Conquer Cancer through AI

2024 4Q, IR Letter

Lunit

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1. Record Accumulative Revenue of 34.1 Billion KRW in Q3 2024
   'Profitability improved while Growth Momentum Continued'
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3. Volpara, Contract with the U.S. Defense Health Agency (DHA) valued at $7.3 million over 5 years
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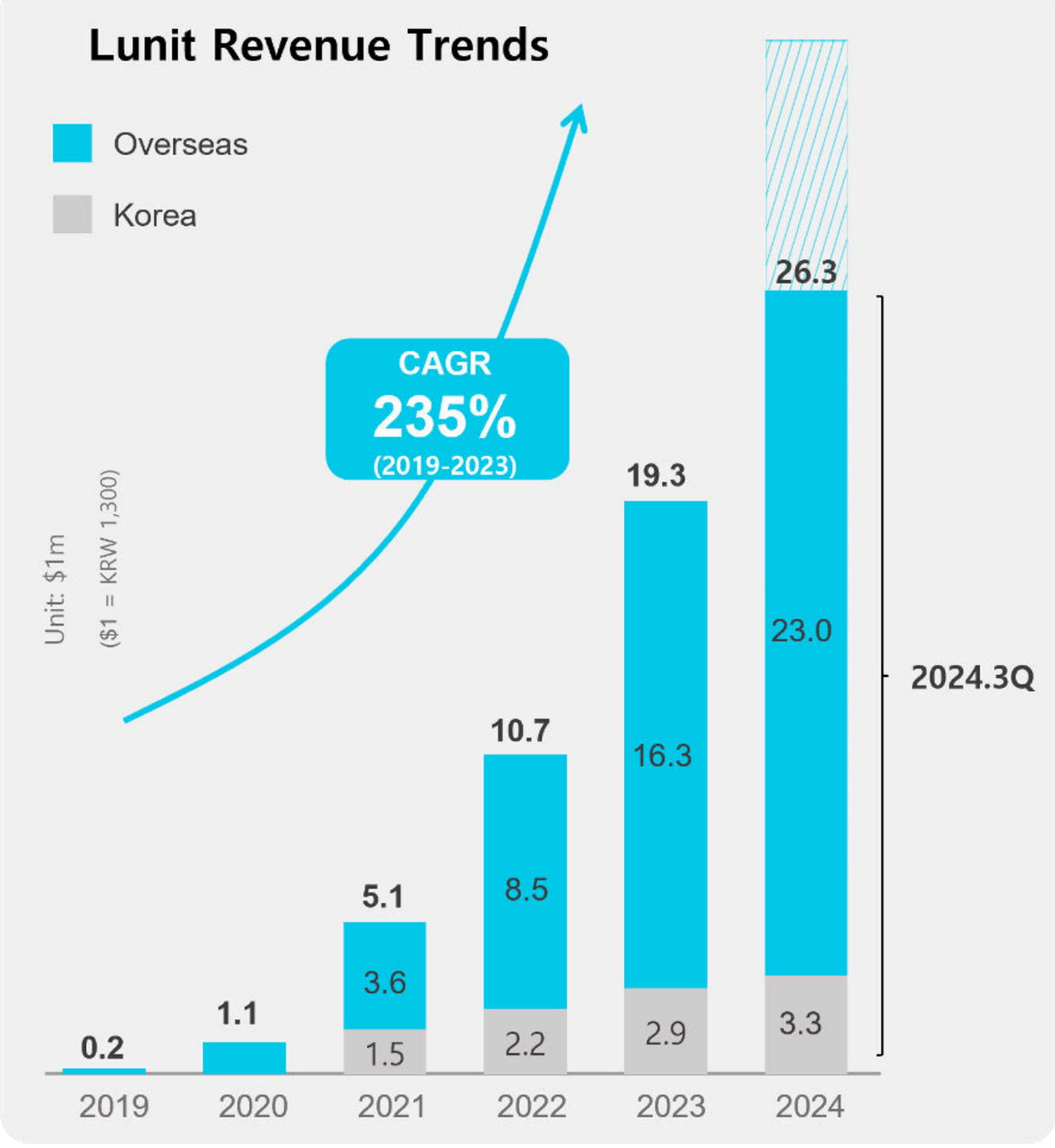
1. Major Activities

(1) Sales Performance

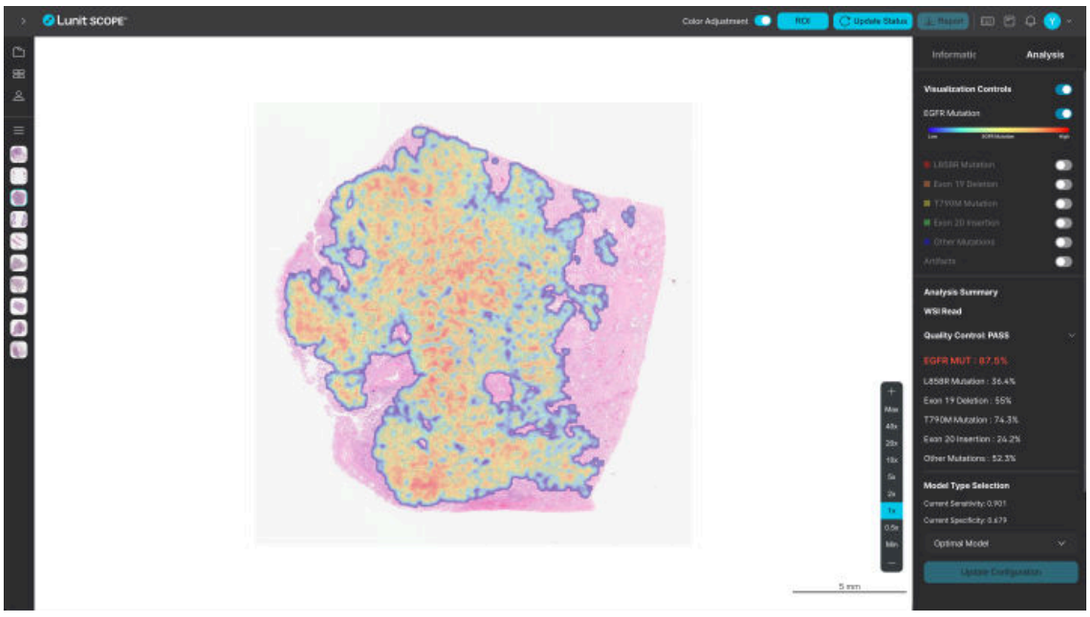
Record Accumulated Revenue of 34.1 Billion KRW in Q3 2024: Improved Profitability amid Continued Growth Momentum



[2024.09] Lunit (hereinafter referred to as "the Company") reported consolidated cumulative revenue of 34.1 billion KRW for 3Q 2024, reflecting a significant year-over-year increase of 73.4%. This growth underscores the successful integration with Volpara Health Technologies (hereinafter referred to as "Volpara"), acquired by the Company May 2024, which has established a stable revenue foundation. In addition to the integration, the global adoption of *Lunit INSIGHT*®, expansion into Korea's non-reimbursed markets, and the growing use of *Lunit SCOPE*® for research use have further accelerated revenue growth. Despite an operating loss of 16.4 billion KRW in Q3-marking a 17.6% decrease loss from the previous quarter-this was largely attributed to the elimination of one-time expenses related to the Volpara acquicisition. The full recognition of Volpara's revenue has offest these costs, signaling improved operational efficiency moving forward. The Company remains committed to strengthening synergies with Volpara and sustaining strong growth momentum. By collaborating with global pharmaceutical companies, Lunit aims to solidify its leadership in the AI biomarker space.

(2) Contracts

Strategic Collaboration with AstraZeneca to Develop AI-Powered Digital Pathology Solution: Potential for Further Expansion



[2024.11] The Company announced a strategic collaboration with global pharmaceutical company AstraZeneca to develop an AI-powered digital pathology solution for non-small cell lung cancer (NSCLC). This marks the Company's first partnership with a global pharmaceutical company since launching its AI biomarker platform, *Lunit SCOPE Genotype Predictor(Lunit SCOPE GP)*, in the global market in 2023.

The solution in focus is *Lunit SCOPE® GP*, an AI-powered tool capable of analyzing H&E slide images and predict the likelihood of tumors harboring NSCLC driver mutations, such as Epidermal Growth Factor Receptor (EGFR) mutations. Identifying patients with such mutations is critical for determining the most suitable therapies for specific cancer types, including NSCLC. Genomic testing in NSCLC often proves resource intensive and time consuming, and is frequently bypassed due to the urgency of initiating treatment. By leveraging the *Lunit SCOPE GP*, the collaboration aims to create a rapid and cost-effective AI screening tool that predicts NSCLC driver mutations directly from H&E-stained tissue samples.

In addition to this initiative, Lunit and AstraZeneca will explore opportunities for future molecular biomarker predictions based on H&E slide analysis. The collaboration is focused on enabling further development, extensive validation, and ultimately making these AI-powered solutions accessible to laboratories and healthcare institutions worldwide.

Partnership with VIDI Group: Bringing AI-Powered Mammography to Over 400 Sites Across France

[2024.11] The company has entered into a strategic alliance with VIDI Group, the largest private radiology and radiotherapy network in France, to supply its AI-powered mammography solution, *Lunit INSIGHT MMG*. VIDI group operates a network of 400+ sites across France, with more than 1,200 doctors and handling approximately 10 million imaging cases annually-representing a 23% of market share in France's private radiology sector.

This collaboration will facilitate the seamless and efficient deployment of *Lunit INSIGHT MMG* across VIDI's 400+ sites. Through this partnership, the Company aims to strengthen its presence in the French market while also exploring broader opportunities with VIDI, including education, communication, and product development, fostering further innovation in radiology.

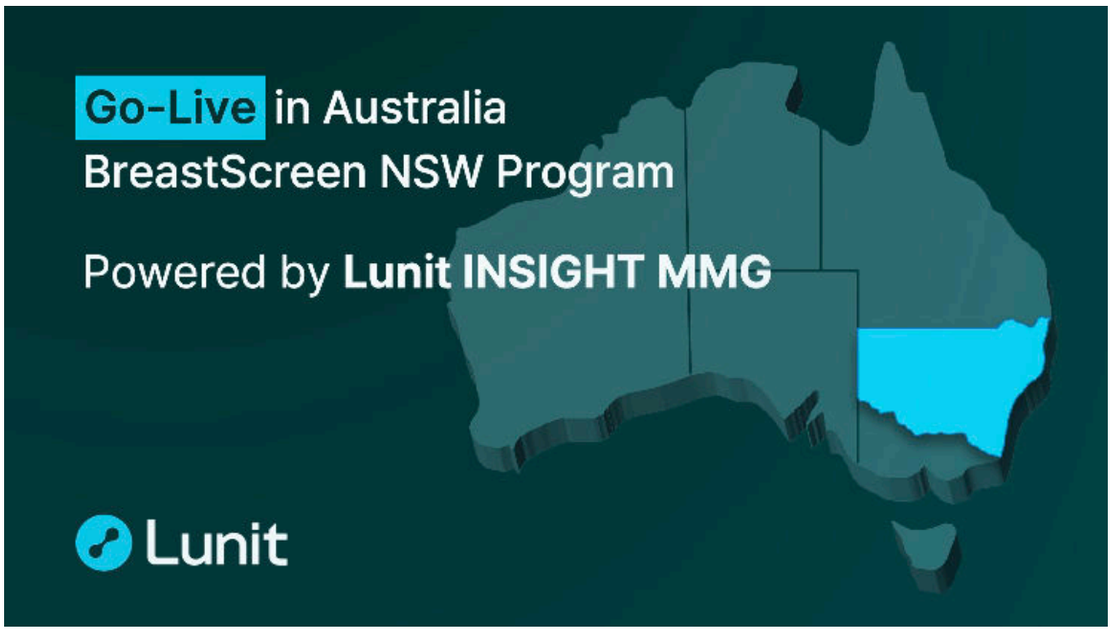
Volpara Secures $7.3 Million Contract with U.S. Defense Health Agency (DHA): A Milestone in Full Integration with Lunit

[2024.11] Volpara has signed a contract with the U.S. Defense Health Agency (DHA) to supply Volpara's *Patient Hub*™, an advanced mammography reporting, cancer risk assessment, and patient tracking system. The DHA, a division of the U.S. Department of Defense, oversees healthcare services for approximately 9.6 million individuals, including active-duty military members, veterans, and their families across the Army, Navy, Air Force, and Marine Corps. Under this contract, *Patient Hub*™ will be newly implemented across DHA sites, with a total value of $7.3 million (approximately 10 billion KRW) over 5 years.

Volpara's successful certification to meet the Department of Defense's stringent security standards underscores its dedication to patient care and data security. This achievement represents a significant milestone, highlighting the synergy generated through the full integration of Volpara with Lunit.

(3) B2G

Go-live in Groundbreaking National AI Cancer Screening Program in BreastScreen New South Wales(BSNSW): Accelerating Expansion of Global B2G Business



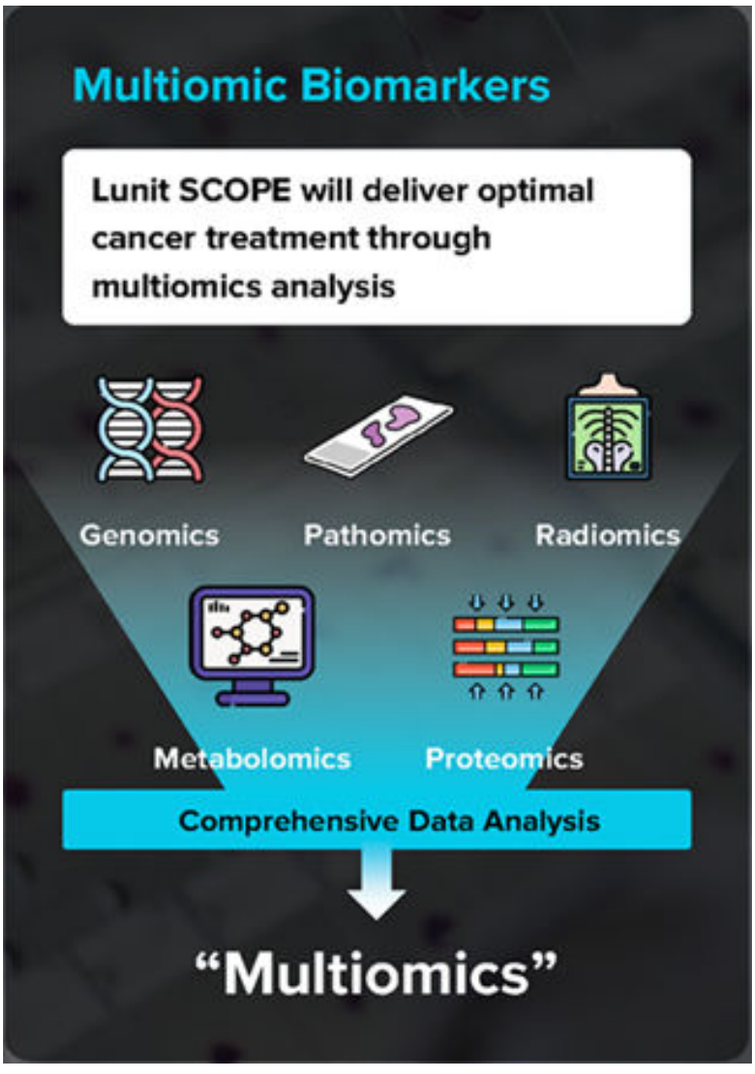
[2024.12] The Company announced the successful Go-Live of collaboration with BreastScreen NSW (BSNSW), initiated as the world's first integration of AI technology into a national cancer screening program. BSNSW, part of BreastScreen Australia, provides mammography screening services to approximately 370,000 women over age of 40 annually across New South Wales.

The BSNSW project has been three years in the making and marks a transformative achievement in advancing early breast cancer detection in the state. With the successful Go-Live, Lunit INSIGHT MMG will initially assist in reading approximately 31,000 mammography exams per year, initially targeting women aged 50–59 undergoing their first round of screening. Upon successful validation of this phase, Lunit is expected to secure the operational rights for BSNSW until 2029 without the need for additional bidding, ensuring stable revenue growth.

In addition to the BSNSW project, the company was also selected for Iceland's national breast cancer screening program earlier this year. The company remains committed to accelerating the adoption of its AI-powered solution in national cancer screening programs globally.

(4) Patents

Patent Registration for Multiomics: Method and System for Predicting Biomarker Expression from Medical Imaging



[2024.11] The Company has secured a U.S. patent for a method that determines the optimal lesion for biopsy by identifying the likelihood of biomarker expression across multiple lesions visible in medical imaging, such as CT (Computed Tomography) and MRI (Magnetic Resonance Imaging). This innovation enables the selection of the most suitable lesion before biopsy, minimizing the need for unnecessary procedures and improving patient outcomes.

In 2023, the company announced its "Vision 2030” during its 10th anniversary, which includes advancing AI-powered "Medical Big Data Platform" development. As part of this vision, the Company has been focusing on multiomics biomarkers to optimize cancer treatment. By integrating radiomics, analyzed using *Lunit INSIGHT*®, with pathomics, analyzed using *Lunit SCOPE*®, the Company aims to enhance cancer treatment predictions. These next-generation multiomics biomarkers are expected to play a pivotal role in identifying the most effective treatment for individual cancer patients.

This patent method uses machine learning models to analyze medical images such as CT and MRI, extracting biomarker expression data from multiple lesions. Based on this biomarker expression data, relevant information regarding biopsy procedures (e.g., tissue collection methods, collection locations, or prioritization of tissue collection) is determined. This approach streamlines the biopsy process, which can be physically challenging to the patient's health. The patent holds significant value as it secures exclusive rights in the U.S. for the integration of radiomics (image analysis) and pathomics (pathological information) within the multiomics technology field.

2. Research

(1) Academic Society

SITC 2024 - Presentation of an Abstract (*Lunit SCOPE*®): *Lunit SCOPE*® Highlights Potential for Predicting Immunotherapy Response in Rare Cancer Patient

[2024.11] The Company presented groundbreaking research findings at the Society for Immunotherapy of Cancer (SITC) 2024 Annual Meeting, demonstrating the potential of its AI, *Lunit SCOPE IO*®, to predict immunotherapy outcomes for patients with rare tumors. The abstract was accepted as a Rapid Oral presentation. And it has also been selected as one of the SITC TOP 100 abstracts, underscoring its potential significance and impact in the field of immunotherapy.

The research, conducted in collaboration with The University of Texas MD Anderson Cancer Center, analyzed biopsy slides from 84 patients across more than 10 rare tumor types. The research utilized Lunit's AI-powered whole-slide image analyzer, *Lunit SCOPE IO*®, to measure intratumoral tumor-infiltrating lymphocyte (iTIL) and tumor content (TC).

Key findings from the study as follow; In certain tumor types, patients with higher pre-treatment iTIL density showed a 51% lower risk of disease progression or death (improved progression-free survival, PFS; HR: 0.49), Patients who had greater iTIL density increase at on-treatment biopsy showed a 35% lower risk of disease progression or death (HR: 0.65) and a 41% lower risk of death (improved overall survival, OS; HR: 0.59), Patients with greater tumor content decrease at on-treatment biopsy had a 49% lower risk of disease progression or death (HR: 0.51) and a 46% lower risk of death (HR: 0.54), Most notably, patients who experienced both a greater iTIL density increase and tumor content decrease showed dramatically improved outcomes: 68% lower risk of disease progression or death, 72% lower risk of death.

This study has demonstrated the value of *Lunit SCOPE IO*® in an important clinical setting, showcasing its potential to personalize treatment for patients who have limited therapeutic options. By expanding the capabilities of *Lunit SCOPE IO*®, the Company aims to further advance innovative cacner care solutions in collaboration with leading cancer research institutions, ultimately transforming treatment paradigms for patients with rare cancers.

RSNA 2024 - Presentation of 24 Abstracts Showcasing *Lunit INSIGHT*® and Volpara Solutions:

- **Multi-Reader Multi-Case Study Using *Lunit INSIGHT CXR*:** Empowering Clinicians Through AI-Assisted Chest X-ray Interpretation
- **First Real-World Results:** Efficiency Gains and Enhanced Screening Metrics

- **Retrospective Analysis Using *Lunit INSIGHT DBT***: Enhancing Breast Cancer Detection Across Diverse Populations
- **Volpara's Imaging Software with the Volpara TruPGMI™ PGMI score:** Confirmed Improvement in overall examination quality
- **Volpara' Volumetric Breast Density (VBD):** Synergy in accuracy with AAPM TG282 method for estimating breast radiation dose compare to current Average Glandular Dose(AGD)
- **New Integrated AI Solutions from Lunit and Volpara**: Unveiled two integrated AI-powered solutions, created through the synergy between the two companies.

[2024.12] The Company and its subsidiary Volpara presented 24 abstracts at RSNA 2024, focusing on advancements in AI-powered cancer screening solutions.

The Company's AI-powered solution for chest X-ray analysis, *Lunit INSIGHT CXR,* demonstrated diagnostic performance with AUCs of 0.83-0.99 across 10 pathologies, significantly improving clinicians' accuracy, with the greatest improvement observed in fibrosis detection with a delta AUC of 0.193.

In addition, the first prospective interventional study from Sweden's Saint Göran Hospital revealed that *Lunit INSIGHT MMG* improves cancer detection rates, reduces radiologist workload, and enhances screening efficiency. *Lunit INSIGHT DBT*, an AI-powered solution for analyzing digital breast tomosynthesis (DBT) images, achieved a comprehensive diagnostic performance with an AUC of 0.92 in a study of over 120,000 DBT cases. The solution demonstrated consistent performance across various subgroups, including race, ethnicity, age, and breast density.

The company's subsidiary Volpara Health presented 4 additional abstracts. One study demonstrated that Volpara's imaging software, featuring the Volpara TruPGMI™ PGMI score, can classify image quality and enable technical retakes for low-quality images, improving overall examination quality and potentially reducing the need for additional tests. Another study showed that using Volpara's Volumetric Breast Density (VBD) in conjunction with the AAPM TG282 method for breast radiation dose estimation provides more accurate and personalized assessments of average glandular dose (AGD) across different breast thicknesses and densities compared to existing protocols.

The Company and Volpara also unveiled two new integrated AI-powered solutions Lunit INSIGHT Risk, a tool for predicting breast cancer risk, and CXR Report Generation, which automates diagnostic report generation. With these solutions, the Company is preparing for FDA approval applications and plans for global market expansion next year.

(2) Paper

JAMA Network Open (Impact Factor=10.5): Study Highlights AI's Potential to Predict Breast Cancer Risk Up to 6 Years in Advance

[2024.10] The research conducted at the Cancer Registry of Norway analyzed data from 116,495 women aged 50-69 who underwent at least three consecutive biennial screening rounds across 9 breast centers in Norway. The research found that *Lunit INSIGHT MMG* can estimate future breast cancer risk up to 4 to 6 years before it becomes detectable.

Lunit's AI assigns each breast a score from 0 to 100, with higher values indicating a greater likelihood of cancer on the current mammogram. The study found that mean

AI scores were consistently higher for breasts that eventually developed cancer compared to those that remained cancer-free, even 4 to 6 years before detection. Over multiple screening rounds, the gap in these AI scores between breasts that developed cancer and those that did not grew larger, indicating the AI's ability to detect subtle signs of cancer earlier.

Specifically, for women who developed screen-detected cancer, the mean absolute differences in AI scores between the two breasts were 21.3 in the first sreening round, 30.7 in the second, and 79.0 in the third. Additionally, Lunit's AI achieved an Area Under the Curve (AUC) for the absolute difference of 0.63, 0.72, and 0.96 across the three screening rounds for screen-detected cancer. These findings indicate that Lunit's AI can effectively identify early signs of cancer and offer a pathway for personalized screening approaches.

This study provides compelling evidence of AI's potential to transform breast cancer screening. It suggests that AI can quantify breast cancer risk, enabling the early identification of high-risk individuals. This, in turn, could facilitate targeted monitoring or additional screenings, and the development of personalized prevention and treatment strategies.

Radiology: Artificial Intelligence (Impact Factor=8.1): *Lunit INSIGHT MMG* Reduces Radiologist Workload in 3 Screening Scenarios

Radiology: Artificial Intelligence

[2024.09] A recent study examined the potential of *Lunit INSIGHT MMG* to enhance double-reading workflows in mammography screening without compromising diagnostic performance. The research team evaluated three AI-integrated screening scenarios across 249,402 mammograms, demonstrating significant reductions in radiologist workload while either maintaining or improving accuracy (Scenario 1: AI replaced first reader; Scenario 2: AI replaced second reader; Scenario 3: AI replaced both for triaging of low and high-risk cases).

Results showed that replacing the first, second, or both radiologists with Lunit's AI could reduce reading volume by 48.8%, 48.7%, and 49.7%, respectively, while maintaining or improving cancer detection accuracy. Most notably, the AI triage scenario (Scenario 3) achieved higher sensitivity, improved positive and negative predictive values, with a lower arbitration rate when compared to standard double-reading.

This research highlights that by utilizing *Lunit INSIGHT MMG*, healthcare systems can significantly reduce radiologists' burden without compromising the screening program's diagnostic performance quality, allowing them to focus on more complex cases and improving overall efficiency. This is expected to serve as a crucial evidence for demonstrating the effectiveness of AI-based healthcare services for countries facing a shortage of radiologists.

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npj Precision Oncology (Impact Factor=6.8): Study Demonstrates AI Model for Analysis of Immunohistochemistry (IHC) Images

[2024.12] The Company announced the publication of a new study in npj Precision Oncology (Imapct Factor: 6.8) detailing the development of its Universal Immunohistochemistry (uIHC) AI model.

This research analyzed slides from 3,046 patients, including PD-L1 staining data from lung, bladder, and breast cancer tissues, as well as HER2 staining data from breast cancer. The study compared two different types AI models: single-cohort (trained using data from a single stain or cancer type) and four multi-cohort (trained on combined datasets spanning multiple stains and cancer types), to evaluate their performance on both familiar and unseen datasets.

The results demonstrated that the multi-cohort AI model, *Lunit SCOPE® uIHC*, outperformed single-cohort models across all datasets. For known cancer types and immunostains, the uIHC model achieved a Cohen's Kappa score of 0.792, surpassing the best single-cohort model score of 0.744. On novel datasets involving previously unseen cancer types and immunostains, the uIHC model achieved a Cohen's kappa score of 0.610, representing a relative improvement of 10.2% over the single-cohort model average of 0.508. Lastly, across multi-stain test sets, the uIHC model achieved an AUC of 0.921 for TPS evaluations and a TPS accuracy of 75.7%, showcasing its reliability in quantifying IHC images.

These findings highlight the model's robust performance across a wide variety of cancer types and immunostains, including those it had not been trained on. The uIHC model's ability to generalize across diverse IHC images marks a transformative step in digital pathology. By reducing the dependency on large stain-specific datasets, it enables scalable and efficient biomarker analysis for clinical diagnostics and drug development. This capability is particularly valuable for evaluating novel biomarkers associated with emerging therapies, addressing a critical bottleneck in precision oncology.

3. Events

Strengthening Internal Regulations for Disclosures: Pre-Disclosure of Stock Sales Exceeding 2 Billion KRW and Disclosure of Stock Sales Within 3 days

[2024.12] The Company sincerely apologizes for causing unnecessary concerns and confusion following the recent block deal involving executives on December 18.

In response, the Company has announced measures to strengthen internal regulations and prevent such occurrences in the future. As outlined in the announcement, the threshold for mandatory disclosure of stock transactions will be lowered from 5 billion KRW to 2 billion KRW, with disclosures required within three days-stricter than the requirements of the capital market law.

Additionally, the Company would like to clarify that the executives who repaid loans through block deal have no plans for further sales in the near future. However, due to unavoidable reasons, such as stock collateral loan repayments, the CEO and Chairman may need to make limited transactions in 2025. Beyond this, the Company assures that there will be no other deals in plan.

The company remains committed to advancing medical AI diagnostics and treatments technologies while strengthening its foundation to enhance long-term shareholder value. Once again, the Company deeply apologizes for the concerns and disappointment caused and pledge to become a more transparent and trustworthy organization.

Thank you for your continued support.

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