

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (date of earliest event reported): April 18, 2022

Heat Biologics, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction of incorporation)

001-35994

(Commission File Number)

26-2844103

(IRS Employer Identification No.)

627 Davis Drive,

Suite 400

Morrisville, North Carolina 27560

(Address of principal executive offices and zip code)

(919) 240-7133

(Registrant's telephone number including area code)

N/A

(Former Name and Former Address)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0002 par value per share	HTBX	NYSE American LLC
Common Stock Purchase Rights		NYSE American LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.01 Completion of Acquisition or Disposition of Assets

As previously reported by Heat Biologics, Inc. ("Heat") in a Current Report on Form 8-K filed by Heat with the Securities and Exchange Commission (the "SEC") on December 21, 2021, Heat entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") by and among Heat, Heat Acquisition Sub 1, Inc., a Delaware corporation and wholly owned subsidiary of Heat ("Merger Sub"), and Elusys Therapeutics, Inc., a Delaware corporation ("Elusys"), providing for, among other things, the merger of Merger Sub with and into Elusys, with Elusys continuing as the surviving entity as a wholly owned subsidiary of Heat (the "Merger").

On April 18, 2022 (the "Closing Date"), Heat closed the Merger contemplated by the Merger Agreement (the "Closing"). Pursuant to the Merger Agreement, as merger consideration ("Merger Consideration") Heat paid at the Closing a cash upfront payment of \$3,000,000 to certain of the equity holders of Elusys (the "Sellers") and assumed and contributed \$867,646 to the payment of 50% of certain Elusys lease termination and employee severance payments. Heat will also pay to the Sellers (i) \$2,000,000 at the same time as the initial pass through revenue is distributed to the Sellers as described below and (ii) earn out payments for a period of 12 years from the date of Closing equal to 10% of the gross dollar amount of payments received during each one year period during such twelve year period with respect to any sale, license or commercialization anywhere in the world of Anthim that either: (a) occurs during the first nine years after the Closing Date in any respect; or (b) occurs thereafter pursuant to any contract, agreement, commitment or order that is placed, granted, awarded or entered into during the first nine years after the Closing Date.

In addition, Elusys is expected to receive additional revenue from the future fulfillment of an existing U.S. Government contract and Heat has agreed to fulfill the future obligations of Elusys under such contract and pass through and distribute to the Sellers the revenue that is received under such contract minus the costs associated with such fulfillment obligations, subject to certain adjustments to the Merger Consideration specified in the Merger Agreement, including income taxes payable with respect to such payments. The Merger Agreement further provides that eighty percent of any amounts paid to and received by Elusys after the Closing and prior to June 30, 2023 with respect to the sale of 1,500 pre-filled vials of Anthim shall be paid to the Sellers, subject to certain adjustments specified in the Merger Agreement. Heat also agreed to use commercially reasonable efforts to maintain, finance, operate and promote Anthim and maintain the existing government contract and to continue to operate the Elusys business so as to allow the Sellers to receive the Merger Consideration.

The Merger Agreement contains customary representations, warranties and covenants of Heat, Elusys and the Merger Sub. Subject to certain customary limitations, the Sellers have agreed to indemnify Heat and its officers and directors against certain losses related to, among other things, breaches of Elusys' representations and warranties, certain specified liabilities and the failure to perform covenants or obligations under the Merger Agreement.

Elusys is a private, commercial-stage biopharmaceutical company that has achieved United States and international licensure in Canada, the United Kingdom, and the European Union for its lead antibody therapeutic, Anthim® (obiltoximab), a medical countermeasure to treat patients following anthrax exposure. Anthim is indicated for prophylaxis of inhalational anthrax due to *B. anthracis* when alternative therapies are not available or are not appropriate. Anthim has been delivered to the US Strategic National Stockpile ("SNS") as the result of a successful, multi-year partnership with the U.S. government.

A Special Committee of Heat's Board of Directors negotiated and approved the transaction and Cassel Salpeter & Co. provided a fairness opinion in connection with the transaction. Cassel Salpeter served as financial advisor to the special committee of Heat's Board of Directors.

The foregoing summary of the Merger Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Merger Agreement that is filed herewith as Exhibit 2.1.

The representations, warranties and covenants contained in the Merger Agreement were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to the Merger Agreement, and may be subject to limitations agreed upon by the contracting parties. Accordingly, the Merger Agreement is incorporated herein by reference only to provide investors with information regarding the terms of the Merger Agreement, and not to provide investors with any other factual information regarding Heat, Elusys or either of their businesses, and should be read in conjunction with the disclosures in Heat's periodic reports and other filings with the Securities and Exchange Commission.

About Elusys

Elusys is a company focused on the commercialization of ANTHIM® (obiltoximab), which has received FDA approval and orphan drug exclusivity for the treatment of inhalational anthrax due to *Bacillus anthracis*.

Elusys has been awarded over \$350 million in procurement and development contracts by the Biomedical Advanced Research and Development Authority (BARDA), the National Institute of Allergy and Infectious Disease (NIAID) and the Department of Defense (DoD). Working closely with these agencies, Elusys has been able to advance ANTHIM to the commercial stage providing a therapeutic for inclusion in the CDC's Strategic National Stockpile (SNS) to strengthen US biosecurity against a potential anthrax attack. ANTHIM was licensed for commercial use by the FDA in 2016.

Elusys owns or licenses five US patents related to obiltoximab, related antibodies, and methods of use. Certain of the patents are licensed from the Board of Regents of the University of Texas System pursuant to the terms of a license agreement effective June 30, 2003 (the "License Agreement") pursuant to which Elusys has been granted a fully paid royalty-bearing, exclusive license under the inventions and discoveries covered by the Patent Rights (as defined therein) to manufacture, have manufactured, use, sell and offer to sell Licensed Products (as such terms is defined in the License Agreement) worldwide in the Licensed Field (as such terms is defined in the License Agreement). The term of the License Agreement is from the effective date to the end of the Patent Rights that have not expired; provided that the License Agreement automatically expires if Elusys becomes bankrupt or insolvent and the licensor has the right to terminate the License Agreement if Elusys is in default of payment; however, no further payments is due under the License Agreement, breach of any provision of the License Agreement and fails to cure such breach within thirty days of notice thereof or Elusys fails to pay certain expenses, which have been fully paid. The foregoing summary of the Merger Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the License Agreement that is filed herewith as Exhibit 10.1.

Elusys was formed in 1998 by Jeff Wolf, our President, Chief Executive Officer and Chairman of the Board of Directors, who directly and through affiliated entities owns approximately 1.2% of the outstanding stock of Elusys, in the form of common stock, which is subordinate in terms of distributions to the Elusys preferred stock. Due to the potential conflict of interest, Heat formed a Special Committee of its Board of Directors to review and negotiate the Merger Agreement. However, pursuant to the terms governing the Elusys preferred stock, the preferred stockholders of Elusys will receive all of the initial \$5 million of Merger Consideration and all of the net payments from the \$31 million of revenues related to fulfillment of the existing SNS contract. While the amount of earn out payments, if any, to be made over the 12 year period following closing is very uncertain, it also presently seems likely that most if not all of such payments will also be paid to the preferred stockholders of Elusys under the terms of such preferred stock.

Item 7.01. Regulation FD Disclosure.

On April 20, 2022, Heat issued a press release announcing the Closing of the Merger. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In addition, Heat will be making several presentations to investors over the next several weeks. In connection with the presentations, Heat intends to discuss the investor presentation, which is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01, in the press release furnished as Exhibit 99.1 and in the investor presentation furnished as Exhibit 99.2 to this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended and shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by Heat, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

The press release furnished as Exhibit 99.1 and investor presentation furnished as Exhibit 99.2 to this Current Report on Form 8-K include "safe harbor" language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained therein are "forward-looking" rather than historical.

Heat undertakes no duty or obligation to update or revise the information contained in this Current Report on Form 8-K, although it may do so from time to time if its management believes it is appropriate. Any such updating may be made through the filing of other reports or documents with the Securities and Exchange Commission.

Item 9.01. Financial Statements and Exhibits.

(a) Financial statements of businesses acquired.

The financial statements required by Item 9.01(a) of Form 8-K will be filed with the SEC no later than 71 calendar days after the date that this Current Report on Form 8-K is required to be filed.

(b) Pro forma financial information.

The pro forma financial information required by Item 9.01(b) of Form 8-K will be filed with the SEC no later than 71 calendar days after the date that this Current Report on Form 8-K is required to be filed.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following Exhibit 99.1 is furnished with this Current Report on Form 8-K:

Exhibit Number	Description
2.1	Merger Agreement, dated December 20, 2021, by and among Heat Biologics, Inc., Heat Acquisition Sub 1, Inc. and Elusys Therapeutics, Inc. (incorporated by reference to the Form 8-K filed with the Securities and Exchange Commission on December 21, 2021 (File No. 001-35994)*)
10.1	Patent License Agreement between the Board of Regents of the University of Texas System and Elusys Therapeutics, Inc.
99.1	Press release, dated April 20, 2022
99.2	Investor Presentation dated April 2022
104	Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: April 20, 2022

HEAT BIOLOGICS, INC.

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

PATENT LICENSE AGREEMENT**UTA#03-005**

THIS Agreement is between the Board of Regents ("Board") of The University of Texas System ("System"), an agency of the State of Texas, whose address is 201 West 7th Street, Austin, Texas 78701, and EluSys Therapeutics, Inc., a Delaware corporation having a principal place of business located at 10 Bloomfield Ave., Pine Brook, NJ 07058 ("Licensee").

TABLE OF CONTENTS

RECITALS

1. EFFECTIVE DATE
2. DEFINITIONS
3. WARRANTY AND SUPERIOR RIGHTS
4. LICENSE
5. PAYMENTS AND REPORTS
6. TERM AND TERMINATION
7. INFRINGEMENT BY THIRD PARTIES
8. ASSIGNMENT
9. PATENT MARKING
10. INDEMNIFICATION
11. USE OF NAME
12. CONFIDENTIAL INFORMATION AND PUBLICATION
13. PATENTS AND INVENTIONS
14. ALTERNATE DISPUTE RESOLUTION
15. GENERAL SIGNATURES APPENDIX A

RECITALS

- A. Board owns certain Patent Rights related to Licensed Subject Matter, which were developed at The University of Texas at Austin ("University"), a component institution of System.
- B. Board desires to have the Licensed Subject Matter developed and used for the benefit of Licensee, Inventor, Board, and the public as outlined in Board's Intellectual Property Policy.
- C. Licensee wishes to obtain a license from Board to practice Licensed Subject Matter.

NOW, THEREFORE, in consideration of the mutual covenants and premises herein contained, the parties agree as follows:

1. EFFECTIVE DATE

This Agreement is effective June 30, 2003 ("Effective Date").

2. DEFINITIONS

As used in this Agreement, the following terms have the meanings indicated:

- 2.1 "**Affiliate**" means any business entity 50% or more owned by Licensee, any business entity which owns more than 50% of Licensee, or any business entity that is more than 50% owned by a business entity that owns more than 50% of Licensee.
- 2.2 "**Licensed Field**" means antibodies that bind immunologically to anthrax antigens.
- 2.3 "**Licensed Product**" means any antibodies made or sold by Licensee consisting of Licensed Subject Matter.
- 2.4 "**Licensed Subject Matter**" means inventions and discoveries covered by Patent Rights within the Licensed Field.
- 2.5 "**Licensed Territory**" means the world.

2.6 "**Patent Rights**" means Board's rights whether domestic or foreign in information or discoveries in the antibodies disclosed and claimed in the patent application entitled: (1) Recombinant Antibodies for the Detection and Neutralization of the Anthrax Toxin, serial number 10/288,269 filed on November 5, 2001, and (2) the U.S. patent

application entitled "Antibodies With Increased Affinities For Anthrax Antigens" inventors Barrett R. Harvey, George Georgiou, and Brent L. Iverson, serial number 10/620,049 filed July 15, 2003. The Patent Rights include all divisions, continuations, reissues, or reexaminations thereof, and any letters patent that issue thereon, which name at least George Georgiou and Brent Iverson as either sole or joint inventors ("Inventors") and which relate to the manufacture, use or sale of anthrax antibodies.

The Patent Rights do not include any subject matter other than the anthrax antibodies or improvements thereof with the exception of claims 47-59 (attached as Appendix A) of serial number 10/288,269, filed on November 5, 2001.

Licensee acknowledges that the Patent Rights do not include technology that may be used for the identification of antibodies and other binding proteins except as specifically recited in claims 47-59 of serial number 10/288,269. Licensee further acknowledges that the Patent Rights specifically exclude any other technology for the identification of antibodies and other binding proteins including, without limitation, Anchored Periplasmic Expression ("APEX") technology and anchor-less library display technology such as Periplasmic Expression with Cytometric Screening ("PEGS").

Licensee acknowledges that one or more of the patent applications referred to herein discloses subject matter that is beyond the scope of the Patent Rights, and that nothing herein will be deemed to grant to Licensee any rights in such subject matter. Licensee specifically acknowledges that this Agreement does not grant to Licensee the right to prosecute patent applications claiming subject matter that is outside the scope of the Licensed Subject Matter.

Licensee agrees that nothing herein will be deemed to grant to Licensee any rights under any other University or System patents or patent applications other than those listed in this Agreement. Licensee further agrees that nothing herein will be deemed to grant any rights in any technology disclosed in the foregoing patent applications other than Licensed Subject Matter.

3. WARRANTY AND SUPERIOR-RIGHTS

3.1 Except for the rights, if any, of the Government of the United States, as set forth below, Board represents and warrants its belief that (i) it is the owner of the entire right, title, and interest in and to Licensed Subject Matter, (ii) it has the sole right to grant licenses thereunder, and (iii) it has not knowingly granted licenses thereunder to any other entity that would restrict rights granted to Licensee except as stated herein.

3.2 Licensee understands that the Licensed Subject Matter may have been developed under a funding agreement with the Government of the United States of America and, if so, that the Government may have certain rights relative thereto. This Agreement is explicitly made subject to the Government's rights under any agreement and any applicable law or regulation. If there is a conflict between an agreement, applicable law or regulation and this Agreement, the terms of the Government agreement, applicable law or regulation will prevail.

3.3 Licensee understands and acknowledges that Board, by this Agreement, makes no representation as to the operability or fitness for any use, safety, efficacy, ability to obtain regulatory approval, patentability, and/or breadth of the Licensed Subject Matter. Board, by this Agreement, also makes no representation as to whether there are any patents now held, or which will be held, by others or by Board in the Licensed Field, nor does Board make any representation that the inventions contained in Patent Rights do not infringe any other patents now held or that will be held by others or by Board ..

3.4 Licensee, by execution hereof, acknowledges, covenants and agrees that it has not been induced in any way by Board, System, University or its employees to enter into this Agreement, and further warrants and represents that (i) it has conducted sufficient due diligence with respect to all items and issues pertaining to this Article 3 and all other matters pertaining to this Agreement; and (ii) Licensee has adequate knowledge and expertise, or has utilized knowledgeable and expert consultants, to adequately conduct the due diligence, and agrees to accept all risks inherent herein.

4. LICENSE

4.1 Board hereby grants to Licensee a royalty-bearing, exclusive license under Licensed Subject Matter to manufacture, have manufactured, use, sell and offer to sell Licensed Products within the Licensed Territory in the Licensed Field. This grant is subject to the payment by Licensee to Board of all consideration as provided herein, and is further subject to rights retained by Board to:

a. Publish the general scientific findings from research conducted in whole or in part at the University or otherwise within the System related to Licensed Subject Matter subject to the terms of Section 14, Confidential Information; and

b. Use Licensed Subject Matter for research, teaching and other educationally-related purposes.

4.2 Licensee may extend the license granted herein to any Affiliate if the Affiliate consents to be bound by this Agreement to the same extent as Licensee.

5. PAYMENTS AND REPORTS

a. In consideration of rights granted by Board to Licensee under this Agreement, Licensee will pay Board the following: A non-refundable, upfront license fee in the amount of \$62,500, due and payable by November 15, 2003;

b. A fee of \$150,000 due and payable on the following schedule:

- i. \$50,000 by August 1, 2004
- ii. \$50,000 by August 1, 2005
- iii. \$50,000 by August 1, 2006

5.1 All amounts payable here by Licensee must be paid in United States funds without deductions for taxes, assessments, fees, or charges of any kind. Checks must be payable to The University of Texas at Austin and sent to:

The Office of Technology Licensing
The University of Texas at Austin
3925 West Braker Lane, Suite 1.9A
Austin, Texas 78759
ATTN: Director

5.2 Due and payable upon execution of this agreement, Licensee will reimburse Board \$15,690.26 for all out-of-pocket expenses thus far incurred by Board. Licensee must pay all future reasonable expenses for filing, prosecuting, enforcing and maintaining the Patent Rights (the "Patent Expenses") within forty five (45) days of receipt of a bill from patent counsel and will copy University on all billing.

5.3 Upon the payment by Licensee of the sum set forth in Paragraph 5.1 (b) (iii) above, Licensee shall obtain a paid-up, worldwide, license under the Patent Rights.

6. TERM AND TERMINATION

6.1 The term of this Agreement is from the Effective Date to the full end of the term or terms for which Patent Rights have not expired.

6.2 This Agreement will earlier terminate:

a. automatically if Licensee becomes bankrupt or insolvent and/or if the business of Licensee is placed in the hands of a receiver, assignee, or trustee, whether by voluntary act of Licensee or otherwise; or at any time by mutual written agreement between Licensee and Board subject to any terms herein which survive termination, which include the balance of the total amount due under 5.1.

6.3 Board may terminate this Agreement at any time if Licensee:

a. is in default in payment of fees

b. is in breach of any provision hereof and Licensee fails to cure any such default, breach or false report within thirty (30) days after confirmed delivery of written notice thereof given by Board; or

c. fails to fulfill its obligations relating to Patent Expenses set forth in Section 5.3.

6.4 If this Agreement is terminated for any cause:

a. nothing herein will be construed to release either party of any obligation matured prior to the effective date of the termination;

b. after the effective date of the termination, Licensee may sell all Licensed Products and parts therefor it has on hand at the effective date of termination, if it pays all amounts due as of the effective date of the termination according to the terms of Article 5; and

c. Licensee will be bound by the provisions of Articles 12 (Indemnification), 13 (Use of Board and Component's Name) and 14 (Confidential Information) of this Agreement.

6.5 Upon termination of this Agreement, Licensee at Board's request will return to University all Confidential Information fixed in any tangible medium of expression.

7. INFRINGEMENT BY THIRD PARTIES

7.1 Licensee, at its expense, has the right but not the obligation to enforce any patent exclusively licensed hereunder against infringement by third parties and it is entitled to retain recovery from such enforcement. Licensee must pay Board an amount on any monetary recovery which is a reasonable approximation of the royalties and other amounts that Licensee would have paid to Board if Licensee had sold the infringing products rather than the infringer, after deducting reasonable legal expenses incurred in connection with such enforcement. If Licensee does not file suit against a substantial infringer of a patent within 6 months of knowledge thereof, then Board may enforce any patent licensed hereunder on behalf of itself and Licensee. Board retaining all recoveries from such enforcement and/or reducing the license granted hereunder to non-exclusive.

7.2 In any infringement suit or dispute, the parties agree to cooperate fully with each other. At the request and expense of the party bringing suit, the other party will permit access to all relevant personnel, records, papers, information, samples, specimens, etc., during regular business hours.

8. ASSIGNMENT

Except in connection with the sale of substantially all of Licensee's assets to a third party, this Agreement may not be assigned by Licensee without the prior written consent of Board, which will not be unreasonably withheld.

9. PATENT MARKING

Licensee will to the extent practical and subject to FDA rules and regulations on labelling, mark all products and documentation manufactured or sold by Licensee under this Agreement with a patent notice as may be permitted or required under Title 35, United States Code.

10. INDEMNIFICATION

Licensee agrees to hold harmless and indemnify Board, System, University, its Regents, officers, employees and agents from and against any claims, demands, or causes of action whatsoever, including without limitation those arising on account of any injury or death of persons or damage to property caused by, or arising out of, or resulting from, the exercise or practice of the license granted hereunder by Licensee, its Affiliates or their officers, employees, agents or representatives except where such causes of action are based on the gross negligence or willful malfeasance of Board, System, University, its Regents, officers, employees or agents.

11. USE OF NAME

11.1 Licensee may not use the name of University, System or Board without express written consent.

11.2 Board and University may use Licensee's name in brochures, webpages and other publications in relation to University's intellectual property and commercialization achievements with the prior review and consent of Licensee, which consent shall not be unreasonably or timely withheld.

12. CONFIDENTIAL INFORMATION AND PUBLICATION

12.1 Board and Licensee each agree that all information contained in documents marked "confidential" and forwarded to one by the other (i) be received in strict confidence, (ii) be used only for the purposes of this Agreement, and (iii) not be disclosed by the recipient party, its agents or employees without the prior written consent of the other party, except to the extent that the recipient party can establish by competent written proof that such information:

a. was in the public domain at the time of disclosure;

- b. later became part of the public domain through no act or omission of the recipient party, its employees, agents, successors or assigns;
- c. was lawfully disclosed to the recipient party by a third party having the right to disclose it;
- d. was already known by the recipient party at the time of disclosure;
- e. was independently developed by the recipient; or
- f. is required by law or regulation to be disclosed.

12.2 Each party's obligation of confidentiality, nonuse and nondisclosure hereunder will be fulfilled by using at least the same degree of care with the other party's confidential information as it uses to protect its own confidential information. This obligation will exist while this Agreement is in force and for a period of 3 years thereafter.

12.3 University will submit its manuscript for any proposed publication of research related to the Licensed Subject Matter conducted at University in whole or in part or in the System to Licensee at least 30 days before publication, and Licensee will have the right to review and comment upon the publication in order to protect Licensee's confidential information. Upon Licensee's request, publication will be delayed up to 60 additional days to enable Licensee to secure adequate intellectual property protection of Licensee's property that would be affected by the publication.

13. PATENTS AND INVENTIONS

13.1 If University, Board and Licensee agree that any additional patent application should be filed for Licensed Subject Matter, Licensee will prepare and file the appropriate additional patent applications, and Licensee will reimburse patent counsel directly for all expenses incurred in searching, preparing, filing, prosecuting and maintaining same. Board will approve all patent counsel chosen by Licensee, which approval will not be unreasonably withheld. Any transfer expenses will be paid directly by Licensee. Licensee will copy University on all billing.

13.2 If Licensee notifies Board that it does not intend to pay the cost of an application, or if Licensee does not respond or make an effort to agree with Board on the disposition of rights in the subject invention, then Board may file an application at its own expense and Licensee will promptly provide Board a copy of any applications, amendments responses, briefs and other documents in connection with the filing or prosecution of patent applications hereunder for Board's review and approval prior to filing as time and other deadlines reasonably permit, as well as copies of any documents received from any patent office or agent, associate, or attorney in connection with the prosecution of Patent Rights. Licensee will not change, drop or abandon any claim of Patent Rights or file any patent application which may adversely affect University or Board's rights in the Patent Rights or the Licensed Subject Matter or any fees due under this Agreement without first obtaining the written consent of Board, which will not be unreasonably withheld.

13.3 Licensee further agrees that any rights under this section are specifically limited to Licensed Subject Matter. Licensee specifically agrees that it will not seek to gain rights under this Agreement in any technology other than Licensed Subject Matter. Licensed Subject Matter absolutely excludes, without limitation, technology that may be used for the identification of anthrax antibodies including Anchored Periplasmic Expression ("APEX") technology and anchor-less library display technology such as Periplasmic Expression with Cytometric Screening ("PECS").

14. ALTERNATE DISPUTE RESOLUTION

14.1 Any dispute or controversy arising out of or relating to this Agreement, its construction or its actual or alleged breach will be decided by mediation. If the mediation does not result in a resolution of such dispute or controversy, it will be finally decided by an appropriate method of alternate dispute resolution, including without limitation, arbitration, conducted in the city of Austin, Texas in accordance with the Commercial Dispute Resolution Procedures [http://www.adr.org/rules/commercial_rules.html] of the American Arbitration Association. The arbitration panel will include members knowledgeable in the evaluation of antibody technology. Judgment upon the award rendered may be entered in the highest court or forum having jurisdiction, state or federal. The provisions of this Article 16 will not apply to decisions on the validity of patent claims or to any dispute or controversy as to which any treaty or law prohibits such arbitration. The decision of the arbitration must be sanctioned by a court of law having jurisdiction to be binding upon and enforceable by the parties.

15. GENERAL

15.1 This Agreement constitutes the entire and only agreement between the parties for Licensed Subject Matter and all other prior negotiations, representations, agreements, and understandings are superseded hereby. No agreements altering or supplementing the terms hereof may be made except by a written document signed by both parties. Nothing contained in this agreement shall be construed as conferring any right by implication, estoppel, or otherwise except as expressly granted herein.

15.2 Any notice required by this Agreement must be given by prepaid, first class, certified mail, return receipt requested, addressed in the case of Board to:

Board of Regents
The University of Texas System 201 West 7th Street
Austin, Texas 78701
ATTENTION: Office of General Counsel
FAX: (XXX) XXX-XXXX
PHONE: (XXX) XXX-XXXX

with copies to:

The Office of Technology Licensing The University of Texas at Austin
3925 West Braker Lane, Suite 1.9A
Austin, Texas 78759
ATTENTION: Director
FAX: (XXX) XXX-XXXX
PHONE: (XXX) XXX-XXXX

or in the case of Licensee to:

EluSys Therapeutics, Inc.
10 Bloomfield Avenue
Pine Brook, NJ 07058
Attention: Vice President of Business Development
FAX: (XXX) XXX-XXXX
PHONE: (XXX) XXX-XXXX

or other addresses as may be given from time to time under the terms of this notice provision.

15.3 Licensee must comply with all applicable federal, state and local laws and regulations in connection with its activities pursuant to this Agreement.

15.4 This Agreement will be construed and enforced in accordance with the laws of the United States of America and of the State of Texas.

15.5 Failure of Board to enforce a right under this Agreement will not act as a waiver of that right or the ability to later assert that right relative to the particular situation involved.

15.6 Headings are included herein for convenience only and will not be used to construe this Agreement.

15.7 If any part of this Agreement is for any reason found to be unenforceable, all other parts nevertheless remain enforceable.

IN WITNESS WHEREOF, parties hereto have caused their duly authorized representatives to execute this Agreement.

BOARD OF REGENTS OF THE
UNIVERSITY OF TEXAS SYSTEM

By: /s/ Juan Sanchez
Name: Juan Sanchez, PhD
Title: Vice President for Research
November 3, 2003

ELUSYS THERAPEUTICS, INC.

By: /s/ Elizabeth G. Posillico
Name: Elizabeth G. Posillico
Title: Vice President of Business Development
Date: October 22, 2003

Appendix A Claims of Serial Number 10/288,269, filed on November 5, 2001



Heat Biologics (“NightHawk Biosciences”) Completes Acquisition of Elusys Therapeutics

Elusys becomes wholly-owned biodefense subsidiary of NightHawk

Plans to expand ANTHIM® distribution abroad

Durham, NC – April 20, 2022 – Heat Biologics, Inc. (NYSE American: HTBX) (to be renamed “NightHawk Biosciences”), a fully-integrated biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, today announced it has completed the acquisition of Elusys Therapeutics, Inc. a commercial-stage biodefense company and developer of ANTHIM® (obiltoximab), a treatment for inhalation anthrax. ANTHIM® is approved for use in the U.S. and Canada, and under the brand name Obiltoximab SFL in Europe and the United Kingdom.

Nighthawk acquired all outstanding shares of Elusys, which will continue to operate as a wholly-owned subsidiary of NightHawk. No stock or warrants were issued in connection with the acquisition, and Elusys had no outstanding term debt.

The strategic acquisition of Elusys significantly expands the Company’s role in the biodefense space, complementing NightHawk’s RapidVax® platform, which is designed to target emerging biological threats. Pursuant to this acquisition, NightHawk also announced it plans to migrate manufacturing of ANTHIM® to its planned 500,000 square foot Scorpion biomanufacturing facility in Manhattan, Kansas, which is being constructed to support development of commercial-scale biologics and large molecules.

To date, Elusys has been awarded over \$350 million in research and development grants, contracts and procurement orders from the Biomedical Advanced Research and Development Authority (BARDA) and the U. S. Strategic National Stockpile (SNS). Through ongoing, multi-year partnerships with the U.S. government, Elusys has been supplying ANTHIM® to the SNS - the government’s repository of critical medical supplies for biodefense preparedness.

Jeff Wolf, CEO of NightHawk, commented, “We are excited to announce the closing of this transformative acquisition, which provides us with a solid foothold in the biodefense space. Elusys has an established a successful track record collaborating with U.S. government agencies including BARDA, NIH, SNS and DOD. We plan to leverage Elusys’ existing relationships and distribution channels as a launching pad for RapidVax®, our “plug and play” platform designed for rapid development and delivery of new vaccines. In addition, we look forward to leveraging our new Kansas facility, which will enable us to manufacture these therapies internally and therefore benefit from significant operating synergies, as well as enhanced oversight, quality control, and speed to market. We are also exploring opportunities to expand ANTHIM® distribution abroad. This transaction is perfectly aligned with our overall vision to establish a fully-integrated ecosystem to deliver medical innovations faster, better, and more efficiently.”

David Lasseter, former Deputy Assistant Secretary of Defense for Countering Weapons of Mass Destruction, and a member of NightHawk’s Biothreat Advisory Board, commented, “This transaction is extremely timely, given the global uncertainty and unprecedented threats from foreign nations and rogue actors. Anthrax is one of the most significant biological warfare threats facing our country, with real potential for mass casualties. ANTHIM® represents a key medical countermeasure for the treatment of inhalation Anthrax.”

A special committee of Heat’s Board of Directors negotiated and approved the transaction and Cassel Salpeter & Co. provided a fairness opinion in connection with the transaction. Blank Rome LLP acted as legal counsel to Heat. Elusys was advised by RBC Capital Markets, LLC. Additional details on the transaction are outlined in Company’s Form 8-K, which will be filed with the Securities and Exchange Commission and will be available on the Company’s website.

About ANTHIM

Anthrax is a life-threatening infectious disease caused by *Bacillus anthracis*. Cases of inhalational anthrax in humans can occur through intentional spread of *B. anthracis* spores as a biowarfare or bioterrorism agent. *B. anthracis* spores introduced through the lungs lead to inhalational anthrax, which is deadly in humans.

ANTHIM is a monoclonal antibody that binds to the protective antigen (PA) component of anthrax toxin. ANTHIM’s toxin neutralizing activity prevents entry of anthrax toxin into susceptible cells, avoiding further spread of the toxin throughout the body and the ensuing tissue damage that leads to death. ANTHIM is supplied as single-dose vials for IV infusion.

Indications and Usage

ANTHIM is indicated in adult and pediatric patients for the treatment of inhalational anthrax due to *Bacillus anthracis* in combination with appropriate antibacterial drugs, and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate. ANTHIM should only be used for prophylaxis when its benefit for prevention of inhalational anthrax outweighs the risk of hypersensitivity and anaphylaxis. The effectiveness of ANTHIM is based solely on efficacy studies in animal models of inhalational anthrax. There have been no studies of the safety or pharmacokinetics (PK) of ANTHIM in the pediatric population. Dosing in pediatric patients was derived using a population PK approach. ANTHIM does not have direct antibacterial activity. ANTHIM should be used in combination with appropriate antibacterial drugs. ANTHIM is not expected to cross the blood-brain barrier and does not prevent or treat meningitis.

IMPORTANT SAFETY INFORMATION Including BOXED WARNING

WARNING: HYPERSENSITIVITY and ANAPHYLAXIS

Hypersensitivity reactions, including anaphylaxis, have been reported during ANTHIM infusion. ANTHIM should be administered in monitored settings by personnel trained and equipped to manage anaphylaxis. Stop ANTHIM infusion immediately and treat appropriately if hypersensitivity or anaphylaxis occurs.

WARNINGS AND PRECAUTIONS

Hypersensitivity and anaphylaxis have been reported during the IV infusion of ANTHIM. Due to the risk of hypersensitivity and anaphylaxis, ANTHIM should be administered in monitored settings by personnel trained and equipped to manage anaphylaxis. Monitor individuals who receive ANTHIM closely for signs and symptoms of hypersensitivity reactions throughout the infusion and for a period of time after administration. Stop ANTHIM infusion immediately and treat appropriately if hypersensitivity or anaphylaxis occurs. Pre-medication with diphenhydramine is recommended prior to administration of ANTHIM. Diphenhydramine pre-medication does not prevent anaphylaxis and may mask or delay onset of symptoms of hypersensitivity.

ADVERSE REACTIONS

The safety of ANTHIM has been studied only in healthy volunteers. It has not been studied in patients with inhalational anthrax. The most frequently reported adverse reactions were headache, pruritus, infections of the upper respiratory tract, cough, vessel puncture site bruise, infusion site swelling, urticaria, nasal congestion, infusion site pain, and pain in extremity.

USE IN SPECIFIC POPULATIONS

Pediatric Use: There have been no studies of the safety or PK of ANTHIM in the pediatric population.

To see the complete prescribing information for ANTHIM, [click here](#).

About Heat Biologics, Inc. / NightHawk Biosciences, Inc.

Heat Biologics (to become “NightHawk Biosciences”) is a fully-integrated biopharmaceutical company focused on the development of new drugs from discovery through biomanufacturing. The Company leverages its integrated ecosystem of subsidiaries to accelerate the creation of novel therapies that arm the immune system, breaking through barriers that prolong traditional drug development. This empowers us to bring our ideas to life with efficient control, superior quality, and uncharacteristic agility.

For more information on the Company and its subsidiaries, please visit: www.nighthawkbio.com, and also follow us on Twitter.

Forward Looking Statement

This release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In some cases forward-looking statements can be identified by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions, and include statements regarding plans to migrate manufacturing of ANTHIM® to the planned 500,000 square foot biomanufacturing facility in Manhattan, Kansas, plans to leverage Elusys' existing relationships and distribution channels as a launching pad for RapidVax, leveraging the new Kansas facility to enable Heat to manufacture therapies internally, expected benefit to be derived from significant operating synergies, as well as enhanced oversight, quality control, and speed to market, exploring opportunities to expand ANTHIM® distribution abroad and establishing a fully-integrated ecosystem to deliver medical innovations faster, better, and more efficiently. Important factors that could cause actual results to differ materially from current expectations include, among others, the ability to migrate manufacturing of ANTHIM® to the Manhattan, Kansas facility, the ability to expand ANTHIM® sales beyond the U.S., the ability to leverage Elusys' existing relationships and distribution channels as a launching pad for RapidVax, the ability to expand ANTHIM® distribution abroad, the ability to derive benefit from operating synergies, as well as enhanced oversight, quality control, and speed to market, the ability to establish a fully-integrated ecosystem to deliver medical innovations faster, better, and more efficiently, whether the combined business of Heat and Elusys will be successful, Heat's and Elusys' ability to maintain license agreements, the continued maintenance and growth of Heat's and Elusys' patent estate, Heat's product candidates demonstrating safety and effectiveness, as well as results that are consistent with prior results, the ability to initiate clinical trials and if initiated, the ability to complete them on time and achieve the desired results and benefits continuing enrollment as expected, the ability to obtain regulatory approval for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to Heat's ability to promote or commercialize its product candidates for the specific indications, acceptance of product candidates in the marketplace and the successful development, marketing or sale of Heat's, developments by competitors that render such products obsolete or non-competitive, and other factors described in Heat's annual report on Form 10-K for the year ended December 31, 2021, subsequent quarterly reports on Form 10-Qs and any other filings Heat makes with the SEC. Heat can give no assurance that the conditions to the Merger will be satisfied. The information in this presentation is provided only as of the date presented, and Heat undertakes no obligation to update any forward-looking statements contained in this presentation on account of new information, future events, or otherwise, except as required by law.

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NIGHTHAWK BIOSCIENCES

CORPORATE PRESENTATION

April 2022

PLEASE NOTE: Heat Biologics, Inc. anticipates transitioning to NightHawk Biosciences, Inc effective May 3, 2022.

Forward Looking Statements

This presentation includes statements that are, or may be deemed, "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "approximately" or, in each case, their negative or other variations thereon or comparable terminology, although not all forward-looking statements contain these words. They appear in a number of places throughout this presentation and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the timing of the opening of our facilities in San Antonio, Texas and Manhattan, Kansas, our ongoing and planned discovery and development of drugs targeting cancer, non-oncology, infectious disease medical countermeasures, our planned biosecurity/biodefense initiative, our planned bioanalytics, process development and manufacturing activities, our biologics drug discovery, the strength and breadth of our intellectual property, our ongoing and planned preclinical studies and clinical trials, the timing of and our ability to complete clinical trials and make regulatory filings and obtain and maintain regulatory approvals for our product candidates, our ability to partner our product development, the degree of clinical utility of our products, particularly in specific patient populations, expectations regarding clinical trial data, our results of operations, the industry in which we operate and the trends that may affect the industry or us.

By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, and healthcare, regulatory and scientific developments and depend on the economic circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. Although we believe that we have a reasonable basis for each forward-looking statement contained in this presentation, we caution you that forward-looking statements are not guarantees of future performance and that our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation as a result of, among other factors, the factors referenced in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2021, our quarterly reports on Form 10-Q for the subsequent quarters and our other subsequent filings with the Securities and Exchange Commission (collectively, our "SEC Filings"). In addition, even if our results of operations, financial condition and liquidity, and the development of the industry in which we operate are consistent with the forward-looking statements contained in this presentation, they may not be predictive of results or developments in future periods. Any forward-looking statements that we make in this presentation speak only as of the date of such statement, and we undertake no obligation to update such statements to reflect events or circumstances after the date of this presentation, except as required by law.

Snapshot of NIGHTHAWK

Fully integrated biopharmaceutical company developing novel therapies that arm the immune system

- Key programs targeting oncology, inflammation, and medical countermeasures
- Well-capitalized with strong balance sheet

NightHawk Bio's ecosystem enables agility to innovate and pivot

- Ecosystem of integrated companies with efficient control of discovery, preclinical/clinical development, and biomanufacturing
- End-to-end development from bench to commercial

Major programs include:

- Anthim® (obiltoximab) – FDA approved best-in-class antitoxin treatment for inhalational anthrax
- HS-110 – “off-the-shelf” cell-based immunotherapy with positive results in NSCLC (Phase 2)
- PTX-35 – potential first-in-class immunomodulatory antibody for treatment of solid tumors (Phase 1)
- RapidVax® – novel vaccine platform designed to accelerate time to clinic to combat emerging biological threats

3



NIGHTHAWK Ecosystem

Streamlining Innovative Discoveries to Accelerate Clinical Development



OUR ECOSYSTEM



Discovery



Preclinical/Clinical Development



Biomanufacturing

4



Skunkworx Bio

Discovery Sciences

“Biology Drives Innovation”

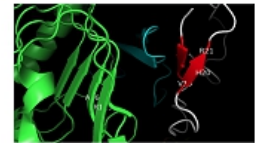
- Primary proprietary platform designed to enable rapid selection and validation of novel therapeutics for preclinical development
- Additional novel therapeutic targeting and drug delivery platforms under development

Unique Hotspot approach based on Pocket Biologics

- Novel, highly diverse, proprietary compound libraries used to identify small proteins and human antibodies which bind to critical druggable targets
- Advanced computational methods and bioinformatics inform target identification and improve development of candidate therapeutics

Located in the New Jersey Bioscience Center - North Brunswick, NJ

- Highly selective bioscience incubator in the heart of New Jersey’s “Research Corridor”



5



Oncology and Inflammation Development

Heat Biologics – Realizing Immune Potential

- Developing first-in-class immunomodulators that realize the potential of the immune system to treat and protect against a wide range of diseases
- Proprietary gp96-based vaccines to re-stimulate the immune system’s anti-tumor response
- Phase 2 candidate HS-110 (vigenpumatucl-L) is an off-the-shelf allogenic cell therapy designed to stimulate immune responses against NSCLC



Pelican Therapeutics – Next Generation T cell Immunotherapy for Cancer

- Lead candidate, the monoclonal antibody PTX-35, is an agonist of TNFRSF25 with the potential to shift the balance between inflammation and immunosuppression
- In Phase I solid tumors as a potential first-in-class T cell co-stimulator
- \$15.2 million Cancer Prevention Institute of Texas (CPRIT) grant (the “CPRIT Grant”) to support development of PTX-35



6



Elusys Therapeutics

Medical Countermeasures

Definitive agreement for acquisition executed in December 2021

- Sophisticated knowledge and hands-on experience in biodefense biologics
- Program Management expertise with government agencies including the NIH, DoD, and BARDA



Developer and marketer of Anthim[®], best-in-class monoclonal antibody antitoxin for anthrax

- For treatment of inhalation anthrax in combination with antibiotics or, and as a prophylaxis when alternative therapies are not available or are not appropriate. Prescribing information: <https://anthim.com/>
- FDA approval in 2016, orphan drug designation
- Approved in 2020 as only licensed anthrax treatment in EU, UK, and CA
- Orphan drug designation in EU at time of approval



Established government partnerships and funding

- Received over \$250M of non-dilutive development contracts from the NIH, DoD, and BARDA
- Completed \$70M in procurement contracts to supply Anthim to the U.S. Strategic National Stockpile (2016, 2018)
- Completed first phase of contract for \$50 million; HHS options to procure up to \$31 million of Anthim by the first half of 2023

7



Scorpion Biological Services

Biomanufacturing and Analytical Labs

Designed to provide scale-up GMP process development and biomanufacturing, cell and immuno-assay development, and bioanalytical lab services

- Dedicated capacity to accelerate NightHawk preclinical and clinical development efforts
- Contract manufacturing and bioanalytical services for external biopharmaceutical companies
- Focus on American supply chain for materials and equipment



Clinical Scale Facility, San Antonio, Texas – grand opening Q3 2022*

- Designed to provide a scalable process development
- Production of GMP material to large-scale clinical manufacturing and cold storage facilities



Commercial Scale Facility, Manhattan, Kansas – breaking ground Q3 2022*

- 500,000 sq. ft. state-of-the-art cGMP commercial biomanufacturing facility
- 48+ bioreactors, ~144,000 liters for biomanufacturing of large-scale biologics



8

* per scheduled timeline



Product Pipeline

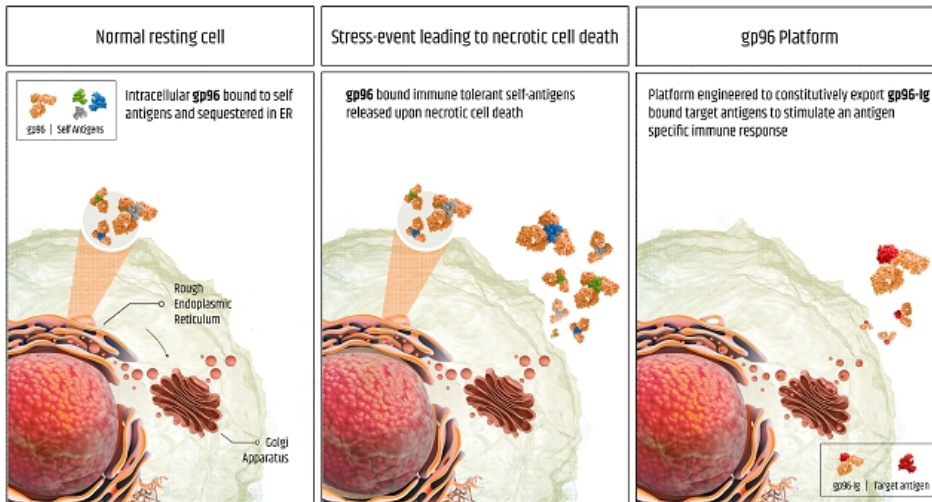
CATEGORY	PROGRAM	MOA (MODALITY)	INDICATION	IND-ENABLING	PHASE 1	PHASE 2	PHASE 3	APPROVED	STATUS
Oncology	HS-110	gp96 + CTAs (Cell Therapy)	NSCLC						End-of-Ph 2 Planning
	HS-130	OX40L (Cell Therapy)	Solid Tumors						Ph 1 Enrollment Complete
	PTX-35	TNFRSF25 (mAb)	Solid Tumors						Ph 1 Enrollment Ongoing
Medical Countermeasures	RapidVax	gp96 + OX40L (Vaccine)	Multiple Indications						Platform Development
	ANTHIM	Antitoxin (mAb)	Anthrax						Marketed Product

CTA = cancer testis antigen
NSCLC = Non-small cell lung cancer



gp96 Platform Overview

Activating the Immune System



Key gp96 platform features

- Leverages gp96's role as a natural molecular warning system
- Can be engineered to secrete target antigens bound to gp96-Ig
- Off-the-shelf allogeneic cell vaccine
- Scalable manufacturing
- Amenable to stockpiling
- Broad applications in infectious diseases and cancer

Lead product: HS-110

- Completed Phase 2 trial for NSCLC



HS-110 (viagenpumatucl-L)

gp96 -Based Cancer Vaccine Targeting Solid Tumors

HS-110 is a first-in-class, “off-the-shelf”, allogeneic cell-based immunotherapy

- Engineered to secrete a wide range of cancer-associated antigens bound to the immunostimulatory chaperone gp96
- Designed to stimulate and facilitate uptake of cancer antigens by antigen presenting cells (APCs), which in turn activate a broad, T-cell mediated immune response against a patient’s cancer
- Worldwide rights available

Enrollment complete for Phase 2 NSCLC evaluating HS-110 in combination with PD-1 therapy

- Positive interim survival data in previously treated PD-(L)1 naïve and PD-(L)1 progressor NSCLC patients
- Plan to discuss registrational pathways with potential partners

Combination of HS-110 and PD-(L)1 therapies may confer additional survival benefit in multiple cancers

- Line extension strategy to include additional indications that have been approved for PD-(L)1 therapies

11



HS-110 Clinical Proof-of-Concept Achieved

HS-110 in Combination with Nivolumab

Cohort A: Previously treated checkpoint inhibitor (CPI) naïve NSCLC patients

	HS-110 + Nivolumab ¹			Nivolumab ²	
	94% non-squamous and 6% squamous			Non-squamous	
	All (N=47)	ISR+ (N=28)	ISR- (N=19)	BMS Checkmate 057 Study ² (N=292)	
mOS (months)	24.6	33.6	4.5	12.2	

HS-110 in combination with nivolumab compares favorably with published data

- Well-tolerated in combination with checkpoint inhibitor

Two NSCLC settings are under evaluation:

- Checkpoint Inhibitor (CPI) naïve patients
- Patients that progressed after CPI treatment

Cohort B: NSCLC patients whose disease progressed on or following CPI treatment

	HS-110 + Nivolumab ¹			Treatment Options ³		
	at ≥2 nd line after CPI failure			at ≥3 rd line after CPI failure		
	All (N=68)	ISR+ (N=52)	ISR- (N=16)	Gemcitabine ⁴ (N=27)	Docetaxel ⁴ (N=25)	Chemotherapy ⁵ (N=28)
mOS (months)	11.9	12.1	6.8	7.5	6.8	9.0

Potential to measure responsiveness

- Improved OS in subsets of patients that experienced a dermal injection site reaction (ISR)

¹ Results as of November 2021 data cut. Subgroup analyses were retrospective; ² Trial did not contain a comparative nivolumab-only arm. Nivolumab-only data is historical published data (Borghaei et al. 2021. J Clin Oncol); ³ Trial did not contain a comparative chemotherapy-only arm. Treatment data is historical published data and not from HS-110 trial; ⁴ Constatini et al. 2018. ERI Open Research; ⁵ Schvartsman et al. 2017. Lung Cancer

12



PTX-35 Overview

Potential First-in-Class TNF Receptor Superfamily Member 25 (TNFRSF25) Agonist Antibody

PTX-35 targets TNFRSF25 to shift the balance between inflammation and immunosuppression

- Context driven T cell responses depending on activation signals and disease setting
- Dynamic immunomodulatory properties of TNFRSF25 make it a compelling therapeutic target for context-dependent regulation of T cell responses and immune stability
- Favorable safety profile demonstrated in non-human primates

Phase 1 trial evaluating safety of PTX-35 treatment for solid tumors

- Anti-tumor activity demonstrated in preclinical colon, lung and breast cancer models
- Preclinical data demonstrate anti-tumor activity, expansion of antigen-specific CD8⁺ T cells and decreased Treg suppression in the presence of tumor antigen (AACR 2021)
- Awarded a \$15.2M CPRIT grant to fund Phase 1 clinical development

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13



PTX-35 Mechanism of Action

Immunomodulatory Activity Dependent on Presence or Absence of Danger Signal

TNFRSF25

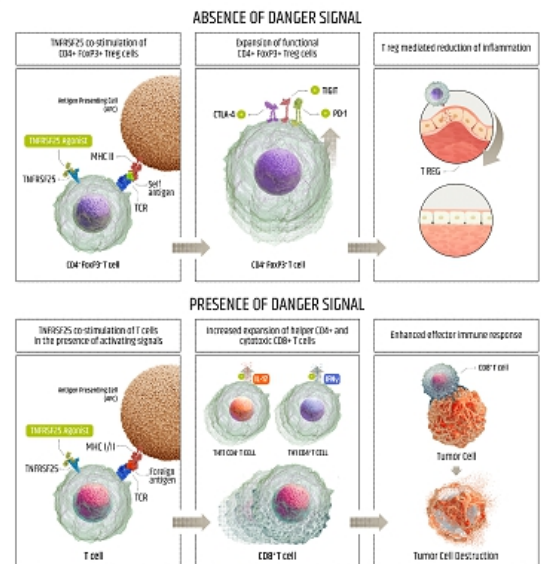
- Recognizes TNF-like ligand 1A secreted by several immune cell types
- Highly and constitutively expressed on CD4⁺ FoxP3⁺ regulatory T cells

Absence of an activating signal, co-stimulation of TNFRSF25 promotes

- Expansion of immunosuppressive Treg cells
- Treg expression of immunosuppressive markers CTLA4, TIGIT, and PD-1
- Minimal impact on resting CD4⁺ and CD8⁺ T cells

Presence of an activating signal, co-stimulation of TNFRSF25 promotes

- Enhanced expansion of activated CD8⁺ effector T cells
- Increased percent of inflammatory IFN γ ⁺ Th1 & IL-17⁺ Th17 CD4⁺ T cells
- Decreased Treg function characterized by reduced CTLA4 expression



14



Anthim[®] Overview

Best-in-Class Antitoxin for the Treatment of Anthrax

Anthim treats & protects against inhalational anthrax disease

- Monoclonal antibody that binds protective antigen (PA83) released by *Bacillus anthracis*
- Neutralizes anthrax toxin
- In combination with antibiotics or prophylaxis when alternative therapies are not available
- For complete prescribing information including limitations of use and box safety warning associated with HYPERSENSITIVITY and ANAPHYLAXIS, see <https://anthim.com/>



US FDA approval in 2016; CA, EU and UK approval as of 2020

- Only anthrax antitoxin to have received international licensure

Anthim is supplied to the US Strategic National Stockpile

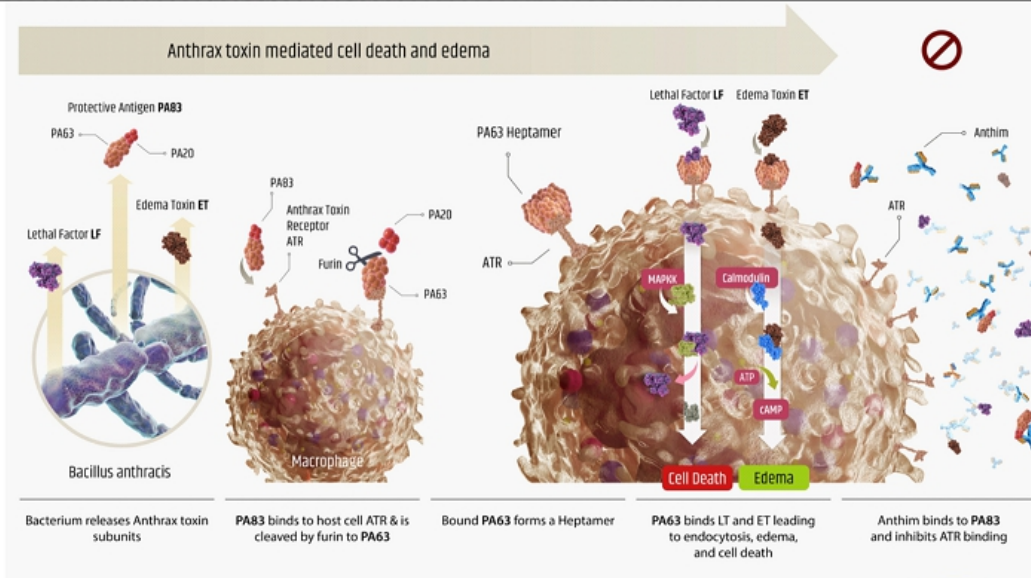
- As part of ASPR's objective to diversify supply and acquire products with a longer shelf-life, completed and shipped 2 orders totaling \$70M in 2016 and 2018
- Completed first phase of contract for \$50 million; HHS options to procure up to \$31 million of Anthim by the first half of 2023

15



Anthim[®] Mechanism of Action

Anthim Binds Protective Antigen to Prevent Anthrax Toxin Receptor Interaction



16

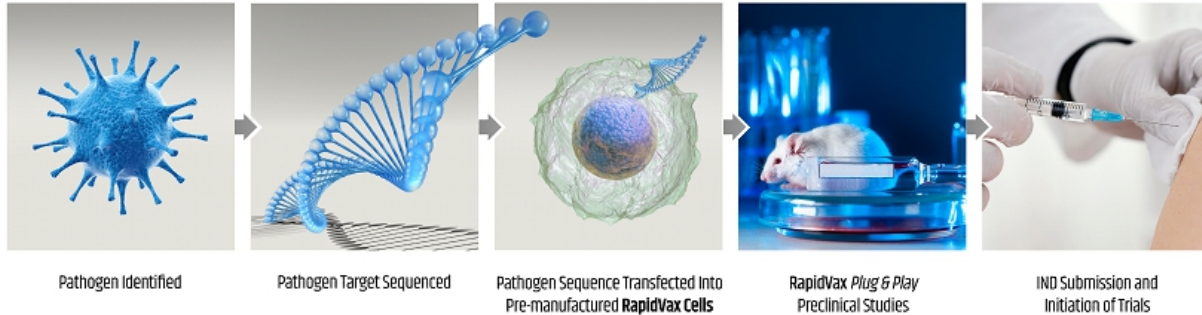


RapidVax® Platform Overview

A Customizable Approach to Countering Emerging Biological Threats

Novel “plug-and-play” vaccine platform

- Premanufactured gp96-Ig/OX40L-Ig stockpile-amenable cells - potential to reduce time from identification to immunization
- Target antigen sequences transfected into premanufactured RapidVax to rapidly create a pathogen-specific vaccine
- Engineered for potential long-term protection via the stimulation of antibody production and immunological memory
- Leverages favorable clinical trial safety profile previously observed for the gp96 platform

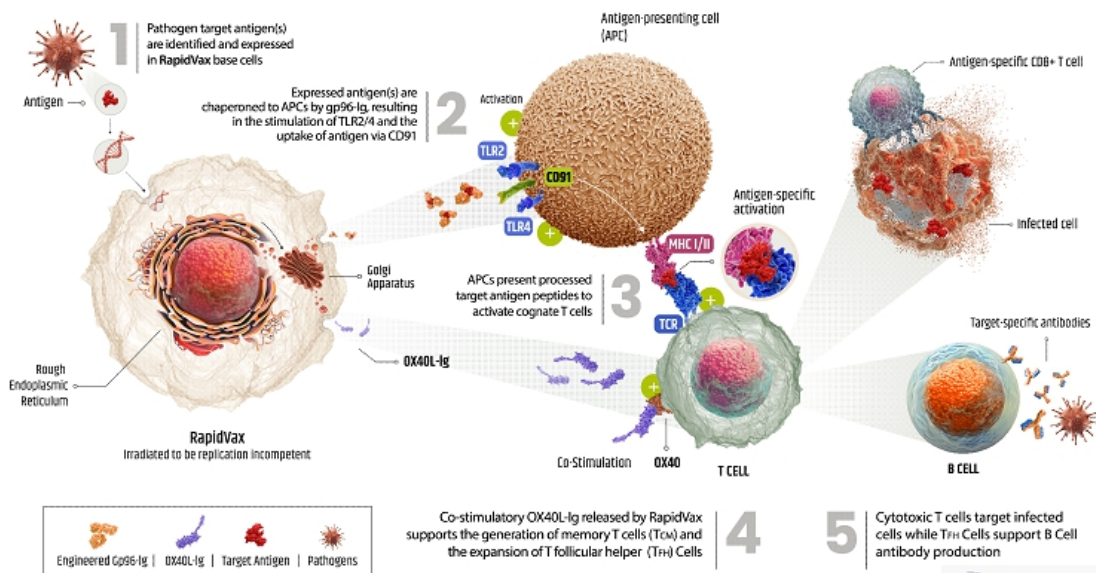


17



RapidVax® Mechanism of Action

Potential to Stimulate Pathogen-Specific Cellular and Humoral Immunity



18



Biothreat Advisory Board

Bipartisan Board Providing Counsel on NIGHTHAWK's Medical Countermeasure Initiatives



**Gen. Richard Myers
(Chairman)**

*Former Chairman
of the Joint
Chiefs of Staff*



**Greg
Burel**

*Former Director
of the Strategic
National Stockpile*



**Jack
Kingston**

*Former US
Representative,
Secretariat of the
Alliance for Biosecurity
(current)*



**Dr. Gregory
Koblenz**

*Professor of
Biodefense at George
Mason University,
Expert on Chemical
and Biological
Weapons*



**David
Lasseter**

*Former Deputy Asst.
Sec. of Defense for
Countering Weapons
of Mass Destruction*



**Mark
Pryor**

*Former US
Senator, AR*



**Andrew
Weber**

*Former Asst. Sec. of
Defense for Nuclear,
Chemical & Biological
Defense Programs*

19



NIGHTHAWK Highlights

Marketed product and robust pipeline of immunomodulators spanning oncology, inflammation, and infectious disease

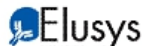
- FDA approved Anthim® (oblitoximab), best-in-class antitoxin for inhalation anthrax
- Multiple biologics advanced from bench to clinic: HS-110 and HS-130 (allogenic cell therapies), PTX-35 (antibody-based therapy)
- RapidVax® in development as a novel vaccine platform designed to accelerate time to clinic to combat emerging biological threats
- Biothreat Advisory Board provides guidance on medical countermeasure initiatives

End-to-end ecosystem designed to accelerate the development of discoveries to the delivery of novel therapeutics

- Skunkworx Bio unique proprietary biologics discovery platform and computational approach to drive intelligent target identification
- Heat Biologics and Pelican Therapeutics preclinical and clinical expertise support efficient trial design and execution
- Elusys Therapeutics sophisticated knowledge and hands-on experience in medical countermeasures biologics and government funding
- Scorpion Biological Services cGMP biomanufacturing and analytical services – 500,000+ sq ft commercial facility expansion in progress



OUR ECOSYSTEM





NIGHTHAWK BIOSCIENCES

PLEASE NOTE: Heat Biologics, Inc anticipates transitioning to NightHawk Biosciences, Inc effective May 3, 2022.