
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): **November 19, 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. 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.

Exhibit Number	Description
<u>99.1</u>	Presentation materials to be provided at Heat Biologics, Inc.’s 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: November 19, 2014

HEAT BIOLOGICS, INC.

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

EXHIBIT INDEX

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Corporate Presentation

November 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, 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, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and 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 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, June 30, 2014 and September 30, 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.

You should read carefully our "Special Cautionary Notice Regarding Forward-Looking Statements" and the factors described in the "Risk Factors" sections of our SEC Filings to better understand the risks and uncertainties inherent in our business.

Heat Biologics (NASDAQ: HTBX): Company Snapshot

- Clinical-stage immunotherapy company developing fully allogeneic “*off-the-shelf*” cell-based cancer therapies
- Founded in 2008; completed IPO in 2013
- Headquarters in Research Triangle Park area

Shares Outstanding	6,452,341
Share Price*	\$4.44
Outstanding Shares	6.48M
Market Capitalization*	~\$28.7M
Cash as of 9/30/14**	\$15.4M
Enterprise Value*	~\$13.3M

*As of market close on Nov 14, 2014

**Does not include \$7.5 million milestone-based debt facility

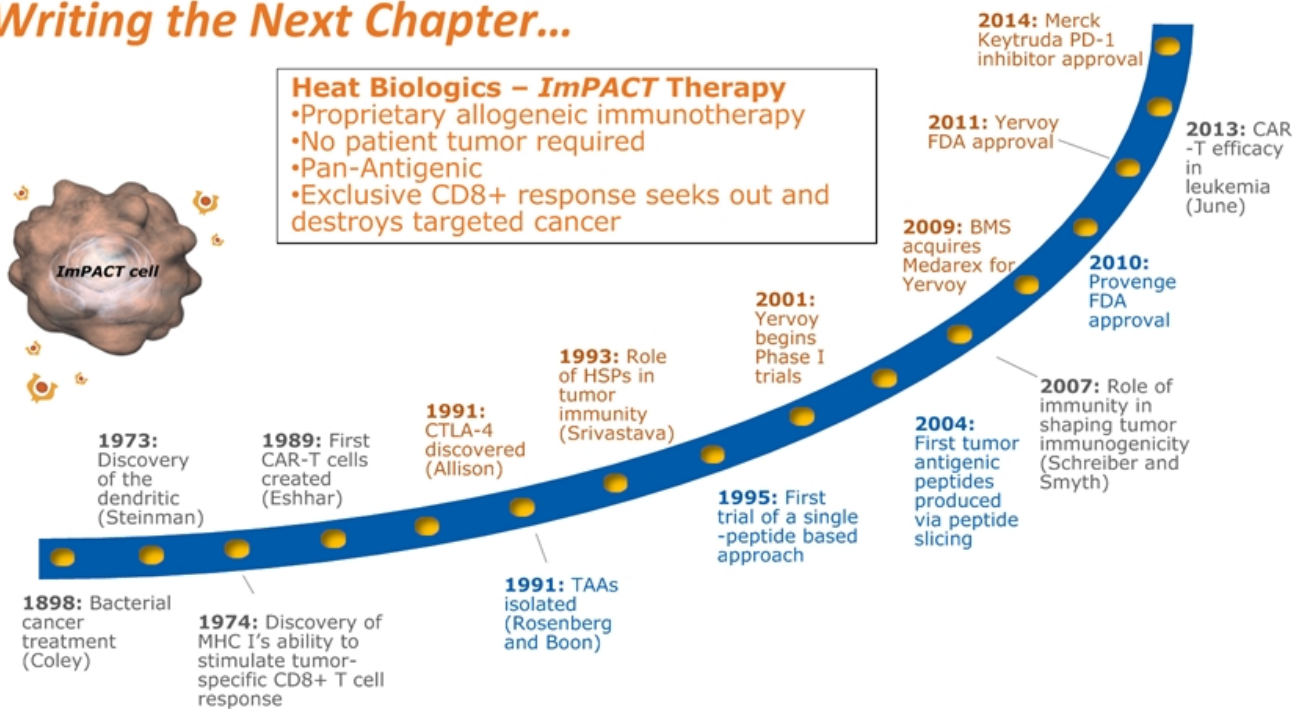


Investment Highlights

- Novel, “*off-the-shelf*” *ImPACT* therapy to combat a wide range of cancers
 - 39 patients dosed* in two phase 1 and two phase 2 trials with positive safety data
- Two product candidates in ongoing multicenter Phase 2 clinical trials:
 - Non-Small Cell Lung Cancer (NSCLC): HS-110 (Viagenpumatumucel-L)
 - Bladder Cancer: HS-410 (Vesigenurtacel-L)
- Combination trial approach leverages *ImPACT* cost advantages
- Multiple, fully-funded near-term catalysts
- Product candidates target large markets with significant unmet medical needs
- Diverse strategic partnership and collaboration opportunities
- Broad, international intellectual property portfolio
- Experienced management team and world-renowned advisory boards
- Cash runway projected through the first quarter 2016

Next-Generation Immunotherapy Company

Writing the Next Chapter...



Experienced Management and World-Class Advisors

Jeff Wolf <i>Founder & CEO</i>	Founded several biomedical companies including Avigen, TyRx Pharma (sold to Medtronic), EluSys Therapeutics, GenerationOne
Matt Czajkowski <i>Chief Financial Officer</i>	15+ years CFO experience: Pozen, AAIPharma, NextRay; Investment Banking experience: Goldman Sachs & Co
Anil Goyal, Ph.D. <i>VP Business Development</i>	20+ years biotech business development experience: Serenex (acquired by Pfizer), Millennium Pharmaceuticals, Genome Therapeutics, Qualiber, Asclepis Pharmaceuticals, Merck
Taylor Schreiber, M.D., Ph.D. <i>VP Research & Development</i>	Co-developer ImPACT and TNFRSF25 technologies; 10+ years laboratory experience; Author numerous immunology and immunotherapy abstracts and publications
Melissa Price, Ph.D. <i>VP Clinical & Regulatory Affairs</i>	14+ years in oncology clinical development in biotech and CRO space: INC Research, Novaquest, Attenuon

Scientific Advisory Board

- **Eckhard R. Podack, M.D., Ph.D. (Chair)**
University of Miami School of Medicine
- **James Allison, Ph.D.**
MD Anderson Cancer Center
- **John Nemunaitis, M.D.**
Mary Crowley Cancer Research Center
- **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. (Chair)**
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

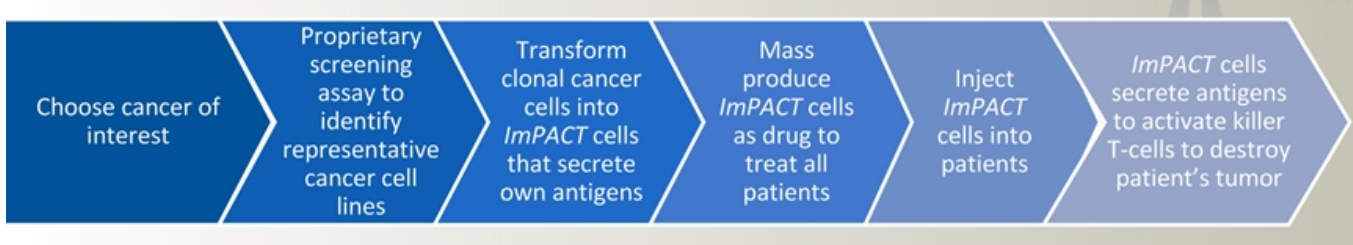
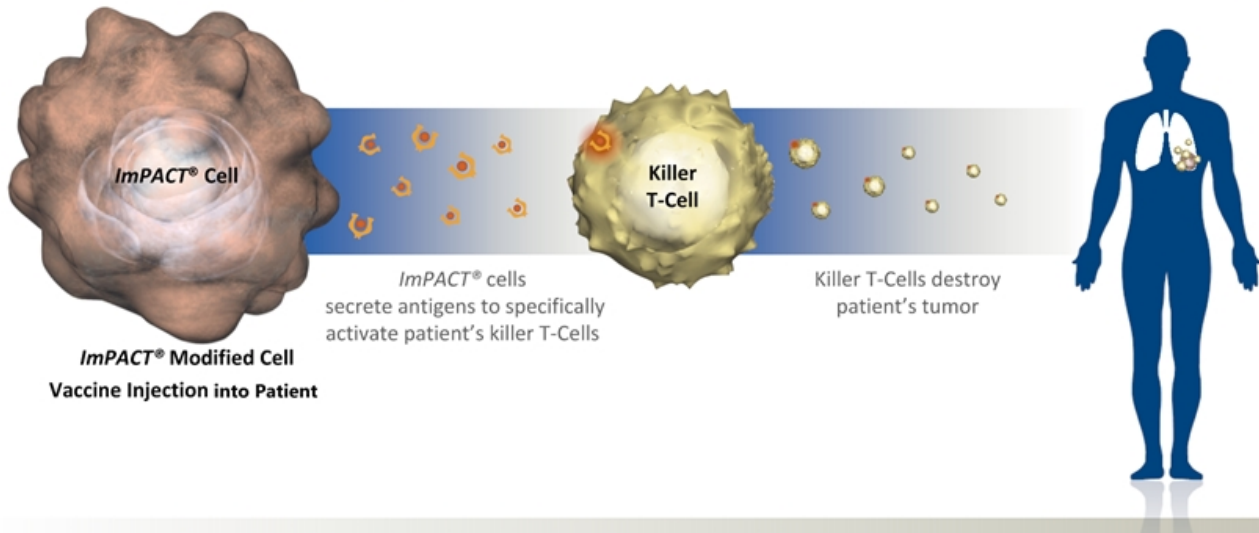
ImPACT Pipeline

- *ImPACT* cancer immunotherapy unleashes immune system against a wide range of cancers
- Two product candidates in ongoing multicenter phase 2 clinical trials with **multiple fully-funded near-term catalysts**
 - Non-small cell lung cancer (NSCLC) - Phase 2
 - Bladder Cancer - Phase 2

Disease		Pre-Clinical	Manufacturing	Phase 1	Phase 2
Oncology	HS-110 (Viagenpumatulcel-L) – NSCLC				
	HS-410 (Vesigenurtacel-L) - Bladder Cancer				
	HS-310 (<i>undisclosed</i>)				
	HS-210 (<i>undisclosed</i>)				
	HS-510 (<i>undisclosed</i>)				

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ImPACT Drug Development and Manufacturing



Low COGS Allogeneic Therapy

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

- Large-scale manufacturing process 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
- **Patient HLA Irrelevant**
- **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

Cell-Based Immunotherapy Approaches

Criteria/Benchmarks	ImPACT [®] Therapy	Other Allogeneic	Autologous Cell-based
Pan-antigen delivery (known and unknown)	✓	Some	Some
Targeted delivery of antigens to APC <i>in vivo</i>	✓	✗	✗
Exclusive cytotoxic CD8 ⁺ T cell response	✓	✗	Some
Dual antigen carrier/adjuvant (not general immune stimulus)	✓	✗	✗
Rapid and Efficient New Product Development	✓	Some	✗
Low Manufacturing COGS	✓	Some	✗
Patient HLA Irrelevant	✓	Some	✗

Heat's Combination Approach

Why think beyond Checkpoint blockade?

- Low response rates
- Immune-related adverse events
- High price limits viability of cost-effective combinations

Heat's Strategy

Pair with complementary cost-effective agents for enhanced payor adoption

- HS-110 NSCLC combined with cyclophosphamide (low cost) to reduce regulatory T-cell activity
- HS-410 Bladder combined with BCG (low-cost) for enhanced immune response

"It is likely that the **most successful cancer immunotherapy will be a combination of two or more therapies** that are very effective in doing their part, rather than a single, do-it-all treatment."¹

Neil Berinstein, M.D. Director, Translational Research, Ontario Institute for Cancer Research

"Many more than **two constituents will possibly be needed to fully engage the immune system**. In fact, some agents that have a negligible effect when administered alone may actually be quite active in the presence of others"¹

*Llew Keltner, M.D., Ph.D.
President and CEO Epistat*

Lung Cancer and HS-110

225,000 new cases of lung cancer and 156,000 new deaths in US in 2014
Annual mortality from lung cancer worldwide is 1.4 million, higher than that from colon, breast, and prostate carcinoma combined

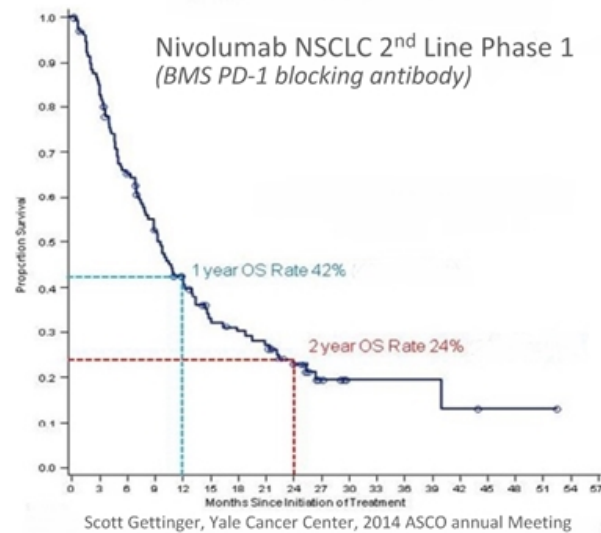
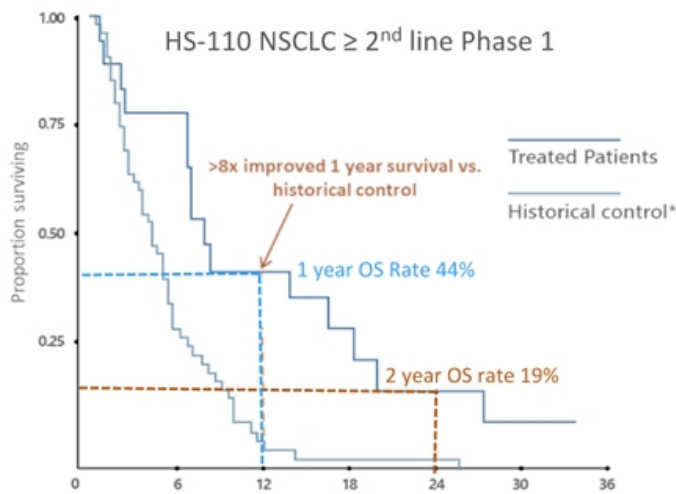
**“Without any chemotherapy, the average person will live about 4½ months.
... Even with chemotherapy, the chance of being alive at one year is about 30-50%”**

— American Society for Clinical Oncology (ASCO) Guidelines

- Little approved after 2nd-line setting in adenocarcinoma, and efficacy is minimal
- Opportunity to treat a non-immunogenic tumor likely to benefit from T-cell activation
- Combination immunotherapy approach with low-dose cyclophosphamide, an orally available, inexpensive, known modulator of tumor-induced immunosuppression
- Allows treatment of patients who have received checkpoint inhibitors



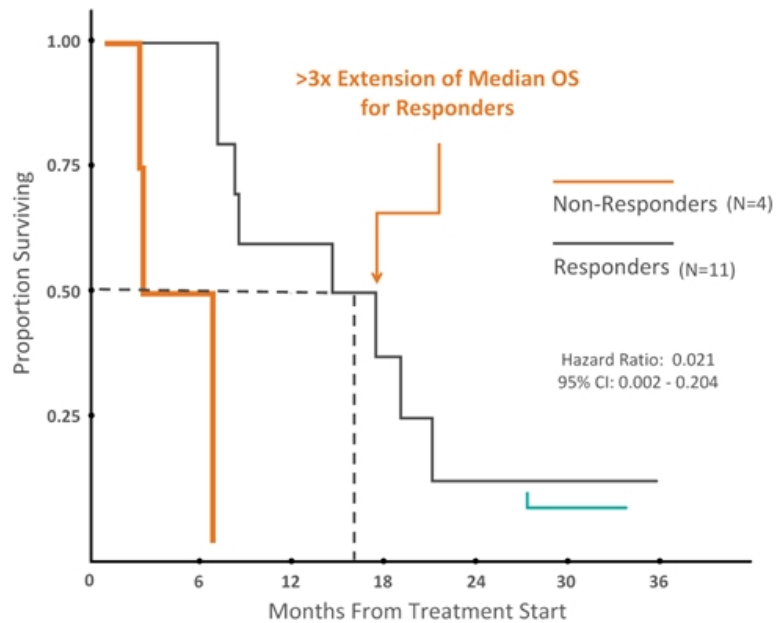
Comparable Efficacy of HS-110 and Checkpoint Blockade



- **Well-tolerated** with no overt toxicity
- **Single agent clinical activity** in heavily pre-treated stage patients with advanced NSCLC
 - 7 of 15 treated patients exhibited stable disease after single course of therapy
- **Median 1 year overall survival rate** of patients in the study was 44% (95% CI: 21.6-65.1) comparing favorably to 42% rate in patients treated with Nivolumab in 2nd line

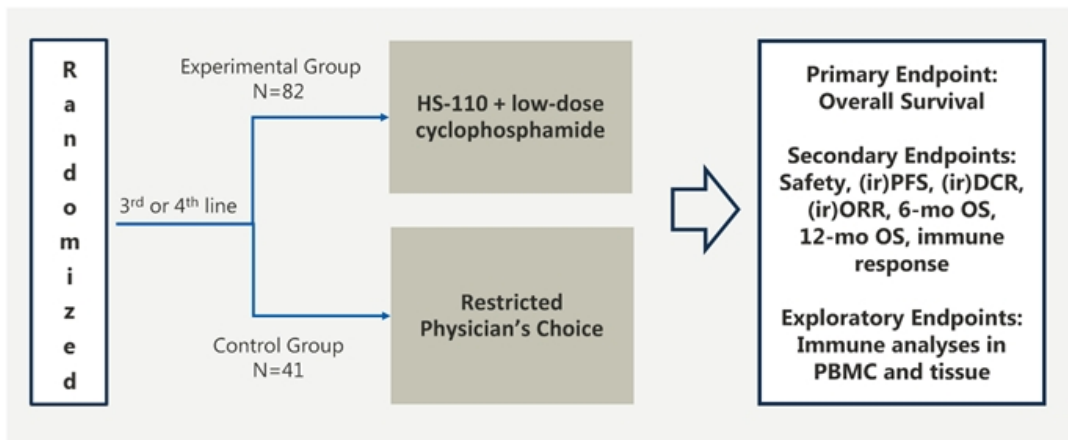
Immune Response Predictive of Survival

- **Immune response observed in 73% (11 out of 15) of patients who completed their first course of therapy**
 - **Immune response predictive of survival**
 - The immune responders exhibited a median survival of 16.9 months while the immune non-responders exhibited a median survival of 4.5 months
 - **Long-term survival**
 - Three patients survive >3 yrs.
 - One patient alive > 4 yrs.



Responders saw a threefold increase in median overall survival compared to non-responders in the trial, from 4.5 months to 16.9 months

Phase 2 HS-110/CY Combo NSCLC Design



Regimen

- Low-dose cyclophosphamide (CY) 50 mg daily for 7 days every 2 weeks for 12 weeks or until progression
- HS-110 10^7 cells weekly for 12 weeks then every 9 weeks until irPD or 12 months, whichever comes first
- Multi-center trial of ~25 sites in US and Australia
- Lead centers: University of Pennsylvania in USA; Peter MacCallum Cancer Center in AUS

Sample Size

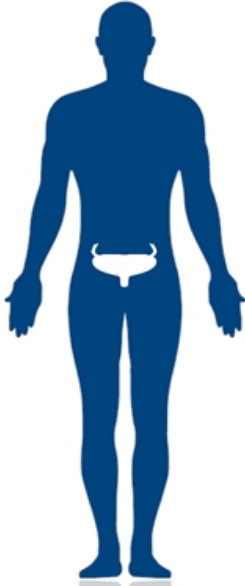
- 123 patients randomized 2:1
- 80% power with $\alpha = 0.1$ to detect a 50% reduction in the risk of death
- Interim analysis for immune response after 14 and 40 patients randomized to experimental group

HS-110 is a viable therapeutic intervention for advanced NSCLC patients and has potential to be highly attractive to potential development and commercialization partners

- **Phase 1 clinical experience**
 - Estimated median survival: 16.5 months (95% CI: 7.1-20.0).
 - Three patients survived >3 years
 - Strong immunologic responses
 - Minimal toxicity
- **Phase 2 in NSCLC initiated in Q1 2014**
 - Protocol developed in collaboration with world's leading KOLs and lung experts
 - Program specifically designed to leverage promising combination immunotherapy approaches

Bladder Cancer and HS-410

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

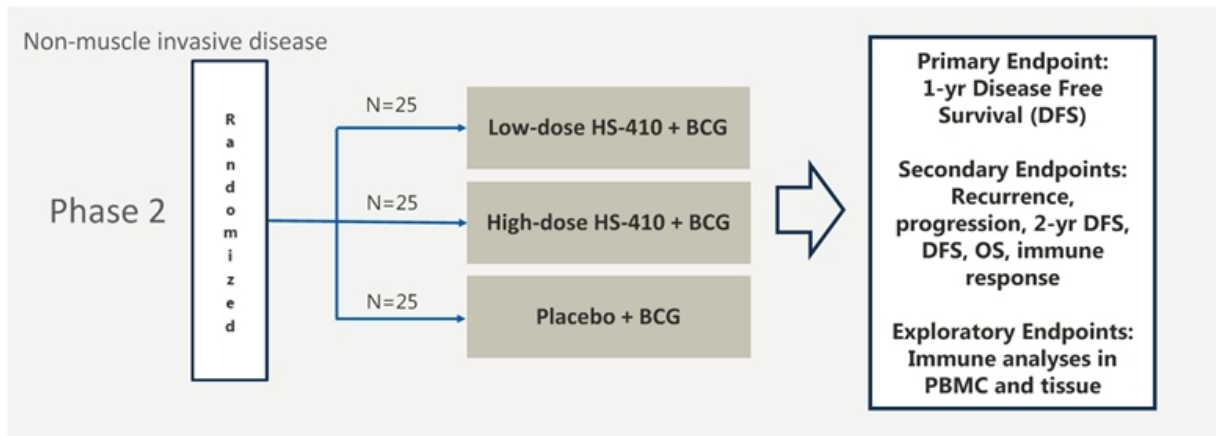


- Currently-available treatments have high failure rate and are poorly tolerated
- Among highest lifetime treatment cost per patient of any cancer due to a high recurrence rate
- Opportunity to treat patients with minimal residual disease and a tumor type sensitive to immunotherapy (BCG)
- No new approved drug for this patient population in >25 years
- Leverage potential synergy with BCG to promote trafficking of HS-410 activated cytotoxic T cells into the bladder

*American Cancer Society



Phase 1/2 HS-410 Bladder Cancer Design



Regimen

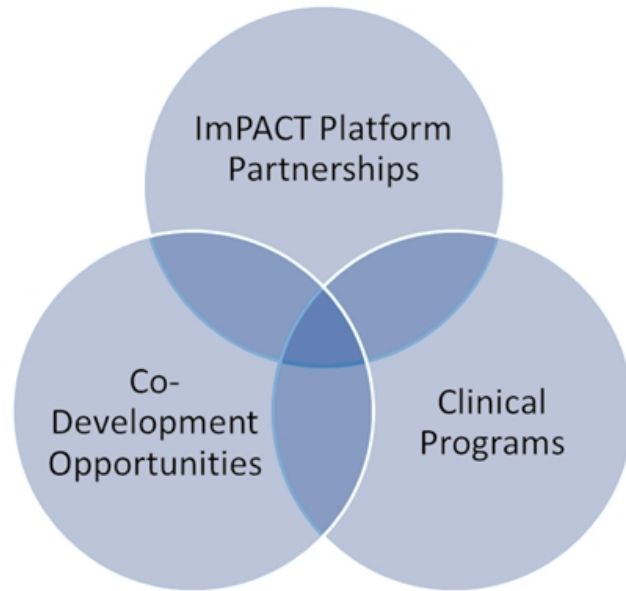
- After TURBT, placebo or HS-410 (10^6 or 10^7 cells per dose) in combination with BCG for 6 weeks followed by 6 weeks of placebo or HS-410 alone then 3 courses of placebo or HS-410 in combination with BCG for 3 weeks at 3, 6, and 12 months after starting therapy (21 total doses)
- Multi-center trial of ~16 sites in US
- Lead center: University of Chicago Pritzker School of Medicine

Sample Size

- Phase 2: 75 patients randomized 1:1:1
- 80% power with $\alpha = 0.1$ to detect a 30% reduction in the risk of recurrence, progression, or death at 1 year

Business Development Strategy

- **ImPACT Platform Partnerships**
 - Strategy to Partner by indication(s)
 - Use platform for new product discovery
 - Product development by partner
- **Clinical Programs (HS-110, HS-410)**
 - Partner at/after Phase 2 data
 - Partner with regional or global rights
- **MoA complementary with checkpoint inhibitors**
 - Explore co-development partnerships with other immunotherapies



Milestones

1H 2014	2H 2014	1H 2015	2H 2015
<ul style="list-style-type: none"> <input checked="" type="checkbox"/> Revised NSCLC strategy <input checked="" type="checkbox"/> Initiated Phase 1 bladder cancer trial <input checked="" type="checkbox"/> <i>ImPACT</i> combination poster presentations 	<ul style="list-style-type: none"> <input checked="" type="checkbox"/> Initiated Phase 2 NSCLC <input checked="" type="checkbox"/> Complete Phase 1 bladder <input checked="" type="checkbox"/> Phase 1 bladder initial safety and secondary endpoints <input checked="" type="checkbox"/> Initiate Phase 2 bladder 	<ul style="list-style-type: none"> <input type="checkbox"/> Phase 1 bladder immune response and post-surgery response to induction therapy <input type="checkbox"/> Phase 2 NSCLC immune response interim analysis <input type="checkbox"/> Combination therapies publication 	<ul style="list-style-type: none"> <input type="checkbox"/> Phase 2 bladder enrollment complete <input type="checkbox"/> Phase 1 bladder one-year recurrence data <input type="checkbox"/> Phase 2 NSCLC immune response second interim analysis
<p>Additional Value-Enhancing Events</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Collaboration opportunities <input type="checkbox"/> Additional research developments <input type="checkbox"/> Various preclinical and clinical publications and presentations 		

Summary

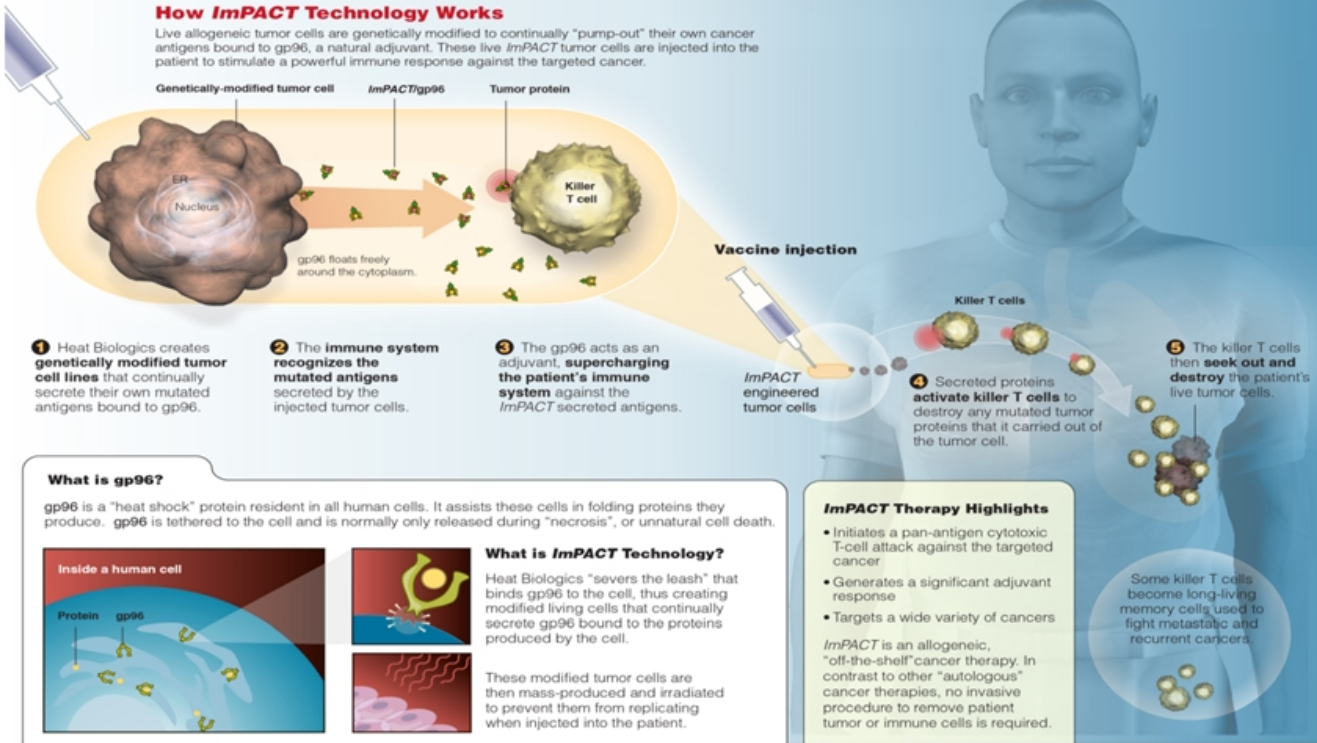
Clinical Stage Platform Technology Generating Promising Human Data

<p>Transformational Technology Platform</p>	<p>Unleash 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• Combination strategy aligned with cutting-edge science• Fully-allogeneic therapy with low COGS
<p>Promising 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 2 bladder cancer trial with additional other cancer products in preclinical development• Multiple near-term enrollment and data readouts• Potential for business development licensing activity

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.



Thank you

for more information visit www.heatbio.com

or

Contact Investor Relations: Michael Wood - investorrelations@heatbio.com

