







ThermoGenesis Holdings, Inc. (NASDAQ:THMO)

## Transforming a Leading Medical Device Company to a CDMO Cell Contract Manufacturing Service Provider

Chris Xu, PhD, MBA, CEO

H. C. Wainwright 25<sup>th</sup> Annual Global Investment Conference (2023)



## Disclosure and Forward-Looking Statement

This presentation includes statements of future expectations and other forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. These statements are based on management's current views and assumptions, speak only as of the date hereof and are subject to change. Forward-looking statements can often be identified by words such as "may," "could," "potential," "continue," and similar expressions and include, but are not limited to, statements regarding research and product commercialization. These forward-looking statements are not guarantees of future results and are subject to known and unknown risks and uncertainties that could cause actual results, performance or events to differ materially and adversely from those expressed or implied in such statements. A more complete description of risks that could cause actual events to differ from the outcomes predicted by these forward-looking statements is set forth under the caption "Risk Factors" in our Annual Report on Form 10-K, in our Quarterly Reports on Form 10-Q, and in other reports filed with the Securities and Exchange Commission from time to time, and you should consider each of those factors when evaluating the forward-looking statements. We undertake no obligation to revise or update publicly any forward-looking statements for any reason, except as required by law.



## **ABOUT THERMOGENESIS (NASDAQ:THMO)**

— Leading bioengineering developer for automated cell processing & cryostorage technologies for the cell banking and cell therapy industry since 1986

**#1** Ranked platform for cord blood banking industry

40 Products marketed in close to 40 countries worldwide

90% FDA BLA-approved CBUs in the U.S. using our BioArchive® automated smart cryostorage system

cGMP cell manufacturing suites dedicated to cell and gene therapies launched in Sacramento, CA (2023) for lease or CDMO contract manufacturing



## About ThermoGenesis Holdings, Inc. (Nasdaq:THMO)

#### Headquarters



2711 Citrus Road Rancho Cordova, CA 95742



#### Company Highlights

History: Founded in 1986, headquartered in Rancho Cordova, CA.
 THMO is a leading medical device company to provide automated cellular processing devices for the cell banking and cell therapy industry.

#### Medical Device Products:

AXP®/BioArchive: #1 ranked automated devices for cord blood banking

• X-Series®: automated derives for cell processing, general laboratory use

• PXP®-Series: FDA 510(k) approved devices for cell processing, clinical use

#### Proprietary Manufacturing Platform:

• CAR-TXpress™: high-efficiency manufacturing platform for cell therapies,

increases cell processing efficiency by 4x-5x folds and reduces

the cost of goods by **50%**.



## Highly Experienced Management Team



Dr. Chris Xu, PhD, MBA | Chairman and CEO

Established Immunologist, 25+ years experiences in life sciences and pharmaceutical industry. Advanced 20+ products into different stages of clinical trials. 40+ publications and patents.



#### Michelle Zhu | President and COO

25+ year of technical, research and development, and marketing experience in stem cell and cell therapy industry. Ms. Zhu started her career in stem cell research at Harvard Medical School.



#### Jeff Cauble, CPA | Chief Financial Officer

20+ years in managerial roles within finance for both private and publicly traded companies. Mr. Cauble obtained his bachelor degree from University of Idaho.



#### Jason Le | VP of Quality

25+ years of experience in medical device and diagnostic industry. Accomplished with diverse experience in Manufacturing and Quality Assurance with US FDA, EUMDR and other international standards.



#### Darrell Drysen | VP of Operation

25+ years of experience within medical device industry with both large corporations and start-ups. Proven track record of success in R&D, Project Management, and Operations. Previous experience includes Johnson & Johnson.



### **Board of Directors**



#### Dr. Chris Xu, PhD, MBA | Chairman and CEO

- Established Immunologist, 25+ years of experiences in life sciences and pharmaceutical industry.
- Advanced 20+ products into different stages of clinical trials. Founder and Chairman of Boyalife Group.



#### Dr. Russell Medford, MD, PhD | Independent Director

- Chairman of The Board at Center for Global Health Innovation, Chairman and CEO of Covanos, Inc.
- Senior biotechnology executive with extensive CEO and board experiences in both public and private companies.



#### Dr. Joseph Thomis, PhD | Independent Director

- 40+ years of experience in drug discovery, clinical development and commercialization.
- Eight commercially successful products launched. Senior executive roles at Quintiles.



#### "Michelle" Haihong Zhu | Director, President and COO

- 25+ years of experience in industry, Ms. Zhu started her career in stem cell research at Harvard Medical School.
- Extensive experience in technical, research and development, and marketing in cell and gene therapy industry.



#### Dr. James Xu, Esq, DBA, PsyD, JD, CPA | Independent Director

- Practicing attorney and licensed CPA in the State of Illinois. A Patent Lawyer licensed by U.S. PTO.
- 25+ years of experience practicing patent laws, corporate laws and tax laws.



#### Dr. Biao Xu, PhD | Independent Director

- Chief Scientific Officer, Co-founder, and member of the Board of Miracure Biotechnology.
- Extensive experience in drug discovery and biomedical research and development.

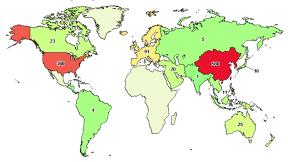


## Fast Growing Cell and Gene Therapy (CGT) Field and Unmet Needs

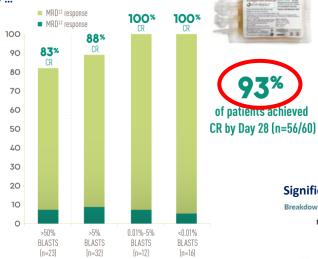
#### Emily Whitehead's Successful Story with CAR-T Cell Therapy ...



Over 1,200 ongoing CAR-T clinical trials worldwide



Source: ¹ Clinicaltrial.gov database (as of 6.30, 2022)
² Alliance for Regenerative Medicine Quarterly Data Report Q4 2021



#### Worldwide CAR-T Trials

- 1200+ Clinical Trials
- 900+ Companies

#### Global Market

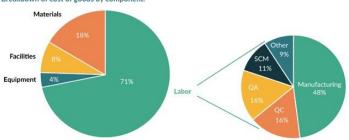
 Global cell therapy market grows to US \$67.6 Billion in 2021

#### CAR-T Cell Therapy Stats

- 6 CAR-T cell therapies been FDA-approved
- 1,200+ ongoing CAR-T/TCR-T clinical trials
- 93% response rate for relapsed/refractory leukemia patients
- \$373,000 \$475,000 per dose. The low mfg. efficiency and high mfg. cost are the most critical unmet need for CAR-T therapies.

#### Significantly unmet manufacturing needs for CGT

Breakdown of cost of goods by component.



Currently, the drug cost for the approved CAR-T cell therapy products in the U.S. are \$400,000 to \$500,000 per patient dose, making them among the most expensive drugs on the market; manufacturing costs for each dose of some CAR-T therapeutics exceeds \$100,000, and 79% of which are attributed to Labor and GMP facility cost.

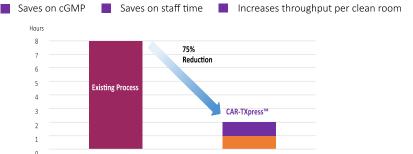
## Our CAR-TXpress™ Platform Addresses Critical Unmet Mfg. Needs

ThermoGenesis' CAR-TXpress™ platform is a semi-automated, closed system for large-scale, high-efficiency cell manufacturing

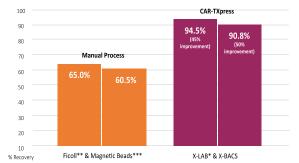
- Significantly reduces processing time while improving cell recovery
- Potentially reduces 50% of the manufacturing cost for CAR-T and other cell therapies
- Creates significant pricing advantage and CDMO opportunity



#### CAR-TXpress™ reduces cell selection time from eight hours to two hours



Improves cell recovery after isolation and selection by 45% and 50%, respectively

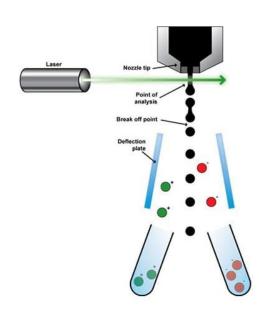


\*\* Unpublished data from third party



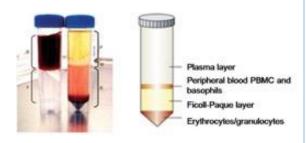
## Our New Cell Isolation Technology - Buoyancy Activated Cell Sorting

#### **Low Capacity**



Fluorescence Activated Cell Sorting (FACS) by Beckman Coulter & Becton Dickinson

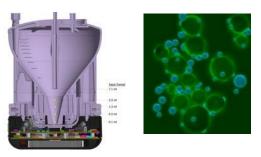
#### **Medium Capacity**

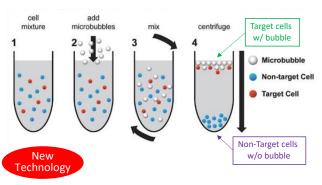




Magnetic Activated Cell Sorting (MACS) by Miltenvi Biotec

#### **High Capacity**





Buoyancy Activated Cell Sorting (BACS) by ThermoGenesis



## We are Leading Provider of Automated Cell Processing Technologies



Global Clients (Partial List)







































Leading tool provider for cord blood (CB) banking industry, over **1,200,000+** automated CB processing performed worldwide, warehoused 90% of FDA's BLA-approved CB units in US.





























































## Rationale to Transform into a Cell Therapy CDMO: Market Outlook

To date, 6 CAR-T cell therapies have been approved. By 2025, the US FDA expects 10-20 approvals/year for additional cell therapy products.

Over **70%** of cell and gene therapy developers outsourced their manufacturing, however, only **5%-10%** of required capacity exists for next 10 years.

Current manufacturing cost is high, \$100K-120K per dose of CAR-T therapy, and \$40-60K per dose of MSC cell therapy.

Currently, 1,200+ CAR-T cell therapies are in active clinical trials, another 1,300+ active clinical studies for stem cell therapies.

Waiting time for a commercial manufacturing slot can be as long as 12-18 months, demands are exacerbated with more approvals.

The global cell & gene therapy manufacturing market is expected to reach \$57.4 billion by 2028.

#### References:

<sup>&</sup>lt;sup>3</sup> PRNewswire: Global \$57.4 Billion Cell And Gene Therapy Manufacturing Market to 2028 - Rising Pressure on Drug Developers/Manufacturers to Meet the Growing Market Demand (from "Cell And Gene Therapy Manufacturing Market Size, Share & Trends Analysis Report by Therapy Type, by Scale (R&D, Commercial), by Mode, by Workflow (Vector Production, Cell Banking), by Region, and Segment Forecasts, 2021 - 2028")



<sup>&</sup>lt;sup>1</sup> Cell Therapy Manufacturing Market (3rd Edition), 2020 - 2030

<sup>&</sup>lt;sup>2</sup> Visualizing the Future of Contract Development and Manufacturing for Cell and Gene Therapies (2020)

## Our Potential Cell Therapy CDMO Customer Profile

#### Based on demographics distribution

#### **Oversea Companies to File US IND**

- Two-thirds (2/3) of the cell therapy companies and research are from overseas.
- There are high demands to use U.S. based CDMO cell manufacturing providers for U.S. FDA's IND filings.

#### **US Companies to Go to Abroad**

- Most U.S. cell therapy companies do not have the global infrastructure to manufacture and register their cellular products overseas.
- HealthBank's global CDMO infrastructure and presence are in high demand.

#### Based on company size

#### **Small-Medium Size Companies**

- Small and medium size companies do not have the resource or capital to build in-house cGMP cell manufacturing facility.
- CDMO enables them to hit key inflection points without huge capital investment.

#### **Academic Investigators**

- Academic cGMP facilities only produce small doses for academic sponsored trials
- Clinical trial will need larger commercial scale production.



## Our Competitive Advantages

Global Infrastructure

THMO continues to build a global infrastructure in U.S., China, and India.

Manufacturing Efficiency

THMO's proprietary platform potentially reduces manufacturing cost by 50%.

**Proprietary Technologies** 

THMO is one of very few CDMOs that owned proprietary mfg. technologies.

35-Year History

THMO's 35-years of experience in the automated cell processing technologies and a mature regulatory team to satisfy the cGMP cell manufacturing needs.



## THMO – A Summary

- o A significant shortage of manufacturing capacity exist for cell & gene therapies.
- o The high manufacturing cost and and low manufacturing capability are key bottlenecks.
- THMO targets to transit from a medical device company to a cGMP CDMO contract manufacturer for the cell and gene therapy field (CGT).
- Our unique high-capacity, high-efficiency cell processing platform CAR-TXpress™, giving us significant competitive advantage.
- 12 newly furnished cGMP manufacturing suite in Sacramento, CA being built to accelerate the transition,

Medical Device CDMO Mfg. Service for Cell & Gene Therapy



# Ensuring the future benefit of cell and gene therapies to everyone in need

**Investor Relationship** 

Paula Schwartz

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For More Information

Please visit our website at: <a href="https://www.thermogenesis.com">www.thermogenesis.com</a>

