Conquer Cancer through AI

2024 3Q, IR Letter

Lunit

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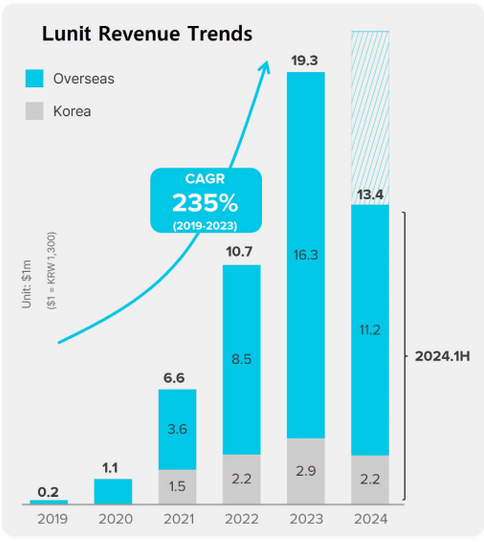
🔔 3Q Highlights 🔔

1. Achieved the highest-ever quarterly revenue of 12.23 billion KRW in Q2 2024.
2. Supplied SecondReadAI to Resolute in the U.S., marking the start of synergies from the Volpara acquisition.
3. Exceeded 5,000 analysis requests for Lunit SCOPE, demonstrating the product's clinical effectiveness.
4. Integrated Lunit AI solutions into Roche Diagnostics' digital pathology platform, Navify.
5. Presented an abstract related to Lunit SCOPE products at the ESMO conference.

1. Major Activities

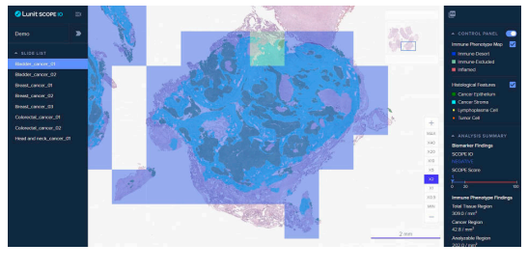
(1) Sales Performance

Record Revenue 12.23 Billion KRW in Q2 2024 Achieving the Highest Quarterly Performance: Contribution to revenue growth through the acquisition of Volpara



[2024.06] Lunit (hereinafter referred to as “the Company”) recorded revenue of 12.23 billion KRW in Q2 2024, achieving the highest quarterly performance to date. This represents 124.6% increase in revenue compared to the same period last year. This growth was driven by the completed acquisition of Volpara and an increase in domestic sales due to the inclusion of non-benefit reimbursement. Although operating loss increased to 19.94 billion KRW compared to the previous year, this was primarily due to increased one-time costs related to the Volpara acquisition and strategic investments aimed at enhancing R&D for products and strengthening global sales networks. The company remains committed to expanding its global business and accelerating finance performance improvements through sustainable strength.

Lunit SCOPE Analysis Request Exceed 5,000 cases: Demonstrating Product Effectiveness and Expanding Revenue in Research Use



[2024.07] Analysis requests for our AI biomarker platform, Lunit SCOPE, from global pharmaceutical companies have surpassed 5,000 cases. Lunit SCOPE analyzes patient tissue slides using AI to predict responses to anticancer therapies, providing optimal treatment options for cancer patients. Research revenue, excluding milestones, was generated for the first time in Q3 last year, and the number of tissue analysis requests through Lunit SCOPE has steadily increased since then. The company is continuously demonstrating the effectiveness of Lunit SCOPE as an AI biomarker in clinical processes alongside more than 20 global pharmaceutical companies. At major oncology conferences such as ASCO, ESMO, and AACR, the company has published over 100 abstracts and papers, garnering significant attention in the pharmaceutical industry. The company is continuously building a foundation for potential partnerships through tissue slide analysis research with global pharma giants and is working towards utilizing Lunit SCOPE as a companion diagnostics biomarker for specific anticancer drugs in the future.

(2) Contract

Supply Agreement with Kangbuk Samsung Hospital for Lunit INSIGHT MMG: 60% of Major Hospitals in Korea Now Utilizing the Lunit INSIGHT Suite

[2024.07] The Company has signed supply agreement for Lunit INSIGHT MMG with Kangbuk Samsung Hospital. With this agreement, approximately 60% of the 47 major general hospitals in South Korea now use the Lunit INSIGHT suite. Following this contract, the company plans to further expand its AI solution offerings to key general hospitals, aiming to continuously demonstrate the practical value of AI in medical settings and actively broaden the foundation of the medical AI industry. Lunit INSIGHT MMG was selected as a “provisional new medical technology” by the National Evidence-based Healthcare Collaborating Agency (NECA) under the Korean Ministry of Health and Welfare in May, making it available for non-reimbursable use in medical settings starting from Q3 this year. The company is committed to generating prospective clinical evidence to support the formal health insurance registration of the Lunit INSIGHT suite following the the evaluation period for new medical technologies, with the goal of establishing a leading position in the domestic breast cancer screening and diagnostic market.

Supply Agreement with Intermountain Health for Volpara Software: Strengthening Presence in the U.S. Market and Anticipating Synergies from the Acquisition with Lunit AI Solutions

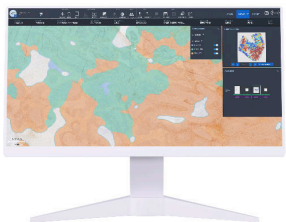
[2024.08] Volpara, a Lunit company, has achieved a significant milestone by entering into a supply agreement with Intermountain Health, one of the largest healthcare systems in the United States, for its breast cancer screening software: Risk Pathways, Analytics, and Scorecard. Intermountain Health is a leader in the adoption of medical AI in the U.S. healthcare sector and was ranked second in the Hospital AI Readiness Index published by CB Insights in July, following the Mayo Clinic, which is recognized as one of the world's top medical institutions. This supply agreement allows Volpara to add a major U.S. healthcare system to its customer portfolio, further strengthening its position in the American market. We aim to further enhance our competitiveness in the U.S. AI market by leveraging the synergy between Lunit's technological capabilities and network.

Lunit-Volpara Supplies Breast Cancer Diagnosis AI Solution to Major Imaging Center in the U.S.: First Instance of U.S. Market Entry

Through Volpara Channel

[2024.08] The company has signed a contract to supply our integrated breast cancer screening AI solution, SecondReadAI, to Rezolut, a major imaging platform company in the U.S. SecondReadAI is based on Lunit INSIGHT MMG and Lunit INSIGHT DBT, and will be implemented across more than 40 imaging centers operated by Rezolut nationwide, analyzing over 300,000 medical images annually. Additionally, the comapny is introducing a new business model where patients directly pay for AI usage fees instead of hospitals paying fees in cases where insurance reimbursement is not available. This change is expected to encourage more hospitals to adopt SecondReadAI. Furthermore, this contract marks a significant milestone as it is the first instance of our AI products being sold in the U.S. through Volpara's sales network following its acquisition. Volpara generates over 90% of its total revenue from the U.S. market and has established a strong presence, with more than 40% of medical institutions offering mammography using at least one Volpara product. We aim to leverage this opportunity to expand our entry into the U.S. market through Volpara's sales channels, maximizing the benefits of the acquisition.

Integration of Lunit AI Solutions into Roche Diagnostics' Navify Digital Pathology Platform: Expanding Presence in the Global Digital Pathology Market



[2024.09] The company announced collaboration agreement to integrate our AI pathology analysis solution, Lunit Scope PD-L1, with Roche Diagnostics' Navify Digital Pathology platform. Navify is a comprehensive platform designed to enhance the efficiency of pathologists' workflows, supporting the entire pathology process from the digitalization of tissue slides to AI-based analysis. Through this integration, the company aims to provide accurate and reliable Lunit AI solutions that contribute critical clinical information, including precise and consistent evaluations of biomarker expression levels that are vital for cancer immunotherapy. Leveraging Roche Diagnostics' extensive global network, the integration will begin with implementation in the United States, followed by expansion into Europe, South Korea, Japan, and other regions. This collaboration is expected to accelerate advancements in precision medicine and personalized cancer treatment across the global market.

(3) B2G

Supply of AI Solutions for Qatar's National Cancer Screening Project: Accelerating Expansion of Global B2G Business

[2024.07] The company announced supply agreement for Lunit INSIGHT MMG with the Primary Health Care Corporation (PHCC) of Qatar for the "National Breast Cancer Screening Project." The PHCC recommends that women aged 45 to 69 undergo breast cancer screenings every three years through its "Screen for Life" program. This initiative marks the first comprehensive implementation of AI products for national breast cancer screening in the Middle East. With the supply of our AI solution, the company aims to enhance the efficiency and accuracy of screenings, contributing significantly to the early detection of breast cancer among women in Qatar. Building on this global achievement, the company plans to expand our B2G business in developing countries, where healthcare service advancement is slower, further solidifying our leading position in the global medical AI market.

Participation in Singapore's 'AI-Based Chest X-Ray Interpretation Enhancement' Project: Securing Stable Revenue Through Ongoing Expansion of B2G Projects

[2024.08] The company announced its participation as the sole contributor to the chest X-ray interpretation workflow enhancement project led by the National Healthcare Group (NHG) in Singapore. NHG oversees public healthcare in the central and northern regions of Singapore and employs approximately 20,000 healthcare professionals. The existing workflow for chest X-ray interpretation involves transferring images taken at primary care facilities to tertiary hospitals, where they are recommended to be interpreted within one hour. However, issues such as a shortage of radiologists and increased patient wait times have been consistently raised. To address these challenges and improve resource efficiency, the company will implement our chest X-ray interpretation AI solution, Lunit INSIGHT CXR, in the field, ultimately contributing to a reduction in healthcare costs in Singapore. Through this project, the company aims to demonstrate the value of our AI solution by August next year and subsequently propose improvements to the imaging interpretation protocols in public hospitals. Additionally, the company is gradually expanding our B2G initiatives in various countries, including Australia, Qatar, and Saudi Arabia, which will serve as a stable revenue source and contribute to our consistent sales growth.

Lunit INSIGHT Selected as a Recipient of the Public Procurement Service's 'Innovative Product Pilot Purchase Program': Contributing to the Improvement of Public Healthcare Infrastructure

[2024.08] Lunit INSIGHT has been selected as a recipient of the Public Procurement Service's '2024 Second Innovative Product Pilot Purchase Program.' This initiative, introduced in 2019, supports the initial market entry of outstanding innovative technologies and aims to enhance public services. As part of this project, Lunit INSIGHT will be piloted in five public healthcare institutions: Seoul National University Hospital, Seoul Medical Center, Gyeongsang National University Changwon Hospital, Cheonan Medical Center, and the Korea Veterans Health Service Medical Center. This initiative will contribute to the early detection and diagnostic accuracy of lung and breast cancers, which rank as the first and second most prevalent cancers worldwide. Notably, our selection for this government-led pilot program reflects recognition of our advanced technology and experience in the public healthcare sector. We are committed to continuously expanding our B2G initiatives both domestically and internationally.

2. Research

(1) Academic Society

ESMO 2024 – Presentation of Abstract (Lunit SCOPE): Demonstrating Classification of Patients with High Efficacy for Combination Therapy in Advanced Gastric Cancer

[2024.09] The company attended the ESMO (European Society for Medical Oncology) Congress 2024 and presented research findings using the AI biomarker Lunit SCOPE IO to predict the efficacy of combination therapy in patients with advanced gastric cancer (AGC). ESMO, alongside ASCO and AACR, is recognized as one of the world's top three oncology conferences, and this marks Lunit's fourth consecutive year of participating and sharing research outcomes related to Lunit SCOPE.

The study involved a total of 585 AGC patients, comparing the median progression-free survival (mPFS) between those receiving combination therapy and those treated with chemotherapy alone. Of these, 275 patients received the immunotherapy Nivolumab in combination with chemotherapy, while 310 received chemotherapy alone. Lunit SCOPE IO was used to classify the immune phenotypes of the patients and analyze their correlation with treatment responses.

The analysis revealed that the median PFS for the combination therapy group was 8.2 months, compared to 5.9 months for the chemotherapy-only group, indicating superior treatment efficacy in the combination therapy cohort. Notably, among the 228 patients classified as inflamed immune phenotype group (IIP) by Lunit SCOPE IO, the median PFS for those receiving combination therapy was 11 months, nearly double that of the 5.8 months observed in the chemotherapy-only group. Conversely, the non-inflamed immune phenotype group (Non-IIP) classified by Lunit SCOPE IO showed a smaller difference in PFS, with 7.3 months for combination therapy and 5.9 months for single-agent treatment.

This study demonstrates that immune phenotype classification using Lunit SCOPE IO is valuable for predicting the efficacy of combination therapy in patients with advanced gastric cancer, potentially guiding treatment decisions and improving outcomes for these patients.

(2) Paper

Lancet Digital Health(Impact Factor=23.8): Lunit INSIGHT CXR Ranked #1 in Tuberculosis Detection Among 12 Global Products

THE LANCET
Digital Health

[2024.08] The company announced that a study comparing the detection performance of 12 global AI solutions in the classification of tuberculosis patients has been published in the prestigious medical journal, The Lancet Digital Health. This reasearch was conducted by an independent team, unaffiliated with AI solution developers, using chest X-ray data from a two-year tuberculosis prevalence survey involving 774 individuals in South Africa. This approach ensured a fair and objective evaluation, enhancing the credibility of the results. The World Health Organization (WHO) recommends the use of computer-aided diagnostic (CAD) devices for the classification of tuberculosis in patients aged 15 and older. Lunit INSIGHT CXR demonstrated performance closely aligned with WHO tuberculosis classification goals, while also achieving the highest detection capability among the AI solutions tested. Tuberculosis remains a significant infectious disease, particularly in developing countries where medical resources are limited. There is a high demand for the integration of AI solutions in tuberculosis screening processes in these regions. The findings from this study validate Lunit's competitiveness in the global healthcare market and increase the potential for Lunit INSIGHT CXR to be utilized as an effective tool for tuberculosis screening, both in developed and developing nations. Lunit expects these results to serve as clinical evidence for entering the global tuberculosis screening market.

Clinical Cancer Research (Impact Factor=10.4): Publication of Study Results on Predicting Treatment Response in Biliary Tract Cancer (BTC) Patients Using Lunit SCOPE IO

Clinical
Cancer
Research

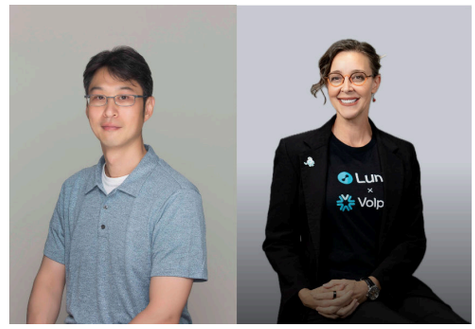
[2024.09] Lunit announced that a study on predicting treatment response in cholangiocarcinoma patients using Lunit SCOPE IO has been published in Clinical Cancer Research (Impact Factor = 10.4), a journal of the American Association for Cancer Research (AACR).

The study involved 339 patients with advanced or metastatic biliary tract cancer (BTC) who received immunotherapy as a second-line or later treatment after first-line chemotherapy. Lunit SCOPE IO was used to evaluate tumor-infiltrating lymphocytes (TILs), classifying patients into three immune phenotypes: inflamed, immune-excluded, and immune desert.

These findings validate that Lunit SCOPE IO can effectively analyze the tumor microenvironment, specifically TIL distribution, to predict the efficacy of immunotherapy in advanced BTC patients.

3. Events

Hiring of CTO from Big Tech and Appointment of New CBO: Attracting Talent for Growth as a Global Medical AI Company



[2024.07] The company has appointed Dr. Seong-Won Yoo as Chief Technology Officer (CTO). Dr. Yoo brings extensive experience from leading global tech companies, including Google and Intel, and possesses a unique background as a "convergence expert" in engineering and medicine. He earned a Bachelor's degree in Electrical Engineering from Seoul National University, a Master's degree in Electrical and Computer Engineering from Georgia Tech, and a Ph.D. in Electrical Engineering from Stanford University. Additionally, he holds a Master's degree in Health Informatics from Harvard Medical School, equipping him with the expertise to bridge engineering and medical fields. The company anticipates that Dr. Yoo's integration will enhance our product capabilities and accelerate our global sales expansion. In addition to Dr. Yoo, the company has appointed Teri Thomas, CEO of Volpara, as our Chief Business Officer (CBO). Teri holds a Bachelor's degree in Zoology from the University of Wisconsin and a Master's degree in Nursing from Wintec in New Zealand. She brings over 25 years of rich experience in the global healthcare industry. As CBO, Teri will oversee sales and marketing strategies, focusing this year on the U.S., European, and Middle Eastern/African (EMEA) markets, with plans to lead expansions into new markets starting in 2025. Her appointment is expected to accelerate the integration and synergy between our company and Volpara.

Selected as a KOSDAQ Rising Star 2024: Demonstrating Technological Excellence and Growth Potential

Lunit

[2024.08] The company has been selected as a KOSDAQ Rising Star 2024 by the Korea Exchange. The KOSDAQ Rising Star initiative identifies and nurtures companies with outstanding technological capabilities and growth potential, fostering the long-term growth of promising KOSDAQ-listed companies since its inception in 2009. A total of 39 companies were chosen as Rising Stars for 2024, with Lunit being the only medical AI company among them. This recognition as the first medical AI company selected as a KOSDAQ Rising Star not only highlights the innovative potential of medical AI as a leading technology for the future but also reaffirms our superior technological capabilities and growth prospects within the medical AI sector.

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