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A Study on the Sustainable Growth of Domestic Medical AI Startups : Focusing on Overseas Expansion

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국내 의료 AI 스타트업의 지속 성장에 관한 연구 : 해외 진출을 중점으로

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Executive Summary (English)

This study explores strategies for achieving sustainable growth for domestic medical AI startups, with a particular focus on overseas expansion as a key growth driver. Medical AI technology is advancing rapidly worldwide, shifting the healthcare paradigm from experience and knowledge-based treatment to data-driven personalized care, precision medicine, and disease prediction through medical data analysis. While Korean medical AI startups are striving to keep pace with these technological advancements, they face numerous challenges in the domestic market, including regulatory barriers, difficulties in securing funding, and limitations in commercialization.

As of 2022, the Ministry of Food and Drug Safety (MFDS) had approved 149 AI medical devices, with over 94% of these devices being manufactured by startups. Although a small number of startups are leading technological development and commercialization, complex regulatory approval processes and the temporary non-reimbursement status of AI medical devices pose significant obstacles to the swift adoption of innovative technologies and revenue generation.

This study analyzes the cases of Lunit, Vuno, and CorelineSoft, which have successfully overcome these domestic market limitations and expanded into overseas markets. Using the SER-M (Subject, Environment, Resources, Mechanism) model, the study explores the key factors that contributed to their success in the global market.

Lunit, from its early days, aimed for global markets by forming partnerships with major medical device companies such as GE and Philips, which accelerated its overseas expansion. This strategy enabled Lunit to rapidly gain recognition in the U.S. and European markets. Vuno has built a diverse product portfolio based on deep learning technology. Collaborating with government agencies to establish AI approval guidelines when none existed, Vuno became the first company in Korea to receive approval for an AI medical device. Its product VUNO Med-DeepCARS was designated as a breakthrough device by the U.S. FDA, further solidifying Vuno's competitive edge in the global market. CorelineSoft, with its lung cancer screening solution, began in Germany and expanded to Italy and other European countries, securing global references through national lung cancer screening programs. CorelineSoft has thus positioned itself as a key player in major lung cancer screening initiatives across Europe.

The analysis of these three companies revealed that, in terms of Subject (S), visionary leadership and a research and development (R&D)-focused organizational structure were critical factors driving continuous innovation. For Environment (E), adapting to global regulatory environments and responding quickly to market trends were essential for international market success. From a Resources (R) perspective, efficient management of technological, financial, and intellectual resources was emphasized as essential for maintaining competitiveness in global markets. Lastly, in terms of Mechanism (M), integrating these elements through strategic partnerships with global companies and implementing tailored business models were crucial for successful market entry and operations.

In conclusion, despite the challenges faced in the domestic market, Korean medical AI startups have the potential to achieve sustainable growth by expanding into international markets. The success stories analyzed in this study demonstrate that understanding local regulations, responding swiftly, securing resources for global expansion, and building strong partnerships are essential for long-term growth. This study aims to provide a practical roadmap to help domestic medical AI startups enhance their global competitiveness and achieve sustainable growth.

Executive Summary (Korean)

본 연구는 국내 의료 AI 스타트업의 지속 가능한 성장을 위한 전략을 모색하며, 특히 해외 진출이 중요한 성장 수단으로 작용할 수 있음을 중점적으로 다룬다. 의료 AI 기술은 전 세계적으로 급속히 발전하고 있으며, 기존의 의사 경험과 지식 기반의 진료에서 벗어나 데이터 기반의 개인 맞춤형 진료, 정밀 의학, 의료 데이터 분석을 통한 질환 예측 등으로 의료 패러다임이 변화하고 있다. 한국의 의료 AI 스타트업들은 이러한 기술적 진보에 발맞춰 성장을 도모하고 있으나, 국내 시장에서는 규제, 자금 조달의 어려움, 기술 상용화의 한계 등 여러 도전 과제에 직면해 있다.

2022 년 기준 식품의약품안전처는 149 개의 AI 의료기기를 승인하였으며, 이 중 94% 이상의 제품이 스타트업에서 제조된 것으로 나타났다. 소수의 스타트업이 기술 개발과 상용화를 주도하고 있지만, 복잡한 규제 승인 절차와 임시 비급여 항목으로 제한되는 AI 의료기기들의 보험 문제는 혁신 기술의 신속한 적용과 수익 창출에 큰 걸림돌이 되고 있다.

본 연구는 이러한 국내 시장의 한계를 딛고 성공적으로 해외로 시장을 확장한 Lunit, Vuno, CorelineSoft 와 같은 국내 의료 AI 스타트업들의 사례를 SER-M(주체, 환경, 자원, 메커니즘) 모델을 바탕으로 분석하고, 이들이 글로벌 시장에서 성공을 이루는 데 기여한 주요 요인을 심층적으로 탐구한다.

Lunit 은 설립 초기부터 글로벌 시장을 목표로 GE, Philips 와 같은 글로벌 의료기기 기업들과의 파트너십을 통해 해외 진출을 가속화했다. 이를 통해 Lunit 은 미국과 유럽 시장에서 빠르게 입지를 다지며 글로벌 기술력을 인정받았다. Vuno 는 딥러닝 기술을 바탕으로 다양한 제품 포트폴리오를 보유하고 있으며, AI 기술의 인허가 제도가 없던 시절 정부 기관과 협력하여 AI 허가 가이드라인을 구축하는 데 기여했다. Vuno 는 국내 최초로 인공지능 의료기기 허가를 취득하였으며, 그 제품 중 하나인 VUNO Med-DeepCARS 는 미국 FDA 로부터 혁신의료기기 (BDD)로 지정되어 글로벌 시장에서의 기술적 우위를 확보하였다. CorelineSoft 는 폐암 스크리닝 솔루션을 기반으로 독일에서 시작해 이탈리아 및 유럽연합과 국가 차원의 폐암 검진 프로그램 사업을 추진하며 글로벌 레퍼런스를 확보했다. 이를 통해 CorelineSoft 는 유럽 전역에서 주요 폐암 검진 프로그램의 핵심 파트너로 자리매김하였다.

3 개 기업의 사례를 분석한 결과, 주체(S) 측면에서는 창업가의 비전 있는 리더십과 연구 개발(R&D) 중심의 조직 구성이 지속적인 혁신을 이끄는 중요한 요소로 나타났다. 환경(E) 측면에서는 글로벌 규제 환경에 적응하고 시장 트렌드에 신속하게 대응하는 것이 국제 시장 진출의 성공을 좌우하는 핵심 요인으로 분석되었다. 자원(R) 측면에서는 기술적, 재정적, 지적 자원의 효율적인 관리가 글로벌 시장에서 경쟁력을 유지하는 데 필수적이라는 점이 강조되었다. 마지막으로 메커니즘(M) 측면에서는 이러한 요소들을 통합하여 글로벌 기업들과의 전략적 파트너십을 구축하고, 맞춤형 비즈니스 모델을 통해 성공적인 시장 진입과 운영을 보장하는 것이 중요하다고 나타났다.

결론적으로, 한국의 의료 AI 스타트업들은 국내 시장에서 직면한 여러 도전 과제에도 불구하고 해외 시장 진출을 통해 지속 가능한 성장을 이룰 수 있는 잠재력을 가지고 있다. 연구에서 분석된 성공 사례들은 공통적으로 현지 규제에 대한 이해와 신속한 대응, 글로벌 진출을 위한 자원 확보, 그리고 강력한 파트너십 구축이 장기적인 성장에 필수적인 요소임을 시사한다. 본 연구는 이를 통해 국내 의료 AI 스타트업들이 글로벌 경쟁력을 강화하고 지속 가능한 성장을 이룰 수 있도록 실질적인 로드맵을 제공하고자 한다.

Table of Contents

List of Tables

List of Figures

I. Introduction

1. Research Background

The Fourth Industrial Revolution has brought about significant transformations across various sectors, driven by the convergence of advanced technologies, with data at the core of this change. Today, the ability to effectively collect, analyze, and utilize information and data has become a critical factor in determining the survival and competitiveness of businesses. This shift is accelerating the digital transformation of industries, and businesses that harness the power of data are positioned to enhance their competitiveness and create new business opportunities.

The healthcare sector is no exception to this transformation. Traditionally, healthcare services have heavily relied on the experience and knowledge of physicians. However, in recent years, there has been a paradigm shift toward evidence-based medicine, which emphasizes decision-making based on scientific evidence. The transition to "data-driven medicine" is enabling personalized diagnostics and treatments through the utilization of large-scale healthcare data, significantly contributing to the improvement of both the quality and efficiency of healthcare services. In particular, data analysis is making personalized care possible, giving rise to a new paradigm known as precision medicine. By analyzing diverse healthcare data, including patient records, genetic information, and clinical trial results, healthcare providers can now offer more accurate diagnoses and treatment plans. This transformation is accelerating the digitalization of the healthcare industry and, ultimately, laying the foundation for more precise and personalized medical services.

Artificial intelligence (AI) technology is at the forefront of innovation in the healthcare field as well. AI systems, capable of efficiently analyzing vast amounts of healthcare data and performing real-time diagnostics and predictions, assist healthcare professionals in making more accurate decisions, which in turn improves patient outcomes. AI is already playing a pivotal role in areas such as medical imaging analysis, disease prediction, and drug discovery, and its integration into healthcare services is driving revolutionary changes in how care is delivered.

Korean medical AI startups are growing in line with these trends but are also facing numerous challenges. According to the “2022 AI Startup Ecosystem Report” published by Startup Alliance, as of 2021, 20.6% of the 314 startups registered in Korea's startup investment database were classified as AI startups related to the healthcare industry, making it the largest sector among the 20 categorized industries. However, around 60% of these AI startups remain in the early stages of investment, and they continue to struggle with securing subsequent funding and generating sustainable revenue. One of the primary challenges facing Korean medical AI startups is maintaining profitability after market entry and overcoming obstacles in scaling up. These issues are significant barriers to achieving sustainable growth.

Despite governmental support and policy efforts, medical AI startups face regulatory hurdles, difficulties in commercializing their technologies, and complex issues during the scale-up process. The domestic regulatory environment continues to impose significant restrictions on the ability of medical AI startups to innovate, leading many to shut down prematurely. This underscores the need for new strategies and solutions to ensure the long-term growth and stability of domestic medical AI startups.

In this context, overseas markets present new opportunities for Korean medical AI startups. The U.S. market, due to its large healthcare industry, is considered a promising entry point for many startups. However, expanding into foreign markets requires more than just market expansion—it necessitates an understanding of complex regulatory and market environments, along with strategies to respond appropriately.

Therefore, for medical AI startups to establish a successful foothold in the global market, a systematic analysis of the factors behind the success of those that have already expanded abroad is essential. This study aims to explore the strategic directions necessary for the sustainable growth of domestic medical AI startups through global market expansion, addressing the challenges they face and how these can be overcome.

2. Research Objective

The primary objective of this study is to systematically analyze strategies that enable Korean medical AI startups to successfully expand into international markets and achieve sustainable growth. While the medical AI industry holds significant growth potential, fueled by rapid technological advancements, Korean startups still face numerous challenges. This study aims to understand these challenges and provide effective and concrete strategies for successful overseas expansion.

First, the study seeks to analyze the key opportunities available to medical AI startups when entering international markets and the critical challenges surrounding these opportunities. To this end, the study investigates the current state of AI technology development, the characteristics of the medical AI industry, related investment and regulatory environments, and the status of Korean medical AI startups.

Second, the study utilizes the SER-M (Subject, Environment, Resource, Mechanism) model to conduct an in-depth analysis of the primary success factors for medical AI startups that have achieved successful international expansion. This model allows for a comprehensive and structured analysis of four elements: internal competitive factors of the company (Subject), the market and regulatory environment (Environment), technological and financial resources (Resource), and operational strategies (Mechanism). The study will primarily focus on case analyses of leading Korean medical AI startups, including Lunit, Vuno, and CorelineSoft, to investigate how these companies achieved successful market entry and growth in foreign markets.

Third, the study aims to provide detailed strategic directions for overseas expansion and practical solutions for medical AI startups to achieve sustainable growth in global markets. The results of this research will offer valuable insights to enhance the global competitiveness of the medical AI industry and propose specific and actionable strategies to help Korean startups successfully establish themselves in international markets.

3. Research Methodology

This study applies the following methodologies to systematically analyze the overseas expansion strategies and success factors of medical AI startups. First, an environmental analysis was conducted to assess the overall status of the medical AI industry. This includes an analysis of AI technology development, the current state of the medical AI industry, and trends in the Korean medical AI market. Additionally, the study reviewed relevant policies and regulations, analyzing government policies and regulations affecting the AI-based healthcare industry while comparing the regulatory environments of Korea and the United States. Based on this analysis, the foundational data for the study was collected, and the research direction was established.

Next, the study utilized case analysis and the SER-M model for further analysis. First, case analyses were conducted on three leading companies in the medical AI field: Lunit, Vuno, and CorelineSoft. The company profiles, domestic and international business statuses, and overseas expansion strategies of these companies were examined. Second, the SER-M model was applied to analyze the success factors of the three companies.

The research methodology employed in this study provides a structured framework for analyzing the complex business environments of medical AI startups and understanding how various factors interact. This comprehensive analysis of success factors and strategies for overseas expansion will contribute to identifying concrete solutions that help startups establish a successful presence in global markets.

II. Environment Analysis and Research Framework

1. Industry Overview

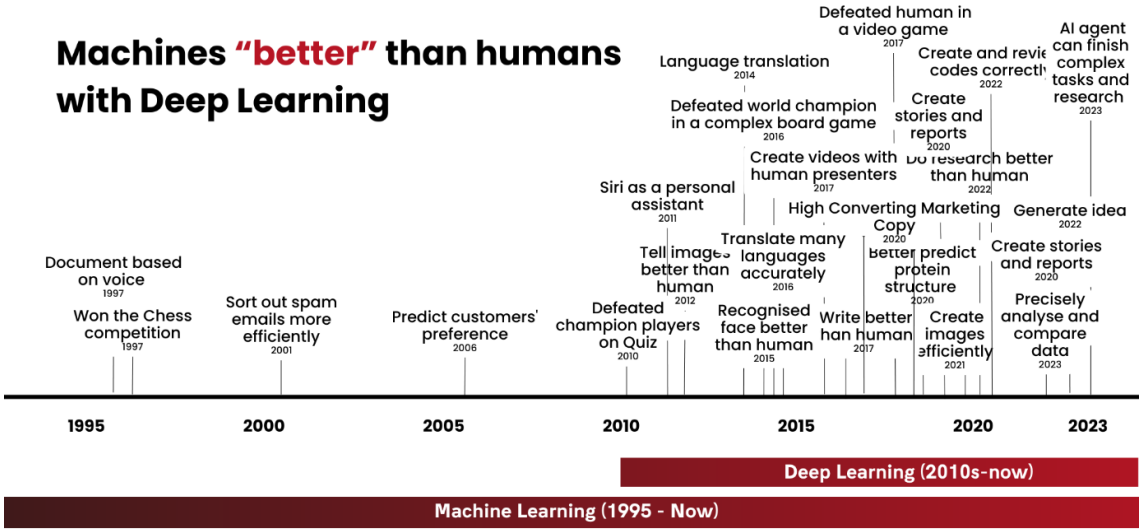
1) Advancements in AI Technology

Artificial intelligence (AI) technology has evolved significantly since the term "AI" was coined in the 1950s, starting with rule-based systems and advancing continuously over several decades. In its early stages, AI was limited to processing data according to predefined rules, offering relatively constrained capabilities. However, the introduction of machine learning (ML) in the 1980s marked a significant turning point, enabling AI to learn and make predictions based on data. This shift drastically improved AI's performance, allowing it to analyze more complex patterns and make decisions more effectively.

In the 2010s, the emergence of deep learning (DL) further revolutionized AI, enabling it to process large-scale data and learn intricate patterns that are difficult for humans to recognize. The accumulation of big data and advancements in high-performance computing have accelerated the development of AI, making it applicable in diverse fields such as natural language processing (NLP), computer vision, and reinforcement learning. These technological innovations have transformed AI from a simple data-processing system to a more autonomous tool capable of learning and making decisions independently (KFDA, 2020).

A pivotal moment for AI occurred in 2022 when OpenAI introduced ChatGPT to the public, drawing widespread attention to AI technology. This milestone spurred many companies to begin utilizing AI tools in various business domains, resulting in measurable productivity improvements across multiple industries. The popularization of AI has led to its integration not only in business but also in everyday life, marking a significant step towards the widespread adoption of AI tools in both professional and personal contexts.

<Figure 1> History of AI

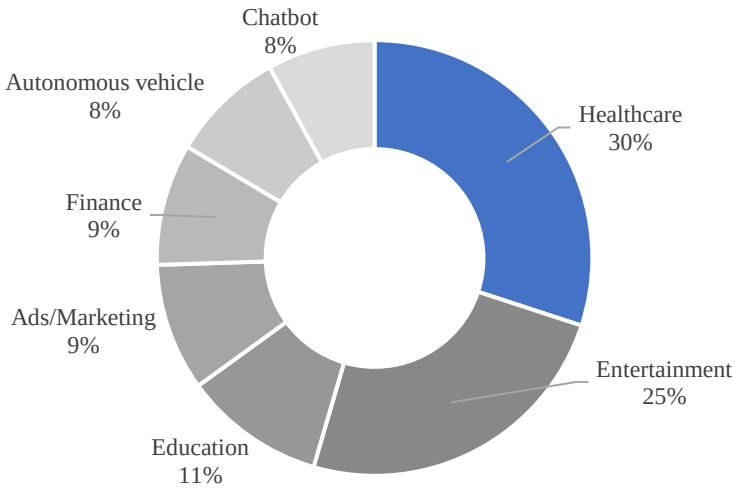


Reference: https://courses.cfte.education/skills-in-ai-world-2023/

The popularization of AI has significantly expanded its application across various industries, enhancing productivity for both businesses and individuals by enabling faster and more efficient task execution. AI is no longer merely a technological innovation; it is now driving substantial change across society as a whole. Globally, AI is expected to be most actively adopted in industries such as healthcare and biotechnology, manufacturing, finance, logistics and distribution, and autonomous vehicles in the near future (Joo Jae-wook, 2022).

AI is projected to see extensive implementation in these sectors soon. In the financial industry, AI is already solving complex problems quickly by supporting the development of investment strategies, managing risks, and detecting fraud. In autonomous driving, AI helps analyze the vehicle's surroundings in real-time to ensure safe navigation. In this way, AI continues to play a pivotal role in leading innovation across diverse industries, serving as a key driver of transformation.

<Figure 2> Distribution of AI Start-up by Industry Sector in Korea



Reference: Artificial Intelligence Startup Ecosystem Report, 2022

2) Medical AI Industry Overview

The recent medical environment is shifting from a disease-centered model to a patient-centered model, with an emphasis on disease prediction and prevention (Korea Health Industry Development Institute, 2020). This transition has been accelerated by the introduction of deep learning and big data technologies, evolving traditional evidence-based medicine into data-based medicine (Park Seung-kyun, 2019).

In the past, it was difficult to find meaningful relationships in medical data. However, AI technology is now integrated into healthcare systems, enabling the real-time collection and analysis of new types of data such as biological and genetic information alongside existing medical data (e.g., medical records, insurance claims, academic papers). AI is used in various areas, including medical imaging analysis, diagnostic support systems, and the development of personalized treatments. Medical professionals are now able to diagnose diseases early and provide personalized care based on large-scale data. AI is bringing about innovative changes throughout the entire healthcare cycle—diagnosis, prevention, treatment, and management—by analyzing and interpreting medical data, offering optimized treatment solutions for patients. This enhances the efficiency of healthcare services and plays a key role in delivering precise, personalized medical care (Korea Health Industry Development Institute, 2020; Park Seung-kyun, 2020).

According to a 2021 report by MarketandMarkets, the global healthcare AI market size is expected to grow from $6.9 billion in 2021 to $20.7 billion by 2024, and to reach $67.4 billion by 2027, with a compound annual growth rate (CAGR) of 46.2%. North America is projected to lead the growth, with the market size increasing from $2.6 billion in 2021 to $26.7 billion by 2027, accounting for about 38.5% of the global market. Meanwhile, the Asia-Pacific region is emerging as a key market, representing 25.4% of the total, driven by the accelerated adoption of AI technologies (MarketandMarkets, 2021).

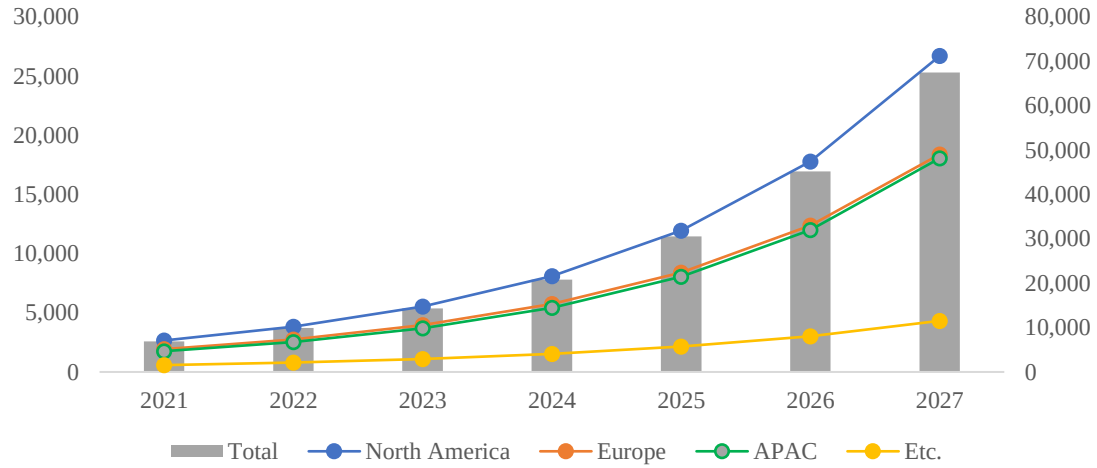
AI technology is thus a critical driver of growth in the healthcare market, improving both the efficiency of healthcare practices and the quality of treatment. By enabling cost reductions and providing personalized treatments, AI plays an essential role in supporting the sustained growth of the global healthcare market.

<Table 1> Global AI Healthcare Market Size (US$M)

Region/Year	2021	2022	2023	2024	2025	2026	2027	CAGR(%)
North America	2,660	3,819	5,533	8,091	11,940	17,782	26,692	46.9
Europe	1,925	2,748	3,955	5,737	8,391	12,373	18,379	45.7
APAC	1,753	2,533	3,692	5,424	8,035	12,003	18,050	47.5
Etc.	576	794	1,100	1,532	2,145	3,019	4,317	39.9
Total	**6,914**	**9,894**	**14,280**	**20,784**	**30,511**	**45,177**	**67,438**	**46.2**

Reference: MarketandMarkets, 2021

<Figure 3> Global AI Healthcare Market Size (US$M)



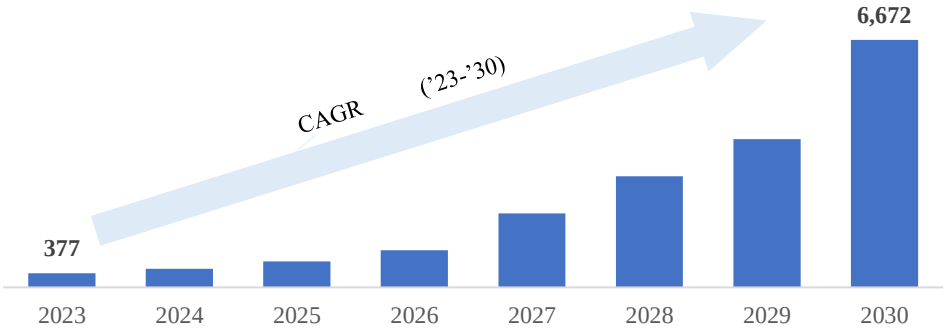
Reference: MarketandMarkets, 2021

3) South Korean Medical AI Industry Overview

The first case of artificial intelligence being introduced into the medical field in Korea occurred in 2016 when Gachon University Gil Medical Center in Incheon adopted IBM's AI medical system 'Watson for Oncology' for cancer treatment. Watson, an AI system that had studied over 600,000 pieces of medical evidence and more than 2 million pages from 42 medical journals, was designed to recommend optimal cancer treatments. Upon its initial implementation, Watson garnered significant attention (Lee Da-eun, 2017). This event marked a pivotal moment, showcasing the potential of AI in Korea's healthcare market and laying the foundation for innovation within the medical system.

According to a 2023 report by MarketandMarkets, the size of the domestic medical AI market in Korea is projected to grow from $370 million in 2023 to over $6.6 billion by 2030, with a compound annual growth rate (CAGR) of 50.8% (MarketandMarkets, 2023).

<Figure 4> Korea Artificial Intelligence (AI) in Healthcare Market 2023 to 2030 (US$M)



Reference: (MarketandMarkets, 2023)

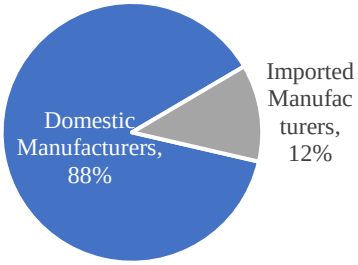
The domestic AI medical device market in Korea began to see significant growth in 2018 when VUNO received the country's first regulatory approval for an AI medical device that analyzes patients' bone age. This milestone spurred numerous other medical AI companies to actively engage in the development of AI-based medical devices.

According to a 2022 approval report from the Ministry of Food and Drug Safety (MFDS), a total of 149 AI medical devices had been approved by 2022, with these devices being manufactured or imported by 58 companies. Notably, 51 of these companies are domestic manufacturers. Among these 51 companies, excluding large corporations such as Samsung Electronics, Samsung Medison, and SK Corp., more than 94% are newly established startups (MFDS, 2022). This demonstrates that startups are playing a leading role in driving innovation in the domestic AI healthcare market.

Furthermore, 7 companies that received approval for more than five AI medical devices accounted for 70 products, representing 50% of the total AI medical devices approved in 2022. This indicates that a small number of startups are playing a pivotal role in the AI medical device market, driving both technological development and commercialization.

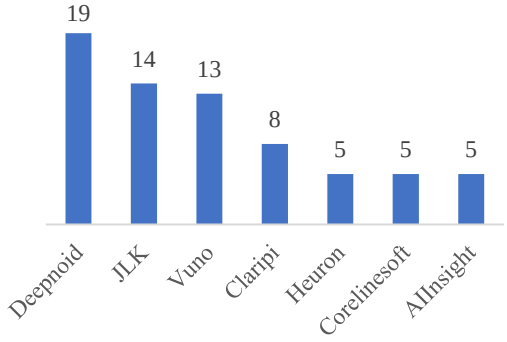
However, to remain competitive and generate sustainable revenue while competing with large domestic corporations and foreign importers in the medical market, these startups must overcome two major obstacles. The first challenge is the complex regulatory approval process, which requires AI medical devices to undergo numerous procedures to verify performance, safety, and clinical effectiveness before entering the market. The second challenge is the issue of insurance coverage, as most AI medical devices are categorized as non-reimbursable, imposing a financial burden on both medical institutions and patients. These structural barriers limit the growth of startups and make it difficult for them to achieve sustainable revenue.

<Figure 5> Distribution of AI Medical Device Approval Companies in Korea (2022)



Reference : Medical Device Approval Report, 2022

<Figure 6> The number of AI medical device approvals per company (2022)



Reference : Medical Device Approval Report, 2022

2. Policy and Regulation

1) Regulatory Approval and Reimbursement Systems affecting Medical AI

For startups, innovative technologies or business models may be sufficient to gain influence in the early stages of the market. However, once a startup reaches a certain level of growth, the ability to monetize these innovations becomes a more critical success factor for achieving market success (Park Mun-su, 2023). In particular, for medical AI products to enter the market and thrive, it is essential to understand and comply with medical device regulatory approval and insurance reimbursement systems. Meeting these requirements is crucial for achieving long-term success in the healthcare market.

(1) Medical Device Regulatory Approval System

AI-based medical devices are software applications that utilize artificial intelligence (AI) to analyze medical data, aiding in the diagnosis of diseases or supporting treatment decisions. For these AI medical devices to be released in the market, they must undergo and pass the regulatory approval processes established by the Ministry of Food and Drug Safety (MFDS), which is responsible for evaluating and managing the safety of medical devices developed domestically and internationally.

The approval process requires rigorous clinical trials to demonstrate the product's performance, safety, and clinical effectiveness. These trials include the submission of technical documentation, such as clinical trial data and training datasets, for review.

AI medical devices, particularly those based on machine learning (ML), analyze patient data to diagnose diseases or propose treatment methods. Given the nature of AI's role in healthcare, verifying the accuracy and predictive capabilities of machine learning models is essential. The evaluation process involves precise clinical trials to ensure that the machine learning models produce results consistent with existing diagnostic methods, confirming their reliability and effectiveness in real-world medical applications.

The process of proving the performance and clinical effectiveness of AI medical devices is one of the most complex and challenging aspects of development. During this process, the clinical data obtained through AI must be compared with existing diagnostic methods to demonstrate its performance. For example, an AI-based medical device that diagnoses lung cancer using chest X-ray images must prove its performance by comparing the AI-generated diagnostic results with those obtained from standard methods such as CT or MRI. To conduct these clinical trials, collaboration with experts in the field, research teams, and hospitals is essential. The data stored in the hospital's Electronic Medical Records (EMR)—including medical images, vital signs, and diagnostic test results—must be utilized for research purposes. However, for startups unfamiliar with statistical research involving experimental and control groups, it is often challenging to develop a comprehensive clinical trial plan.

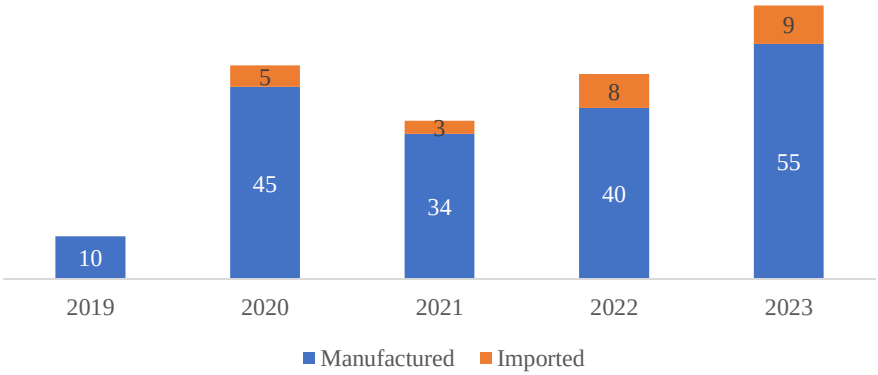
Additionally, to initiate the research, companies must pass rigorous Institutional Review Board (IRB) evaluations, which focus on ethical standards, including compliance with privacy protection laws. Given the complexity of this process, support from healthcare institutions with extensive IRB experience is critical, yet it is often difficult for startups to overcome the high barriers to collaboration with hospitals. As a result, the regulatory approval process for medical devices presents significant time and financial burdens. The preparation and procedures required for clinical trials are complex, and the costs involved are substantial, posing a major hurdle for many startups.

In a 2021 Healthcare Future Forum, hosted by the Ministry of Health and Welfare and the Korea Health Industry Development Institute, Professor Kim Jong-yeop of Konyang University College of Medicine highlighted four major issues that medical AI startups face when entering the market. These include: ΔDifficulty in collaborating with healthcare professionals ΔLack of understanding of medical laws and IRB procedures ΔDiscrepancies between developed technologies and the needs of medical practitioners ΔChallenges in clinical validation.

Professor Kim emphasized that the issues faced by medical AI startups are not limited to technology development but also involve challenges related to collaboration with medical institutions, navigating complex regulatory procedures, and aligning with the practical needs of healthcare providers. He stressed the importance of cooperative support from both the government and healthcare institutions to help overcome these barriers (Money Today, 2021).

Despite these challenges, the number of AI-based medical devices approved, certified, or registered by the MFDS had reached 213 as of 2023. There has been a sharp increase in approvals since 2020, with 48 devices approved in 2022 and 64 in 2023, reflecting a 33% year-over-year increase (MFDS, 2023).

<Figure 7> Status of AI-based Medical Devices Approved and by Year in Korea



Reference: Medical Device Approval Report, 2023

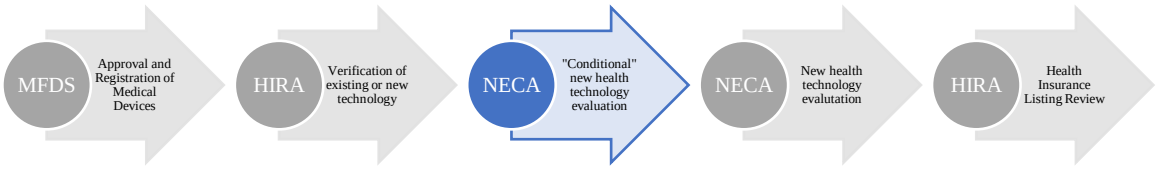
(2) Reimbursement Systems

Even after receiving regulatory approval for a medical device, the process of generating revenue through health insurance coverage is not straightforward. In South Korea, for a medical device incorporating new health technology to be used in clinical practice, several steps must be completed: ΔApproval by the Ministry of Food and Drug Safety (MFDS) ΔVerification by the Health Insurance Review and Assessment Service (HIRA) to confirm if it qualifies as new health technology ΔnHTA (new Health Technology Assessment) by the National Evidence-based Healthcare Collaborating Agency (NECA) ΔHealth insurance listing review by HIRA, after which the device may be covered by health insurance (Guideline for AI-based Innovative Medical Technology, 2023).

However, many AI medical devices struggle to immediately undergo the new heatlh technology assessment due to insufficient clinical evidence from real-world medical use, making it difficult to present adequate materials for evaluation. To address this issue, the "Conditional" New Health Technology Evaluation System" was introduced, allowing devices that have already received MFDS approval to be temporarily used as non-reimbursable in clinical settings.

Under this system, new medical technologies granted conditional evaluation can be used without undergoing a full assessment for up to two years, as non-reimbursable, in order to gather the necessary clinical evidence. During this two-year period, the devices are permitted to be used in clinical settings under Article 9, Paragraph 1, Appendix 2 of the "National Health Insurance Act on Medical Care Benefit Standards" (Guidelines for Managing New Medical Technology Evaluation Deferment, 2022). As of September 2024, a total of 37 devices are being used in clinical practice under this system.

<Figure 8> From Medical Device Approval to Insurance Reimbursement: Application Process



Reference: Guideline for Conditional New Health Technology Evaluation System, 2022

Unlike reimbursable items, non-reimbursable items do not receive financial support from the national health insurance system. However, having at least a non-reimbursable classification is crucial as it acknowledges the clinical necessity of the AI medical device, allowing medical institutions to charge patients for the costs. This classification can serve as a foundation for the rapid adoption of unfamiliar AI medical products in the healthcare system.

Despite the rapid pace of AI technology development, there are concerns that this progress is happening without sufficient societal consideration. Critics argue that the actual effects of AI technology are not always based on strong evidence, leading to calls for stricter evaluation standards (Byrne, 2023). Additionally, there is a growing emphasis on the potential risks AI could pose to public health and safety, necessitating careful deliberation (Lee Il-hak, 2023). These concerns are among the reasons why many AI medical devices remain in a temporary listing status.

AI medical devices with a temporary listing can only receive health insurance coverage for a limited period, after which their inclusion in the insurance system depends on the results of a thorough evaluation. As a result, AI medical devices face challenges in setting long-term strategies, and their potential for revenue generation remains uncertain, particularly in light of policy changes.

Furthermore, AI medical devices with a temporary listing must accumulate sufficient evidence while being used in the market to determine whether they will be permanently listed as reimbursable. This forces companies to rely on temporary insurance applications while hoping for revenue generation. This situation creates significant constraints for domestic AI medical startups, many of which experience substantial financial burdens from the moment they receive approval to the point of generating revenue. Under the current insurance system, it is particularly challenging for startups to develop long-term strategies.

In April 2024, the government announced its "2024 National Health Insurance Comprehensive Plan," which included a proposal to extend the evaluation period for new health technologies from two years to four years. This announcement is undergoing administrative review. The extension was prompted by growing recognition of the importance of Real-World Data (RWD) in new medical technology evaluations, and the belief that the original two-year period was insufficient to gather adequate evidence. This policy change offers companies an additional two years to gather RWD, providing them with more opportunities to compile favorable data for evaluation. However, this sudden announcement has caused significant disruption for companies that had built their strategies around the original two-year timeframe. These companies now face the challenge of revising their strategies and adapting to the new timeline, which has created additional burdens in terms of planning and execution.

Ultimately, for AI medical devices to generate long-term revenue and establish a stable position in the market, consistent and stable policy support from the government is essential. In fact, Soundable Health, a domestic AI startup, relocated its headquarters to the U.S. in 2018 to expand its business due to the complexity of the regulatory approval process and issues with insurance coverage in Korea. The company received FDA approval in 2020 and is currently pursuing health insurance coverage in the U.S. Soundable Health’s CEO, Song Ji-young, noted, "If we had continued operating in Korea, it would have taken much

longer for the company to grow," emphasizing that the U.S. regulatory environment was more favorable for business expansion (Korea Economic Daily, 2023).

Currently, AI medical devices with temporary listings in Korea struggle to generate substantial revenue due to regulatory and policy uncertainties, and these challenges are driving many startups to look to overseas markets for new opportunities. These structural issues are hindering the development of the domestic AI healthcare industry, pushing many startups to seek growth in foreign markets.

2) Comparison of Regulatory Environments between South Korea and U.S.

The regulatory frameworks for medical AI in the United States and South Korea adopt fundamentally different approaches, with the U.S. following a Negative System and South Korea adhering to a Positive System. This distinction significantly impacts how startups enter the market in each country.

In the U.S., the Negative System outlines only what is legally prohibited, with everything else generally permitted. This creates an environment where innovative technologies can quickly enter the market. The FDA (Food and Drug Administration) supports the rapid commercialization of breakthrough technologies through programs such as the Breakthrough Devices Program, which expedites the approval process for innovative medical devices. For example, Optellum's Virtual Nodule Clinic, an AI software for lung cancer prediction, received FDA approval in 2021 through the 510(k) process. The product was assigned an APC insurance code, allowing hospitals to bill approximately $600–700 per patient (ASTI, 2022).

In contrast, South Korea’s Positive System specifies only what is legally approved, meaning technologies that have not received prior approval cannot enter the market. This system tends to be more conservative in adopting new technologies, requiring a longer time and more complex procedures before medical devices can be commercialized. The stringent regulatory barriers, especially in proving safety and efficacy, can severely delay the market entry of innovative technologies. While this approach thoroughly manages the safety of medical devices, it can create critical delays in an era where rapid commercialization is essential for global competitiveness, posing significant challenges to the survival and growth of startups.

In the U.S., AI-based medical devices and software are classified as Software as a Medical Device (SaMD) and regulated according to their risk level as Class I, II, or III. Devices in Class II and Class III are subject to FDA approval via the 510(k) or De Novo pathways. The 510(k) pathway is used for devices similar to those already approved, while the De Novo pathway applies to novel devices without a predicate. For instance, HeartFlow's FFR-CT, an AI software that analyzes coronary blood flow, was approved as a Class II device through the De Novo process in 2014. Starting in 2020, it was assigned an APC insurance code (Level 11), allowing healthcare providers to bill approximately $900–1,000 per patient (Study on Evaluation Methods for the Application of AI Software Medical Devices in Clinical Settings, 2023).

The U.S. insurance reimbursement system provides additional compensation for innovative medical devices through programs such as the New Technology Add-On Payment (NTAP), which supports the rapid adoption of new technologies in clinical practice. For example, Caption Health's Caption Guidance, an AI for cardiac ultrasound analysis, received De Novo approval in 2020, allowing hospitals to bill up to $1,868.10 per use. Such reimbursement programs play a crucial role in encouraging the swift integration of AI technology into healthcare settings (The Healthcare Industry Revolution Triggered by AI, 2024).

In conclusion, the Negative System in the U.S. creates a favorable environment for the rapid market entry of innovative medical devices and AI software, significantly accelerating commercialization compared to South Korea’s Positive System. This makes the U.S. market an attractive option for medical AI startups, offering them a strategic pathway for survival and growth in the global arena.

3. Research Framework

The SER-M model, a representative framework for analyzing corporate activities, consists of four key elements: Subject, Environment, Resource, and Mechanism.

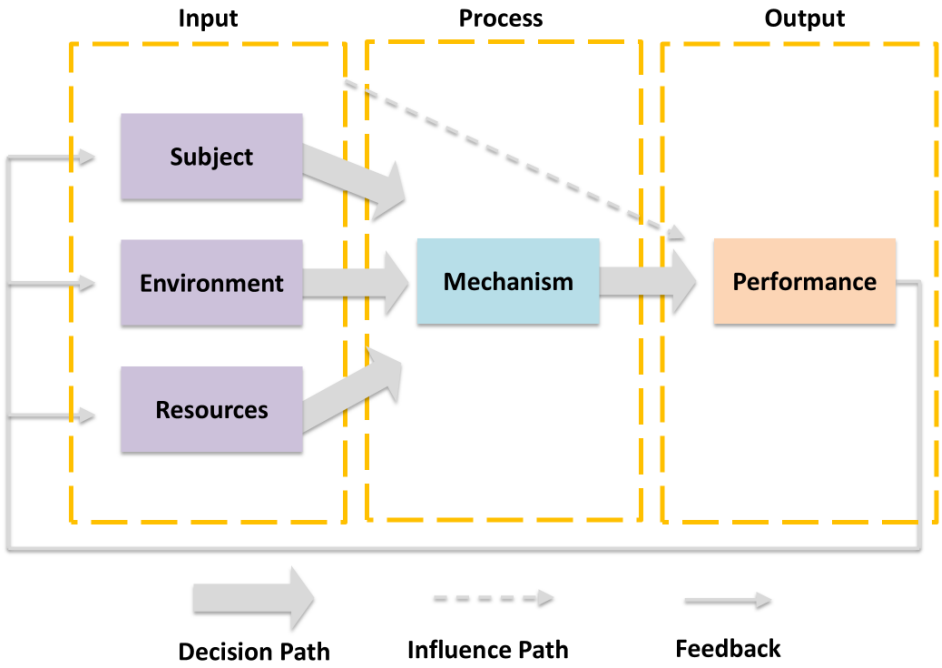
- Subject: This focuses on the internal competitive factors of the startup, including the founder's educational background, industry experience, leadership style, organizational structure, human resources, and corporate culture, which significantly influence the company's strategic decision-making and execution capabilities. These internal competencies are crucial for successful overseas expansion.

- Environment: This involves analyzing external expansion factors such as market competitiveness, regulatory environment, market trends, customer demands, and competitor movements. Responding effectively to external conditions is essential for success in international markets.

- Resource: This element focuses on analyzing the resources necessary for a startup to maintain competitiveness in the market. It includes technological resources (e.g., AI algorithm patents and technological advantages), financial resources (e.g., funding and investment), and intellectual resources (e.g., R&D achievements and industry knowledge). Efficient management and utilization of these resources are key factors in achieving growth and global competitiveness.

- Mechanism: This integrates the three elements (Subject, Environment, and Resource) to analyze the strategic direction of the company. It covers strategic decision-making processes, business model establishment and adjustment, and operational efficiency improvements. An effective mechanism is essential for achieving corporate goals and maintaining a competitive edge in the market.

<Figure 9> SER-M Model



Reference: https://dbr.donga.com/article/view/1203/article_no/5851

By fleshing out these four elements—Subject, Environment, Resource, and Mechanism—the SER-M model provides a holistic framework for analyzing the critical factors that determine a startup's ability to succeed in international markets. Each component plays a pivotal role in shaping the startup's capacity to compete globally, adapt to market demands, and sustain long-term growth.

III. Case Analysis

For Korean AI startups, successfully establishing a presence in global markets and achieving sustainable growth holds significant importance for the domestic startup ecosystem. While domestic growth based on technological prowess is crucial, there are inherent limitations in relying solely on the local market. As a result, global market expansion has become an essential strategic choice for Korean medical AI startups. Advanced markets like the United States, with their vast market size and high demand for technological innovation, are seen as key destinations for Korean AI startups to explore. However, significant barriers such as regulatory hurdles, cultural differences, and the complexities of commercializing technology pose considerable challenges in the process of expanding abroad.

Therefore, this chapter aims to analyze the overseas expansion strategies and success factors of Korean AI startups that have successfully entered global markets. The case studies focus on three notable companies in the medical AI sector—Lunit, Vuno, and CorelineSoft—all of which have established a strong foothold in the global medical AI market through unique technological innovations and strategic approaches. By applying the SER-M model (Subject, Environment, Resource, Mechanism), I will explore the key factors that contributed to their success in international markets.

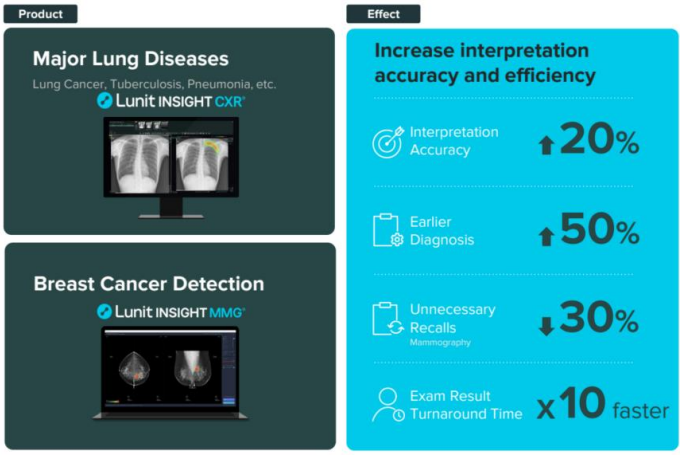
Through this case analysis, I will closely examine the challenges each company faced during their overseas expansion and the strategies they employed to overcome these obstacles. By doing so, I aim to derive specific insights and actionable recommendations for other domestic medical AI startups seeking sustainable growth through international market entry in the future. This analysis will provide valuable lessons and strategic guidance for startups navigating the complexities of global expansion in the medical AI industry.

1. Lunit

1) Company Overview

Lunit, founded in 2013, is a specialized medical artificial intelligence (AI) company that provides innovative solutions in the field of cancer diagnosis and treatment using AI technology. Established by six deep learning experts from KAIST, Lunit operates under the vision of "Conquering cancer through AI," with a focus on developing AI-driven solutions for early cancer detection and personalized treatment. Lunit's flagship products, Lunit INSIGHT and Lunit SCOPE, use AI to analyze chest X-rays and mammograms, assisting in the early detection of various diseases, including lung and breast cancer. These products support medical professionals in their decision-making, thereby improving the accuracy of diagnoses (Park Ji-hoon, 2022; Lunit IR Letter, 2023).

<Figure 9> Product Portfolio of Lunit



Reference: Lunit IR Report, 2024

From its inception, Lunit has pursued strategic management with a focus on the global market. Guided by the management philosophy of "Global, even if we fail," Lunit set its sights on securing competitiveness in the international arena rather than limiting itself to the domestic market. Based on this philosophy, Lunit quickly formed partnerships with global medical device companies and aggressively pushed forward its expansion strategy for global entry (Money Today, 2022).

In July 2022, Lunit went public on the KOSDAQ market through the technology-based special listing system, a move that validated the technical excellence of its AI-driven medical solutions. This IPO marked a critical turning point for Lunit, providing the financial foundation needed to invest in research and development (R&D) and accelerate its global market expansion. Following its listing, Lunit further cemented its reputation both domestically and internationally, achieving a record-breaking revenue of KRW 250 billion (USD 190 million) in 2023 (Lunit Annual Report, 2023).

Lunit has consistently worked to overcome the limitations of the domestic market by leveraging its technological strengths to grow on the global stage. This strategic approach is regarded as one of the key factors behind Lunit's international success. Through continuous innovation in technology development and forming global partnerships, Lunit has established a strong presence in the medical AI field. Its management strategy, which combines investment in R&D with global expansion efforts, has been instrumental in accelerating the company's growth (Money Today, 2022).

2) Status of Overseas Expansion

From its early days, Lunit has actively pursued global expansion, strategically targeting key regions such as the United States, Europe, and Asia to establish a strong presence in the global healthcare market. Partnerships with seven global medical device companies, including GE Healthcare, Philips, and Fujifilm, have played a crucial role in accelerating Lunit's international growth (Lunit IR Letter, 2023). As of 2023, Lunit’s AI solutions have been adopted by more than 3,000 medical institutions across over 50 countries, and the company's overseas revenue surpassed KRW 10 billion (USD 7.6 million) for the first time. Notably, 85% of Lunit's business is now driven by international sales, translating into significant growth from its global expansion efforts.

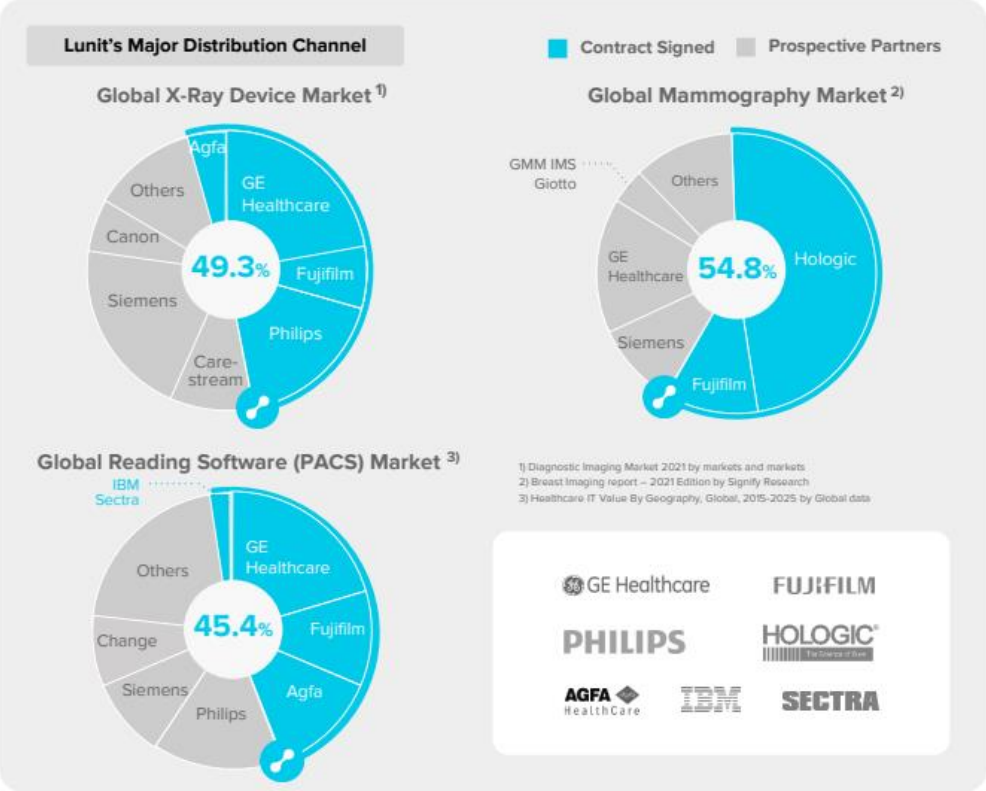
Lunit’s AI-based medical solutions have particularly proven their value through active engagement in the U.S. market. This expansion was further boosted by the company’s success in obtaining FDA approvals. In 2019, Lunit received FDA clearance for Lunit INSIGHT CXR and Lunit INSIGHT MMG, paving the way for its AI solutions to be used in hospitals and healthcare facilities across the United States. Lunit INSIGHT CXR is AI software that assists in the early detection of diseases like lung cancer and tuberculosis through chest X-ray analysis, while Lunit INSIGHT MMG helps diagnose breast cancer with a high accuracy rate of 97-99% in mammography (Park Ji-hoon, 2023).

Lunit's acquisition of Volpara Health, a New Zealand-based global company specializing in breast cancer screening and management platforms, significantly strengthened its technological capabilities in breast cancer diagnostics. Through this acquisition, Lunit gained access to more than 1 million breast cancer screening datasets, enabling the company to enhance the precision of its AI solutions and further bolster its competitiveness in the global healthcare market (Lunit IR Letter, 2023).

Lunit's global activities go beyond product exports. The company actively participates in global healthcare innovation programs, such as the U.S. Cancer Moonshot Initiative, contributing to research and technological development aimed at reducing cancer mortality rates. Participation in such programs has further validated Lunit's AI technology on the international stage. Additionally, Lunit’s AI solutions have been adopted by numerous medical institutions across Europe and the Middle East, contributing to the company's continuous expansion in the global market (Lunit Annual Report, 2023).

Lunit’s successful global expansion has been driven by strategic partnerships, regulatory approvals, and the acquisition and utilization of large-scale data, positioning the company as a leader in the global medical AI market. With international sales now accounting for 85% of its total revenue, Lunit's global expansion strategy goes beyond merely entering new markets— it has cemented its role as a leader in AI-driven diagnostic solutions within the global healthcare industry.

<Figure 10> Global Market Share of Lunit Products



Reference: Lunit IR Report, 2024

3) Analysis of Overseas Expansion Strategy Through the SER-M Model

To analyze Lunit's global expansion strategy, the SER-M model (Subject, Environment, Resources, Mechanism) can be applied to understand how each component contributed to the company's international success.

(1) Subject

At the heart of Lunit's global success are its founders and core team members. The company's initial team, including founders from KAIST, leveraged their deep understanding of deep learning and medical technology to secure a competitive edge in the global market. Lunit's founders used their industry experience to develop differentiated technology, which played a critical role in establishing the company's position in the international medical AI market.

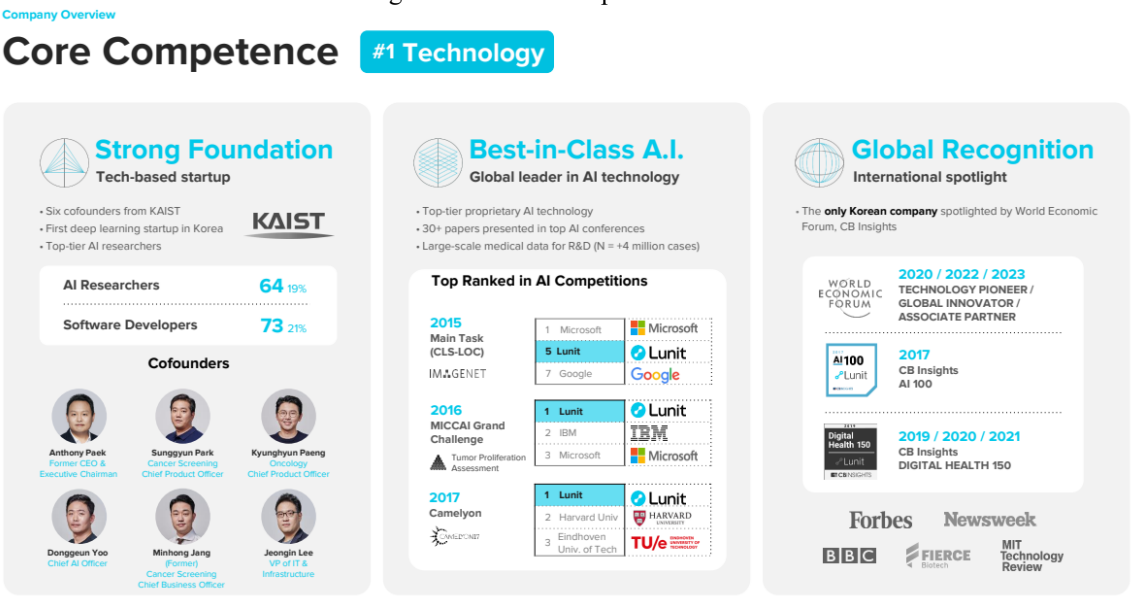
In terms of organizational structure and human resources, Lunit is highly technology-driven. Over 50% of the company's workforce consists of AI researchers and medical professionals, which serves as the driving force behind continuous product development and innovation. Notably, Lunit employs 15 full-time physicians, whose expertise in the medical field supports the development of AI solutions by validating their clinical effectiveness. This collaboration with medical experts has allowed Lunit to create trusted products for the global market. Additionally, Lunit has published over 30 papers at prestigious AI conferences, earning high regard in the AI research community.

Lunit has also actively recruited globally competitive talent to support its international expansion. As of 2024, the company employs 59 global experts, including leading scholars and medical professionals who provide strategic advice. This strong human capital has been pivotal in securing both technological

superiority and credibility, helping Lunit solidify its position in the global market. These human resources have played a key role in maintaining the company's competitiveness on a global scale (Lunit Annual Report, 2023).

Rather than using AI technology as a mere tool, Lunit has applied it as a crucial solution to improve diagnostic accuracy and enable the early detection of serious diseases like cancer. Lunit's INSIGHT product line, which boasts high diagnostic accuracy in diseases such as breast and lung cancer, has seen growing demand from medical institutions worldwide. These technical strengths enabled Lunit to successfully gain FDA approval in the U.S. and CE certification in Europe, facilitating its entry into the global market (Park Ji-hoon, 2023).

<Figure 11> Core Competence of Lunit



Reference: Lunit IR Report, 2024

(2) Environment

Lunit has successfully leveraged its understanding of global market environments to drive its overseas expansion. In the U.S. market, Lunit effectively utilized the advantages of the Negative System regulatory framework, which allows for faster commercialization of innovative technologies. Through the FDA's 510(k) and De Novo pathways, Lunit was able to swiftly bring its AI solutions to market. This regulatory system provides opportunities for the rapid introduction of cutting-edge technologies, a significant advantage compared to Korea's Positive System, which tends to require a longer approval process before new technologies can enter the market (Lunit Annual Report, 2023).

Lunit's success in the U.S. also opened doors for its participation in innovative medical projects such as the Cancer Moonshot Initiative, a government-led effort aimed at reducing cancer mortality. Lunit's involvement in this initiative was a critical moment that showcased its technological capabilities on an international level. This project played a significant role in helping Lunit establish itself in the U.S. market and boosted its credibility in the global healthcare community (Lunit IR Letter, 2023).

In the European market, Lunit achieved success by obtaining CE certification, allowing it to provide AI solutions to hospitals and medical institutions across Europe. Despite the European Union's stringent regulations on medical data protection, Lunit navigated these challenges by implementing tailored strategies that complied with the regulatory requirements. By offering customized solutions that matched market competitiveness and customer demands, Lunit successfully introduced its AI solutions to various European markets (Lunit Annual Report, 2023).

Furthermore, partnerships with global medical device companies have played a crucial role in securing Lunit's competitive edge in the international market. Collaborations with GE Healthcare, Philips, and Fujifilm facilitated the rapid adoption of Lunit's products in a wide range of medical institutions. These partnerships significantly accelerated Lunit's global expansion. As of 2023, 85% of Lunit's revenue comes from international markets, a testament to the effectiveness of its global strategy (Lunit Annual Report, 2023).

(3) Resources

Lunit's ability to secure critical resources has played a pivotal role in its global expansion. The company's AI algorithms, trained on more than 5 million medical data records, boast high accuracy, which has driven demand for Lunit's products from healthcare institutions worldwide. Lunit holds various patents based on the superiority of its AI algorithms, which have strengthened its competitive position in the global market. Notably, AI-based solutions such as Lunit INSIGHT and Lunit SCOPE are products of Lunit's advanced technological capabilities, and they have gained international trust through FDA approval in the U.S. and CE certification in Europe.

In terms of financial resources, Lunit has achieved significant success. The company raised over KRW 159 billion (USD 121 million) in funding, securing the capital necessary for further AI technology development. Additionally, Lunit's listing on KOSDAQ in 2022 via the technology-based special listing system allowed the company to raise further capital. Lunit's ability to attract KRW 95 billion (USD 72 million) in investment from foreign institutional investors, as well as participation from a U.S.-based healthcare-focused venture capital firm in the Pre-IPO stage, demonstrates the company's international recognition. The fact that 15% of Lunit's shares are held by foreign investors further reflects its attractiveness in global markets (Lunit Annual Report, 2023).

On the intellectual resource front, Lunit's acquisition of Volpara Health in New Zealand played a critical role. Volpara Health is a global leader in breast cancer screening data, and this acquisition enabled Lunit to further enhance its AI technology in the breast cancer screening and management sector. Through the acquisition, Lunit secured access to more than 1 million breast cancer screening datasets, improving the accuracy and efficacy of its AI solutions (Lunit IR Letter, 2023).

Lunit also continues to invest heavily in research and development (R&D). The company has presented over 340 abstracts and papers at prestigious AI conferences worldwide, earning recognition for its technological excellence. These academic achievements not only support Lunit's technical superiority but also contribute to its credibility and trust in the global medical market.

(4) Mechanism

A key mechanism behind Lunit's global success is its commercialization strategy based on strategic global partnerships and securing regulatory approvals. By collaborating with global medical device giants such as GE Healthcare, Philips, and Fujifilm, Lunit was able to swiftly introduce its AI solutions to large-scale healthcare institutions. These partnerships played a crucial role in accelerating the global adoption of Lunit's products, facilitating their widespread use across various medical institutions worldwide (Lunit Annual Report, 2023).

Additionally, Lunit prioritized obtaining FDA approval in the U.S. and CE certification in Europe, ensuring that its products met international regulatory standards. These approvals were pivotal in establishing Lunit's credibility in global markets, enabling products like Lunit INSIGHT to be rapidly adopted in both the U.S. and Europe. This quick commercialization strategy contributed significantly to the widespread use of AI-based medical solutions in clinical settings (Lunit IR Letter, 2023).

In conclusion, Lunit's global success is attributed to its technological capabilities, resource acquisition, and its ability to respond effectively to regulatory and market environments. By devising strategies tailored to the demands of global markets and navigating various regulatory systems efficiently, Lunit has emerged as a leader in the global medical AI market. These strategies provide a solid foundation for Lunit's continued sustainable growth in the future (Lunit Annual Report, 2023).

2. Vuno

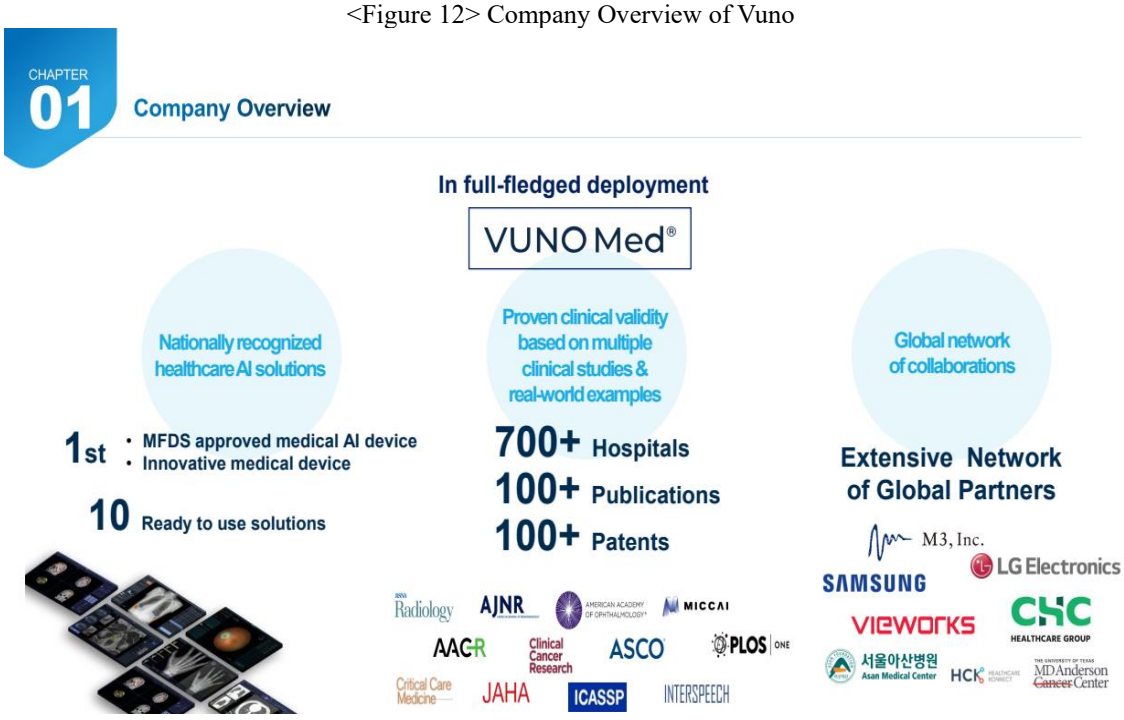
1) Company Overview

VUNO, founded in 2014, is a leading South Korean medical AI company specializing in providing various AI-driven healthcare solutions using deep learning technology. VUNO applies AI across multiple domains, including medical imaging, biosignal analysis, medical voice, and pathology, to assist healthcare professionals in diagnosis and treatment. VUNO's solutions have been implemented in over 700 medical facilities worldwide, significantly improving efficiency and accuracy in clinical settings, positioning the company as a globally recognized leader in medical AI (VUNO IR Book, 2023).

In 2018, VUNO became the first company in Korea to receive regulatory approval for an AI medical device with its product VUNO Med-BoneAge, strengthening its presence in the Korean medical AI market. VUNO has since launched various solutions, including VUNO Med-Chest X-Ray, VUNO Med-DeepBrain, and VUNO Med-DeepCARS, establishing itself as a leading player in AI-based medical imaging and diagnostics. Particularly notable is VUNO Med-DeepCARS, which predicts cardiac arrest risk using biosignal analysis. This solution has been generating revenue as a non-reimbursable service under the Conditional New Health Technology Evaluation System, allowing for two years of clinical use. It is currently deployed in 94 hospitals across Korea, including major institutions like Samsung Medical Center and Asan Medical Center. As of 2023, VUNO recorded approximately KRW 5.5 billion (USD 4.2 million) in revenue, demonstrating rapid growth in profitability (Edaily, 2023).

In February 2021, VUNO went public on the KOSDAQ market via the technology-based special listing system. The company's technological excellence in AI medical solutions and its potential for global expansion were recognized, enabling VUNO to utilize the special listing system. Following the IPO, VUNO has expanded its investment in research and development and actively pursued product commercialization and partnerships in global markets. Since its listing, VUNO has continuously increased its corporate credibility both domestically and internationally, achieving sustained growth (VUNO IR Book, 2024).

<Figure 12> Company Overview of Vuno



Reference: Vuno IR Report, 2024

2) Status of Overseas Expansion

Building on its success in the domestic market, VUNO is actively expanding its presence in global markets, focusing on regions such as the United States, Japan, and Europe. The company has made significant strides in product commercialization by obtaining key regulatory approvals, including FDA approval in the U.S., insurance reimbursement approval in Japan, and CE certification in Europe. These milestones have enabled VUNO to accelerate its market entry and product adoption in these major markets, contributing to both revenue growth and enhanced international competitiveness.

(1) United States

In 2021, VUNO established a local subsidiary in the U.S., marking its official entry into the American market, where it is working towards product commercialization through FDA approvals. One of its flagship products, VUNO Med-DeepBrain, completed FDA certification in 2023 and is currently undergoing CPT code approval procedures. With this progress, VUNO anticipates officially launching DeepBrain in the U.S. market by 2024. DeepBrain is also proving its performance and utility through a comparability assessment with the similar U.S. product, NeuroQuant.

In addition, VUNO Med-DeepCARS has been designated as a Breakthrough Device by the FDA, enabling an expedited approval process. This AI solution predicts the risk of cardiac arrest within 24 hours and is currently undergoing clinical trials in collaboration with Massachusetts General Hospital (MGH), one of the top medical institutions in the U.S. Once FDA approval is obtained, rapid commercialization in the U.S. market is expected (VUNO IR Book, 2023).

(2) Japan

In Japan, VUNO Med-LungCT AI, an AI solution for early detection of lung cancer, received PMDA approval in 2019. As of January 2024, it has been recognized for insurance reimbursement in Japan and is being supplied to hospitals through additional payment systems. VUNO has entered into a partnership with M3, a subsidiary of Sony, enabling the distribution of the product to over 90 hospitals in Japan, significantly expanding VUNO's presence in the Japanese market.

Moreover, with the change in the insurance coverage guidelines by Japan's Ministry of Health in June 2023, the number of hospitals VUNO can target is expected to increase. This has led to growing revenue in Japan, and VUNO is quickly expanding its market share in the lung nodule detection solutions segment. Based on its success in Japan, VUNO is strengthening its competitive position in the broader Asian market and is pursuing further commercialization in other countries.

(3) Europe

In the European market, VUNO has successfully commercialized its products through CE certification. Key solutions such as VUNO Med-BoneAge, VUNO Med-Chest X-Ray, and VUNO Med-DeepBrain are widely used in major hospitals and clinics across Europe, receiving positive evaluations. The products commercialized in Europe contribute significantly to VUNO's global revenue and play a critical role in the company's international expansion efforts (VUNO IR Book, 2023).

<Table 2> Global Approval Status of Vuno Products

Product Name	Regulatory Status	Function
VUNO Med-Chest X-Ray	Korea, Europe, Taiwan, Malaysia, Thailand, Saudi Arabia, Switzerland, UK, Türkiye	Assists in detecting and diagnosing major chest X-ray findings based on Chest X-Ray images
VUNO Med-Fundus AI	Korea, Europe, Switzerland, Taiwan, Malaysia, Singapore, Thailand, UK, Türkiye	Assists in detecting and diagnosing abnormalities in fundus images
VUNO Med-BoneAge	Korea, Europe, Japan, Taiwan, Switzerland, UK, Türkiye	Assists in diagnosing bone age by analyzing pediatric hand X-ray images
VUNO Med-LungCT AI	Korea, Europe, Japan, Malaysia, Switzerland, Brazil, UK, Türkiye	Detects and quantifies lung nodules in low-dose Chest CT scans
VUNO Med-DeepBrain	Korea, USA, Europe, Switzerland, Brazil, UK, Türkiye	Accurately segments and locates brain regions in MRI images
Hativ P30	Korea	Measures, analyzes, and records ECG, detects arrhythmias
VUNO Med-DeepCARS	Korea	Analyzes basic vital signs data of general ward patients and suggests risk of cardiac arrest within 24 hours

Reference: Vuno IR Letter,2021

3) Analysis of Overseas Expansion Strategy Through the SER-M Model

Analyzing VUNO's global expansion strategy through the SER-M model (Subject, Environment, Resource, Mechanism) offers insights into how each element contributed to the company’s international success.

(1) Subject

VUNO was founded in 2014 by three researchers—Chairman Lee Yeha, CEO Kim Hyun-joon, and CTO Jung Kyu-hwan—who were working on artificial intelligence technology at Samsung Advanced Institute of Technology. Recognizing the potential for applying AI technology in the healthcare field, the founders entered the medical sector, which they believed had high growth potential. In an interview, CEO Kim Hyun-joon mentioned, "There were many problems that could be solved with AI and deep learning in healthcare, but there were very few companies tackling these issues." Despite the high entry barriers, VUNO chose to focus on medical AI devices, seeing the potential for significant innovation.

VUNO’s organizational structure is centered around innovative technology development, and as of March 2023, the company employed a total of 155 people. More than 60% of these employees are involved in research and development (R&D), playing a crucial role in maintaining VUNO’s AI solutions and technological excellence. Additionally, 66% of the employees have more than five years of experience, further enhancing the performance and reliability of VUNO’s medical AI solutions through their expertise and knowledge (VUNO Business Overview, 2023).

(2) Environment

VUNO entered the medical AI device market at a time when there was no established regulatory framework for such devices. In 2017, while VUNO had developed early versions of its AI medical devices, there was no approval process for AI medical devices, and there was widespread skepticism in the market about AI in healthcare. In response, VUNO worked closely with government agencies, such as the Ministry of Food and Drug Safety (MFDS), to help establish the regulatory process for AI medical devices. Chairman Lee Yeha and CEO Kim Hyun-joon leveraged their technical expertise to build relationships with the government and actively participated in the development of AI medical device approval guidelines. As a result, in November 2017, guidelines for AI medical devices were established, and by May 2018, VUNO Med-BoneAge became the first AI medical device in Korea to receive approval (Kim Gi-yong, 2022).

In addition to regulatory efforts, VUNO actively engaged in government-funded research projects, completing eight government projects worth more than KRW 500 million (USD 380,000) by 2020. These initiatives not only bolstered VUNO's technical capabilities but also strengthened its relationship with government entities. This collaborative approach helped VUNO navigate the unregulated AI medical device landscape while maintaining a strong partnership with the government.

VUNO successfully overcame regulatory hurdles in key global markets such as the U.S. (FDA), Japan (PMDA), and Europe (CE certification), enabling rapid international market entry. In countries utilizing the Negative System for regulatory approval, VUNO capitalized on the relatively faster adoption of innovative technologies, thus enhancing its global competitiveness.

A significant achievement for VUNO came in June 2023, when its product VUNO Med-DeepCARS was designated as a Breakthrough Device by the FDA. This designation is part of the Breakthrough Device Designation (BDD) program, which allows for the expedited approval of innovative medical devices that are expected to be more effective in diagnosing or treating serious conditions compared to existing devices. The BDD designation for DeepCARS, an AI solution capable of predicting cardiac arrest, signifies the FDA’s recognition of its superior performance potential in comparison to traditional methods. This designation is a key milestone that will enable DeepCARS to be commercialized more rapidly in the U.S. through the FDA’s accelerated review process (Medical Times, 2023).

The BDD designation also provides VUNO with significant advantages, such as fast-track approval, reducing the time to commercialization in the U.S. market. This accelerated approval is expected to play a pivotal role in VUNO’s global expansion strategy, allowing the company to bring its innovative AI solution to market swiftly and secure a strong position in the competitive healthcare technology sector.

(3) Resources

VUNO secured significant funding through multiple investment rounds prior to its listing, which allowed the company to focus on developing its medical AI technology and expanding into global markets. Between 2014 and 2019, VUNO completed four major investment rounds, raising KRW 800 million (USD 610,000) in the pre-Series A stage, KRW 3 billion (USD 2.3 million) in Series A, and KRW 18 billion (USD 13.7 million) in Series B. These funds were crucial in advancing the research and development (R&D) of key AI medical solutions and preparing for commercialization and global expansion (The Bell, 2018).

In February 2021, VUNO raised an additional KRW 44 billion (USD 33.5 million) by listing on KOSDAQ through the technology-based special listing system. This listing enabled VUNO to further invest in R&D and global expansion strategies while significantly enhancing the company’s credibility.

Even after going public, VUNO continued to actively secure funding. In December 2022, VUNO raised KRW 30 billion (USD 22.9 million) through the issuance of convertible bonds, and in May 2023, it raised an additional KRW 35 billion (USD 26.7 million) through a rights offering. These funds were primarily allocated for product commercialization in the U.S. market, FDA approval processes, strengthening R&D, and expanding into global markets (Daily Medi, 2022; Maeil Business, 2023).

From a technological resource's standpoint, VUNO has focused on securing high-quality data to enhance its AI capabilities. It has concentrated on obtaining extensive medical data from major hospitals in the Seoul metropolitan area, where a wide range of patients are treated, enabling the collection of diverse, high-quality datasets. To this end, VUNO has established partnerships with Seoul Asan Medical Center, Kangbuk Samsung Hospital, and other leading hospitals through MOUs. These collaborations provide VUNO with data for AI training in fields such as medical imaging, pathology, and medical voice recognition.

As of the end of 2020, VUNO had accumulated approximately 220.4TB of medical imaging, voice, and signal data, equivalent to around 200 million X-ray images. The company's major AI solutions have been trained on at least 20,000 cases, resulting in high accuracy levels. This data-driven learning has contributed to the enhanced performance of VUNO's commercial products, such as VUNO Med-BoneAge, VUNO Med-Chest X-Ray, and VUNO Med-DeepBrain.

VUNO continues to collaborate on joint research and clinical validation with major medical institutions in Korea, including Seoul National University Hospital, Asan Medical Center, and Korea University Hospital. These partnerships help improve the performance of VUNO's AI solutions and demonstrate their clinical efficacy, further strengthening the company's competitiveness in global markets (Kim Gi-yong, 2022).

To secure technological superiority as a startup, VUNO has actively promoted its capabilities through research papers and participation in various competitions. By 2020, VUNO had published over 50 papers, earning recognition for its AI technology in both academic and industrial sectors. The company also won first place in the AWS AI Startup Challenge 2018 and received the 2020 K-ICT New Software Product Grand Prize, further showcasing its technological prowess and innovation.

In addition, VUNO has participated in several government projects to strengthen its R&D efforts, completing government-funded research worth over KRW 500 million (USD 380,000) by 2020. These projects, supported at the national level, contributed to the enhancement of VUNO's AI medical solutions, improving their performance and facilitating commercialization (VUNO IR Book, 2024).

(4) Mechanism

VUNO's global expansion strategy has centered around localization and the provision of tailored solutions. By developing products that meet the regulatory requirements and market characteristics of different countries, VUNO has accelerated its market entry through swift government approvals. The rapid deployment of VUNO's products in hospitals in Japan and Europe, through CE certification and PMDA approval, highlights the success of this localization strategy (VUNO IR Report, 2022).

VUNO has built its successful global expansion strategy using the SER-M model, with its AI solutions now implemented in over 700 hospitals worldwide, demonstrating the company's technical excellence. One standout example is VUNO Med-DeepCARS, which was selected as a Breakthrough Device by the FDA, allowing it to undergo expedited approval processes in the U.S., further strengthening VUNO's global competitiveness. Moreover, VUNO has partnered with Sony's subsidiary M3, enabling the delivery of its products to over 90 hospitals in Japan, and it is also working with major hospitals in Europe to commercialize its AI solutions. These partnerships have been pivotal in expanding VUNO's market presence and enhancing its credibility (VUNO IR Book, 2024).

In conclusion, VUNO's global expansion mechanism has focused on meeting local regulatory requirements, providing customized solutions, obtaining government approvals, and collaborating with local healthcare institutions. These strategies have allowed VUNO to rapidly enter different markets and successfully commercialize its products. This approach has been essential to VUNO's global growth and opens the door for further commercialization of AI solutions in more countries in the future (VUNO IR Book, 2024).

3. CorelineSoft

1) Company Overview

CorelineSoft, founded in 2012, is a specialized company in 3D medical imaging analysis software based on artificial intelligence (AI). The company offers innovative solutions for the early diagnosis and analysis of various diseases, including lung cancer, emphysema, and coronary artery disease. CorelineSoft's flagship product, AVIEW LCS PLUS, is the world's first comprehensive screening solution capable of diagnosing multiple smoking-related diseases simultaneously, gaining attention in the global healthcare market.

In September 2023, CorelineSoft was listed on the KOSDAQ market through a SPAC merger, securing capital for global expansion and commercialization. The listing has provided CorelineSoft with the necessary foundation to rapidly deploy its AI-based medical solutions in both domestic and international healthcare institutions.

CorelineSoft's AI-based software is actively involved in various screening projects across the United States, Europe, and Asia, solidifying its presence in the global market. As a result, as of 2023, the company's overseas sales accounted for 24.6% of its total revenue, reflecting continued growth in international markets (Korea IR Council, 2024).

2) Status of Overseas Expansion

CorelineSoft has consistently pursued global market expansion, with a focus on the U.S. and Europe. In the U.S., CorelineSoft has successfully entered the market by supplying its products to large healthcare institutions, such as UMM Health. The company has collaborated with major hospitals in the U.S. to implement its AI-based lung cancer screening solutions, which play a critical role in early lung cancer detection (Coreline IR Book, 2024).

In Germany, CorelineSoft participated in the HANSE Project, a large-scale national lung cancer screening program utilizing low-dose CT (LDCT) for early detection. The company's AVIEW LCS PLUS solution significantly contributed to improving the accuracy of lung cancer diagnoses within the program, expanding CorelineSoft's collaborations with multiple healthcare institutions in Germany.

In Italy, CorelineSoft took part in the Italian Lung Screening Project (ILSP), a government-led initiative aimed at early lung cancer detection. By providing its AVIEW LCS PLUS solution, CorelineSoft has supported lung cancer screening in Italy, while its multi-disease diagnostic capabilities have also aided in the early detection of other conditions, such as chronic obstructive pulmonary disease (COPD).

CorelineSoft is also involved in the 4-ILTR Project, a lung cancer screening initiative led by the European Union and conducted across six European countries. In this project, CorelineSoft's AVIEW LCS PLUS product supports multinational lung cancer screening efforts, helping the company build global references through collaborations with a variety of European healthcare institutions. This experience has led to CorelineSoft's selection as a software provider for practical training in lung cancer screening certification in Europe.

Furthermore, CorelineSoft has submitted a bid for the UK National Lung Cancer Screening Program, a large-scale project targeting individuals aged 55-74 with a history of smoking. The program anticipates around 1 million CT scans per year, and if CorelineSoft secures the contract, the company expects to generate approximately KRW 450 billion (USD 340 million) in annual revenue. The results of this bid are expected to be announced in the second half of this year (IR Council, 2024).

These achievements in Europe have played a critical role in strengthening CorelineSoft's competitiveness in the global lung cancer screening market, and the company plans to expand into more countries in the future.

In the Asian market, CorelineSoft has also made significant progress, particularly in Taiwan, where its AI solutions are used for lung cancer screening in more than 13 hospitals, including Taiwan Veterans

General Hospital. These accomplishments have helped CorelineSoft expand its influence in Asia, and the company plans to continue accelerating its global expansion efforts (Coreline IR Book, 2024).

<Figure 12> Lung Cancer Screening Project throughout the world by CorelineSoft

Reference: CorelineSoft IR Book, 2024

3) Analysis of Overseas Expansion Strategy Through the SER-M

Analyzing CorelineSoft's global expansion strategy through the SER-M model (Subject, Environment, Resources, Mechanism) provides a comprehensive understanding of how each factor has contributed to the company's international success.

(1) Subject

The successful global expansion of CorelineSoft is largely attributed to the entrepreneurial vision of CEO Choi Jung-pil and the strategic approach taken by the company's core team. CorelineSoft's flagship product, AVIEW LCS, is an AI-based solution that can simultaneously diagnose lung cancer, chronic obstructive pulmonary disease (COPD), and cardiovascular diseases using a single low-dose chest CT scan. Since 2017, this product has been exclusively used in Korea's National Lung Cancer Screening Program for six consecutive years, proving its performance and reliability. These achievements laid the groundwork for CorelineSoft's global expansion.

CEO Choi Jung-pil adopted a strategic approach to international market entry by first supplying CorelineSoft's products as "research-use only" to overseas hospitals before seeking formal regulatory approvals in each country. This allowed foreign physicians to use CorelineSoft's solutions in research, leading to clinical publications and journal articles that provided the necessary clinical evidence for the product. By utilizing clinical data from local sources, CorelineSoft was able to establish trust in the product and later use the data to support regulatory approval applications. This approach not only facilitated regulatory approval but also served as a proof-of-concept for the business viability of the product in new markets, allowing the company to test the performance and market potential before committing to full-scale commercial entry.

Furthermore, during the 2022 KoSAIM (Korean Society for Artificial Intelligence in Medicine) seminar on global expansion strategies for medical AI companies, CEO Choi emphasized that international expansion is crucial for medical AI firms, as relying solely on the domestic market is not sustainable. He highlighted the importance of understanding the needs of local physicians and the market dynamics of the target countries before pursuing regulatory approval. Recognizing that hospitals in foreign markets prioritize having local reference sites when adopting AI solutions, Choi implemented a strategy of supplying at least one research-use solution to a local hospital, providing demo sessions, and closely managing these relationships. This approach was instrumental in helping CorelineSoft build trust in the global market and expand business opportunities (Rapportian, 2022).

(2) Environment

CorelineSoft's success in the global lung cancer screening market is largely driven by external factors such as the high global mortality rate from lung cancer. According to the World Health Organization (WHO), lung cancer accounted for approximately 1.8 million deaths worldwide in 2020, double the mortality rate of the second-highest cancer, colorectal cancer. In response to this alarming statistic, governments around the world have actively implemented national lung cancer screening programs to promote early detection and prevention. Countries such as the UK, Germany, Italy, and the European Union have initiated large-scale screening projects, which have significantly increased the demand for AI-based medical solutions (IR Council, 2024).

With the introduction of low-dose CT (LDCT) in early lung cancer screening, the need for AI-based imaging analysis solutions from companies like CorelineSoft has grown significantly. Governments in regions like the EU and the UK are increasingly adopting AI solutions to improve diagnostic accuracy and reduce healthcare costs. These market trends and technological requirements have played a crucial role in driving CorelineSoft's global success (IR Council, 2024).

In response to these environmental changes, CorelineSoft meticulously prepared for each country's regulatory and certification processes. The company secured K-GMP certification and medical device manufacturing approval from Korea's Ministry of Food and Drug Safety (KFDA) in 2016, followed by participation in the National Lung Cancer Screening Pilot Project in 2017, where it successfully demonstrated the performance of its AVIEW product. In the same year, CorelineSoft obtained CE certification in Europe and FDA approval in the U.S. in 2018, laying the groundwork for its global expansion. By 2020, the company had also secured approval from Japan's Ministry of Health, and it participated in the 4-ITLR lung cancer screening research project involving six European countries, further strengthening its presence in Europe.

To support its international operations, CorelineSoft established local subsidiaries such as Coreline Europe GmbH in Germany and Coreline North America, Inc. in the U.S., following a collaborative research agreement with Massachusetts General Hospital. These local offices enabled CorelineSoft to accelerate its market penetration in key regions.

CorelineSoft also built a solid global sales network through strategic partnerships. It collaborated with global AI platform companies like Nuance (a subsidiary of Microsoft), region-specific AI platform providers like Ferrum and Deepc, and major global medical device companies like GE Healthcare. CorelineSoft's collaboration with GE Healthcare Korea involved supplying CT equipment integrated with its AVEW product to hospitals, with plans to expand this partnership to other countries. Additionally, CorelineSoft forged partnerships with global PACS image companies to further expand its market reach.

One of the most notable partnerships is with GE HealthCare, through which CorelineSoft has been supplying its AVEW (a cerebral vascular imaging solution) along with GE's CT equipment to hospitals. The company is actively pursuing the expansion of this collaboration to other countries outside Korea, boosting its presence in the global medical market. These partnerships have not only supported CorelineSoft's rapid expansion but have also strengthened its competitiveness in the global medical imaging market.

In conclusion, the increasing demand for lung cancer screening and the corresponding rise in the need for AI-based imaging solutions have been key external factors that have propelled CorelineSoft's growth in the global market. By securing regulatory approvals from major health authorities, targeting top-tier hospitals as key clients, establishing international subsidiaries, and forming global partnerships, CorelineSoft has successfully expanded its market presence worldwide. This strategy has allowed the company to solidify its position as a leading player in the global lung cancer screening market.

(3) Resources

CorelineSoft's successful global expansion can be attributed to its efficient utilization of technological, financial, and intellectual resources.

In terms of technological resources, CorelineSoft has gained global recognition for its AI-based 3D medical imaging analysis technology. The company's flagship product, AVIEW LCS, uses low-dose CT (LDCT) to simultaneously diagnose lung cancer, COPD, and cardiovascular diseases. This solution has been exclusively used in Korea's National Lung Cancer Screening Program for six consecutive years, validating its performance and reliability. As of the end of 2020, CorelineSoft holds 35 patents, which are a testament to the uniqueness and technological innovation of its products (Korea IR Council, 2024).

On the financial side, CorelineSoft secured substantial funding through multiple investment rounds. In 2021, the company raised KRW 10.6 billion (USD 8 million) in a Series C funding round, with a post-valuation of approximately KRW 110 billion (USD 83 million). This funding provided a solid financial foundation for strengthening R&D and expanding into global markets (Korea IR Council, 2024). In September 2023, CorelineSoft secured additional capital by merging with a SPAC and listing on the KOSDAQ. The proceeds from the listing are being used for global business expansion and commercialization, further solidifying CorelineSoft's presence in the international market (Korea IR Council, 2024).

In terms of intellectual resources, CorelineSoft has academically validated its technology through the publication of numerous research papers and clinical studies. The company has collaborated with leading global hospitals, such as Massachusetts General Hospital (MGH), to accumulate clinical data and continuously improve the performance and reliability of its AI solutions. These academic achievements play a crucial role in enhancing CorelineSoft's credibility and competitiveness in the global medical device market, while also facilitating the smooth navigation of medical device regulatory processes worldwide (Korea IR Council, 2024).

Since 2017, CorelineSoft has been a sole participant in Korea's National Lung Cancer Screening Program, collecting and analyzing large amounts of screening data to continually improve its AI models. The company has collaborated with major domestic and international hospitals to gather clinical data. For instance, Seoul Asan Medical Center provided data from 2,985 patients to verify the clinical performance of CorelineSoft's lung cancer diagnostic solutions. The company also strengthened its technology using

databases from countries like the Netherlands and Saudi Arabia. As a result, CorelineSoft has amassed more than 220.4TB of medical imaging data, equivalent to approximately 200 million X-ray images, which serves as a significant technological asset for training its AI models and continuously improving product performance (Korea IR Council, 2024).

CorelineSoft's competitive edge in the global market is built upon its technological assets, financial investments, and intellectual resources. By leveraging these resources, CorelineSoft has successfully expanded into the global medical AI market and continues to strengthen its position as a leader in AI-based medical imaging solutions.

(4) Mechanism

CorelineSoft has established a comprehensive mechanism to achieve successful global business expansion. The company focused on gaining competitive advantages through participation in pilot projects across Europe and reorganizing its internal structure to prioritize project acquisition and execution in the global market.

Over the past 3-4 years, CorelineSoft has accumulated competitive advantages by participating in pilot projects such as HANSE, ILSP, and 4-ITLR across different regions in Europe. These pilot projects provided the company with a deep understanding of the requirements in the lung cancer screening market, while allowing CorelineSoft to validate the performance of its AI-based imaging analysis solutions in real-world settings. Based on this experience, the company has established a comprehensive project acquisition system and is well-prepared to take the lead in securing global lung cancer screening projects (Korea IR Council, 2024).

A significant turning point in CorelineSoft's mechanism was the shift from a research and development (R&D) focused organization to one centered on project acquisition and execution. To capitalize on opportunities in the global market, the company implemented a company-wide system dedicated to winning and managing large-scale projects. CorelineSoft has concentrated its efforts on participating in national lung cancer screening programs in major countries such as the UK, Germany, and Italy. This organizational restructuring has enhanced the company's ability to effectively respond to global project acquisition opportunities (Korea IR Council, 2024).

Additionally, CorelineSoft developed a systematic approach to meet the regulatory and certification requirements of various countries. After obtaining KFDA approval for medical device manufacturing and K-GMP certification in 2016, the company secured CE certification in Europe in 2017 and FDA approval in the U.S. in 2018, solidifying its position in the global market. This regulatory compliance has been a crucial factor in establishing CorelineSoft as a trustworthy partner in the global healthcare industry (Korea IR Council, 2024).

In conclusion, CorelineSoft's transition to a project acquisition-focused organization, combined with the competitive advantages gained from pilot projects in Europe, has been instrumental in driving the company's success in the global market. This shift in the company's mechanism, focusing on project wins rather than solely on R&D, has significantly contributed to CorelineSoft's expansion in the global medical AI market (Korea IR Council, 2024).

4. SER-M Model Comparison Analysis of Lunit, Vuno, and CorelineSoft

By analyzing the global expansion and success of Lunit, Vuno, and CorelineSoft using the SER-M model (Subject, Environment, Resource, Mechanism), several common factors contributing to their achievements in the global medical AI market can be identified. Below is a summary of these common factors aligned with the SER-M framework:

<Table 3> Common Success Factors of the Three Companies (SER-M Model)

SER-M Factors	Common Factors	Lunit	Vuno	CorelineSoft
Subject	Visionary Leadership and R&D-Centric Organization	Visionary founders from KAIST with a strong focus on R&D, technology-driven organization, and innovation-centric corporate culture	Founders from Samsung Advanced Institute of Technology (SAIT), seizing opportunities in the medical AI field, specialized AI technologies	Founders targeting the lung cancer screening market, organizational restructuring for global expansion
Environment	Adaptation to Global Regulatory Requirements and Market Trends	Comprehensive regulatory compliance, securing FDA, CE, PMDA, and MFDS certifications for global market entry	FDA, PMDA, CE, and MFDS certifications, and selected for FDA Breakthrough Device Designation (BDD)	FDA, PMDA, CE, and MFDS certifications, participation in major national lung cancer screening projects
Resource	Efficient Utilization of Technical, Financial, and Intellectual Resources	utilizing 5 million medical data points, global partnerships (e.g., GE Healthcare), KOSDAQ listing via the 2020 technology exception	Deep learning algorithms, large-scale clinical data, strengthening through government projects, KOSDAQ listing via the 2021 technology exception	Large-scale clinical data, 35 patents, and a SPAC listing in 2023
Mechanism	Building Strong Global Partnerships and Localized Strategies	Rapid commercialization strategy based on global partnerships	Localization strategy, passing regulatory hurdles like FDA and PMDA and commercialization	Partnerships with GE Healthcare, Microsoft subsidiary Nuance, and successful bids for national projects

All three companies were founded by visionary leaders with deep expertise in AI and healthcare. The core competitive advantage of each company lies in its technological capabilities and innovative product development. To succeed in the medical AI market, the founders and key personnel must possess a profound understanding of both the medical and AI fields. These companies made significant investments in R&D personnel, creating organizations that were composed of medical professionals and AI experts. The leadership and expertise of the founders played a critical role in ensuring that these companies remained competitive in the global market.

Furthermore, the medical AI market is highly regulated, with each country having its own set of regulatory frameworks. From the outset, all three companies strategically prepared for global expansion by meticulously navigating the regulatory and certification processes in different countries. By obtaining key certifications from bodies like the U.S. FDA, European CE, and Japanese PMDA, they established credibility in global markets. Additionally, they capitalized on the increasing demand for early detection solutions for major diseases such as cancer, lung diseases, and neurological disorders. By providing solutions that catered to these global healthcare trends, the companies successfully entered international markets.

On top of that, the three companies effectively leveraged their technological, financial and intellectual resources. They used technological resources by securing numerous patents and continuously improving their AI algorithms using large datasets of clinical and medical imaging data. They also secured financial resources early on by successfully raising Series A and B investments, which allowed them to fund their

research and development. Additionally, they raised further capital through public offerings, which was reinvested into R&D and global market expansion. Intellectual resources, including clinical collaborations and academic research, strengthened the companies' credibility and ability to navigate global regulatory hurdles.

Lastly, a key factor in the success of all three companies was their localization strategy, which allowed them to tailor their products to meet the specific needs of different markets. Furthermore, their partnerships with global firms like GE Healthcare, Nuance, and others helped to establish their technology credibility and expand their market presence. By building trust with local healthcare institutions and academic organizations, these companies were able to successfully enter and thrive in the global market.

Through this analysis, the key factors that enabled the three companies—Lunit, Vuno, and CorelineSoft—to achieve success in the global market have been identified. Based on this, I can derive strategic approaches that outline how each company was able to secure successful global expansion.

IV. Strategic Suggestions

In this study, I analyzed the key factors that contributed to the global market success of CorelineSoft, Lunit, and Vuno to propose strategic directions for domestic AI medical device startups aiming to expand internationally. Through this case study, I identified several essential strategies that can guide Korean AI medical startups toward successful global expansion. These include securing references in the domestic market, having visionary leadership and an R&D-centric organization, adapting to global regulatory requirements and market trends, efficiently utilizing technological, financial, and intellectual resources, and establishing strong global partnerships along with a localization strategy.

Based on these findings, I offer the following key strategic recommendations for Korean AI-based medical device startups to consider when entering global markets. These recommendations are derived from the successful examples of the studied companies and provide insights on how to maintain competitiveness and achieve sustainable growth in international markets.

1. Recommendations Derived from the SER-M Model

1) Visionary Leadership and R&D-Centric Organization

A common factor among Lunit, Vuno, and CorelineSoft is that their founders have led the companies with deep expertise and vision in both the AI and healthcare sectors. These founders recognized the potential for AI to revolutionize the healthcare industry early on, establishing leadership in the market through their innovative application of AI technologies. This vision and expertise have paved the way for continued investments in research and development (R&D), fostering an R&D-centric culture within their organizations.

As startups grow, one of the most crucial factors for success is having a clear vision and leadership that can actualize it. Establishing an R&D-focused organization that continuously pursues technological innovation while maintaining the flexibility to adapt quickly to changing market conditions is essential. It is also critical to create a collaborative internal environment where technology and business strategies are closely linked, and all departments share a common vision to achieve innovative goals. This approach not only drives short-term performance but also enables long-term growth for the company.

2) Adaptation to Global Regulatory Requirements and Market Trends

All three companies successfully navigated the stringent regulatory requirements of various countries, including obtaining FDA approval in the United States and CE certification in Europe, enabling them to expand internationally. They quickly identified and responded to the growing demand for AI medical solutions in various markets, aligning with global trends such as early detection and medical innovation.

For domestic startups aiming to enter the global market, it is crucial to thoroughly analyze the regulatory requirements and healthcare environments of each country and develop strategies that meet these conditions. For instance, in the U.S., securing FDA approval is a vital step to establishing product reliability and market entry. Similarly, CE certification is required to meet the regulatory standards of the European Union. By carefully preparing for these regulatory processes, startups can overcome entry barriers and establish a foothold in the global market. Collaborating with regulatory authorities and seeking guidance from local market experts is key to understanding and addressing regulatory requirements effectively.

Moreover, it is important to closely monitor global market trends and identify areas where the demand for AI-based medical devices is rising. For example, the expansion of early detection programs for major diseases like lung cancer presents significant opportunities for AI solutions. Regularly analyzing market trends and developing localized products based on this insight can help startups secure a competitive advantage.

Finally, since AI-based medical devices are applied to patients, proving the safety and efficacy of the product through clinical data is essential. Startups must establish strategies to conduct clinical trials in

collaboration with leading domestic and international medical institutions to obtain high-quality clinical data that meets regulatory standards. These partnerships play a critical role in building trust and credibility as the company enters the global market. By fulfilling the clinical data requirements of regulatory authorities, startups can secure a competitive edge in the global arena and enhance the trustworthiness of their products.

3) Efficient Utilization of Technical, Financial, and Intellectual Resources

Lunit, Vuno, and CorelineSoft have effectively leveraged their technical, financial, and intellectual resources to strengthen their competitive edge in the global market.

From a technical resources standpoint, all three companies have continuously improved their AI solutions by utilizing large-scale clinical data and successfully commercializing innovative AI technologies. The consistent development of AI algorithms based on real-world clinical data has been instrumental in enhancing the accuracy and reliability of their products.

In terms of financial resources, the companies secured funding through multiple investment rounds, including Series A, B, and C, while also raising additional capital by going public via IPOs through the technology-based special listing system. These financial inflows provided the necessary resources to fuel extensive research and development (R&D) efforts and enabled them to enter new markets and establish global partnerships.

To secure funding, startups must prove their technological capabilities and growth potential to investors. Initially, this often involves attracting venture capital, followed by securing larger funding through IPOs in the medium and long term. With the capital raised, it is essential to establish clear plans for allocating resources effectively to R&D and expanding into global markets.

On the intellectual resources front, the companies have demonstrated their technological capabilities through numerous domestic and international publications and academic achievements. These accomplishments have helped them build credibility in the global medical device market. Especially, the continuous acquisition and analysis of large-scale clinical data have been key to improving their AI models, ensuring that the companies maintain a competitive edge. Additionally, promoting technological superiority through various academic activities has enhanced their reputation and trustworthiness in the global market.

4) Building Strong Global Partnerships and Localized Strategies

All three companies succeeded in expanding into global markets by forming strong global partnerships and implementing effective localization strategies. For instance, CorelineSoft rapidly introduced its AI products into global markets through its collaboration with GE Healthcare. Similarly, Vuno and Lunit expanded their presence by partnering with global medical device companies and local healthcare institutions, securing trust and establishing credibility in their respective markets.

To succeed in global markets, localized strategies that cater to local healthcare systems and regulatory environments are crucial. Localization extends beyond language support; it requires offering solutions tailored to local medical practices and treatment methods. By providing custom solutions that align with the healthcare environment of each country, startups can build trust and establish a stable foothold in the local market.

Collaboration with local partners is vital to adapting products to meet the needs of local customers, and maintaining long-term relationships is essential. Particularly, when entering new markets, collaborating with local partners for joint research and clinical data utilization can help demonstrate product reliability, thus reinforcing competitiveness through local references. Partnering with local healthcare institutions, large hospitals, and global healthcare companies can lower market entry barriers, facilitating rapid market penetration and the development of expansion strategies based on local success.

2. Extended Success Factors Beyond the SER-M Model

Through the case analysis of Lunit, Vuno, and CorelineSoft, several success factors were identified that fit within the SER-M framework—focusing on leadership, regulatory adaptation, resource utilization, and partnership strategies. However, in the course of this analysis, it became evident that there are additional factors that play a critical role in the success of these companies but extend beyond the traditional SER-M model. Specifically, the establishment of a strong domestic reference base and the continuous innovation of products emerged as crucial elements for sustaining growth and enhancing credibility in global markets. These factors, though not directly categorized under SER-M, have been instrumental in driving the international success of these companies and therefore deserve further attention.

1) Establishing a Strong Reference Base in the Domestic Market

All three companies built a strong reference base in the domestic market before expanding globally, which played a key role in securing trust when entering international markets. Lunit, for example, gained initial trust by successfully implementing AI-based imaging analysis in domestic hospitals, which later enabled them to collaborate with foreign hospitals. Similarly, Vuno strengthened its position in disease prediction by deploying its DeepCARS solution in major Korean hospitals, which served as a foundation for expanding into Japan and Europe. CorelineSoft also leveraged its experience in domestic hospitals to build references that proved valuable when entering foreign markets.

Korean AI medical startups must first establish a reference in the domestic market to secure trust when expanding globally. Strengthening collaborations with domestic hospitals and participating in public healthcare projects or national medical programs are important strategies. Success in the domestic market enhances brand credibility when venturing abroad, making evidence-based marketing grounded in local achievements essential for global expansion.

2) Continuous Product Innovation and Performance Improvement

Lunit, Vuno, and CorelineSoft have maintained their competitiveness by continuously upgrading their products and launching new AI solutions in response to market changes. For instance, Vuno provided early diagnosis solutions for brain diseases through VUNO Med-DeepBrain, consistently improving product performance through updates. Likewise, CorelineSoft advanced its AVIEW LCS PLUS solution to enable the simultaneous diagnosis of multiple diseases.

Startups must continually pursue innovation to keep pace with evolving healthcare environments and technological advancements. It is critical to consistently improve the performance of existing products and develop new solutions that meet market demands to maintain a competitive advantage. By incorporating customer feedback into product updates and technological advancements, startups can enhance customer satisfaction and build the capability to respond to emerging markets.

For success in the global AI medical device market, visionary leadership, R&D-focused organizational structure, adaptation to global regulatory requirements and market trends, efficient utilization of technical, financial, and intellectual resources, strong global partnerships, and localized strategies, as well as establishing domestic references, are essential. By adopting these strategies, Korean AI medical device startups can enhance their global competitiveness and achieve long-term growth.

V. Conclusions & Implications

1. Summary and Implication

This study analyzed how three leading Korean AI healthcare startups (Lunit, Vuno, and CorelineSoft) successfully entered the global market. By examining the AI technologies developed by each company, their regulatory approvals, and commercialization strategies in key markets such as the United States, Europe, and Japan, the study employed the SER-M model (Subject, Environment, Resources, and Mechanism) to evaluate their strategies.

Lunit successfully commercialized AI-based lung and breast cancer diagnostic solutions by obtaining FDA and CE certifications in the U.S., Europe, and Japan, and expanded its global reach through partnerships with major international medical device companies. Vuno, which developed deep learning-based medical imaging and biosignal analysis technology, became the first Korean company to obtain approval for an AI medical device. The company has grown rapidly both domestically and internationally, strengthening its competitiveness in the global market through FDA approval. CorelineSoft, specializing in 3D medical imaging analysis for lung cancer and chronic disease diagnosis, has distinguished itself through screening programs in the U.S. and Europe, expanding its market presence through global partnerships.

Through this analysis, the study identified several common success factors that contributed to the companies' global market success: visionary leadership and R&D-centric organizational structures, adaptation to global regulatory requirements and market trends, efficient utilization of technical, financial, and intellectual resources, strong global partnerships, localized strategies, and the establishment of a domestic reference base.

These findings reveal several important strategic insights that can guide other Korean AI healthcare startups in their efforts to enter and succeed in global markets.

First, the importance of establishing a domestic reference base is critical. All three companies analyzed in this study were able to expand into global markets based on their successful achievements in the domestic market. This underscores the significance of domestic success as a stepping stone for global market entry. By collaborating with domestic hospitals and medical institutions, companies can build a trustworthy reference base, which serves as a strategic advantage when introducing products to international medical institutions. This approach can be a crucial strategy for Korean startups aiming for success in the global market.

Second, obtaining global regulatory certifications is essential. AI-based medical products must meet the regulatory requirements of each country to be commercialized, with particularly stringent certification processes like the FDA (U.S.) and CE (Europe) being mandatory. As demonstrated in this study, all three companies systematically prepared for these certifications before their global expansions, facilitating their rapid market entry. Korean startups must also plan and systematically execute clinical data collection and regulatory preparation from the early stages.

Third, the continuous enhancement of technological capabilities is vital. Since the performance of AI-based medical devices is largely dependent on data learning and algorithm improvements, sustained investment in research and development (R&D) is indispensable. The companies in this study consistently invested in R&D to improve the performance of their AI solutions, which allowed them to maintain a competitive edge in the global market. A strategic focus on developing specialized solutions for specific diseases and using these to differentiate themselves in the global market is a crucial direction that domestic startups should consider.

Fourth, localization strategies are of paramount importance. All three companies achieved successful market entry by offering tailored solutions that adhered to the local healthcare systems and regulations. Building partnerships with local medical institutions and providing localized solutions significantly increases the chances of success in the global market. Korean startups should actively pursue local partnerships as part of their strategy to enter and grow in new markets.

Finally, it is crucial to continuously build sustainable growth strategies. The AI medical device industry is rapidly expanding, but without a swift response to technological advancements and regulatory changes, achieving sustainable growth can be challenging. This study highlights that for successful global expansion,

companies must establish long-term sustainable growth strategies. A strategic roadmap that considers both technological development and market expansion can help mitigate the risks associated with growth transitions. Additionally, securing efficient resource allocation and financial stability is essential. Demonstrating a company's technological strengths and growth potential to investors is critical to attracting continued investment for long-term success.

In conclusion, the experiences of Lunit, Vuno, and CorelineSoft provide valuable insights for Korean AI healthcare startups seeking to enter global markets. By strategically applying these lessons—domestic reference base creation, regulatory preparation, technological advancement, localization, and sustainable growth— by incorporating these approaches, startups can enhance their international competitiveness and establish a solid foundation for long-term growth.

2. Limitation and Future Research Directions

This study presents strategic directions for Korean AI medical device startups to succeed in the global market by analyzing the cases of Lunit, Vuno, and CorelineSoft. However, there are several limitations to this research.

First, the scope of the companies studied is limited. While the analysis focuses on the success stories of Lunit, Vuno, and CorelineSoft, these represent only a small sample of leading Korean AI startups. Broader research encompassing various industries and market cases would offer a more comprehensive perspective on strategic approaches for global success.

Second, there is a lack of in-depth analysis of the specific failure factors related to global expansion strategies. This study primarily examines successful companies, but analyzing cases of failure or challenges faced by other companies could provide more realistic and practical strategic recommendations. Including detailed analyses of the challenges and failures encountered by companies could lead to more concrete suggestions for risk management and crisis mitigation strategies.

Third, the discussion regarding government support measures is insufficient. While there is some mention of government regulations, the current study lacks a thorough discussion of the structured government support programs available to aid international expansion. Although various government programs and financial support exist to help startups enter the global market, the effectiveness of these initiatives and how startups can best utilize them were not explored in detail. There needs to be a more in-depth discussion on how these startups can maximize the benefits of government support.

Therefore, future studies should analyze a more diverse range of Korean AI medical device startups to derive more generalized success factors and strategies. By including case studies of small and early-stage startups, more practical strategies applicable to companies of various sizes and stages could be proposed.

Also, it is necessary to analyze cases where companies failed in the global market to identify the factors that hindered their success. This would enable the identification of potential risks that domestic startups may face in the global market and offer insights into how to avoid or overcome these challenges.

Lastly, more specific research on government support measures is required. Future studies could analyze the effectiveness of policy support for global expansion and explore how Korean AI medical device startups can benefit from these programs. Research should focus on improvements in policy areas such as regulatory relief, financial assistance, and support for building international networks. This would help optimize government support for startups aiming to expand globally.

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