Computer-Aided Decision Software for Breast Ultrasound Lesions

Business Plan

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Dedication

To my husband, Jack: You will not be able to join me on graduation day, but I remember every day how greatly you supported me in my career and educational endeavors.

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Executive Summary

Problem

Breast cancer is the most frequently occurring female cancer in the United States (Shen et al., 2021). Survival rate improvement is directly dependent on early diagnosis. However, breast cancer detection by radiologists from imaging modalities like mammography and ultrasound is neither highly accurate nor consistent. Radiologists aren't given enough time to keep up with analyzing the increasing amount and complexity of breast ultrasound images. Due to an aging population, more women are being diagnosed with breast abnormalities and require frequent follow-up, further increasing the breast imaging workload.

Solution

Our company, Ultrasound.AI, is launching a hybrid deep learning algorithm. that will collaborate with radiologists in order to forecast the presence of breast cancer using ultrasound imagery. Our algorithm is unique in its ability to reduce radiologist time spent reviewing a patient's images, thus improving throughput. Our algorithm can preview all images in a patient study and prioritize them for the radiologist. The Ultrasound.AI algorithm can match the accuracy of radiologists while reducing the need for unwarranted breast biopsies. Our algorithm uniquely offers transparency to the radiologist. A heatmap process allows the radiologist to measure how the algorithm arrived at its breast cancer prediction. With our next update, the

Ultrasound.AI algorithm in collaboration with partner, Visage Imaging, will further save radiologist time by generating standardized diagnosis and treatment data (BI-RADS report) for the patient's electronic medical record.

Market

The worldwide market for breast cancer imaging and diagnosis, with the United States as the leading participant, is estimated to exceed $10 billion and experience a compound annual growth rate of more than 7% for the coming seven years (Emergen Research, 2022). Our company is aiming for the early detection market, which is a growing division of the overall breast cancer health care market. Our primary audience includes radiologists as well as healthcare companies who employ radiologists. We also focus on companies that develop software for radiologists and we are pursuing relationships with manufacturers of ultrasound equipment.

Business Objective

Ultrasound.AI will license our Computer Aided Diagnosis software to radiology clinics, ultrasound equipment makers, and companies who produce radiologist workstation software. We aim to partner with other companies that develop diagnostic products for breast abnormalities. We will offer a site license for $20,000 and individual clinician licenses for $1,000, annually. We expect to obtain 80% of our revenue from software sales and 20% from customization of our deep learning algorithm.

Management Team

Ultrasound.AI's management team includes leadership experts in the fields of radiology, computer assisted imaging diagnosis, medical startup financing and marketing. Our management team has extensive experience with the medical imaging market segment. Ultrasound.AI has a partnership with Visage Imaging, the largest producer of radiology workstation software, Mayo Clinic, and the University of Wisconsin La-Crosse.

Financial Plan

We estimate that Ultrasound.AI will generate $1,660,000 in revenue during its startup year. We expect to be profitable within three years. We expect to get initial investment funding from partners Mayo Clinic and Visage Imaging.

Milestones

- Q3 2023: Ultrasound.AI will publish results of its deep learning algorithm in a radiology journal.
- Q3 2023: Ultrasound.AI will obtain FDA clearance for its deep learning algorithm.
- Q4 2023: We will publish an article about the Ultrasound.AI article in a medical imaging journal and get a booth at the RSNA Annual Meeting: Nov. 26–30, 2023 to demonstrate the Computer Aided Diagnosis Software to prospective customers (Radiological Society of North America, 2023).

- Q1 2024: We will introduce a commercial product that extends beyond the realm of Mayo Clinic radiologists.
- Q2 2024: Ultrasound.AI will partner with an ultrasound imaging machine maker to incorporate our deep learning algorithm into the software of their equipment.

Challenges

A major challenge facing Ultrasound.AI is identifying potential customers before our computer assisted diagnosis software receives FDA approval. Strict regulatory approval procedures may pose a challenge for market growth, increasing the time and cost of commercializing our software. Distinguishing our algorithm from competitor products in the minds of our customers is another challenge. Although only two other computer assisted diagnosis algorithms have received FDA clearance, numerous machine learning algorithms are under development for breast cancer prediction, driven by the high incidence of cases and the sizable market potential.

Sustainable Competitive Advantage

Our company has a competitive hybrid deep learning model to launch into the breast cancer diagnostics market. Ultrasound.AI plans to license its Computer Aided Diagnosis software to radiology clinics, ultrasound equipment makers, and companies who produce radiologist workstation software. Ultrasound.AI's software not only provides correct breast cancer prediction, but also incorporates exclusive features to enhance radiologist workflow and considerably reduce the time spent on ultrasound image analysis. Our deep learning algorithm

offers the versatility to preprocess images for the radiologist or have the radiologist manually review images and utilize the algorithm to predict malignancy for a specific lesion.

Our management team is seasoned, uniquely complementary, and up to the task to steer this startup successfully. We plan to improve the lives of women, diagnosed with breast abnormalities. Ultrasound.AI expects to get initial investment funding from partners Mayo Clinic and Visage Imaging. Financial projections estimate a revenue of $1,660,000 in the startup year, with a goal to be profitable within three years. We are accepting further investment to help us improve the lives of women with breast cancer through earlier, more accurate diagnosis and more precise treatment planning.

General Company Description

Our company will be a partnership, prospectively named Ultrasound.AI for branding reasons. It will develop and provide deep learning algorithms to interpret ultrasound breast images for the healthcare industry. The company may sell or license the technology to healthcare providers or medical device manufacturers. Artificial Intelligence (AI) is the general concept of creating intelligent machines and computer programs. Machine learning is a subclass of AI that involves algorithms that can learn from data, without requiring explicit programming. Deep learning is a component subfield of machine learning that uses neural networks to process substantial amounts of data and identify more complex patterns. Deep learning algorithms improve upon older machine learning techniques by computing many paths in parallel.

Guiding Principles

Mission Statement

We commit to improve breast cancer diagnosis accuracy and efficiency by leveraging deep learning technology in our partnership.

Vision Statement

Our long-term vision involves implementing innovative deep learning algorithms that accurately classify breast ultrasound images, reducing the potential for human error and missed diagnoses. We aim to collaborate with universities, medical institutions, radiology software

makers and ultrasound equipment makers to collect and analyze copious amounts of data. We will refine our algorithms to provide radiologists with increasingly accurate and efficient diagnostic tools. Our goal is to become a reliable partner for healthcare companies, aiding in earlier detection and improving the quality of diagnosis for patients with breast cancer or other breast conditions.

Values Statement

Primary company values include growth, innovation, collaboration, accountability, diversity and inclusion, accessibility, ethics, transparency, and compliance. We are dedicated to using our technology to improve breast cancer diagnosis, while prioritizing responsible and transparent use of deep learning algorithms.

Company Goals and Objectives

Ultrasound.AI will reduce the time and rework needed for the radiologist to develop a diagnosis for each patient utilizing the following objectives:

- **Objective 1**: Develop a business proposition based on a hybrid deep learning model that assists the radiologist in predicting the overall probability of breast cancer. The accuracy of this hybrid model (deep learning algorithm plus radiologist) will exceed image classification accuracy performed by a radiologist alone. The area under the receiver operating characteristic curve will exceed an area under the receiver operating characteristic curve, AUROC, of 0.96 (Shen et al., 2021). This curve visually portrays a computer model's ability

to discern true positive rates (sensitivity) against false positive rates (specificity) across different threshold values. An AUROC score of 0.96 signifies a high precision in the model's capacity to differentiate between the presence and absence of breast cancer.

- **Objective 2**: The deep learning model will convert the probability of malignancy to a BI-RADS (Breast Imaging Reporting and Data System) score. BI-RADS is a standardized system used by radiologists to report the results of a breast imaging exam (Shen et al., 2021).

- **Objective 3**: The Ultrasound.AI prototype software, formed from a hybrid deep learning model, provides decision support for radiologists to classify ultrasound breast lesions that are neither clearly malignant nor clearly benign. These lesions fall into the category of BI-RADS 3 (follow-up recommended, but no biopsy) or BI-RADS 4 (biopsy recommended (Shen et al., 2021).

- **Objective 4**: Radiologists will decrease their false positive rates by at least 35%, (Shen et al., 2021), while maintaining the same level of sensitivity (proportion of true positive cases that are correctly identified by the model). Sensitivity measures the model's ability to detect true cases of disease. This emphasizes the capability of AI to improve the accurateness, and reliability of ultrasound breast cancer diagnosis.

- **Objective 5**: Radiologists will reduce requested biopsies by at least 25%, while not compromising sensitivity (Shen et al., 2021). AI can assist with diagnosing breast cancer more efficiently.

- **Objective 6**: The deep learning algorithms will be explainable. They will provide a heat map to assist the radiologist with identifying regions of interest (breast lesions). Based on radiologist feedback, they will want this type of explain ability in a prototype because it improves consistency of image interpretation. The next version of the algorithm will also determine important BI-RADS characteristics of the breast lesion.

- **Objective 7**: The next version of the deep learning model will allow the radiologist to manually override items such as the predicted BIRADS score, the lesion boundary and other BIRADS characteristics. The model will subsequently produce an updated assessment of malignancy likelihood.

Business Philosophy

Ultrasound. AI's partnerships improve breast cancer diagnosis and treatment by prioritizing accuracy, collaboration, and transparency in the development of deep learning algorithms. We believe in creating a capable and complimentary team, and prioritizing competence and moral values in all our interactions with stakeholders and clients. For example, we are interested in promoting algorithms that are explainable and can be queried by the clinician rather than falling prey to the often encountered "black box" phenomenon of machine learning models (Rudin & Radin, 2019).

Industry Overview

Ultrasound.AI operates in the medical imaging and diagnostics industry, providing deep learning algorithms to classify breast ultrasound images for accurate diagnosis. This industry has seen significant growth due to advances in computer assisted technology and increased requirements for time saving diagnostic procedures. In the short term, the company can take advantage of the growing demand for breast ultrasound image analysis software.

Market Segment Overview

Ultrasound. AI's target market is the medical imaging industry. This sector includes hospitals, clinics, and diagnostic centers offering breast ultrasound imaging services to patients. This market sector also includes medical imaging equipment makers as well as producers of software for radiologists.

The potential market size for a deep learning algorithm that classifies breast ultrasound images is significant. The market is also competitive due to a robust pipeline of established players and new entrants developing similar technologies. Differentiating the algorithm based on its accuracy, speed, and especially ease of radiologist use, as well as its ability to integrate with existing medical imaging systems or software is crucial.

Company Strengths and Competencies

Company strengths and core competencies that will make an AI company for classifying breast ultrasound (US) images succeed include:

1. **Deep learning expertise**: Strong expertise in deep learning algorithms and techniques is essential for building accurate and effective AI models for classifying breast US images. The

UW-LaCrosse CADBusi Project team has computer scientists, data scientists, mathematicians and a radiologist who have years of experience with computerized interpretation of ultrasound images (Professor Jeffrey Baggett, personal communication, February 21, 2023).

2. **Extensive data sets**: Access to large and diverse data sets of breast ultrasound images, along with associated clinical data, can help to train and refine AI models for accurate performance without causing overfitting. The UW-LaCrosse CADBusi Project team has access to Mayo Clinic ultrasound data from the entire United States (Dr. Rich Ellis, personal communication, March 7, 2023).
3. **Medical domain expertise**: Understanding breast anatomy, pathology, and clinical practice is crucial for developing computer aided models that are clinically relevant and can be integrated into healthcare workflows. The CADBusi Project team has an expert radiologist working with the data scientists to guide algorithm development and integration into the radiologist workflow (Dr. Rich Ellis, personal communication, March 7, 2023).
4. **Industry partnerships:** Collaborations with healthcare providers, medical device manufacturers, and research institutions provide valuable insights into market needs and opportunities, as well as access to data and resources. The CADBusi Project team is collaborating with Visage Imaging to incorporate their algorithms into the radiology workflow software (Wolfgang Holler, Visage Imaging, personal communication, January 6, 2023). We are seeking to collaborate with an ultrasound equipment maker to directly incorporate the algorithm into software of the ultrasound machine as an add-on function.

5. **Regulatory compliance**: FDA approval for AI assisted diagnosis software is covered under medical device certification and is needed for safeguarding AI technology in healthcare settings. Deidentification of images needs to be compliant with data privacy laws.
6. **Scalable infrastructure**: Robust and scalable computing infrastructure is necessary for processing large volumes of data and running complex AI algorithms in real time. If the CadBusi team can partner with either a radiology software company or with an ultrasound equipment manufacturer, the deep learning algorithm will be able to scale with the market reach that these products have (Wolfgang Holler, Visage Imaging, personal communication, March 7, 2023).
7. **Intellectual property protection:** Protecting intellectual property through patents, trademarks, and trade secrets creates competitive advantage and defends against imitators. Plans are to copyright any novel deep learning model that Ultrasound.AI produces (Professor Jeffrey Baggett, personal communication, February 21, 2023). A copyright may be used to protect the code that implements the model or the data that was used to train it (Singh et al., 2020, p. 30367).

Legal Form of Ownership

Ultrasound.AI will operate as a partnership, comprised of the CADBusi team from the UW-Lacrosse University, the Mayo Clinic and Visage Imaging (producer of Radiology software) as well as a future ultrasound equipment maker (Professor Jeffrey Baggett, personal communication, March 7, 2023).

Products and Services

Product Description

Ultrasound.AI aims to provide one or more prototype deep learning algorithms that can be integrated with radiologist workstation software or ultrasound equipment. These algorithms will provide decision support for the radiologist and furnish the following capabilities (Rudin & Radin, 2019, p. 12)

1. Prioritize images for each patient to highlight regions of most concern (breast lesions).
2. Allow the radiologist to select lesions (regions of interest, ROI) manually or with assistance of the deep learning model.
3. Score the malignancy probability for each lesion as a percentage.
4. Translate the malignancy percentage to a BI-RADS score.
5. In the next version, the Ultrasound.AI algorithm will identify prominent features that characterize each lesion as annotations for the BI-RADS report (Professor Jeffrey Baggett, personal communication, March 7, 2023).

Product Pricing and leasing structures

Potential pricing models for the deep learning models produced by our partnership include:

1. **B2B model:** Ultrasound.AI may sell its AI-powered ultrasound breast imaging classification procedure as a B2B solution to hospitals, clinics, and medical imaging centers who would integrate the algorithm into their existing imaging procedures.

2. **Subscription-based model:** Ultrasound.AI will lease its software to radiology providers and make it accessible via a subscription. Radiologists and healthcare providers could access the software from anywhere and receive ongoing updates and technical support from Ultrasound.AI.
3. **Collaboration with medical device manufacturers:** Ultrasound.AI plans to partner with ultrasound equipment manufacturers to integrate its AI-powered ultrasound breast imaging classification software into new devices, increasing its market reach and visibility.
4. **Data licensing:** In addition to selling the software, the company could generate revenue by licensing the deidentified and anonymized breast image data generated from the use of the software. For example, this data could be valuable to healthcare imaging equipment makers and medical research institutions.

Product Market Description

Ultrasound.AI markets a deep learning algorithm that classifies breast ultrasound images to medical professionals and institutions involved in the diagnosis and treatment of breast cancer. These include:

1. **Healthcare providers:** Hospitals and clinics interested in having their radiologists use AI technology to improve the accuracy and efficiency of breast ultrasound image interpretation are a prime market target. AI technology helps healthcare providers make more informed diagnostic and treatment decisions in a shorter amount of time (Shen et al., 2021).
2. **Medical device manufacturers:** Ultrasound equipment manufacturers often want to integrate AI technology into their products to improve performance and standardize image annotation and interpretation. AI technology can enhance the capabilities of ultrasound

equipment and provide a competitive advantage in the market (Villa-Camacho et al., 2023, p. 12).

3. **Insurance companies:** Insurance companies are evaluating AI technology to improve breast cancer screening, and reduce costs associated with misdiagnosis or delayed treatment. With more accurate and consistent results, AI technology helps to identify potential cases of breast cancer earlier, leading to more effective treatment.
4. **Research institutions:** Academic research institutions utilizing AI technology to study breast cancer can develop new diagnostic and treatment methods. With more accurate and consistent results, AI technology helps researchers identify patterns and trends in breast ultrasound images, leading to new insights and discoveries.

Industry Description

Ultrasound.AI operates in the medical imaging industry by providing algorithms to interpret breast ultrasound images. This industry is growing substantially, due to many factors, including:

1. **Increase in breast cancer screening:** As more women are undergoing regular breast cancer screening, the number of mammograms and ultrasounds that need to be reviewed by radiologists is increasing.
2. **Advances in imaging technology:** Advances in computer imaging technology have led to an increase in the number of images produced by mammograms and ultrasounds for each patient study. These images can be incredibly detailed, and it takes time for radiologists to carefully review each one (Dr. Rich Ellis, personal communication, March 7, 2023).
3. **Shortage of radiologists:** There is currently a lack of radiologists in many geographical areas, both globally and in the United States. Radiology subspecialties, such as “Breast

Radiology," are becoming the norm and these subspecialties are not well represented in rural areas. This leads existing radiologists to be under pressure to work more quickly. (Dr. Rich Ellis, personal interview, February 24, 2023).

4. **Emphasis on efficiency:** Healthcare systems place a growing emphasis on efficiency and reducing patient wait times, creating pressure on radiologists to review images quickly so that patients can receive their results promptly (Amy Fowler, Koios Sales VP, personal communication, March 6, 2023).

Factors Providing a Competitive Advantage or Disadvantage

A deep learning algorithm can offer several competitive advantages over traditional methods of diagnosis, including:

1. **Improved accuracy:** Deep learning algorithms learn from large datasets of images to make highly accurate predictions, improving diagnostic accuracy over traditional methods.
2. **Speed:** Deep learning algorithms analyze images much faster than a human radiologist.
3. **Consistency:** Deep learning algorithms provide consistent and objective interpretations of ultrasound images, reducing the potential for human variability (Villa-Camacho et al., 2022).
4. **Cost-effectiveness:** Deep learning algorithms reduce the need for additional diagnostic tests and follow-up appointments, resulting in cost savings for patients, healthcare systems and insurance providers (Villa-Camacho et al., 2022).
5. **Scalability:** Deep learning algorithms scale up to analyze large volumes of images, potentially improving efficiency and reducing the workload for clinicians.

6. **Integration with existing systems:** Deep learning algorithms can be designed to integrate with existing medical imaging systems, making them easier to adopt for radiologists **(Dr.** Rich Ellis, personal interview, February 24, 2023).

Company Strengths and Core Competencies

The firm developing a deep learning algorithm for breast ultrasound imaging brings the following strengths to a potential partnership: expertise in deep learning, strong data analytics capabilities, collaboration with established medical partnerships, and the ability to offer customization and integration services to partners. These strengths make the company an attractive partner for healthcare providers looking to improve breast cancer diagnosis accuracy, efficiency, and cost-effectiveness.

Legal Form of Ownership

Plans are to run Ultrasound.AI as a partnership. Funding is expected from partners, UW-Lacrosse University, the Mayo Clinic and Visage Imaging. Visage Imaging will provide software expertise. We are seeking an ultrasound equipment maker to develop a competitive commercial product.

Marketing Plan

Market Research & Economics

The Computer-Aided Diagnosis (CAD) imaging sector is expanding and is anticipated to grow rapidly over the projected period of 2022 to 2029 (Data Bridge Market Research, 2022) . The healthcare sector is advancing based on technical innovations, increased healthcare spending and more complex healthcare facilities. Hospitals and clinics are embracing sophisticated imaging devices. Revenue growth of the global Computer Aided Detection (CAD) market is boosted by: Increased chronic disease prevalence, medical care advancements, higher adoption of new medical tools and techniques, and increased funding by public and private sectors. The growing need for precision medicine and point-of-care imaging diagnostics, as well as greater investment in research, contributes to the rise in revenue of the imaging market. expected throughout the forecast period of 2022-2029.

Computer-Aided Diagnosis (CAD), including deep learning models, support radiologist image classification for an increasing number of diseases, many of them age-related, including breast cancer and other breast abnormalities.

The Covid-19 pandemic changed the dynamics of the health services industry. Shortages of staff and healthcare devices in hospitals are unresolved challenges. These challenges will open up profitable opportunities for market competitors able to deftly use artificial intelligence.

Market Growth

In 2021, the global market for computer-aided diagnosis had a revenue of USD 742.8 Million. It is projected to grow at a CAGR of 7 % from 2021 to 2030. The rising rate of cancer,

and especially breast cancer, is a noteworthy factor pushing market revenue growth (Emergen Research, 2022).

CAD vendors can explore opportunities, such as collaboration with original equipment manufacturers offering breast screening systems, and integration of CAD triage (CADt) to minimize human errors and enhance productivity.

Numerous factors affect the growth of the CAD breast ultrasound imaging market. Medical technology can boost the accuracy, productivity, and accessibility of CAD systems for this type of imaging. For instance, the integration of artificial intelligence and deep learning can improve the performance of CAD systems, leading to more reliable diagnosis, which can in turn increase the demand and adoption of CAD systems among healthcare providers and patients. Additionally, government regulations can affect the approval, reimbursement, and quality standards of CAD systems for breast ultrasound imaging. For example, strict regulatory approval procedures may pose a challenge for market growth, increasing the time and cost of introducing new products to the market. Conversely, favorable reimbursement guidelines can encourage the utilization of CAD systems for breast ultrasound imaging by reducing the financial burden on patients and providers. Economic factors can also impact the affordability and availability for these CAD systems. The high cost of equipment and maintenance can hinder market growth by limiting access to CAD systems for breast ultrasound imaging, particularly in low and middle-income regions of the country. Public-private healthcare investments can help market growth by providing funding and research grants for the development of CAD systems.

Market Segmentation

The market for computer aided detection (CAD) is categorized according to usage in various applications, imaging techniques, imaging modalities, and end users. This market includes several imaging modalities (Reports and Data, 2021):

Segmentation by application is broken down into oncology, including breast cancer, neurological, musculoskeletal, cardiovascular, and others.

Segmentation by CAD Imaging modalities is broken down into ultrasound imaging, mammography, tomosynthesis, X-Ray Imaging, computed tomography, magnetic resonance imaging, nuclear medicine imaging, and others.

Segmentation by CAD Regional Outlook (Data Bridge Market Research, 2022):

- North America: U.S., Canada, Rest of North America
- Europe: U.K., Germany, France, Italy, Spain, Rest of Europe
- Asia Pacific: India, China, Japan, Australia, Rest of Asia Pacific
- Latin American: Brazil, Argentina, Peru, Mexico, Rest of Latin America
- Middle East & Africa: Saudi Arabia, South Africa, U.A.E, Rest of Middle East & Africa

Market Obstacles

Unfavorable insurance reimbursement policies, scarcity of trained personnel to operate sophisticated systems, and limited awareness in rural areas may hinder the growth of the CAD market. Elevated costs linked to CAD tools along with the risk of failure in detecting abnormalities on ultrasound images are likely to pose challenges to the Computer-Aided Diagnosis (CAD) market during the 2022-2029 period. Challenges such as absence of

standardization and validation of CAD algorithms and regulatory obstacles for AI-based CAD solutions remain a concern.

Target Market & Market Share

The target market for CAD for Ultrasound Breast Imaging is chiefly composed of healthcare providers who offer breast cancer screening services using ultrasound as a primary or adjunct tool. The mammography segment accounts for the largest revenue share, followed by ultrasound and MRI segments. (Emergen Research, 2022)

Product

From the viewpoint of the Breast Radiologist

Computer Aided Diagnosis (CAD) systems can automatically detect, segment, and classify breast masses based on their morphological features and provide a second opinion to radiologists. Newer CAD systems use deep learning algorithms and elastography techniques (ultrasound imaging that can measure the stiffness of breast tissues and differentiate between hard tumors and soft normal tissues) to improve the accuracy and efficiency of diagnosis. While the number of images per patient study increases and images get more complex, the radiologist is still expected to process an increasing number of patient studies in a shorter time period (Dr. Rich Ellis, personal interview, February 24, 2023). Any tasks that a CAD algorithm can help with, e.g. ordering and prioritizing images, outlining breast lesions, annotating lesions, will make the radiologist significantly more productive. CAD systems can help radiologists reduce human

error, increase confidence, and save time. However, CAD systems are not a substitute for radiologists' expertise and judgment, and they still require validation and standardization across different ultrasound devices and methods (Dr. Rich Ellis, personal interview, February 24, 2023).

Despite many benefits, clinicians such as Dr. Rich Ellis (personal interview, February 24, 2023) have expressed concerns regarding CAD algorithms. Challenges include cost-effectiveness, compatibility with various ultrasound devices and methods, validation and standardization of algorithm performance, ethical and legal implications, and integration with existing radiology workflows and systems. Radiologists, in particular, are hesitant to incorporate any algorithm that takes longer than a minute to run.

Features and Benefits

Initially, Ultrasound.AI (the proposed brand name for a partnership between UW LaCrosse CADBusi team, Mayo Clinics, and Visage Imaging) will deploy a prototype deep learning algorithm for breast cancer classification. This algorithm will be hosted on Visage Imaging's Visage 7 Enterprise Imaging Platform. This platform is a cloud-engineered server-side computing environment that provides fast performance for complete PACS (radiology image management) operations. The environment also offers accelerated AI, and medical communication assistance (Wolfgang Holler, Visage Imaging, personal communication, January 6, 2023).

Important features of our algorithm include calculating a percentage score for breast malignancy, rather than just providing a binary classification of benign or malignant. Secondly, the algorithm will translate the malignancy percentage into a BI-RADS (Breast Imaging-Reporting and Data System) score. A BI-RADS score between 0 and 6 estimates a patient's

breast cancer risk from imaging results. Significantly, this scoring system provides consistency and is linked to comprehensive follow-up actions for the patient. By helping the radiologist generate a BI-RADS score, our algorithm will assist with providing precise treatment planning steps to benefit the patient (Professor Jeffrey Baggett, personal communication, February 21, 2023).

Optionally, our algorithm will overlay a heatmap onto the image to help the radiologist identify the regions of interest (salient pixels) in an ultrasound breast image that may indicate the presence or absence of breast cancer. The algorithm can also provide annotations or explanations for why a region has been highlighted. For example, our algorithm may highlight a spiculated edge of a breast lesion to indicate that it should be investigated further. This special interactive feature allows the radiologist to generate a heatmap only when desired. A good use case would be if the radiologist and the AI algorithm disagree on malignancy scoring for a breast lesion (Dr. Rich Ellis, personal interview, February 24, 2023).

Customers

The primary users of our deep learning algorithm will be healthcare providers and professionals who utilize breast ultrasound for the screening, diagnosis, and management of patients with breast cancer or other breast abnormalities. These individuals may include radiologists, oncologists, surgeons, nurses, ultrasound, and technicians working in hospitals, clinics, or mobile units.

Competition

Healthcare providers and professionals, who use breast ultrasound for screening, work with companies of different sizes and types, based on factors like location, market share, customer base, and product portfolio. The world-wide automated breast ultrasound systems (ABUS) market is led by major players such as GE Healthcare (U.S.), Hitachi Ltd. (Japan), Siemens Healthineers AG (Germany), SonoCine Inc. (U.S.), and Philips Healthcare (Netherlands). These companies offer a variety of ABUS devices that utilize 2D and 3D ultrasound technology to provide accurate and efficient diagnosis for womens breast health.

Typically, these large multinational corporations offer several tiers of products and services across various healthcare sectors and segments. They may also collaborate with other companies or organizations to expand their reach. Additionally, some competitors have products that have received FDA clearance for computer-aided diagnosis for breast ultrasound images.

SWOT Analysis

Following is a SWOT analysis for primary Computer Aided Diagnosis (CAD) for Breast Ultrasound competing products, GE Healthcare Invenia ABUS 2.0 and Siemens Healthineers AG ACUSON S2000 ABVS (Automated Breast Volume Scanner). These products are two major competitors for the deep learning algorithm being developed by our CADBusi team.

Strengths:

• Both products are advanced technologies that use artificial intelligence to analyze ultrasound images of breast masses and provide a diagnosis of benign or malignant.

• Both products can help a radiologist diagnose breast cancer, although these products use different measurements for accuracy and effectiveness. (Applied Radiology, 2023), (Mango et al., 2020)

• Both products can reduce unnecessary biopsies and provide consistent, operator-independent results.

• Siemens Healthineers AG has a strong brand reputation and global presence in the medical technology market.

• GE Healthcare has a diversified portfolio of medical imaging products and healthcare services.

Weaknesses:

• Both products are expensive and require high maintenance costs.

• Both products are subject to stringent FDA regulatory approval procedures and quality standards.

• Siemens Healthineers AG faces intense competition from other players in the medical technology market, such as Philips, Canon Medical Systems, and Hitachi Medical Systems.

• GE Healthcare is facing declining revenues and profitability due to the COVID-19 pandemic and other challenges in its core businesses.

Opportunities:

• Both products can leverage the increasing demand for advanced diagnostic technologies, especially in emerging regions such as Asia-Pacific and Latin America.

• Both products can benefit from the increasing capabilities for early breast cancer detection and the growing incidence of breast cancer worldwide.

• Siemens Healthineers AG has many strategic partnerships and is expected to increase its customer base.

• GE Healthcare can focus on its digital transformation and innovation initiatives to enhance its operational efficiency and customer satisfaction.

Threats:

• Both products face technological obsolescence due to rapid changes in imaging technology.

• Both products may face legal or ethical issues related to data privacy, security, accuracy, and liability.

• Siemens Healthineers AG may face regulatory or political risks due to trade disputes, tariffs, and sanctions.

• GE Healthcare may face financial or operational risks due to debt restructuring, asset divestitures, and litigation costs.

Table 1: Competitive Analysis

FACTOR	Me	Strength	Weakness	GE HealthCare	Siemens Healthineers AG	Importance to Customer (1 high-5 low)
Products	Ultrasound.AI			Koios DS	MAMMOVISTA B.smart	
Accuracy	Plan to decrease false positives by 35%	✓		30% decrease in false positives	increase diagnostic accuracy by up to 10%; decrease image load time by 75%	1
Certification Status	In progress		✓	FDA Clearance K212616	FDA Clearance K212621	1

Expertise in machine learning	High	✓		High	High	2
Reliability	Continued Validation results are medium high		✓	Continued Validation results are high	Continued Validation results are high	
Company Reputation	Not yet established, but we collaborate with Mayo Clinics	✓		High	High	3
Market Penetration	Prototype AI version to be released to Mayo Clinics.		✓	AI tools work for all major Ultrasound devices	AI tools work for all major Ultrasound devices	3
Sales Method	(Planned) Subscription-based services for local network or cloud based AI algorithms.		✓	(Primary) Subscription-based services for local network based AI algorithms.	Variety, including Strategic Selling and Large Account Management Process	5
Price	Not yet determined		✓	Unavailable (proprietary)	Unavailable (proprietary)	3
Service	(Planned) Full Service Plan		✓	Full Service Plan	Full Service Plan	3
Credit Policies	(Planned) No credit. Trial license will be available		✓	Fair market value leasing (FMV leasing) or Capital Lease	Fair market value leasing (FMV leasing) or Capital Lease	5
Advertising	Radiology Conferences, Publications, word of mouth		✓	Product Website, Radiology Conferences, Publications	Product Website, Radiology Conferences, Publications	4

Niche

A market niche is a subsegment of a larger market with its own character. Computer-Aided Diagnosis (CAD) or AI modeling for breast cancer diagnosis is a component of the larger ultrasound imaging market. A market niche for CAD breast ultrasound imaging could be broken out in numerous ways. Examples are: imaging modality, method of machine learning assistance, radiology clinician, and patient segment.

When looking at imaging modality, the breast cancer portion has been the largest revenue generator in the global computer aided diagnosis market in 2021 (Biospace, 2022). Radiology clinicians are the main beneficiaries for having their workflow optimized through leveraging AI CAD techniques. According to the Radiology Key website, (Radiology Key, 2021), AI technology shows promise in breast imaging to improve tasks across the radiology workflow stack, such as organizing and prioritizing images, computer-aided diagnosis, breast lesion identification, lesion annotation and breast cancer prediction.

Strategy

Ultrasound.AI's market strategy should address major business needs: developing a reliable, accurate deep learning algorithm for diagnosis assistance and integrating it seamlessly into radiologist workflows while decreasing image review time. A software subscription model could be an ideal play. Ultasound.AI machine learning engineers could make sure the software remains patched, updated and FDA certified. The deep learning algorithm should be continually verified with current real world ultrasound images from clinic patients. Secondly, the prototype being developed by Ultrasound.AI should fit seamlessly into the radiologist workflow and decrease overall time spent reviewing patient image studies. Radiologists are sometimes expected to review image studies for 100 patients per hour (Smart City Journal, 2021), where

each study may contain 5 to 50 images. AI algorithms can save a significant amount of radiologist time by helping to 1) prioritize and order important images within the study, 2) discover and draw a bounding box around each lesion 3) classify the cancer risk for breast lesions selected by the radiologist and 4) help the radiologist complete the BI-RADS report (documents breast ultrasound findings in a standardized way for the patient's electronic medical record).

Promotion

Primary competitors, GE Healthcare (Koios DS) and Siemens (MAMMOVISTA B.smart), both promote their products on their product website. This practice allows each company to provide complex, up-to-date information on their AI algorithmic products for their customer base, ultrasound equipment customers.

A product website is a good solution for organizing disparate types of information such as listing or summarizing breast cancer research articles, and publishing FDA clearance and European Union's CE conformity mark. The website would display educational materials so prospective customers could learn more about the benefits and payback opportunities for adding a computer aided diagnosis to their radiology image review workflow. A "call to action" button should be included to help develop sales leads. A product website could offer a demo so potential clients can see how the product feels and works. Koios medical does a good job by letting a user run a machine learning on a generic radiology image. Patient and clinician testimonials along with excerpts from social media posts can also be featured on a product website. Our partnership, Ultrasound.AI, should create a product website along these lines.

Publishing research papers, case studies, and white papers that demonstrate the effectiveness and accuracy of the Ultrasound.AI machine learning algorithm would be an effective way to get the attention of medical professionals and prospective healthcare clinics.

Conferences for radiologists and ultrasound imaging professionals are a good, and perhaps necessary venue for explaining and promoting AI assisted medical imaging techniques, like the Ultrasound.AI algorithm.

Finally, partnering with reliable and well-known healthcare providers and medical institutions can help build a more end-user friendly and scalable product. For example, Ultrasound.AI will be a partnership between the UW LaCrosse CADBusi team (developers of the algorithm) and Mayo Clinic (owners of annotated ultrasound images used for training data) and Visage Imaging (producers of radiology workstation software).

Promotional Budget

Ultrasound.AI will work with our partner, Visage Imaging on promotion during the startup year. The “Mayo Foundation for Medical Education and Research” may also help us with marketing tasks and funding. We intend to use the “objective and task method”, where the promotion budget is set, based on the specific objectives, tasks, and costs of the promotional campaign (Shelters, D. 2013).

Most likely, before startup, a research paper will be published, documenting the results of the Ultrasound.AI deep learning model. These results will be seen by radiology clinicians, radiology software companies and ultrasound equipment makers.

Once the Ultrasound.AI algorithm is ready for commercial use and has achieved FDA clearance, Visage Imaging will assist us with promotional tasks and costs when it offers our

algorithm as an optional feature with their Visage 7 Enterprise Imaging Platform to selective clients (Visage Imaging, 2021).

Pricing

Pricing will depend on how Ultrasound.AI wants to proceed when we have developed a competitive algorithm for assisted breast cancer detection. On the one hand, the algorithm may be bought by a competitor (before or after FDA clearance is achieved). The competitor may use it as is, or adapt it to their technical specifications or customer base. The competitor may also scuttle the algorithm entirely. (Dr. Rich Ellis personal communication, March 7, 2023).

On the other hand, if Ultrasound.AI proceeds with commercializing the algorithm, Visage Imaging may include it with their Visage 7 Enterprise Imaging Platform and price it as an optional feature as part of a client (concurrent use) or enterprise wide software license. Visage Imaging offers a per feature pricing model for their Visage 7 Enterprise Imaging Platform (Visage Imaging, 2021). Other pricing options also remain on the table.

Proposed Location and Computing Environment

The Ultrasound.AI algorithm would initially live on Visage Imaging's computing platform and be available to radiology customers who already have a purchase or licensing agreement with Visage Imaging for managing radiology workflow.

Distribution Channels

Initially, the distribution channel for the Ultrasound.AI algorithm would be the Visage Imaging product website. Interested clients can contact the Visage Imaging sales force through their website, visageimaging.com.

Visage Imaging is a wholly owned subsidiary of Pro Medicus Limited. According to the official website of Visage Imaging, Home - Visage Imaging, some of the software distributors for Visage Imaging's Visage 7 platform are: Agfa HealthCare, Amazon Web Services (AWS) Partner Network, Change Healthcare and Philips Healthcare. (AuntMinnieEurope, 2022)

Sales Forecast

Visage Imaging sells software to manage radiology images in the US PACS market. They offer several products for radiologists, including ultrasound viewing software. Visage Imaging contributed $52.8 million (Australian dollars) revenue to its parent company, Pro Medicus Limited in 2020. The Visage 7 Enterprise platform was the most popular product (Pro Medicus Limited, 2020).

Beginning in 2023, assume $4,000,000 annual income from software licenses for the Ultrasound.AI breast image classification algorithm when hosted on the Visage 7 Enterprise platform. An additional $1,000,000 income is projected from professional services (Appendix A). We will use a CAGR of 7.1% during the forecast period, 2025 – 2030. (Emergen Research, 2022).

Table 2 - Possible Annual Sales Forecast Scenario

Year	Beginning Value	Ending Value	CAGR
2023	$20,000	$1,666,667	8,233%
2024	$1,666,667	$5,000,000	200%
2025	$5,000,000	$5,355,000	7.1%
2026	$5,736,405	$5,736,405	7.1%
2027	$6,146,173	$6,146,173	7.1%
2028	$6,586,405	$6,586,405	7.1%

The above sales forecast uses hypothetical numbers, but can illustrate several points: Based on the anticipated growth in the ultrasound imaging market, where breast cancer diagnosis is the largest player, the sales forecast shows solid revenue growth after 2025. More detail for the years 2023 and 2024 are available in the Startup Plan and Financial Plan documents. Essentially, we expect to sell 80 – 90 site licenses in 2023 to Mayo Clinic radiologists, and increase that number to 250 site licenses in 2024, priced at $20,000 each. These estimates are based on figures from our competitor, Koios Medical (Amy Fowler, Koios Sales VP, personal communication, March 6, 2023).

The above table may be conservative, since the Visage 7 Enterprise Platform is a cost effective replacement for legacy radiology clinic PACS systems and won the prestigious KLAS award in 2023, sales will probably beat prior years growth.

Operational Plan

Visage Imaging Platform

The Ultrasound.AI algorithm will be hosted on the Visage AI Accelerator platform during the first two years of operation. The Visage AI Accelerator program is a solution that connects AI research institution algorithms with diagnostic imaging on the same platform. This program allows researchers to use Visage's tools and data to develop and deploy AI models. It also enables clinicians to access and apply AI models within their workflow prior to purchase. The Visage interface seamlessly creates semantic annotations and exchanges them with other third-party applications. Radiologists use semantic annotations to record the visual appearance of anatomic structures and lesions found in images (Wolfgang Holler, Visage Imaging, personal communication, March 7, 2023).

The Visage 7 Enterprise platform is a server-side cloud platform for complete PACS operations (manages images and communication for radiologists**)**. The Visage 7 platform was ranked the number one Universal Viewer Imaging platform for radiologists. (KLAS Research, 2023)

Visage 7 is able to consume the output of externally created, researcher developed, AI deep learning models, and integrate them smoothly into the radiologist interpretation workflow. An example is the Visage Breast Density classification algorithm with FDA 510(k) clearance, developed by Visage working with customers, all using Visage 7 (Visage Imaging, 2021).

Visage Imaging uses embedding to integrate artificial intelligence tools into its Visage 7 diagnostic workstation. For example, Visage Imaging has embedded a deep-learning model for brain tumor segmentation and a feature extraction tool for radiomics analysis (massive extraction of measurable, numerical attributes or characteristics from medical images using data description algorithms) into the Visage platform (Visage Imaging, 2021). Visage Imaging also uses

embedding to capture and import photos, video, and voice memos from mobile devices into the patient electronic medical record (EMR).

Visage partners with research institutions like UW LaCrosse and uses its native integration capabilities to combine Visage Imaging software to manage radiology images from PACS (Picture Archiving and Communication System) and integrate them with algorithms developed by researchers. Visage servers have sufficient GPUs (graphic processing units) needed for imaging processing tasks and can run deep learning algorithms quickly on many images. The Visage open API can process many types of coding languages like Python, and PyTorch. Granular configuration allows patient images to be deidentified and made available only to selected partners, such as Ultrasound.AI. (Wolfgang Holler, Visage Imaging, personal communication, March 7, 2023).

A likely operational scenario for the Ultrasound.AI python deep learning algorithm includes (Wolfgang Holler, Visage Imaging, personal communication, March 7, 2023):

1. A radiologist examining a breast ultrasound study (multiple images for a single patient) clicks a button to send the study for AI analysis to the Visage AI Accelerator (AIA).
2. The Visage AI Accelerator sends relevant patient images from the Visage Mayo production system to the Visage research system via DICOM. (Radiologists use DICOM to store, exchange, transmit and manipulate medical images from various imaging modalities such as ultrasound).
3. Patient PHI (Protected Health Information) will be removed and hashed to a separate key file before the image reaches the research server. During the startup year, these studies would be only visible to members of Ultrasound.AI.

4. Each patient study opens up in a special hanging protocol (a way to arrange the patient breast image study in a consistent manner with an empty layout of multiple views. The radiologist drags the best two orthogonal breast images into viewer 1 and viewer 2 and the best breast doppler image in viewer 3. This step prioritizes and orders the best images for review by the radiologist and lets the deep learning algorithm know what type of image to expect. Plans are to train the Ultrasound.AI is able to prioritize images for the radiologist ahead of time.
5. The radiologist fills out a FHIR (Fast Healthcare Interoperability Resources questionnaire) that automatically opens on study load. The FHIR questionnaire captures, and communicates the data from a breast radiology exam. This data will later update the patient's EMR (electronic medical record) and BI-RADS (Breast Imaging Reporting and Data System) report.
6. At this point everything is prepared for the radiologist to view images for a patient and for the deep learning algorithm to act as a second reader. A Visage Imaging Python API can extract the raw pixel data and regions of interest (lesions), as well as relevant DICOM metadata so the radiologist can more quickly and accurately report findings for the patient.
7. Visage would then call the Ultrasound.AI python deep learning model, produced by UW La Crosse researchers, to classify the two orthogonal breast images and the doppler breast image. Our model produces a probability of malignancy for each image and writes malignancy probabilities into a separate temporary file.
8. Visage displays the images and malignancy probabilities in a pop-up window to the radiologist.

9. If desired, the radiologist clicks a button to overlay a heatmap (a machine learning algorithm to help identify regions of interest or salient pixels in an ultrasound breast image that indicate the presence or absence of breast cancer) on images in the 3 viewers.
10. If the AI agrees with the radiologist, Visage sends the captured information and relevant DICOM metadata to the patient EMR.
11. If the AI does not agree with the radiologist, the radiologist will 1) review more images for this particular patient, and 2) review the heatmap provided by the AI to understand how the deep learning algorithm arrived at its malignancy classification.

Production

Production for the Ultrasound.AI algorithm is fairly straight forward. The algorithm will be located on the Visage 7 Enterprise platform and will be available to clients as an optional software feature. Physical requirements for Visage Imaging to accommodate this additional algorithm involves one graphical processing GPU to run one concurrent instance of the algorithm (Professor Jeffrey Baggett, personal communication, March 7, 2023). Alternatively, if clients want to access the algorithm locally (for security and privacy reasons), the client radiology network will need enough GPU capacity to run the algorithm quickly on multiple images.

Customers will receive a licensing key to access the algorithm. This method controls for authorized use and provides immediate and ongoing inventory feedback to the producer, Visage Imaging. For example, as more licenses are consumed concurrently, the server or cloud instance needs to make more GPUs available to maintain high image throughput and customer

satisfaction. Visage Imaging will use their existing customer service process for their AI Accelerator to support client needs during the first two years.

Quality control for the algorithm is an important concern. A good quality practice might be for Visage Imaging to work with Mayo Clinic and UW LaCrosse on implementing the following type of feedback loop: On an ongoing basis, a new validation set of breast ultrasound images should be passed through the Ultrasound.AI algorithm and compared to actual (deidentified) patient biopsy and follow up imaging results. The algorithm's accuracy would be recalculated on an ongoing basis, depending on whether the images it classified as malignant actually proved to be malignant when biopsied or followed up. A quality control mechanism along these lines is also necessary to maintain FDA clearance for the algorithm (U.S. Food & Drug Administration, 2022).

The UW LaCrosse CADBusi team along with Visage Imaging will continue to develop the Ultrasound.AI algorithm to improve accuracy and add new features over time.

Location & Software Access

Access to the Ultrasound.AI algorithm requires adequate software licensing and ample network computing resources. Clients will be able to trial the algorithm before purchase via a trial license and will obtain a concurrent software user license or enterprise wide software license from Ultrasound.AI upon purchase.

The computing and network needs for running the new Ultrasound.AI deep learning algorithm to classify breast ultrasound images will depend on multiple factors, including size of the image dataset, the complexity of the deep learning model, the inference time requirements (throughput time per AI classified image or text annotation), and available network hardware and

software resources. Deep learning algorithms for breast ultrasound images require high-performance Graphics Processing Units (GPU), such as the NVIDIA Tesla V1001, or the NVIDIA GeForce RTX 2080 Ti2, or the AMD Radeon VII3. These processors offer multiple cores for running parts of the deep learning model in parallel. Memory bandwidth is high, allowing massive computations to be more easily completed. The Ultrasound.AI algorithm uses the python library, PyTorch, and these processors natively support the PyTorch deep learning framework. (Wolfgang Holler, Visage Imaging, personal communication, March 7, 2023). Running one instance of the Ultrasound.AI algorithm should require no more than one high-performance GPU (Wolfgang Holler, Visage Imaging, personal communication, March 7, 2023).

The Visage 7 Enterprise Imaging Platform can be dispersed through two main channels: cloud or on premise. Customers can choose to have their medical images stored and accessed either on Visage's cloud servers or, for security reasons, on their own local servers. During the startup year, 2023, Ultrasound.AI will follow Mayo Clinic policies for data privacy and access all images on the Mayo Clinic research server in Rochester, MN. (Wolfgang Holler, Visage Imaging, personal communication, March 7, 2023)

Legal Environment

Insurance coverage

Legal liability concerns are raised in a medical setting when algorithms cannot explain how they reached their decisions or if they make errors that harm patients (Dr. Rich Ellis, personal interview, February 24, 2023). There is no clear answer to what kind of insurance coverage

should be arranged for a deep learning algorithm to do breast cancer classification, but it depends on factors such as:

- **The level of involvement and supervision of human professionals using the algorithm**. The Ultrasound.AI algorithm falls into the decision support category, meaning it functions as a second reader after the radiologist reviews an image.
- **The accountability and transparency features designed into the learning algorithm**. Although more expensive to develop and maintain, deep learning algorithms can be built so the developer is able to query them and find out how they arrived at their predictions. Ideally the clinician is also able to check up on the algorithm. Ultrasound.AI will provide heatmap capability, meaning in rare cases where the algorithm does not agree with the radiologist, the clinician can review the heatmap to see how the algorithm came to its classification decision.
- **The type and extent of harm caused by the algorithm's error or failure**. The most important way to avoid algorithm error or failure is to validate it often against real (deidentified) patient images with known outcomes.
- **The regulatory framework and standards that apply to the algorithm and its developers**. The Ultrasound.AI algorithm will need FDA clearance before commercialization beyond Mayo Clinic radiologists.

Some possible options for insurance coverage include:

- Professional liability insurance for health care providers who use the algorithm as part of their practice.
- Product liability insurance for technology manufacturers who develop and sell the algorithm as part of a medical device.

Intellectual Property Protection

Copyright protection will be the best option for intellectual property protection for the Ultrasound.AI algorithm (Professor Jeffrey Baggett, personal communication, February 28, 2023). A copyright can protect the original expression of a software algorithm in its source code or object code form. However, a copyright does not protect the underlying ideas, concepts, methods, or functions of the algorithm. This protection seems appropriate, since the algorithm is built from standard python, PyTorch, and other coding libraries.

Patent protection is less applicable because to obtain a patent, the original work must be publicly disclosed in detail in a patent application. This can expose the algorithm to potential competitors. A patent can be expensive and time-consuming to obtain and enforce.

Simply keeping the Ultrasound.AI algorithm as a trade secret is not sufficiently protective. While a trade secret can safeguard aspects of a software algorithm that provide a competitive advantage, a trade secret does not prevent others from independently reverse engineering the algorithm through lawful means. A trade secret can be rendered moot if someone breaches a confidentiality agreement or violates business practices.

Personnel

Initially, personnel for the initial commercialization of the Ultrasound.AI algorithm will include the UW LaCrosse CADBusi team, a breast radiologist from Mayo Clinic and Visage

Imaging IT, business, sales, and legal staff. Key roles for rolling out the Ultrasound.AI algorithm are:

- **Domain experts**: Mayo Clinic's expert breast radiologist, Dr. Rich Ellis has deep knowledge and experience in the field of breast ultrasound classification as well as radiology AI tools. He can provide valuable insights and feedback to the AI development process. Mayo Clinic will fund this position. (Dr. Rich Ellis, personal communication, March 7, 2023).
- **Data scientists**: Initially, the CADBusi team will design, implement, test, and optimize the deep learning algorithm using various tools and frameworks, e.g. PyTorch 4 and other Python libraries. The team is led by mathematics professor, Jeffrey Baggett, and his position is funded by UW LaCrosse. Other team members are graduate and undergraduate students who work for free. These individuals have strong skills in data analysis, statistics, and machine learning (Professor Jeffrey Baggett, personal communication, March 7, 2023).
- **Product designers**: Visage Imaging will provide staff who can create and manage user-friendly interfaces and experiences for the customers who will use the Ultrasound.AI product. They manage the Visage Imaging AI Accelerator and related tools. They have skills in user research, prototyping, and testing. (Wolfgang Holler, Visage Imaging, personal communication, January 6, 2023).
- **Sales engineers:** Visage Imaging Sales Engineers will demonstrate, support, and sell the Ultrasound.AI algorithm along with related services to healthcare customers. The sales engineer also works closely with prospective customers during the trial licensing period.
- **Technical Support Engineers:** Visage Imaging Technical Support Engineers will help customers learn and use the Ultrasound.AI algorithm. These engineers will also work with the UW LaCrosse CADBusi team to provide applicable training materials.

- **Contract lawyers**: Visage Imaging can provide lawyers to help draft and review contracts with customers, partners, vendors, and employees that involve the use of the Ultrasound.AI product. They can also help us protect intellectual property rights and ensure compliance with data privacy laws.
- **Health Care lawyers**: Visage Imaging can provide lawyers to help navigate the complex health care regulatory landscape for medical devices or diagnostics. They can also help Ultrasound.AI obtain FDA approval or clearance for our breast cancer classification algorithm product, as well as deal with potential liability issues. The FDA generally classifies these type of breast image classification algorithms as medical devices for the purpose of certification. (U.S. Food & Drug Administration, 2022)

Inventory

The most important inventory issues for a software algorithm are availability and reliability. It is important that the Ultrasound.AI algorithm be available whenever a customer wants to use it or trial it. Furthermore, the algorithm needs to be maintained and validated, and sometimes updated as patient image characteristics change from the data the algorithm was trained on. A good example would be the type of ultrasound machine that takes the patient images. At first, the algorithm will only be used for Mayo Clinic images, where the same ultrasound equipment is used in clinic (GE LOGIQ®9) as was used to train the algorithm (Professor Jeffrey Baggett, personal communication, April 13, 2023). If the Ultrasound.AI algorithm is used by a hospital or clinic with different ultrasound equipment, the algorithm first needs to be validated on images from this equipment. If model performance deviates from

published accuracy statistics (known as data drift), the algorithm needs to be updated. To detect data drift, one can use methods such as detection of novelty, dynamic window adjustment, or similar statistical tests. These methods can help identify whether new input data varies significantly from the training data, and alert the model developers to retrain or update the model.

Suppliers

Visage Imaging will host the Ultrasound.AI breast image classification algorithm during the startup year. The supply chain for Visage Imaging is comprised of the components involved in the production and distribution of its imaging solutions from the supplier to the end customer. Basic supply chain components include:

Supplier: Visage Imaging is a wholly owned subsidiary of Pro Medicus Limited [ASX:PME], a leading provider of medical imaging software and services. Pro Medicus Limited is headquartered in Melbourne, Australia, and supplies Visage Imaging with financial, business, and technical support.

Manufacturer: Visage Imaging develops and produces its flagship product, the Visage 7 Enterprise Imaging Platform, which is a fast, clinically powerful, and highly scalable radiology software solution for PACS (picture archiving and communication system) management hosted on a cloud service through AWS. Visage Imaging is headquartered in North America (San Diego, California) and Europe (Berlin, Germany) where it produces its software.

Distributor: Visage Imaging has joined the AWS Partner Network (APN) as an Advanced Technology Partner. This allows Visage Imaging to leverage AWS cloud services to deliver its

Visage 7 Enterprise Imaging Platform to customers worldwide via CloudPACS, a cloud-based platform that offers anytime secure access to radiology images.

Retailer: Visage Imaging sells its enterprise imaging solutions directly to customers such as academic medical centers, integrated delivery networks, community hospitals, radiology groups and imaging centers. Key customers are Mayo Clinic, Partners Healthcare System, Emory Healthcare System and Siemens Healthineers.

Consumer: The end users of Visage Imaging's enterprise imaging solutions are healthcare professionals such as radiologists, clinicians and administrators who use the software to view, interpret and manage diagnostic images across various modalities such as Ultrasound, CT, MRI, PET/CT.

Voted best radiology viewer in imaging by the 2023 Best in KLAS Software & Services Report, Visage Imaging enjoys a prominent reputation (KLAS Research, 2023). Visage Imaging has also partnered with premium companies like Amazon, Partners HealthCare, and Siemens.

Credit Policies

It is unlikely that Ultrasound.AI will offer credit sales, at least in the beginning. We will not need to worry about managing Accounts Receivable. We will use standard practices for this type of medical software by letting potential clients trial our algorithm before purchase. In the arena of AI algorithms that assist with medical decision support, this practice can lead to a highly ethical and virtuous feedback loop. The basic process works as follows.

1. A prospective customer contacts the Visage Imaging Sales staff for a demo.

2. If our algorithm is a good fit for the customer, a Sales Engineer will help the customer set up the workflow with a 30 day trial license. All pre sales technical support is handled by Sales Engineers.
3. During the trial period, the customer can see how our algorithm fits into their workflow.
4. All parties involved with the success of the Ultrasound.AI algorithm can verify that it produces sufficiently accurate results for the customer by running through a validation set of client breast ultrasound images. This step is also important to fulfill FDA requirements for an AI medical device technology (U.S. Food & Drug Administration, 2022)
5. Once everyone is satisfied that the Ultrasound.AI algorithm works as expected and the client pays for the desired number of commercial licenses, they will receive commercial licenses, training materials and production level technical support.

Managing Your Accounts Payable

Managing Accounts Payable should not require significant extra labor or cost for the Ultrasound.AI algorithm, initially. The algorithm will run on the Mayo Clinic research server, where more GPU capacity is readily available. Salaried staff from UW LaCrosse CADBusi team and Mayo Clinic will collaborate with Visage Imaging staff to launch the algorithm in research and commercial settings.

Management and Organization

An effective corporate governance framework and a skilled management team are necessary for the success of our Ultrasound.AI startup. The executive team focuses on strategic

decision-making and prioritizes adherence to pertinent regulations. For successful commercialization of a deep learning algorithm that classifies ultrasound breast images, it's vital to implement clear Key Performance Indicators (KPIs) for the management team (Eccles & Vogel, 2022). Subsequent sections detail the suggested governance structure, management team composition, and smart KPIs.

Board of Directors

When selecting the Board of Directors for a company focused on commercializing a deep learning algorithm to classify ultrasound breast images, it is essential to look for personnel with complimentary skills. Although these individuals are not involved in daily company operations, they should help the company grow quickly, create durable brand awareness, and navigate the rough waters of startup related technical obstacles.

Ideally, board members will have a performance history of successful business leadership, particularly with rapidly growing medical technology companies. These individuals should be able to demonstrate strategic decision making capabilities, based on prior job performance or board memberships.

Members of the Board of Directors need industry and financial expertise as well as business acumen in the area of AI, deep learning, and medical imaging. To help manage risks, the board should include members with a knowledge of healthcare guidelines and AI transparency standards.

Board members must have excellent communication skills and be able to able to explain company objectives and challenges as well as persuade others to invest in Ultrasound.AI.

Board members should have widespread professional networks in the AI medical imaging sector, so they can help Ultrasound.AI create partnerships, obtain venture capital financing, and access helpful resources from the radiology community. A complementary board is resilient and can bring many different perspectives to bear on problems encountered during startup (Younger, 2021).

Board member compensation will consist of a combination of equity and stock options. This remuneration rewards their fiduciary responsibilities and contribution to decision-making. (Feld & Ramsinghani, 2014)

Plans are to create an ongoing recruitment process for potential board members. An ongoing process to engage a pool of skilled candidates will strengthen the board member network and help identify avenues to recruit high level talent for Ultrasound.AI.

Ideally, the board of directors will have members who can fulfill the following roles: One member should have an industry background in medical imaging and cancer diagnosis. This is one of the individuals who will guide the company's strategy. This member will work closely with board members and executives involved in steering marketing decisions and partnership creation.

During this startup phase, it is especially important for Ultrasound.AI to have a board member with medical imaging marketing expertise for input on strategies, brand awareness, product positioning, partnership development, and oversight of marketing metric policies. This individual will work closely with executives and board members involved in all over strategic planning.

One board member should be a physician or medical researcher with expertise in breast cancer diagnosis. This person will provide medical credibility. This expert will work closely with

the lawyer to navigate how Ultrasound.AI's addresses healthcare regulations and insurance matters, in order to mitigate compliance and liability risks.

One board member should have a background in Computer Assisted Diagnosis (CAD) or deep learning, and experience in developing and deploying AI solutions in the medical imaging healthcare sector. This individual can help steer Ultrasound.AI's strategy for refining its algorithm, which is after all the company's core product. This board member would also be able to introduce flexibility and agility to Ultrasound.AI's strategic planning, by guiding what type of algorithmic customizations or additional features may make the Ultrasound.AI software a more competitive product.

Ultrasound.AI would benefit greatly from having a member who is a lawyer with experience in healthcare regulations, intellectual property, and patient data privacy. This member will control risk by overseeing that the company complies with relevant medical and data regulations. Ideally, this individual will have prior board or executive experience with medical software startup companies. In that case, this board member can shape fundraising and investor activities as well as guide equity structures to grow the startup.

Finally, Ultrasound.AI needs a member with a financial background who can manage budgets, raise capital, and oversee financial planning for an AI technology company. This member will work closely with the law professional board member to mitigate risk and achieve financial stability for Ultrasound.AI. This board member will also support strategic planning actions.

Management team

Ultrasound.AI's management team will partner with its board of directors to achieve company goals and launch a competitive algorithm into the medical imaging marketplace. The management team consists of executive personnel who excel at delivering efficient daily leadership, implementing strategic decisions, and overseeing operations.

The management team should have a deep understanding of how AI technology can be used in healthcare companies serving radiologists. The executive team carries out strategies designed by the board of directors and will execute and update Ultrasound.AI's business plan. These executives will oversee company finances, employees, and contractors, as well as manage marketing and customer relations functions. Ultrasound.AI executives will establish new industry relationships, manage regulatory compliance, and attract needed technical and management talent. Additionally, they will build a strong brand identity, and develop flexible approaches in the rapidly evolving AI medical imaging market. Executives will be skilled leaders in their respective domains.

Key qualifications for the management team include: Leadership and decision-making abilities, experience in growing medical imaging technologies, excellent communication, and interpersonal skills, demonstrated strategic and problem-solving capabilities. Additionally, the management team should have a deep and wide professional network among radiologists, medical imaging device companies, and research institutions that develop AI assisted imaging software.

Management team roles are covered in the following section.

CEO (Chief Executive Officer): The CEO develops and executes the company's overall strategy, leads the executive team, and develops associations with investors, partners, and other

stakeholders. This individual also works closely with the Chief Operating Officer and Chief Financial Officer to oversee the financial performance for the company. Ideally, for Ultrasound.AI, the CEO will be able to grow successful partnerships with universities developing medical imaging algorithms, radiology software companies and imaging device makers. The CEO should be able to communicate Ultrasound.AI's value proposition to potential investors. This individual must also be able to address regulatory challenges and technical obstacles that could limit Ultrasound.AI's growth.

CTO (Chief Technology Officer): The CTO will oversee Ultrasound.AI's core product, the development and improvement of the deep learning algorithm and related technologies. This individual will lead the research and development team. For Ultrasound.AI, the CTO will need to develop a talent pipeline of machine learning and deep learning software engineers who can collaborate on validating, maintaining, improving, and extending the Ultrasound.AI algorithm. The CTO will work closely with legal executives to manage intellectual property and technology partnerships. The CTO should have a strong technical background in deep learning related to medical imaging. This individual needs experience in managing research teams and the ability to leverage emerging medical technologies. The CTO also needs to have a professional network among institutions and companies that develop or produce medical imaging software.

The startup success of Ultrasound.AI is intrinsically bound up in the ability to retain suitable high performing technical talent. The concept of the 10 times software engineer has been validated since first studied and reported in 1968 (Sackman et al., 1968). This study found that the best software engineers are at least ten times as productive as the lowest performing software

engineers. Compensation plans for Ultrasound.AI should offer equity as well as salaries to attract top technical talent who are able to develop or improve AI assisted radiology software.

COO (Chief Operating Officer): The COO is the primary executive to oversee day-to-day activities of Ultrasound.AI. This individual will support the CEO in implementing strategic plans for the company. Important duties for the COO include seamlessly managing logistics. This individual makes sure that infrastructure needs are met for employees, contractors, and customers. Initially, this individual will work closely with personnel managing the Visaging AI Accelerator environment. Ultrasound.AI needs adequate GPU resources and access to Mayo Clinic's research server. During the initial commercialization phase, potential customers will need to access the Visage AI Accelerator environment and validate the Ultrasound.AI algorithm on their clinic's ultrasound breast images. The Visage Imaging infrastructure will need to be flexible enough to acquire customer images (Wolfgang Holler, Visage Imaging, personal communication, March 7, 2023). The COO should have demonstrated skill in operations management, preferably in AI or CAD for the medical imaging industry.

CMO (Chief Marketing Officer) This individual will develop and execute Ultrasound.AI's marketing plans. For Ultrasound.AI, the CMO position is key to growing the company quickly by expanding the company's brand and reputation. Testimonials from Mayo Clinic radiologists will help to promote the Ultrasound.AI algorithm. The CMO manages the marketing team and will oversee efforts to identify trends for AI assisted breast image interpretation as well as new markets for the Ultrasound.AI algorithm. One example would be to customize the algorithm to classify ultrasound

thyroid images to predict thyroid cancer. This individual will create and manage marketing campaigns across numerous channels, including digital, social media, medical conferences, and traditional media. During the startup period, the CMO will work closely with the CTO and company radiologists to publish articles in radiology journals about the efficacy and capabilities of the Ultrasound.AI algorithm. The CMO will partner with the sales team to generate leads. Presenting at radiology conferences would be a potential route to engage radiologists and generate new leads. This individual is also charged with monitoring marketing performance metrics. The CMO should have proven experience in leading marketing teams and campaigns, preferably in AI image classification, medical imaging, or related technologies.

CFO (Chief Financial Officer) a. The CFO will oversee the company's financial planning, budgeting, and accounting activities and manage relationships with investors and financial institutions. This individual will implement financial procedures, controls, compliance with financial standards, and manage the company's financial risks. The CFO will prepare financial reports for the executive team and board of directors. This individual should have proven experience in financial leadership roles, preferably in medical AI, healthcare, or related industries. The CFO will assist other executives and board members to network with potential investors in the field of computer-aided radiology diagnostics.

Key Advisors

Key advisory roles supporting the management team in establishing Ultrasound.AI may include the following direct hires or consultants:

Accountant: The accountant will help Ultrasound.AI establish procedures for financial and tax planning, financial reporting, and will advise on audit practices for the company.

Attorney: The attorney is a key advisory role for Ultrasound.AI and can help the company manage risk by supervising partnerships, contracts, and licensing agreements. An attorney can protect Ultrasound.AI's intellectual property rights, including copyrights, and trade secrets. The attorney may assist with the company's incorporation documents. This individual will work with legal specialists to make sure that Ultrasound.AI adheres to healthcare regulations, such as FDA approval processes, and HIPAA laws. The attorney may also advise whether Ultrasound.AI needs insurance coverage.

Insurance Agent: During the startup phase for Ultrasound.AI, an insurance agent may be needed to recommend appropriate insurance policies for general liability, professional liability, property, and workers' compensation insurance. This individual will know whether to recommend cybersecurity and product liability insurance for Ultrasound.AI's deep learning algorithm.

Banker: The bank selected for Ultrasound.AI will provide financial services such as credit cards, checking and savings accounts. Bank professionals will assist the startup with obtaining loans and other financing options. The bank may advise solutions to manage cash flow.

Other Key Advisors: Some individuals may assist Ultrasound.AI during the startup phase with valuable knowledge based on their experience in harnessing machine learning processes for medical imaging. Other individuals may facilitate introductions to potential partners, investors, customers, or other key stakeholders. It will be especially important to identify and meet with potential venture capitalists. Regarding initial funding for Ultrasound.AI, Mayo Clinic will likely provide money and personnel, once the UW LaCrosse team is close to developing a minimally viable product (MVP) that is better than our major competitor's product, the Koios DS system. Initially, Ultrasound.AI may assist Mayo breast radiologists with classifying ultrasound images owned by Mayo Clinic.

Performance Metrics

Assessing the performance of the CEO and executive management team provides important feedback for the success of Ultrasound.AI. Quantitative and qualitative metrics, known as Key Performance Indicators (KPIs), can be implemented. Following are some smart measures to consider when assessing team performance (James Brausen, MBA, personal communication, March 8, 2023):

Revenue growth: Evaluate the company's quarter-over-quarter revenue growth compared to industry standards or financial data from competitors.

Profit margin: Assess the company's ability to maintain or improve its profit margin over time.

Return on investment (ROI): Analyze the ROI on projects led by the executive team.

Cost efficiency: Monitor how well operating expenses are managed.

Product development milestones: Track the progress of developing and updating Ultrasound.AI's deep learning algorithm to classify images for breast cancer against documented milestones.

Market share: Compare the company's market share and its growth to competitors. Koios Medical is our major competitor.

Brand awareness: Evaluate the effectiveness of marketing efforts and brand recognition among our target market, breast radiologists.

Customer satisfaction: Radiologists are our major customers. Keep track of customer satisfaction rates through surveys and having the sales team follow up via phone calls. Validate deep learning algorithm performance against clinical radiology images on a regular basis.

Talent acquisition: Evaluate the success of recruitment efforts, especially the ability to retain machine learning experts with experience in CAD for breast cancer image classification.

Leadership development: Analyze the professional growth of management team members.

Strategic alignment: Check that the CEO and executive management team align their decisions with the company's long-term goals.

Risk management: Evaluate the team's ability to identify, assess, and mitigate potential risks to Ultrasound.AI.

Regulatory compliance: Verify that the CEO and management team adhere to applicable laws, medical device regulations, and radiology imaging standards.

Board engagement: Evaluate the effectiveness of cooperation between executives and members of the board.

Startup Expenses and Capitalization

Ultrasound.AI is a startup company that seeks to commercialize a deep learning algorithm that will classify breast ultrasound images. The startup budget functions as a financial blueprint for the company's initial stages and helps to apportion resources properly. Principally, the startup budget needs to address key expense categories such as equipment and software costs, image acquisition and data storage (U.S. Small Business Administration, 2021).

A primary concern during the startup stage will be to produce a competitive deep learning algorithm that is able to predict malignancy for breast ultrasound images. A process needs to be developed to validate the algorithm against actual clinic ultrasound images prior to purchase. Continual investment needs to be available to improve the accuracy and throughput of the algorithm.

The budget needs to manage expenses related to obtaining FDA and potentially European Union clearance for Software as a Medical Device (SaMD).

During the startup phase, it will be particularly important to hire and retain appropriate talent to help Ultrasound.AI expand quickly and address technical problems with commercializing a new deep learning algorithm. Technical personnel need to be both experienced and have a broad skillset in the areas of deep learning, medical imaging, data science, and technical support.

Offering stock or equity in lieu of salary could be a valuable practice for Ultrasound.AI, especially in the early stages when venture capital and cash flow may be restricted (Rose, 2016). This approach can help attract needed talent and align employee interests with the company's path to success.

The startup budget will allot funds for marketing and sales efforts to create brand awareness, and showcase the company's medical imaging offerings. The startup budget also includes initial operational expenses for day-to-day costs, such as office rent, utilities, hardware, and software (DeBaise, 2010).

Table 3 gives detailed annual start-up expenses and revenues for Ultrasound.AI. This financial data is based on financial data from our main competitor, Koios Medical (Appendix A, Appendix B) These tables are also available in Appendix C for quick reference.

Between 20% to 50% of the first year's operating expenses should be budgeted for startup costs (Rose, 2016). Using $4.1 million in annual operating expenses for Koios Medical (Appendix A), the total startup budget for Ultrasound.AI will be estimated at $2,100,000 (Table 2).

Based on consulting a variety of startup calculators for technical companies, the total $2,100,000 is divided among individual startup expenses in an apportioned manner. A typical 10% of these expenses were designated as contingency expenditures (Black, 2022). I also consulted my team to get an idea of what expenses are most important during the startup phase, and allocated extra money for these expenses (Professor Jeffrey Baggett, personal communication, March 21, 2023).

Table 3 – Startup Budget for Ultrasound.AI

Startup Revenues


Startup-Revenues.xlsx

Startup Expenses


Startup-Expenses.xlsx

Financial Plan

The financial plan for Ultrasound.AI consists of a twelve month profit and loss estimate, a cash flow plan, a projected balance sheet for 2023, the startup year, and for 2024, the first year of operation. A break-even calculation is also included. These documents are included at the end of each section and again for quick reference in Appendices D – G. Collectively, these statements provide an initial estimate of the company's financial outlook. Ultrasound.AI will primarily sell two products. An enterprise site license for a deep learning algorithm to classify ultrasound breast cancer images will be priced at $20,000, annually. Individual licenses, registered to a single radiologist will be priced at $1,000, annually (Amy Fowler, Koios Sales VP, personal communication, March 6, 2023). Key financial data was sourced from a purchased financial report about Koios Medical, a private company, who is our primary competitor. Overall financial numbers include an annual revenue of $5,000,000, annual operating expenses equal to $4,100,000 and annual investments of $4,200,000 (Appendix A, Appendix B).

Twelve month profit and loss projection

The centerpiece of the financial plan is a profit and loss projection based on twelve months of revenue and twelve months of expenses, attached below. A key component for this document is the Cost of Goods and Services, also known as Cost of Sales (COGS). COGS categorizes costs spent by the company to directly produce its main goods or services (Alexander, 2018). For a medical deep learning algorithm, these costs entail research and development of the algorithm. Maintenance and improvement of the algorithm also fall into this category. Less obvious are expenses such as wages or FDA certification. However, salaries for technical personnel who work directly with the algorithm should be considered COGS, while Human Resources and other business related personnel costs would be considered a non COGS expense. Regulatory costs such as FDA certification could also be considered a COGS expense. Gross profit represents total revenue minus Cost of sales. Finally, net profit equals total revenue minus total expenses (Alexander, 2018).

A twelve month profit and loss statement is a standard way for the company's financial personnel and investors to quickly understand how profitable the company will be over the next twelve months (Black, 2022) . Sometimes, a technology company will not be profitable in the early stages. In that case, financial personnel and executives will know how much external investment is needed and what major categories of expenses need to be covered. The revenue portion of the document will clearly show potential investors or lenders what revenue the company expects to achieve. Ideally the profit and loss statement will be updated and extended into the future as months go by. The attached profit and loss statement estimates an annual net profit of $475,000 for Ultrasound.AI in 2024, the first year of operation. An estimate of

$5,000,000 annual revenue was sourced from our competitor Koios Medical. It is broken down into 80% from the sale of the deep learning algorithm and 20% for professional services (James Brausen, MBA, personal communication, March 8, 2023). Professional services include customizing and revalidating the algorithm for different radiology clinic workstations. Total cost of sales are estimated to be $1,500,000, 30% of total revenue. This cost includes the labor needed to maintain, improve, certify, and continually validate the Ultrasound.AI algorithm (Professor Jeffrey Baggett, personal communication, April 13, 2023). Since Cost of Sales is not expected to increase much, and revenue is anticipated to grow around 7 % annually, Cost of Sales will represent a much smaller portion of revenue going forward (Emergen Research, 2022).

Other expenses are estimated at $3,025,000, annually, based on our Competitor, Koios Medical (Appendix 1). The breakdown of these expenses is based on startup calculators (Black, 2022) and input from project team members. A standard 10% of these expenses were designated as contingency expenditures (Rose, 2016)

Table 4 – Twelve Month Profit and Loss Projection

Cash Flow Projection

A twelve month cash-flow projection shows monthly inflows and outflows of money to the company, and is attached below for Ultrasound.AI. A key feature of this document highlights monthly differences in revenue and expenses, rather than just focusing averages (Alexander,

2018). For example, Ultrasound.AI's main source of revenue will be enterprise site software subscriptions. Ideally the subscription fee will be collected in advance of providing the service. The initial Ultrasound.AI cash flow forecast, however, shows the same cash inflows and outflows each month. This represents a starting point and should be updated as the year progresses. Cash outflows are usually not the same every month. For example, taxes may be paid quarterly. Subscription fees for developer software tools may be paid at the beginning of the year. A cash flow statement is good at highlighting the vagaries of monthly income and payments. In case the cash balance at the end of any month is projected to be near zero, it is important to add revenue, or money from an investor or lender prior to this point. Accurately maintaining the cash flow plan ensures discipline so that the company does not unexpectedly run out of money. Financial personnel and potential investors want to understand how Ultrasound.AI creates steady income and covers expenses at a detailed, monthly level. The attached Ultrasound.AI cash flow document shows a starting cash position of $4,500 in January 2024 (sourced from the projected balance sheet) and an end of year cash position of $2,079,500. Monthly cash flowing in comes from software sales and professional services revenue ($416,667). Monthly investment during 2024 is estimated at $350,000, or $4,200,000 broken into 12 equal installments (Appendix A).

Monthly Cost of Sales equals $41,667 and represents about 13% of operating expenses ($312,500) This percentage is typical for the first years of a software startup company (James Brausen, MBA, personal communication, March 8, 2023). The largest monthly Cost of Sales are wages ($16,667), paid to individuals maintaining the algorithm.

Monthly operating expenses, unrelated to Cost of Sales, equal $312,500. The largest expense ($133,333) represents payroll and benefits. The next largest expense categories are sales

($16,667) and marketing ($16,667). It is important to spend enough money on sales and marketing in the early years of a new startup in order to achieve a 7 % compound annual growth rate in revenue available to the medical imaging market (Emergen Research, 2022). Other monthly cash outflows include principal loan repayments ($200,000) and payments to the owners ($50,000). It is felt that the steady increase in the monthly cash balance, ranging from $4,500 to $2,079,500 at year end can cover this level of repayments.

Table 5 – Cash Flow Projection


Cash-Flow-Projection.xlsx

Projected Balance Sheet

A balance sheet exhibits the assets and the liabilities held by a company. Assets minus liabilities equals owner equity (Alexander, 2018). The balance sheet represents a financial snapshot in time for our company, Ultrasound.AI, and is attached below. This statement also shows financial information not captured on a profit and loss, or a cash flow document, for example “Goodwill”.

The Ultrasound.AI balance sheet shown below has three tabs. The first summary tab, consolidates assets and liabilities and shows the annual balance or owner’s equity. This tab also graphs assets and liabilities. The second tab details assets and the third tab details liabilities and investments. The annual investment for Ultrasound.AI is shown as a liability because the money comes from lenders and investors and needs to be paid back with interest. As a result, the

summary tab shows a small positive opening day balance ($4,500) at the end of the start up year and the beginning of the first operating year. This balance indicates that Ultrasound.AI will not be very profitable at the end of the start up year but appears much more profitable at the end of the first operating year (balance or owner equity equals $2,054,500). The increased balance is due to $2,100,000 assigned to "Goodwill" during the first operating year, compared to $50,000 during the startup year. These figures are based on Koios data (Appendix 1) and are typical for successful medical companies that sell deep learning algorithms (Amy Fowler, Koios Sales VP, personal communication, March 6, 2023). Typically, after a startup period, when the algorithm demonstrates clinical results that validate results in previously published papers, it can generate substantial Goodwill assets that a buyer would pay for if the company were sold at this point (Yahoo Finance, 2022).

Table 6 – Projected Balance Sheet

Break-Even Analysis

A break-even analysis forecasts the sales volume necessary to cover expenses at a specific price point (Shelters, 2013). For a medical AI startup, the break-even analysis can help financial and sales personnel set software pricing and understand the effort involved in selling enough software licenses to cover costs (James Brausen, MBA, personal communication, March

8, 2023). In the case of Ultrasound.AI, the software will initially be priced at two levels. The break-even point for the enterprise site license is only 198 licenses (analysis attached below), which may not seem an overwhelming target for the sales personnel. However at $20,000 per site license, sales personnel may need to put forth a lot of effort to develop relationships with potential customers, healthcare companies, imaging device makers and other players in the healthcare imaging sector, to prove how adding the algorithm to the radiology workflow will make economic sense.

On the other hand, when pricing the algorithm at $1,000 per registered radiologist license, the break-even analysis shows that nearly 4,000 licenses need to be sold to cover costs. In this case sales personnel need to go after volume sales with less time spent engaging each individual customer. Targeting well crafted presentations at radiology conferences or break-out sessions could be a way to reach many radiologists at one time.

Further break-even analyses can be generated by forecasting a mix of selling site licenses and individual licenses. Additionally, more revenue can be obtained by selling professional services like training or customization of the algorithm.

Table 7 – Break Even Analysis

Next Steps

"I will not follow where the path may lead, but I will go where there is no path, and I will leave a trail" (Strode, n.d., para. 1).

Situation

The most prevalent cancer diagnosed in women is breast cancer. Approximately 300,000 new cases are diagnosed annually in the United States (Shen et al., 2021). Human radiologists are not keeping up with the imaging workload based on multiple factors. United States breast cancer rates keep increasing in an aging female population. Ultrasound images are becoming more complex and time consuming to review. More images are generated for each patient study (Dr. Rich Ellis, personal interview, February 24, 2023). Survival rates improve with early detection. Computer Assisted Diagnosis, especially deep learning algorithms can help the radiologist prioritize images, as well as review additional images more quickly and more accurately.

Target

Ultrasound.AI seeks to develop a deep learning algorithm to help radiologists diagnose breast abnormalities earlier and more accurately, compared to image review conducted solely by humans. We aim to reduce unneeded biopsies (false positives) by at least 35 % (Shen et al., 2021). This improvement will free up radiologist time and save money for insurance companies and patients. The Ultrasound.AI algorithm is easy to use for the radiologist and offers much wanted flexibility. The algorithm is able to preview and rank all images for a patient, as well as identify lesions. Alternatively, radiologists can manually inspect images, identify lesions, and

request the algorithm to assess the associated cancer risk (Wolfgang Holler, Visage Imaging, personal communication, March 7, 2023). Since our algorithm is more flexible than competitor products, it is poised to gain broad acceptance and adoption.

Path and Proposal

Ultrasound.AI expects to commercialize its algorithm within two years. We expect to publish results of our deep learning algorithm in a radiology journal this year.

With our next update, the Ultrasound.AI algorithm in collaboration with partner, Visage Imaging, will further save radiologist time by generating standardized diagnosis and treatment data (BI-RADS report) for the patient's electronic medical record.

Ultrasound.AI plans to partner with an ultrasound equipment maker. Customizing the algorithm for a brand of ultrasound machine will make the algorithm even more accurate. Validation to keep the algorithm updated is also more robust if deidentified patient biopsy results can be correlated with image prediction for a single equipment brand.

Ultrasound.AI plans to expand the "human in the loop" concept for our algorithm. In the forthcoming version, we will take markings made by the ultrasound technician and use those to guide the deep learning algorithm's lesion detection capabilities. This feature enhancement will provide several benefits. By having a trained technician indicate possible lesions, the algorithm is less prone to flagging image areas as potential lesions that humans do not recognize as such. A future benefit would be the provision of deidentified biopsy data back to the ultrasound technician, in order to provide feedback on improving lesion detection.

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Appendix A – Koios Medical Revenue, Growth & Competitor Profile

KOIOS MEDICAL Competitor Profile.do

Appendix B – Koios Medical - Crunchbase Company Profile & Funding

Koios Medical Crunchbase.pdf

Appendix C – Startup Budget

Startup-Revenues.xlsx

Startup-Expenses.xlsx

Appendix D – Twelve month profit and loss projection

Profit_and_Loss_Projection.xlsx

Appendix E – Cash Flow Projection

Cash-Flow-Projection.xlsx

Appendix F – Projected Balance Sheet

Projected_balance_sheet.xlsx

Appendix G – Break Even Analysis

Break-even-Analysis.xlsx