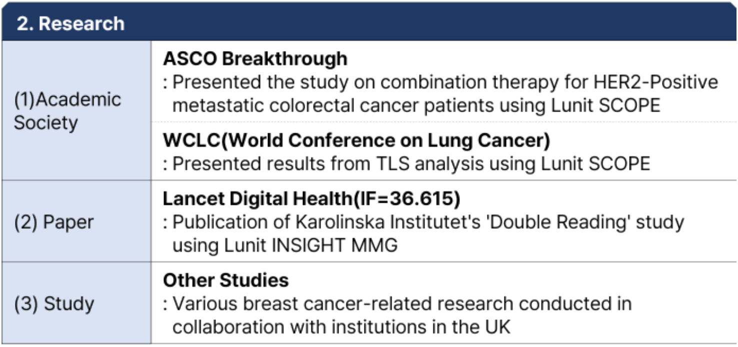
Conquer Cancer through AI

2023 3Q, IR Letter

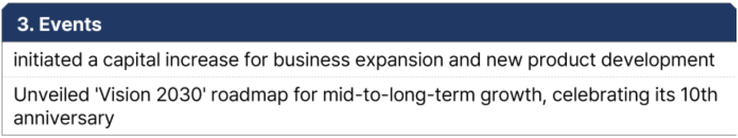
Lunit

INDEX

1. Major Activities	
(1) Sales Performance	**Sales exceeding $12m in the first half of 2023** : YoY 200%↑
(2) Contracts	**Lunit INSIGHT MMG was supplied to HMG** : Achieving the first milestone in Saudi Arabia's private sector
	Guardant Health's 'Cancer Diagnosis Services' Launch in South Korea : Contribution to Domestic Revenue and Securing a Distribution Network for Lunit SCOPE
	Lunit INSIGHT CXR was delivered to National Police Hospital : Improving and expanding public healthcare infrastructure
(3) Regulatory Approval	**Lunit INSIGHT MMG obtained approval from Malaysia** : Expansion into the Southeast Asian market



2. Research	
(1)Academic Society	**ASCO Breakthrough** : Presented the study on combination therapy for HER2-Positive metastatic colorectal cancer patients using Lunit SCOPE
	WCLC(World Conference on Lung Cancer) : Presented results from TLS analysis using Lunit SCOPE
(2) Paper	**Lancet Digital Health(IF=36.615)** : Publication of Karolinska Institutet's 'Double Reading' study using Lunit INSIGHT MMG
(3) Study	**Other Studies** : Various breast cancer-related research conducted in collaboration with institutions in the UK



3. Events
initiated a capital increase for business expansion and new product development
Unveiled 'Vision 2030' roadmap for mid-to-long-term growth, celebrating its 10th anniversary

🔔 3Q Highlights 🔔

1. Sales exceeding $12m in the first half of 2023 (YoY 200%↑)
2. Prospective study in Sweden backs the possibility to replace one human reader in 'Double

Reading', published in the Lancet Digital Health (IF=36.615)

3. Initiated a capital increase for new business ventures and new product development

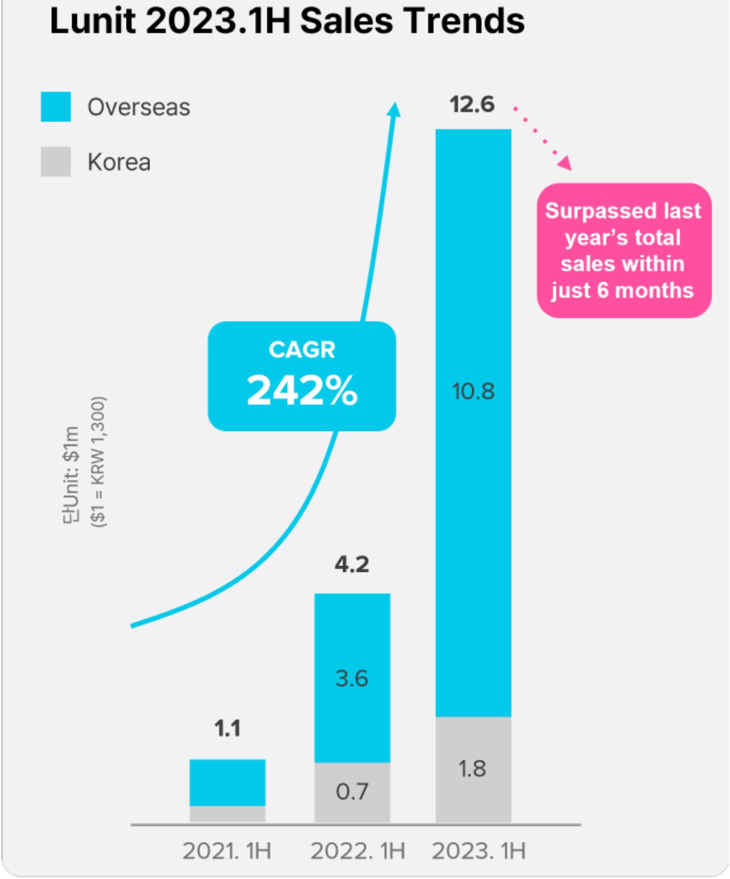
4. Securing a domestic distribution network for Lunit SCOPE through Guardant Health's 'Cancer Diagnosis Services' Launch in South Korea

5. Unveiled 'Vision 2030' roadmap for mid-to-long-term growth, celebrating its 10th anniversary

1. Major Activities

(1) Sales Performance

Sales exceeding $12m in the first half of 2023: YoY 200%↑



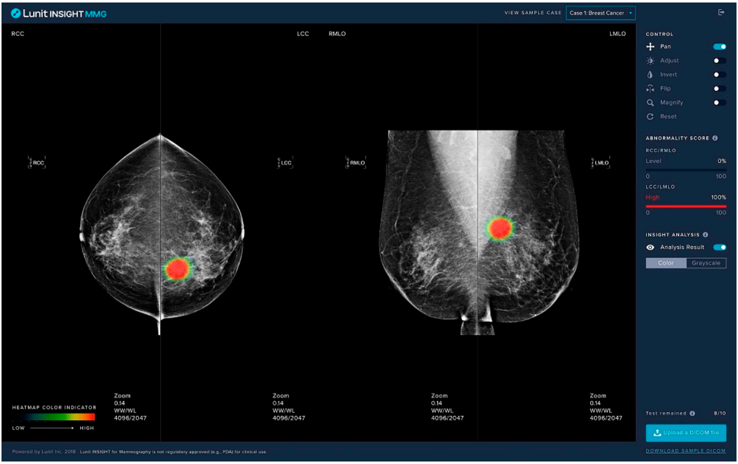
[2023.06] Lunit (hereinafter referred to as "the Company") **recorded sales revenue of $12.6m in the first half of 2023, increasing 200% year-over-year**, and demonstrated a significant upward trend in revenue as the years go by.

86% of the first-half revenue comes from overseas sales, in line with the rapid expansion of medical institutions worldwide adopting our AI solutions. Following last year's achievement of reaching $8m in annual revenue **for Lunit INSIGHT, this year, we have already surpassed $8m in just the first half**, firmly establishing our position as the global leader in the field of cancer diagnosis AI solutions.

In addition, the Company is **striving to maintain robust revenue growth by expanding B2G business, increasing possibility to get reimbursement**, and more.

(2) Contracts

Lunit INSIGHT MMG was supplied to HMG: Achieving the first milestone in Saudi Arabia's private sector



[2023.07] The Company has **signed a supply contract for Lunit INSIGHT MMG with Al-Habib Medical Group(HMG), the largest private healthcare institution in Saudi Arabia**.

Previously, we announced our participation in the 'SEHA Virtual Hospital' project, which is a part of Saudi Arabia's national project 'Vision 2030,' and expanded our scope into the private healthcare sector. With this, our company has **achieved success in both the public and private sectors in Saudi Arabia**.

In particular, HMG is the largest private healthcare institution in the Middle East, operating more than 20 hospitals across the Middle East, including Saudi Arabia, the United Arab Emirates, and Bahrain. We will collaborate with HMG for the next 3 years, **utilizing Lunit INSIGHT MMG in Saudi Arabia's national breast cancer screening program**. Additionally, we will actively **pursue technical cooperation to enhance our AI technology through HMG's cloud AI platform**. Based on the collaboration, we plan to supply Lunit INSIGHT CXR and Lunit INSIGHT DBT to HMG later this year.

Guardant Health's 'Cancer Diagnosis Services' Launch in South Korea: Contribution to Domestic Revenue and Securing a Distribution Network for Lunit SCOPE

Lunit

x

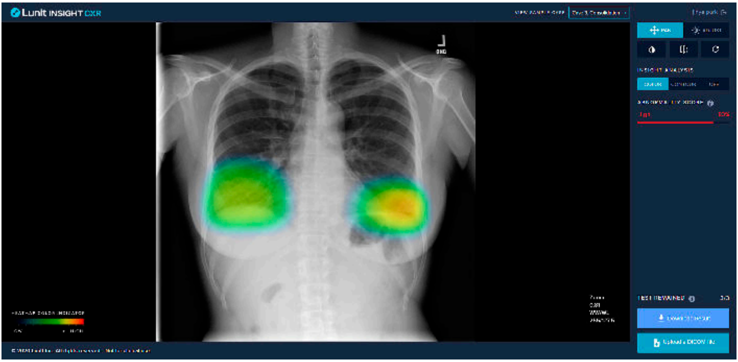
GUARDANT™

[2023.09] The Company has **signed a domestic distribution agreement for cancer diagnosis and analysis services with Guardant Health**.

Guardant Health is a leading liquid biopsy company in the United States. Liquid biopsy features faster and more convenient for diagnosing cancer by analyzing DNA in blood or bodily fluids, compared to traditional tissue biopsy.

Through this distribution agreement, the Company will supply a variety of liquid biopsy services from Guardant Health, including Guardant 360 and Guardant Reveal, to the domestic market. This will allow the Company to **diversify its revenue structure in the domestic market**. Furthermore, the distribution network secured through this agreement is expected to be of **significant importance for the future distribution of Lunit SCOPE products domestically**.

Lunit INSIGHT CXR was delivered to National Police Hospital: Improving and expanding public healthcare infrastructure



[2023.07] The Company has **signed a contract to deliver Lunit INSIGHT CXR to the National Police Hospital**, providing cancer diagnosis solutions to police and firefighter personnel nationwide.

Lunit INSIGHT CXR is an AI solution capable of detecting ten different chest abnormalities from chest X-ray images. Under this agreement, **our AI solution will perform precise readings of chest X-ray images of patients at the National Police Hospital for one year**.

In addition, the Company previously announced in May that Lunit INSIGHT CXR had been introduced at overseas military hospitals. The company is consistently working to **enhance both domestic and international public healthcare infrastructure through our AI solution**.

(3) Regulatory Approval

Lunit INSIGHT MMG obtained approval from Malaysia: Expansion into the

Southeast Asian market

[2023.06] **Lunit INSIGHT MMG, an AI solution for breast cancer detection, has received approval for sale from the Medical Device Authority(MDA) in Malaysia**. This allows us to sell Lunit INSIGHT MMG in Malaysia for the next 5 years. Building on this approval, we poised to expand our business network to neighboring countries, including Indonesia.

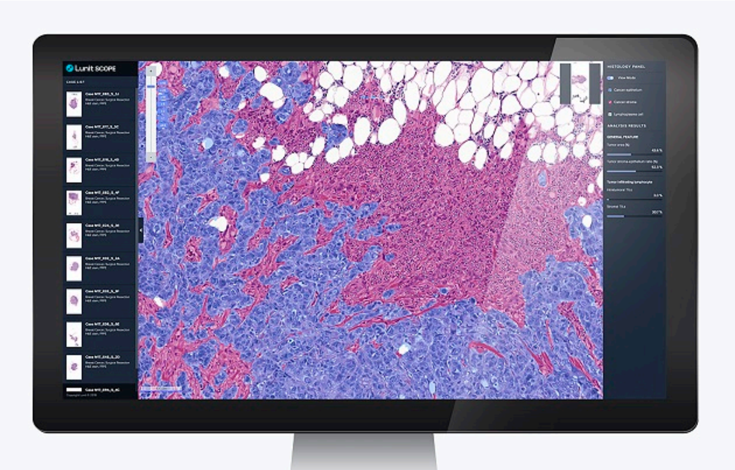
The Lunit INSIGHT suite has been cleared in more than 40 countries, removing regulatory barriers in most major countries. This legal and regulatory foundation positions us well to successfully expand our global business.

2. Research

(1) Academic Society

🔎 Study Details

ASCO Breakthrough: Presented the study on combination therapy for HER2-Positive metastatic colorectal cancer patients using Lunit SCOPE



[2023.08] The Company recently **presented the results of a combination therapy study for HER2-positive metastatic colorectal cancer patients** at the ASCO Breakthrough conference held in August. This collaborative research with the National Cancer Center Hospital East (NCCHE) in Japan, a leading institution in cancer treatment and study in Japan, gained significant attention as it was selected for oral presentation(Oral PT). It demonstrated the significance and impact of the research and drew great interest from the academic community. The research details are as follows.

Using 'Lunit SCOPE HER2,' a product that quantifies HER2 expression levels by analyzing patient tissue slides, and 'Lunit SCOPE IO,' an AI biomarker predicting patient treatment responses, we conducted a phase 2 clinical trial of combination therapy with trastuzumab(Herceptin) and pertuzumab(Perjeta) in 30 HER2-positive metastatic colorectal cancer patients. The research team classified the patients based on HER2 staining intensity into 1+, 2+, and 3+ using Lunit SCOPE HER2 to detect tumor cells and analyzed the tumor microenvironment, including immune cells, using Lunit SCOPE IO.

The results showed that among all 30 patients, the objective response rate(ORR) to the combination therapy was only 26.7%. However, **among the 23 patients classified as HER2 3+ by Lunit SCOPE HER2, the ORR was 34.8%**. Moreover, when applying a threshold of HER2 3+ 50%, higher than the standard criteria for breast and gastric cancer(ASCO/CAP guidelines), 19 patients were classified, and **their ORR increased to 42.1%. Additionally, significant**

improvements were observed in progression-free survival(PFS) and overall survival(OS) for these patients.

Notably, these results are significant as HER2-positive colorectal cancer is an infrequent condition compared to breast and gastric cancer, and **Lunit SCOPE showed a significant potential in assisting precise treatment for HER2-positive colorectal cancer patients**. This research has been conducted with approval for a clinical trial plan(IND) in Japan, **marking the first clinical trial of HER2-targeted therapy for metastatic colorectal cancer in Japan**. Based on these research findings, the Company intends to pursue the regulatory approval process for Lunit SCOPE HER2 to be used as a biomarker for combination therapy with trastuzumab and pertuzumab for metastatic colorectal cancer treatment in Japan.

* Artificial intelligence (AI)-powered HER2 quantification continuous score (QCS) and tumor microenvironment (TME) analysis in HER2-amplified metastatic colorectal cancer (mCRC) treated with pertuzumab plus trastuzumab.

Mitsuho Imai, Yoshiaki Nakamura, Wataru Okamoto, Takeshi Kato, Taito Esaki, Ken Kato, Yoshito Komatsu, Satoshi Yuki, Toshiki Masuishi, Tomohiro Nishina, Akihiro Sato, Takeshi Kuwata, Riu Yamashita, Takao Fujisawa, Hideaki Bando, Jongchan Park, Seunghwan Shin, Chan-Young Ock, Satoshi Fujii, and Takayuki Yoshino

JCO Global Oncology 2023 9:Supplement_1, 34-34

WCLC(World Conference on Lung Cancer): Presented results from TLS analysis using Lunit SCOPE

IASLC

2023 World Conference on Lung Cancer

SEPTEMBER 9-12, 2023 | SINGAPORE

[2023.09] TheCompany participated in the World Conference on Lung Cancer (WCLC 2023) and **presented the results of using Lunit SCOPE to analyze tertiary lymphoid structures and predict treatment responses** in collaboration with leading U.S. hospitals and medical school researchers.

Tertiary Lymphoid Structures(TLS) are formed only in places with chronic inflammation or cancer, so they are considered one of the components that can regulate immune responses within the tumor microenvironment. Researchers analyzed tissue slides from 85 non-small cell lung cancer patients, utilizing 'Lunit SCOPE TLS' which was trained on the characteristics of TLS from

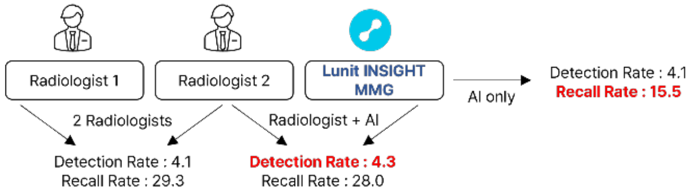
1,439 pathological H&E slides, including 18 different types of cancers.

The results showed that among the 85 patients, **the overall survival rate(OS) of the 25 patients classified by 'Lunit SCOPE TLS' was significantly longer**. Furthermore, the study confirmed that the presence of TLS is independent of the PD-L1, well-known biomarker in non-small cell lung cancer patients, **indicating that 'Lunit SCOPE TLS' can be used as a new biomarker for these patients**.

(2) Paper

Lancet Digital Health(IF=36.615): Publication of Karolinska Institutet's 'Double Reading' study using Lunit

INSIGHT MMG



[2023.09] A study conducted by the Karolinska Institutet in Sweden **demonstrated that Lunit INSIGHT MMG can replace on human reader in breast cancer screening. The study was recently published in the prestigious international journal, the Lancet Digital Health**.

In Europe, the practice of 'double reading' is recommended for interpretation of mammography, where two radiologists must jointly interpret the images due to the complexity of the readings of mammography. To address issues such as increased healthcare costs and a shortage of radiologists caused by double reading, the Karolinska Institutet, a Nobel Prize-awarding institution, conducted research using our AI solution.

The research findings showed that **when AI replaced one of the two radiologists in double reading, the recall rate was reduced while the cancer detection rate increased**, compared to readings by two radiologists. This significant research, now published in a prominent journal, is expected to have a wide-reaching impact. It is anticipated that **this will contribute to the expanded use of our AI solution in Europe and support future activities related to healthcare reimbursement in Europe**. Additionally, it is expected that our recently established subsidiary, Lunit Europe Holdings, will also boost up the business expansion in Europe.

* Dembrower, Karin, et al. "Artificial intelligence for breast cancer detection in screening mammography in Sweden: a prospective, population-based, paired-reader, non-inferiority study. " *The Lancet Digital Health* (2023).

(3) Study

Other Studies: Various breast cancer-related research conducted in collaboration with institutions in the UK

Over the past quarter, the Company has achieved significant milestones in breast cancer-related research.

(1) We conducted a research in collaboration with the University of Nottingham in the UK to compare the diagnostic performance of Lunit

INSIGHT MMG with that of human readers. The research, published in the academic journal ***Radiology*, demonstrated that **Lunit INSIGHT MMG recorded a sensitivity of 91% and specificity of 77%, surpassing the average sensitivity of 90% and specificity of 76% among 552 human readers**. This highlights the exceptional performance of our AI product, positioning it as a valuable tool in breast cancer diagnosis.

(2) We also **embarked on a groundbreaking prospective study, the first of its kind globally, in collaboration with Leeds Teaching Hospitals in the UK**. This study involves comparing the diagnostic results of two human readers with those of two human readers assisted by our AI solution for 5,500 breast clinic patients over a two-year period. The outcomes of this study will provide crucial insights into the potential for our

AI solution to change the double-reading standard within Europe.

(3) Our research on predicting breast cancer treatment responses using Lunit SCOPE IO was featured in **'*NPJ Breast Cancer*,' a sister journal of *Nature*. This study addresses the significant variability in measuring stromal tumor-infiltrating lymphocytes (sTILs) in breast cancer patients by pathologists. **Lunit SCOPE IO was found to mitigate this issue and accurately predict the treatment responses of breast cancer patients undergoing 'neoadjuvant chemotherapy'** before surgery.

These achievements underscore our commitment to advancing breast cancer research and improving the accuracy of diagnosis and treatment outcomes.

* Performance of a Breast Cancer Detection AI Algorithm Using the Personal Performance in Mammographic Screening Scheme

Yan Chen, Adnan G. Taib, Iain T. Darker, and Jonathan J. James

Radiology 2023 308:3

** Choi, S., Cho, S.I., Jung, W. *et al.* Deep learning model improves tumor-infiltrating lymphocyte evaluation and therapeutic response prediction in breast cancer. *npj Breast Cancer* **9**, 71 (2023).

3. Event

initiated a capital increase for business expansion and new product development

[2023.08] In the board of directors meeting held on August 23rd, the Company **resolved both a capital increase and 1:1 bonus share issuance, to support new business ventures and new product development**. Through this capital increase, the Company has secured approximately

$215m(subject to change) in funds. These funds will serve as a foundation for our aggressive business expansion and innovative growth strategies.

Specifically, the funds will be allocated for the **development of a whole-body MRI AI solution, R&D expenses related to the discovery and acquisition of new drug candidates, overseas subsidiary investments, expenses for M&A and investment activities, and the establishment of a CVC for these purposes**. We have also adopted a **shareholder-friendly policy** to enable our participating shareholders in the capital increase to automatically participate in the 1:1 bonus share issuance. The funds obtained through this capital increase will be a strong driving force for our future growth and will play a vital role in propelling us towards becoming a global leader in the industry.

Unveiled 'Vision 2030' roadmap for mid-to-long-term growth, celebrating its 10th anniversary

Lunit
루닛 창립 10주년 기념식
Lunit 10th Anniversary Celebration

[2023.08] The Company **announced its 'Vision 2030' business plan during the 10th-anniversary conference** held at the headquarters on August 24th, **outlining the roadmap for mid-to-long-term growth.**

Firstly, the Company unveiled its plan to **enter the platform business**. We expect to enhance data acquisition and accessibility by developing an 'AI platform' that integrates and manages medical big data based on AI. To achieve this, the Company plans to gather various cancer-related data, activate the data-AI virtuous cycle ecosystem, and build a platform that integrates patient data.

In the field of cancer diagnosis, the Company mentioned **(1) autonomous AI product development, (2) AI-based cancer risk prediction, and (3) whole-body MRI AI solution development**. We emphasized that in the future, as AI's reading accuracy approaches 100%, we will enter an era where autonomous AI independently interprets medical images. Furthermore, we announced several plans to develop a product that can predict the probability of breast cancer occurrence in the next 5 years and an AI product that can screen for whole-body cancer through whole-body MRI scans.

In the field of oncology, the Company will expand the coverage to **include all anticancer drugs, such as ADC, beyond the primarily addressed immunotherapy**. We also have the plan to **apply a multi-omics approach**, which encompasses various analyses and approaches, including genomics and microbiology, to develop multi-omics biomarkers for optimal cancer treatment. Finally, we expressed our ambition to play a role as a drug discovery company **by discovering new drug candidates** based on Lunit SCOPE.

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