
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): **March 20, 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

Heat Biologics, Inc. (“Heat”), will be hosting an investor conference call on Thursday, March 20, 2014. In connection therewith, Heat’s management 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 conference call.

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: March 20, 2014

HEAT BIOLOGICS, INC.
(Registrant)

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

EXHIBIT INDEX

Exhibit Number	Description
99.1	Presentation materials to be provided at the Heat Biologics, Inc. investor conference call.



Heat Biologics
**INVESTOR CONFERENCE CALL AND
WEBCAST**

***HS-110 PHASE 2 CLINICAL STUDY FOR
TREATMENT OF NSCLC***

March 20, 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 By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and 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.

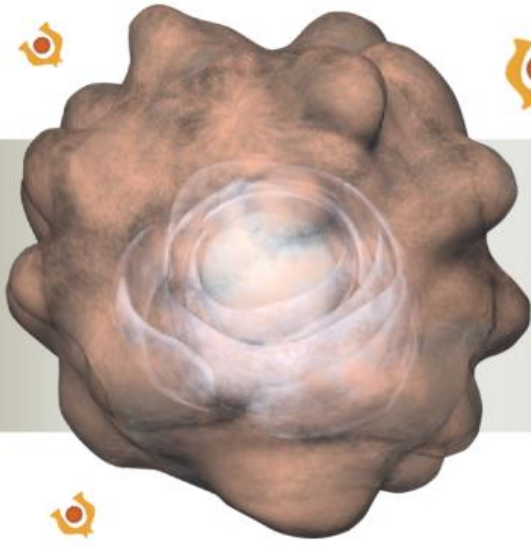
You should read carefully our “Special Cautionary Notice Regarding Forward-Looking Statements” and the factors described in the “Risk Factors” sections of our SEC Filings to better understand the risks and uncertainties inherent in our business.

Heat Biologics

Agenda

- Introduction
 - *Jeff Wolf, Chief Executive Officer*
- Overview of Heat's *ImPACT* Technology
 - *Taylor H. Schreiber, M.D., Ph.D., Vice President of Research and Development*
- Lung Cancer Market and Checkpoint Inhibitors
 - *Justin Stebbing, M.D., Ph.D., Chairman of Clinical Advisory Board and Chief Medical Advisor*
- HS-110 Phase 2 Protocol Design
 - *Melissa Price, Ph.D., Vice President of Clinical and Regulatory Affairs*
- Business Development Opportunity
 - *Anil K. Goyal, Ph.D., Vice President of Business Development*
- Closing Comments
 - *Jeff Wolf, Chief Executive Officer*
- Q&A





Introduction

Jeff Wolf, Chief Executive Officer

Company 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

Diverse Pipeline with Multiple Registration Opportunities

From drug discovery to late-stage clinical development



Overview

- Management focused on advancing lead development programs HS-110 and HS-410 with proprietary *ImPACT* Technology
- Recent groundbreaking clinical development advancements studying checkpoint inhibitors will be important for lung cancer treatment
- Worked with preeminent KOL's and advisors to optimize and revise HS-110 NSCLC development program
- HS-110 Ph2 study specifically designed for future combination regimens to address a large and growing market
- Robust business development strategy in place to identify the best development and commercialization partner



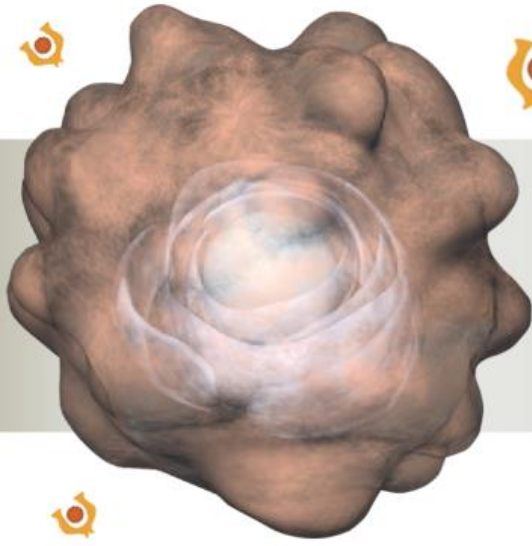
World Renowned Advisory Boards

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
- **Sol J. Barer, Ph.D.**
Chairman, Celgene Corporation
- **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.**
Johns Hopkins University



Heat's *ImPACT* Therapy

*Taylor H. Schreiber, M.D., Ph.D., Vice
President of Research and Development*

Fully-Allogeneic Cell-based
Immunotherapy

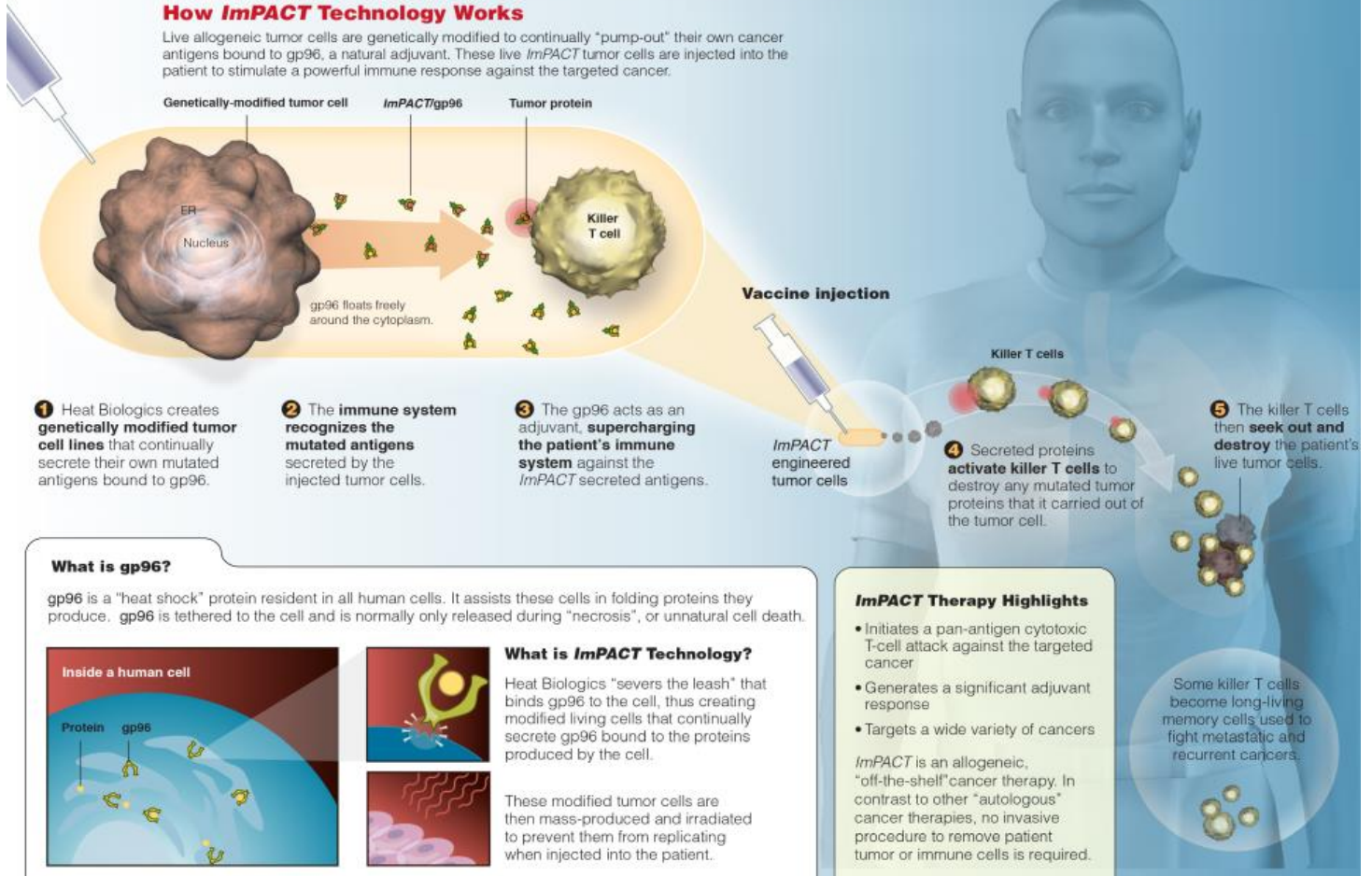
Tumor associated antigens and powerful
adjuvant delivered in a single package



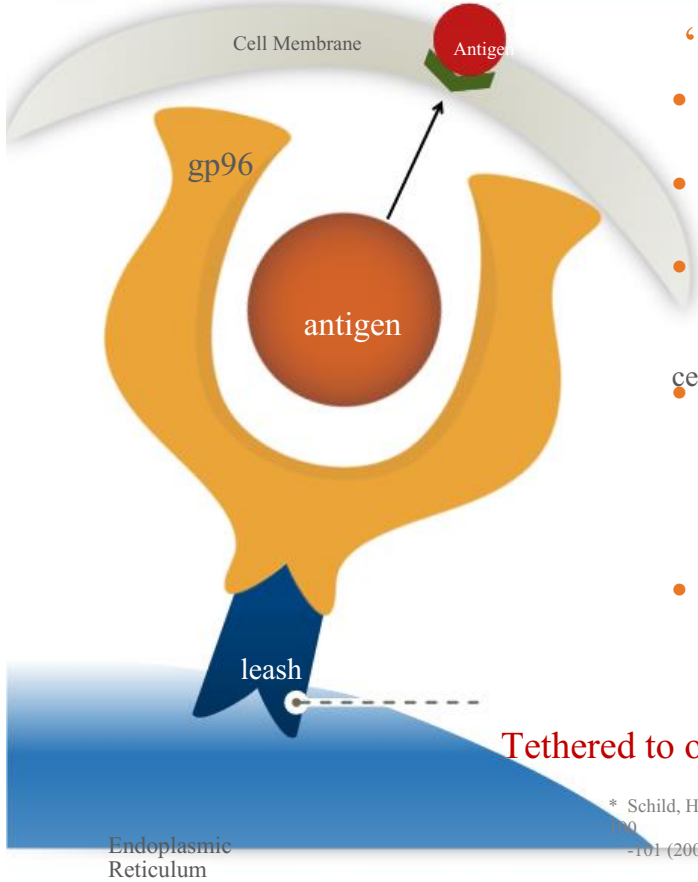
Heat Biologics' proprietary **Immune Pan Antigen Cytotoxic Therapy (ImPACT)** reprograms live "allogeneic" cancer cells to continually secrete their own antigens bound to gp96, a natural adjuvant. These live *ImPACT* tumor cells are injected into the patient to stimulate a powerful immune response against the targeted cancer.

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.



Introducing gp96 — Immune System's "Swiss Army Knife"*



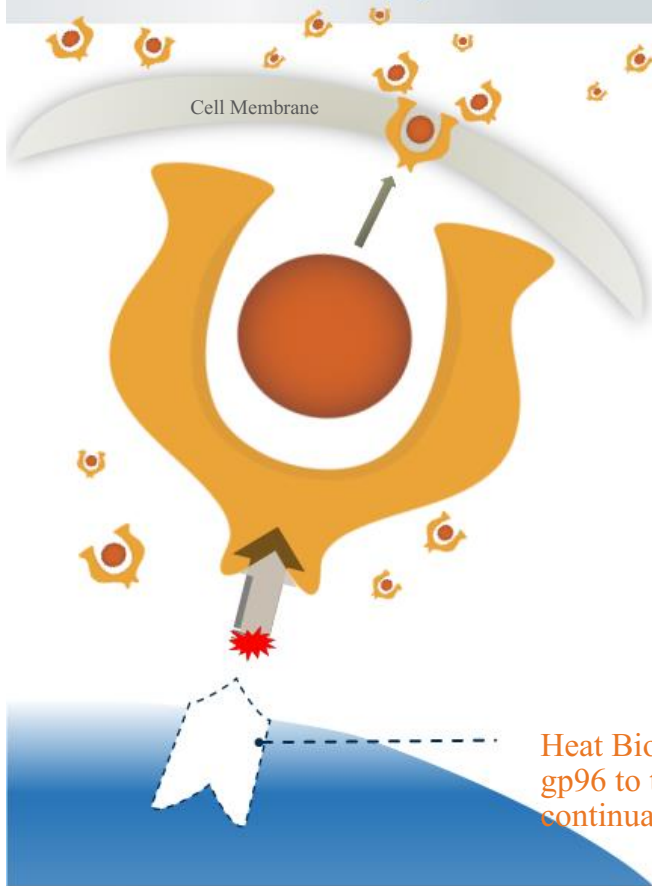
"Molecular Warning System"

- 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, 100-101 (2000)

ImPACT Therapy — “Severing the Leash”



Heat Biologics *ImPACT* technology reprograms

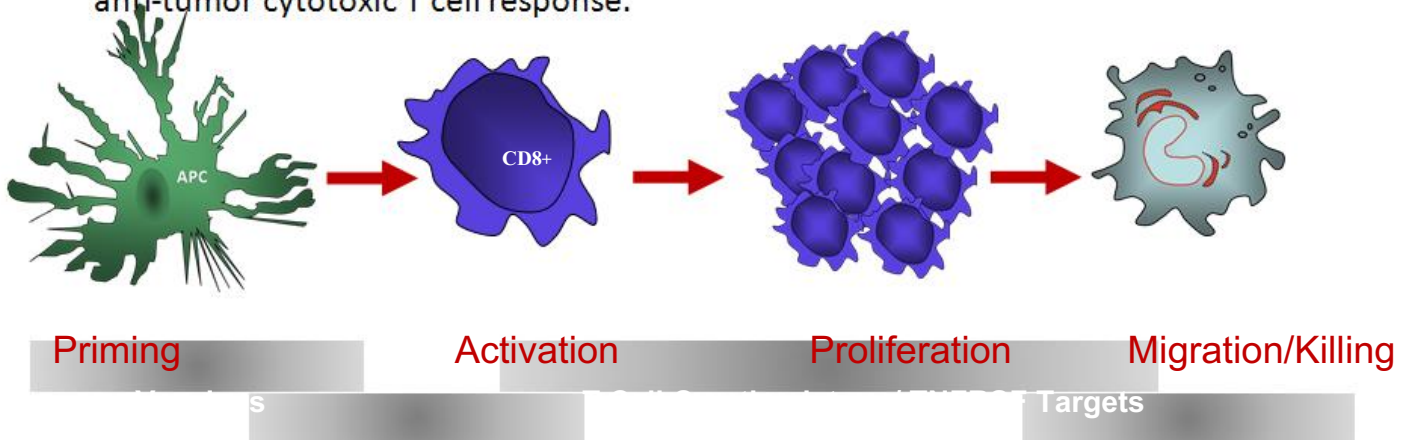
cancer cells to continuously secrete their own antigens bound to heat shock protein gp96 to seek out and destroy a variety of tumours

- 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

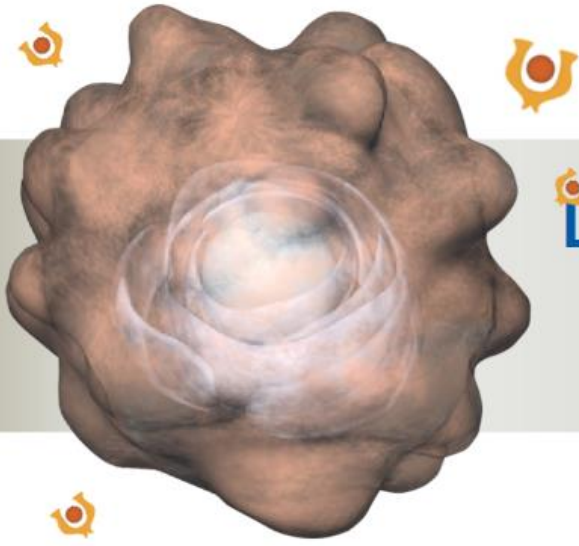
Heat Biologics *ImPACT* technology removes the leash that binds gp96 to the cell, replacing with a sequence that allows cells to continually secrete gp96 along with their “chaperoned” antigen

Immuno-Oncology Vision

- Both the immune system itself, and the way the immune system interacts with cancer, is complex. The dominant immune cell that can kill cancer cells is the T cell, specifically the CD8+ cytotoxic T cell. There are four main elements (priming, activation/proliferation, migration to the tumor site and tumor cell killing) for an anti-tumor cytotoxic T cell response.



Preclinical data indicate that *ImPACT* vaccines synergize with checkpoint inhibitors and T cell costimulators. It is anticipated that combination clinical trials with these agents will provide similar benefit by addressing each phase of anti-tumor immunity.

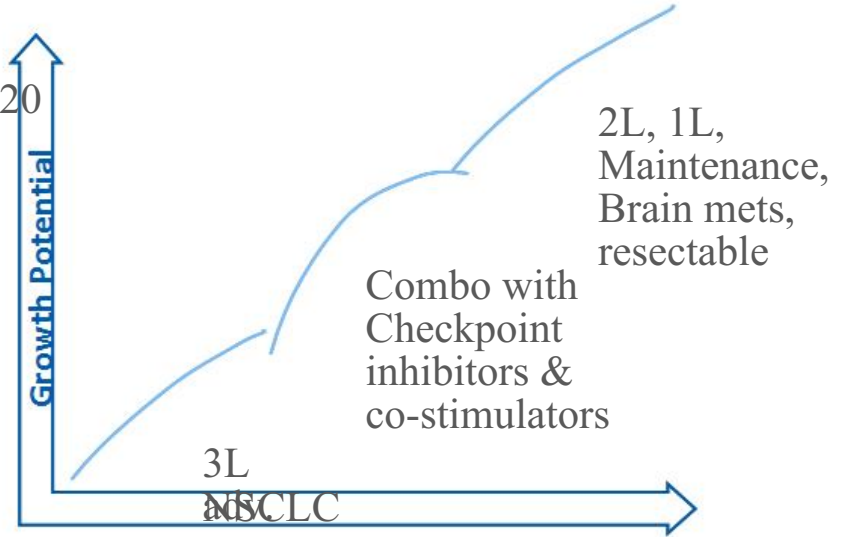
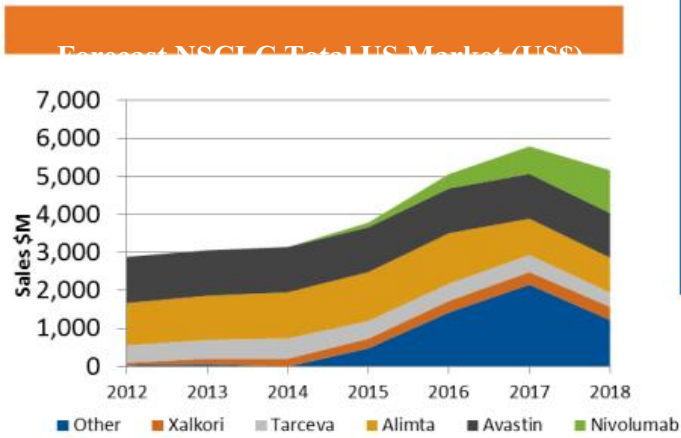


Lung Cancer Market & Checkpoint Inhibitors

Justin Stebbing, M.D., Ph.D., Chairman of Clinical Advisory Board and Chief Medical Advisor

NSCLC Third Line (3L) adenocarcinoma opportunity

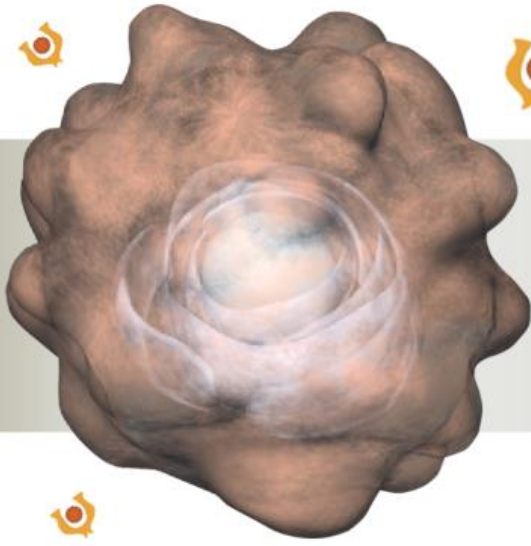
- In 2020 Estimated adeno NSCLC Patients
 - ~291,000 new cases per year (US alone)
- Target US Patient Population in 2020
 - ~22,000 will receive 3L therapy



Source: Catenion
Research

Rationale for Study

- 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 3rd-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



HS-110 Phase 2 Protocol Design

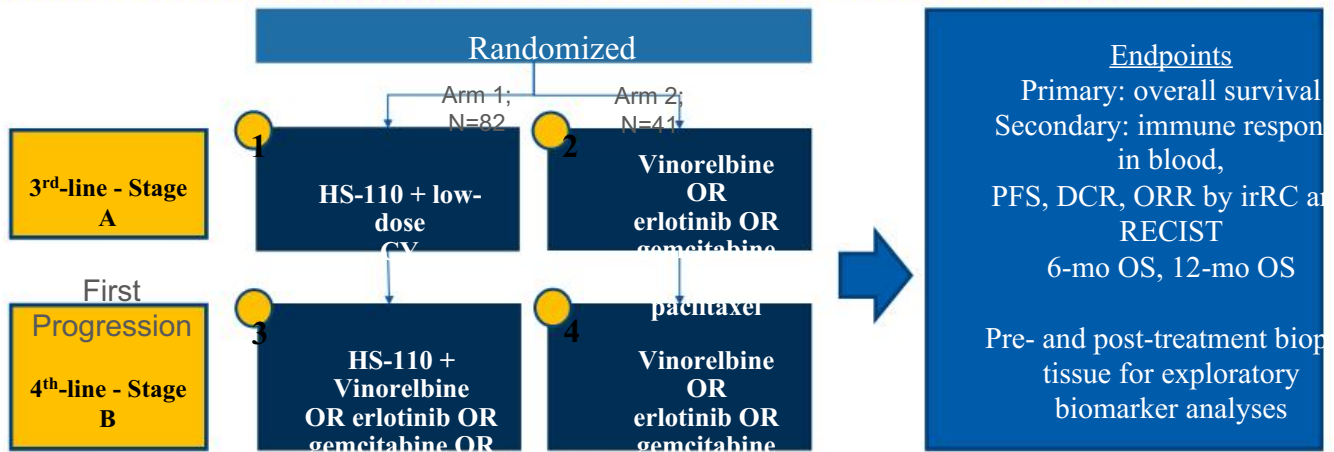
Melissa Price, Ph.D., Vice President of Clinical and Regulatory Affairs



Phase 2 HS-110/CY Combo NSCLC Design



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



Regimen

- Low-dose cyclophosphamide (CY) 50 mg daily for 7 days q2weeks for 12 weeks or until 1st progression
- HS-110 10¹¹ cells weekly for 12 weeks then q3 weeks until 2nd irPD or 24 months whichever comes first

Sample Size

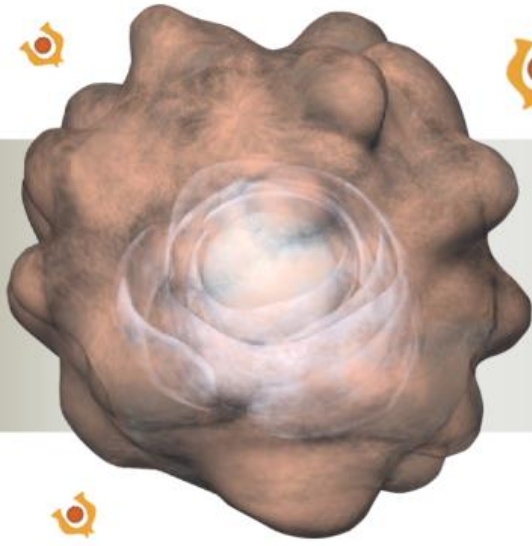
- 123 patients randomized 2:1
- 80% power with alpha = 0.1 to detect a 50% reduction in the risk of death with 59 events in the experimental group and 33 events in the control group



Key Study Timelines and Milestones

Phase 2 Clinical Trial for NSCLC

Milestone	Target Completion
FDA Submission	✓ 1Q 2014
First patient enrolled	Q3 2014
Enrollment complete	Q2 2016
Antigen expression readout	Q4 2016
Top-line efficacy readout	Q3 2017
Phase 3 trial commences	Q4 2017



Business Development Opportunity

*Anil K. Goyal, Ph.D., Vice President of
Business Development*

Business Development Strategy

Heat's *ImPACT* Immunotherapy platform is:

- Differentiated from other allogeneic cell-based approaches
- Extended half life of antigen release, potentially more effective in generating immune response
- Complementary with checkpoint inhibitors and could expand application of CPI into non-immunogenic cancers

1. Clinical Programs (HS-110, HS-410)

- Ideal partner with regional capabilities to fund and expand in EU, Asia, AU
- Heat to retain US commercialization rights (where possible)

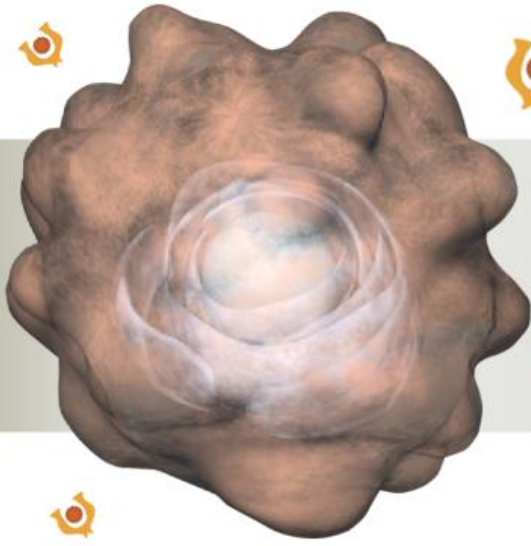
2. *ImPACT* Platform Partnerships

- Use platform for new product discovery funded by partner
- Partner by specific indication(s)
- Clinical development & commercialization by partner in selected territories,
- Heat retaining rest of the world rights

3. MoA complementary with checkpoint inhibitors

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





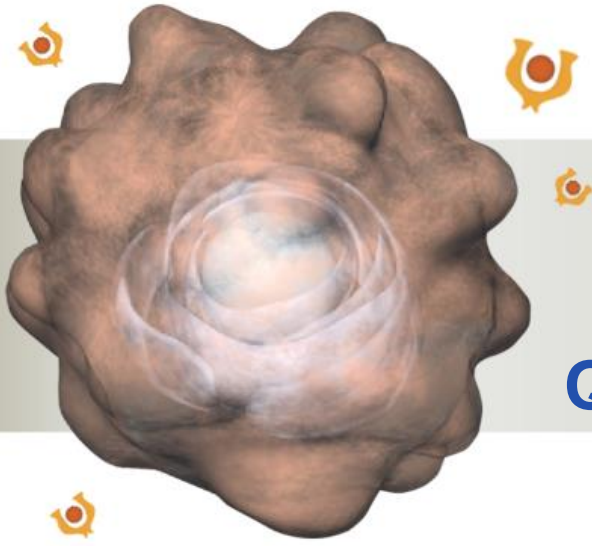
Summary

Jeff Wolf, Chief Executive Officer

HS-110 Lung Cancer Program Designed for Success



- ✓ Transformative, differentiated **Immunotherapy** platform with clinical data supporting advancement into Phase 2 program
- ✓ Revised protocol *developed in collaboration with world's leading KOLs* and lung experts
- ✓ Program *specifically designed with potential to be complementary in combination* with next generation oncology treatments
- ✓ HS-110 with *potential to be highly attractive* to potential development and commercialization partners



Q&A



