



<https://www.linkedin.com/company/automics-biotechnology-inc/>

**AutOmics Biotechnology Inc. (Canada),
A subsidiary of LifeVault Group Ltd. (Hong Kong)**

An AI-driven Automated Platform for Multi-Omics-Based Analysis and Diagnostics **Primordia Analyzer**

Founders: Yuming Zhang, Hongtao Gu, Bang'an Wang, Chenghong Lin

Business Plan 2025 November

Endorsed by **Canadian government funding agencies** including **Intellectual Property Ontario (IPON)**
and **Innovation, Science and Economic Development Canada (ElevateIP)**

Limitations in Current Diagnostics

— Limited 2D information from 3D tissue

Diagnostics — State-of-the-art

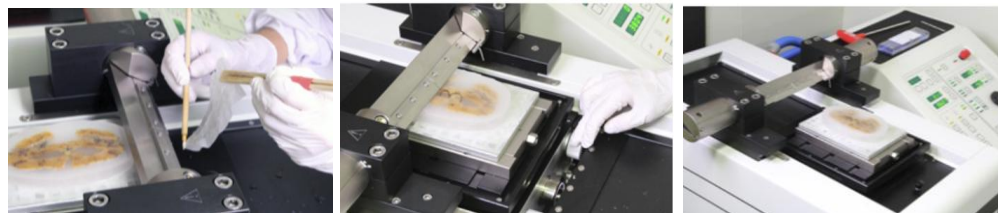
- ⚠ Traditional methods (X-ray, CT, MRI) lack **molecular-level insights**
- ⚠ Blood tests, microbe cultures, and PCR provide **limited** biological information



References: Newman-Toker DE et al. Diagnosis (Berl). 2020 May 14;8(1):67-84. doi: 10.1515/dx-2019-0104.

Critical Information Loss in high-resolution tissue pathological tests

- ⚠ 2D tissue sections result in **massive loss of biological information**
- ⚠ Adjacent slices show up to **50% variability** in cellular morphology



Manual/Slow/Inefficient/Discontinuous/Low-throughput/10-15% misdiagnosis rate

NOW

Fixation/Dehydration

Embedding

Sectioning (microtomy)

Staining

Microscopic examination

Pathological analysis

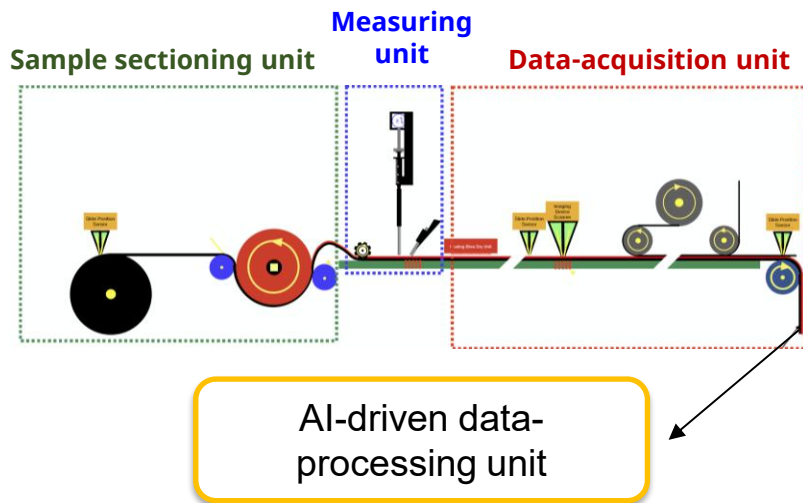
Diagnosis

The Near Future

The Primordia Analyzer: An integrated platform

The Solution: the Primordia Analyzer

Fully Automated Multi-Omics System (prototype in development)

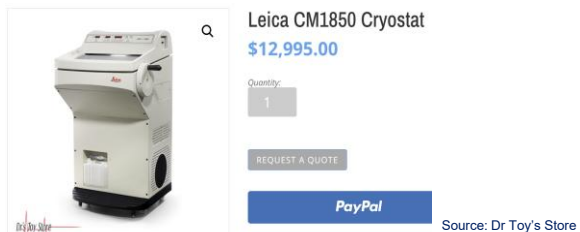


Simplified System Operation Flowchart

Key Benefits

- ✓ **Enhanced efficiency** with 1000x higher sample processing capacity
- ✓ **No bioinformation loss** through continuous molecular-Omics profiling
- ✓ **Comprehensive analysis** of tissues and organs of any size
- ✓ **3D spatial reconstruction** with AI-driven pathology
- ✓ **Complete elimination** of missed/misdiagnoses caused by biological information loss
- ✓ **Versatile compatibility** with both solid and liquid samples
- ✓ Expedites **biomarker discovery** for various diseases
- ✓ Advances **individualized precision medicine**

Microtomy comparison: Leica vs. Primordia Analyzer



Leica CM1850 Cryostat or similar



Primordia Analyzer

Manual, low throughput / labor intensive	Automated, high throughput / continuous (24/7)
Average 2 h per section	Average 5 s per section
Requires pathology technicians, high labor costs HKD 400,000/(yr · technician)	Saves 90% of labor costs
Cannot reflect 3D information, rely on manual observation	Automated data collection within one day to reconstruct sub-μm resolved 3D organ models
No built-in software database or discrete information for record only	Built-in multi-modal 3D histology database and AI-simulated 4D information for predicted disease progression
Single sectioning function	Integrated system for tissue embedding / sectioning / preprocessing / staining / data collection automation

Competition Analysis: Market from the full industrial chain

Similar companies only have separated modules of our prototype.

Upstream (Cryosectioning, paraffin sectioning machines):



LabTech

Midstream (Sample processing, data acquisition):



Agilent



Downstream (Data analysis, diagnosis):



CluePoints



**Our platform
disrupts,
re-integrates,
Improves,
And expands
the current industrial chain**



Market opportunities

1. Research Market

Academic labs, biotech/pharma R&D, CROs





Applications:

-  **3D** Single-cell genomics, proteomics, metabolomics
-  Fast Real Spatial Multi-Omics at **whole organ and body level**
-  Biomarker research: **Digital organ/digital human**
-  The **best digital platform** for Drug discovery & Pharmacological simulation
-  **AI-powered** systems biology, Digital Twin Organ and Body

2. Clinical Market

Hospitals, diagnostic labs, precision medicine centers






Applications:

-  **AI-powered** digital pathology
-  Tumor **3D** microenvironment analysis
-  Faster and standardized diagnostics
-  Companion diagnostics, therapy selection with **patient specific** disease progression prediction powered by **4D-AI-extrapolation**
-  Longitudinal monitoring via liquid biopsies

3. Consumer Market

Portable, user-friendly multi-omics profiling devices

Applications:

-  Viral testing (multiplex respiratory virus detection)
-  Glucose/metabolic monitoring with expanded biomarkers
-  STD screening (HPV, HIV via home saliva kits)
-  Early cancer signals detection
-  Home health monitoring with **built-in AI-diagnostic capabilities**

Our platform's versatility enables applications across multiple markets, maximizing revenue potential and market penetration.

Market Analysis: Market from the full industrial chain

Pathology diagnostics Market in China (USD 45B)

Tissue Pathology: **USD 4B**

Microtomes Leica, Thermofisher etc.

Single-cell sequencing pathology: **USD 28B**

Increasing outsourcing by hospitals

Immune omics-based pathology: **USD 6B**

CAGR 15% in China

Molecular pathology: **USD 7B**

CAGR 20% in China

Pathologist global total ([the-pathologist.com](https://www.the-pathologist.com)):

90k × USD 150K/yr = USD 13.5B/yr

Global Market (2024): \$108 billion USD ([grand view research](#))

2030 Projection: \$169 billion USD (CAGR 7.8%)

China combined (2024): \$ 28 billion USD

2030 Projection: \$ 35 billion USD (CAGR 10.2%)

Addressable Market (clinical + research + household): USD 10B

Current status of the market (In China)

Shortage and high cost in workforce worldwide

66,000 shortage of registered pathologist in China

More shortage in the **North America, Europe**

Low throughput and high price

Up to **USD 360 per check** in China for molecular pathology test, only few slides get checked, less than 1% of total bioinformation

Increasing need for pathological tests

More than 4,000,000 new cancer patient increase per year, **only 50% market infiltration**, more than **100 tests** per patients, **USD 200 per patient** spending during treatments in immune pathology only.

References: Western securities

Approval Timeline + 1 Year Projected Revenue in Canada

Regulatory Approval Process:

- Medical Device Single Approval Program (MDSAP)
- Approval in **US, Canada, Australia, Japan, Brazil** all at once

Step	Time (working days)
Conformity notification	5
Remediation	15
Evidence of implementation	30
Complete report if approved	45
Complete report if not approved	90

Organizations with **≤ 5 employees** receives a reduction in a **42% shorter processing time** according to ISO/IEC 17021-1:2015

Pre-sale activities start **in parallel** with the regulatory approval processes

Customers	Projected Market Size	Projected Revenue
Schools	USD 100M – 150M , 30%-50% of which directly used for industrialization	USD 1-1.5M
CDMO/CRO	~ 50 devices in total	USD 2 – 5M
Hospitals	1000 hospitals, 500 ~ 1000 devices	USD 10 – 20M

Sources:

Food and Drug Administration (.gov): www.fda.gov; Research funding and awards – Canada.ca; University Health Network – uhn.ca;

Timeline for Market Approval in Mainland China and the Greater Bay Area (Guangdong–Hong Kong–Macao)

Mainland China Market Approval Process

- Products **exempted** from clinical trials: **12–18 months**.
- Products **requiring** clinical trials: **24–36 months**.

Step	Time (working days)
Provincial Drug Administration Preliminary Review	20
Technical Review	60
Administrative Approval	20
Manufacturing License Issuance	10

Products **with significant innovation** may apply for the **Special Review Procedure for Innovative Medical Devices (also known as the "green channel")**. Once admitted, they receive priority communication with review agencies, potentially reducing the overall approval timeline **by 6–12 months** (excluding product preparation and clinical trial time).

Greater Bay Area Approval Mechanism: "Hong Kong–Macao Medicine & Device Connect" Policy

- Medical devices already approved for clinical use in Hong Kong and Macao public hospitals may be granted **priority access**.
- In cases of **urgent clinical need**, designated hospitals within the Greater Bay Area may also be authorized to use these devices.

Channel Type	Target / Scenario	Key Acceleration Measures	Related Policies / Mechanisms
Hong Kong–Macao Device Connect	Urgent clinical needs , devices already approved in HK/Macao	Review timeline shortened to ≤10 working days for catalogued products, or ≤ 20 working days for non-catalogued products	<i>Regulations on the Administration of Imported Drugs and Medical Devices in the Greater Bay Area</i>
Guangdong Province Domestic Innovation Channel	Class II medical device recognized as innovative products	Evaluation timeline reduced by more than 50% compared to statutory time	<i>Measures on Optimizing the Evaluation and Approval of Class II Medical Devices</i>
Greater Bay Area Overall Support	Innovative medical devices	Government procurement inclusion, shortened to ≤ 15 working days	<i>Action Plan for Promoting the High-Quality Development of Guangdong Biopharmaceutical Industry</i>

<Shenzhen Full-Chain Support Measures for Pharmaceuticals and Medical Devices>: Overseas companies with domestic R&D and sales entities in Shenzhen can receive a reward of up to **5%** of their first-year sales revenue, capped at RMB 10,000,000 (HKD 11,000,000).

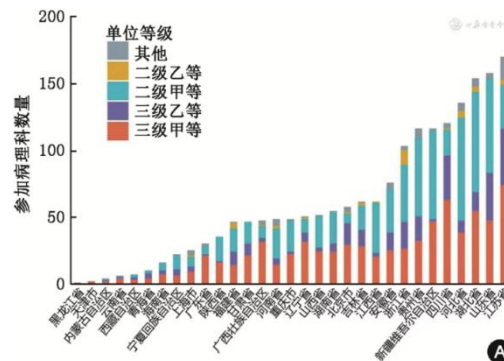
AutOmes Estimated Sales Units and Profits in the Chinese Public Hospital Market After Listing

This study is based on survey reports of the pathology departments in hospitals across **31 provinces** and autonomous regions as of the **end of 2018**. Among them, **25 provinces** and autonomous regions provided the number of surveyed hospitals (**a total of 3,831**). Shanghai, Liaoning, Heilongjiang, Anhui, Shandong, and Hubei did not provide complete pathology department data.

In each province, the proportion of tertiary grade-A hospitals ranged from **27.3% to 100.0%**, while the proportion of secondary grade-A and above hospitals ranged from **80% to 100%**. The vast majority of participating institutions were public general hospitals, with public general hospitals accounting for **66.7% to 100.0%**.



图1 全国各省设置有病理科的医院的分布情况

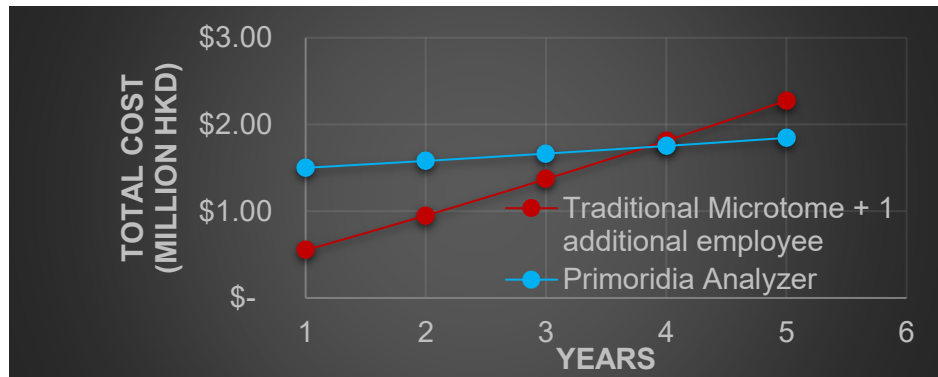


	Estimated Number of Hospitals	Estimated Sale Units	Estimated Gross Profit (HKD)	Estimated Total Profit (HKD)
Tertiary Hospitals	3,000	600	1,230,000	737,000,000
Secondary Hospitals	1,300	130	1,230,000	160,000,000

Source: Chinese Society of Pathology, Chinese Journal of Pathology "Survey and Reflection on the Status of Pathology Departments in 3,831 Hospitals Across 31 Provinces and Autonomous Regions" "2019-2020 Survey Report on Chinese Pathology Personnel, Equipment, and Workload"

Comparative Analysis (With Microtome **alone**)

Cost analysis — a conservative estimate (with 1 additional employee's work replaced)



Product	Price	Cost Savings: No need to train staff for sectioning, imaging, and analysis (saving approximately HKD 400,000/(yr · person)), replacing the equivalent of two technicians' annual salaries. Efficiency Gains: Throughput increased by 1,000× , biological information yield expanded by 100× , misdiagnosis rate reduced by 99% , and 100% of the workflow achieved with no manual intervention.
The Machine	1,500,000 HKD	
Bundled Consumables	80,000 HKD/Year	



Primordia Analyzer

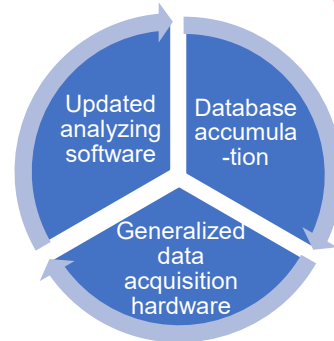
Our Competition Advantages (with PCT

patents):

- Theoretically **unlimited competitive edge** (99% market occupancy rate) for at least **14 years** in China and broader international protective benefits.
- Higher performance and lower total cost beyond only 4 years**



Database Value-added Ecosystem:



Once established, it will be extremely difficult for competitors to break through.

Primordia Analyzer : Cost Analysis

Fixed Cost Structure (Hardware BOM + Assembly)

Core machinery / motors / sensors:	\$6,000 – \$8,000
Sectioning blade head / optical components / data acquisition software:	\$3,000 – \$5,000
Automation control system / embedded chips:	\$2,000 – \$3,000
Housing + structural parts + processing:	\$1,000 – \$2,000
Assembly / testing / quality inspection:	\$1,000 – \$1,500
Total hardware cost ≈	\$14,000 – \$20,000

R&D, Marketing & Regulatory Certification

Early-stage R&D, production line development, algorithm development, IVD certification, consumables costs.
Allocated to the first batch of equipment: **\$10,000 – \$20,000**

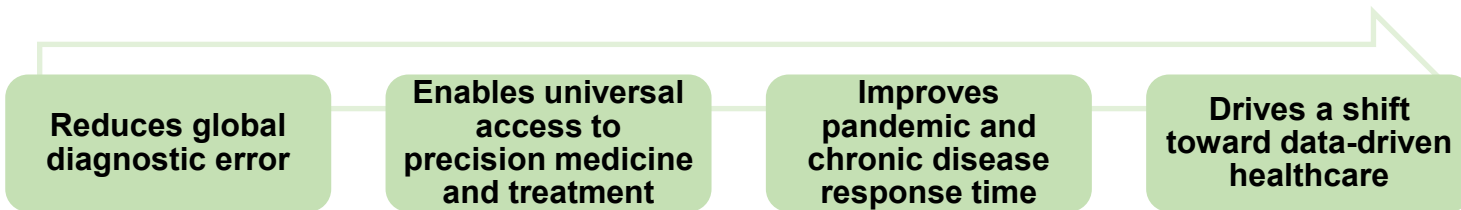
Per-Unit Comprehensive After-Sales Cost

Average labor / travel:	\$800
Average spare parts:	\$400
Software maintenance:	\$200
Quality liability and marketing:	\$300
Management allocation:	\$100
Total after-sales cost per unit:	\$1,800

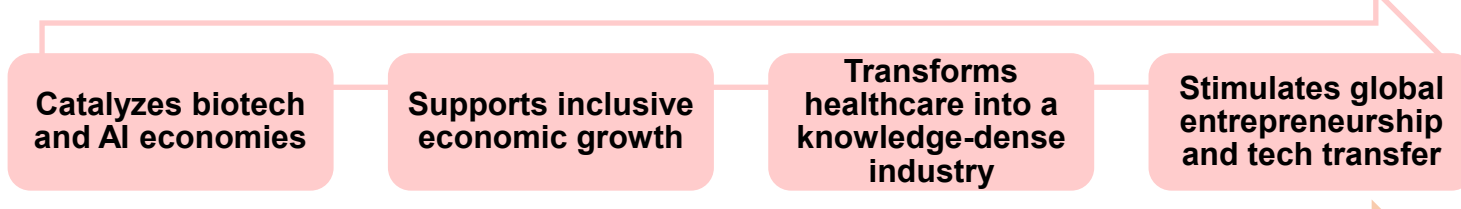
Per Unit Total Cost ≈ \$25,800 – \$41,800

UN SDG Alignment: The impact of AutOmics

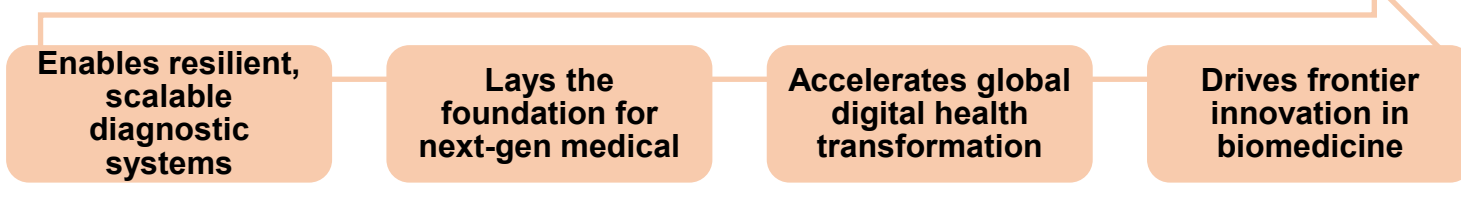
3 GOOD HEALTH AND WELL-BEING



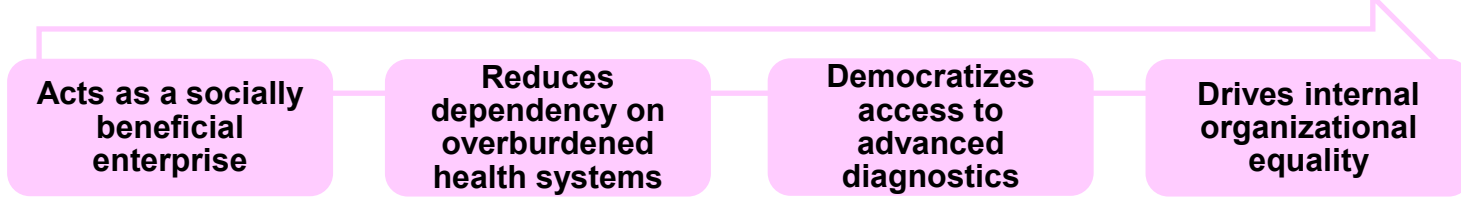
8 DECENT WORK AND ECONOMIC GROWTH



9 INDUSTRY, INNOVATION AND INFRASTRUCTURE



10 REDUCED INEQUALITIES



The Multidisciplinary Team

Dr. Yuming Zhang

CEO /
Engineering Expert



PhD in Biomaterials, Tissue Engineering, and Regenerative Medicine; Bachelor of Mechanical Engineering,
University of Toronto

Expertise:

3 Years of experiences in building startups

- Microfluidic Device Fabrication
- Artificial Tissue Engineering (skin, blood vessels, bile ducts) with sensitive cell culture
- Organoid Culture
- 2 pending patents for innovative tissue engineering technologies

Hongtao Gu

Founder /
Inventor
Medical Expert



MD;
Master of Immunology;
Islet Transplantation Scientist at Toronto
General Hospital

Expertise:

- GMP cell production and Cell Therapy
- Cancer Immunotherapy
- Clinical Human Islet Isolation
- Over 10 years** of clinical experience
- Multiple patented technologies

Bangan Wang

CTO /
Automation Engineering
and AI Expert



Bachelor of Mechanical Engineering,
University of Toronto;
MS in Mechatronics and Robotics Systems,
University of Pennsylvania

Expertise:

- Mechatronic System Design and Prototyping
- Artificial Intelligence and Machine Learning
- Automation Control Systems Design and Implementation

Chenghong Lin

COO / Strategy Expert



Undergraduate in Philosophy,
University of Toronto

Expertise:

- Strategic Planning
- The "ultimate problem" of Philosophy
- Psychoanalysis and Formal Logic
- Meta-Ethics and Regulations

Combined expertise in **medical science** and **engineering** creates the **perfect foundation for developing revolutionary diagnostic technologies**

The 5-year Roadmap

December 2026 (§ 1.0 First-generation device completed testing.)

- Product begins applying for medical device production license and registration as a Class III medical device (**NMPA/FDA/MDR progressing in parallel**).
- Begin building a multi-group data repository; start software + hardware design validation (**approx. 12–24 months**).
- **Conduct Series A financing, approx. USD 2 million**, covering the engineering prototype's readiness for registration testing and initial production ramp-up (estimated **USD 280k–700k**).
- Regulatory fees (registrations approx.: **NMPA USD 200k, NMPA filing USD 300k, FDA USD 400k, MDR USD 400k**) and **USD 700k for contingency**.

December 2027 (§ 1.0 First-generation device enters early large-scale production)

- The original production line begins replacement, and multi-group data repository construction shows initial effectiveness.
- Scientific research value emerges.
- Use the database as promotional material; the Bureau approves § 1.0 first-generation device for expanded sales.
- Expected to obtain orders totaling **USD 3.9 million within 6 months**, supplying **20 first-generation units**.
- Begin preparing the diagnostic-function-enabled § 2.0 enhanced scientific-research product; launch integrated service package sales, while initiating software optimization and AI model training.
- **Conduct Series B financing, approx. USD 4 million**, covering data-center leasing and related talent recruitment.

December 2028 (§ 1.0 first-generation device for production and sales)

- Achieving **USD 4 million** in sales revenue
- Continue expanding the database and accept official laboratory supervision. FDA and NMPA approve.
- Integrated services generate **USD 800k**, and database access generates **USD 1 million** in sales.
- Nationwide launch of consumable sales and software subscription sales; continue developing the diagnostic-enabled § 2.0 enhanced scientific-research new product and begin R&D for § 3.0 home-use enhanced product, synchronizing with military-use preparations.
- **Conduct Series C financing, approx. USD 50 million**, covering clinical-data collection, AI diagnosis, large-scale production-line expansion and upgrades, major database expansion, data-center leasing, regulatory registration, and legal fees.

December 2029 (Comprehensive annual sales exceed USD 100 million.)

- A **3D microscopic-resolution spatial multi-omics digital human model** is completed.
- Use digital-human model data outputs to perform **Series D financing, approx. USD 100 million**.

December 2030

- Begin applying for § 2.0 enhanced scientific-research product and § 3.0 home-use enhanced product production licenses.
- **Start building an indestructible industrial ecosystem and initiate equity repurchase.**