
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): **January 13, 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.)

**100 Europa Drive
Chapel Hill, NC 27517**

(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

Jeff Wolf, the Chairman, Chief Executive Officer and President of Heat Biologics, Inc. (“Heat”), will be making several investor presentations over the next few weeks, including and beginning with a presentation on Tuesday, January 14, 2014 at the 6th Annual Biotech Showcase investor and partnering conference held at the Parc 55 Wyndham - Union Square, San Francisco, California. In connection with that presentation, Mr. Wolf 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 Exhibits 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.

Exhibit Number	Description
<u>99.1</u>	Presentation materials to be provided at the Heat Biologics, Inc. investor presentations.

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: January 13, 2014

HEAT BIOLOGICS, INC.
(Registrant)

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

EXHIBIT INDEX

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Corporate Presentation

January 2014

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, 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, the industry in which we operate and the healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future

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 Registration Statement on Form S-1, as amended, declared effective by the Securities and Exchange Commission on July 23, 2013 and our quarterly report on Form 10-Q for the period ended September 30, 2013 (collectively, our "SEC Filings"). In addition, even if our results of operations, financial condition and liquidity, and the development

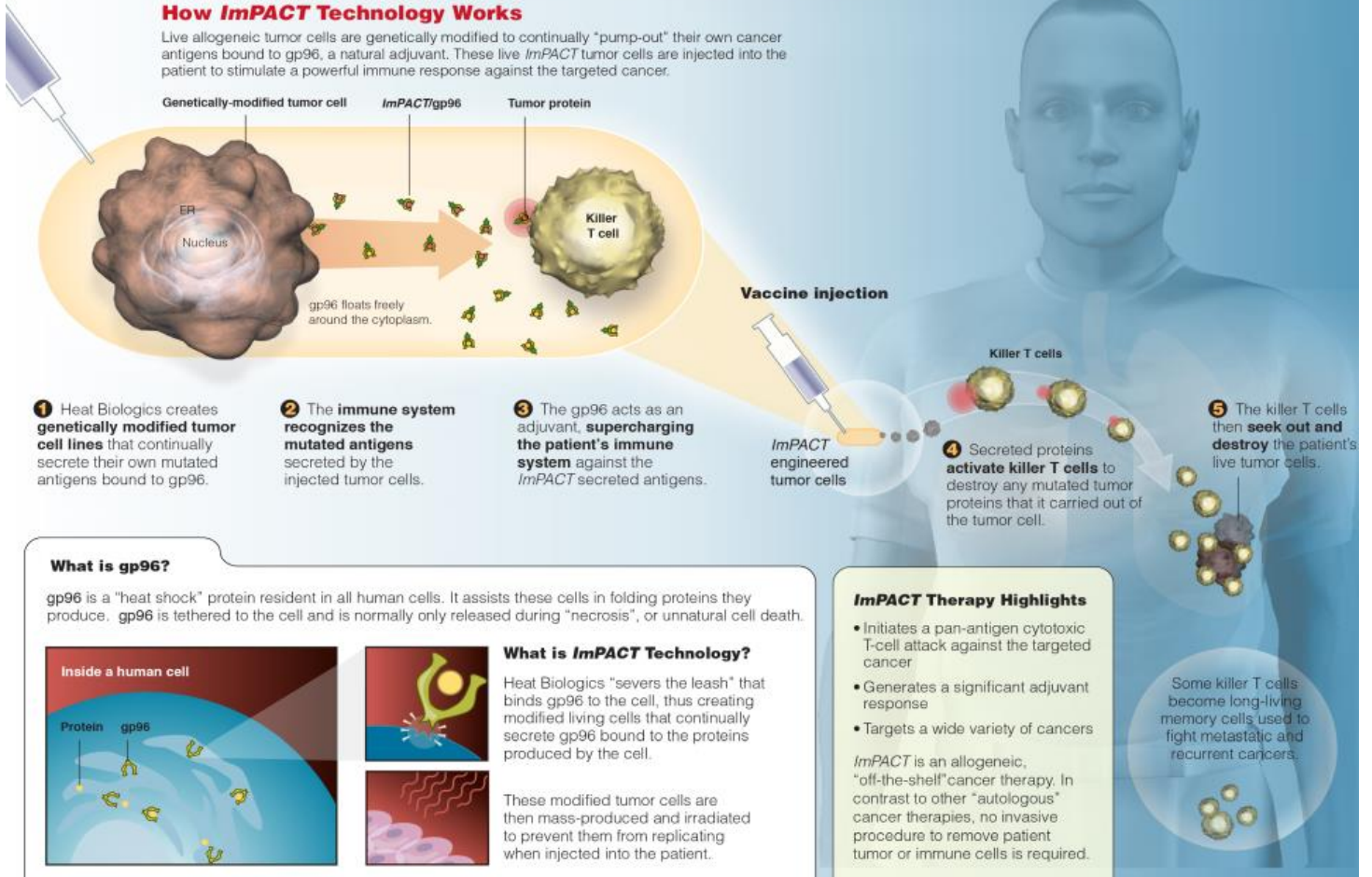
of the industry in which we operate are consistent with the forward-looking statements contained in this presentation, they may not be predictive of results or developments in future periods. Any forward-looking statements that we make in this presentation speak only as of the date of such statement, 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

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.



1 Heat Biologics creates **genetically modified tumor cell lines** that continually secrete their own mutated antigens bound to gp96.

2 The **immune system recognizes the mutated antigens** secreted by the injected tumor cells.

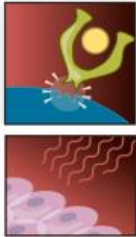
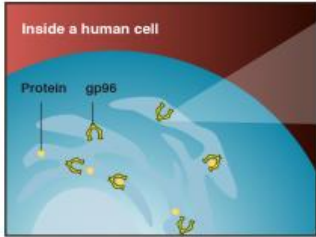
3 The gp96 acts as an adjuvant, **supercharging the patient's immune system** against the ImPACT secreted antigens.

4 Secreted proteins **activate killer T cells** to destroy any mutated tumor proteins that it carried out of the tumor cell.

5 The killer T cells then **seek out and destroy** the patient's live tumor cells.

What is gp96?

gp96 is a "heat shock" protein resident in all human cells. It assists these cells in folding proteins they produce. gp96 is tethered to the cell and is normally only released during "necrosis", or unnatural cell death.



What is ImPACT Technology?

Heat Biologics "severs the leash" that binds gp96 to the cell, thus creating modified living cells that continually secrete gp96 bound to the proteins produced by the cell.

These modified tumor cells are then mass-produced and irradiated to prevent them from replicating when injected into the patient.

ImPACT Therapy Highlights

- Initiates a pan-antigen cytotoxic T-cell attack against the targeted cancer
- Generates a significant adjuvant response
- Targets a wide variety of cancers

ImPACT is an allogeneic, "off-the-shelf" cancer therapy. In contrast to other "autologous" cancer therapies, no invasive procedure to remove patient tumor or immune cells is required.

Some killer T cells become long-living memory cells used to fight metastatic and recurrent cancers.

Investor Highlights

- Transformative, differentiated **Immunotherapy** platform generating diverse pipeline with strong patent estate
- Promising clinical data yielding impressive survival supports 2 programs advancing into late-stage studies in 2014
- Clinical development programs with clear path to registration in high-potential markets
- 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 and Scientific Advisory Board

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 Pharma, Inventure funded private companies
- Chief Executive Officer of NextRay, 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
- Managed strategic BD roles with, Streamline, Milestone pharmaceuticals, Genome Therapeutics Corporation, Qualiber, and Asletis Pharmaceuticals.

Melissa Price, Ph.D.

VP, Clinical and Regulatory Affairs

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

WORLD RENOWNED SCIENTIFIC ADVISORY BOARD

- Eckhard R. Podack, M.D., Ph.D.
- James Allison, Ph.D.
- Sol J. Barer, Ph.D.
- John Nemunaitis, M.D.
- Justin Stebbing, M.D., Ph.D.
- Daniel D. Von Hoff, M.D.



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 NSCLC	→	→	→	Planned →
	HS-410 Bladder	→	→	→	
	HS-310	→			
	HS-210	→			
	HS-510	→			

Broad Issued Patents on *ImPACT* Platform & Pipeline

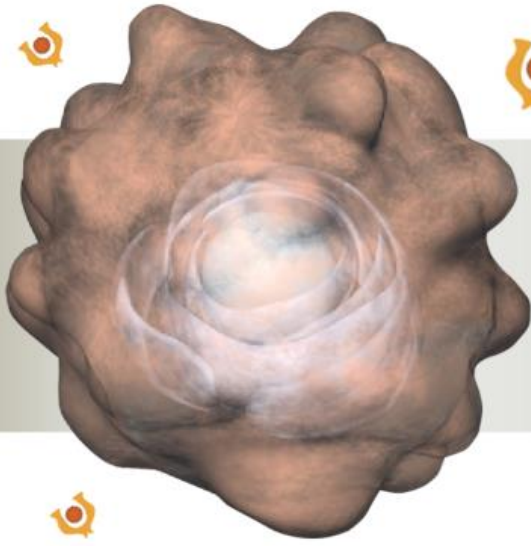
IP Estate with Broad and Early Filings

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
-

Worldwide Filings

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



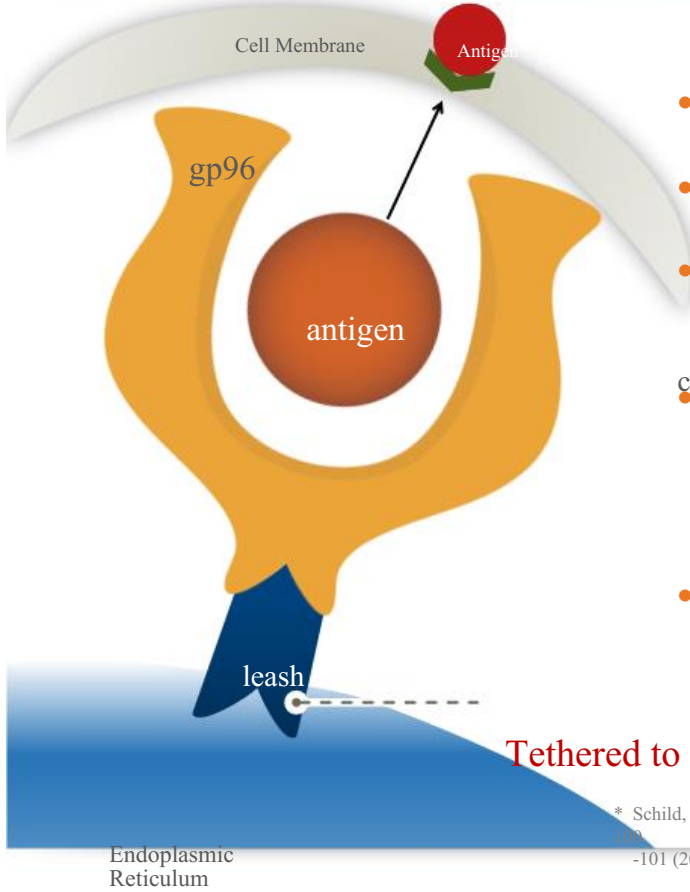
Heat's *ImPACT* Therapy

Living Drug Factories

Antigen and adjuvant delivery in a single package



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



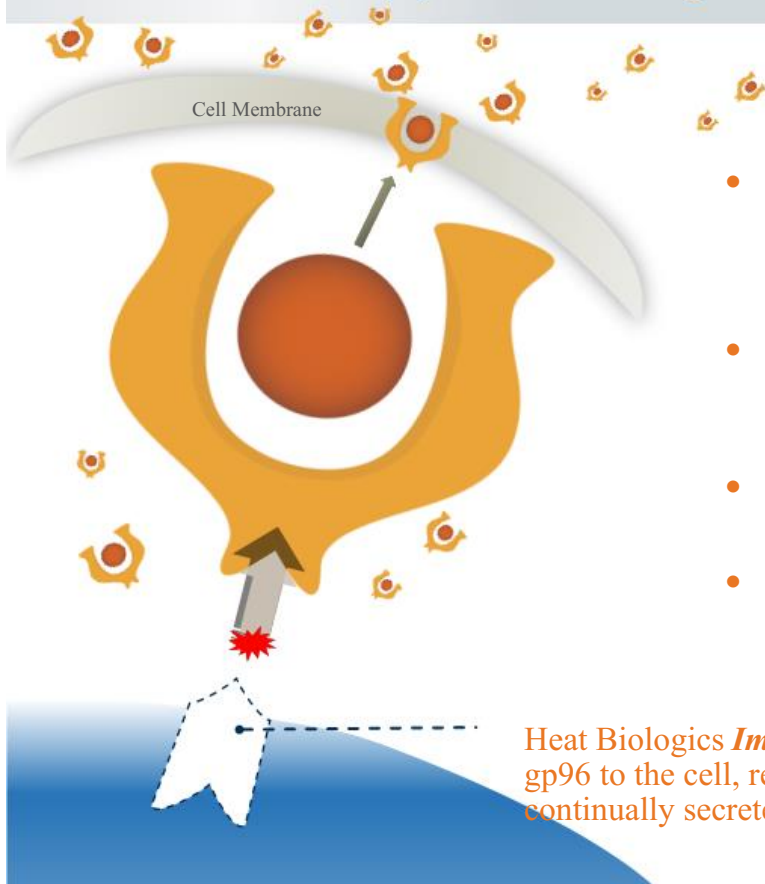
“Molecular Warning System”

- 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, 109-110 (2000)

ImPACT Therapy — “Severing the Leash”

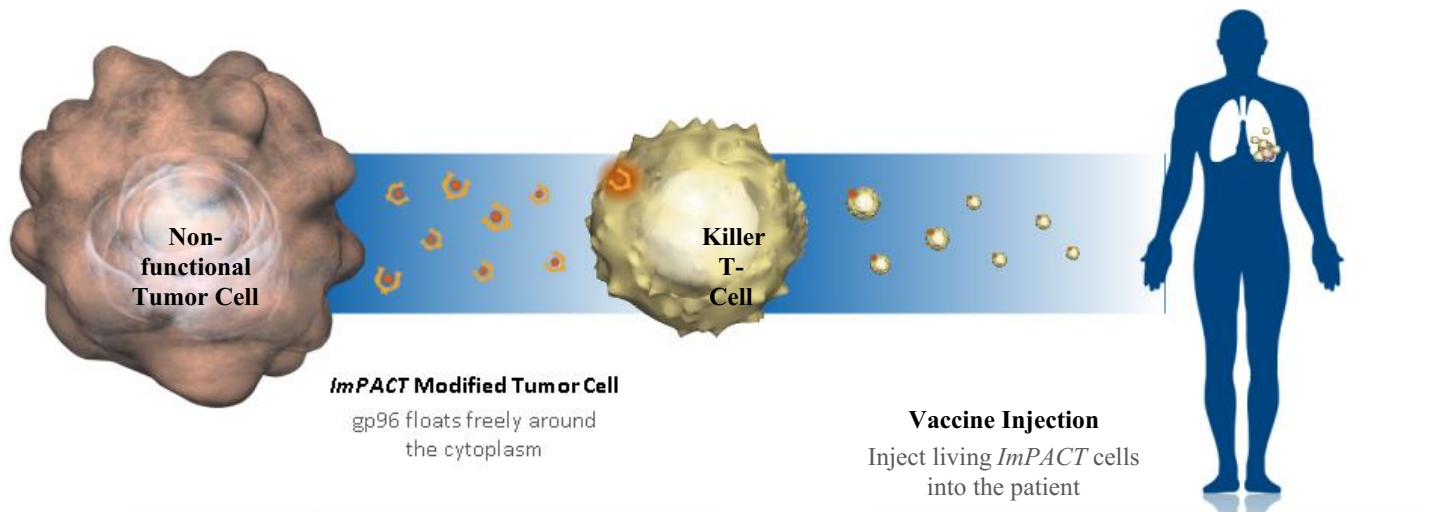


- Genetically modify tumor cells by “severing the leash” that binds the gp96 to the endoplasmic reticulum of the cell and replacing it with a sequence that pumps gp96 out of the cell
- Enables living cancer cells to “pump-out” their own surface antigens along with their gp96 chaperone
 - Mimics necrotic 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.



ImPACT — Highlights

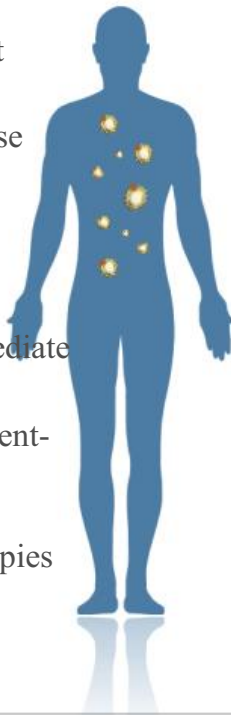
An “Off-the Shelf” Therapy to Generate a *Pan-antigen T-cell Immune Attack*

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

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%.”

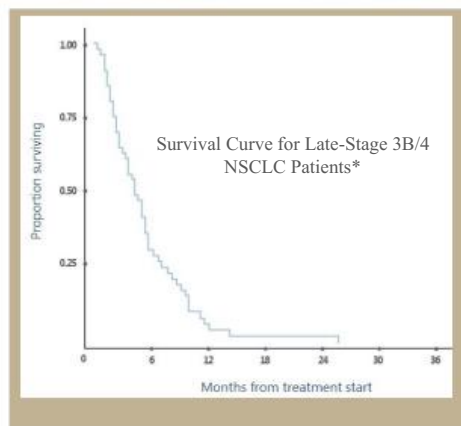
— American Society for Clinical Oncology (ASCO) Guidelines

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

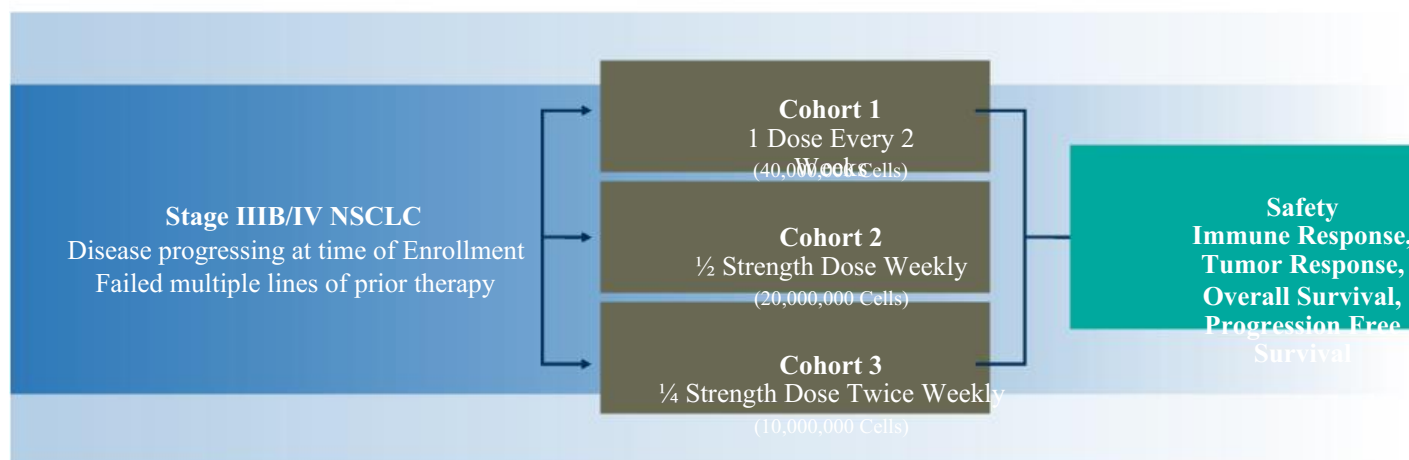
Treatment

- 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

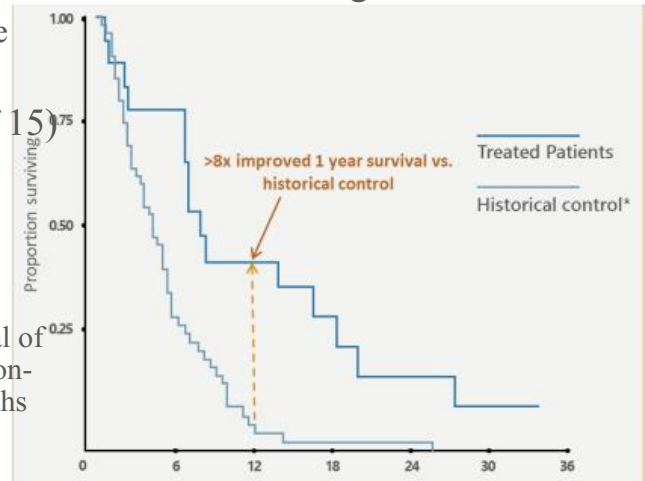
- **Immune response predictive of survival** (HR: 0.021, 95% CI:0.002-0.204)

- 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

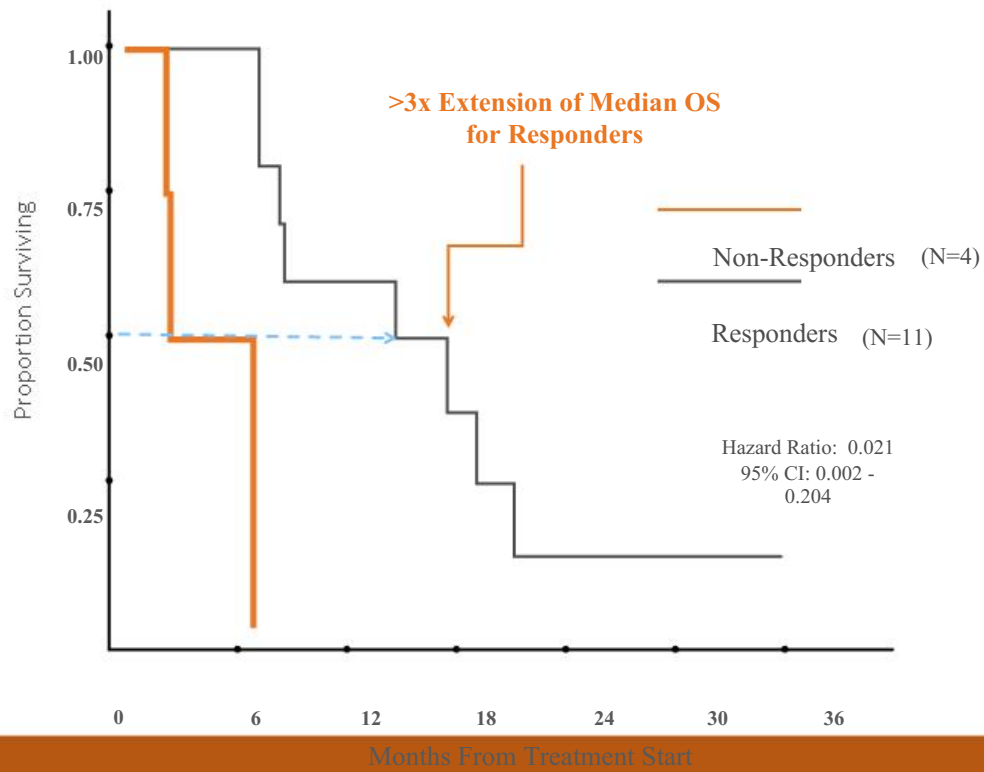
- **Two late-stage patients survive >3 years**

- 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-expressing interferon-gamma (CD8⁺ CTL-IFN- γ) following vaccination. The responders saw a three-fold increase in median OS compared to non-responders.

HS-410 Lung Cancer Program Next Steps

Lung cancer Phase 2 program designed in collaboration with KOLs

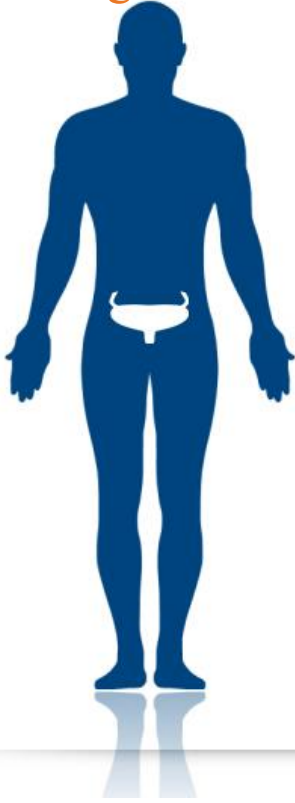


1H 2014

- ✓ Finalize Phase 2 protocol
- ✓ Submit revised protocol to FDA
- ✓ Announce Phase 2 protocol
- ✓ Commence patient enrollment and dosing

Bladder Cancer and HS-410

Background

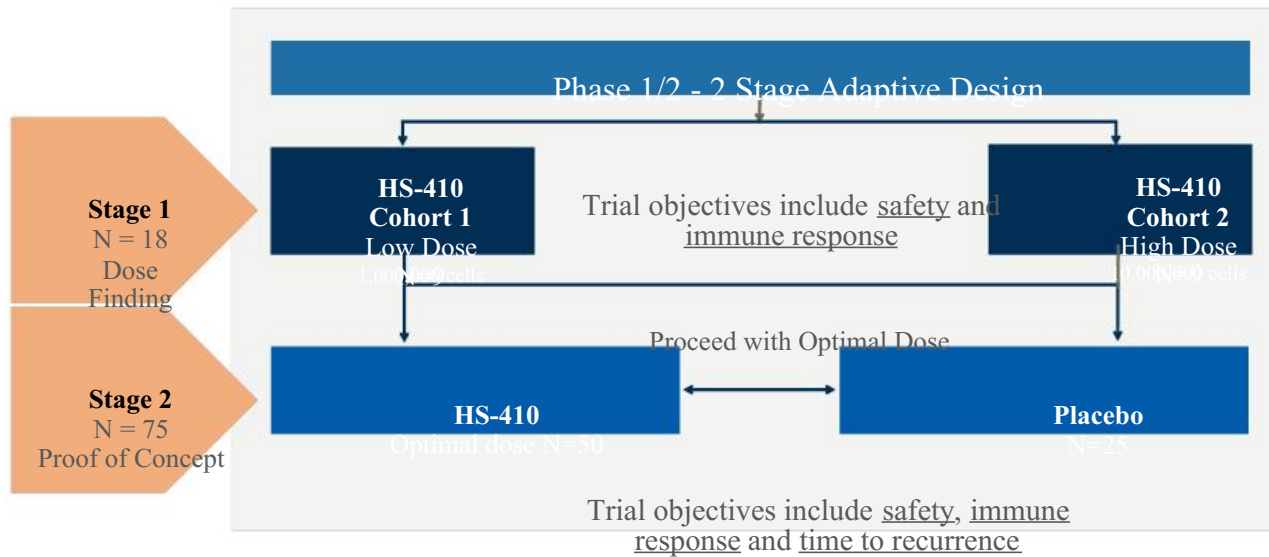


In 2012 Alone, There Were 73,000 New Cases of Bladder Cancer Reported and 15,000 Deaths

- 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
- Drug manufacturing and preparation of IND and protocol for HS-410 in progress
- No new drugs for this patient population in >25 years
- HS-410 Phase 1/2 trial will include ~93 patients

HS-410: Bladder Cancer Phase 1/2

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



- **Study opened for enrollment December 2013**
- Patient recruitment ongoing
- Population includes non-muscle invasive disease, treated with surgery followed by 3-6 weeks of BCG therapy

Business Development Strategy

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

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

Selected Immunotherapy Deals		
Companies	Date	Financials
AZ-Immunocore	Jan '14	\$20M+300M/ program
Novartis-UPenn	Aug '12	\$20M+MS
Sanofi-CureVac	Nov '11	\$33M+200M



Financial Snapshot

Financial strength to execute on our business plan

Ticker	NASDAQ: HTBX
Shares Outstanding	6,375,426
Share Price*	\$7.98
Market Capitalization*	~\$50M
Cash as of 9/30/13	\$23.6M

**as of market close on January 9, 2014*



Near-Term Milestones

Program	1H 2014	2H 2014
HS-110 Lung Cancer Program	<ul style="list-style-type: none"> <input type="checkbox"/> Submit revised protocol to FDA <input type="checkbox"/> Initiate Phase 2 enrollment <input type="checkbox"/> Phase 2 patient dosing 	<ul style="list-style-type: none"> <input type="checkbox"/> Preliminary data
HS-410 Bladder Cancer Program	<ul style="list-style-type: none"> <input type="checkbox"/> Commence patient dosing <input type="checkbox"/> Complete Cohort 1 enrollment 	<ul style="list-style-type: none"> <input type="checkbox"/> Cohort 1 immune response data
3rd Product	<ul style="list-style-type: none"> <input type="checkbox"/> Generate multiple product candidates 	<ul style="list-style-type: none"> <input type="checkbox"/> Announce 3rd product program
Corporate	<ul style="list-style-type: none"> <input type="checkbox"/> Seek development and commercialization partners - Ongoing <input type="checkbox"/> Continued grant filings and notifications <input type="checkbox"/> Additional research developments <input type="checkbox"/> Various clinical publications 	

Summary

Clinical Stage Platform Technology Generating Promising Human Data

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





Heat Biologics
