
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 6, 2017**

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 an investor presentation at the Biotech Showcase 2017 Conference on Wednesday, January 11, 2017, at 9:30 a.m. Pacific Standard Time at the Hilton San Francisco Union Square in San Francisco, California and additional presentations over the next few weeks. In connection with the presentations, the Company intends to discuss the updated slide presentation furnished as Exhibit 99.1 hereto, which is incorporated herein by reference.

The slide presentation attached as Exhibit 99.1 to this Current Report on Form 8-K 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 are “forward-looking” rather than historical.

The information included in this Item 7.01 and in Exhibit 99 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 filing. The Company undertakes no duty or obligation to update or revise information included in this Current Report on Form 8-K or any of the Exhibits.

Item 9.01 – Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are being filed as part of this Report.

[99.1](#) Presentation materials to be provided at Heat Biologics, Inc. 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 6, 2017

HEAT BIOLOGICS, INC.

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 Heat Biologics, Inc. presentations



NASDAQ:HTBX

January 2017

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, 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, 2015 and our quarterly report on Form 10-Q for the subsequent quarters (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 the factors described in the “Risk Factors” sections of our SEC Filings to better understand the risks and uncertainties inherent in our business.

Investment Opportunity

Platform technologies designed to activate and expand “killer” T cells against multiple tumor antigens

» Clinical proof of concept for platform mechanism

Increased CD8+ T cells in tumors associated with clinical response

Favorable safety profile to-date

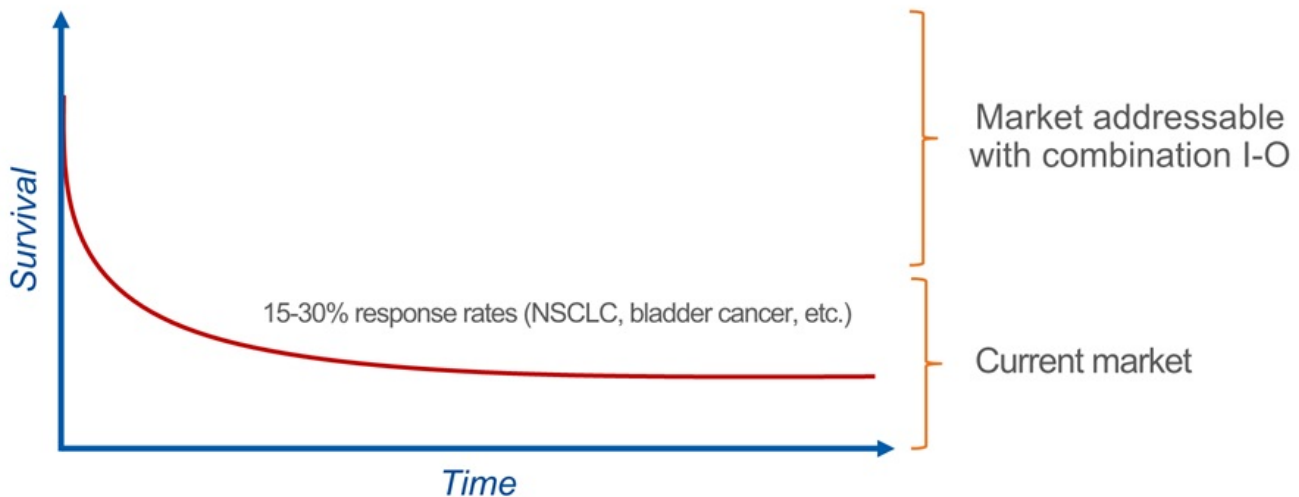
Conducting vaccine + PD-1 checkpoint
inhibitor combo trial in non-small cell lung
cancer (NSCLC)

Over 1,000 doses administered in
~200 patients

**Focused on immuno-oncology (I-O) combinations that have the potential
to dramatically improve patient outcomes**

Unmet Need in Immuno-Oncology (I-O)

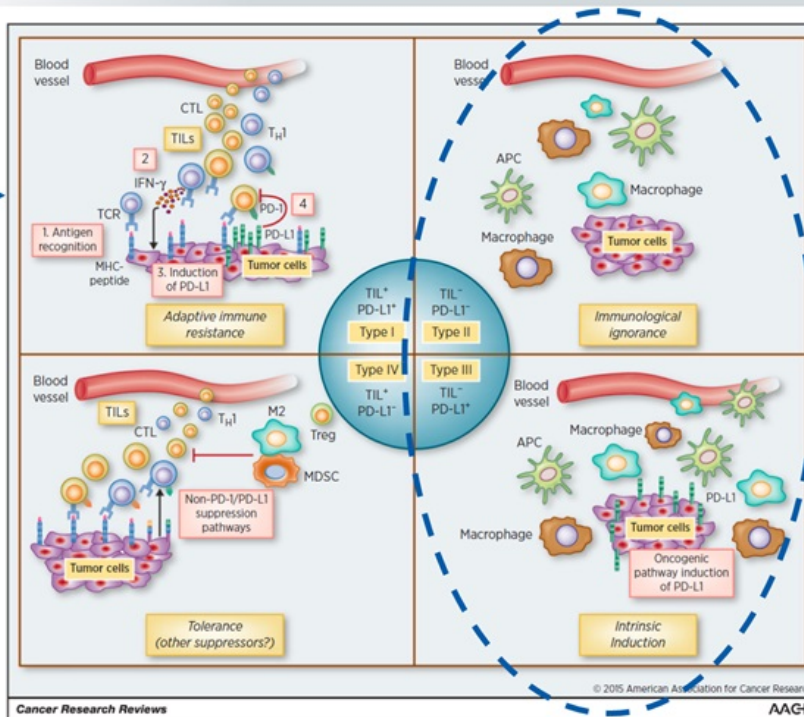
- Clinical responses to checkpoint therapy (e.g., Opdivo®) occur primarily in patients who are:
 - PD-L1 positive
 - Tumor infiltrating lymphocyte (TIL) positive



Majority of patients are not benefiting from current I-O treatment

Majority of Patients do not Respond to Checkpoints

Only ~25% of patients respond to checkpoints

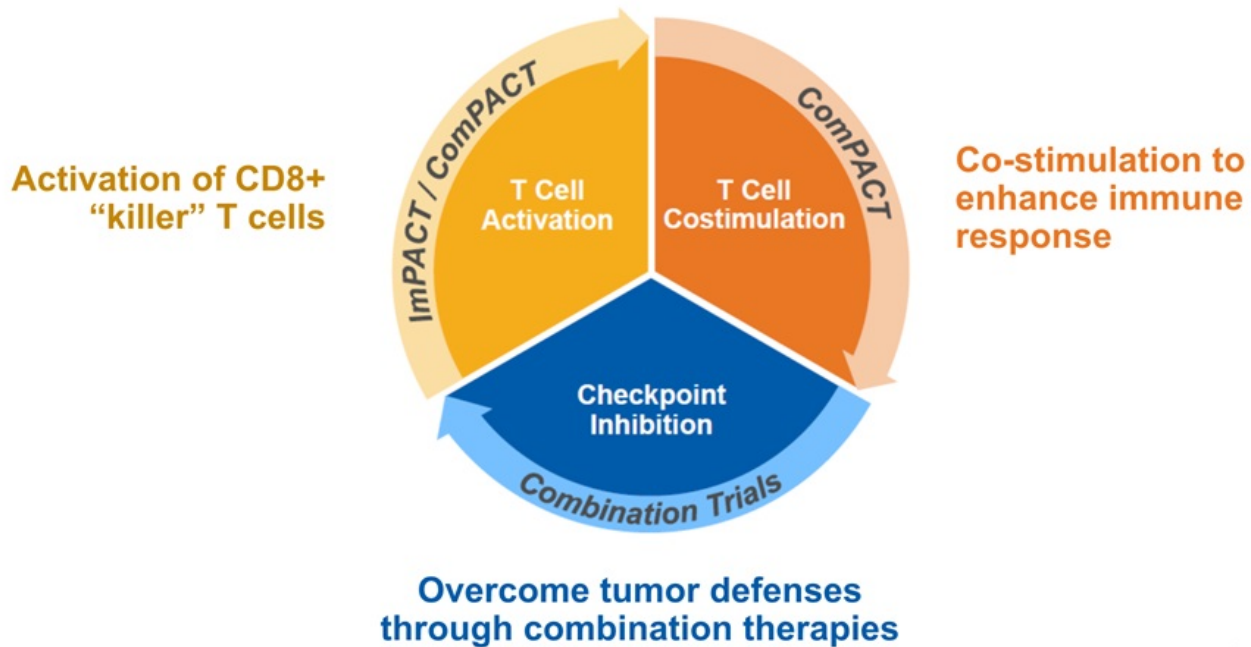


Heat's focus is on the majority of patients who do not respond to checkpoint therapy (low TIL)

Heat is focusing on converting 'cold' tumors to 'hot' tumors by activating highly specific "killer" T cells

Vision and Strategy

Focused on I-O combinations that have the potential to dramatically improve patient outcomes



Heat's Product Development

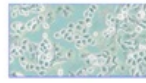
Cancer Cell
Lines & Patient
Samples



Heat's Antigen
Screening &
Selection Algorithm



Select Cell Line
with Most Antigen
Overlap



Transfect with
Heat's
Technology



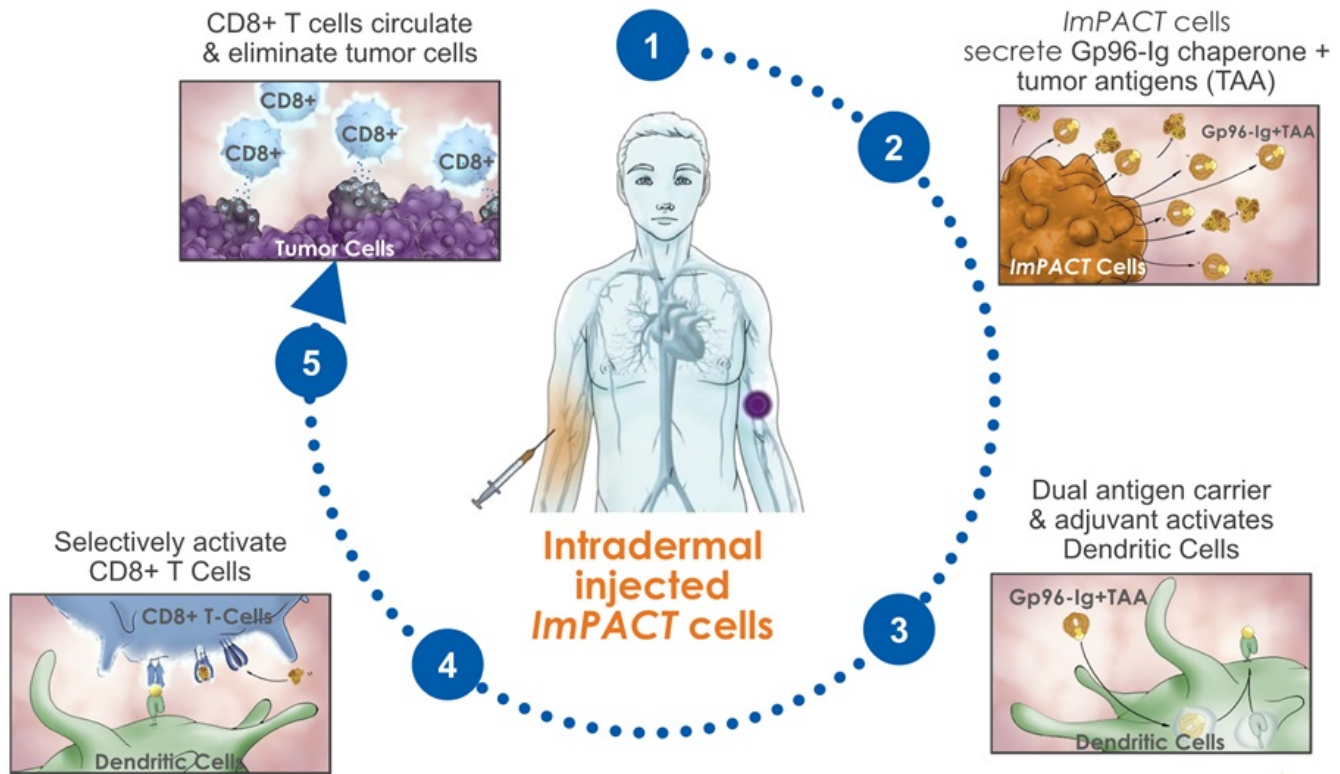
Transition to CMO
to Mass Produce



Platform Technology Highlights

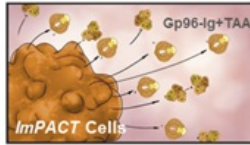
- Applies to multiple cancers and infectious diseases
- Designed to activate “killer” T cells
- Targets multiple tumor antigens
- Enables scalable, low cost manufacturing relative to autologous cell therapies

ImPACT Platform Technology

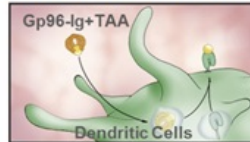


Clinical Proof of Concept

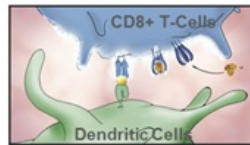
**Secrete
Gp96-Ig**



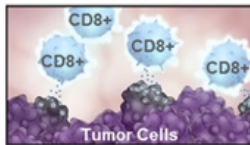
**Pan-
Antigen**



**T Cell
Activation**

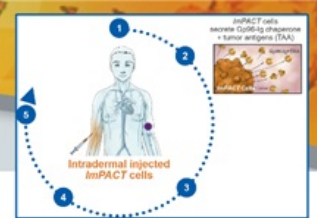


**Tumor
Infiltration**



**Future I-O combinations will
focus on checkpoint blockade
and durable T cell responses**

Antigen Overlap with Patient Tumors



Antigen	HS-410
ACTL8	+++
ADAM22	+++
ADAM23	+++
ATAD2	+++
ATAD2B	+++
BIRC5 (survivin)	+++
CASC5	+++
CEP290	+++
CEP55	+++
CTAGE5 (NY-ESO-1)	+++
DCAF12	+++
DDX5	+++
FAM133A	+++
IL13RA2	+++
IMP3	+++
KIAA0100	+++
MAGEA11	+++
MAGEA3	+++
MAGEA6	+++
MPHOSPH10	+++
ODF2	+++
ODF2L	+++
OIP5	+++
PBK	+++
RQCD1	+++
SPAG1	+++
SPAG4	+++
SPAG9	+++
TMEFF1	+++
TTK	+++



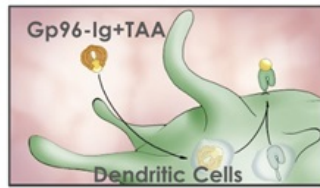
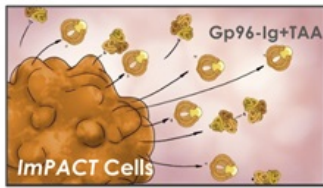
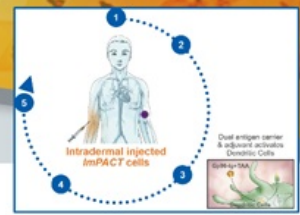
Antigen	23-002	25-001	25-004	25-005	25-003	25-007	25-008
ACTL8	---	---	---	---	---	---	---
ADAM22	+++	+++	++	+++	+++	+++	+++
ADAM23	+	++	+++	---	+++	+++	+++
ATAD2	+++	+++	---	+++	+++	+++	+++
ATAD2B	+++	+++	---	+++	+++	+++	+++
BIRC5	+++	+++	---	---	++	++	+++
CASC5	+++	+++	++	++	+++	+++	+++
CEP290	+++	+++	++	+++	+++	+++	+++
CEP55	+++	+++	++	++	+++	++	++
CTAGE5	+++	+++	++	+++	+++	+++	+++
DCAF12	+++	+++	---	+++	+++	+++	+++
DDX5	+++	+++	---	+++	+++	+++	+++
FAM133A	---	---	---	---	+	---	---
IL13RA2	++	++	---	---	*	+++	---
IMP3	+++	+++	---	+++	+++	+++	+++
KIAA0100	+++	+++	---	+++	+++	+++	+++
MAGEA11	+	+	+++	---	---	---	+
MAGEA3	---	+	++	---	*	---	++
MAGEA6	---	++	---	---	*	---	++
MPHOSPH10	+++	+++	+++	+++	+++	+++	+++
ODF2	+++	+++	++	+++	+++	+++	+++
ODF2L	+++	+++	---	+++	+++	+++	+++
OIP5	++	+	+++	+	+	---	+
PBK	+++	++	+++	---	*	+	++
RQCD1	+++	+++	++	+++	+++	+++	+++
SPAG1	++	+++	+++	+++	+++	+++	+++
SPAG4	++	++	---	++	++	+	++
SPAG9	+++	+++	+++	+++	+++	+++	+++
TMEFF1	---	+	---	---	---	---	---
TTK	+++	+++	---	*	++	++	*



This information can be used to track whether the proliferating T cells are tumor antigen specific

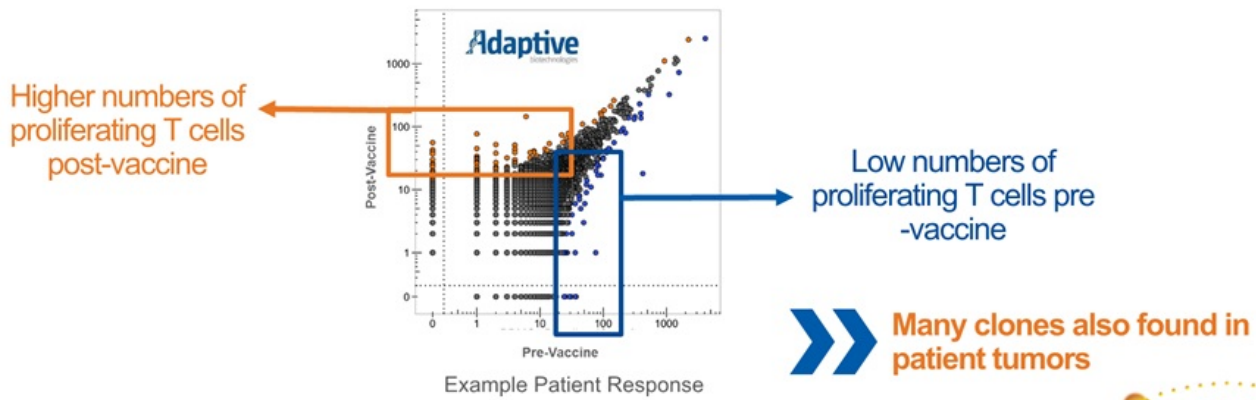
- Product candidate was selected due to high expression of >30 shared cancer antigens
- >15 of these antigens were also found in individual patient tumors

Polyclonal T Cell Activation

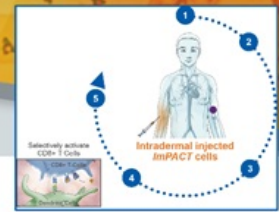


T Cell
Proliferation

T Cell Receptor Sequencing from Patient Blood Revealed:



Pan-Antigen “Killer” T Cell Activation

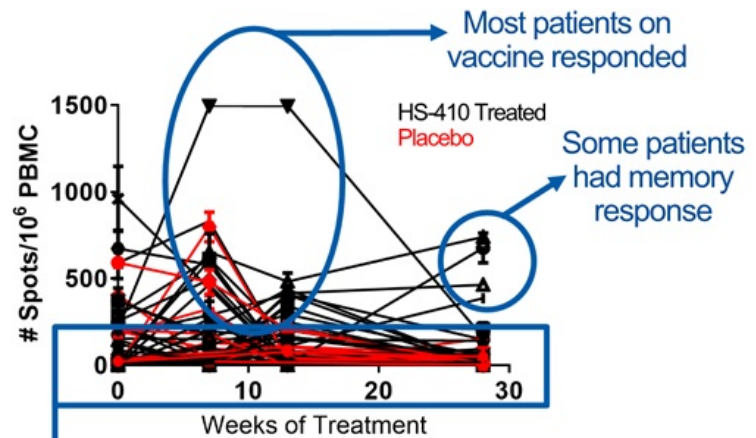


Antigen-specific immune responses were measured against individual antigens (e.g., survivin and NY-ESO-1)

Antigens included in initial analysis

Antigen	HS-410
ACTL8	+++
ADAM22	+++
ADAM23	+++
ATAD2	+++
ATAD2B	+++
BIRC5 (survivin)	+++
CASC5	+++
CEP290	+++
CEP55	+++
CTAGE5(NY-ESO-1)	+++
DCAF12	+++
DDX5	+++
FAM133A	+++
IL13RA2	+++
IMP3	+++
KIAA0100	+++
MAGEA11	+++
MAGEA3	+++
MAGEA6	+++
MPHOSPH10	+++
ODF2	+++
ODF2L	+++
OIP5	+++
PBK	+++
RQCD1	+++
SPAG1	+++
SPAG4	+++
SPAG9	+++
TMEFF1	+++
TTK	+++

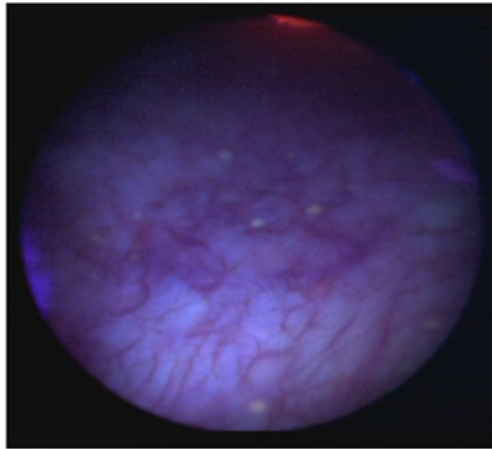
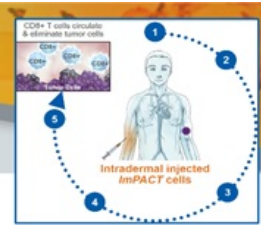
Patient ELISPOT Responses (IFN γ)



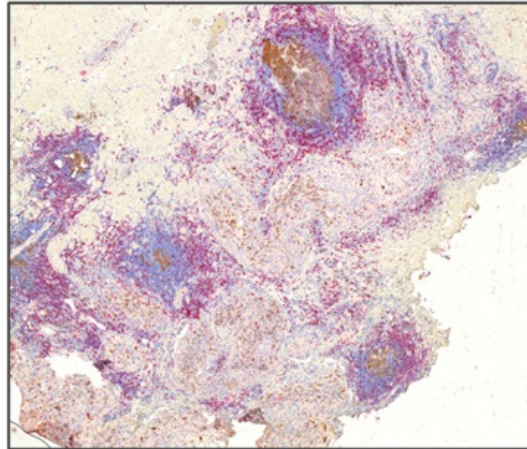
BCG did not cause T cell activation

Clinical data indicate antigen specific T cell response

Increasing TILs at the Tumor Site



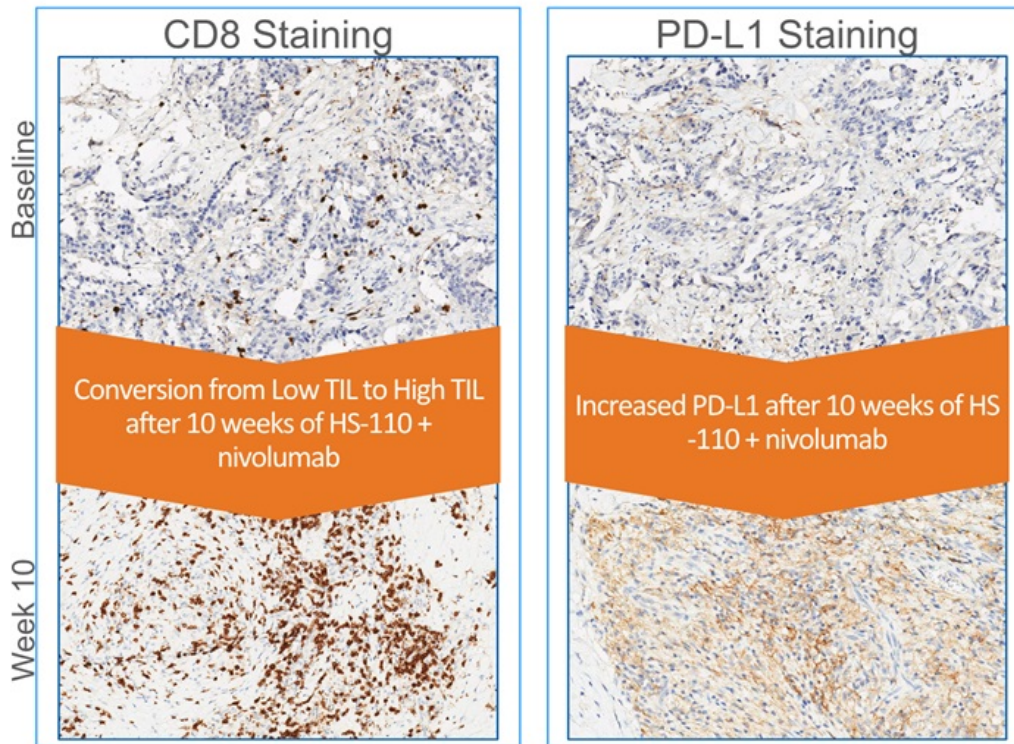
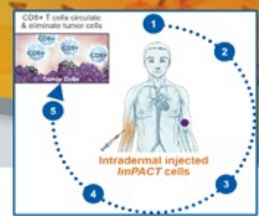
Blue-light cystoscopy from patient treated with HS-410



Tumor biopsy from patient treated with HS-410

- Images of the bladder (above) showed changes that resemble lymphoid (T cell rich) structures, which we believe indicates that HS-410 leads to a localized immune response within the bladder

ImPACTing the Tumor Microenvironment



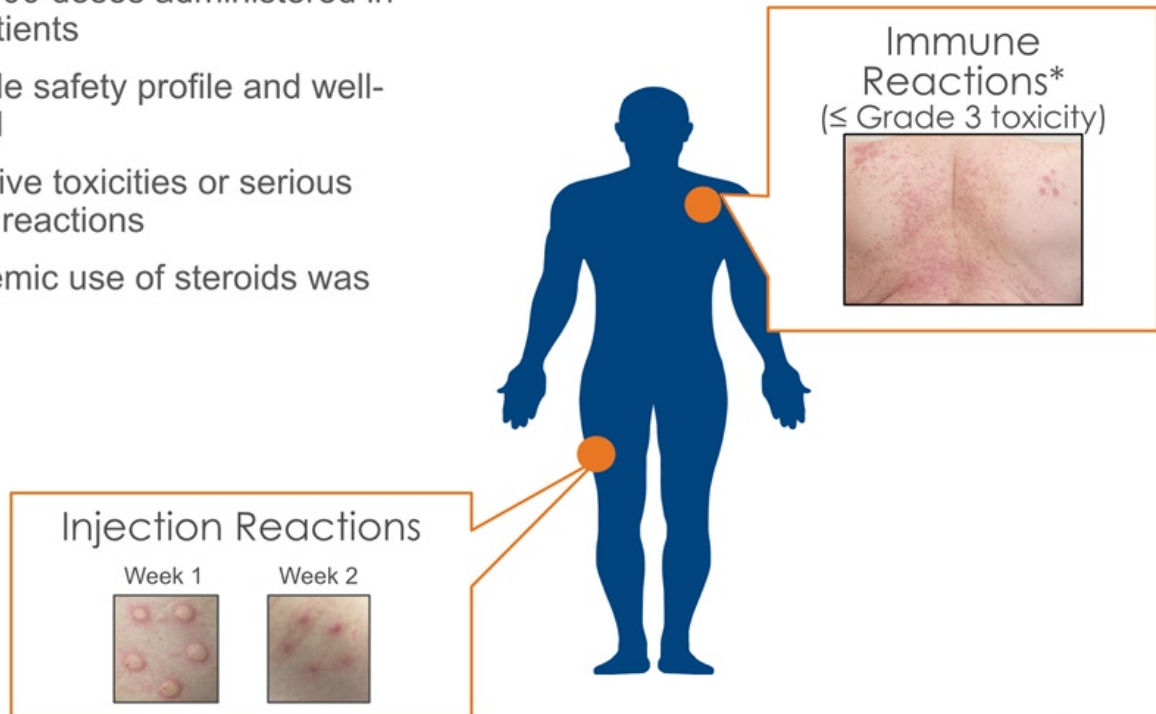
Clinical proof of mechanism

Drives “killer” CD8+ T cells into tumors

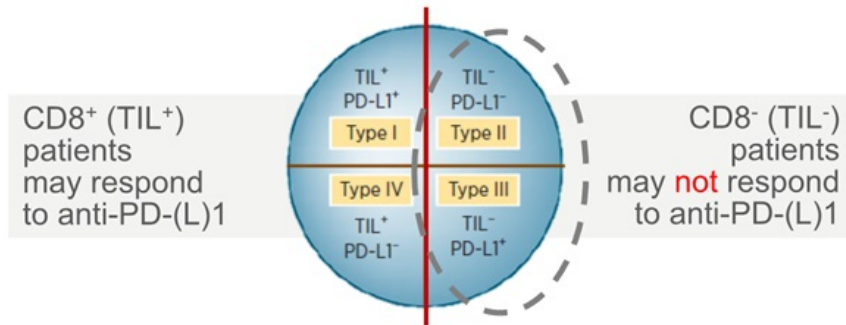
Increases PD-L1 expression

Favorable Safety Profile To-Date

- Over 1,000 doses administered in ~200 patients
- Favorable safety profile and well-tolerated
- No additive toxicities or serious adverse reactions
- No systemic use of steroids was required



Fulfill Unmet Need for Non-Small Cell Lung Cancer



Approx. 50% PD-1 ORR

Approx. 10% PD-1 ORR



Estimated 45% NSCLC patients being underserved by single-agent anti-PD-(L)1 may benefit from vaccine combination

HS-110 NSCLC Trial Overview

Objective

- Evaluate safety and tolerability of HS-110 + a PD-1 checkpoint inhibitor

Patient Population

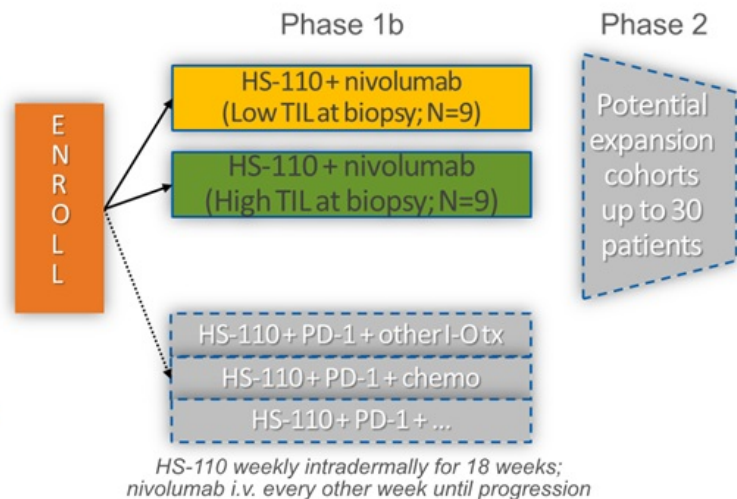
- Potential to expand each cohort up to 30 patients¹

Secondary Endpoints

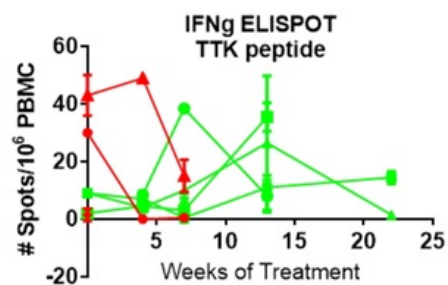
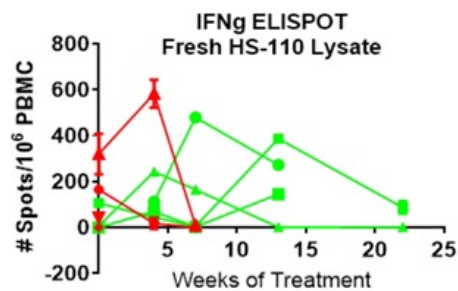
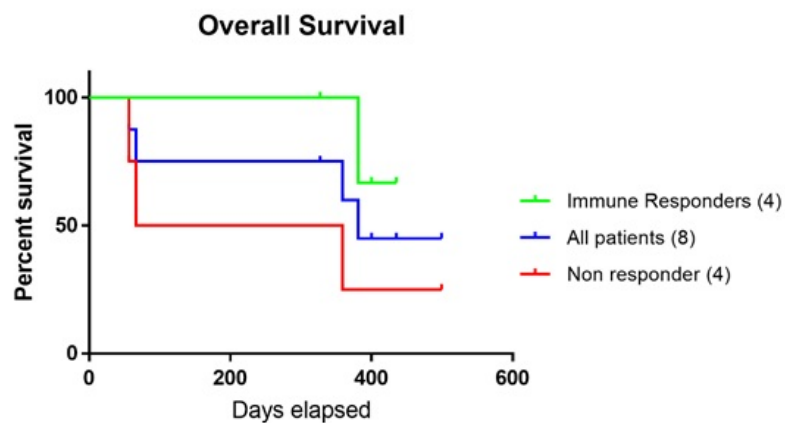
- Immune response, overall response rate, overall survival and progression-free survival

Enrollment

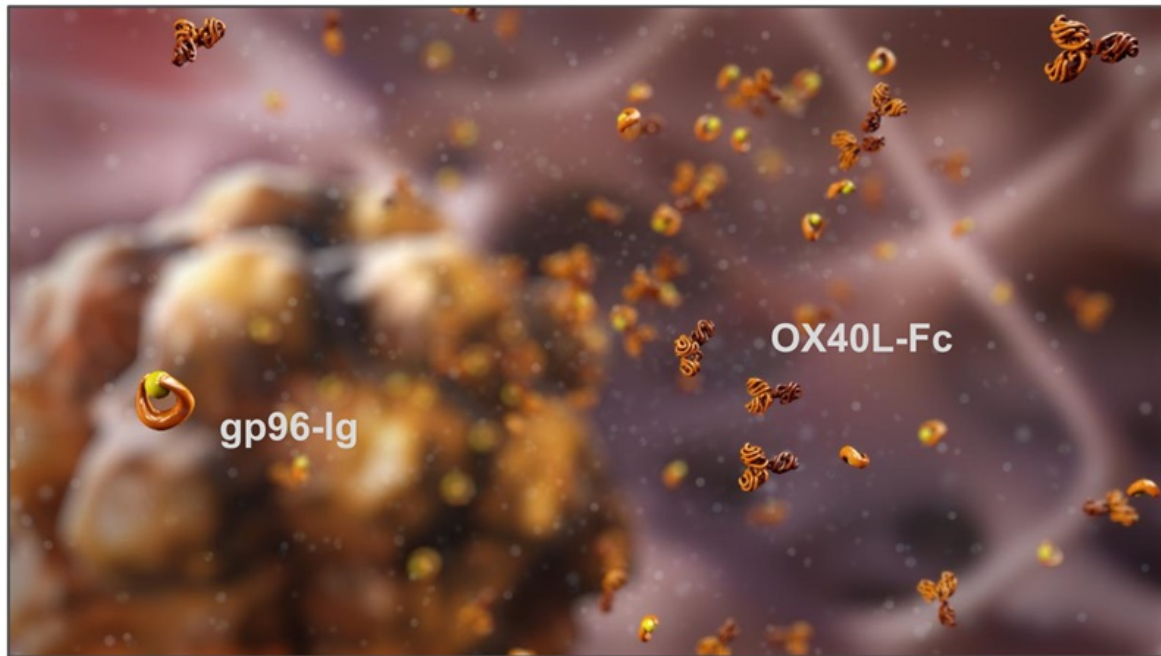
- 5 – 10 U.S. sites
- Partnership with Yale Cancer Center on TIL analysis



Immune Response Correlates with Overall Survival

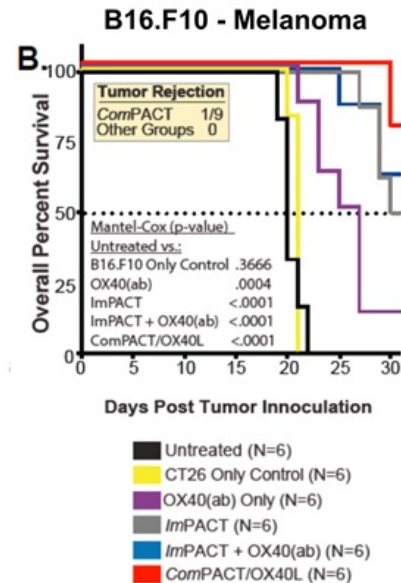
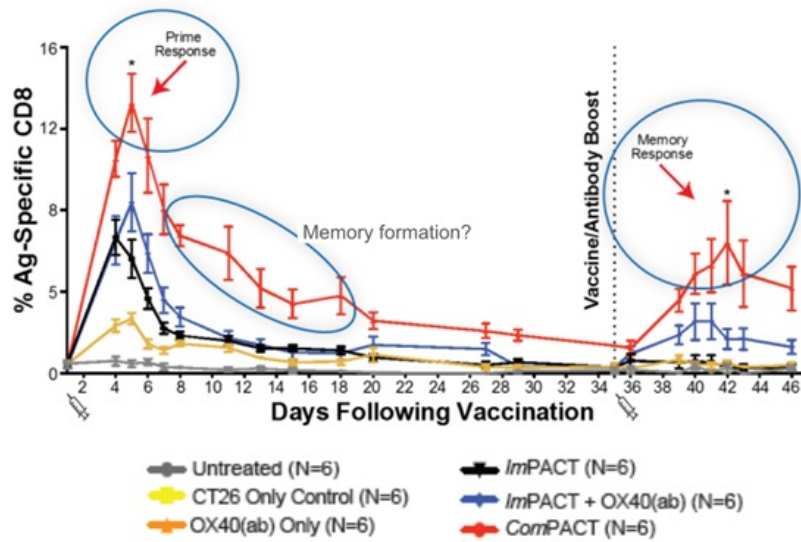


ComPACT Platform Technology



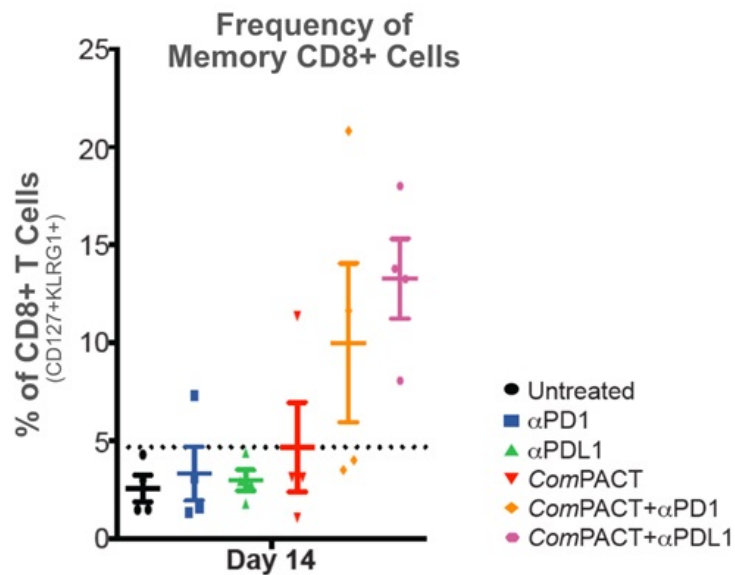
The first potential dual-acting immunotherapy designed to deliver T cell activation and costimulation in a single product – combination therapy without additive costs

ComPACT Outperforms OX40 Monoclonal Antibodies in Preclinical Models



ComPACT alone leads to ~50% complete tumor rejection as compared to ~16% with OX40 agonist antibody combinations¹

ComPACT Synergizes with PD-1 Blockade



ComPACT synergizes with PD-1 blockade to drive memory “killer” T cell differentiation

Leveraging gp96 Platform to Target Zika Virus & Other Infectious Diseases

- Zolovax, a wholly-owned subsidiary, formed to leverage our platform into infectious diseases
- Collaborating with the University of Miami (UM) to explore whether the gp96 vaccine might stimulate a similar virus-specific response in the placenta of Zika-infected women that could clear the virus
- Focusing on the unmet need of protecting the fetus of Zika-infected women
- Compelling data generated
 - In NIH-funded studies, the gp96-based vaccine induced a potent and localized immune response and mucosal immunity
 - U.S. Department of Defense funded research grant awarded to UM in malaria

Highlights

- ✓ Clinical proof of concept
- ✓ Favorable safety profile and low toxicities to-date
- ✓ Pan-antigen “killer” T cell activation and expansion
- ✓ Applicable to multiple cancers and infectious diseases
- ✓ Ready-to-use; scalable, low cost manufacturing
- ✓ Unencumbered commercialization rights



Focused on I-O combinations that have the potential to dramatically improve patient outcomes

Financial Snapshot

 Founded in 2008, completed IPO 2013

Nasdaq	HTBX
Shares Outstanding	23.9M
Share Price	\$0.90 ¹
Market Cap	\$21.5M ¹
Cash & Equiv.	\$8.5M ²



THANK YOU

