Globalization of Single Enzyme Activity-based Liquid Biopsy（Cosomil, Inc.）

City	Year of Establishment	Founder
Tokyo, JAPAN	2022	Yu Kagami

Partner VC	Latest round of Fundraising	Valuation
ANRI Inc.	Pre-series A	Non-Disclosure

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○ Business Plan

We revolutionize disease diagnosis and drug development with our proprietary 'Single Enzyme Activity-based Liquid Biopsy' technology, enabling enzyme activity analysis at single protein level.

○ Research Outline

This grant project aims to achieve the following and increase the likelihood of expansion into the U.S. market:

1. Conduct a clinical study of approximately 1,000 U.S. participants to provide the basis for selling a pancreatic cancer diagnostic laboratory developed test (LDT) in the U.S.
2. Conduct a clinical study using very early stage (Stage 0-I) pancreatic cancer samples to differentiate and demonstrate the utility of the pancreatic cancer test
3. Conduct a clinical study to provide the basis for selling a colorectal cancer diagnostic LDT in Japan
4. Develop a home test kit to enable at-home testing using fingertip blood collection
5. Develop a fully automated measurement system to significantly increase testing throughput
6. Conduct PMDA consultations and obtain FDA Breakthrough Device Designation for obtaining regulatory approval in Japan and the U.S.

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	STS 2024～2025FY	JPY 499 million	United States

○International collaborative technology demonstration

・Contract with local partners
・ Local base establishment

We will conduct clinical development and prepare for the sale of our cancer screening test in the United States, which is the largest market for the test. Specifically, we will collect blood samples from approximately 1,000 American pancreatic cancer patients and healthy individuals to evaluate the test's performance and establish the evidence needed to sell the test in the U.S. We will also obtain the FDA Breakthrough Device Designation to receive prioritized support for future clinical development. Additionally, we will conduct research for establishing our company's laboratory in the United States.

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