



Management:

Interim CEO: Mitchel May

CSO: Roger Vertrees, Ph.D.

CCO: Jan Winetz, MD

Director: Gary Keeling

CFO: Jay Smith, CPA

FDA Consultants: Kinexum Services, LLC

Industry: *Life Sciences*

Date of Incorporation:

Verthermia, Inc. - 7/12.

Verthermia Acquisition, Inc. - 3/18

Law Firms: *Fenn C. Horton III*

Of Pahl & McCay, PLC

IP Counsel: Richard L. Bigelow

Patent Attorney LLC

Securities Counsel: Craig V. Butler

PCAOB Auditor: *Squar, Milner,*

LLP (Publicly Certified Accounting Oversight Board)

Prior Financing Rounds:

\$3.3+M (Friends & Family, Angel)

Financing:

\$10-20 million

Use of Funds: *FDA Clearance, IP, Engineering, Operations, Right to Try Law deployment, Licensing for Southern CA., Acquisitions, Product development for all markets.*

BUSINESS DESCRIPTION: Cutting edge cancer treatment which induces whole body hyperthermia (WBH) by directly heating circulating blood to raise the core temperature of the human body to 42°C, branded as Hyperthermic Extracorporeal Applied Tumor Therapy – HEATT®. Provide equipment and disposables for the treatment of metastatic cancer, either alone or as an adjunct to chemo and radiation, and to possibly treat other diseases. Technologies are based on founders’ 30+ years of prior research and knowledge as well as over \$30 million in grants and equivalent scientific value using WBH to treat lung cancer and infectious diseases (HIV/AIDS). There is a completed non-small cell Lung cancer trial and Verthermia is completing a FDA approved Human clinical trial in San Jose, CA for ovarian cancer and will be expanding to implement treatment under the “Right to Try” Law.

PRODUCTS: Proprietary system, with integrated safety features allowing safe heating of the entire body. Core temperatures via HEATT® at 42°C destroys most cancer cells throughout the body, while not harming normal tissue. The Core HFC™ device is deployed in the only FDA approved WBH trial. The Company is pleased with the trial results as median survival times dramatically exceeded published norms.

MECHANISM OF ACTION: Heat has direct lethal effect on tumors; is retained in the tumor longer than normal tissue because of the vascular disarray present in solid tumors compared to normal tissues. Heat causes disruption of the cancer cell membrane; creates apoptosis (programed cell death) and has been shown to stimulate the immune response. Heat also reverses chemotherapy-resistance in cancer cells especially to platinum-based drugs.

MARKETS: HEATT® market has potential applications for all solid metastatic cancers (estimated at 685k+ new cases in the US annually x multiple treatment cycles). The market size of radiation is a \$4.4B industry, growing at 5.3%/year; chemotherapy is estimated to reach \$150B by 2020, growing at

8%/year. Overall US market for oncology will grow to \$230B by 2023.

COMPETITORS: Nearly all cancer therapies carry significant side effects and are very costly affording patients’ little benefit in quality of life or overall survival. Veno-venous WBH is a new medical treatment space with limited deleterious side effects, a significant extension of life and at competitive prices.

Subsequent to treatment with hyperthermia (HEATT®) in our trials, these patients had dramatic improvements in their quality of life. They were able to pursue interests and activities that they had been unable to do for years. One patient went kayaking 2-weeks after her first treatment: Another patient climbed Half Dome in Yosemite: There was another patient who vacationed in Europe: And another who was able to visit her family in Mexico. These are just a few examples of the dramatic improvement in the quality of life in our patients treated with Hyperthermia. In addition to the improvement in their life's qualities, their longevity was dramatically improved. “In my over 30-years of practicing medicine, I have never encountered another therapy that improved both the QUALITY and QUANTITY of life.” (Dr. Jan Winetz, Nephrologist and Intensivist, CCO-VAI).

The following table compares the efficiency in terms of an increase in survival between HEATT® and the most recently approved cancer drugs. We had no bias in selecting these other than we wanted the most recently approved and most advanced with which to compare. We indicate the type of cancer, the increase in

survival in months, the approximate cost which is extrapolated from their published literature. The final column divides the approximate cost by the number of months that the drug conferred. The average of all of these, cost/survival month was \$25,000, with the range being from \$5000 to \$150,000 per survival month and as can be seen in the first two rows HEATT® compares very favorably in cost. The average increase in survival months was 6.48, range being 1 to 24 months; HEATT® trials were both about 12 months average.

Table 1; Cost Analysis Comparisons per Survival Month

Therapy	Disease (cancer type)	Increase in Survival	Approximate Cost	Cost Comparison/ Survival Month
HEATT®	Lung	12 m	\$250 k	\$21,800
HEATT®	Ovarian	12.2 m	\$250 k	\$21,800
2019				
Bavencio	Renal Cell	5.4 m	\$388 k	\$71,851
Cyramza	Hepatocellular	1.2 m	\$21 k	\$17,500
Keytruda	Esophageal	2.3 m	\$29 k	\$12,609
Keytruda	Lung	2.8 m	\$35 k	\$12,500
Keytruda	Renal Cell	5 m	\$62.5 k	\$12,500
Piqray	Breast	5.3 m	\$46 k	\$8,700
Polivy	B cell Lym	7.7 m	\$100 k	\$12,987
Rozlytrek	Lung	5 m	\$85 k	\$17,000
Tecentriq	Lung	2 m	\$25 k	\$12,500
Tecentriq	Breast	2.6 m	\$33 k	\$12,700
Xpovio	Myeloma	3.8 m	\$84 k	\$22,105
2018				
Braftovi	Melanoma	7.6 m	\$137 k	\$18,026
Copiktra	CLL	7.3 m	\$84 k	\$11,506
Daurismo	AML	4 m	\$68 k	\$17,000
Erleada	Prostate	24 m	\$240 k	\$10,000
Lenvima	Hepatocellular	1.3 m	\$8 k	\$6,154
*Lorbrena	Lung	12.5 m	\$70 k	\$5,600
Opdivo	Lung	1 m	\$150 k	\$150,000
Opdivo	Colorectal	15 m	\$150 k	\$10,000
Poteligio	T Lymphoma	4.5 m	\$280 k	\$62,222
Talzenna	Breast	3 m	\$260 k	\$86,666
Tibsovo	AML	8.2m	\$250 k	\$30,487
Vitraki	Solid tumors	6 m	\$30 k	\$5,000
2017				
Zejula	Ovarian	3.8 m	\$84 k	\$22,105
2015				
Onivyde	Pancreas	2.1 m	\$22 k	\$10,476
AVERAGE		6.48 m		\$25,971

Abbreviations: Acute lymphocytic Leukemia (ALL), Chronic Lymphocytic leukemia (CLL), Acute Myelogenous Leukemia (AML). * Lorbrena in the ALEX trial showed this increase in survival for ALK-NSCLC only. The genetic defect is present in less than 5% of NSCLC patients no results reported for other 95%.

INTELLECTUAL PROPERTY STRATEGY:

- “Method and System for Controlled Hyperthermia” Provisional Patent application filed in the USPTO in April 2019. This Provisional Patent Application will be transformed to a Non-Provisional Patent Application and further expanded upon receipt of funds.
- This Provisional Patent Application is comprehensive and encompasses the critical components of delivering whole body hyperthermia.

- Carbon block/ filtration bed sorbent reactor is clearly patentable over prior sorbent technology. We will pursue patents of this technology for regeneration of dialysate, plasma, and other biologic fluids.
- Proprietary Sorbent regeneration for removing toxins and balancing chemistries during whole body hyperthermia. Critical for administering WBH safely we will pursue patents of this technology.
- We will seek additional patents will be generated as engineering and development proceeds.

REGULATORY PATHWAY:

- 510K Submission for generic label. “Directly warming circulating blood from the jugular vein to the femoral vein in order to raise the patient’s core temperature to the desired temperature of the treating physician.”
- Submission for approval as a “Therapy”. “For treatment of terminally ill cancer patients.” Directly warming circulating blood from the jugular vein to the femoral vein in order to raise the patient’s core temperature to the desired temperature of the treating physician.”

DEVELOPMENT PATHWAY:

- The Core HFC prototype will be further developed and produced by Verthermia® Acquisition, Inc. (Verthermia®). Verthermia® will own all IP associated with such development. Verthermia® will own the “labels” as well and may subcontract some of these projects to Independent Contractors.
- Submissions will also include carbon block column and sorbent technology and “Smart-control”.
- Verthermia® may license and or partner on sorbent technology and carbon block/calcium phosphate system for world-wide use in dialysate or plasma regeneration for all uses in whole body hyperthermia.
- Kinexum Corp (FDA-Specialists) are currently and will continue to assist in submission and interaction with FDA.

UNIQUELY SKILLED TEAM: The Team:

Clinical

- Roger. Vertrees, Ph.D, Director Scientific Board, has 30 years’ of experience in hyperthermia basic science research as well as pre-clinical animal studies and was instrumental in the design of the only human trial to safely treat lung cancer patients in the US.
- Jan Winetz, MD, nephrologist is responsible for developing a proprietary algorithm to improve the overall margin of safety for WBH.
- Medical Advisory Board includes many of the country’s leading oncology thought leaders:
 - David Bartlett, MD, Surgical Oncology, University of Pennsylvania Medical Center;
 - Dennis Chi, MD, Chief OB/GYN Surgical Oncology, Memorial Sloan Kettering;
 - James Cusack, MD, Surgical Oncology, Associate Professor Surgery; Harvard and Mass Gen;
 - Robert DeBernardo, MD, Associate Professor, OB/GYN Surgical Oncology., Cleveland Clinic;
 - Daniel Labow, MD, Chair Dept. of Surgery, Mt. Sinai Hospital, New York City;
 - Joseph Zwischenberger, MD, Surgical Oncologist, Chair Dept. of Surgery, University of Kentucky Medical Center.

Management

- Mitchel K. May, JD Interim CEO, Mitchel has over 30-years of experience in complex transactions, investing and operational management. He has been involved in the formation and management of over 15-successful businesses through his corporate consulting company. He has an exceptional ability to be thorough and organized as seen when structuring deals for his high net worth clients. He was a principal investor in the In The Car venture and brings his many years of skill and success to the team. Mitchel was also instrumental in the startup of several health care related businesses, sports publications and novelty items. His area of expertise is his willingness to propel an idea into a reality. Mitchel May holds a JD from Fordham University School of Law as well as a Bachelor of Administration from Clark University. Mitchel is an admitted member of the State Courts of New York and The Bar Association of New York as well as the American Bar Association. Mitchel started his career practicing law in New York City and while his law degree provides him with knowledge of the law, it is his passion for business that drives him.

- Jay Smith, Interim CFO. Jay was trained as a small business CPA with a large National firm. He brought that experience into the private sector in 1980 where he has guided smaller businesses in numerous management positions resulting in successful and profitable operations. His focus has been primarily in established businesses in manufacturing, distribution, importing and agriculture. Recently he has been supporting new businesses in start-up mode. Jay joined Verthermia® in 2018 to support the Company's drive to secure funding and bring their valuable treatment to market. Jay obtained his BS degree in Accounting and an MBA at the University of Southern California. He obtained his CPA certificate in California but is not currently practicing.
- Gary Keeling and his brother Glenn have been in the hyperthermia space since 1992 and received the first FDA IDE to treat AIDS patients with whole body hyperthermia in 1995. The Keeling brothers went on to receive the first FDA cleared device for intraperitoneal hyperthermia in 1999 and created an entire medical space commercially with the HIPEC procedure, which is used by surgical oncologists to treat advanced abdominal cancer as standard of care in over 172-prestigious hospitals throughout the United States, including Mass General, Cleveland Clinic, Johns Hopkins, MD Anderson and Mayo Clinic.

Board of Directors:

- Dr. Roger Vertrees, Chairman
- Dr. Jan Winetz
- Gary Keeling
- Jay Smith

ACCUMULATED RESEARCH AND BODY OF KNOWLEDGE OVER 30 YEARS

Dr. Vertrees and the Keeling brothers contributed a vast body of knowledge and value to the company including clinical trials technology and processes when it was founded in 2010 (Incorporated in 2012). Their basic science research was on parallel paths which intersected in 1994. Dr. Vertrees at the University of Texas Galveston and the Keeling brothers with IDT/ViaCirq, Inc. Pittsburgh, PA. The Keelings moved forward with the first FDA human whole body hyperthermia clinical trials treating AIDS patients in 1995. Dr. Vertrees and ViaCirq collaborated on the first human whole-body hyperthermia trial to treat patients with advanced non-small cell lung cancer in 2000.

VERTHERMIA HUMAN STUDY FOR ADVANCED LUNG CANCER 2000

Patients (n=10) with stage IV lung cancer were treated at the University of Texas Medical Branch in an FDA approved clinical trial, conducted by Dr. Vertrees. These patients received a target temperature of 42°C for 120 minutes. All patients survived and indeed recovered well from the procedure. Hospital stay was 4.6 days, median length-of-survival after hyperthermia was 271 days. For concurrent controls (n=16, stage IV lung cancer), median length-of-survival from time of diagnosis to death was 96 days, but for the whole-body hyperthermia patients it was significantly longer at **450 days** (p, sig at <0.05). All patients returned to pretreatment status following an FDA-treatment (limited to one cycle only) and died from progression of lung cancer.

VERTHERMIA HUMAN STUDY FOR OVARIAN CANCER 2015

Selection of this patient population with such extensive disease and after their receiving such diverse pre-HEATT® trial therapies, (various chemo regimens and side effects, surgery, radiation) presented us with many unexpected challenges not seen in the previous lung cancer patients or our research swine. These issues extended from atrophied veins, hyper-coagulated states, lack of metabolic reserve (physiological buffering capacity) base-line deranged electrolytes, resting hyperthermic temperatures, and low hemoglobin and white cell counts. We met and successfully resolved these issues both on a patient basis as well as an investigational group. This diverse group of patients ranged from failed 2nd line to failed 7th line. Overall survival from their first HEATT® cycle is **633 days**. Historical controls for this group's overall survival is 240 days (Harkin et al 2012)

EXIT STRATEGY: Should Verthermia choose the IPO route, it will, upon closing that public financing, conduct a search and recruit a “Wall Street experienced Life Sciences” CEO and CFO. Thereafter all necessary steps will be taken to become Sarbanes-Oxley compliant, file its S-1 filing and apply for up listing to one of the three major U.S. exchanges. Verthermia may also choose to be acquired by another life sciences company. Nonetheless, Verthermia® will enjoy first mover advantage as well as an extensive IP portfolio in addition to trade secrets. FDA clearance will provide its own protections to the company.

Investor Considerations

The terms and conditions set forth herein are subject to change, customary legal review, and the conduct of due diligence. This summary does not constitute an offer and does not constitute an agreement or obligation on the part of any person to purchase or sell the securities of the Company.

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Notices

The information contained in this Executive Summary (this “Summary”) has been provided by (the “Company”, “we” or “us”). Any estimates, forecasts or other forward-looking statements contained in this Summary have been prepared by the management of the Company in good faith on a basis it believes is reasonable. Such estimates, forecasts and other forward-looking statements involve significant elements of subjective judgment and analysis and no representation can be made as to their attainability. No representation or warranty (express or implied) is made or is to be relied upon as a promise or representation as to the future performance of the Company.

Cautionary Note Regarding Forward Looking Statements

This Executive Summary contains certain forward-looking statements within the meaning of Section 27A of the Act. All statements that address expectations or projections about the future, including statements about product development, market position, expected expenditures and financial results are forward-looking statements. These forward-looking statements are based on current expectations, estimates and projections for our industry, management’s beliefs and assumptions made by management. Words such as “anticipates,” “expects,” “intends,” “plans,” “believes,” “seeks,” “estimates,” “should,” “could,” “may,” and variations of such words and similar expressions are intended to identify such forward-looking statements. These statements are not guarantees of future performance and are subject to certain risks, uncertainties and assumptions that are difficult to predict. Accordingly, actual results or performance of The Company, Inc. may differ significantly, positively or negatively, from forward-looking statements made herein. Unanticipated events and circumstances are likely to occur. Factors that might cause such differences include, but are not limited to, those discussed under the heading “Risk Factors,” which investors should carefully consider. These factors include, but are not limited to, risks that our products and services may not receive the level of market acceptance anticipated; anticipated funding may prove to be unavailable; potential competition in our market may result in lower than anticipated revenues or higher than anticipated costs, and general economic conditions, such as the rate of employment, inflation, interest rates and the condition of the capital markets may change in a way that is not favorable to us. This list of factors is not exclusive. We undertake no obligation to update any forward looking statements.

AN INVESTMENT IN THE SECURITIES OF THE COMPANY IS SPECULATIVE AND INVOLVES A HIGH DEGREE OF RISK. SEE “RISK FACTORS” FOR A DISCUSSION OF CERTAIN FACTORS THAT SHOULD BE CONSIDERED IN CONNECTION WITH ANY PURCHASE OF THE SECURITIES. THERE IS NO PUBLIC MARKET FOR ANY OF THE COMPANY’S SECURITIES AND NO SUCH MARKET IS EXPECTED TO DEVELOP FOLLOWING THE PLACEMENT OF THE DEBENTURES. SIGNIFICANT RESTRICTIONS ON TRANSFER WILL APPLY. YOU SHOULD BE PREPARED TO BEAR THE ECONOMIC RISK OF YOUR INVESTMENT FOR AN INDEFINITE PERIOD OF TIME AND BE ABLE TO WITHSTAND A TOTAL LOSS OF YOUR INVESTMENT. THIS SUMMARY DOES NOT CONSTITUTE AN OFFER TO SELL OR SOLICITATION OF AN OFFER TO BUY, ANY SECURITIES TO ANY PERSON IN ANY JURISDICTION IN WHICH SUCH AN OFFER OR SOLICITATION IS UNLAWFUL.

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NASAA Legend

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