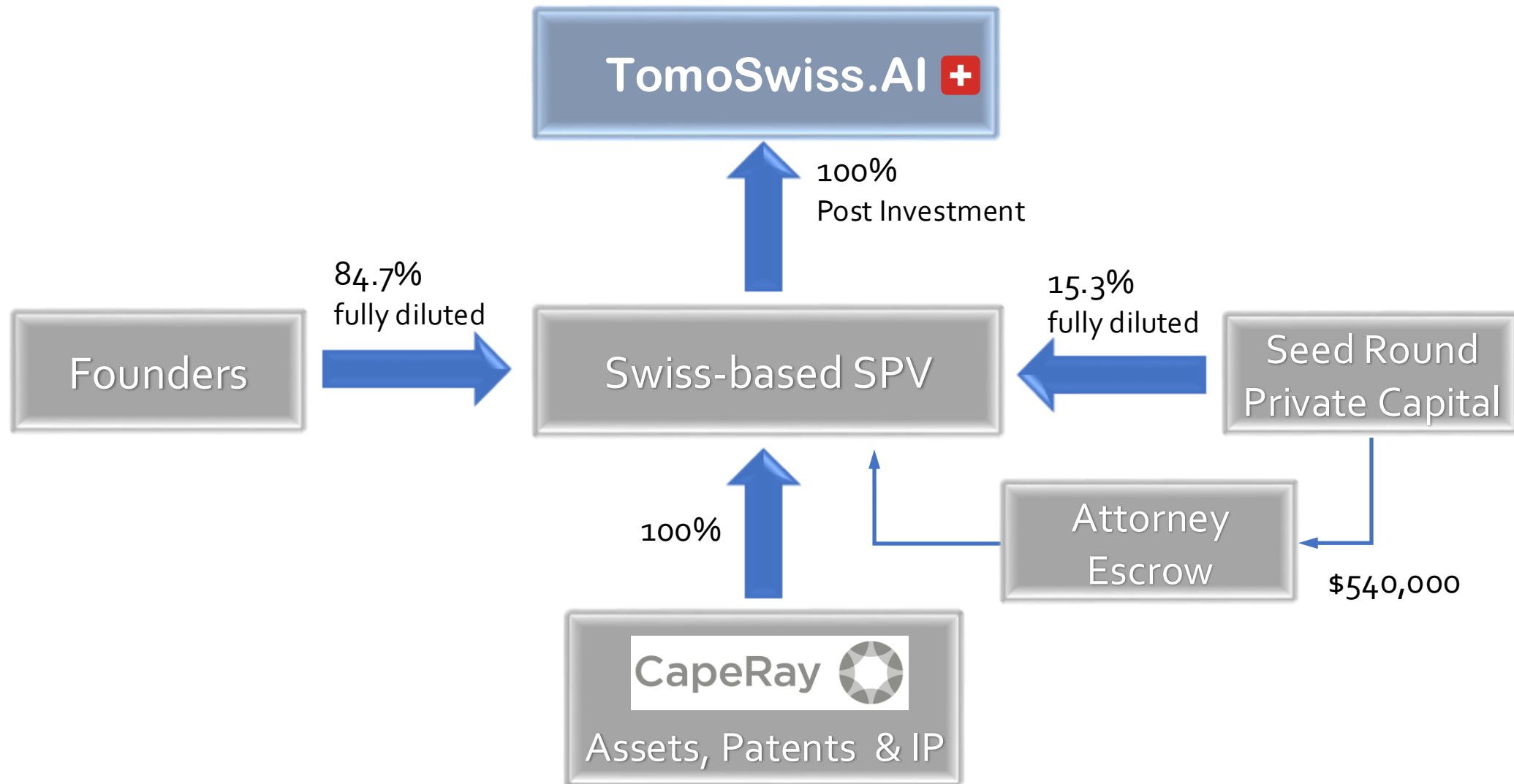
Swissray Technologies AG (<https://bit.ly/4biBCS1>) offers a range of innovative products, including mobile X-ray systems, smart mini C-arms, X-ray therapy, and software. The company is located in the heart of Switzerland, 20km north of Lucerne in Hochdorf, and is very easy to reach both by public transport and by car.



The Team at Swissray Technologies is Committed to Offer These Services

- Experience in the development of both Hardware and Software medical imaging systems
- Creation of the Technical File of the IASO system, to be used for submission to the Food & Drug Administration (FDA) in the USA, and for securing the CE mark in Europe under the new medical device regulations (MDR)
- Assistance in building a quality management system (QMS) for **TomoSwiss.AI** that will enable the company to secure the ISO 13485 certificate
- Build on their extensive know-how and networks for the development of novel medical devices
- The Swissray team has to date successfully registered 7 different X-ray products with both the FDA and the CE authority
- Provide project management services for the plan to develop, coordinate, execute and control the novel IASO system
- Build on their experience with *InnoSuisse* (<https://bit.ly/3VZMEqO>) to help secure non-dilutive funding
- **TomoSwiss.AI** will be established at their offices in Hochdorf, providing office and R&D space as well as a production area (seen at left)
- Assist with marketing and sales by building on their network of international contacts in all continents, benefiting from their distribution channels, and capitalising on the brand name of Swissray Technologies AG

Seed Investment via Special Purpose Vehicle (SPV) located in Switzerland



Capitalisation Table for TomoSwiss.AI

Pre-Seed Round of Funding				
Pre-Money Valuation	\$3,000,000			
Net Amount Invested	\$540,000			
Post-Money Valuation	\$3,540,000			
% Ownership of new investor	15.25%			
Price per share	\$600.00			
Initial Shares Issued	5,000			
Post-Investment Shares Issued	5,900			
New shares issued to investor(s)	900			

Note: Pre-Money Valuation of \$3m is a significant discount on the \$5m invested by the IDC and CapeRay's shareholders to develop the patents and other intellectual property assets

Exit Examples

Over the last few years, startups in the MedTech sector — telemedicine, medical devices and AI — have raised record funding, particularly in the European market (investment levels increased to \$6.7bn in 2021), with investment declining slightly in 2022, reflecting geopolitical concerns over the conflict in Ukraine. However, transaction values in these sectors have remained high relative to slower-growth industries.

Some Examples of MedTech Companies Exiting via Trade Sale or Listing

- Caption Health – Maker of AI-enabled ultrasound guidance software, the company raised \$53M in venture funding in 2020; it was acquired by GE HealthCare in February 2023 for an undisclosed amount but believed to be at a substantial premium on its enterprise value.
- Integer Holdings (NYSE: ITGR) – One of the world's largest medical device outsourcing manufacturers, the company raised \$435M total funding before listing, with current market cap of \$3.9bn.
- Medinotec Inc (OTC:QX MDNC) – Manufacturer of airway dilation balloon and other devices, 1st Round Reg S Private Placement at \$2/share in 2022, against independent valuation of \$27M pre-FDA approval for its primary medical device; the device was approved by the FDA for sale in the U.S. in November 2022, which resulted in an increased independent valuation of the company. Medinotec currently has a market cap of \$59M. *
- Paragon 28 (NYSE: FNA) – Founded in 2010 as an orthopaedic device company, Paragon 28 listed on NYSE in October 2021, with current market cap of \$476M.
- The Butterfly Network (NYSE: BFLY) – Founded in 2011 as a point-of-care ultrasound company, spent \$100M before listing on NYSE in 2020, with current market cap of \$196M.
- Hyperfine (NasdaqGM: HYPR) – Founded in 2014 as manufacturer of portable magnetic resonance imaging (MRI) systems, now with AI-driven point-of-care neuroimaging software, the company listed on Nasdaq in 2021, with current market cap of \$60M.
- Volpara Health Technologies (ASX: VHT.AX) – Founded in 2009 as a software company that offers software for the early detection of breast cancer with its AI-powered mammography solutions, has recently been acquired by Lunit Inc. (KOSDAQ: 328130.KQ) in a deal valued at \$193M, a 47% premium on Volpara's stock price at the time of the transaction.

Note: All market cap data recorded as of June 24, 2024

* Disclosure: Centauri Markets was the Lead Advisor and Bookrunning Manager on this transaction.

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