

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): **November 14, 2022**

**NightHawk Biosciences, 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)*

**Heat Biologics, Inc.**

*(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 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	NHWK	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 2.02 Results of Operations and Financial Condition.**

On November 14, 2022, NightHawk Biosciences, Inc., a Delaware corporation (the “Registrant”), issued the attached press release that included financial information for its quarter ended September 30, 2022. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K. The information contained in this Item 2.02 and in the press release is being furnished to the Securities and Exchange Commission (the “Commission”) and shall not be deemed incorporated by reference into any of the Registrant’s registration statements or other filings with the Commission.

**Item 8.01 Other Events.**

The Registrant will be making corporate presentations over the next several weeks. In connection with the presentations, the Registrant intends to discuss the new corporate slide presentation attached as Exhibit 99.2 hereto, which is incorporated herein by reference.

The slide presentation attached as Exhibit 99.2 to this Current Report on Form 8-K includes “safe harbor” language pursuant to the Private Securities Litigation Reform Act of 1995, as amended, indicating that certain statements contained in the slide presentation are “forward-looking” rather than historical.

The Registrant undertakes no duty or obligation to update or revise information included in this Current Report on Form 8-K or Exhibit 99.2.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press Release issued by NightHawk Biosciences, Inc. November 14, 2022.</u></a>
<a href="#"><u>99.2</u></a>	<a href="#"><u>Corporate Presentation dated November 2022</u></a>
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

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**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: November 14, 2022

NIGHTHAWK BIOSCIENCES, INC.

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

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### NightHawk Biosciences Provides Third Quarter 2022 Business Update

**Durham, NC – November 14, 2022 – NightHawk Biosciences (NYSE American: NHWK)**, a fully-integrated biopharmaceutical company focused on developing first-in-class therapies to modulate the immune system, today provided strategic, financial, and operational updates for the third quarter ended September 30, 2022.

Jeff Wolf, Chief Executive Officer of NightHawk, commented, “We are continuing to progress our biodefense and biomanufacturing efforts within our Elusys and Scorpion subsidiaries. Towards this end, we are making substantial investments in our biomanufacturing capabilities, including our Scorpion San Antonio biologics manufacturing facility, as well as our planned biomanufacturing facility in Manhattan, Kansas.

Mr. Wolf continued, “Given our evolving focus, we are deprioritizing our oncology programs and discontinuing further development of our clinical-stage oncology assets, including HS-110 and PTX-35, to focus on our biomanufacturing efforts and the discovery, development, and commercialization of innovative medical countermeasures to address unmet and emerging biothreats.”

Mr. Wolf added, “During the quarter, we also recognized \$6 million of one-time revenue, related to the sale of ANTHIM® to Canada’s National Emergency Strategic Stockpile, with 80% of these proceeds to be paid out to the former shareholders of Elusys as part of the original purchase consideration. Nevertheless, we believe this is validation of our strategic decision to acquire Elusys earlier this year.”

#### Third Quarter 2022 Financial Results

- Recognized \$6.0 million of revenue for the quarter ended September 30, 2022, which included \$5.98 million of product sales revenue, \$0.06 million of contract revenue, and no CPRIT grant revenue. For the three months ended September 30, 2021 we recognized \$0.5 million of grant revenue for qualified expenditures under the CPRIT grant. The increase in product sales revenue is due to the sale of ANTHIM to the Canadian government. The decrease in grant revenue in the current-year period is due to the fact that we have recognized all \$15.2 million of CPRIT grant revenue. As of September 30, 2022, we had a grants receivable balance of \$1.5 million for CPRIT proceeds not yet received, but for which the costs had been incurred or the conditions of the award had been met. We continue our efforts to secure future non-dilutive grant funding to subsidize ongoing research and development costs.
  - Product cost of sales for the three months ended September 30, 2022 was \$6.4 million. No product sales were recognized for the three months ended September 30, 2021. The increase was due to the cost of sales related to the ANTHIM sale to Canada’s National Emergency Strategic Stockpile. Cost of sales was \$5.9 million of inventory, \$0.3 million of pre-acquisition backlog, \$0.2 million of shipping and fulfillment expense and \$0.01 million of royalty expense.
  - Research and development expenses increased to \$6.9 million for the three months ended September 30, 2022 compared to \$4.4 million for the three months ended September 30, 2021.
  - General and administrative expenses were \$5.1 million and \$3.4 million for the three months ended September 30, 2022 and 2021, respectively. The increase was primarily due to increased personnel costs, as well as higher consulting and professional expenses, offset by a decrease in stock-based compensation expense of \$0.2 million.
  - Net loss attributable to NightHawk Biosciences was approximately \$13.0 million, or (\$0.51) per basic and diluted share for the three months ended September 30, 2022, compared to approximately \$7.4 million, or (\$0.30) per basic and diluted share for the three months ended September 30, 2021.
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- As of September 30, 2022, the Company had approximately \$57.4 million in cash and cash equivalents, and short-term investments.

### **NightHawk Biosciences, Inc.**

NightHawk Biosciences is a fully-integrated biopharmaceutical company focused on the discovery and commercialization of innovative medical countermeasures to defend against emerging biothreats. The Company leverages its integrated ecosystem of subsidiaries to streamline the advancement of novel therapies, 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](http://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 such as continuing to make progress in our biodefense and biomanufacturing efforts through our Elusys and Scorpion subsidiaries the planned biomanufacturing facility in Manhattan, Kansas and the sale to Canada's National Emergency Strategic Stockpile being validation of NightHawk's strategic decision to acquire Elusys earlier this year. Important factors that could cause actual results to differ materially from current expectations include, among others, the ability to continue to make progress in our biodefense and biomanufacturing efforts through our Elusys and Scorpion subsidiaries, the ability to successfully integrate Elusys and expand ANTHIM® distribution abroad, NightHawk's ability to commence operation in Kansas when anticipated and to successfully operate as a CDMO in San Antonio and Kansas, NightHawk's and its subsidiaries' ability to maintain license agreements, the continued maintenance and growth of NightHawk's and its subsidiaries' patent estates, NightHawk'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, the ability to obtain regulatory approval for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to NightHawk'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 NightHawk's products, developments by competitors that render such products obsolete or non-competitive, and other factors described in NightHawk'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 NightHawk makes with the SEC. The information in this presentation is provided only as of the date presented, and NightHawk 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.*

### **Media and Investor Relations Contact**

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# NIGHTHAWK BIOSCIENCES

CORPORATE PRESENTATION

November 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 facility in Manhattan, Kansas, our ongoing and planned discovery and development of drugs targeting 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



## **US biopharmaceutical company with fully integrated ecosystem to expeditiously streamline drug development**

- Wholly owned GMP biomanufacturing and bioanalytical services support internal and revenue-generating client clinical and commercial projects
- In-house discovery, clinical, and regulatory capabilities propel internal drug development biodefense programs
- Commercial team experienced in government procurement of medical countermeasures to expand into global markets

## **Focused on the rapid development and delivery of innovative life-saving medical countermeasures**

- Development programs target the creation of novel assets to combat unmet and emerging biothreats
- Renowned biothreat advisory board provides counsel on biodefense initiatives

## **Anthrax Antitoxin ANTHIM® (obiltoximab)**

- Monoclonal antibody approved in the US & CA, UK, and the European Union
- Stockpiled by the U.S. Strategic National Stockpile and the Public Health Agency of Canada



# NIGHTHAWK Ecosystem

Streamlining Development and Manufacturing to Commercialize Innovative Medical Countermeasures



## OUR ECOSYSTEM



Discovery

Development / Commercial

Biomanufacturing



# Scorpion Biological Services

GMP Biomanufacturing and Bioanalytical Services Supporting Clinical and Commercial Projects

## Providing GMP biomanufacturing, cell and immuno-assay development, and bioanalytical lab services

- Dedicated capacity to accelerate NightHawk clinical and commercial efforts
- Contract manufacturing and bioanalytical services for biopharmaceutical companies
- Focus on American supply chain logistics

## Clinical Scale Facility, San Antonio, Texas

- Opened October 2022
- Providing scalable process development and GMP biomanufacturing
- Supports seamless transition to large-scale commercial biomanufacturing Kansas facility

## State-of-the-art cGMP commercial biomanufacturing facility, Manhattan, Kansas

- Flexible modular biodefense-focused campus layout
- First phase of development underway - ~180K sq. ft. & ~36K liters of mammalian production
- All phases - ~500K sq. ft., 48+ bioreactors, ~144,000 liters for large-scale biologics



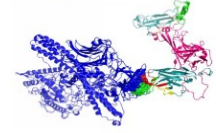
## Unique Hotspot discovery approach based on Pocket Biologics

- Novel, highly diverse, proprietary compound libraries used to identify small proteins and human antibodies which bind to critical druggable targets
- Shifts the paradigm of drug discovery by integrating biologic wet labs with computational biology, accelerating the validation of innovative therapeutics



## Research synergies designed to advance the speed of medical innovation

- Identification of unique medical countermeasure candidates for preclinical development
- Discovery of broad application platform technologies



# Elusys Therapeutics

Medical Countermeasures

## Development and commercialization of biologics to combat unmet and emerging biothreats

- Strong record of delivering countermeasures to the US National Stockpile and Public Health Agency of CA
- Renowned biothreat advisory board providing counsel on biodefense strategies & initiatives

## Developer and marketer of ANTHIM® (obiltoxaximab)

- Monoclonal anthrax antitoxin binds protective antigen (PA83) released by *bacillus anthracis*
- For treatment of inhalation anthrax in combination with antibiotics or, and as a prophylaxis when alternative therapies are not available or are not appropriate: <https://anthim.com> and <http://elusys.com>



## Only anthrax antitoxin to receive US and international approval

- FDA approval in 2016; EU and CA approval in 2020, UK approval in 2021 – orphan drug designation
- Over \$250M USD of non-dilutive development contracts from the NIH, DoD, and BARDA
- Awarded \$151M USD in procurement contracts to supply ANTHIM to the U.S. Strategic National Stockpile
- Awarded \$7.8M CAD to deliver ANTHIM to the Public Health Agency of Canada in 2022



# Biothreat Advisory Board

Renowned Experts 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  
Koblentz**

*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*

# NIGHTHAWK Highlights

Fully Integrated Ecosystem Streaming the Development and Delivery of Innovative Medical Countermeasures

## Scorpion Biological Services – Biomanufacturing and bioanalytical services

- Large biologics CDMO currently supporting internal and external revenue-generating client projects
- Commercial facility expansion underway, all phases totaling ~500K sq. ft. and ~144,000 liters for biomanufacturing

## Elusys Therapeutics – Development and commercial

- ~ \$400 million in grants, contracts and procurement orders from BARDA and SNS through ongoing, multi-year partnerships
- Developer and marketer of ANTHIM® (obiltoximab) - monoclonal anthrax antitoxin stockpiled by US and CA governments

## Skunkworx Bio – Discovery

- Research synergies designed to expedite the identification of unique medical countermeasure candidates for development





# NIGHTHAWK BIOSCIENCES

