
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): September 8, 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 Rodman & Renshaw 16th Annual Global Investment Conference on September 9, 2014 in New York and the Aegis Capital Corp. Healthcare & Technology Conference on September 12, 2014. 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: September 8, 2014

HEAT BIOLOGICS, INC.
(Registrant)

By: /s/ Jeffrey Wolf
Name: Jeffrey Wolf
Title: Chief Executive Officer



Corporate Presentation

September 2014

Forward Looking Statements

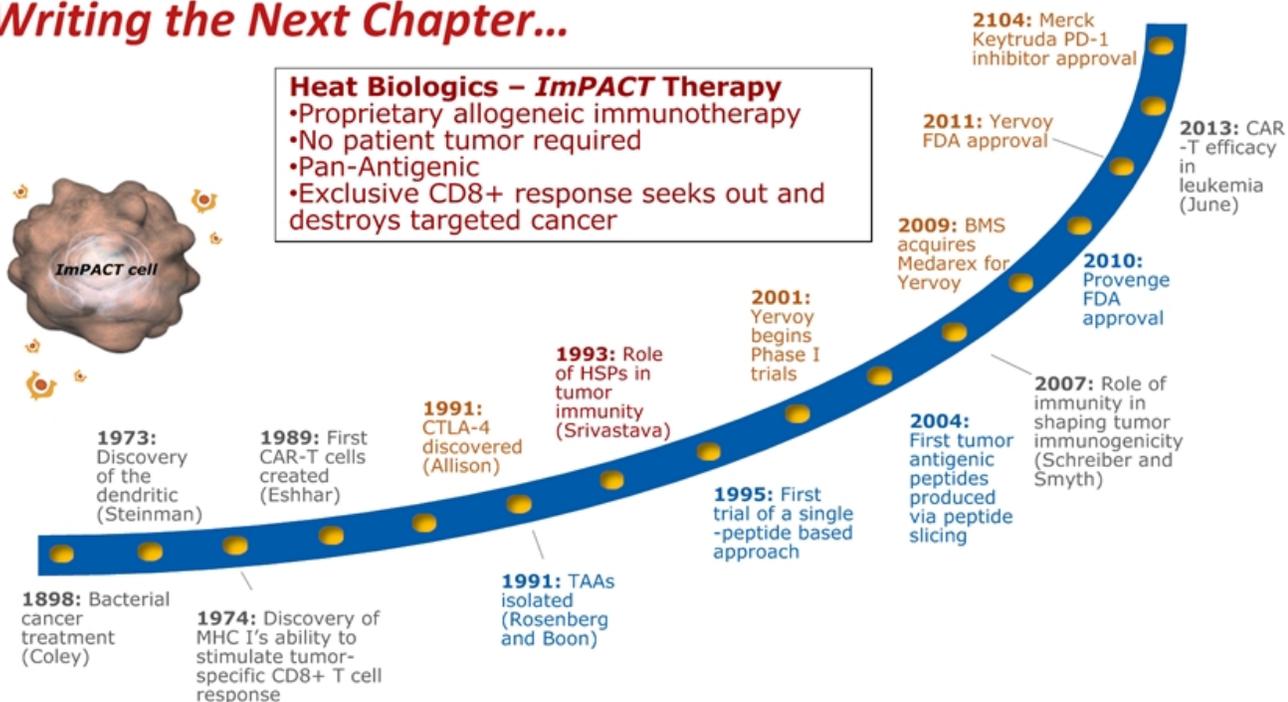
This presentation includes statements that are, or may be deemed, "forward-looking statements." In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "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 and June 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.

Next-Generation Immunotherapy Company

Writing the Next Chapter...



HTBX Overview

- Next-generation *ImPACT*[®] cancer immunotherapy unleashes immune system against a wide range of cancers
 - IPO on June 24, 2013
- Two ongoing multicenter phase 2 clinical trials with **multiple fully-funded near-term catalysts**
 - Bladder Cancer - Phase 1/2
 - Non-small cell lung cancer (NSCLC) - Phase 2

Disease		Pre-Clinical	Manufacturing	Phase 1	Phase 2
Oncology	HS-110 (Viagenpumatucl-L) - NSCLC				
	HS-410 (Vesigenurtacel-L) - Bladder Cancer				
	HS-310 (undisclosed)				
	HS-210 (undisclosed)				
	HS-510 (undisclosed)				

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World-Renowned Advisory Boards

Scientific Advisory Board

- **Eckhard R. Podack, M.D., Ph.D.**
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

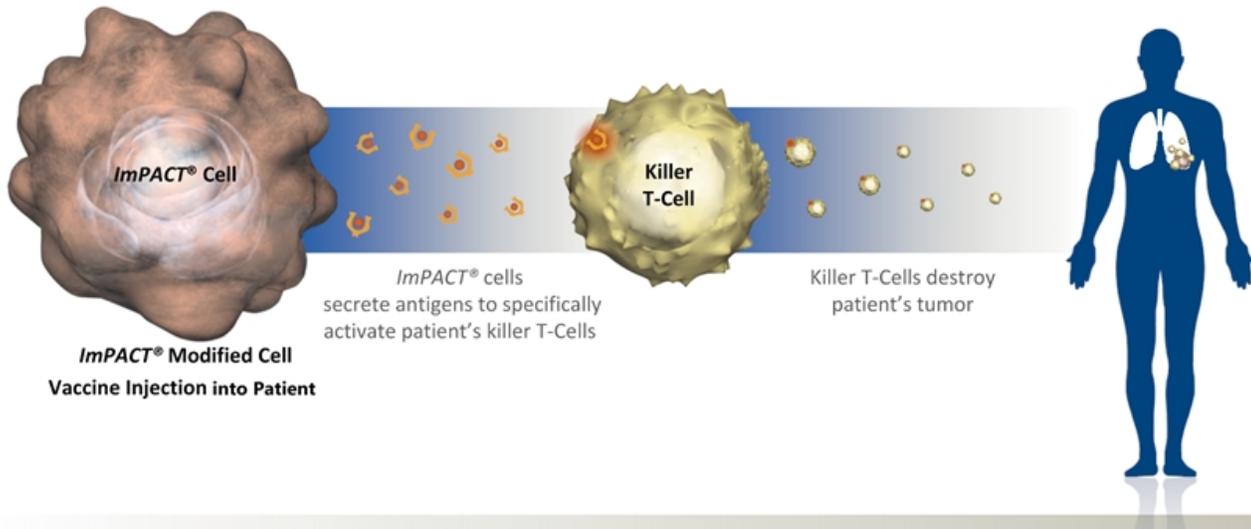
Clinical Advisory Board

- **Justin Stebbing, M.D., Ph.D.**
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

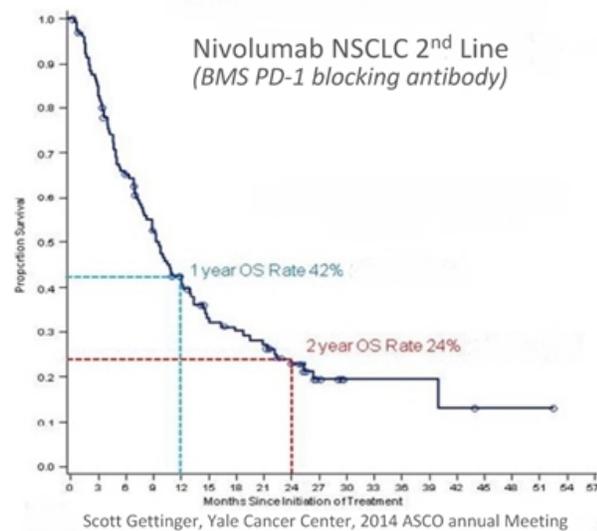
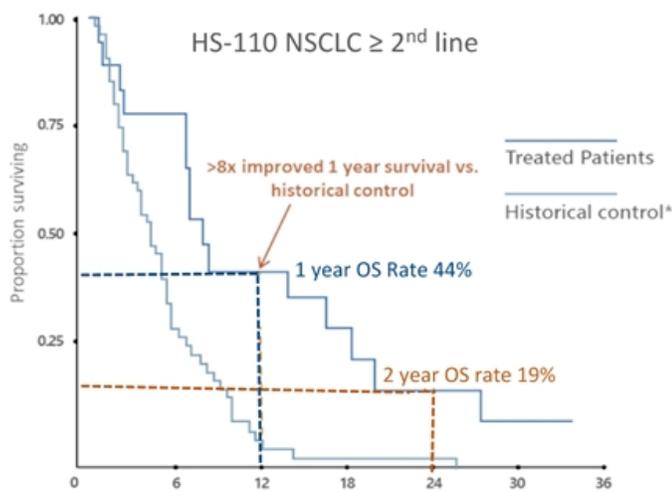
ImPACT Therapy vs. Other Cell-Based Immunotherapy Approaches

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	✗

ImPACT[®] Therapy



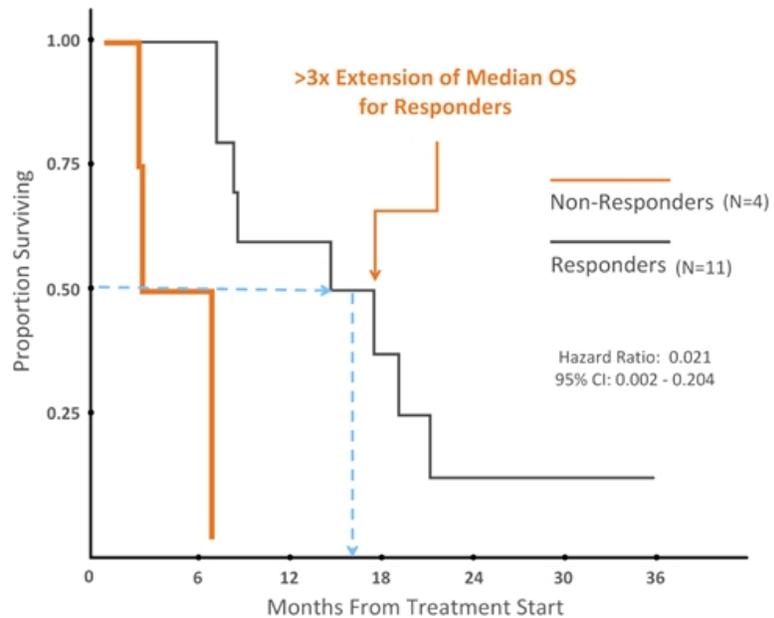
HS-110 NSCLC Phase 1 Clinical Trial Results



- **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

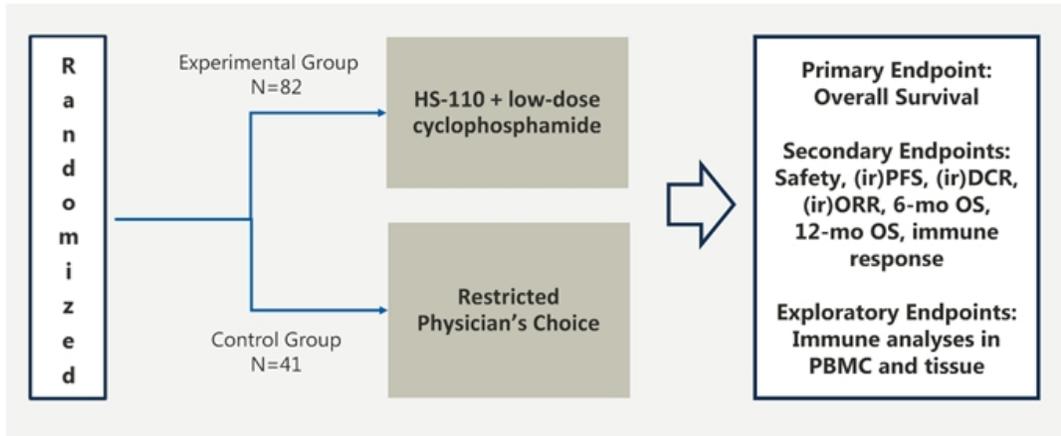
- **Immune response observed in 73% (11 out of 15) of patients who completed their first course of therapy**
 - **Immune response predictive of survival**
 - The immune responders exhibited a median survival of 16.9 months while the immune non-responders exhibited a median survival of 4.5 months
 - **Three patients survive >3 years**
 - One HS-110 patient alive >3 yrs. and another 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

3rd or 4th line



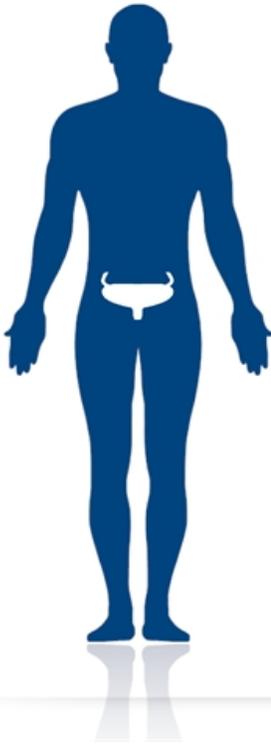
Regimen

- 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

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 20 patients

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

Phase 1/2 HS-410 NMIBC Bladder Cancer Design



Regimen

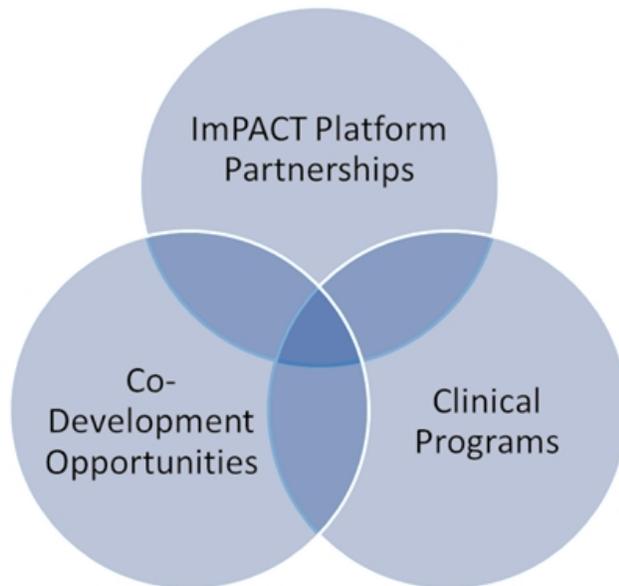
- After TURBT, placebo or HS-410 (10^6 or 10^7 cells per dose) in combination with BCG for 6 weeks followed by 6 weeks of placebo or HS-410 alone then 3 courses of placebo or HS-410 in combination with BCG for 3 weeks at 3, 6, and 12 months after starting therapy (21 total doses)

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



Investment Considerations

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"/> ImPACT combination poster presentations 	<ul style="list-style-type: none"> <input type="checkbox"/> Initiate Phase 2 NSCLC <input type="checkbox"/> Complete Phase 1 bladder <input type="checkbox"/> Phase 1 bladder initial safety and secondary endpoints <input type="checkbox"/> Initiate Phase 2 bladder 	<ul style="list-style-type: none"> <input type="checkbox"/> Phase 1 bladder final immune response and 6-mo recurrence data <input type="checkbox"/> Phase 2 NSCLC trial 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

Ticker	NASDAQ: HTBX
Shares Outstanding	6,452,341
Share Price*	\$6.51
Market Capitalization*	\$42M
Cash as of 6/30/14**	\$16.8M
Enterprise Value	\$25.2M

*As of market close on Sep. 2, 2014

**Does not include \$7.5 million debt facility available upon achieving certain milestones

Summary

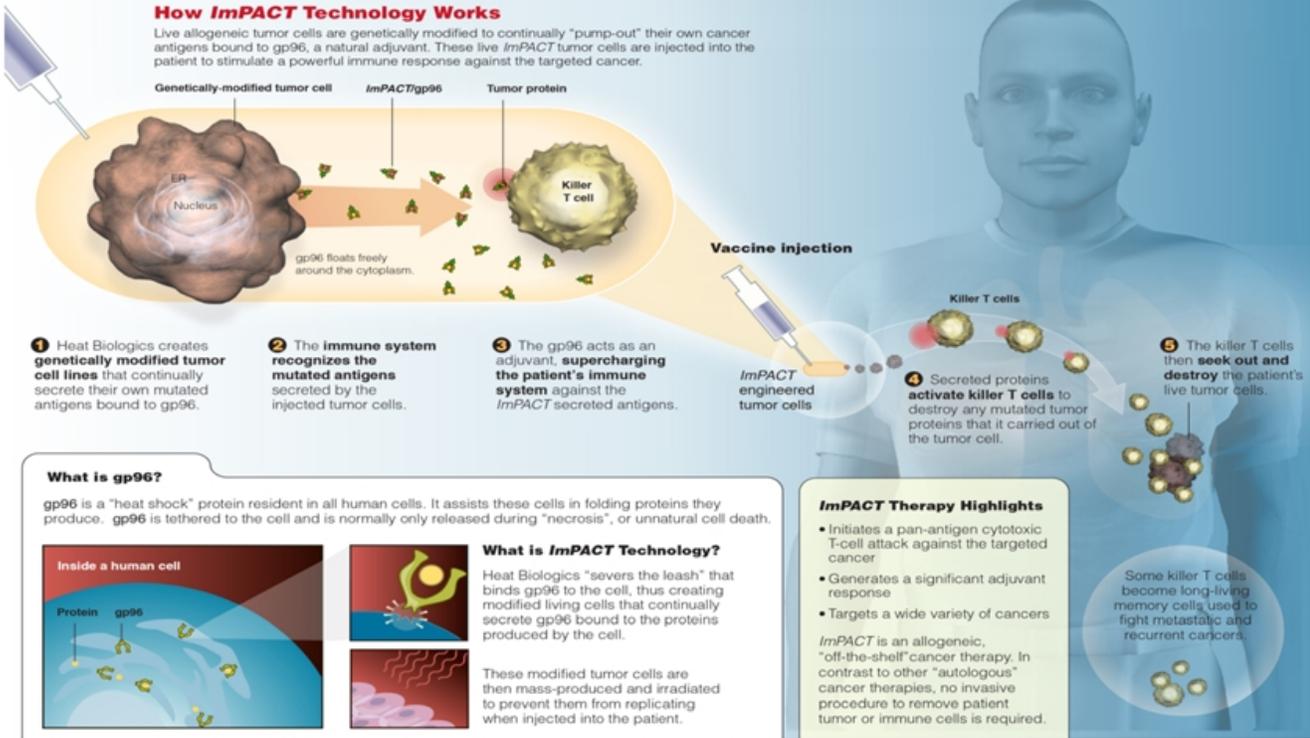
Clinical Stage Platform Technology Generating Promising Human Data

<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 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.

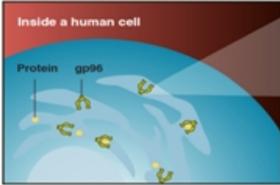
How ImPACT Technology Works

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.



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-shell" cancer therapy. In contrast to other "autologous" cancer therapies, no invasive procedure to remove patient tumor or immune cells is required.