

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): **May 15, 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)

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 (see General Instruction A.2. below):

- 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 May 15, 2023, NightHawk Biosciences, Inc., a Delaware corporation (the “Registrant”), issued the attached press release that included financial information for its quarter ended March 31, 2023. A copy of the press release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 2.02 and in the press release attached as Exhibit 99.1 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. The information contained in this Item 2.02 and in the press release attached as Exhibit 99.1 to this Current Report on Form 8-K shall not be incorporated by reference into any filing with the U.S. Securities and Exchange Commission made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by NightHawk Biosciences, Inc. May 15, 2023.
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101)

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: May 15, 2023

NIGHTHAWK BIOSCIENCES, INC.

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



NightHawk Biosciences Provides Q1 2023 Business Update

Durham, NC – May 15, 2023– NightHawk Biosciences (NYSE American: NHWK) a fully integrated biopharmaceutical company specializing in the end-to-end development, manufacturing, and commercialization of innovative medical countermeasures that combat unmet and emerging biothreats, today provided strategic, financial, and operational updates for the quarter ended March 31, 2023.

Jeff Wolf, Chief Executive Officer of NightHawk, commented, “We continue to invest in and advance our research and biomanufacturing efforts, including our San Antonio and Manhattan, Kansas biologics manufacturing facilities. We are making steady progress and look forward to providing further updates.”

2023 Financial Results

- For the three months ended March 31, 2023 we recognized \$0.1 million of revenue from a licensing agreement with Shattuck Labs and \$0.7 million of revenue from process development. For the three months ended March 31, 2022 we recognized \$0.2 million of grant revenue for qualified expenditures under the CPRIT grant. 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 March 31, 2023, 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.
 - Research and development expenses increased approximately 79.5% to \$7.0 million for the three months ended March 31, 2023 compared to \$3.9 million for the three months ended March 31, 2022. The components of R&D expense are as follows, in millions: HS-110 expense decreased \$0.1 million primarily due to a decrease in consultants and contract labor expense; HS-130 expense decreased to \$0 from \$0.5 million due to the deprioritization of the oncology assets; PTX-35 expense increased by \$0.3 million primarily due to the expensing of prepaid expenses associated with the discontinued clinical trials and development of the product candidate in the third quarter of 2022; ANTHIM[®] (obiltoximab) was not acquired until the second quarter of 2022 and the 2023 expense primarily relates to fill finish; other programs expense increased by \$0.4 million primarily due to increase in laboratory supplies expense related to preclinical R&D expenses and the operations of the CDMO facility; Unallocated research expenses increased by \$2.7 million primarily due to increased personnel costs, including stock-based compensation from stock awards, contractor expense and supplies purchased for discovery projects;
 - Cost of revenues were \$0.6 million for the three months ended March 31, 2023. These expenses primarily reflect direct cost of labor, overhead and material costs. There was no cost of revenues for the three months ended March 31, 2022 as the Scorpius facility was not operational.
 - Selling, general and administrative expenses were \$6.8 million and \$3.8 million for the three months ended March 31, 2023 and 2022, respectively. The increase was primarily due to an increase of \$1.9 million for consulting and other professional expenses to manage the business and increased personnel costs of \$1.0 million, and to a lesser extent, an increase in rent expense of \$0.3 million, offset by a decrease in stock-based compensation expense of \$0.1 million.
 - Net loss attributable to NightHawk Biosciences was approximately \$12.8 million, or (\$0.49) per basic and diluted share, for the three months ended March 31, 2023, compared to approximately \$8.1 million, or (\$0.32) per basic and diluted share, for the three months ended March 31, 2022.
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- As of March 31, 2023, the Company had approximately \$28.6 million in cash, cash equivalents, and short-term investments.

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](#).

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, 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 invest in and advance NightHawk's research and biomanufacturing efforts, including its San Antonio and Manhattan, Kansas biologics manufacturing facilities and making steady progress. Important factors that could cause actual results to differ materially from current expectations include, among others, the ability to continue to invest in and advance NightHawk's research and biomanufacturing efforts, including its San Antonio and Manhattan, Kansas biologics manufacturing facilities, the ability to increase sales of ANTHIM® (obiltoxaximab) including distribution abroad, NightHawk's financing needs, its cash balance being sufficient to sustain operations and its ability to raise capital when needed, 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, 2022, 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.

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