AEGIS CAPITAL CORP

Biotechnology
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Initiating Coverage

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Key Metrics

HTBX - NASDAQ	$12.19
Pricing Date	Sep 17 2013
Price Target	$36.00
52-Week Range	$13.50 - $9.01
Shares Outstanding (mm)	6.2
Market Capitalization ($mm)	$75.6
3-Mo Average Daily Volume	68,808
Debt/Total Capital	NM
ROE	NM
Book Value/Share	$0.68
Price/Book	17.9x
Dividend Yield	NM
LTM EBITDA Margin	NM

EPS ($) FY: December

	2013E	Prior 2014E	Curr. 2014E	Prior	Curr.
1Q-Mar	(1.66)A	--	(0.36)E	--	--
2Q-Jun	(0.92)A	--	(0.34)E	--	--
3Q-Sep	(0.31)E	--	(0.34)E	--	--
4Q-Dec	(0.27)E	--	(0.36)E	--	--
FY	(2.15)E	--	(1.39)E	--	--
P/E	NM		NM		

Company Description:
Heat Biologics, Inc. (http://www.heatbio.com/) is an emerging biotechnology firm focusing on the development of novel oncology-focused therapeutics.

Heat Biologics, Inc.

Rating: Buy

Heat Biologics: Making An ImPACT™ In Cancer

Investment Highlights:

- **Initiating Coverage.** We are initiating coverage of Heat Biologics, Inc., an emerging biotechnology company focusing on the development of novel therapeutics in the oncology domain, with a Buy rating and an 18-month price target of $36.00 per share. In our view, Heat Biologics possesses a highly differentiated, targeted technology platform (ImPACT™) for the treatment of various types of solid tumors. The company's scientific founder, Dr. Eckhard Podack, is the Chairman of Immunology at the University of Miami and boasts a significant track record in drug development. He was responsible for the characterization of the CD30 antigen's role in hematological malignancies and the discovery of an anti-CD30 antibody that became the basis for Adcetris (brentuximab vedotin), a marketed monoclonal antibody product that is the sole approved drug for Seattle Genetics (SGEN/NASDAQ, Not Rated), a firm with a market capitalization of ~$6bn. In our view, Dr. Podack is one of the rare academic researchers with a focus on translational medicine.
- **Powerful Proprietary Platform.** The company's technological approach is based on the discovery by Dr. Podack's group that the gp96 chaperone protein can be harnessed as an all-purpose tool - a molecular Swiss Army knife - to present cancer-associated antigens to the immune system of cancer patients. This novel methodology leads to a robust cytotoxic response against the patient's own tumor cells mediated by CD8+ cytotoxic T lymphocytes (CTLs), and has been shown in a proof-of-concept Phase 1 study to correlate with significant increases in patient survival. Prior characterization of CTL-based immune responses has demonstrated that this is the most effective way to eradicate cancer via active immunotherapy.
- **Multiple Value Drivers Approaching.** We anticipate the initiation of two Phase 2 studies by Heat Biologics near-term; a trial in non-small cell lung cancer (NSCLC) with its lead agent HS-110, which has already shown positive proof-of-concept data in this indication; and a trial in bladder cancer with the firm's second candidate HS-410. These studies could both report interim data in 2014.
- **Attractive Valuation.** Heat Biologics currently trades at a roughly $55mm enterprise value, following an IPO in July 2013 that was underwritten by Aegis Capital Corp. as sole book runner. Another recent IPO, NewLink Genetics (NLNK/NASDAQ, Not Rated), trades at a ~$400mm enterprise value. We feel that the Heat platform, while relatively early-stage, is superior to the NewLink platform and that Heat Biologics shares could trade at a premium to NewLink's current valuation within the next 12 - 18 months as awareness of Heat's unique positioning continues to grow.

The Disclosure section may be found on pages 46 - 47 of this report.

Investment Thesis

Heat Biologics, Inc. is an emerging biotechnology firm focused on the development of a novel therapeutic platform aimed at eradicating cancer. The basis for the firm's approach to drug development is a system for producing novel allogeneic, "off-the-shelf" cellular vaccines to combat a wide range of cancers and infectious diseases. The Heat Biologics proprietary platform, known as ImPACT™ Immune Pan Antigen Cytotoxic Therapy, delivers live, genetically-modified, irradiated human cells, which are reprogrammed to "pump out" a broad spectrum of cancer-associated antigens tethered to a potent immune adjuvant called "gp96" in order to activate a cancer patient's immune system to recognize and kill cancerous cells. The firm plans to deploy these ImPACT™ cells to secrete an antigen-adjuvant complex that generates anti-cancer immune responses in patients by mobilizing and activating cytotoxic "killer" T cells that target multiple cancer antigens, thus harnessing the patient's own immune system to fight cancer.

Unlike "autologous" or "personalized" therapeutic vaccine approaches, which require extraction and processing of cancer or blood from each individual patient, Heat's ImPACT therapeutic vaccine uses a common master cell line to mass-produce a single vaccine product applicable to all patients for each particular cancer type. We believe that the firm's off-the-shelf, allogeneic immunotherapy offers significant logistical, manufacturing and cost-of-goods benefits vs. autologous patient-specific approaches.

We are initiating coverage on HTBX with a Buy rating and an 18-month price target of $36.00 per share, given a ~$350mm total firm value and ~9.7mm shares outstanding (fully-diluted) projected at end-2014. Investing in HTBX may entail above-average risk and volatility, reflecting its status as an emerging company.

Investment Positives

Significant Market Opportunity. We note that the markets being targeted by Heat's lead ImPACT™ programs in bladder cancer and non-small cell lung cancer are substantial, with roughly 70,000 – 80,000 cases of bladder cancer and 130,000 – 140,000 cases of non-small cell lung cancer occurring annually in the U.S. alone. Further, we believe that investors can treat the potential applicability of the Heat Biologics technology platform to other cancer types – especially solid tumors – as a set of free call options currently because the firm's enterprise value is so significantly discounted vs. other oncology-focused firms.

Favorable Comparison vs. Other Cancer Vaccine Companies. In our view, Heat Biologics represents a significantly undervalued opportunity, considering the fact that it currently trades at a roughly $40 million enterprise value despite having a technology platform that we believe to be superior to that of the company's closest comparator, NewLink Genetics. The NewLink enterprise value is roughly $350 million. In addition, Heat Biologics possesses a substantially cheaper manufacturing process vs. makers of autologous cancer vaccines, such as Dendreon Corporation. Dendreon, despite the commercial disappointment of its lead cancer vaccine product Provenge (sipuleucel-T), still has a >$500 million market cap.

Multiple Near-Term Value-Driving Catalysts. We anticipate that Heat Biologics is likely to initiate patient dosing in both bladder cancer and non-small cell lung cancer studies prior to the end of the year. In addition, we expect that – assuming the trials begin on schedule – interim data could be available from the bladder cancer study by mid-2014 and similar data could be yielded by the lung cancer trial later in the year. In our view, if this data is positive in both contexts, Heat Biologics should be considered a prime acquisition candidate. The early clinical data was also very promising.

Investment Risks

Development Risk. While Heat Biologics could develop multiple potential product candidates for the treatment of distinct types of cancer, demonstrating the flexibility and reach of its proprietary technology platform, thus far none of the firm's product candidates have entered pivotal trials or demonstrated success in such studies. The firm's lead candidates may not show positive safety and efficacy, which could preclude their approval and commercialization. If both the bladder cancer and non-small cell lung cancer Phase 2 proof-of-concept studies fail to show efficacy, Heat Biologics could be unable to secure partnerships with established firms or raise sufficient capital to continue to fund operations. The firm does not generate revenue from operations and is dependent upon the success of its candidates to attract partnering interest.

Regulatory Risk. Oncology drug development guidelines from the U.S. FDA have undergone substantial revision in recent years. While previously data on endpoints such as progression-free survival and tumor response were sufficient to obtain approval for drugs – especially those targeting difficult-to-treat patient populations – more recently the FDA has exhibited an unwillingness to accept less stringent endpoint-based data as hard evidence of efficacy. We note that it will be crucial for Heat Biologics to obtain regulatory authority acceptance of the firm's proposed clinical trial designs in order to permit the company's product candidates to stand a chance of approval.

Commercial Risk. Heat Biologics is an unproven firm in the domain of therapeutic agent commercialization. The company currently has no sales or marketing infrastructure and is therefore dependent on its ability to raise additional funds with which to build such an infrastructure, and/or its capacity to partner its candidate therapies with a more established entity in order to permit successful commercialization.

Partnership Risk. Should Heat Biologics elect to out-license the commercial and/or development rights to its clinical-stage candidates, it would need to find a partner or partners for whom these candidates represent tangible value, and under whom said candidates would be developed and commercialized in a timely manner. If Heat were to enter into partnerships with entities that do not have sufficient clinical knowhow or commercial capability, the development and marketing of the company's assets could suffer. Heat Biologics may also be forced to enter into such partnerships under terms that are unfavorable or that do not accrue meaningful revenue to the firm. Heat's strategic partners may not prioritize the development of its candidates sufficiently.

Competitive Landscape Risk. Many of the target markets that Heat Biologics could compete in using product candidates developed with its ImPACT™ technology platform are already at least partially addressed using existing drugs. In the case of bladder cancer, agents such as Adriamycin (doxorubicin hydrochloride), Camptosar (irinotecan), Gemzar (gemcitabine), Halaven (eribulin), Platinol (cisplatin), and interferon-alfa-2b are typically deployed. Approved drugs that are routinely used for treatment of other types of cancer are continually being assessed in bladder cancer, both as single-agent therapy or in combination. Such agents include Sutent (sunitinib), Nexavar (sorafenib), Velcade (bortezomib), and Votrient (pazopanib). Product candidates currently in clinical testing for use in bladder cancer include EOquin (apaziquone), being developed by Spectrum Pharmaceuticals; TMX-101, being developed by Telormedix; AZD4877 from AstraZeneca; ALT-801, a p53-specific scTCR/IL-2 fusion protein, being developed by Altor Therapeutics; AMG 386 (trebananib) from Amgen; and BKM120 from Novartis AG. The lung cancer landscape is, if anything, even more crowded. Heat Biologics would need to show highly compelling efficacy and safety data to compete with these agents in a sustainable manner and eke out a market niche.

Royalty / Milestone Liability Risk. The business model for Heat Biologics implies that the company should enter into R&D arrangements with third parties that often require milestone and royalty payments to the third party contingent upon the occurrence of certain future events linked to the success of the asset in development. Milestone payments may be required, contingent upon the successful achievement of an important point in the development life-cycle of the pharmaceutical product (e.g., approval of the product for marketing by a regulatory agency). Under existing arrangements, Heat Biologics must make royalty payments to its licensors based upon a percentage of the sales of its proprietary products if regulatory approval for marketing is obtained.

Patent Risk. The pharmaceutical industry is an inherently litigious arena. Generic drug manufacturers may challenge Heat Biologics's issued patents. If the firm's patent estate is found to be invalid or unenforceable upon challenge from generic competitors, significant pricing pressure could result in destruction of the franchise. Investors should take note that some of the core patents in the Heat Biologics intellectual property (IP) begin to expire in the 2019 time frame. However, we note that the vast majority of the patents in the Heat Biologics portfolio have expiration dates in 2029 and beyond without factoring in the potential impact of patent term extensions.

Reimbursement Risk. Recently, reimbursement agencies have grown more wary of systematically reimbursing for drugs that do not provide cost-effective benefit. If Medicare spending growth continues to outpace GDP growth, changes could be made to reimbursement policy that would negatively affect the commercial prospects for Heat's product candidates, years before these agents even reach the market.

Additional Risks. As of June 30th, 2013, Heat Biologics had about $3.0 million in cash and equivalents, to which was added $23 million in net proceeds from the firm's Initial Public Offering (IPO). Given the estimated operational cash burn of roughly $3.3 million over the remainder of 2013 and $11 million for the whole of 2014, we believe that the current cash position should be sufficient to fund operations until mid-2015. Additional funding could come from equity offerings, warrant exercises, and partnerships. Should the firm's clinical programs in bladder cancer and lung cancer fail in proof-of-concept efficacy testing, however, the firm may not be able to raise cash at all.

Industry Risks. Emerging development-stage healthcare-focused stocks are inherently volatile and increasingly subject to regulatory risk. Meeting or missing clinical milestones may result in a significant change in the perception of the company and the stock price. We do not expect volatility to subside near term.

For additional risk considerations, please refer to the company's SEC filings.

Valuation

Comparables Analysis: Given that Heat Biologics is currently unprofitable and likely to remain so for the foreseeable future, we use a comparables analysis as part of our valuation approach. This results in an 18-month target valuation of roughly 36.00 per share, utilizing our estimate of a ~$350 million total firm value. This assumes that the shares trade in-line with the comp group's average enterprise value of ~$300 million and that the firm has roughly 9.7 million shares outstanding (fully-diluted) as of end-2014.

Table 1: Comparable Company Analysis
(Millions, Except Per-Share Data)

Development Stage	Therapeutic Area	Company	Ticker	Rating	Closing price 9/17/2013	Shares (MM)	Market cap ($MM)	Cash ($MM)	Debt ($MM)	Enterprise value ($MM)
Phase 2 / 3	Cancer Vaccines	Advaxis	ADXS	Not Rated	$6.03	5	29	1	3	31
Phase 3	Cancer Vaccines	Agenus	AGEN	Not Rated	$3.02	30	90	13	9	86
Phase 3	Oncology	ArQule, Inc.	ARQL	Not Rated	$2.20	63	138	80	2	60
Phase 3	Oncology	CytRx Corporation	CYTR	Buy	$2.39	30	73	28	0	45
Marketed	Cancer Vaccines	Dendreon Corporation	DNDN	Not Rated	$3.13	153	478	207	592	862
Phase 3	Oncology	Endocyte	ECYT	Not Rated	$15.51	36	559	111	0	448
Phase 2 / 3	Oncology	Epizyme	EPZM	Not Rated	$33.40	28	949	149	0	800
Phase 2 / 3	Cancer Vaccines	Galena BioPharma	GALE	Buy	$1.93	105	202	55	10	157
Phase 2 / 3	Cancer Vaccines	ImmunoCellular Therapeutics	IMUC	Not Rated	$2.70	55	147	25	0	122
Phase 2	Oncology / Asthma / Inflammation	Infinity Pharmaceuticals	INFI	Not Rated	$20.72	48	994	277	0	717
Phase 2	Cancer Vaccines	Inovio Pharmaceuticals	INO	Hold	$2.55	190	484	31	0	453
Phase 2 / 3	Oncology	Merrimack Pharmaceuticals	MACK	Not Rated	$3.79	102	387	62	41	366
Phase 3	Cancer Vaccines	NewLink Genetics	NLNK	Not Rated	$17.51	26	450	59	1	392
Phase 3	Cancer Vaccines	Northwest BioTherapeutics	NWBO	Not Rated	$3.35	30	101	0	3	104
Phase 3	Cancer Stem Cell Targeting	OncoMed Pharmaceuticals	OMED	Not Rated	$16.63	28	463	56	0	406
Phase 2 / 3	Oncology	Oncolytics Biotech	ONCY	Not Rated	$2.90	85	246	39	0	207
Phase 3	Oncology	Oncothyreon	ONTY	Not Rated	$1.78	63	113	51	0	62
Phase 2b	Cancer Stem Cell Targeting	Stemline Therapeutics	STML	Buy	$37.33	12	459	93	0	366
Phase 2	Cancer Stem Cell Targeting	Verastem, Inc.	VSTM	Not Rated	$14.18	26	363	57	0	305
Phase 2 / 3	Oncology	ZIOPHARM Oncology	ZIOP	Not Rated	$3.23	83	268	39	0	229
		Average					**382**			**300**
								Discrepancy		
Current valuation	**Cancer Vaccines**	**Heat Biologics**	**HTBX**	**Buy**	**$12.19**	**7**	**85**	**25**	**0**	**60**
			Derived 18-month comparable value							**Projected**
Target valuation (18-month)	**Cancer Vaccines**	**Heat Biologics**	**HTBX**	**Buy**	**$36.00**	**10**	**346**	**46**	**0**	**300**

Source: First Call and Aegis Capital Corp. estimates

Free Cash Flow: We estimate that Heat Biologics could be free cash flow-negative for the foreseeable future. We project that the firm might only obtain regulatory approval for its lead clinical program in bladder cancer in the late 2017 / early 2018 timeframe.

We define free cash flow as operating cash flow minus capital expenditures and dividend payments. We utilize a combination of a comparables-based enterprise value framework and a discounted cash flow analysis including risk-adjusted Net Present Value (rNPV) calculations for Heat Biologics's pipeline in order to derive our $36.00 price target.

We have conservatively modeled future cash flows from sales of the firm's drug candidates assuming a 40% corporate tax rate, since Heat Biologics's low burn rate and relatively limited operating history mean that there is no significant net loss carry-forward amount available to offset future tax liability. Our valuation methodology may be conservative and there could be upside to our estimates if the firm succeeds in accruing substantial net operating loss carry-forwards during the clinical development process or is able to accumulate R&D tax credits to offset future taxable income.

Risk-Adjusted Net Present Value (rNPV) Analysis: We have herein presented our discounted cash flow (DCF)-based analysis of Heat Biologics. Our assessment provides for risk-adjusted Net Present Value (rNPV)-based valuations of each of Heat's clinical and preclinical candidates as well as the firm's ImPACT™ technology platform, which in total yields a projected enterprise value of $300 million. We add to this the projected cash position of $46 million to derive our total firm value projection of ~$350 million, which implies a projected price per share of $36.00 at the end of 2014.

Table 2: Heat Biologics Risk-Adjusted Net Present Value (rNPV)

Heat Biologics, Inc.								
	Product	Launch Year	Patent Expiry	Peak Sales	Royalty Rate	Probability To Launch	NPV	Amount Per Share
Phase 2								
Bladder Cancer	**HS-410**	2017	2029	$1.3B	15-30%	50%	$110MM	$11.50
Lung Cancer	**HS-110**	2019	2029	$1.5B	12-25%	60%	$140MM	$14.50
Preclinical								
Pancreatic Cancer	**HS-210**	2021	2029	NA	NA	NA	$15MM	$1.50
Ovarian Cancer	**HS-310**	2020	2029	NA	NA	NA	$10MM	$1.00
Triple Negative Breast Cancer	**HS-510**	2022	2029	NA	NA	NA	$5MM	$0.50
Platform								
ImPACT™ Technology	**NA**	NA	2029	NA	NA	NA	$20MM	$2.00
Total							$300MM	$31.00
Debt at end-2014							$0MM	$0.00
Cash at end-2014							$46MM	$5.00
Firm Value							$346MM	$36.00

Source: Company reports and Aegis Capital Corp. estimates

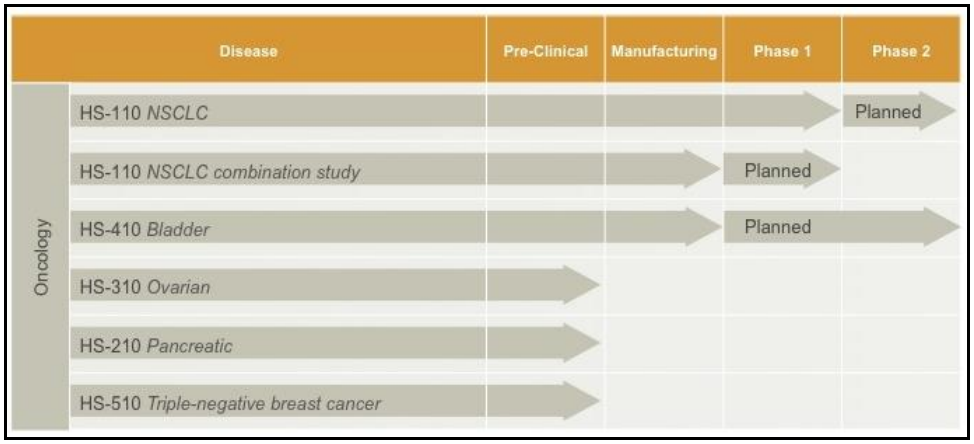
Our assumptions include a patent window through to 2029 (without factoring patent term extensions); an effective tax rate of 40% applied to future revenues; and a discount factor of 15% applied to future cash flows. We have provided a $20 million rNPV for the firm's ImPACT™ technology platform, which may be conservative when considering the fact that the platform could potentially permit the generation of therapeutic candidates that could be deployed against virtually any solid tumor type.

Company Overview

A new entrant in the cancer immunotherapy sector, Heat Biologics is an emerging biotechnology company focusing on the development of a proprietary set of product candidates based on its novel Immune Pan-Antigen Cytotoxic Therapy (ImPACT™) technology platform, a form of active immunotherapy that aims to "educate" or "train" the cancer patient's own immune system to specifically react against the patient's tumors so as to eradicate the cancer from the patient's body. The ImPACT™ approach utilizes an endogenous antigen presentation process involving the gp96 peptide to selectively present cancer-associated antigens to the patient's immune system, using irradiated, engineered human cancer cell lines through which to deliver these antigens. In our view, this makes Heat Biologics a uniquely-positioned platform opportunity in oncology because its approach can target virtually any solid tumor type and utilizes multiple cancer-associated antigens instead of single antigens for optimal immune system priming.

As shown below, the firm has already developed multiple product candidates using the ImPACT™ platform, which target distinct cancer types. Heat Biologics has already observed favorable results in Phase 1 testing with its HS-110 product candidate, which is the subject of a currently-open Investigational New Drug (IND) application in the U.S. for non-small cell lung cancer (NSCLC). We expect the firm to begin enrolling patients in a proof-of-concept Phase 2 trial of HS-110 in NSCLC within the coming months, and to advance its next candidate, HS-410, into proof-of-concept clinical testing in bladder cancer over the course of the next 2 – 3 months as well. Additional product candidates and combination regimens involving existing standard-of-care drugs (including both targeted therapies and chemotherapeutic agents) are under development as well. From our perspective, these initiatives constitute risk-mitigated "multiple shots on goal" and make Heat Biologics one of the world's most diversified cancer immunotherapy firms.

Figure 1: Heat Biologics Product Candidate Portfolio



Source: Corporate presentations

Heat Biologics is headquartered in the Chapel Hill, NC area – well-known in life sciences circles as the location of the famous Research Triangle Park campus – the largest research park in the world – that has spawned several biopharmaceutical companies. Research Triangle Park is also the site at which notable researchers such as Ray Schinazi conducted groundbreaking work on the development of novel small molecule therapeutics addressing viral diseases such as hepatitis C virus infection. Furthermore, various multinational life sciences-focused companies have discovery sites located at RTP, including firms such as Biogen Idec, GlaxoSmithKline, Merck & Co., and Syngenta. In our view, the physical location of Heat Biologics's headquarters should prove an advantage to the nascent company as its pipeline matures and it increases its business development and licensing activities.

Unlike many other companies of its size, Heat Biologics has a solid scientific pedigree that can be traced directly to the track record of the individual behind its technology platform, Dr. Eckhard Podack. Currently Chairman of Immunology at the University of Miami, Dr. Podack is principally affiliated with the Sylvester Comprehensive Cancer Center and is a highly regarded scientist. In the course of our due diligence process, we had the opportunity to interview him multiple times and made the following observations:

- **Focus on translational research**: Dr. Podack is an example of an academician with a keen interest in translational medicine. He primarily devotes his energy to initiatives that he considers to have true potential in treating patients and improving their lives. This is not only true of the Heat Biologics technology platform, but also of the work he is currently engaged in with respect to the investigation of the role of hypoxia in tumor function, particularly the manner in which this permits tumor cells to evade eradication by tumor-reactive cytotoxic T lymphocytes.

- **Comprehensive knowledge of cancer immunology**: The field of immunology is immensely complex, and it is very difficult to elucidate which complex mechanisms are relevant to a particular biological process. Dr. Podack not only possesses a highly detailed level of knowledge about immunological signaling, but also has a profound understanding of how this fits into the immune privilege of cancer cells. Furthermore, because of his ability to grasp how different antigens and signaling pathways affect tumor-reactive cytotoxic T lymphocyte function, Dr. Podack is able to design ways to counteract these processes in a pragmatic manner.

- **Pedagogical prowess**: Dr. Podack possesses the ability to render highly complex and arcane concepts in immunology understandable. He is not only a quality scientist but also a rigorous teacher. This has substantial implications for Heat Biologics, because the scientific backbone of the company originates from Dr. Podack's group at the University of Miami. In our view, Dr. Podack's abilities as a scientific educator have allowed Heat Biologics to develop an internal scientific culture that is much more sophisticated than that of the average company their size.

- **Track record in delivering value**: Many scientists in the domain of academia possess exceptional analytical and experimental skills, yet fail to translate these attributes into anything tangible from an investment perspective. This is not the case with Dr. Podack. In 1992, he played a central role in the characterization of the role of the CD30 antigen in hematological malignancies[1] and in the discovery and characterization of an antibody against this target. A proprietary antibody-drug conjugate developed on the basis of this work became the commercial drug now known as Adcetris (brentuximab vedotin)[2]. Known as a member of the therapeutic class colloquially referred to as "armed antibodies" or "smart bombs", Adcetris selectively ablates malignant cells in various blood cancers[3].

Originally submitted in the U.S. in February 2011 and approved in August of that year, Adcetris – marketed in the U.S. and Canada by Seattle Genetics and by Takeda Pharmaceutical Co. Ltd. in the rest of the world – is today considered one of the most promising drugs available for treatment of refractory lymphomas, including Hodgkin's lymphoma, anaplastic large cell lymphoma, and cutaneous T cell lymphoma, and may have potential to move up the treatment continuum into newly diagnosed lymphoma patients. Seattle Genetics – a company that only has one product on the market – has generated over $3 billion in shareholder value within the past three years due to the improving expectations for Adcetris. Given its usage potential, we believe that this drug could eventually generate peak sales of nearly $2 billion worldwide.

[1] Bowen *et al.*, Journal of Immunology 151: 5896-5906 (1993)
[2] Deutsch *et al*., Leukemia and Lymphoma 52: 1641-1654 (2011)
[3] Deng *et al*., Clinical Cancer Research 19: 22-27 (2013)

Firm History

The company was originally founded as a spin-off entity from the University of Miami in June 2008 and is incorporated in Delaware. Heat Biologics was originally based in Miami with principal R&D efforts being conducted at the university, but subsequently relocated to its present headquarters in 2011. Currently, the company is organized into four subsidiaries – Heat Biologics I, Inc. (of which the firm owns a 92.5% interest, with the remainder being owned by the University of Miami), Heat Biologics III, Inc., Heat Biologics IV, Inc. and Heat Biologics GmbH, a wholly-owned limited liability company.

Initially, Heat Biologics I, Inc. and Heat Biologics II, Inc. were incorporated in 2009. In June 2012, the firm divested its 92.5% interest in Heat Biologics II, Inc., which resulted in Heat Biologics II, Inc. being classified as discontinued operations in its consolidated financial statements for the years ended December 31, 2012 and 2011. On May 30, 2012, the firm formed two wholly-owned subsidiaries, Heat Biologics III, Inc. and Heat Biologics IV, Inc., and assigned its proprietary rights related to the development and application of the ImPACT™ Therapy for the treatment of non-small lung cancer to Heat Biologics III, Inc. and all proprietary rights related to the development and application of its ImPACT™ Therapy to the treatment of bladder cancer to Heat Biologics IV, Inc. There has been no activity in Heat Biologics GmbH since its inception.

In March 2013, the company closed the first tranche of its Series B Preferred Stock private placement offering, in which it sold an aggregate of 1.9 million shares of Series B-1 Preferred Stock for gross proceeds of roughly $5 million. From inception in 2008 to the closure of the Series B round, Heat Biologics had raised $2.6 million from the issuance of convertible notes to investors, of which roughly $2.3 million were issued to one investor, Brightline Ventures III, LLC. The notes accrued interest at a rate of 3% per annum and were scheduled to mature 18 months after issuance. In 2011, the firm raised roughly $1.5 million from the issuance of notes to three investors, one of which was Brightline Ventures III, LLC. The notes accrued interest at a rate of 3% per annum and were scheduled to mature 18 months after issuance. All of the notes were converted into shares of Series A Preferred Stock in September 2011.

Initially, Heat Biologics filed an S-1 registration statement to go public via IPO in May 2013, seeking proceeds of roughly $10 million – $12 million in order to finance a roughly 125-patient Phase 2 trial of HS-110, its lead drug candidate, in non-small cell lung cancer (NSCLC) and a 93-patient proof-of-concept trial of HS-410, its second drug candidate, in bladder cancer. The size of the offering, which was led by Aegis Capital Corp. as sole book runner, was subsequently increased to $25 million – $30 million. Heat Biologics became a publicly-traded company on the NASDAQ Capital Market as of July 24, 2013, raising $25 million in gross proceeds from the sale of 2.5 million shares of common stock at $10 per share. The offering closed on July 29, 2013 and the firm subsequently raised an additional $2 million from the partial exercise of the underwriters' over-allotment. 200,000 shares of the total 375,000 shares available under the over-allotment were sold.

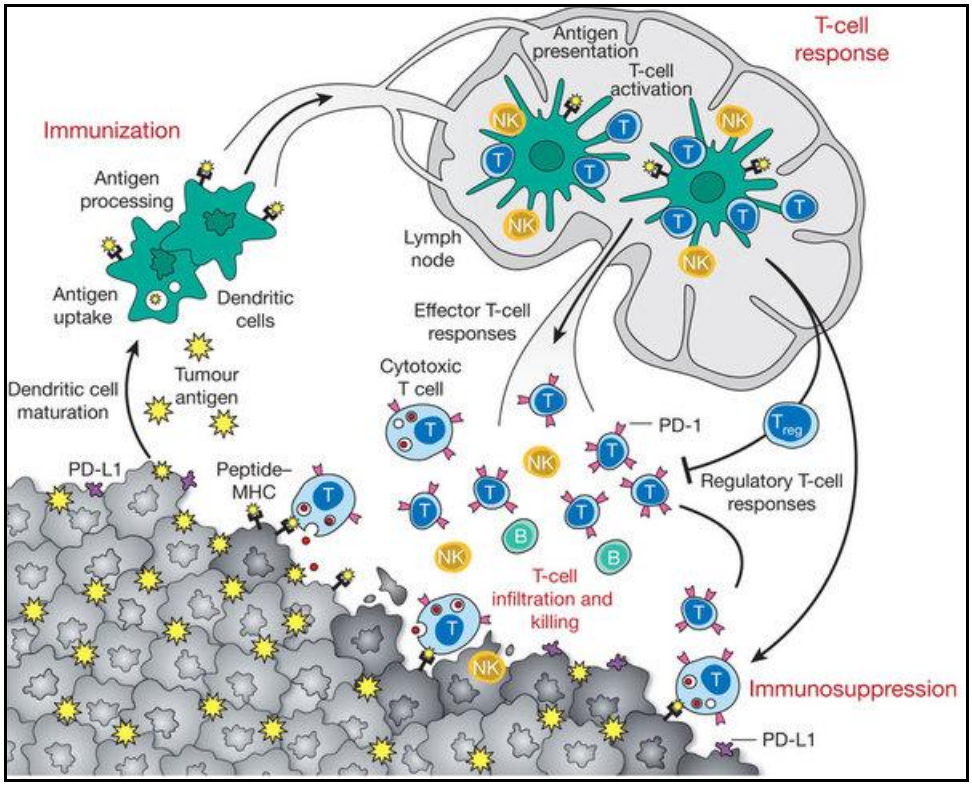
One of the unique aspects of Heat Biologics as a company is its extremely lean organizational structure and its ability to advance the scientific testing of its technology platform through the use of non-dilutive sources of funding. Since inception, roughly $15 million in grant funding has been awarded to Dr. Eckhard Podack, the primary inventor of the technology platform that Heat has licensed, by the National Institutes of Health (NIH). Through this and other research and clinical grants, the company's ImPACT™ technology platform has been persistently developed and refined and continues to be investigated on the basis of the funding that Dr. Podack's group obtains. Funding of studies investigating the platform's applicability in treating human immunodeficiency virus (HIV) infection – which is responsible for acquired immune deficiency syndrome (AIDS) – is being provided entirely by the NIH.

Cancer Vaccine Overview

In this section, we provide an overview of the cancer vaccine domain within the oncology landscape. Such vaccines are active immunotherapies, aimed at triggering the patient's immune system. These targeted therapeutic approaches do not constitute generalized immune system boosting; rather, they are designed to stimulate specific immune system components to attack the cancer cells, honing in on either single or multiple cancer-associated antigens. Examples of cancer vaccines include: tumor cell vaccines (e.g. Heat Biologics's HS-110, or the NewLink Genetics candidate algenpanteucel-L), antigen vaccines (e.g. Advaxis's ADXS-HPV for cervical cancer), dendritic cell vaccines (e.g. Dendreon Corporation's Provenge), DNA vaccines (e.g. Inovio Pharmaceuticals' VGX-3100 and INO-5150), and vector-based vaccines (e.g. Bavarian Nordic's ProstVac®).

A cancer vaccine may contain cancer cells, parts of cells, or purified tumor-specific antigens, and is designed to increase the targeted immune response against cancer cells already present in the patient. Cancer vaccines may be combined with other substances (either molecules or cells) called adjuvants, which are intended to help to boost the immune response even further. These vaccines generally fall into two categories: a) cell-based cancer vaccines, which are created using cells from the patient's own cancer that have been cultured with the patient's own immune cells; and b) vector-based cancer vaccines in which an engineered virus or other vector is used to introduce cancer-specific proteins and other molecules so as to stimulate the patient's immune system inside the body to recognize tumor cells and fight cancer. The figure below recapitulates many of the immune system processes, particularly the cycle of antigen uptake and presentation, which can be regulated by the introduction of cancer vaccines and utilized in order to redirect specific immune system components (such as the $CD8^+$ cytotoxic T lymphocyte response discussed earlier in this report) to attack tumors and circulating cancer cells.

Figure 2: Cancer Vaccine-Regulated Immune System Processes



Source: Nature Biotechnology (2011)

Both approaches are designed to stimulate the patient's own immune system to attack tumor cells. Cancer vaccines can either use the patient's own tumor cells directly in order to derive tumor-associated or tumor-specific antigens with which to "train" the patient's immune system, or utilize cancer cell lines that may be specific to the cancer type in question but that do not correspond directly to the patient being treated. The former are known as autologous vaccines (derived from the patient specifically), while the latter are termed allogeneic. In the case of cell-based vaccines, these activated immune cells from the patient are delivered back to the same patient with other immunostimulatory proteins – e.g., interleukin-2 (IL-2) – in order to further facilitate immune activation of these tumor antigen-primed immune cells. Vector-based vaccines can also be administered that carry both tumor-specific antigens as well as so-called costimulatory molecules, designed to increase the likelihood of an immune response.

The history of cancer vaccine development has been lengthy, arduous and filled with high-profile hype and disappointment. Recent widely-publicized pivotal trial setbacks for cancer vaccines included the failures of CancerVax's Canvaxin, a therapeutic polyvalent allogeneic whole-cell vaccine developed in 1984 from three different melanoma cell lines; Merck KGaA and Oncothyreon's Stimuvax (tecemotide or emepepimut-S), a liposomal peptide-based vaccine derived from the mucin 1, cell surface associated (MUC1) tumor-associated antigen; and, most recently, Agenus and GlaxoSmithKline's MAGE-A3, another peptide-based vaccine that also utilized the MUC1 antigen. Tellingly, all of these vaccines failed in late-stage trials in melanoma, a notoriously difficult indication even within the context of the overall cancer space. However, the table below shows how broad-based the scope of failure has historically been in the cancer vaccine domain. Multiple Phase 3 trials have missed their primary endpoints of either showing survival benefit or statistically significant tumor responses.

Table 3: Pivotal Cancer Vaccine Trial Failures

Name	Company	Phase	Mode of action	Indications	Class of vaccine
Insegia	Aphton Corp./Sanofi-Aventis	Preregis-tration	G17-like peptide conjugated to diphtheria toxin	Pancreatic cancer	Antigen specific
PANVAC-VF	Therion Biologics	III	CEA and MUC1 expressing recombinant virus	Pancreatic cancer	Antigen specific
Theratope	Biomira	III	Sialyl-Tn antigen	Breast cancer	Antigen specific
GMK	Progenics	III	GM2 ganglioside	Melanoma	Antigen specific
MDX-1379	Medarex/Bristol-Myers Squibb	III	gp100 melanoma peptides	Melanoma	Antigen specific
IGN-101	Igeneon	III	EpCAM-targeting monoclonal antibody	Breast cancer, NSCLC, colorectal cancer	Antigen specific
FavID	Favrille	III	Anti-idiotype patient-specific protein	NHL	Antigen specific
BiOVAXID	Biovest/Accentia	III	Anti-idiotype patient-specific protein	NHL	Antigen specific
MyVax	Genitope	III	Anti-idiotype patient-specific protein	NHL	Antigen specific
Allovectin-7	Vical	III	DNA plasmid/lipid complex encoding MHC-1 antigen	Melanoma, head and neck cancer	Antigen specific
GVAX	Cell Genesys	III	Allogeneic cell lines	Prostate cancer	Polyvalent
Canvaxin	CancerVax/Serono	III	Allogeneic whole cells	Melanoma	Polyvalent

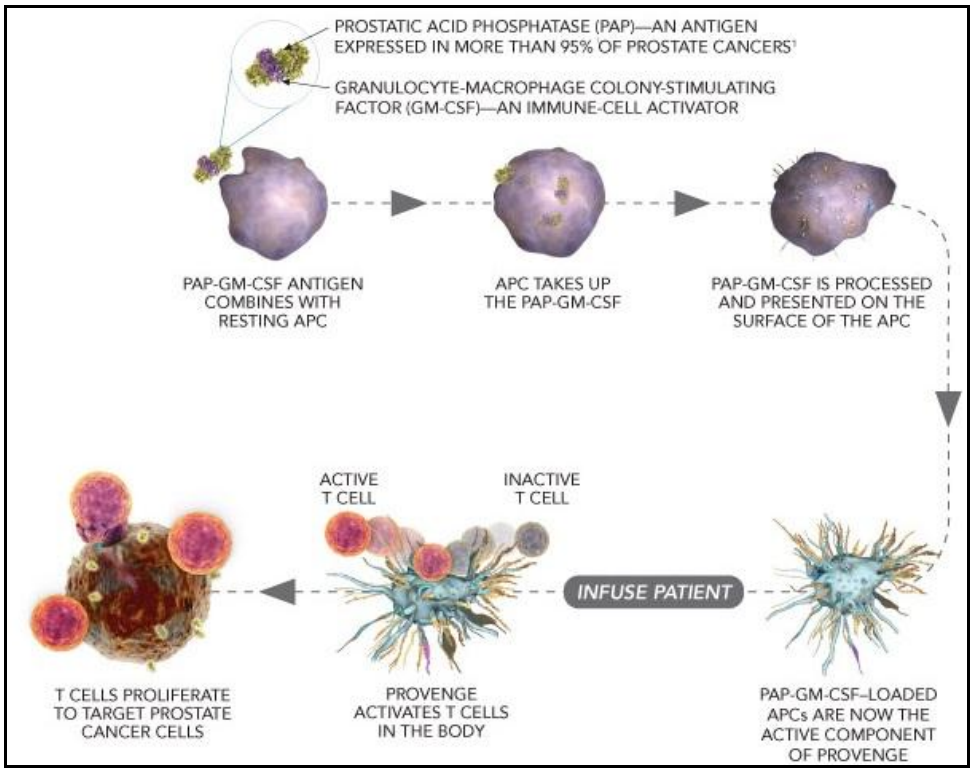
Source: Nature Biotechnology (2011)

From the above table, it may be seen that cancer vaccines have failed to show benefit in both liquid as well as solid tumor settings. Furthermore, different types of cancer vaccines have failed to show benefit. However, there are several potentially significant reasons for the historically poor performance of this class of therapeutics. Firstly, many of the above vaccine candidates were developed during a period when the function of the immune system and its relationship to cancer were poorly understood. For example, the camouflaging or "immune braking" role of molecules such as transforming growth factor beta (TGF-β) had not been fully characterized. In addition, the nature of antigen presentation and how to adapt this in order to ensure an optimal anti-tumor response by the patient's own immune system in the wake of receiving the vaccine were also "black box" areas. Accordingly, therefore, previous cancer vaccine product candidate development has suffered from a lack of understanding of the principal mechanisms that drive cancer-based immune privilege and the central ways in which this can be overcome.

However, in recent years there have been a number of notable advances that have led us to become more enthusiastic about the prospects of product candidates in the cancer immunotherapy arena. Firstly, looking at the antibody side of the ledger it is immediately clear that antibody-based therapeutic intervention has been extremely successful in the treatment of cancer. Many blockbuster drugs have been brought to market over the course of the past 20 years that invoke this paradigm – Avastin® (bevacizumab) in colorectal and other solid cancers; Herceptin® (trastuzumab), Perjeta® (pertuzumab) and Kadcyla® (trastuzumab emtansine) in breast cancer; Rituxan® (rituximab) in non-Hodgkin's lymphoma and other B cell-mediated malignancies; and various others.

In addition, immunostimulatory antibodies such as Yervoy® (ipilimumab) have demonstrated that it is possible to achieve clinically meaningful results in cancer therapy by modulating the activity of the immune system and destroying the ability of the cancer to evade cytotoxic attack by T lymphocytes. Yervoy® antagonizes the CTLA-4 antigen, which is used by tumor cells to avoid cytotoxic attack. This kind of evidence indicates that cancer vaccines should work, in principle. We believe, therefore, that it is simply a question of time and that the cancer vaccine space should continue to grow in strength and value over the course of the coming years. In addition, it was only in April 2010 that the first targeted cancer vaccine, Provenge® (sipuleucel-T), was approved in the U.S. The Provenge® mechanism of action is shown below.

Figure 3: Sipuleucel-T Mechanism of Action



Source: Dendreon Corporation

While the approval of Provenge® finally showed the life sciences community that a cancer vaccine could reach the market in the U.S., the product itself has not been commercially successful, hampered by an extremely expensive manufacturing process – since, as shown above, it is an autologous vaccine that must be prepared by isolating white blood cells from the patient's own blood via leukapharesis – and competitive pressure from other drugs in the prostate cancer space. We believe that drug candidates like those Heat Biologics is developing are unlikely to face similar issues, since they are allogeneic and thus would be far less expensive to manufacture on a commercial scale.

Table 4: Cancer Vaccine Competitive Landscape

Vaccine	Generic Name	Company	Type	Mechanism of Action	Status	Indications	Antigens
CRS-207 / GVAX	NA	Aduro BioTech	Tumor cell vaccine	GM-CSF-transfected tumor cell line-based antigen presentation	Phase 2	Pancreatic cancer	Multiple
CRS-207	NA	Aduro BioTech	Antigen vaccine	Live-attenuated Listeria vaccine expressing mesothelin	Phase 1	Mesothelioma	Single
CRS-207	NA	Aduro BioTech	Antigen vaccine	Live-attenuated Listeria vaccine expressing mesothelin	Preclinical	Non-small cell lung cancer	Single
ADU-623	NA	Aduro BioTech	Antigen vaccine	Live-attenuated Listeria vaccine expressing mesothelin	Preclinical	Glioblastoma	Single
Lm Prostate	NA	Aduro BioTech	Antigen vaccine	Live-attenuated Listeria vaccine expressing prostate antigens	Preclinical	Prostate cancer	Multiple
Lm Melanoma	NA	Aduro BioTech	Antigen vaccine	Live-attenuated Listeria vaccine with two melanoma antigens	Preclinical	Melanoma	Multiple
ADXS-HPV	NA	Advaxis	Antigen vaccine	Listeriolysin fusion protein-based antigen presentation	Phase 2	Cervical cancer	Single
ADXS-HPV	NA	Advaxis	Antigen vaccine	Listeriolysin fusion protein-based antigen presentation	Phase 1	Head and neck cancer	Single
ADXS-HPV	NA	Advaxis	Antigen vaccine	Listeriolysin fusion protein-based antigen presentation	Phase 1	Anal cancer	Single
ADXS-PSA	NA	Advaxis	Antigen vaccine	Listeriolysin fusion protein-based antigen presentation	Preclinical	Prostate cancer	Single
ADXS-cHER2	NA	Advaxis	Antigen vaccine	Listeriolysin fusion protein-based antigen presentation	Phase 1	Canine osteosarcoma	Single
Oncophage™	vitespen	Agenus	Antigen vaccine	Tumor-derived heat shock protein gp96 peptide complex	Marketed	Renal cell carcinoma	Multiple
Oncophage™	vitespen	Agenus	Antigen vaccine	Tumor-derived heat shock protein gp96 peptide complex	Phase 3	Melanoma	Multiple
HerpV	NA	Agenus	Antigen vaccine	QS-21 Stimulon adjuvant-containing herpes simplex vaccine	Phase 2	Herpes simplex 2 infection	Multiple
ProstVac®	NA	Bavarian Nordic	Viral vector vaccine	Vector with modified PSA and three co-stimulatory molecules	Phase 3	Prostate cancer	Single
CDX-011	rindopepimut	Celldex Therapeutics	Peptide vaccine	EGFRv3 peptide conjugated to keyhole limpet hemocyanin (KLH)	Phase 3	Glioblastoma	Single
Provenge™	sipuleucel-T	Dendreon Corp.	Dendritic cell vaccine	Autologous vaccine presenting prostatic acid phosphatase (PAP)	Marketed	Prostate cancer	Single
DN24-02	NA	Dendreon Corp.	Dendritic cell vaccine	Autologous vaccine presenting HER2/neu antigen	Phase 2	Bladder cancer	Single
NeuVax™	nelipepimut-S	Galena Biopharma	Peptide vaccine	E75 HER2-derived peptide antigen plus Leukine® (GM-CSF)	Phase 3	Breast cancer	Single
FBP-39	NA	Galena Biopharma	Peptide vaccine	E39 folate binding protein (FBP)-derived peptide plus GM-CSF	Phase 1 / 2	Endometrial / ovarian cancer	Single
MAGE-A3	NA	GlaxoSmithKline	Peptide vaccine	MUC1 antigen-derived 25-amino acid liposomal peptide formulation	Phase 3	Melanoma / lung cancer	Single
HS-110	NA	Heat Biologics	Tumor cell vaccine	Lung cancer cell line engineered to secrete gp96-tethered antigens	Phase 2	Non-small cell lung cancer	Multiple
HS-410	NA	Heat Biologics	Tumor cell vaccine	Bladder cancer cell line secreting gp96-tethered antigens	Phase 2	Bladder cancer	Multiple
HS-310	NA	Heat Biologics	Tumor cell vaccine	Ovarian cancer cell line designed to secrete gp96-tethered antigens	Preclinical	Ovarian cancer	Multiple
HS-210	NA	Heat Biologics	Tumor cell vaccine	Pancreatic cancer cell line secreting gp96-tethered antigens	Preclinical	Pancreatic cancer	Multiple
HS-510	NA	Heat Biologics	Tumor cell vaccine	Breast cancer cell line designed to secrete gp96-tethered antigens	Preclinical	Triple-negative breast cancer	Multiple
ICT-107	NA	ImmunoCellular Therapeutics	Antigen vaccine	Autologous dendritic cell vaccine	Phase 2	Glioblastoma multiforme	Single
ICT-121	NA	ImmunoCellular Therapeutics	Universal vaccine	Anti-CD133 response-focused vaccine (aimed at cancer stem cells)	Phase 1	Recurrent glioblastoma	Single
L-BLP25 (Stimuvax™)	tecemotide	Merck KGaA Oncothyreon	Peptide vaccine	MUC1 antigen-derived 25-amino acid liposome with adjuvant	Phase 3	Melanoma	Single
HyperAcute™	algenpanteucel-L	NewLink Genetics	Tumor cell vaccine	Tumor-specific cancer cell line (pancreas) expressing α-galactose	Phase 3	Pancreatic cancer	Multiple
HyperAcute™	tergenpumatucel-L	NewLink Genetics	Tumor cell vaccine	Tumor-specific cancer cell line (lung) expressing α-galactose	Phase 2b / 3	Non-small cell lung cancer	Multiple
DCVax®-L	NA	Northwest Biotherapeutics	Dendritic cell vaccine	Autologous dendritic cells activated with tumor antigens + adjuvant	Phase 3	Glioblastoma multiforme	Single
DCVax®-Prostate	NA	Northwest Biotherapeutics	Dendritic cell vaccine	Autologous dendritic cells activated with tumor antigens + adjuvant	Phase 3	Prostate cancer	Single
Lucanix®	NA	NovaRx	Tumor cell vaccine	Allogeneic cancer cell lines modified to block TGF-β secretion	Phase 3	Non-small cell lung cancer	None
Intuvac™-RCC	NA	Immunicum	Antigen vaccine	Intra-tumorally injected allogeneic dendritic cell vaccine	Phase 1 / 2	Renal cell carcinoma	Multiple
Intuvac™-Mel	NA	Immunicum	Antigen vaccine	Intra-tumorally injected allogeneic dendritic cell vaccine	Phase 1	Melanoma	Multiple

Source: Company Reports, Bloomberg BDRUG, Wolters Kluwer, ADIS R&D Insight

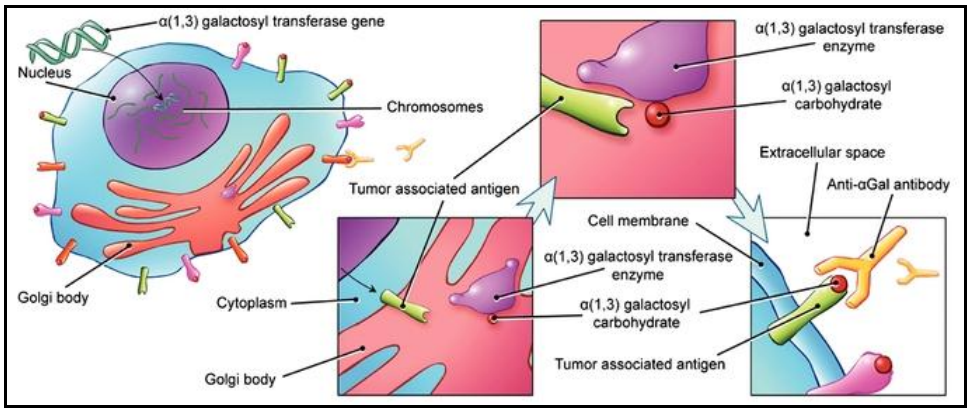
Allogeneic Cancer Vaccine Approaches

In this section, we discuss select companies that we consider to be the closest comparable entities to Heat Biologics because they are also developing allogeneic vaccine approaches, and typically utilize cancer cell lines in order to achieve this. However, following our due diligence on each of these programs, we remain convinced that Heat Biologics possesses a competitive edge against all of these companies and thus constitutes an undervalued and underappreciated investment opportunity.

NewLink Genetics – Ames, IA

An emerging firm in the cancer vaccine sector, NewLink Genetics is based at the Iowa State University Research Park in Ames, IA. The company was founded in 1999 and went public in 2012 on the NASDAQ Global Market. It possesses a technology platform that it calls the HyperAcute approach, with which it has generated several candidates to date. We believe that the HyperAcute approach, while scientifically sound, is inferior to the Heat Biologics platform in a number of key ways. Firstly, while both NewLink and Heat utilize tumor-specific cancer cell lines in order to stimulate the patient's immune system, NewLink's mechanism of action involves utilizing galactose-α-1,3-galactose (alpha-gal), a foreign molecule that is known to cause hypersensitivity and allergic reactions in human subjects. The immune reaction caused by alpha-gal is likely to be substantially less specific and therefore potentially less effective than the immune response stimulated by the Heat Biologics ImPACT™ approach. While the HyperAcute product candidates have thus far been tested in roughly 500 subjects with no significant safety issues, we cannot rule out the possibility of hypersensitivity reactions occurring in the future. This would not be a concern with the Heat Biologics ImPACT™ technology. The figure below depicts the mechanism of action for the NewLink Genetics platform.

Figure 4: Tumor Antigen Presentation Facilitated Via Alpha-Gal



Source: NewLink Genetics

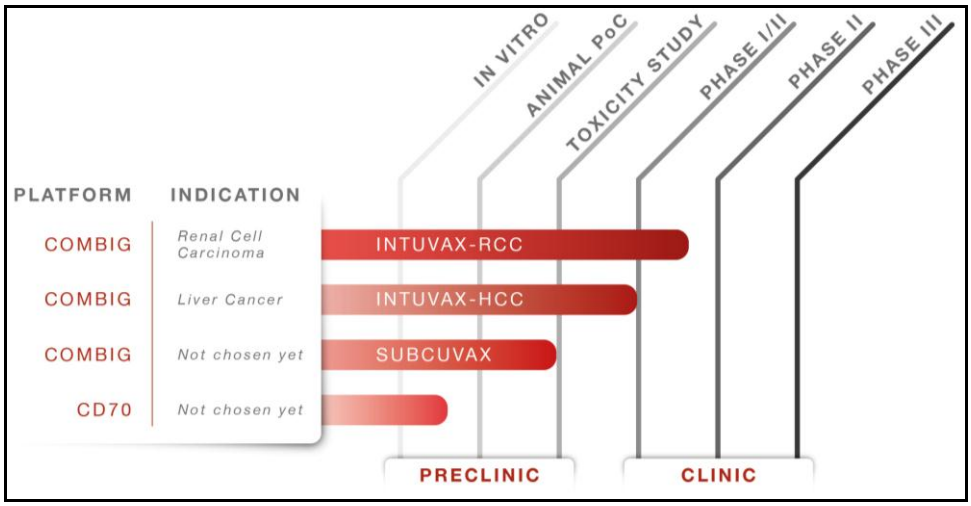
NewLink's lead product candidate, HyperAcute Pancreas (algenpantucel-L), is being studied in two Phase 3 clinical trials. In 2010, NewLink initiated its Phase 3 IMPRESS trial in patients with surgically resected pancreatic cancer. The company expects to complete patient enrollment in this trial in summer 2013 and plans to complete the first and second interim analyses of data from this study in early 2014 and mid-2014, respectively. We note that NewLink has stated publicly that the first interim look in the IMPRESS study would occur after 222 events have occurred, and that the company reported in August 2013 that this threshold had not yet been reached. In our view, positive interim data from the first analysis readout in the IMPRESS trial should not only bode well for NewLink but for Heat Biologics as well, since the NewLink HyperAcute technology platform and the Heat Biologics ImPACT™ approach are similar in concept.

The IMPRESS trial is being conducted under a Special Protocol Assessment (SPA) from the FDA. The HyperAcute Pancreas product candidate has received Fast Track and Orphan Drug designations from the FDA for the adjuvant treatment of surgically-resected pancreatic cancer. In addition, in 2012 the company initiated a Phase 3 clinical trial with HyperAcute Pancreas in patients with locally advanced pancreatic cancer. The firm's HyperAcute pipeline includes additional earlier stage product candidates focused on a number of other tumor types, including lung cancer, melanoma and renal cell carcinoma.

Immunicum AB – Gothenburg, Sweden

A spin-off from the Sahlgrenska University Hospital in Gothenburg, Immunicum is a nascent oncology-focused company with a novel cancer vaccine technology platform. The platform, which is called COMBIG, was developed on the basis of the idea that if the immune system undesirably rejects transplanted organs, perhaps it could be taught to (desirably) reject tumor tissue and cancer cells as well. Immunicum was in principle solely a basic research-focused startup until September 2007, when it was accepted into the local Chalmers Innovation's business incubator. Currently, the firm has one product candidate in human testing, with an overall portfolio of four projects protected by an issued Swedish patent, an issued European patent, and six other pending applications.

Figure 5: Immunicum AB Product Candidate Portfolio



Source: Immunicum AB

The COMBIG approach involves immunological principles underlying the acute rejection of transplanted organs. In solid organ transplantation – for the sake of illustration, assume a kidney transplant – patient and recipient are matched on the basis of human leukocyte antigen (HLA) comparison (so-called "HLA-matching") and should be matched as closely as possible in order to prevent rejection. If a donor kidney is not appropriately HLA-matched to the recipient, it can be rejected in either the acute or chronic setting. Acute rejection is mediated by donor antigen-presenting cells (dendritic cells or macrophages) that are transplanted along with the donor kidney. The donor dendritic cells migrate out of the donor kidney in the transplant recipient and some of the recipient T cells (usually $CD8^+$) can recognize antigens on the donor antigen-presenting cells (usually the HLA antigens) and become activated. Rejection in the chronic setting is different in that antigen presentation is not performed by the donor antigen-presenting cells, but instead by recipient antigen-presenting cells. These cells engulf and process donor HLA antigens from the transplanted kidney. Thus, acute rejection takes place when donor dendritic cells present donor HLA antigens to recipient T cells. Those T cells become activated against the HLA antigens. Since all the cells in the donor kidney also express these antigens, the T cells then attack the kidney, typically causing rejection.

The concept involves "tricking" the patient's immune system to mediate acute rejection of tumors by injecting those tumors with allogeneic dendritic cells. It is reasonable to believe that the injection of allogeneic dendritic cells could stimulate inflammation both in the tumor microenvironment and in tumor draining lymph nodes, and this inflammation could conceivably facilitate activation of tumor specific T cells through a bystander-like effect. However, in our view the preclinical data that Immunicum cites as evidence does not clearly support this conclusion, and the data collected to date are limited to *in vitro* studies and prophylactic – not therapeutic – tumor models in rodents. Importantly, the main effector mechanism mediating acute rejection of transplanted organs is not active in this system because, unlike transplanted organs, the tumor into which these dendritic cells are injected are not allogeneic and therefore do not express allogeneic HLA antigens. Thus, this is not a true "allo-reaction", as the company claims.

Although this is not an autologous product, there are several complicated steps to its commercialization. The company is developing its product from plasmapheresis from healthy donors. Although not as problematic as collecting autologous material, this is still a complicated manufacturing process that will be very difficult to both standardize and bring to scale. Basic questions such as the predicted ratio of donors to patients, sterility and comparability procedures from donor to donor, among other issues, have not yet been clearly addressed. Furthermore, the drug must be injected intra-tumorally using image-guided methods. This is expensive and complicated. More crucially, there is no preclinical evidence demonstrating that intra-tumoral injection into any particular lesion leads to any discernible effect on metastatic lesions. This is clearly a critical question for the clinical setting that Immunicum is pursuing with its main program (metastatic renal cell carcinoma). In summary, therefore, we believe that – while Immunicum should bear watching in the months and years to come – the technology does not currently appear mature enough to be considered a real threat to the Heat Biologics ImPACT™ platform. Even if the concept were to be proven in human studies, the COMBIG platform appears to be inferior from both a manufacturing as well as a clinical feasibility perspective.

NovaRx – San Diego, CA

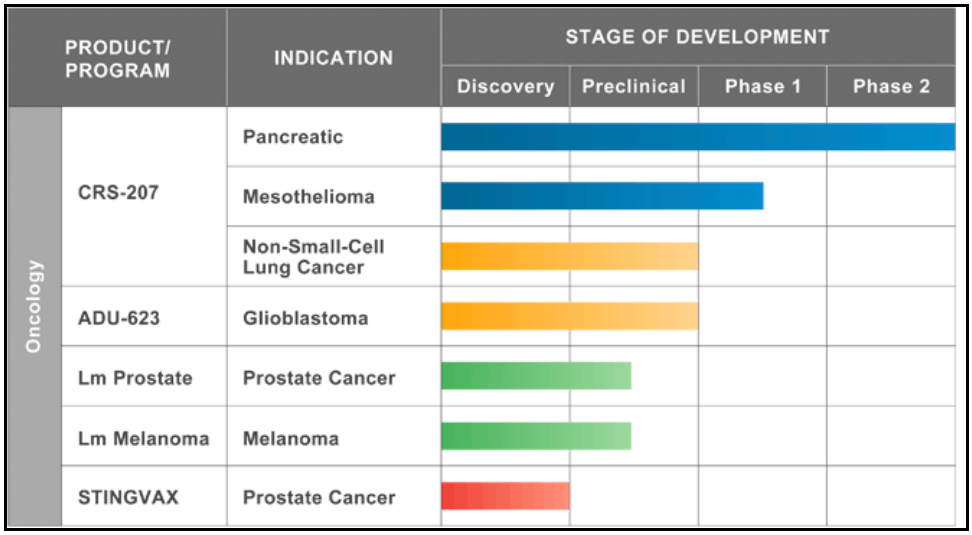
This firm was founded in May 1997 on the scientific research of Dr. Habib Fakhrai at the Sidney Kimmel Cancer Center in San Diego, CA and at the College of Medicine of the University of California at Los Angeles. The crux of this work was the discovery that transforming growth factor-beta (TGF-β), long known as a key effector molecule and cytokine, could turn off the activation of cytotoxic immune cells. Cancer cells produce substantial amounts of TGF-β. NovaRx's lead product candidate is Lucanix®, a cell-based therapeutic vaccine for patients with non-small cell lung cancer (NSCLC). In contrast to conventional cancer therapies, where systemic chemotherapeutic drugs nonspecifically kill normal cells as well as tumor cells, Lucanix® induces a patient's immune system to specifically target the cancer. The drug consists of four NSCLC cell lines that have been recombinantly genetically modified to block the secretion of TGF-β.

The vaccine was tested in a Phase 2 clinical trial. In the trial, advanced stage NSCLC patients (stages IIIB and IV) who had received 0 – 5 prior cycles of chemotherapy demonstrated one-year survival of 61% and two-year survival of 41%, with median survival being 16 months. The FDA subsequently granted NovaRx Fast-Track and Special Protocol Assessment approval for the Phase 3 Lucanix® trial. This study commenced in August 2008 and NSCLC patients are being treated in the trial globally. However, given the fact that this vaccine works primarily by aiming to reduce cancer cells' immune privilege and does not actively induce a cytotoxic T lymphocyte response, and considering how long the Phase 3 trial has taken thus far, we do not regard this firm as a credible competitor to Heat Biologics either. Indeed, even if NovaRx were to succeed with Lucanix®, it is possible to envisage HS-110 and Lucanix® being used concomitantly as their mechanisms of action should in theory be complementary.

Aduro BioTech – Berkeley, CA

A privately-held immunotherapy-focused firm, Aduro BioTech is developing a group of cancer vaccines based on the principle of combination immunotherapy. The firm has three distinct technology platforms – the GVAX vaccines, which are – analogous to the Heat Biologics and NewLink Genetics approaches – based on human cancer cell lines that are genetically modified to secrete granulocyte-macrophage colony-stimulating factor (GM-CSF), an immune-stimulatory cytokine; the live, attenuated Listeria platform focused on effective presentation of single tumor-associated antigens to the immune system; and the cyclic dinucleotide (CDN) platform, which focuses on CDN molecules secreted by Listeria that signal through the so-called STING receptor and induce immune responses. Aduro has already combined its proprietary CDNs with GVAX in a novel vaccine product candidate and has shown superiority vs. GVAX alone with this combination approach in animal models.

Figure 6: Aduro BioTech Product Candidate Portfolio



Source: Aduro BioTech, Inc.

In February 2013, Aduro BioTech, Inc. announces the acquisition of all GVAX assets from BioSante Pharmaceuticals, Inc., the original holder of the rights to this technology. Aduro previously licensed two GVAX vaccines, GVAX Pancreas and GVAX Prostate, for use in combination with its Listeria-based vaccines. The most recent acquisition covers all uses and includes additional vaccines for multiple myeloma and breast and colon cancer and assumes rights to the existing license agreement for GVAX Melanoma. Aduro paid $1 million upfront to BioSante (now known as Ani Pharmaceuticals, Inc.) and has committed to pay additional milestone and royalty payments upon the successful commercialization of any GVAX products.

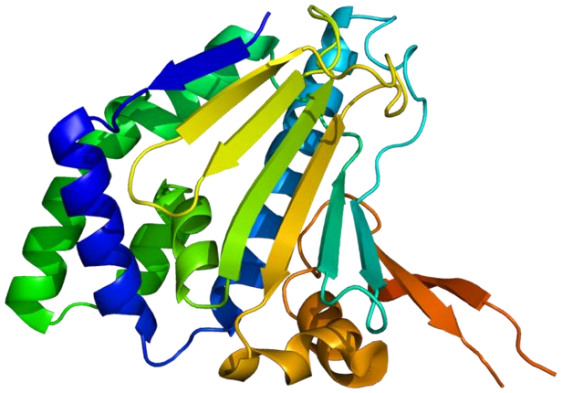
While we consider Aduro an intriguing prospect in the cancer immunotherapy field because of its broad pipeline and access to multiple technology platforms, we note that the GVAX vaccine approach has thus far not demonstrated success in pivotal trials and that it is not designed – unlike the Heat Biologics platform – to present tumor-associated antigens to the immune system in a manner known to elicit a powerful $CD8^+$ cytotoxic response. Accordingly, therefore, we do not view Aduro as a direct threat to Heat Biologics at this juncture. We would also remind investors that the GVAX technology platform has not performed creditably in the pivotal trial setting – in early 2009, Cell Genesys (the then-owner of the technology) reported negative results from a Phase 3 trial conducted in prostate cancer with GVAX immunotherapy vs. Taxotere.

ImPACT™ Technology Platform Overview

Heat Biologics possesses exclusive rights to a therapeutic approach initially formulated by the group of Dr. Eckhard Podack at the University of Miami. This platform relies upon the function of the gp96 protein (HSP90B1). It aims to "train" the immune system to recognize otherwise immune-privileged cancer cells and elicit a powerful anti-tumor response triggered by cytotoxic T lymphocytes (CTLs).

Heat shock protein 90kDa beta member 1 (HSP90B1), known also as endoplasmin, gp96, grp94 and ERp99, is a chaperone protein, encoded in humans by the HSP90B1 gene, which is classified as an HSP90 paralogue found in the endoplasmic reticulum. It plays roles in folding secretory pathway proteins such as Toll-like receptors and integrins, and functions as an essential immune chaperone regulating innate and adaptive immunity.

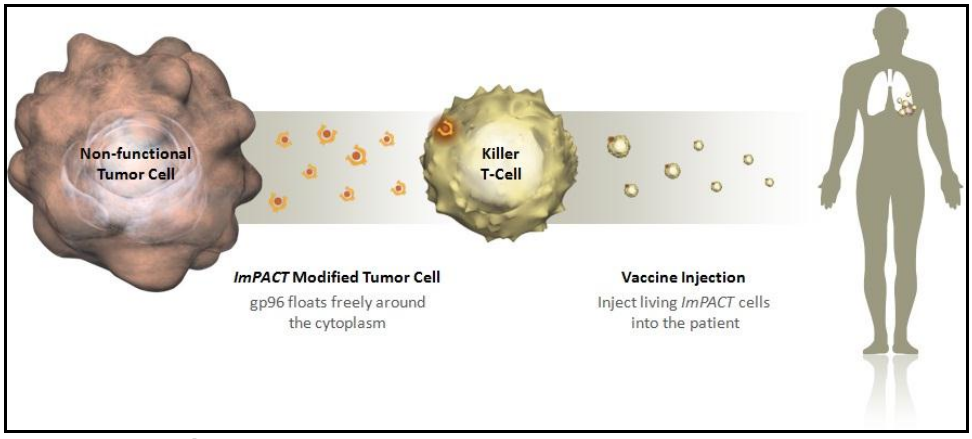
Figure 7: HSP90B1 (gp96) Protein Structure



Source: Brookhaven Protein Data Bank

The main innovation from Dr. Podack's group was the discovery of a way to sever the peptide "leash" that binds gp96 to the cell surface. Following this, cancer cell lines engineered to express antigens bound to gp96 effectively secrete gp96-encapsulated antigens into their immediate surroundings, mimicking the consequences of necrotic cell death. These antigens constitute the basis for the CTL-mediated anti-tumor response that is elicited via the ImPACT™ technology platform[4].

Figure 8: gp96 Linker Technology

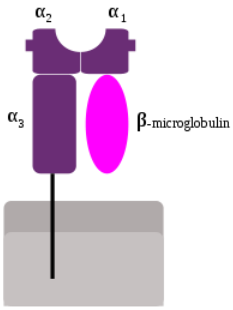


Source: Heat Biologics

[4] Oizumi *et al.*, Journal of Immunology 179: 2310-2317 (2007)

The gp96 chaperone associates with the endoplasmic reticulum, where "loading" of antigens for presentation to the major histocompatibility complex (MHC) Class I set of molecules – in humans, the human leukocyte antigen (HLA) complex – governing antigen presentation to CTLs. Unlike the NewLink Genetics methodology, hypothesized to result in broad-based immune activation (including activation of a subset of $CD8^+$ CTLs), the Heat Biologics system specifically enhances activation of $CD8^+$ CTLs, since it employs the only agent involved in MHC Class I-mediated antigen presentation.

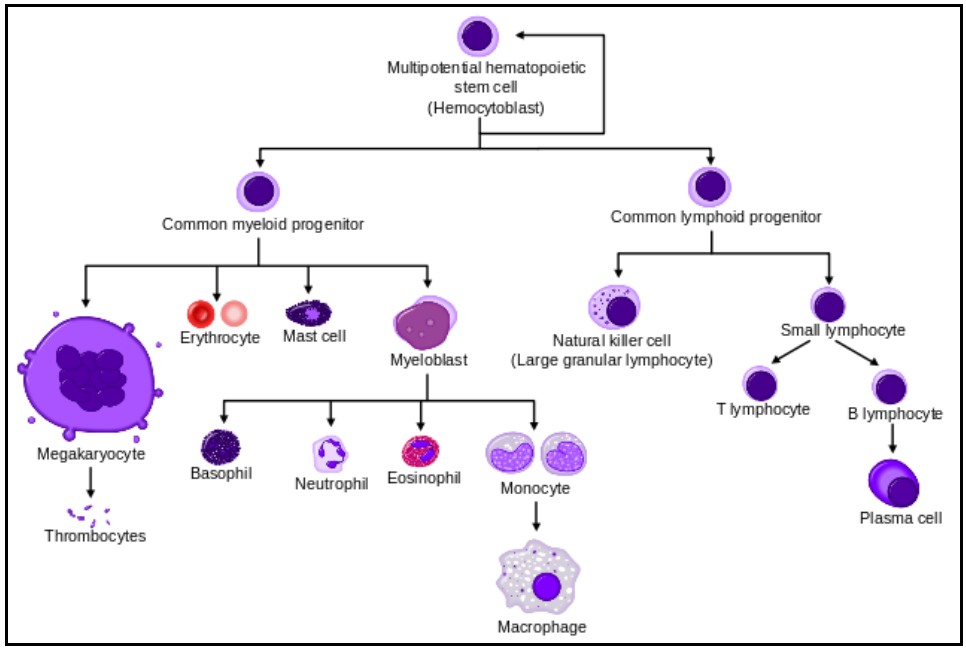
Figure 9: Major Histocompatibility Complex Class I Structure



Source: Alex Tropos, Grand Rapids, MI

The so-called "classical" MHC Class I molecules present epitopes to $CD8^+$ CTLs. When the CD8 cell surface proteins on the surfaces of $CD8^+$ CTLs docks to the MHC Class I – if its T cell receptor (TCR) recognizes its matching epitope – the killer T cell induces apoptosis of the target cell expressing the MHC class I-associated epitope. Thus, MHC Class I molecules help to mediate cellular immunity. MHC Class I occurs as an α chain composed of three domains—α1, α2, α3. The α1 rests upon a unit of the non-MHC molecule β2 microglobulin. The peptide being presented is held by the floor of the peptide-binding groove, in the central region of the α1/α2 heterodimer (a molecule composed of two non-identical subunits). The amino acid sequence of the peptide-binding groove's floor determines which particular peptide residues it binds. The figure below depicts the lineage of immune cells (T lymphocytes shown on the right).

Figure 10: Immune System Cell Lineage

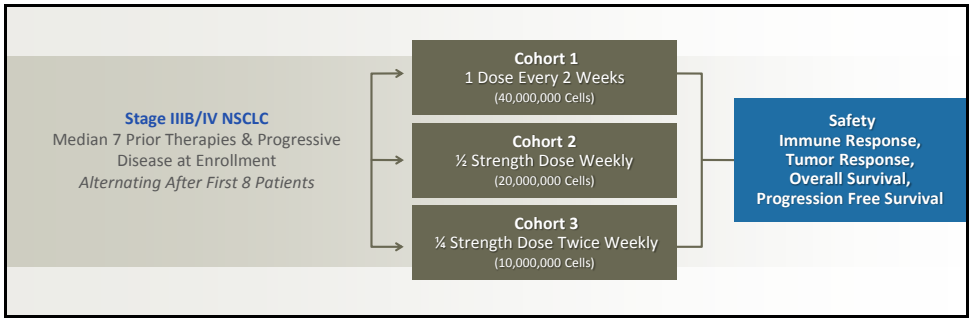


Source: Mikael Häggström, Uppsala, Sweden

Lung Cancer Clinical Data Overview

The design of the Phase 1 trial that was conducted with HS-110 in lung cancer patients is depicted in the schematic below. This was an entirely NIH-funded, open-label, single-center trial performed under an investigator-initiated IND, which enrolled 18 patients with late-stage NSCLC. Participants in this trial had previously failed multiple rounds of standard-of-care chemotherapy (including treatment with various platinum agents).

Figure 11: HS-110 NSCLC Phase 1 Trial Design



Source: Heat Biologics

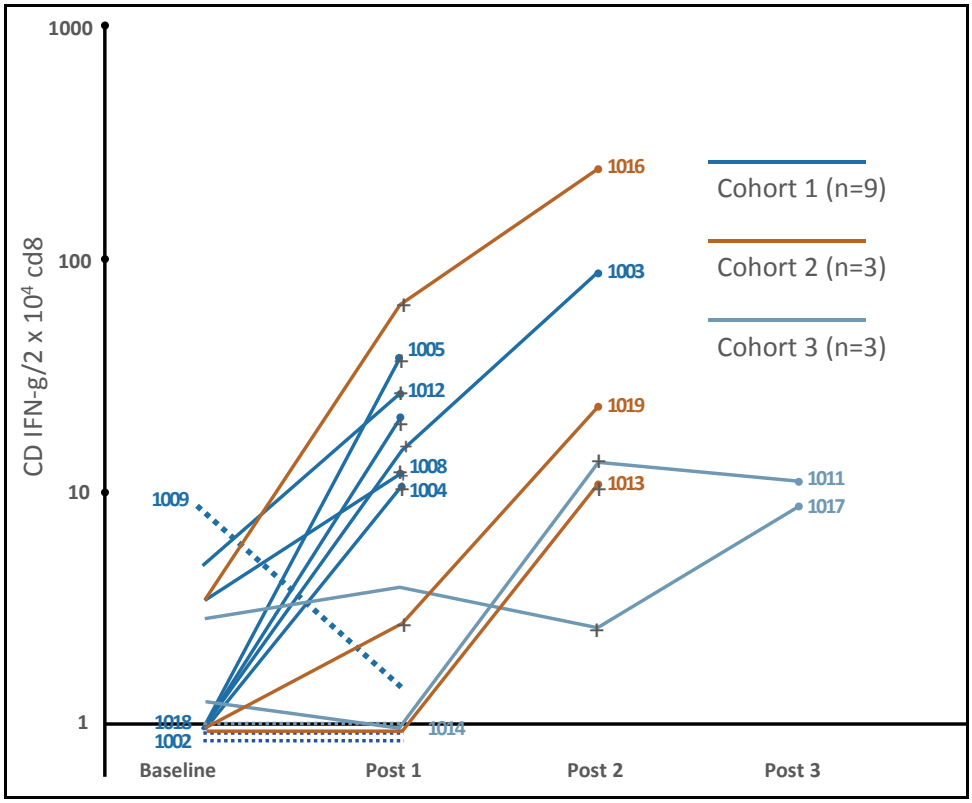
This patient population had histologically or cytologically confirmed malignant solid tumors that had relapsed or proven refractory to standard therapy, and had received prior radiation therapy with stable CNS metastasis and no progression of brain metastases as assessed via CT/MRI scan in the prior four weeks. Life expectancy was > three months. Among the 18 patients treated, 15 completed the first course of therapy, while two patients completed three courses of therapy. The key findings were as follows:

- HS-110 administration was well-tolerated with no overt toxicity and no treatment-related SAEs
- Single-agent clinical activity was observed in late-stage 3b and 4 lung cancer
- As is typical in immunotherapy, no observed partial or complete responses
- Seven patients exhibited stable disease after single course of therapy
- A clear and robust immune response was observed in 73% (11 out of 15) of patients who completed their first course of therapy
- The immune response was shown to be predictive of survival (HR: 0.021, 95% CI:0.002-0.204)
- The 11 immune responders exhibited a median survival of 16.9 months (95% CI: 7.1-20) while the four immune non-responders exhibited a median survival of 4.5 months, which is consistent with the expected survival times in this patient population
- Two late-stage patients have survived for >3 years; one HS-110 patient remains alive >3 years after treatment, and another patient is still alive >4 years later
- The median one-year overall survival rate of patients in the study was 44% (95% CI: 21.6-65.1), comparing highly favorably to a 5.5% rate based on published data from a 43-patient advanced NSCLC population

We believe that there are two principal takeaways from this. It has not escaped our attention that the vast majority of single-center, open-label, non-randomized studies in oncology do not typically turn out to be reproducible in a controlled, more robustly-powered context. However, we would point out that a) the survival impact seen here was quite striking, even in such a small patient population; and b) there was a clear mechanistic rationale for why the responders performed so well and this dovetails highly plausibly with the mechanism proposed for the drug itself.

The figure below depicts the results of immune response characterization assessments that were performed on the patients who were treated in this Phase 1 trial. Essentially, these measurements were conducted in order to ascertain whether specific immune system sub-components were being preferentially activated – which was the basis for the entire hypothesis underlying the ImPACT™ platform. Samples were collected for immune response analysis at baseline and after a minimum of one six-week course of therapy. In order to determine the frequency of $CD8^+$ cytotoxicity, $CD8^+$ T lymphocytes were collected from patients and stimulated with vaccine.

Figure 12: HS-110 Sub-Cohort Immune Response Analysis



Source: Corporate presentations

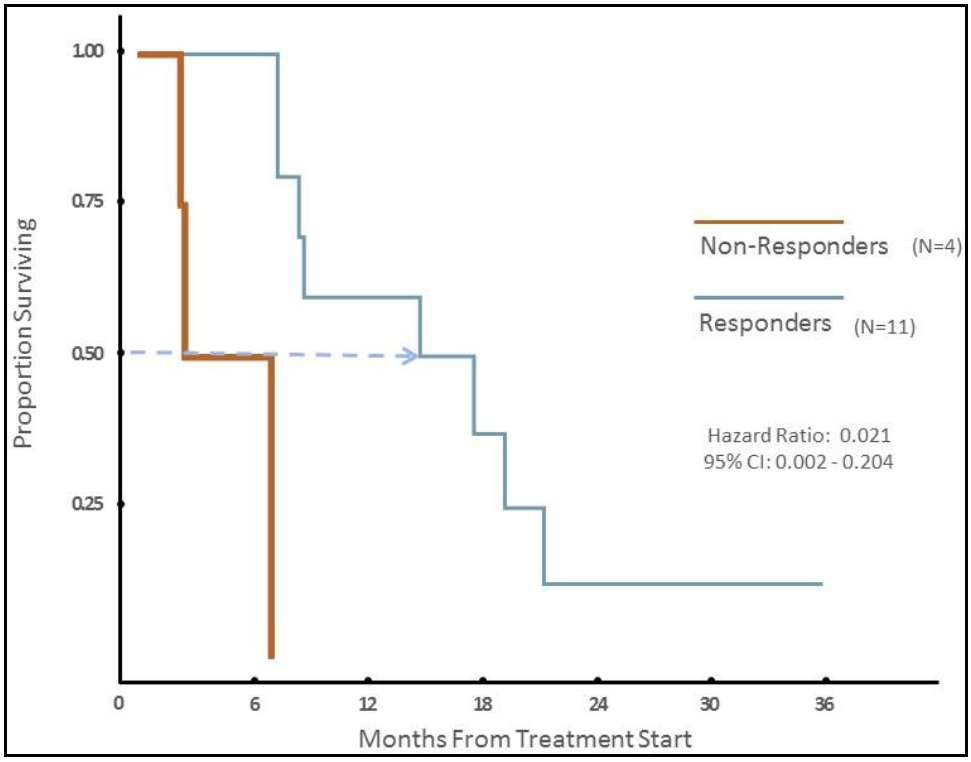
The results indicated that, in 11/15 patients assessed, 73% showed a >2-fold increase in $CD8^+$ T cells secreting measurable amounts of interferon-gamma (IFN-γ). We believe that this data represents a reasonable indicator of drug activity; IFN-γ is a well-known pro-inflammatory cytokine that is considered a reliable marker of cytotoxicity[5] and that accompanies the expression of potent cell-killing factors such as perforin and granzyme B[6]. The fact that $CD8^+$ cytotoxic T lymphocytes activated against tumor antigens express these kinds of T_H1 cytokines means that they have substantially better cytotoxic impact on tumor cells than predominantly T_H2 lymphocytes. Essentially, the data depicted above indicate that HS-110 appears capable of reliably inducing a substantial $CD8^+$ cytotoxic response. The next question to answer is whether this correlates to survival.

As mentioned earlier, the survival data from this Phase 1 study appeared to show a significant benefit for immune responders vs. non-responders. What factors specifically drove lack of response in certain patients are unclear at this juncture. It is also necessary to note that the data indicating a correlation between immunological responses and

[5] He *et al.*, Medical Oncology 29: 2261-2269 (2012)
[6] Tajima *et al.*, International Immunology 23: 751-759 (2011)

survival was not generated based on a pre-specified analysis. However, the numbers are certainly noteworthy – a roughly three-fold increase in survival time (4.5 months → 16.9 months) if a patient was a responder vs. a non-responder, along with an extremely low hazard ratio of only 0.021. The fact that this was seen in a patient population of only 18 individuals provides us with some confidence that this was a real observation and not an artifact. Nevertheless, confirmation of the validity of this result needs to be obtained in larger studies, including the Phase 2 trial that Heat plans to commence near-term. In our view, if this kind of survival benefit can be confirmed, Heat Biologics should be able to obtain Breakthrough Therapy designation from the FDA on this product candidate.

Figure 13: HS-110 Sub-Cohort Immune Response Analysis



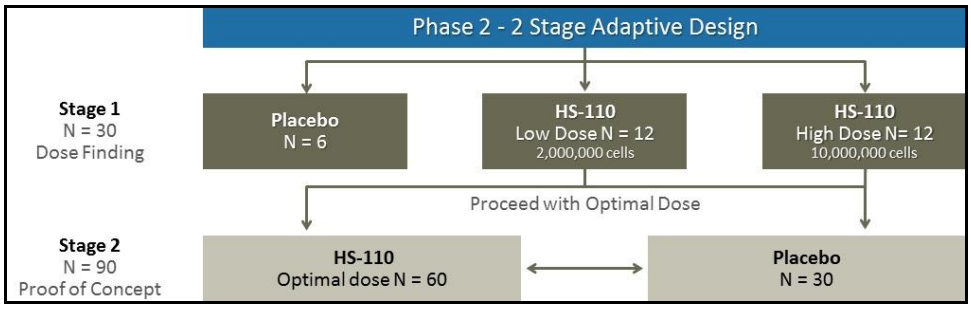
Source: Corporate presentations

The data from the Phase 1 trial appears to confirm the results of Dr. Podack's own experiments in animal models. We are also encouraged by the fact that various trials with different immunotherapeutic approaches in cancer have demonstrated similar findings – i.e. the format of antigen presentation is extremely crucial; the specific immune cell population that is activated is likely to have a significant impact on efficacy; and tumor-reactive T lymphocytes already exist in the body but because of endogenous immunological masking by tumor cells, they do not demonstrate any substantial tumor-killing impact. In other words, they need, according to Dr. Podack, to be "woken up." In murine studies, tumor cell-secreted gp96 fusion proteins induced specific $CD8^+$ cytotoxic T lymphocyte (CTL) expansion and, when used as a vaccine, mediated tumor rejection and long-lasting tumor immunity by $CD8^+$ cells with the help of natural killer (NK) cells[7]. Murine preclinical data suggest that human tumor cells secreting gp96-fused antigens could constitute a powerful, therapeutic $CD8^+$ CTL vaccine, because gp96-fused antigens provide both the adjuvant effect and the specific peptides for dendritic cell activation and presentation to cytotoxic T lymphocytes[8].

[7] Schreiber *et al*., Cancer Research 69: 2026-2033 (2009)
[8] Podack and Raez, Expert Opinion on Biological Therapy 7: 1679-1688 (2007)

We note that HS-110 is likely to arouse interest from strategic buyers and potential licensees only upon achievement of statistically significant impact in a proof-of-concept, randomized Phase 2 study. The proposed trial design – an adaptive design, two-stage approach – is shown below; Heat Biologics already has an open IND in the U.S. for HS-110 in the treatment of NSCLC, under which this study is proposed to be conducted.

Figure 14: HS-110 NSCLC Phase 2 Proof-of-Concept Trial Design



Source: Corporate presentations

Inclusion criteria would comprise enrollment of Stage III / IV NSCLC patients, who have undergone prior therapy with platinum doublet chemotherapeutic agents, Tarceva (erlotinib) or Xalkori (crizotinib) as first-line treatment and who achieved a clinical response (either complete or partial in nature) or disease stabilization following administration of the initial front-line therapy. The principal objectives in this study would be dose-finding and safety (in Stage 1) and the impact of HS-110 therapy on progression-free survival (in Stage 2). We anticipate that enrollment in Stage 1 of the above-described trial could be completed within four to six months of initiating the study. In our view, immune response data and PFS readouts could be available in the second half of 2014. If this data demonstrates the same strong correlation between immune responses following HS-110 administration and survival, we believe that Heat Biologics could be in position to apply to the FDA for Breakthrough Therapy designation to be applied to HS-110. Assuming that positive data is generated in Stage 1, we believe that advancement of HS-110 into Stage 2 and completion of this phase is likely to take an additional 8 – 10 months. The study could be completed in mid-2015. If a clear PFS signal is observed in Stage 2 of the trial, we believe that Heat Biologics could secure a development and marketing partner relatively swiftly after that data release.

Breakthrough Therapy Designation

We consider it advisable at this juncture to provide investors with a few key perspectives on Breakthrough Therapy designation. This is a relatively new regulatory pathway at the FDA that was designed specifically to accelerate the approval of novel, highly effective therapeutic approaches aimed at addressing significant unmet medical needs. While Breakthrough Therapy designation does not automatically guarantee drug approval, it implies a substantially shorter path to commercialization than is typically the case with standard drug development. Breakthrough Therapy designation can substantially reduce drug review times at the FDA, and, perhaps most crucially, can specify that a drug aimed at a major life-threatening condition – such as advanced NSCLC – can be approved on the basis of relatively small patient data sets, as long as the efficacy evidence is compelling. On the following page, we provide a list of drug candidates to which the FDA has assigned Breakthrough Therapy designation, along with the number of patients in whom these drugs were tested prior to receiving such designation. We believe that this evidence indicates potential for HS-110 to receive Breakthrough Therapy designation if the drug shows potent activity in Stage 1 of the proposed Phase 2 NSCLC trial. However, we note that Heat Biologics would need to apply for such designation and that it is not assigned to drug candidates automatically by the FDA.

Table 5: Breakthrough Therapy Designation Drug Candidates

Drug Name	Generic	Mechanism of action	Developers	Indications	Stage Granted	Patients Tested
Kalydeco / Kalydeco + VX-809	ivacaftor / ivacaftor + lumacaftor	CFTR potentiation	Vertex Pharmaceuticals	Cystic fibrosis	Phase 1	72 patients
PCI-32765	ibrutinib	Covalent Bruton's tyrosine kinase inhibitor	Pharmacyclics	Leukemia / lymphoma	Phase 2	80 patients
LDK378	NA	Selective ALK inhibitor	Novartis	ALK-positive non-small cell lung cancer	Phase 2	612 patients
PD-0332991	palbociclib	Selective cyclin-dependent kinase inhibitor	Pfizer	Metastatic breast cancer	Phase 2	30 patients
MK-3475	lambrolizumab	Anti-PD-1 monoclonal antibody	Merck & Co.	Advanced melanoma	Phase 2	300 patients
BMS-790052 / BMS-650032 / BMS-7913325	daclatasvir / asunaprevir / BMS-791325	NS5A / NS3 protease inhibition	Bristol-Myers Squibb	Hepatitis C infection	Phase 2	296 patients
SD-101	NA	Not disclosed	Scioderm	Epidermolysis bullosa	Phase 2	NA
HuMax®-CD38	daratamumab	Anti-CD38 monoclonal antibody	Genmab / Johnson & Johnson	Double refractory multiple myeloma	Phase 2	178 patients
ABT-450/r / ABT-267 / ABT-333	ABT-450 / ritonavir / ABT-267 / ABT-333	Protease / nucleoside polymerase inhibition	AbbVie	Hepatitis C infection	Phase 2	79 patients
GA101	obinutuzumab	Anti-CD20 monoclonal antibody	Roche	Chronic lymphocytic leukemia	Phase 3	787 patients
SBC-102	sebelipase alfa	Recombinant lysosomal acid lipase	Synageva BioPharma	Lysosomal acid lipase (LAL) deficiency	Phase 3	29 patients
ENB-0040	asfotase alfa	Alkaline phosphatase targeting enzyme	Alexion Pharmaceuticals	Pediatric-onset hypophosphatasia	Phase 2	48 patients
RLX030	serelaxin	Recombinant relaxin-2 hormone	Novartis	Acute heart failure	Phase 2	71 patients
GSK2402968 (PRO051)	drisapersen	Exon-skipping RNA-based inducer	GlaxoSmithKline / Prosensa	Duchenne muscular dystrophy	Phase 1/2	35 patients
Firdapse™	3,4-diaminopyridine	Potassium channel blocker	Catalyst Pharmaceutical Partners BioMarin Pharmaceuticals	Lambert Eaton myasthenic syndrome	Phase 3	30 patients

Source: Food and Drug Administration; ClinicalTrials.gov (http://www.clinicaltrials.gov/), EvaluatePharma

Lung Cancer Competitive Landscape

Cancer of the lung has the highest mortality rate of all cancers and is the second most commonly-diagnosed cancer in both men and women; such cancers are aggressive and treatment remains a challenge. Molecular targeted agents have had a major impact on the treatment of NSCLC – the most common form of lung cancer, which is estimated to comprise 80% – 85% of all such malignancies – in the past decade. As a result, there is now a range of personalized approaches available to treat the disease. In fact, the NSCLC indication is now a leader in the domain of personalized medicine. With the entry of these new targeted therapies, as well as new options in other categories such as immunotherapy – which includes the approach being developed by Heat Biologics – the NSCLC market is expected to grow to over $6 billion in 2020, according to Thomson Reuters' market research tool Cortellis™. This growth is considered likely despite the generic/biosimilar erosion of sales of cytotoxic agents currently used in the management of the disease. We note that substantial growth in the prevalence and incidence of lung cancer is likely in the coming years among the emerging markets of the world, as these geographies continue to exhibit a high propensity for tobacco consumption (i.e. smoking), poor air quality, and significant atmospheric pollution. In particular, smoking rates in emerging markets such as China and India are likely to remain high well into this century, making it highly likely that the overall global population of individuals suffering from NSCLC will increase significantly in the coming years.

As oncology moves away from a "one size fits all" strategy in cancer therapy, by identifying markers that reliably predict which patients will benefit from treatment, so drug development in lung cancer has increasingly focused on molecular targets. There are three common gene mutations which have been identified in non-squamous NSCLC to date: EGFR, KRAS, and ALK. Approximately 10% – 15% of patients harbor EGFR mutations and are best treated with EGFR inhibitors, while a recently-approved ALK inhibitor (Pfizer's Xalkori, or crizotinib) is used for a subset of NSCLC patients with an ALK kinase rearrangement. As yet, there is no drug approved for use in lung cancer patients exhibiting KRAS mutations. Less success has been noted with molecular targeting in squamous-cell NSCLC, with no targeted therapies being widely utilized to date. However, numerous directions are currently being explored.

One-year survival rates for advanced NSCLC (40% – 45%) have been increasing, but the five-year survival rate remains at roughly 15%. Except for patients with tumors harboring an EGFR-sensitizing mutation, the recommended first-line treatment strategy in NSCLC is a two-drug combination (doublet), involving a platinum compound and a third-generation chemotherapeutic agent. Four cycles are given in stable disease and up to six in cases of objective response. The platinum-containing drug is usually cisplatin or carboplatin; cisplatin is associated with slightly improved response rates, but increased toxicity compared with carboplatin. Chemotherapy agents included in the doublet are typically docetaxel, paclitaxel, vinorelbine or Gemzar (gemcitabine), and latterly Alimta (pemetrexed); Alimta combined with platinum chemotherapy is now considered the standard-of-care regimen in patients with non-squamous NSCLC, while patients with squamous cell NSCLC typically receive Gemzar, vinorelbine, or a taxane plus platinum chemotherapy. Disease progression typically means that 50% – 70% of NSCLC patients will receive second-line therapy and 25% – 35% receive a third-line regimen. Refractory patients can also receive further chemotherapy (any drug not included in their earlier regimens). Docetaxel was the first drug approved in second-line chemotherapy, followed by Alimta, Tarceva (erlotinib) and Iressa (gefitinib). The table on the following page lists the currently-approved drugs used in NSCLC. Multiple targeted therapeutic agents are currently in development for NSCLC as well; however, we have elected to focus on marketed agents because we believe that these regimens are of greatest relevance when considering the future clinical development and commercial path of HS-110 in NSCLC.

Table 6: Non-Small Cell Lung Cancer (NSCLC) Approved Therapeutic Agents

Drug	Generic Name	Company	Patent Expiry	Drug Class	Mechanism of Action
Gilotrif	afatinib maleate	Boehringer Ingelheim	NA	HER2/EGFR dual tyrosine kinase inhibitor	growth factor receptor blockade
Xalkori	crizotinib	Pfizer	March 2025	ALK / ROS1 inhibitor	protein kinase inhibitor
Abraxane	albumin-stabilized paclitaxel	Celgene Corporation	2024 (U.S.) / 2018 (E.U.)	Nanoparticle-formulated taxane	mitosis inhibition
Tarceva	erlotinib hydrochloride	Roche / Genentech	November 2020	EGFR tyrosine kinase inhibitor	growth factor receptor blockade
Alimta	pemetrexed	Eli Lilly & Co.	July 2016	Folate antimetabolite	purine / pyrimidine synthesis inhibitor
Avastin	bevacizumab	Roche / Genentech	2019 (U.S.) / 2022 (E.U.)	Anti-VEGF monoclonal antibody	angiogenesis blockade
Iressa	gefitinib hydrochloride	AstraZeneca	May 2017	EGFR tyrosine kinase inhibitor	growth factor receptor blockade
Taxotere	docetaxel	Sanofi S.A.	July 2012	Taxane	microtubule stabilizer
Gemzar	gemcitabine hydrochloride	Eli Lilly & Co.	November 2010	Nucleoside analog	DNA replication inhibitor
Paraplatin	carboplatin	Bristol-Myers Squibb	October 2004	Platinum-based chemotherapeutic	DNA crosslinker (blocks cell division)
Navelbine	vinorelbine	Pierre Fabre	February 2003	Vinca alkaloid	microtubule stabilizer
Taxol	paclitaxel	Bristol-Myers Squibb	Expired	Taxane	microtubule stabilizer
Platinol	cisplatin	Various	Expired	Platinum-based chemotherapeutic	DNA crosslinker (blocks cell division)

Source: Food and Drug Administration, European Medicines Agency, Wolters Kluwer

Lung Cancer Market Model

Herein, we have modeled sales of HS-110 in treatment of NSCLC alone. We have assumed that this ImPACT™ technology-based approach would be deployed in patients primarily as second-line therapy, following the front-line administration of platinum doublet regimens. We note that the NSCLC market has gradually been gaining in attractiveness because of the emergence of maintenance therapy as a treatment paradigm.

Maintenance treatment in NSCLC is gaining traction in all markets and an early goal in the development of epidermal growth factor receptor (EGFR) tyrosine kinase inhibitors was to demonstrate that these agents could maintain disease control beyond the standard effectiveness window of only 4 – 6 cycles for standard chemotherapy. Initial trials in the maintenance setting, which involved use of EGFR inhibitors following combination use with platinum doublet chemotherapy in the first line (INTACT-1 and INTACT-2 for Iressa, and TRIBUTE and TALENT for Tarceva) failed to demonstrate any advantage in terms of response rate, time to progression or overall survival. However, none of these trials selected patients for EGFR mutations. Since these initial trials were carried out, Tarceva and Iressa have moved into the front-line setting in patients with known EGFR mutations; front-line use of the targeted agents as monotherapy in selected patients until progression has shown superior PFS and response rate compared with first-line platinum doublet chemotherapy. EGFR inhibitors have also been studied in the maintenance switch setting following front-line chemo, where patients who achieved a response or stable disease with front-line chemo were switched to a new agent to extend or maintain disease control. The SATURN trial showed that maintenance Tarceva in this setting improved overall survival (12 months vs. 11 months), which was a noteworthy finding in an unselected patient population and which could have a positive commercial impact.

Our market model for HS-110 assumes launch in 2019 in the U.S. and in 2020 in Europe. We have projected that interim data from the Phase 2 study that Heat Biologics is planning to run could become available in 2014 and that final survival data could be released in mid- to late 2015. Assuming that this occurs, we would anticipate that Heat could utilize this data to ink a transformative partnership on HS-110. The candidate could then be developed in the pivotal setting as an adjunct to chemotherapy, at least initially in Stage III/IV NSCLC patients who have already failed initial lines of chemotherapy and/or treatment with targeted therapeutics such as the EGFR inhibitors. We would anticipate that a single, randomized, multi-center, placebo-controlled clinical trial would be necessary to secure approval in NSCLC, with such a study likely to require the enrollment of 800 – 1,000 patients. This trial could begin enrolling patients in 2016 and report data in mid- to late 2018. In our view, HS-110 could obtain regulatory approval within a year of this data release.

Pricing is set at $20,000 per patient on an annualized basis in the U.S. and $15,000 per patient on an annualized basis in Europe. We believe that this pricing level is conservative and defensible, since pricing for an agent like Avastin (bevacizumab) – a drug that provides minimal survival benefit in this patient population – is already in excess of $50,000 per patient on an annualized basis. Using these assumptions, we derive peak sales potential of ~$840 million in the U.S. in the 2026 time frame and ~$750 million in Europe in the same year. Total peak sales globally are likely to be roughly $1.5 billion and could substantially exceed this level in considering the market potential in emerging countries such as China and India. Taken together, the above assumptions provide a basis for our risk-adjusted Net Present Value (rNPV) calculation, which also utilizes a 15% discount rate applied to future cash flows, a 40% effective tax rate, and a 60% probability of success (based on positive proof-of-concept Phase 1 results). This yields, as mentioned earlier, an rNPV of $130 million for this product candidate.

Table 7: Estimated Sales – Non-Small Cell Lung Cancer Market Size Model

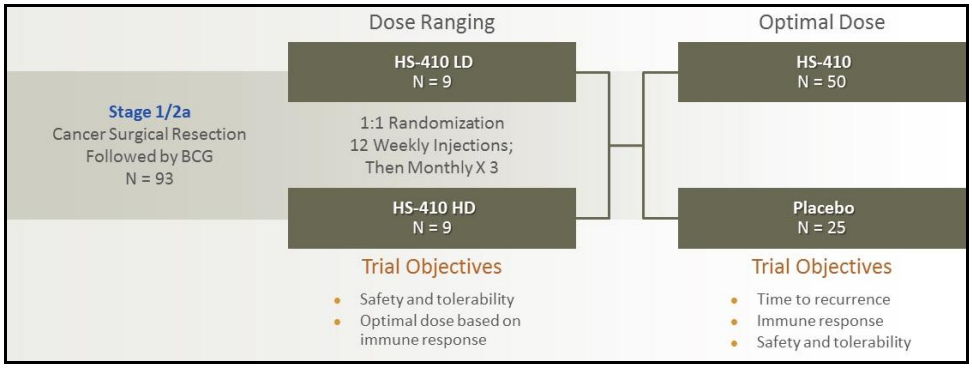
U.S. market														
	2013	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
Total patients with NSCLC	135,696	139,767	143,960	148,279	152,727	157,309	161,242	165,273	169,404	173,640	177,981	182,430	186,535	190,732
Stage I (16%)	*21,711*	*20,965*	*21,594*	*22,242*	*22,909*	*23,596*	*24,186*	*24,791*	*25,411*	*26,046*	*26,697*	*27,365*	*27,980*	*28,610*
Stage II-III (25%)	*33,924*	*34,942*	*35,990*	*37,070*	*38,182*	*39,327*	*40,310*	*41,318*	*42,351*	*43,410*	*44,495*	*45,608*	*46,634*	*47,683*
Stage III-IV (51%)	*69,205*	*71,281*	*73,420*	*75,622*	*77,891*	*80,228*	*82,233*	*84,289*	*86,396*	*88,556*	*90,770*	*93,039*	*95,133*	*97,273*
Penetration % (front-line plus chemo)	0%	0%	0%	0%	0%	0%	3%	8%	14%	19%	21%	25%	31%	35%
Patients treated	0	0	0	0	0	0	2,467	6,743	12,095	16,826	19,062	23,260	29,491	34,046
Revenue per patient	$0	$0	$0	$0	$0	$0	$20,000	$20,600	$21,218	$21,855	$22,510	$23,185	$23,881	$24,597
Annual sales ($MM)	**0**	**0**	**0**	**0**	**0**	**0**	**49**	**139**	**257**	**368**	**429**	**539**	**704**	**837**
RoW (mainly Europe)														
	2013	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**
Total patients with NSCLC	200,000	206,000	212,180	218,545	225,102	231,855	237,651	243,592	249,682	255,924	262,322	268,881	274,930	281,116
Stage I (10%)	*20,000*	*20,600*	*21,218*	*21,855*	*22,510*	*23,185*	*23,765*	*24,359*	*24,968*	*25,592*	*26,232*	*26,888*	*27,493*	*28,112*
Stage II-III (30%)	*80,000*	*82,400*	*84,872*	*87,418*	*90,041*	*92,742*	*95,060*	*97,437*	*99,873*	*102,370*	*104,929*	*107,552*	*109,972*	*112,446*
Stage IV (60%)	*120,000*	*123,600*	*127,308*	*131,127*	*135,061*	*139,113*	*142,591*	*146,155*	*149,809*	*153,555*	*157,393*	*161,328*	*164,958*	*168,670*
Penetration % (front-line plus chemo)	0%	0%	0%	0%	0%	0%	0%	2%	7%	11%	15%	21%	25%	22%
Patients treated	0	0	0	0	0	0	0	2,923	10,487	16,891	23,609	33,879	41,240	37,107
Revenue per patient	$0	$0	$0	$0	$0	$0	$0	$15,000	$15,450	$15,914	$16,391	$16,883	$17,389	$17,911
Annual sales ($MM)	**0**	**0**	**0**	**0**	**0**	**0**	**0**	**44**	**162**	**269**	**387**	**572**	**717**	**665**
Total WW Sales ($MM)	**0**	**0**	**0**	**0**	**0**	**0**	**49**	**183**	**419**	**637**	**816**	**1,111**	**1,421**	**1,502**
Stepped royalty rate on global sales	0%	0%	0%	0%	0%	0%	12%	14%	15%	18%	20%	22%	24%	25%
Total Revenue to Heat Biologics	**0**	**0**	**0**	**0**	**0**	**0**	**6**	**26**	**63**	**115**	**163**	**244**	**341**	**376**

Source: Company Reports and Aegis Capital Corp. estimates

Bladder Cancer Clinical Program

Heat Biologics has developed a protocol for an exploratory Phase 2 trial. In a manner analogous to the Phase 2 NSCLC trial for HS-110, Heat has elected to pursue an adaptive design. In this case, the company is planning to utilize the Phase 2 study in bladder cancer to conduct both dose-ranging assessments in order to select the optimum immunologically stimulating dose as well as efficacy measurement via time to recurrence. In our view, the hurdle in such a trial is relatively low and Heat Biologics should easily observe an efficacy signal if the ImPACT™ platform hypothesis is valid.

Figure 15: HS-410 Bladder Cancer Phase 2 Trial Design



Source: Heat Biologics

In this study, the majority of patients enrolled are likely to have either *in situ* bladder cancer or minimally invasive disease. The treatment paradigm is likely to be surgery followed by six weeks of interstitial BCG therapy, with HS-410 being administered within existing standard-of-care guidelines. Heat Biologics has already gone through a significant amount of advance preparation for this Phase 2 trial, which is expected to begin enrolling patients within the next two to three months. The trial is anticipated to complete enrolment in the first stage before the end of 2013. Heat believes that immune response data from this first stage could become available early in 2014.

If the immune response data are favorable and the dose-ranging portion of the trial permits Heat to select an optimal dose, which we view as a low-risk event, the company plans to move on to the second stage of the trial, which will be aimed at determining efficacy. Since the time-to-recurrence parameter is likely to be a relatively straightforward endpoint to measure and bladder cancer patients tend to recur relatively rapidly after surgery, Heat Biologics anticipates obtaining efficacy data from this trial before the end of 2014.

We believe that positive data on the time-to-recurrence parameter, clearly correlated with immune response data, should clearly establish the validity of the ImPACT™ technology platform approach and potentially position Heat Biologics to execute a broad licensing deal or a product development partnership with a more established company in the biopharmaceutical sector. Alternatively, the company could pursue a strategic sale. As mentioned previously, the firm's organizational structure lends itself well to a wide range of possible options. Since each individual clinical program is housed inside a separate, wholly-owned subsidiary, Heat Biologics could either sell itself in its entirety or elect to sell off discrete subsidiaries as the candidates inside those entities reach maturity on the clinical development front. In our view, this approach maximizes shareholder value and allows Heat to pursue the course that yields the most significant return on investment.

Bladder Cancer Competitive Landscape

In our view, the bladder cancer indication is intriguing from two perspectives – firstly, it constitutes a relatively underserved market and a domain within oncology that has historically received less attention from drug developers than other indications such as breast cancer, colorectal cancer, NSCLC, prostate cancer, acute myeloid leukemia (AML), chronic myelogenous leukemia (CML), or myelodysplastic syndrome (MDS). Second, there is an established practice of utilizing immunotherapy to treat this type of cancer. For example, broad-spectrum immune system boosters such as the Bacille Calmette-Guerin (BCG) bacterium – typically used in tuberculosis vaccines – or interferon-alfa-2b have been employed in order to enhance the immune system response against bladder cancer (sometimes referred to as urothelial carcinoma). Thus, we believe that Heat Biologics could benefit significantly from targeting this disorder.

The current treatment continuum in bladder cancer is relatively straightforward, and patients are positioned at points on this continuum based primarily on the level of invasiveness of their cancer. Non-invasive, or *in situ*, bladder cancer resides solely in the bladder and does not have any migratory characteristics. Minimally invasive cancer of this type may invade deeper tissue layers within the bladder area, but does not migrate to distal sites. In a very small proportion of patients afflicted with bladder cancer, the tumor cells do migrate distally and establish metastases in a rapid and aggressive manner. This form of bladder cancer is likely to have the poorest outcome.

Chemotherapy treatment for bladder cancer usually involves two or more chemotherapy drugs used in combination. It can be administered either systemically (via intravenous infusion), or locally to the bladder by passing a tube through the urethra, which is referred to as intravesical therapy. Chemotherapy may be used to kill cancer cells that might remain after surgery. It may also be used before surgery. In this case, chemotherapy may shrink a tumor enough to allow the surgeon to perform a less invasive procedure. Chemotherapy is sometimes combined with radiation therapy, which is generally used infrequently in patients with bladder cancer. Radiation therapy for bladder cancer usually comes from a machine that moves around the body, directing the energy beams to precise points. The principal chemotherapeutic agents employed in bladder cancer include doxorubicin, cisplatin, gemcitabine and irinotecan.

There is a significant amount of activity in the bladder cancer space currently involving drugs that are already approved for use in other types of malignancies. These include agents such as Pfizer's Sutent (sunitinib) and Amgen's Nexavar (sorafenib), which are primarily deployed in renal cell carcinoma (kidney cancer). Other agents that have already been approved for use in different indications include Takeda's proteasome inhibitor Velcade (bortezomib) and GlaxoSmithKline's kinase inhibitor Votrient (pazopanib). In our view, Heat Biologics could eventually insert its therapeutic candidate, HS-410, into the treatment continuum following surgery and possibly front-line therapy, either ahead of or in conjunction with targeted therapies that companies are currently seeking to combine with platinum-containing agents and other earlier-generation chemotherapeutic drugs.

Investors should note that the following key characteristics of the bladder cancer market make it a particularly attractive opportunity for Heat Biologics to pursue with its technology platform:

- Currently-available treatments have high failure rate and are poorly tolerated
- Among highest lifetime treatment cost per patient of any cancer due to high recurrence rates
- Potential to treat patients with minimal residual disease
- No new drugs have been approved for use in this patient population in >25 years

Table 8: Bladder Cancer Drugs

Drug	Generic	Company	Drug Class	Mechanism of Action	Status
Adriamycin	doxorubicin	Various	anthracycline	DNA intercalation (damages genetic material)	Marketed
Platinol	cisplatin	Various	platinum chemotherapeutic	DNA crosslinker (blocks cell division)	Marketed
Camptosar	irinotecan	Pfizer	topoisomerase I inhibitor	DNA replication blocker (inhibits DNA unwinding)	Marketed
Gemzar	gemcitabine	Eli Lilly & Co.	nucleoside analog	DNA replication inhibitor (induces apoptosis)	Marketed
Sutent	sunitinib	Pfizer	tyrosine kinase inhibitor	Raf kinase growth factor receptor blockade	Phase 2
Nexavar™	sorafenib	Amgen (originally Onyx) Bayer AG	tyrosine kinase inhibitor	Raf kinase growth factor receptor blockade	Phase 2
Velcade™	bortezomib	Takeda (originally Millennium)	proteasome inhibitor	protein turnover blockade (induces apoptosis)	Phase 2
Votrient™	pazopanib	GlaxoSmithKline	multi-tyrosine kinase inhibitor	angiogenesis / cell division inhibitor	Phase 2
EOquin™	apaziquone	Allergan Spectrum Pharmaceuticals	indolequinone	mitomycin C analog (DNA alkylation)	Phase 3
TMX-101	NA	Telormedix	small molecule immunomodulator	NA	Phase 2
BKM120	NA	Novartis AG	PI3K lipid kinase inhibitor	pan-class I: blocks cancer cell growth / survival	Phase 2
AMG 386	trebananib	Amgen	neutralizing peptibody	angiogenesis inhibitor (binds Angiopoietin-1 and 2)	Phase 2
AZD4877	NA	AstraZeneca	mitotic spindle apparatus inhibitor	blocks mitosis	Phase 2
PF-03446962	NA	Pfizer	anti-ALK1 monoclonal antibody	anti-ALK1 kinase inhibitor (blocks proliferation)	Phase 2
HS-410	NA	Heat Biologics	cancer vaccine	active immunotherapy - induces CTL response	Phase 2
ALT-801	NA	Altor Bioscience	p53-specific scTCR / IL-2 fusion	targeted immunotherapy agent	Phase 1 / 2
PF-00299804	dacomitinib	Pfizer	multi-tyrosine kinase inhibitor	pan-HER receptor blocker (inhibits proliferation)	Preclinical

Source: Bloomberg BDRUG, ClinicalTrials.gov (http://www.clinicaltrials.gov/), EvaluatePharma

Bladder Cancer Commercial Perspectives

Herein, we have modeled sales of HS-410 in treatment of both invasive and non-invasive bladder cancer. We have assumed that this ImPACT™ technology-based approach would be deployed in patients mainly as an adjunct to chemotherapy or as a way to prevent recurrence. We note that the bladder cancer market has historically been one of the most under-served in the oncology arena, with no new therapies being approved for the past 25 years. Recurrence rates are high, and this should drive demand.

There are three types of bladder cancer that begin in cells in the lining of the bladder. These cancers are named for the type of cells that become malignant (cancerous):

- Transitional cell carcinoma: Cancer that begins in cells in the innermost tissue layer of the bladder. These cells are able to stretch when the bladder is full and shrink when it is emptied. Most bladder cancers begin in the transitional cells.
- Squamous cell carcinoma: Cancer that begins in squamous cells, which are thin, flat cells that may form in the bladder after long-term infection or irritation.
- Adenocarcinoma: Cancer that begins in glandular (secretory) cells that may form in the bladder after long-term irritation and inflammation.

We have split the major markets into two categories – invasive bladder cancer and non-invasive (also known as superficial or *in situ*) bladder cancer. In our view, the bulk of the market penetration is likely to be in the invasive setting.

Our market model for HS-410 assumes launch in 2017 in the U.S. and in 2019 in Europe. We have projected that interim data from the Phase 2 study that Heat Biologics is planning to run could become available in the first half of 2014 and that final survival data could be released in mid-2015. Assuming that this occurs, we would anticipate that Heat could utilize this data to ink a transformative partnership on HS-410. The candidate could then be developed in the pivotal setting as an adjunct to chemotherapy, at least initially in patients with invasive disease who have experienced recurrence or who are considered highly likely to recur. We would anticipate that a single, randomized, multi-center, placebo-controlled clinical trial would be necessary to secure approval in the invasive forms of bladder cancer (urothelial carcinoma), with such a study likely to require the enrollment of 400 – 500 patients. This trial could begin enrolling patients in late 2014 and report data in mid- to late 2016. In our view, if the trial is successful, HS-410 could obtain regulatory approval within a year of this data release.

Pricing is set at $25,000 per patient on an annualized basis in the U.S. and $18,000 per patient on an annualized basis in Europe for individuals with invasive disease. We believe that this pricing level is conservative and defensible, since the currently-available drugs for bladder cancer have relatively poor efficacy and do not generally prevent recurrence. We use $18,000 per patient in the U.S. and $15,000 per patient in Europe as our pricing assumptions for those with non-invasive bladder cancer. Employing these assumptions, we derive peak sales potential of ~$530 million in the U.S. in the 2024 time frame and ~$480 million in Europe by 2027. Total peak sales globally are likely to be roughly $900 million and could substantially exceed this level in considering the market potential in emerging countries such as China and India.

Taken together, the above assumptions provide a basis for our risk-adjusted Net Present Value (rNPV) calculation, which also utilizes a 15% discount rate applied to future cash flows, a 40% effective tax rate, and a 50% probability of success (given the fact that no clinical data has yet been generated in bladder cancer). This yields, as mentioned earlier, an rNPV of $110 million for this product candidate.

Table 9: Estimated Sales – Bladder Cancer Market Size Model

U.S. market																		
	2013	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
Total patients with bladder cancer	70,000	70,875	71,761	72,658	73,566	74,486	75,417	76,360	77,009	77,663	78,323	78,989	79,660	80,338	81,020	81,709	82,404	83,104
Non-invasive patients	*42,000*	*42,525*	*43,057*	*43,595*	*44,140*	*44,691*	*45,250*	*45,816*	*46,205*	*46,598*	*46,994*	*47,393*	*47,796*	*48,203*	*48,612*	*49,025*	*49,442*	*49,862*
Invasive patients	*28,000*	*28,350*	*28,704*	*29,063*	*29,426*	*29,794*	*30,167*	*30,544*	*30,803*	*31,065*	*31,329*	*31,596*	*31,864*	*32,135*	*32,408*	*32,684*	*32,961*	*33,242*
Penetration % (non-invasive)	0%	0%	0%	0%	0%	0%	2%	5%	8%	11%	13%	15%	13%	11%	9%	8%	7%	6%
Bladder cancer patients treated (front-line)	0	0	0	0	0	0	905	2,291	3,696	5,126	6,109	7,109	6,214	5,302	4,375	3,922	3,461	2,992
Penetration % (invasive bladder cancer)	0%	0%	0%	0%	3%	7%	15%	21%	27%	34%	41%	45%	41%	38%	34%	29%	25%	22%
Bladder cancer patients treated (invasive)	0	0	0	0	883	2,086	4,525	6,414	8,317	10,562	12,845	14,218	13,064	12,211	11,019	9,478	8,240	7,313
Revenue per patient (non-invasive)	$0	$0	$0	$0	$0	$0	$18,000	$18,540	$19,096	$19,669	$20,259	$20,867	$21,493	$22,138	$22,802	$23,486	$24,190	$24,916
Revenue per patient (invasive)	$0	$0	$0	$0	$25,000	$25,750	$23,000	$23,690	$24,401	$25,133	$25,887	$26,663	$27,463	$28,287	$29,136	$30,010	$30,910	$31,837
Annual sales ($MM)	**0**	**0**	**0**	**0**	**22**	**54**	**120**	**194**	**274**	**366**	**456**	**527**	**492**	**463**	**421**	**377**	**338**	**307**
RoW (developed countries - mainly Europe)																		
	2013	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2028**	**2029**	**2030**
Total patients with bladder cancer	85,000	87,550	90,177	92,882	95,668	98,538	101,002	103,527	106,115	108,768	111,487	114,274	116,845	119,474	122,163	124,911	127,722	130,276
Non-invasive patients	*51,000*	*52,530*	*54,106*	*55,729*	*57,401*	*59,123*	*60,601*	*62,116*	*63,669*	*65,261*	*66,892*	*68,565*	*70,107*	*71,685*	*73,298*	*74,947*	*76,633*	*78,166*
Invasive patients	*34,000*	*35,020*	*36,071*	*37,153*	*38,267*	*39,415*	*40,401*	*41,411*	*42,446*	*43,507*	*44,595*	*45,710*	*46,738*	*47,790*	*48,865*	*49,964*	*51,089*	*52,110*
Penetration % (non-invasive)	0%	0%	0%	0%	0%	0%	0%	0%	3%	4%	5%	6%	7%	8%	10%	8%	7%	5%
Bladder cancer patients treated (front-line)	0	0	0	0	0	0	0	0	1,592	2,610	3,345	4,114	4,908	5,735	7,330	5,996	5,364	3,908
Penetration % (invasive bladder cancer)	0%	0%	0%	0%	0%	0%	2%	7%	11%	15%	19%	23%	25%	29%	31%	28%	24%	21%
Bladder cancer patients treated (invasive)	0	0	0	0	0	0	808	2,899	4,669	6,526	8,473	10,513	11,685	13,859	15,148	13,990	12,261	10,943
Revenue per patient (non-invasive)	$0	$0	$0	$0	$0	$0	$0	$15,000	$15,450	$15,914	$16,391	$16,883	$17,389	$17,911	$18,448	$19,002	$19,572	$20,159
Revenue per patient (invasive)	$0	$0	$0	$0	$0	$0	$18,000	$18,540	$19,096	$19,669	$20,259	$20,867	$21,493	$22,138	$22,802	$23,486	$24,190	$24,916
Annual sales ($MM)	**0**	**0**	**0**	**0**	**0**	**0**	**15**	**54**	**114**	**170**	**226**	**289**	**336**	**410**	**481**	**442**	**402**	**351**
Total WW Sales ($MM)	**0**	**0**	**0**	**0**	**22**	**54**	**135**	**248**	**387**	**536**	**683**	**816**	**829**	**872**	**901**	**819**	**740**	**659**
Stepped royalty rate on worldwide sales	0%	0%	0%	0%	15%	16%	20%	22%	25%	26%	28%	28%	30%	30%	30%	30%	30%	30%
Total Revenue to Heat Biologics	**0**	**0**	**0**	**0**	**3**	**9**	**27**	**55**	**97**	**139**	**191**	**229**	**249**	**262**	**270**	**246**	**222**	**198**

Source: Company Reports and Aegis Capital Corp. estimates

Intellectual Property Portfolio

Heat Biologics has thus far obtained exclusive rights to five different patent families directed to therapeutic compositions and methods related to the company's proprietary vaccine platform and preclinical development programs for cancer. These families comprise five PCT applications, six issued patents, one allowed or accepted patent application, and thirty-eight pending patent applications. These patents and applications cover the U.S., Europe, and Japan as well as several other countries that each represent commercially significant markets.

Table 10: Key Issued Patents & Pending Applications

Number	Title	Issue Date	Expiry Date	Country	Description
1829551	Modified Heat Shock Protein-Antigenic Peptide Complex	9/29/2010	2/19/2019	European Union	Validation of EP Patent 1829551 (EP 07007299) -Validated in ES, FR, CH, IE, DE, SE, BE, DK, IT, GB, and NL
8,475,785	Allogeneic Cancer Cell-based Immunotherapy	7/2/2013	10/31/2029	United States	Allogeneic cancer cell-based immunotherapy
757600	Modified Heat Shock Protein-Antigenic Peptide Complex	6/12/2003	2/19/2019	Australia	Modified Heat Shock Protein-Antigenic Peptide Complex
1054683	Modified Heat Shock Protein-Antigenic Peptide Complex	4/11/2007	2/19/2019	European Union	EP - Patent 1054683 - Modified Heat Shock Protein-Antigenic Peptide- Validated in DE, ES, FR, IT, and GB.
4768122	Modified Heat Shock Protein-Antigenic Peptide Complex	6/24/2011	2/19/2019	Japan	Modified Heat Shock Protein-Antigenic Peptide Complex
2009223838	Allogeneic cancer cell-based immunotherapy	11/29/2012	3/3/2029	Australia	Allogeneic cancer cell-based immunotherapy
2009226077	HSP GP96 Vaccination and Methods of Using Same	8/2/2012	3/19/2029	Australia	Heat Shock Protein GP96 Vaccination and Methods
2011/04485	HIV/SIV Vaccines for the Generation of Mucosal and Systemic Immunity	3/28/2012	11/23/2029	South Africa	HIV/SIV Vaccines for the Generation of Mucosal and Systemic Immunity

Source: Company reports, U.S. Patent & Trademark Office

Licensing Agreements

Technology Platform

In July 2008, Heat Biologics entered into an exclusive license agreement with the University of Miami for intellectual and tangible property rights relating to the ImPACT™ technology platform. This license agreement was subsequently assigned to the firm's subsidiary, Heat Biologics I, Inc. which issued to the University of Miami shares of its common stock representing 7.5% of its common stock. The term of the license is the length of the last to expire patent, unless terminated earlier.

This agreement granted Heat Biologics I, Inc. exclusive worldwide rights to the following U.S. patent applications: Serial number 60/075.358 (the " '358 application") entitled "Modified Heat Shock Protein-Antigenic Peptide Complex" and filed on February 20, 1998; Serial number 09/253,439 (the " '439 application") entitled "Modified Heat Shock Protein-Antigenic Peptide Complex" and filed on February 19, 1999; serial number 11/878,460 (the " '460 application") entitled "Recombinant Cancer Cell Secreting Modified Heat Shock Protein-Antigenic Peptide Complex" and filed on July 24, 2007; and all related patent filings. The license agreements provide that the licensor has the right to terminate the license if Heat Biologics has not introduced, or at least used best efforts to introduce, a licensed product in the commercial marketplace in the U.S., E.U., or Japan by December 31, 2020; and otherwise exercise diligence to bring licensed products to market; or in the event of Heat Biologics's insolvency or bankruptcy.

The company is obligated to pay the University of Miami upfront license fees, additional yearly and milestone payments and a royalty based on net sales of products covered by the patent-related rights described above. More specifically, the licensee is obligated to pay the University of Miami (i) all past and future patent costs associated with the licensed patent-related rights; (ii) a license issue fee of $150,000; (iii) annual payments of $10,000 in 2010, 2011 and 2012, and $20,000 each year thereafter; (iv) a milestone

payment of $250,000 by the earlier of May 31, 2017 or approval of a BLA for the lung cancer vaccine or for a cancer vaccine other than lung cancer; and (v) royalties equal to a percentage (ranging from low to mid-single digits) of net sales of licensed products.

In February 2011, the company's primary subsidiary, Heat Biologics I, Inc., entered into four additional exclusive license agreements with the University of Miami. In each of these agreements, Heat Biologics I, Inc. obtained exclusive worldwide rights to the following patent claims:

1. Cancer treatment portfolio: U.S. patent application serial number 61/347,336 entitled "Cancer Treatment" and filed on May 21, 2010, along with any related patent filings.

2. Allogeneic cancer-based immunotherapy portfolio: U.S. patent application serial number 61/033,425 entitled "Allogeneic Cancer –Based Immunotherapy" and filed on March 3, 2008 and PCT application number PCT/2009/001330 "Allogeneic Cancer –Based Immunotherapy" filed on March 3, 2009, along with all U.S. patents and foreign patents and patent applications based on these U.S. applications.

3. Heat shock protein gp96 portfolio: U.S. patent application serial number 61/033,425 entitled "Heat Shock Protein GP96 Vaccination and Methods of Using Same" filed on March 20, 2008 and PCT application number PCT/ 2009/001727 "Heat Shock Protein GP96 Vaccination and Methods of Using Same" filed on March 19, 2009, along with any U.S. or foreign patent filings.

4. HIV treatment portfolio: U.S. patent application serial number 61/116.971 entitled "HIV/SIV Vaccine for the Generation of Mucosal and Systemic Immunity" filed November 28, 2008 and PCT application number PCT/ 2009/065500" "HIV/SIV Vaccine for the Generation of Mucosal and Systemic Immunity" filed on November 23, 2009, in addition to all patent filings based on these applications.

As consideration for the rights granted in these additional four license agreements, Heat Biologics is obligated to pay the University of Miami certain upfront license fees, past and future patent costs and royalties based on net sales on commercialized products covered by the patent claims described above. No annual or milestone payments are required to be paid. The upfront license fees for the cancer treatment patent portfolio and the HIV/SIV vaccine portfolio license agreements were $10,000 and $50,000, respectively. No upfront license fees were required under the license agreements for the allogeneic cancer–based immunotherapy and the heat shock protein gp96 portfolios. Under each of these four additional license agreements, the royalties are equal to a percentage (ranging from low to mid-single digits) of net sales of products covered by the patent-related rights in the respective license agreements.

In exchange for additional consideration (including the requirement that Heat Biologics I, Inc. pay additional milestone payments of $25,000 before initiation of any pivotal clinical trials for products covered by any of the licenses, and an additional payment equal to 18% annual interest on the amounts due or a note convertible into an equivalent value of shares in Heat's Preferred Stock), the University of Miami agreed to postpone the payment due dates for each of these licenses. On April 26, 2013, the outstanding balances to the University of Miami under the license agreements were paid in full.

All five of the above-described license agreements provide that the licensor has the right to terminate a subject license if the licensee has (i) not introduced, or at least used its best efforts to introduce, a licensed product in the commercial marketplace in the U.S., European Union, or Japan by December 31, 2020; (ii) not otherwise exercised diligence to bring licensed products to market; or (iii) files for bankruptcy or is declared insolvent.

In April 2013, Heat Biologics inked another agreement with the University of Miami under which Heat was granted an option to obtain an exclusive license to U.S. patent application 12/303,036 entitled "Perforin-2 Proteins" filed December 2, 2008; U.S. patent application 61/637.455, entitled "Perforin-2 Defense Against Invasive and Multi-drug Resistant Bacteria" and "Modified Heat Shock Protein-Antigenic Peptide Complex", filed on April 21, 2012, plus related filings. The term of the option is twelve months and may be extended as long as Heat pays all patent-related expenses.

Cancer Cell Line Licensing Agreements

In addition to the licenses obtained from the University of Miami, Heat Biologics has inked agreements with (i) the Regents of the University of Michigan; and (ii) the American Type Culture Collection (ATCC) in order to access certain cancer cell lines.

In July 2011, Heat Biologics inked an exclusive, perpetual license agreement with the University of Michigan providing Heat with access to certain bladder cancer cell lines. The University of Michigan is entitled to upfront, milestone and license maintenance payments under this agreement. Heat Biologics paid an option exercise fee of $2,000, a license issue fee of $10,000 and is obligated to pay an annual maintenance fee of $10,000 each year until the first commercial sale of a licensed product, at which time the annual maintenance fee increases to $50,000. In addition, Heat Biologics is obligated to make milestone payments of $25,000, $50,000 and $75,000 upon completion of a Phase 1, Phase 2 and Phase 3 trial; $250,000 upon the first commercial sale of a licensed product; and $350,000 upon achievement of annual net sales of $250,000,000 or more for products developed using the licensed bladder cancer cell lines. The University of Michigan has the right to terminate the license agreement if the following milestones are not met: completion of a Phase 1 trial on or before January 1, 2015, completion of a Phase 2 trial on or before January 1, 2017, a Phase 3 clinical trial on or before January 1, 2019 and the first commercial sale of a product that includes the materials supplied by the University of Michigan on or before January 1, 2020.

In April 2011, Heat Biologics established an evaluation and biological material license agreement with the ATCC to evaluate, use, market, sell and/or sub-license materials and processes related to various different cell lines. The agreement provides for an evaluation term of twelve months, subject to two additional twelve-month renewals and a non-exclusive commercial use license upon termination of the evaluation period. The agreement with ATCC has a term of forty years. Heat paid an evaluation fee of $5,000, two $5,000 evaluation fees, and are obligated to pay a license issue fee of $50,000 and a percentage of net sales (low single digits) based on sales of products derived from the in-licensed cell lines. In addition, Heat is obligated to make milestone payments of $15,000, $30,000 and $60,000 upon initiation of a Phase 1, Phase 2, and Phase 3 trial, respectively; and $200,000 upon receipt of marketing authorization for any such products.

In our view, the licensing arrangements that Heat Biologics has thus far established provide the company with access to all of the crucial elements that it requires to build and develop its proprietary ImPACT technology platform. The crucial elements of the technology itself come from the University of Miami, while the basis for the company's future products – the human cancer cell lines – come from the University of Michigan and the American Type Culture Collection (ATCC). In our view, these agreements should be sufficient to serve the future needs of the company from a licensing perspective for the ImPACT platform, since the ATCC cancer cell line collection spans most, if not all, of the currently-characterized solid tumor types. We note that, in all of these agreements, the actual payments that Heat Biologics must make to maintain its licenses are extremely low and there are very few milestone payments necessary as well. The royalties on future net sales are low single-digit percentages and therefore we believe that Heat Biologics negotiated the terms of these licenses favorably and cost-effectively.

Capital Structure

As of June 30th, 2013, Heat Biologics had approximately $3 million in cash and cash equivalents. In late July 2013, the company raised gross proceeds of $25 million in a registered direct offering of 2.5 million shares of common stock priced at $10 per share. Subsequently, in August 2013, the firm received an additional $200,000 in gross proceeds from the partial exercise of an over-allotment granted to the underwriters of the IPO. The firm had approximately 6.3 million shares outstanding and issued as of mid-2013. The table below depicts the firm's current capital structure, including all remaining options and warrants associated with previous financings. As shown below, the fully-diluted share count for Heat Biologics currently stands at about 7 million shares.

Table 11: Heat Biologics Current Capital Structure

	Number of Shares	Exercise Price	Expiration Date	Total Cash
Cash, cash equivalents and marketable securities				$27,089,720
Common Stock	6,294,719			$32,160,674
Options	662,543	$0.002-$8.81	2019-2020	$5,899,320
Common stock warrants	32,609	$0.48		$15,652
Warrants	20,549	$4.83	2021-2022	$99,252
				$0
Fully Diluted Shares	**6,989,871**			**$33,004,692**

Source: Company reports

Financing History

Since inception, Heat Biologics has raised a total of approximately $33 million. In the most recent financing, the company raised net proceeds of approximately $23 million in an initial public offering of 2.5 million shares plus an over-allotment amount of 200,000 shares, priced at $10.00 per share. The additional 200,000 shares represent a partial exercise of the total granted over-allotment of 375,000 shares of common stock. We note that, from inception until the point of the IPO, Heat Biologics has demonstrated an extremely cost-effective operating strategy that led to an accumulated deficit of only $8.3 million over the course of roughly five years in operation. The company has judiciously funded its drug development efforts with grants and other non-dilutive forms of capital.

Table 12: Heat Biologics Financing History

		Net Proceeds	Shares	Price	Notes
Private Company					
	Common Stock	$ 1,290	1,861,689	$.0002-$.76	
	Preferred Series 1	$ 250,000	49,960	$ 5.00	
	Preferred Series A	$ 3,912,569	810,057	$ 4.83	
	Preferred Series B	$ 5,050,090	872,833	$ 5.79	The number of Series B shares includes dividends of 14,291 & an additional 36,167 shares of common stock
Public Company					
	IPO	$ 22,946,725	2,500,000	$ 10.00	
	Secondary	$ 930,000	100,000	$ 10.00	
Total Amount		$ 33,090,674	6,194,539		

Source: Company reports

Financial Review and Outlook

Revenue: We forecast no sales-based revenue for 2013 and 2014, respectively. Management does not provide guidance.

- **Initiation of a Phase 2 proof-of-concept trial in bladder cancer:** We anticipate the initiation of a Phase 2 proof-of-concept study of a product candidate using the ImPACT™ technology platform in late 2013. This study is expected to yield data in mid-2014, and could pave the way for Heat Biologics to apply for Breakthrough Therapy designation for its lead candidate in bladder cancer.

- **Initiation of a Phase 2 proof-of-concept study in non-small cell lung cancer:** We anticipate the initiation of a Phase 2 proof-of-concept trial of a different product candidate – also utilizing the ImPACT™ technology platform – in early 2014. In our view, interim data from this study are unlikely to become available until late 2014 / early 2015. However, in our view, positive data from such a trial are likely to spur significant licensing and / or acquisition interest in Heat Biologics.

Gross Margins: As a development-stage firm, there are historically no costs of goods sold. We project that the gross margins on products like the candidates being developed using the Heat Biologics ImPACT™ platform are likely to exceed 80% if these drugs succeed in pivotal clinical trials. This should enable healthy cash flow generation.

Operating Expenses: For 2013 and 2014, we estimate operating expense levels that are significantly higher than those seen in 2011 and 2012. We estimate total R&D expenses of $2.6 million in 2013 and $6.3 million in 2014, as the firm moves into clinical trials.

Taxes: Thus far, since the company has been run in an extremely lean manner, significant net operating loss carry-forwards have not been accrued. Based on the effective tax rate, the amounts available to offset taxable income as of end-2012 are considered negligible. We have accounted for a roughly 40% effective tax rate, which includes the statutory U.S. federal corporate tax rate of 35% and an additional amount for state corporate taxes, when modeling out future cash flows.

Share Count: The outstanding fully-diluted share count stands at 7.0 million shares currently. The fully-diluted shares account for the conversion of roughly 660,000 outstanding options and roughly 53,000 warrants. Given the firm's cash position, strategic goals, and capital structure, a share repurchase program is unlikely, in our view.

EPS: We forecast diluted EPS of ($2.15) and ($1.39) for 2013 and 2014, respectively. We estimate that the company could achieve breakeven in late 2017 or early 2018.

Balance Sheet: The firm held roughly $3.0 million in cash as of June 30, 2013 and subsequently raised roughly $23 million in net proceeds in a registered direct offering.

Cash Flow: The firm is slated to consume roughly $8 million in operating cash flows during 2013 and could burn $11 million in 2014, according to our projections. Additional funding may be required starting in late 2014 / early 2015. In our view, the company currently possesses sufficient capital to fund two concomitant clinical development programs – one in bladder cancer and the other in lung cancer – and continue operations through mid-2015.

Guidance: The firm does not provide financial guidance.

Management Team

The company seeks to align the management team's interests with those of shareholders by using equity-based long-term incentive awards, which generally consist of either stock options or shares of restricted stock that vest over time or upon achievement of a milestone, such as product approval. In addition, management is motivated to achieve product development and operating objectives via a compensation program that rewards the achievement of predetermined performance objectives in areas that the Board of Directors believes are critical to the company's success.

Jeff Wolf, J.D., M.B.A.
Founder & Chief Executive Officer
The principal founder of Heat Biologics, Jeff Wolf has served as CEO since the inception of the company. He was formerly the founder and managing director at Seed-One Ventures, a firm focused on the systematic formation and management of new biomedical companies based upon novel research breakthroughs. Since founding Seed-One, Jeff has started and run several biomedical companies. His start-ups include Avigen (co-founder and director), a San Francisco-based gene therapy company; TyRx Pharma (co-founder and chairman) which is focused on the development of novel bio-compatible polymers; EluSys Therapeutics (founder and CEO), focused on the development of a novel antibody technology against a range of diseases; GenerationOne (founder and CEO), focused on mobile-based collaborative care and Heat Biologics. Mr. Wolf received his M.B.A. from Stanford Business School, his J.D. from New York University School of Law and his B.A. from the University of Chicago, where he graduated with honors in Economics.

Sandra Silberman, M.D., Ph.D.
Chief Medical Officer
Dr. Silberman began her career in clinical development at Pfizer, Inc., where she initiated the company's first program in clinical oncology and oversaw the introduction of Tarceva™ (erlotinib HCl), one of the world's first targeted therapeutics in the oncology domain and one of the earliest tyrosine kinase inhibitors ever to receive regulatory approval, into clinical trials. She then served as Senior Director for Novartis Clinical Research, where she led the global development of Gleevec™ (imatinib mesylate), a highly innovative drug and the first targeted therapy for chronic myelogenous leukemia (CML). Dr. Silberman then joined Eisai Medical Research as Global Therapeutic Area Head (Oncology), a role in which she advanced six novel compounds into trials spanning Phase 1 through Phase 3 in clinical development. As an independent industry consultant over the years, Dr. Silberman has advised Bristol-Myers Squibb, AstraZeneca, ImClone Systems, Roche and GPC-Biotech in their oncology programs. Dr. Silberman earned her Ph.D. in tumor immunology from Johns Hopkins University and her M.D. from Cornell University Medical College. She completed a fellowship in hematology/oncology at the Brigham & Women's and the Dana Farber Cancer Institute in Boston. Dr. Silberman has published numerous times in peer-reviewed journals and is named on several patents in the cancer drug development field, including novel anti-tubulin agents for advanced solid tumors. She is board-certified in both internal medicine and hematology.

Matt Czajkowski, M.B.A.
Chief Financial Officer
Mr. Czajkowski serves as the CFO of Heat Biologics. Over the past 15 years, he has served in a similar capacity at a variety of early stage and public companies. He was CFO of Pozen, Inc. (NASDAQ/POZN, Not Rated), guiding it through its' IPO and subsequent transition to a public reporting company. He also served as CFO of AAIPharma, Inc., as a senior member of the team brought in to restructure the company and improve its controls and public reporting. Mr. Czajkowski has also served as CFO of several early-stage, venture-funded private companies and most recently was CEO of

NextRay, Inc. a company developing the next generation of imaging technology. Prior to joining Pozen in 2000, Matt was an investment banker with several firms. During the course of his investment banking career he founded and ran Goldman Sachs & Co.'s Asia-Pacific Mergers and Acquisition Group in Tokyo, Japan. He is a graduate of Harvard College and Harvard Business School.

Vadim V. Deyev, M.D., Ph.D.
Director of Applied Research
Dr. Deyev joined Heat Biologics in January 2009 as Director of Research. Prior to joining the firm, he worked as Associate Scientist of Microbiology and Immunology and Hybridoma and Fusion Protein Core Director at the University of Miami's School of Medicine. Dr. Deyev joined the University of Miami's scientific staff in 1996. Working with Dr. Eckhard Podack, Heat Biologics' Scientific Advisor and Chairman of its Scientific Advisory Board, Dr. Deyev made significant contributions to the development of technologies that were later licensed by the company. He received his Ph.D. in immunology/oncology from Cancer Research Center in Moscow, Russia and his M.D. from Russian State Medical University.

Scientific Advisory Board

Given the early-stage nature of Heat Biologics and the innovative concept underlying its approach to treatment of cancer, the role of the company's scientific advisory board is likely to be extremely crucial. In our view, this firm has an outstanding scientific advisory board for a company of its size – most notably, luminaries such as Eckhard Podack (inventor of the Seattle Genetics antibody Adcetris, known generically as brentuximab vedotin), Sol Barer (former CEO of Celgene Corporation, one of the most respected oncology-focused companies in the world), and Daniel von Hoff (who possesses an extensive resume as advisor or principal investigator on a multitude of clinical trials assessing investigational therapeutics in the oncology sector).

Eckhard R. Podack, M.D., Ph.D.
Chairman, Scientific Advisory Board
Dr. Podack is the inventor of the technology that Heat Biologics is deploying in cancer. He chairs the SAB at Heat Biologics. Dr. Podack received his medical degree from the Johan Wolfgang Goethe University in Frankfurt in 1968 and his Medical License in 1970. Following service in the German Army as a captain and battalion physician, he completed his Ph.D. in biochemistry at the Georg August University in Gottingen, Germany. From 1974-1984 he studied immunology at the Scripps Clinic and Research Foundation in La Jolla, CA, where he received an Established Investigatorship from the American Heart Association. Dr. Podack is the discoverer of perforin and is world-renowned as the father of the field of pore-forming proteins. He is the Sylvester Distinguished Professor of Microbiology & Immunology and Medicine and serves as Chairman of the Department of Microbiology at the University of Miami's Miller School of Medicine. He is currently directing three investigator-initiated clinical vaccine trials; he has published extensively and is the principal investigator on trials that have received over $13 million in grant funding, primarily from the National Institutes of Health (NIH).

Sandra Silberman, M.D., Ph.D.
Chief Medical Officer / Member, Scientific Advisory Board
See bio in Management Team section of this report.

James Allison, Ph.D.
Member, Scientific Advisory Board
Dr. Allison is a leader in the field of immunology, particularly in developing ways to help the immune system recognize and destroy cancer cells. His research is focused on the

mechanisms that regulate the immunological response of T lymphocytes, especially strategies to manipulate those responses in clinically relevant areas, including autoimmunity, allergies, vaccinations, and tumor therapy. Dr. Allison's work, therefore, is crucial to Heat Biologics, which is focusing on the development of an effective cancer vaccine that elicits exactly the type of immune response required to ablate tumors. He is Chairman of the Immunology Program, Director of the Ludwig Center for Cancer Immunotherapy, Attending Immunologist, and David H. Koch Chair in Immunologic Studies at Memorial Sloan-Kettering Cancer Center in New York, NY.

Sol J. Barer, Ph.D.
Member, Scientific Advisory Board
Chairman of Celgene Corporation, a global biopharmaceutical company engaged in the discovery, development and commercialization of novel therapies for the treatment of cancer and inflammatory diseases, Sol Barer needs no introduction. He has spent the past 20 years with Celgene, and its predecessor Celanese Research Company, acting in various capacities as president, COO, CEO, senior vice president of science and technology, and vice president/general manager of the Chiral Products Division. Dr. Barer holds a Ph.D. in organic chemistry from Rutgers University.

John Nemunaitis, M.D.
Member, Scientific Advisory Board
As an experienced oncologist and executive medical director of the Mary Crowley Cancer Research Centers (MCCRC), Dr. Nemunaitis has been exploring novel targeted therapies for treating cancer patients for over 20 years. He came to Dallas in 1993 to establish the clinical research program for Texas Oncology Physicians Association (TOPA). He later established a not-for-profit translational research program (the MCCRC). Dr. Nemunaitis is a committee member of the Western Institutional Review Board (WIRB) and recently co-founded a molecular therapeutic / vaccine biotechnology company with GMP manufacturing capacity called Gradalis, Inc. He has authored over 250 peer-reviewed publications and 36 book chapters; instituted study establishment of over 350 trials, overseen FDA-sponsored experimental treatment of nearly 4000 cancer patients at MCCRC, and has carried out 14 government regulatory (FDA, RAC) presentations for biotechnology product development. He is also the primary developer and holder of eight new molecular and vaccine Investigational New Drug Applications (INDs). His research focus is clinical in orientation and involves determination of molecular signals in order to optimize targeted therapy, RNAi-based therapeutics, and cancer vaccine approaches. Dr. Nemunaitis received his B.A. and M.D. degrees from Case Western Reserve University, completed a residency at Boston City Hospital and then performed a Hematology and Oncology fellowship at the University of Washington and the Fred Hutchinson Cancer Research Center in Seattle from 1988 to 1993.

Justin Stebbing, M.D., M.A., FRCP, FRC Path, Ph.D.
Member, Scientific Advisory Board
Dr. Stebbing is a member of the Royal College of Physicians, the American Board of Internal Medicine and a Fellow of the Royal College of Pathologists. Originally, Dr. Stebbing trained in medicine at Trinity College Oxford, obtaining a triple first class degree. After completion of junior doctor posts in Oxford, he completed a residency program (junior doctor) training at the Johns Hopkins Hospital in the U.S., before returning to London to continue his training in oncology at The Royal Marsden. Dr. Stebbing then undertook a Ph.D., funded by the Medical Research Council, investigating the interplay between the immune system and cancer. Specifically, the role of heat shock proteins in viral infections and tumorigenesis were examined helping in the development of vaccines that are currently in clinical trials. Dr. Stebbing has published over 300 peer-reviewed papers in journals such as the *Lancet*, *New England Journal*, *Blood*, *PNAS*, The *Journal of Clinical Oncology* and *Annals of Internal Medicine*, the majority as first or last author, as well as over 100 book chapters. They mainly focus on early and late stage

trials of new drugs, mechanisms of disease, and prognostic indicators. He is on the scientific advisory board of a number of biotechnology companies and the editorial board of a number of world-leading journals such as the Journal of Clinical Oncology. Dr. Stebbing is currently a senior lecturer at Imperial College, London.

Daniel D. Von Hoff, M.D.
Member, Scientific Advisory Board
Dr. Von Hoff is currently Physician-in-Chief and Director of Translational Research at TGen (Translational Genomics Research Institute) in Phoenix, Arizona. He is also Chief Scientific Officer for Scottsdale Healthcare's Clinical Research Institute and Scientific Medical Officer for U.S. Oncology. He holds an appointment as Clinical Professor of Medicine at the University of Arizona's College of Medicine. Dr. Von Hoff's major interest is in the development of new anticancer agents, both in the clinic and in the laboratory. He and his colleagues were involved in starting the development of many of the agents we now use routinely, including: mitoxantrone, fludarabine, paclitaxel, docetaxel, gemcitabine, irinotecan, nelarabine, capecitabine, lapatinib and others. At present, he and his colleagues are concentrating on the development of molecularly-targeted therapies, particularly for patients with advanced pancreatic cancer. Dr. Von Hoff has published over 560 papers, 134 book chapters and over 1000 abstracts.

Dr. Von Hoff was appointed to President Bush's National Cancer Advisory Board, and served on that body from June 2004 to March 2010. Dr. Von Hoff is the past President of the American Association for Cancer Research (the world's largest cancer research organization), a Fellow of the American College of Physicians, and a member and past board member of the American Society of Clinical Oncology. He is a founder of ILEX™ Oncology, Inc. (acquired by Genzyme after Ilex had two agents, alemtuzumab and clofarabine, approved for patients with leukemia). He is founder and the Editor Emeritus of *Investigational New Drugs – The Journal of New Anticancer Agents*; also, he is currently Editor-in-Chief of *Molecular Cancer Therapeutics*. He is also proud to have been a mentor and teacher for multiple medical students, medical oncology fellows, graduate students, and post-doctoral fellows. He is a co-founder of the AACR/ASCO Methods in Clinical Cancer Research Workshop.

Board of Directors

The firm's Board of Directors includes several senior-level individuals with substantial investment expertise, particularly in the venture capital and private equity domains. In particular, we would point out to investors that several members of the company's Board of Directors have substantial medical and industry experience, while others have successfully founded their own investment vehicles.

Jeff Wolf, J.D., M.B.A.
Director, President & Chief Executive Officer
See bio in Management Team section of this report.

Paul Belsky, M.D.
Vice Chairman
Dr. Belsky has served on the Heat Biologics Board since November 2009. He is currently an advisor at Seed-One Ventures and has been a partner at Concorde Medical Group, LLC since June of 1998. Dr. Belsky served as a scientific advisor to Elusys Therapeutics, Sensatex, GenerationOne and TyRx Pharma. He possesses extensive expertise in the clinical practice of internal medicine and cardiovascular diseases, and was formerly on the clinical academic faculty of the Weill College of Medicine at Cornell University. He is a fellow of the American College of Cardiology, the American College of Chest Physicians, and the American College of Physicians, and a clinical assistant

professor of medicine at New York University's School of Medicine. Dr. Belsky received his M.D. degree from the University of California at San Francisco, and his A.B. in Biology from Brown University, where he was elected Phi Beta Kappa.

Michael Kharitonov, Ph.D.
Director
Dr. Kharitonov has been the CEO of Voleon Capital Management, an investment management firm, since July 2007. He is a high technology entrepreneur and computer scientist whose areas of expertise include advanced computer and communication technologies and quantitative finance. Dr. Kharitonov is a founder and CEO of Voleon Capital Management LLC. He was a co-founder and former Chairman and CEO of Netli, Inc., a successful Silicon Valley startup that pioneered the development of Application Delivery Networks. Under Dr. Kharitonov's leadership, Netli raised over $20 million in venture financing from a number of Silicon Valley's best-known venture capital firms. In 2007 Netli was acquired by Akamai Technologies (NASDAQ/AKAM, Not Rated). Dr. Kharitonov also served as a Vice President of D. E. Shaw and Co., an international investment firm known as one of the most quantitatively advanced and computerized securities trading firms in the world. He holds a Ph.D. degree from the Department of Computer Science at Stanford University. At Stanford, he held a Hertz Fellowship and was also the winner of several scholarly awards. He holds a B.A. in Computer Science and Mathematics with highest honors from University of California at Berkeley.

Edward B. Smith, M.B.A.
Director
Since April 2005, Mr. Smith has been the Managing Partner of Brightline Capital Management, LLC, a New York-based investment firm founded in 2005. BCM is the investment manager of Brightline Ventures I, LLC, Brightline Ventures II, LLC, Brightline Ventures III, LLC and Brightline Capital Partners, LP. Prior to founding BCM, Mr. Smith worked at Gracie Capital from 2004-2005, GTCR Golder Rauner from 1999-2001 and Credit Suisse First Boston from 1997-1999. He holds a Bachelor of Arts in Social Studies from Harvard College and an M.B.A. from Harvard Business School. He is currently a Director of Z Trim Holdings Inc (OTCBB/ZTHO, Not Rated), a manufacturer of environmentally friendly agricultural functional ingredients.

John Monahan, Ph.D.
Director
Dr. Monahan is currently the Chief Technology Officer of Synthetic Biologics, Inc., a biotechnology company focused on the development of synthetic DNA-based therapeutics and innovative disease-modifying medicines for serious illnesses. He also co-founded Avigen Inc. (NASDAQ/AVGN, Not Rated) in 1992, a company which has become a leader in its sector for the development of novel pharmaceutical products aimed at treating serious human diseases. Over a 12-year period as CEO of Avigen, he raised over $235 million in several private and public financings including the IPO for the company. From 1989-1992, he was VP of R&D at Somatix Therapy Corp., Alameda, CA and from 1985-1989 he was Director of Molecular & Cell Biology at Triton Biosciences Inc., Alameda, CA. Prior to that from 1982-1985, he was Research Group Chief, Department of Molecular Genetics, Hoffmann-LaRoche, Inc. Nutley, NJ, and from 1975 to 1977 he was an instructor at Baylor College of Medicine in Houston, TX. He received his Ph.D. in Biochemistry in 1974 from McMaster University in Canada and his B.Sc. from University College Dublin, Ireland in 1969. Dr. Monahan is a board member of Tacere Therapeutics. He is also a board member of a number of Irish biotech firms, including Genable, Cellix, Luxcel, Identigen, Pharmatrin and GK Technologies.

Table 13: Heat Biologics, Inc. (HTBX) – Historical Income Statements, Financial Projections

FY end December 31
$ in thousands, except per share data

				2013E					2014E						
	2010A	2011A	2012A	1QA	2QA	3QE	4QE	2013E	1QE	2QE	3QE	4QE	2014E	2015E
Revenue														
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Service revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Research and other	376	187	3	-	-	-	-	-	-	-	-	-	-	-
Total revenue	376	187	3	-	-	-	-	-	-	-	-	-	-	-
Expenses														
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Research & development	810	1,247	903	440	689	700	800	2,629	1,300	1,500	1,700	1,800	6,300	8,900
Clinical and regulatory	-	255	253	62	455	450	500	1,467	550	600	650	700	2,500	3,900
General and administrative	246	721	1,190	268	438	300	350	1,356	400	450	500	600	1,950	3,400
Total expenses	1,056	2,223	2,346	770	1,582	1,450	1,650	5,452	2,250	2,550	2,850	3,100	10,750	16,200
Gain (loss) from operations	(680)	(2,036)	(2,343)	(770)	(1,582)	(1,450)	(1,650)	(5,452)	(2,250)	(2,550)	(2,850)	(3,100)	(10,750)	(16,200)
Other income/expense														
Interest income/expense	(42)	(63)	(101)	(28)	(32)	(35)	(40)	(135)	(45)	(50)	(55)	(60)	(210)	(210)
Realized loss on marketable securities				(2,300)	-	-	-	(2,300)						
Other income/expense	-	(14)	(27)	10	(60)	(50)	(30)	(130)	(30)	(30)	(30)	(30)	(120)	(120)
Total investment income and other	(42)	(77)	(128)	(2,318)	(92)	(85)	(70)	(2,565)	(75)	(80)	(85)	(90)	(330)	(330)
Loss before provision for income taxes	(722)	(2,113)	(2,471)	(3,088)	(1,674)	(1,535)	(1,720)	(8,017)	(2,325)	(2,630)	(2,935)	(3,190)	(11,080)	(16,530)
Deferred income tax benefit	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss)	(722)	(2,113)	(2,471)	(3,088)	(1,674)	(1,535)	(1,720)	(8,017)	(2,325)	(2,630)	(2,935)	(3,190)	(11,080)	(16,530)
Net income (loss) - non-controlling interest	-	-	-	-	(53)	-	-	(53)	-	-	-	-	-	-
Net income (loss) attributable to common shareholders	(722)	(2,113)	(2,471)	-	(1,621)	(1,535)	(1,720)	(8,071)	(2,325)	(2,630)	(2,935)	(3,190)	(11,080)	(16,530)
Net loss per share (basic)	(0.40)	(1.15)	(1.32)	(1.66)	(0.92)	(0.31)	(0.27)	(2.15)	(0.36)	(0.34)	(0.34)	(0.36)	(1.39)	(1.82)
Net loss per share (diluted)	(0.40)	(1.15)	(1.32)	(1.66)	(0.92)	(0.31)	(0.27)	(2.15)	(0.36)	(0.34)	(0.34)	(0.36)	(1.39)	(1.82)
Weighted average number of shares outstanding (basic)	-	-	2,055	1,790	1,762	4,995	6,445	3,748	6,545	7,645	8,745	8,845	7,945	9,095
Weighted average number of shares outstanding (diluted)	-	-	2,055	1,790	1,762	4,995	6,445	3,748	6,545	7,645	8,745	8,845	7,945	9,095

Source: Company Reports and Aegis Capital Corp. estimates

Public Companies Mentioned in this Report:

Advaxis (ADXS/OTCBB – $6.03)
Agenus (AGEN/NASDAQ – $3.02)
ArQule Inc. (ARQL/NASDAQ – $2.20)
CytRx Corp. (CYTR/NASDAQ – $2.39 – Buy)
Eli Lilly & Co. (LLY/NYSE – $48.92)
Endocyte (ECYT/NASDAQ – $4.56)
Epizyme (EPZM/NASDAQ – $33.40)
Galena Biopharma, Inc. (GALE/NASDAQ – $1.93 – Buy)
ImmunoCellular Therapeutics (IMUC/NASDAQ – $2.70)
Infinity Pharmaceuticals (INFI/NASDAQ – $20.72)
Inovio Pharmaceuticals (INO/NASDAQ – $2.55 – Hold)
Merrimack Pharmaceuticals (MACK/NASDAQ – $3.79)
NewLink Genetics (NLNK/NASDAQ – $17.51)
Northwest BioTherapeutics (NWBO/NASDAQ – $3.35)
OncoMed Pharmaceuticals (OMED/NASDAQ – $16.63)
Oncothyreon (ONTY/NASDAQ – $1.78)
Seattle Genetics (SGEN/NASDAQ – $47.87)
Stemline Therapeutics (STML/NASDAQ – $37.33 – Buy)
Verastem (VSTM/NASDAQ – $14.18)
ZIOPHARM Oncology (ZIOP/NASDAQ – $3.23)

Required Disclosures

Price Target

Our 18-month price target is $36.00 per share.

Valuation Methodology

We utilize a discounted cash flow analysis supporting a risk-adjusted Net Present Value framework to derive the price target. Intrinsic value for the company's product candidates is calculated based upon the size of the market, projected peak penetration rate, competitive landscape, probability of approval based on publicly available clinical data, length of patent term protection and other factors. Intrinsic values are then added to derive the price target.

Risk Factors

Issues that could prevent the achievement of our price objective include, but are not limited to, clinical, regulatory, competitive, reimbursement and financial risks. Drugs in clinical development may not advance due to inadequate safety, efficacy, or tolerability. Regulatory agencies may decline to approve regulatory submissions in a timely manner, or may not approve a drug candidate at all. The firm may require substantial funding to advance the clinical progress of its candidates, which could be dilutive to current shareholders. We expect competition for the company's drugs from several public and private companies developing pharmaceuticals. Sales of the firm's products could depend upon reimbursement from private, as well as public, reimbursement agencies.

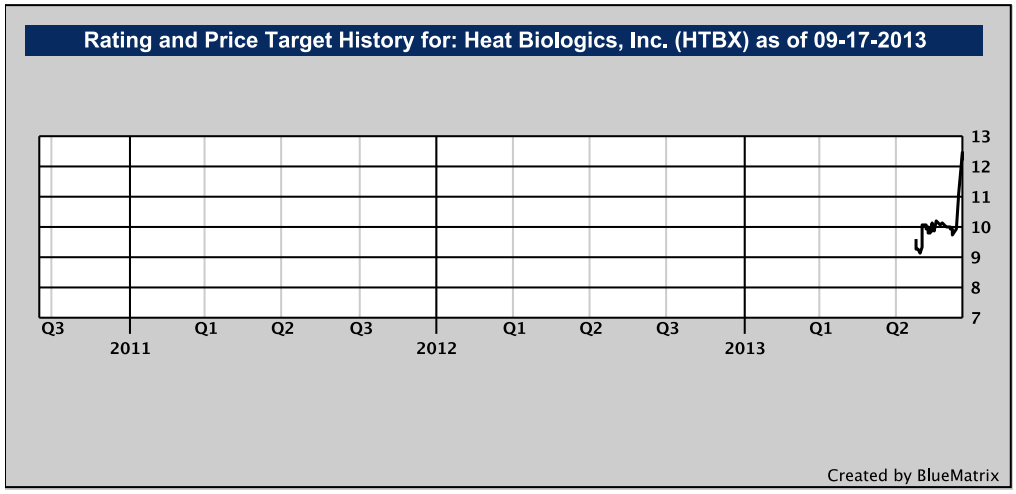
For important disclosures go to www.aegiscap.com.

Research analyst compensation is dependent, in part, upon investment banking revenues received by Aegis Capital Corp.

Aegis Capital Corp. intends to seek or expects to receive compensation for investment banking services from the subject company within the next three months.

Aegis Capital Corp. has performed investment banking services for and received fees from Heat Biologics, Inc. within the past 12 months.

Aegis Capital Corp. makes a market in Heat Biologics, Inc..



Rating	Percent	Investment Banking Services/Past 12 Mos. Percent
BUY [BUY]	88.89	21.88
HOLD [HOLD]	11.11	0.00
SELL [SELL]	0.00	0.00

Meaning of Ratings

A) A Buy rating is assigned when we do not believe the stock price adequately reflects a company's prospects over 12-18 months.
B) A Hold rating is assigned when we believe the stock price adequately reflects a company's prospects over 12-18 months.
C) A Sell rating is assigned when we believe the stock price more than adequately reflects a company's prospects over 12-18 months.

Other Disclosures

The information contained herein is based upon sources believed to be reliable but is not guaranteed by us and is not considered to be all inclusive. It is not to be construed as an offer or the solicitation of an offer to sell or buy the securities mentioned herein. Aegis Capital Corp., its affiliates, shareholders, officers, staff, and/or members of their families, may have a position in the securities mentioned herein, and, before or after your receipt of this report, may make or recommend purchases and/or sales for their own accounts or for the accounts of other customers of the Firm from time to time in the open market or otherwise. Opinions expressed are our present opinions only and are subject to change without notice. Aegis Capital is under no obligation to provide updates to the opinions or information provided herein. Additional information is available upon request.

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