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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): **May 28, 2014**

**Heat Biologics, Inc.**

*(Exact name of registrant as specified in charter)*

**Delaware**

*(State or other jurisdiction of incorporation)*

**001-35994**

*(Commission File Number)*

**26-2844103**

*(IRS Employer Identification No.)*

**801 Capitola Drive  
Durham, NC 27713**

*(Address of principal executive offices and zip code)*

**(919) 240-7133**

*(Registrant's telephone number including area code)*

**N/A**

*(Former Name and Former Address)*

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 7.01. Regulation FD Disclosure**

Heat Biologics, Inc. (the “Company”) will be making several investor presentations over the next few weeks, including a presentation at the 3<sup>d</sup> Annual Marcum LLP MicroCap Conference on May 29, 2014 in New York. In connection with the presentations, the Company intends to discuss the slide presentation furnished as Exhibit 99.1 hereto, which is incorporated herein by reference.

The slide presentation attached as Exhibit 99.1 to this Report includes “safe harbor” language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained in the slide presentation or in the press release are “forward-looking” rather than historical.

The information included in this Item 7.01 and in Exhibit 99.1 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. The Company undertakes no duty or obligation to update or revise information included in this Report or any of the Exhibits.

**Item 9.01 – Financial Statements and Exhibits.**

(d) Exhibits.

The following exhibit is being filed as part of this Report.

| <b>Exhibit<br/>Number</b>   | <b>Description</b>  |
|-----------------------------|---|
| <a href="#"><u>99.1</u></a> | Presentation materials to be provided at Heat Biologics, Inc.’s presentations |

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: May 28, 2014

HEAT BIOLOGICS, INC.

By: /s/ Jeff Wolf  
Name: Jeff Wolf  
Title: Chairman, President and  
Chief Executive Officer

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## EXHIBIT INDEX

| Exhibit<br>Number    | Description   |
|----------------------|---|
| <a href="#">99.1</a> | Presentation materials to be provided at Heat Biologics, Inc.'s presentations |



*Corporate Presentation*

May 2014

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# Forward Looking Statements

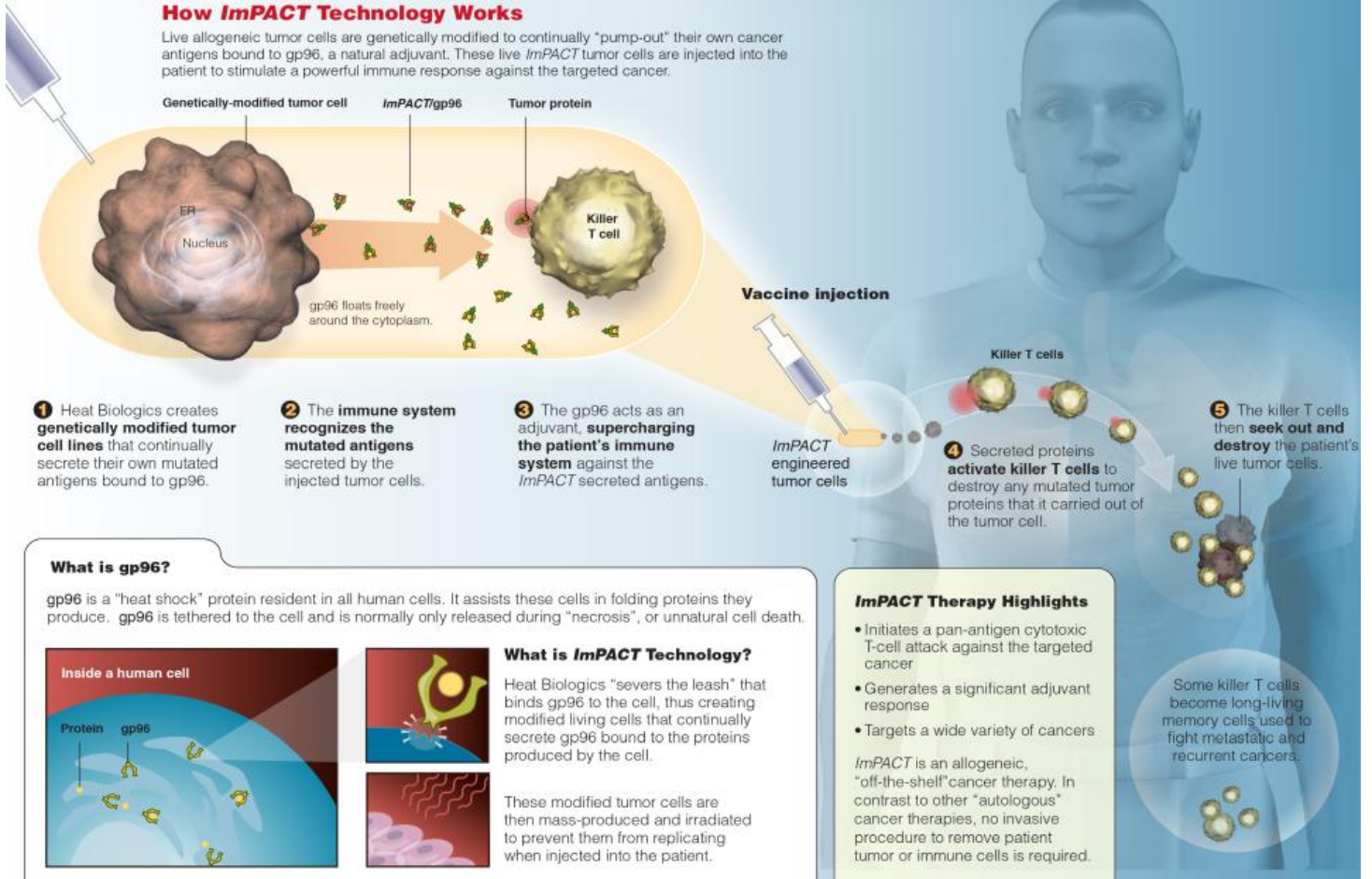
This presentation includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, our ongoing and planned discovery and development of drugs targeting cancer stem cells, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to make regulatory filings and obtain and maintain regulatory approvals for our product candidates, our ability to partner our product development, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, financial condition, liquidity, prospects, growth and strategies, the length of time that we will be able to continue to fund our operating expenses and capital expenditures, our expected financing needs and sources of financing, or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation as a result of, among other factors, the factors referenced in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2013 and our quarterly report on Form 10-Q for the quarter ended March 31, 2014 (collectively, our "SEC Filings"). In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this presentation, they may not be predictive of results or developments in future periods. Any forward-looking statements that we make in this presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this presentation, except as required by law.



Heat Biologics' proprietary **Immune Pan Antigen Cytotoxic Therapy (ImPACT)** reprograms live "allogeneic" cancer cells to continually secrete their own antigens bound to heat shock protein gp96 to seek out and destroy a variety of tumors.

### How ImPACT Technology Works

Live allogeneic tumor cells are genetically modified to continually "pump-out" their own cancer antigens bound to gp96, a natural adjuvant. These live ImPACT tumor cells are injected into the patient to stimulate a powerful immune response against the targeted cancer.



## Investor Highlights

- Transformative, differentiated **immunotherapy** platform generating diverse pipeline with strong patent estate
- Promising monotherapy clinical data in lung cancer with impressive survival results
- 2 clinical development programs advancing into Phase 2 studies in 2014 expected to generate key near-term catalysts
- Robust business development initiative with potential for multiple regional and global partnering opportunities
- Experienced team with extensive oncology operational, scientific, clinical and business development expertise





# Management Team with Proven Track Record

## Jeff Wolf

### Founder and CEO

- Founder and managing director of Seed-One Ventures
- Co-founder and director, Avigen
- Co-founder and Chairman, TyRx Pharma
- Founder and CEO, EluSys Therapeutics

## Matt Czajkowski

### Chief Financial Officer

- Fifteen years experience as Chief Financial Officer for a variety of early stage and public companies: Pozen, Inc., AAI
- Chief Executive Officer of Lexipar, Inc.
- Investment Banker, Goldman Sachs & Co.'s Asia Pacific Mergers and Acquisition Group in Tokyo, Japan.

## Anil K. Goyal, Ph.D.,

### VP, Business Development

- 20 years of experience at private and public biotechnology companies covering all aspects of licensing, deal making, and strategic alliances
- Management and BD roles with Serenex, Inc., Millennium Pharmaceuticals, Genome Therapeutics Corporation, Qualiber, and Asclepis Pharmaceuticals.

## Melissa Price, Ph.D.

### VP, Clinical and Reg. Affairs

- Led numerous oncology programs in both the biotech arena and the CRO space
- Leadership roles at INC Research, Novaquest, (a Quintiles Company) and Attenuon
- Published in numerous scientific journals

## Taylor Schreiber, M.D., Ph.D.

### VP, Research and Development

- Co-inventor of significant elements of *ImPACT* technology platform
- Co-inventor of TNFRSF25 agonist technology
- Author of numerous immunology and heat shock protein-based cancer immunotherapy publications
- Post-doctoral fellowship with Eckhard R. Podack, M.D., Ph.D., at University of Miami



# World Renowned Advisory Boards

## Scientific Advisory Board

- **Eckhard R. Podack, M.D., Ph.D.**  
*University of Miami, Miller School of Medicine*
- **James Allison, Ph.D.**  
*MD Anderson Cancer Center*
- **John Nemunaitis, M.D.**  
*Mary Crowley Cancer Research Centers*
- **Justin Stebbing, M.D., Ph.D.**  
*Imperial College, London*
- **Daniel D. Von Hoff, M.D.**  
*Translational Genomics Institute*

## Clinical Advisory

### Board

- **Justin Stebbing, M.D., Ph.D.**  
*Imperial College, London*
- **Gary Acton, M.D.**  
*Cancer Research UK, former CMO of Antisoma*
- **Roger Cohen, M.D.**  
*University of Pennsylvania, Abramson Cancer Center*
- **Llew Keltner, M.D., Ph.D.**  
*EPISTAT*
- **Mark Schoenberg, M.D.**  
*Albert Einstein College of Medicine of Yeshiva University, Montefiore Medical Center*

# Diverse Pipeline with Multiple Registration Opportunities

*From drug discovery to late-stage clinical development*

|          | Disease                                    | Pre-Clinical | Manufacturing | Phase 1 | Phase 2   |
|----------|--|--------------|---------------|---------|-----------|
| Oncology | HS-110 (Viagenpumatulcel-L) - NSCLC        | →            | →             | →       | Planned → |
|          | HS-410 (Vesigenurtacel-L) - Bladder Cancer | →            | →             | →       |           |
|          | HS-310                                     | →            |               |         |           |
|          | HS-210                                     | →            |               |         |           |
|          | HS-510                                     | →            |               |         |           |
|          |  |              |               |         |           |

# Broad Issued Patents on *ImPACT* Platform & Pipeline

## IP Estate with Broad and Early Filings

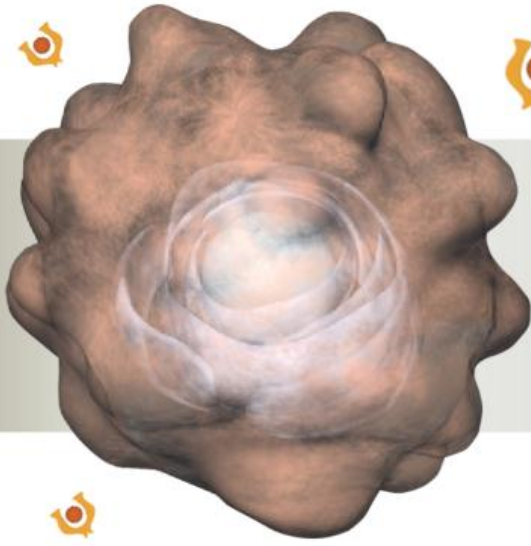
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### *ImPACT* Platform Technology

- US and foreign patents issued for *ImPACT* technology for the treatment of cancer and viral disease
  - Additional patents on proprietary cell lines and clinical data
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### Worldwide Filings

- Over 50 patent applications across 5 patent families
- Enforceable patents issued in 15 countries and counting

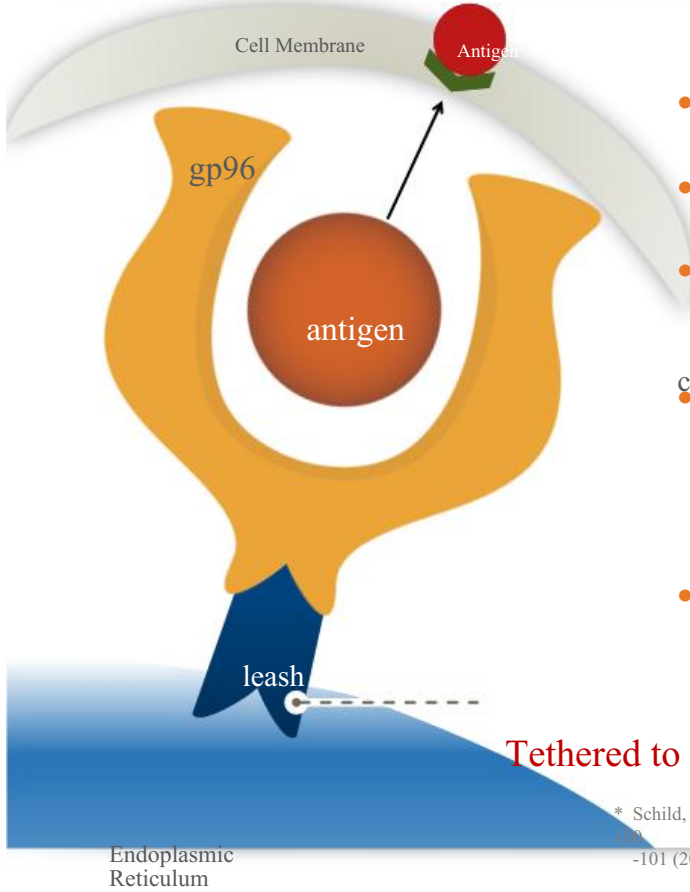


## Heat's *ImPACT* Therapy

### Living Drug Factories

Antigen and adjuvant delivery in a single package

# Introducing gp96 — Immune System’s “Swiss Army Knife”\*



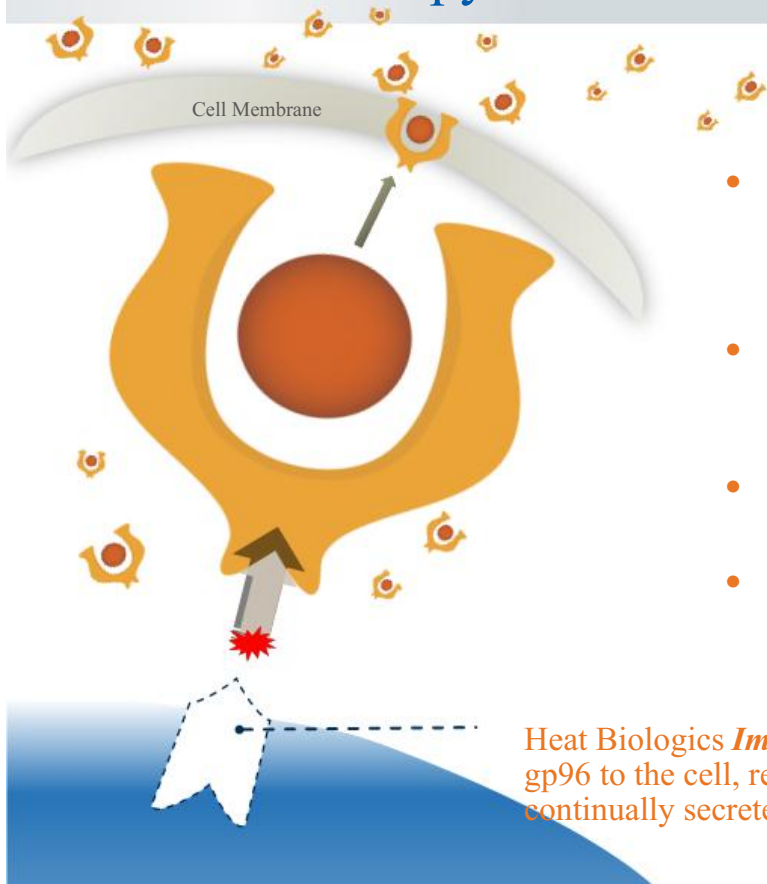
## “Molecular Warning System”

- Natural biological process to deliver proteins (antigens) + gp96 adjuvant to our immune system
- Gp96 “chaperones” newly-created proteins to the cell membrane where they are released and embedded
- Activates a cytotoxic T-cell response to the antigen it is carrying
  - Enables MHC I antigen cross-presentation to CD8+ T-cells
- Gp96 + protein are only naturally released via necrosis
  - Exposure of gp96 outside the cell activates an immune response to the antigen it is carrying
  - Enables MHC I antigen cross-presentation specifically to CD8+ T-cells
- Among the most powerful adjuvants and the only adjuvant to show exclusive specificity to CD8+ (“killer”) T-cells
  - Provides long-term immunity against the infectious agent

Tethered to our cells with a “KDEL” leash

\* Schild, H. & Rammensee, H. *Gp-96 - The Immune System’s Swiss Army Knife*. Nature Immunology 2, 109-111 (2001)

## *ImPACT* Therapy — “Severing the Leash”



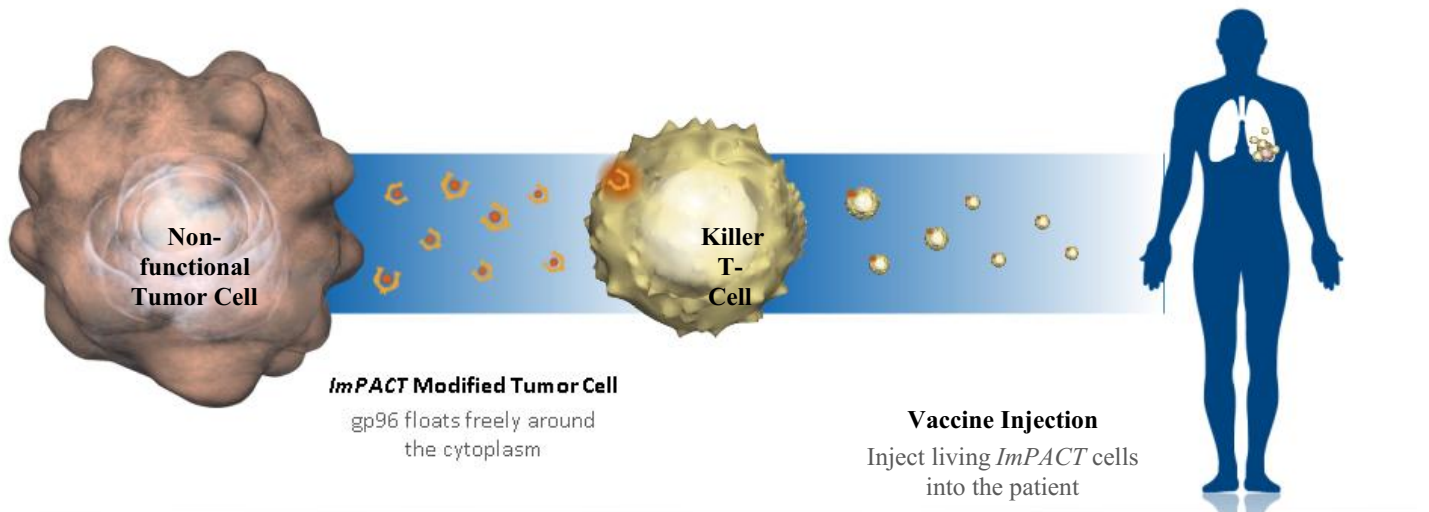
- Genetically modify tumor cells by “severing the leash” that binds the gp96 to the endoplasmic reticulum of the cell and replacing it with a sequence that pumps gp96 out of the cell
- Enables living cancer cells to “pump-out” their own surface antigens along with their gp96 chaperone
  - Mimics necrotic cell death
- Activates a powerful pan-antigen cytotoxic T-cell immune response
- “Off-the-shelf” therapy designed to enable a fully in vivo attack against a wide variety of cancers

Heat Biologics *ImPACT* technology removes the leash that binds gp96 to the cell, replacing with a sequence that allows cells to continually secrete gp96 along with their “chaperoned” antigen





# ImPACT Therapy — Process



- 1 Choose cancer of interest and identify a cell line representative of that cancer.
- 2 Heat Biologics creates genetically modified tumor cell lines to continually secrete their own mutated antigens bound to gp96.
- 3 Scale-up production of these living tumor cells as our “drug” to treat all patients with a particular cancer. Irradiate these cells so they can’t replicate and vial for distribution.
- 4 Inject these living, genetically-modified cells into patients. These cells continuously secrete tumor proteins bound to gp96.
- 5 Secreted proteins activate killer T-cells to seek-out and destroy the targeted cancer.





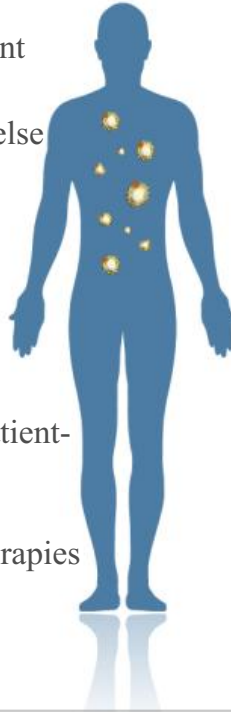
## An “Off-the Shelf” Therapy to Generate a *Pan-antigen T-cell Immune Attack*

### Approach

- Allogeneic, “off-the-shelf” treatment created from a master cell line
- No tumor cells, blood or anything else extracted from the patient
- Non-invasive

### Benefits

- Unlimited drug supply enables immediate treatment
- Frequent administration with no patient-specific processing
- **Less expensive** to produce and administer than autologous therapies with COGS < 5% of autologous approaches with fewer logistical hurdles



- **Pan-antigen** immune attack
  - Unleashes an immune attack against a wide variety of *known and unknown* cancer antigens
- **Cytotoxic T-cell exclusive** immune response
- **Antigen + adjuvant in a single complex**
  - Antigen + adjuvant presented simultaneously
  - Activates robust and highly specific immune response against secreted cancer antigens
- **Continuous secretion** of gp96-antigen/adjuvant complex
  - Generates more robust and sustained antigen-specific immune response

# Lung Cancer and HS-110 (Viagenpumatulcel-L)

## Background

Lung Cancer is the Second Most Common Cancer in US with No Reliable Treatment Options for Late-Stage Patients

**“Without any chemotherapy, the average person will live about 4½ months. With chemotherapy most will live longer and some will live a shorter time. More recent chemotherapy trials have shown that people live about 3 months longer than if they did not get chemotherapy. ... Even with chemotherapy, the chance of being alive at one year is about 30-50%; the chance of dying within this year is 50-70%.”**

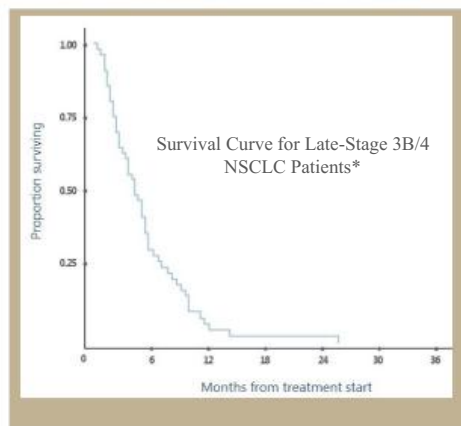
— American Society for Clinical Oncology (ASCO) Guidelines

## Current Treatment

- Surgical Resection
- Radiation Therapy
- Chemotherapy
  - 3-6 cycles
  - Each cycle lasts 3-4 weeks
- Targeted Therapies

## Survival Prospects

- Median survival ~ 4.5 months\*
- 1 year survival ~6%\*



\* Massarelli E. Lung Cancer;2003;39 - Meta Analysis

## Heat's HS-110 Therapy

- Cells are genetically modified to secrete gp96 and most known (and many unknown) lung cancer antigens
- Pan-antigen cytotoxic T-cell immune response

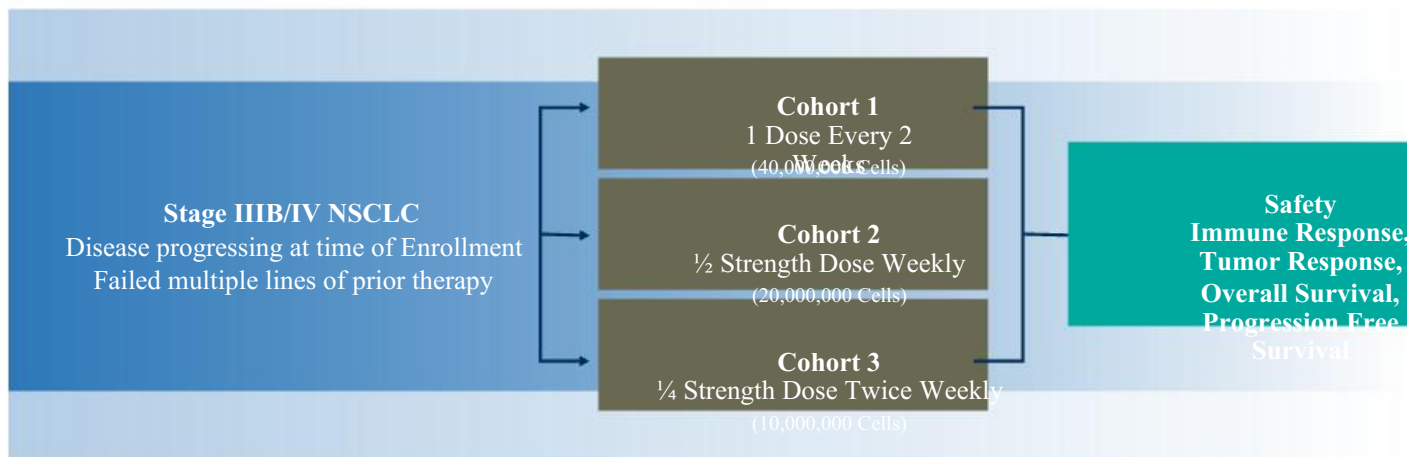
## Treatment

- Powerful immune activation
- Positive safety profile based on preclinical studies and one clinical study
- The drug is administered in a simple, once-a-week injection



# HS-110: Successful Completion of Phase 1 Study

## *Phase 1 NSCLC Trial Design*



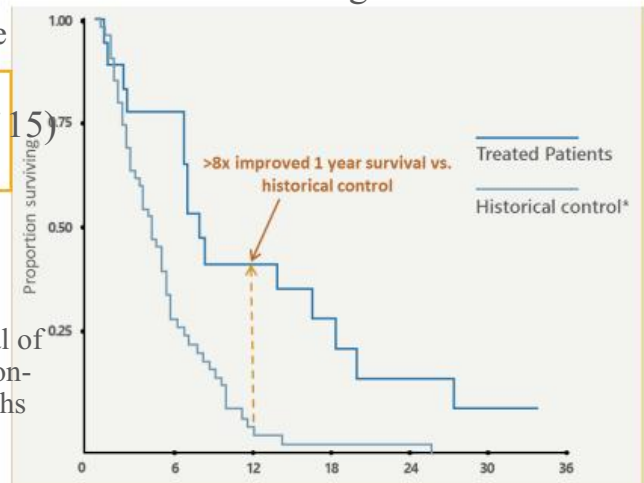
- NIH-funded, open-label, single center investigator-sponsored IND
- 18 patients with late-stage NSCLC
- Enrollment alternating in 3 cohorts after first 8 patients

# HS-110 NSCLC Phase 1 Clinical Trial Results

- **Well-tolerated** with no overt toxicity
- **Single agent clinical activity** in late-stage 3b and 4 non-small cell lung cancer
  - 7 of 15 surviving patients exhibited stable disease after single course of therapy

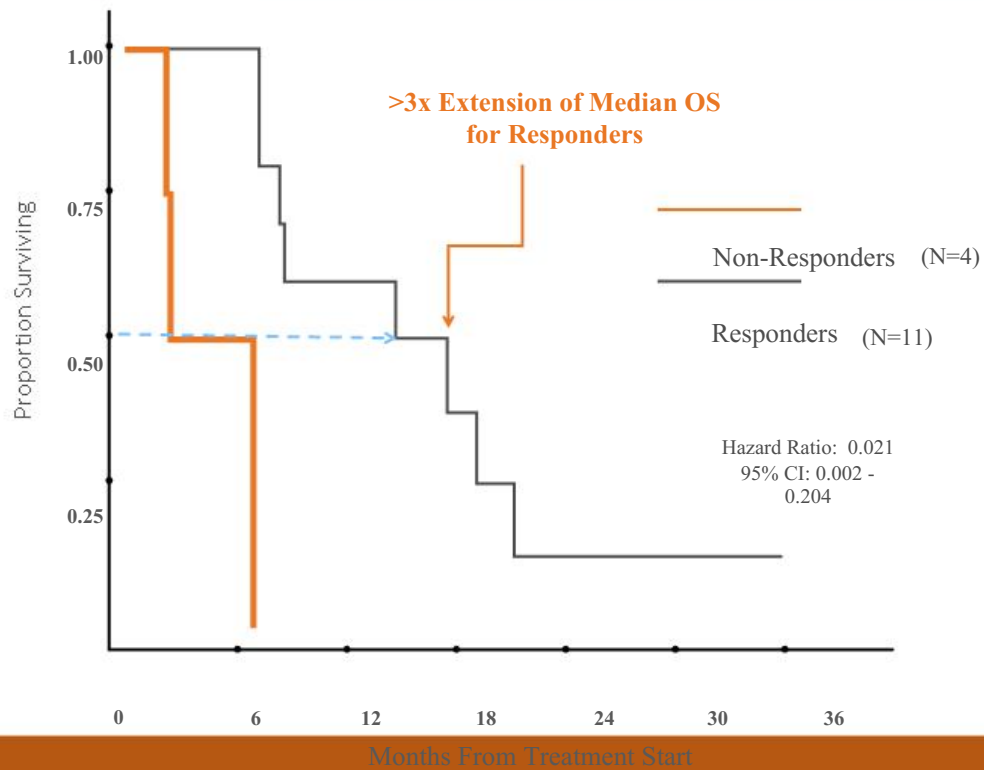
- **Immune response observed** in 73% (11 out of 15) of patients who completed their first course of therapy

- **Immune response predictive of survival** (HR: 0.021, 95% CI:0.002-0.204)
  - The immune responders exhibited a median survival of 16.9 months (95% CI: 7.1-20) while the immune non-responders exhibited a median survival of 4.5 months
- **Two late-stage patients survive >3 years**
  - One HS-110 patient alive >3 yrs. and another patient still alive >4 yrs.



- **Median 1 year overall survival rate** of patients in the study was 44% (95% CI: 21.6-65.1) comparing favorably to a 5.5% rate based on historical control\*

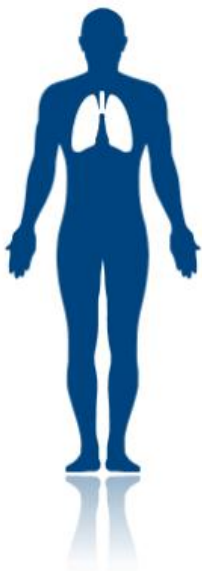
# Immune Response Predictive of Survival



In 11 of the 15 patients (73%) completing the first course of therapy with HS-110, there was a twofold or greater increase in CD8 co-inhibiting inter-feron gamma (CD8<sup>+</sup> CTL-IFN $\gamma$ ) following vaccination. The responders saw a three-fold increase in survival.

## HS-110 Lung Cancer Phase 2 Clinical Program

*Specifically designed in collaboration with leading KOLs to be complementary in combination with next generation oncology treatments*



### 1H 2014

- ✓ Finalize Phase 2 protocol
- ✓ Submit revised protocol to FDA
- ✓ Announce Phase 2 protocol

### 2H 2014

- Commence patient enrollment and dosing

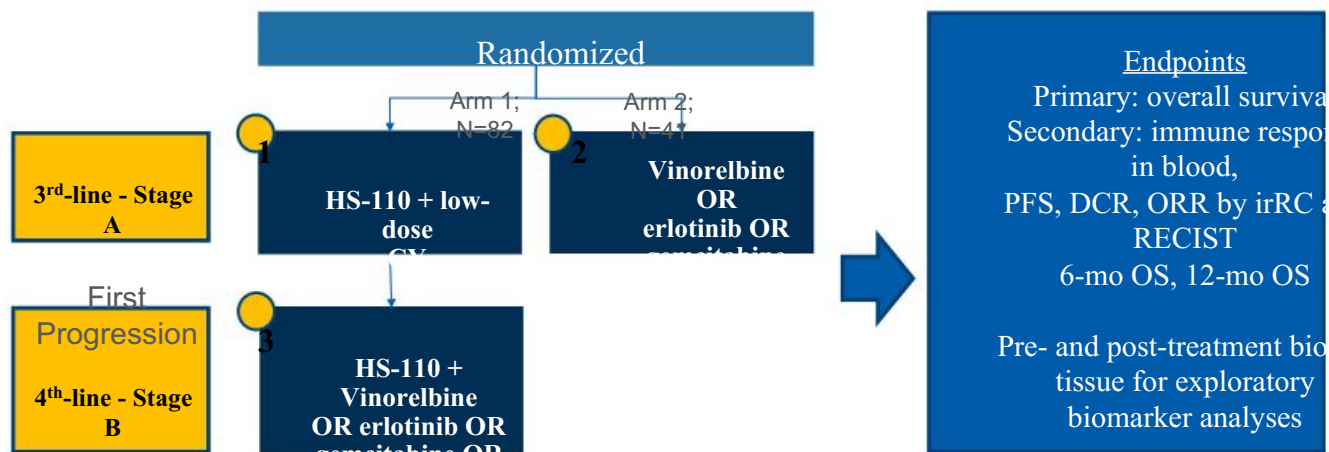
## Phase 2 Protocol Designed to Complement Next Generation Oncology Treatments

- Address unmet need by offering patients access to investigational agents with presumably a more favorable safety profile than chemo in a setting where there is little approved in 3<sup>rd</sup>-line and the efficacy of these agents is minimal
- Maximize antigen expression overlap by testing an adenocarcinoma vaccine to an adenocarcinoma population
- Mimic future combinations with checkpoint inhibitors by utilizing low-dose cyclophosphamide
- Evaluate the effect of concomitant chemotherapy on the immune response to HS-110 and of subsequent chemotherapy after HS-110 tumor response
- Evaluate multiple endpoints due to short time to event in this population (overall survival, objective response, disease control rate, PFS, immune response, 6-mo OS, 12-mo OS)
- Capture pre- and post-treatment biopsy tissue when appropriate in order to correlate antigen expression, TILs and T-cell receptor sequences with outcomes, potentially leading to proof of concept and precision in patient selection



# Phase 2 HS-110/CY Combo NSCLC Design

3<sup>rd</sup>-line vs. physician's choice, continue vaccine in combo with 3L chemo after 1<sup>st</sup> progression



## Regimen

- Low-dose cyclophosphamide (CY) 50 mg daily for 7 days q2weeks for 12 weeks or until 1<sup>st</sup> progression
- HS-110 cells weekly for 12 weeks then q3 weeks until 2nd irPD or 12 months whichever comes first

## Sample Size

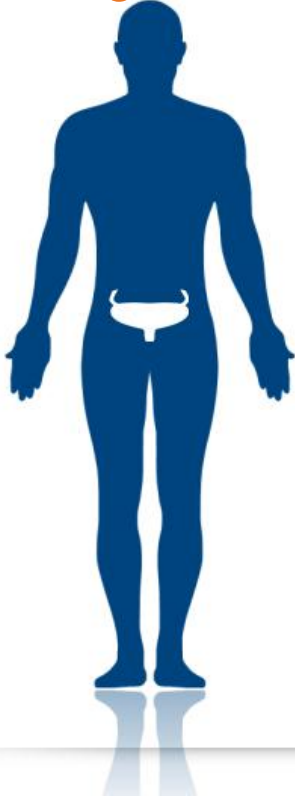
- 123 patients randomized 2:1
- 80% power with alpha = 0.1 to detect a 50% reduction in the risk of death with 59 events in the experimental group and 33 events in the control group





## Bladder Cancer and HS-410

### Background



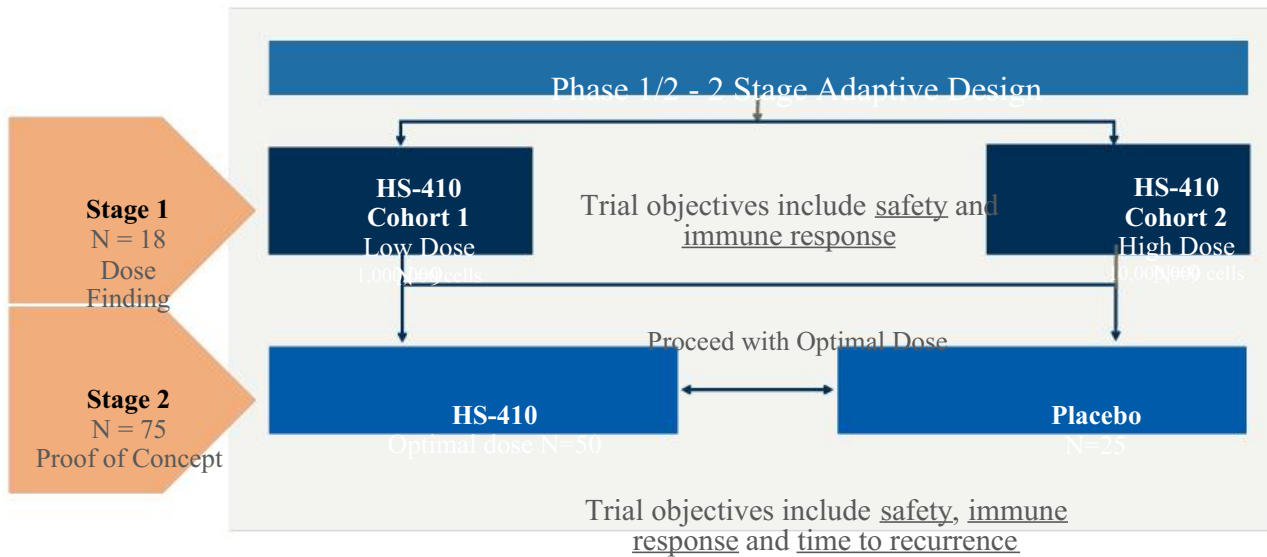
In 2012 Alone, There Were 73,000 New Cases of Bladder Cancer Reported and 15,000 Deaths

- Currently-available treatments have high failure rate and are poorly tolerated
- Among highest lifetime treatment cost per patient of any cancer due to a high recurrence rate
- Opportunity to treat patients with minimal residual disease
- No new drug for this patient population in >25 years



# HS-410: Bladder Cancer Phase 1/2

**93 patient, fully-randomized, placebo-controlled trial**  
**Weekly injections for 12 weeks followed by 3 monthly injections**



- Population includes non-muscle invasive disease, treated with surgery followed by 3-6 weeks of BCG therapy

# Key Study Timelines and Milestones

## Phase 1/2 Clinical Trial for Bladder Cancer

| Milestone                            | Target Completion |
|--------------------------------------|-------------------|
| First patient enrolled and dosed     | ✓ Q1 2014         |
| Cohort 1 enrollment complete         | Q3 2014           |
| Cohort 2 enrollment initiates        | Q4 2014           |
| Cohort 1 safety and antigen profiles | Q1 2015           |
| Cohort 2 enrollment complete         | Q1 2015           |
| Cohort 2 safety and antigen profiles | Q1 2015           |
| Phase 2 enrollment initiates         | Q1 2015           |

# Business Development Strategy

## 1. ImPACT Platform Partnerships

- Strategy to Partner by indication(s)
- Use platform for new product discovery
- Product development by partner

## 2. Clinical Programs (HS-110, HS-410)

- Partner at/after Phase 2 data
- Partner with regional or global rights
- Retain US commercialization rights

## 3. MoA complementary with checkpoint inhibitors

- Explore co-development partnerships with anti-PD1 & anti-PDL1 products

*The Power of T Cells*

**Immunocore, Genentech Seal Multi-Target, High-Dollar Deal**

**Immatics, Roche Ink Potential \$1B Cancer Immunotherapy Deal**

*Another \$275M in Potential Milestones*  
**Astrazeneca's Gambit: \$225M for Early Stage Amplimmune**

**Vaccine Developer Okairos Goes to GSK in \$324M Buy**

**Selected Immunotherapy Deals**

| Companies      | Date    | Financial              |
|----------------|---------|------------------------|
| AZ-Immunocore  | Jan '14 | \$20M+300M/<br>program |
| Novartis-UPenn | Aug '12 | \$20M+MS               |
| Sanofi-CureVac | Nov '11 | \$33M+200M             |



## Financial Snapshot

*Financial strength to execute on our business plan*

| <b>Ticker</b>          | <b>NASDAQ: HTBX</b> |
|------------------------|---------------------|
| Shares Outstanding     | 6,452,341           |
| Share Price*           | \$4.77              |
| Market Capitalization* | ~\$30M              |
| Cash as of 3/31/14     | \$19.4M             |
| Enterprise Value       | ~\$10M              |

*\*as of market close on May 22, 2014*



## Multiple Near-Term Milestones Expected to Build Momentum

| Program                                 | 1H 2014   | 2H 2014  |
|---|---|--|
| <b>HS-110</b><br>Lung Cancer Program    | ✓ Submit revised protocol to FDA  | <input type="checkbox"/> Initiate Phase 2 enrollment   |
| <b>HS-410</b><br>Bladder Cancer Program | ✓ Commence patient dosing   | <input type="checkbox"/> Complete Cohort 1 enrollment<br><input type="checkbox"/> Cohort 1 immune response data<br><input type="checkbox"/> Initiate Cohort 2 enrollment |
| <b>3rd Product</b>                      | <input type="checkbox"/> Generate multiple product candidates   | <input type="checkbox"/> Announce 3 <sup>rd</sup> product program  |
| <b>Corporate</b>                        | <input type="checkbox"/> Seek development and commercialization partners<br><input type="checkbox"/> Continued grant filings and notifications<br><input type="checkbox"/> Additional research developments<br><input type="checkbox"/> Various clinical publications |  |

# Summary

## Clinical Stage Platform Technology Generating Promising Human Data

|   |   |
|---|---|
| <p>Transformational<br/>Technology Platform</p> | <p>Unleashes the immune system against a wide range of cancers</p> <ul style="list-style-type: none"><li>• Over a decade of published research and recent clinical data</li></ul>   |
| <p>Encouraging<br/>Clinical Data</p>            | <p>Data to Date Demonstrate:</p> <ul style="list-style-type: none"><li>• Positive safety profile</li><li>• Powerful, disease-specific immune activation</li><li>• Immune activation corresponds with increased overall survival</li></ul>   |
| <p>Value Creating<br/>Milestones</p>            | <p>Strong Clinical Pipeline</p> <ul style="list-style-type: none"><li>• Phase 2 NSCLC clinical trial and Phase 1/2 bladder cancer trial with additional IND submissions planned in other cancer indications</li><li>• Multiple near-term enrollment and data readouts</li><li>• Potential for business development licensing activity</li></ul> |



