

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): **March 31, 2023**

**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 300  
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 March 31, 2022, NightHawk Biosciences, Inc., a Delaware corporation (the “Registrant”), issued the attached press release that included financial information for its year ended December 31, 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 9.01 Financial Statements and Exhibits.**

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
<u>99.1</u>	<u>Press Release issued by NightHawk Biosciences, Inc. March 31, 2023.</u>
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: March 31, 2023

NIGHTHAWK BIOSCIENCES, INC.

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

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### NightHawk Biosciences Provides 2022 Year End Business Update

**Durham, NC – March 31, 2023 – 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 year ended December 31, 2022.

Jeff Wolf, Chief Executive Officer of NightHawk, commented, “We are making progress on our transition towards biodefense and biomanufacturing through our Elusys and Scorpion subsidiaries as we wind down our HS-110 and PTX-35 oncology programs. Pursuant to this, we are investing in our biomanufacturing technologies and capabilities, including our San Antonio and Manhattan, Kansas biologics manufacturing facilities, which we believe will position us well in the future. The manufacturing capabilities associated with these facilities are designed to streamline the development and delivery of life-saving medical countermeasures, while enabling us to offer excess capacity to third parties on a fee-for-service model.”

#### 2022 Financial Results

- For the year ended December 31, 2022, the Company recognized revenue of \$6.4 million, which included \$6.0 million of product sales revenue, \$0.1 million of contract revenue, and \$0.3 million of CPRIT grant revenue. For the year ended December 31, 2021, the Company recognized revenue of \$2.1 million for qualified expenditures under the CPRIT grant. The increase in product sales revenue was due to the sale of ANTHIM® (obilttoxaximab) to the Canadian government. The decrease in grant revenue was due to the fact that the Company recognized all \$15.2 million of CPRIT grant revenue. For the year ended December 31, 2022, the Company 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.
  - For the year ended December 31, 2022, the Company recognized \$6.4 million of cost of sales. No product sales were recognized for the year ended December 31, 2021, and thus no cost of sales was recorded. The increase was due to the cost of sales related to the ANTHIM® (obilttoxaximab) sale to the Canadian government. Cost of sales includes \$5.9 million of inventory, \$0.3 million of pre-acquisition backlog, and \$0.2 million of shipping and fulfillment expenses.
  - Selling, general and administrative (“SGA”) expenses for the years ended December 31, 2022 and 2021 were \$21.1 million and \$16.8 million, respectively. The increase of \$4.3 million was primarily due to an increase in consulting and other professional expenses to manage the business of \$3.2 million, an increase in facilities expense of \$1.2 million primarily due to the opening of the Company’s San Antonio facility, an increase in personnel expense of \$0.8 million due to an increase in headcount, an increase in rent expense of \$0.5 million, an increase in insurance expense of \$0.3 million, an increase in depreciation of \$0.3 million, an increase in marketing expenses of \$0.2 million, an increase in software expense of \$0.2 million offset by a decrease in stock-based compensation of \$2.4 million.
  - Research and development expenses increased to \$23.5 million from \$16.5 million for the years ended December 31, 2022 and 2021, respectively. HS-110 R&D expense decreased by \$1.2 million, HS-130 expense decreased by \$0.2 million, and PTX-35 expense decreased by \$0.3 million, all due to a decrease in site and investigator fees as a result of the closing of the clinical trials. ANTHIM® (obilttoxaximab) expenses increased due to the Company’s acquisition of Elusys in April 2022. Other program expenses decreased by \$0.7 million, including preclinical costs associated with the RapidVax program, T-cell costimulatory programs, and laboratory supplies. Unallocated research expenses increased by \$8.2 million primarily from license fees, sponsored research agreements for
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preclinical research, as well as increased clinical and CMC consulting expenses and Skunkworx lab and personnel costs.

- Net loss attributable to NightHawk Biosciences was approximately \$43.4 million, or (\$1.70) per basic and diluted share, for the year ended December 31, 2022, compared to approximately \$35.1 million, or (\$1.41) per basic and diluted share, for the year ended December 31, 2021.
- As of December 31, 2022, the Company had approximately \$44.3 million in cash, cash equivalents, and short-term investments.

Pursuant to the disclosure requirements of the NYSE American Company Guidelines Sections 401(h) and 610(b), NightHawk reports that its audited financial statements for the year ended December 31, 2022, included in the 2022 Form 10-K, contain an audit opinion from its independent registered public accounting firm that includes an explanatory paragraph related to the Company's ability to continue as a going concern due to the fact that the Company has suffered recurring losses from operations and has not generated significant revenue or positive cash flows from operations.

## 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.

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## 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.**

### **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. 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 NightHawk's Elusys and Scorpion subsidiaries, investing in biomanufacturing technologies and capabilities, including NightHawk's San Antonio and Manhattan, Kansas biologics manufacturing facilities, positioning NightHawk well in the future, the manufacturing capabilities associated with these facilities streamlining the development and delivery of life-saving medical countermeasures while enabling us to offer excess capacity to third parties on a fee-for-service model. Important factors that could cause actual results to differ materially from current expectations include, among others, the ability to continue to make progress in NightHawk's biodefense and biomanufacturing efforts through Elusys and Scorpion subsidiaries, the ability to 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 most recent annual report on Form 10-K, 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**

David Waldman  
+1 919 289 4017  
[investorrelations@heatbio.com](mailto:investorrelations@heatbio.com)

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