Conquer Cancer through AI

2023 4Q, IR Letter

Lunit

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🔔 4Q Highlights 🔔

1. Signed an acquisition agreement with Volpara Health, a New Zealand-based medical software company to leap into a platform company.
2. Accumulative sales exceeding $15m in the third quarter of 2023 (YoY 98% ↑)
3. Raised approximately $154m through a paid-in capital increase, securing the capital for new business expansion.
4. Expecting domestic health insurance reimbursement for Lunit INSIGHT CXR with approval as an innovative medical technology.
5. Clinical Phase 3 study results for immuno-chemical combination therapy using Lunit SCOPE IO in NSCLC patients, published in JCO (Impact Factor=50.739)

1. Major Activities

(1) M&A

Acquisition agreement with Volpara Health: First step towards entering the U.S. market and transforming into a platform company

[2023.12] On December 14th, Lunit (hereinafter referred to as "the Company") signed an agreement to acquire Volpara Health (hereinafter referred to as "Volpara").

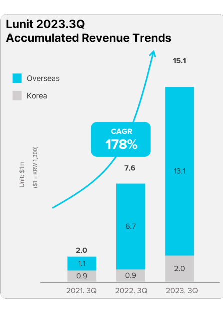
Volpara, founded in 2009 and listed on the Australian Securities Exchange, is a company that provides software and technology solutions related to breast cancer. Volpara has successfully commercialized the world's leading breast density product and **generating 97% of its revenue from the U.S. market.**In addition, they also launched software product for breast imaging density analysis, patient and regulatory compliance reporting, and EHR-integrated risk assessment. **With this effort, 42% of major breast cancer exmanination center in the U.S. using at least one Volpara's products.**

Through the acquisition of Volpara, we can begin the **transition to becoming a platform company,** as announced during our 10th-anniversary event. **With access to over 100 million breast imaging data accumulated by Volpara, the Company aims to leap into a platform company while refining algorithms to achieve near-perfect accuracy.**

Moreover, the Company has **secured various sales channels** through this acquisition. Leveraging Volpara's strong recognition in the U.S., our products can smoothly enter the U.S. market, and conversely, Volpara's products can enter our channels outside the U.S., maximizing profitability. In addition, the Company aims to **provide customers with a more diverse full-package solution through synergy with Volpara products.**

(2) Sales Performance

Accumulative sales exceeding $15m in the third quarter of 2023: YoY 98%↑

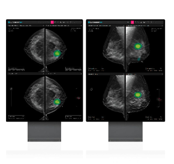


[2023.09] The Company **recorded a cumulative revenue of $15.1m in the third quarter of 2023, increasing 98% year-over-year.**

87% of the total revenue comes from overseas sales with AI solutions adopted by over 3,000 healthcare institutions worldwide. By continually expanding its global business footprint, the Company is playing a leading role in the global medical AI field. Additionally, **with the anticipated application of national health insurance reimbursement for Lunit INSIGHT CXR starting in the first half of 2024,** domestic revenue is expected to experience significant growth.

(3) Regulatory Approval

FDA approval for Lunit INSIGHT DBT: Targeting the U.S. Market



[2023.11] **The Company has received pre-market clearance(510(k) Clearance) from the U.S. Food and Drug Administration(FDA) for its three-dimensional Digital Breast Tomosynthesis(DBT) AI image analysis solution, Lunit INSIGHT DBT.** With this approval, the Company is ready to enter the widespread U.S. market where DBT equipment is prevalent. And the company is actively working to expand its sales network, **particularly focusing on advanced countries with high demand for 3D breast tomosynthesis.**

With the FDA clearance for Lunit INSIGHT DBT, the Company now has a total of three products approved by the FDA, including 'Lunit INSIGHT CXR Triage' and 'Lunit INSIGHT MMG'. Furthermore, by successfully obtaining FDA approval for its DBT AI solution, the Company has demonstrated its outstanding technological capabilities, marking a significant achievement as **the first company in South Korea to receive FDA approval for a DBT AI solution.**

(4) Contracts

Singed Contract for Supply of AI solutions to 5 major hospitals in Saudi Arabia: Targeting key public and private healthcare institutions in Saudi

[2023.11] **The Company has signed a supply contract for Lunit INSIGHT CXR with five major medical institutions in Saudi Arabia.**

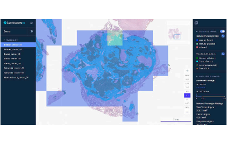
Following the supply contract for Lunit INSIGHT MMG with Al-Habib Medical Group, the largest private medical institution in Saudi Arabia, in July 2023, the Company has successfully entered the Saudi public and private healthcare markets with Lunit INSIGHT CXR. The AI solution will be installed in a total of five institutions, including 'National Guard Hospital,' 'King Abdullah Medical City,' 'Al Takasussi Hospital,' 'Al Musa Specialist Hospital,' and 'Security Forces Hospital.' This supply contract further strengthens the Company's presence in the Middle East healthcare market.

Supply of Lunit INSIGHT CXR to a military hospital in the Philippines: First entry into overseas military hospitals and health centers

[2023.11] **The Company has supplied Lunit INSIGHT CXR to the Victoriano Luna Medical Center military hospital and General Tinio Health Center in Manila, Philippines.** This marks the first case of introducing our AI solution to overseas military hospitals and health centers, and the Company expects it to assist in detecting ten chest diseases and screening for tuberculosis among overseas military personnel and local residents. The Company contributes to improving global health infrastructure by expanding the supply chain of AI solutions to military hospitals and health centers both domestically and internationally.

(5) Patents

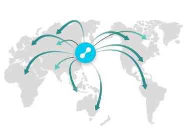
"Method and Apparatus for Providing Information Associated with the Immunophenotype of Pathology Slide Images": Meaningful patent granted for Lunit SCOPE



[2023.09] The Company has acquired a patent for the **"Method and Apparatus for Providing Information Associated with the Immunophenotype of Pathology Slide Images."** This technology involves a method for providing immunophenotype information for pathology slide images using a computing device. It includes obtaining information associated with the immunophenotype for each of multiple unit areas included in one or more regions of interest in pathology slide images, and generating and outputting an image representing this information.

This patent, the first to be granted among those directly related to Lunit SCOPE, gives the Company exclusive rights to the technology for imaging biomarkers related to cancer treatment. The Company plans to leverage this patent to secure a dominant position in the Korean market and actively pursues business opportunities. Additionally, this patent has been filed not only in Korea but also in the United States, Europe, and Japan. The Company will make diverse efforts to quickly secure patent rights in other countries.

(6) B2G

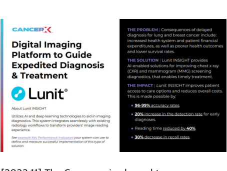


Participation in Saudi Arabia's 'Healthcare Sandbox': Expanding installation of Lunit AI solutions to 150 virtual hospitals nationwide in Saudi Arabia.

[2023.10] **As part of the Saudi Arabian government's "Vision 2030," the Company has joined the "Healthcare Sandbox," a project for digital innovation in the healthcare sector.** The Company has **become the first Korean company to officially participate in this project.**

The 'Healthcare Sandbox' is a project initiated by the Saudi Ministry of Health (MoH) to innovate national healthcare services. Participating companies receive comprehensive support from the MoH of Saudi to actively contribute to the modernization of the national healthcare system and the establishment of a digital ecosystem. Through this participation, **the Company signed an MOU to expand the supply of AI solutions to "SEHA Virtual Hospital" and 150 virtual hospitals across Saudi Arabia.**

First participation in Cancer X's official project: Immediate availability of AI solutions in healthcare institutions across the United States.



[2023.11] The Company is pleased to announce that we have become the **first Korean company to participate in the CancerX initiative,** a public-private partnership aimed at advancing the Cancer Moonshot project led by the Biden administration in the United States.

CancerX has unveiled a 'Solution Catalog,' serving as a guide for digital solutions in cancer diagnosis and treatment. Among the 14 companies participating in this project, Lunit is introduced as the first case, particularly in the area of cancer diagnosis. The catalog provides active guidance in three sections: cancer diagnosis, treatment and care, and treatment management. **With Lunit INSIGHT being highlighted as the first case in cancer diagnosis, our global standing in this field has been further emphasized.**

With this announcement, **healthcare institutions across the United States are now able to access immediately cancer-related products and solutions from all 14 companies featured in the Solution Catalog.** By participating in this project, the Company aims to contribute to the early diagnosis of cancer in patients, ultimately reducing healthcare costs for both individuals and government.

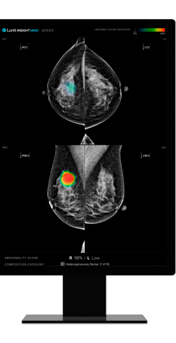
Selected as final contractor for Singapore's 'National Medical AI Platform Construction': Establishing a foundation for ASEAN expansion

[2023.12] The Company is pleased to announce that **we have been selected as the final contractor for the bidding of the 'AimSG(AI Medical Imaging Platform for Singapore)' construction project presented by Synapse, a Singaporean state-owned medical technology institution.**

Synapse is a government agency that integrates and manages the IT systems of Singapore's public hospitals. In order to manage medical data at Singapore's public hospitals, the use of Synapse's system is mandatory. Therefore, **Lunit INSIGHT CXR will be actively utilized in the chest X-ray image analysis within the national medical AI platform service, AimSG, by Synapse.**

This project allows us to **supply AI solutions to major public hospitals in Singapore utilizing Synapse.** Additionally, the Company aims to **expand business scope to the entire ASEAN region,** using Singapore as a stepping stone. The Company has already announced B2G projects with Saudi Arabia, Australia, and Singapore, and we are currently in discussions for B2G projects with more than 10 countries.

Official commencement of phase 2 of the BSNSW Project: Demonstrating technical accuracy and reliability

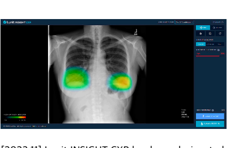


[2023.12] **The Company has successfully completed the verification Phase 1 of the BSNSW(BreastScreen NSW) project in New South Wales, Australia, and has officially commenced Phase 2.** In the previous Phase 1, Lunit INSIGHT MMG analyzed around 650,000 breast screening images, demonstrating the technical accuracy and reliability of AI solution. **In Phase 2, before actual installation, the Company will conduct six months of solution optimization and validation using approximately 200,000 examination data.**The final Phase 3 will involve medical professionals utilizing Lunit INSIGHT MMG for real screenings.

In November 2022, **the Company was selected as the supplier of AI solutions for the BSNSW project, which is a government-led cancer screening project supporting free breast cancer screenings every two years for women aged 40 and above in New South Wales, Australia.** Participating in a nationally led cancer screening project through the BSNSW project not only provides an opportunity for revenue expansion but also proves company's outstanding technological capabilities and robust brand value by surpassing global competitors in the bidding process.

(7) Reimbursement

Approval of Lunit INSIGHT CXR as an Innovative Medical Technology: the first step forward for health insurance reimbursement in Korea



[2023.11] Lunit INSIGHT CXR has been designated as an innovative medical technology through the Ministry of Health and Welfare's 'Integrated Examination and Evaluation of Innovative Medical Devices' notice. Consequently, It can be deployed in clinical medical sites from March 2024 to February 2027.

The Company are now eligible to enter the selective benefit or non-benefit reimbursement market for the next three years. Additionally, within this period, the Company plans to get a re-

Research

Academic Society

ESMO 2023 - Presentation of 8 abstracts (Lunit SCORE) Research results on predicting the efficacy of immune-oncology (IO) and chemotherapy (CT)

[2023.10.20] The Company attended ESMO 2023 (European Society for Medical Oncology) to present research results on predicting the efficacy of immune-oncology (IO) and chemotherapy (CT) using artificial intelligence (AI) and PD-L1 assays.

Firstly, the study analyzed cancer tissue images of patients treated with immune-oncology drugs (Keytruda, Tecentriq, and Imfinzi) and CT-treated patients from chi-three clinicgenes based on the Lunit SCORE artificial intelligence (AI) quantitative PD-L1 biomarker and immune-oncology and immune-oncology-chemotherapy combination therapy **overall survival. Progression-Free Survival, Objective response rate, and Disease control rate. The study compared the immune-oncology (IO) and immune-oncology-chemotherapy (IO+CT) treatment groups based on the Lunit SCORE artificial intelligence (AI) PD-L1 assay in patients with advanced NSCL.**

Secondly, in the study of advanced/metastatic breast cancer, the Lunit SCORE PD-L1 (combined/immune cell) was used to predict the response to immune-oncology (IO) and immune-oncology-chemotherapy (IO+CT) treatment in patients with advanced/metastatic triple TN. Density. This validates the Lunit SCORE PD-L1 (combined/immune cell) immunotherapy in patients with MSCL.

NTC 2023 - Presentation of 6 abstracts(Lunit SCORE) Research results on predicting the efficacy of chemotherapy (CT) NSCLC with EGFR mutation

RSNA 2023 - Presentation of 3 abstracts (Lunit SCORE) Research results on preventing missed signs of chest abnormalities using Lunit SCORE Chest

[2023.10.23] The Company **presented 6 NTC and presented research results on predicting the efficacy of various cancer drugs (chemotherapy) for NSCLC patients with EGFR mutations.**

The results presented at ESMO 2023 **showed that patients classified as PD-L1 high in the Lunit SCORE PD-L1 (combined/immune cell) assessment had a higher response to immune-oncology (IO) and immune-oncology-chemotherapy (IO+CT) treatment than patients classified as PD-L1 low.** The results showed that **patients classified as PD-L1 high in the Lunit SCORE PD-L1 (combined/immune cell) assessment had a longer Progression Free Survival (progression-free survival) and higher response rate and disease control rate when treated with immune-oncology (IO) or immune-oncology-chemotherapy (IO+CT) than patients classified as PD-L1 low patients with metastasis after TN treatment.**

[2023.10.23] The Company presented research results on **preventing missed signs of chest abnormalities using Lunit SCORE Chest.**

Among 8,225 Chest X-ray images, the AUC of Lunit SCORE Chest, which is a lung lesion detection artificial intelligence (AI) solution, was 0.9 or higher, and the sensitivity and specificity were 0.9 or more, respectively. The sensitivity of Lunit SCORE Chest was 0.9 or more, and the specificity was 0.8 or more, respectively, when the cut-off was set to the point where the sensitivity and specificity were the same. This indicates that **preventing missed signs of chest abnormalities when combined with Lunit SCORE Chest.**

Study Details

Journal of Clinical Oncology (JCO) 2023 Publication of results from clinical phase 3 study of Lunit SCORE PD-L1 (combined/immune cell)

[2023.10.20] The results of exploratory biomarker analysis of the Phase 3 study of Lunit SCORE PD-L1 (combined/immune cell) in combination for non-small cell lung cancer patients treated with Merck's Keytruda (pembrolizumab) and Axis Pharmaceuticals' Pemetrexed and platinum-based chemotherapy drugs, published in the prestigious international journal, the Journal of Clinical Oncology (JCO), **the impact of PD-L1 TB on the field of oncology.** The Company's **Lunit SCORE PD-L1 (combined/immune cell) was used as the biomarker.**

While GSK and Merck's Keytruda's lung cancer treatment is the first immunotherapy, these results showed the potential of Lunit SCORE PD-L1 (combined/immune cell) as a biomarker for predicting the efficacy of immunotherapy chemotherapy combination therapy for non-small cell lung cancer patients, and **Lunit SCORE PD-L1 (combined/immune cell) was confirmed to be a biomarker that can more accurately predict the survival of patients who may significantly benefit from immunotherapy chemotherapy combination therapy.**

NRI Precision Oncology (JP-US) CEO Publication of study on predictive biomarkers for cancer immunotherapy and radiotherapy

[2023.10.24] The Company's CEO Pete Chonchol participated in a panel discussion on the topic of "Precision Medicine" at the Japan Society for Clinical Oncology (JSCO) and presented research results using AI Biomarker. **Lunit SCORE PD-L1 has been used as a biomarker for immune-oncology drugs.**

The CEO of Genomic Medicine of Sloan Kettering Institute participating in the panel discussion, Dr. Ronald Chandarlapaty, **presented a collaboration study of Lunit SCORE PD-L1 (combined/immune cell) and Lunit SCORE Tumor Bed Density (TBD).** The study showed that patients with high TBD scores had significantly better PD-L1 density and better survival rates.

These results indicate that **Lunit SCORE accurately assesses the tumor immune microenvironment, and Lunit SCORE is a promising valuable biomarker for selecting patients who may significantly benefit from immunotherapy and radiotherapy combination therapy.**

European Radiology (IF=7.0) Publication of comparative study results on AI Specialist Mammography Interpretation

[2023.10.26] The results of **exploratory biomarker analysis of the Phase 3 study of Lunit SCORE PD-L1 (combined/immune cell)** in combination with Merck's Keytruda (pembrolizumab) and platinum-based chemotherapy drugs for non-small cell lung cancer patients, published in the prestigious international journal, the Journal of Clinical Oncology (JCO), **the impact of PD-L1 TB on the field of oncology.** The Company's **Lunit SCORE PD-L1 (combined/immune cell) was used as the biomarker.**

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Scientific Reports SF=4.0 Publication of research results on diagnosis of pulmonary tuberculosis

[2023.10.26] The results of study on pulmonary tuberculosis diagnosis using Lunit SCORE Chest published in Scientific Reports, a sister journal of Nature, a world-class scientific journal. Nature

The study analyzed chest X-ray (CXR) images aged 18 and above, which included the overseas data of Lunit SCORE Chest, and **Lunit SCORE Chest showed high performance** in distinguishing pulmonary tuberculosis using Lunit SCORE Chest, and it was confirmed that it was more **accurate** than that of the existing artificial intelligence (AI) medical image analysis solution. In addition, Lunit SCORE Chest **showed high performance** in distinguishing pulmonary tuberculosis from other lung diseases, and it was confirmed that it could be used as a tool for **early detection of lung diseases.**

Study

Lunit joins Cancer Research UK as Associate Member and Partner in Innovation as the First Korean Company among Korean Start-up Company

[2023.10.27] The Company has become an Associate Member of Cancer Research UK, a company in the Korean Pharmaceutical Industry. Following selection as a "Technology Provider" for the Cancer Research UK Grand Challenge, Lunit has joined Cancer Research UK's **mission to establish a global research crisis** and cancer treatment and prevention. In the past year, The results mentioned by as a technology provider, Lunit has been **recognized for its technology and contributed to the development of a platform for healthcare on a global scale.**

Closing of the Point to Capital Increase Secured approximately KRW10bn for the business expansion and product development

[2023.10.31] The Company has successfully completed its capital increase through a rights issue, approved by the board of directors held on August 31, 2023. The Company's **capital increase** aims to **strengthen its foundation for business expansion and enhance shareholder value.**

The underwriter was Mirae Asset Securities, and the **subscription rate of 100%** for the paid-in capital increase, with a total of KRW 10.1 billion raised. The Company's **capital increase** is a method of a whole body IRR in collaboration, **investment in subsidiaries, expanding the overseas market and developing the business model, and strengthening the foundation for business.**

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Lunit joins KOSDAQ 150 Anticipating inflow of passive fund capital

[2023.11.01] On December 2023, the Company has been newly included KOSDAQ 150 and is expected to receive passive capital inflows. The KOSDAQ 150 is a stock index jointly developed by KRX and KOSDAQ and calculating the index based on factors such as market capitalization and liquidity. The Company, **following an inclusion in the MSCI Global Small Cap Index in May 2023, the inclusion is expected to attract a significant inflow of capital from passive funds through this KOSDAQ 150 index.** The Company's **Lunit SCORE** will continue to enhance shareholder value.

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