UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

☑ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES ACT OF 1934**

For the transition period from _____ to _____

Commission file number: 001-35994

NightHawk Biosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**26-2844103**
(State or other jurisdiction of incorporation or organization)	*(I.R.S. Employer Identification No.)*
627 Davis Drive, Suite 300 **Morrisville, NC** *(Address of principal executive offices)*	**27560** *(Zip Code)*

(919) 240-7133
(Registrant's telephone number, including area code)

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

Securities registered pursuant to Section 12(g) of the Act: **None.**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☑

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☑

Indicate by check mark whether the issuer: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☑ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (section 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☑ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer, "accelerated filer" "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☑	Smaller reporting company	☑
		Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☑

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive- based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

As of June 30, 2022, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $65,407,051 (based upon the closing sale price of the registrant's common stock reported on that date). This calculation excludes shares held by the registrant's current directors and executive officers and stockholders that the registrant has concluded are affiliates of the registrant.

As of March 31, 2023, the issuer had 26,049,209 shares of common stock outstanding.

Documents incorporated by reference: None.

NIGHTHAWK BIOSCIENCES, INC.

FORM 10-K

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Explanatory Note

NightHawk Biosciences, Inc., and its consolidated subsidiaries (the "Company", "we" or "us") is filing this comprehensive Annual Report on Form 10-K for the fiscal years ended December 31, 2022 and 2021 (this "Annual Report"). This Comprehensive Form 10-K contains our audited financial statements for the fiscal year ended December 31, 2022, as well as summarized financial information related to the restatement of the following previously filed periods: (i) our unaudited consolidated financial statements covering the quarterly reporting periods during fiscal year 2022, consisting of June 30, 2022 and September 30, 2022.

Restatement Background

As previously disclosed, on March 17, 2023, the Audit Committee (the "Audit Committee") of the Board of Directors of NightHawk Biosciences, Inc. (the "Company") concluded, after discussion with the Company's management and BDO USA, LLP ("BDO"), the Company's independent registered public accounting firm, that the Company's (i) unaudited consolidated interim financial statements as of and for the period ended June 30, 2022 included in the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022 and the (ii) unaudited consolidated interim financial statements as of and for the period ended September 30, 2022 included in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2022 (collectively, the "Specified Financial Statements"), should no longer be relied upon due to errors in such financial statements, and therefore a restatement of these specified financial statements is required. These errors resulted in net loss being overstated but have no effect on the Company's cash position, pre-tax loss or the Company's operating expenses and will result in a decrease in the net loss and loss per share for those periods.

During the preparation and review of its annual tax provision for the year ended December 31, 2022, it was determined that the Company made certain errors in the manner in which it recognized a deferred tax asset valuation allowance related to the acquisition of Elusys Therapeutics, Inc. ("Elusys"). Under ASC 740 – *Income Taxes*, the release of an acquirer's valuation allowance on the acquirer's (i.e., the Company's) deferred tax assets in the amount of the acquired Elusys deferred tax liability ("DTL") should be recorded as an income tax benefit, and be reported as a component of net loss. The DTL was on the balance sheet at June 30, 2022 and September 30, 2022, however the DTL was not and should have been recorded as an income tax benefit on the income statement for the quarter ending June 30, 2022. This error resulted in net loss being overstated by $3.3 million for the three and six months ended June 30, 2022, understated by $0.3 million and overstated by $3.1 million for the three and nine months ended September 30, 2022.

Items Restated in this Form 10-K

This Annual Report reflects changes to the Consolidated Balance Sheets for the periods ended June 30, 2022 and September 30, 2022 and the Consolidated Statements of Income and Comprehensive Loss, Stockholders' Equity, and Cash Flows for the quarters ended June 30, 2022 and September 30, 2022, and the related notes thereto. Restatement of the summarized consolidated financial information for the quarterly periods are disclosed in Note 17 to the consolidated financial statements.

The Company has not filed, and does not intend to file, amendments to the previously filed Quarterly Reports on Form 10-Q for the quarters ending June 30, 2022 and September 30, 2022. Accordingly, investors should rely only on the financial information and other disclosures regarding the restated periods in this Annual Report or in future filings with the Securities and Exchange Commission ("SEC") (as applicable), and not on any previously issued or filed reports, earnings releases or similar communications relating to these periods.

In addition, as required by Rule 12b-15 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), new certifications by the Company's principal executive officer and principal financial officer are filed herewith as exhibits to this Form 10-K pursuant to Rule 13a-14(a) of the Exchange Act and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. 1350).

See Note 17 to the consolidated financial statements, included in Part II, Item 8 of this Annual Report, for additional information on the restatement and the related consolidated financial statement effects.

PART I

Forward-Looking Statements

This Annual Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. "Business," Part I, Item 1A. "Risk Factors," and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this Annual Report and in some cases you can identify forward-looking statements by terminology such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. These statements are based on our current beliefs, expectations, and assumptions and are subject to a number of risks and uncertainties, many of which are difficult to predict and generally beyond our control, that could cause actual results to differ materially from those expressed, projected or implied in or by the forward-looking statements.

You should refer to Item 1A. "Risk Factors" section of this Annual Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We do not undertake any obligation to update any forward-looking statements. Unless the context requires otherwise, references to "we," "us," "our," and "NightHawk," refer to Nighthawk Biosciences, Inc. and its subsidiaries.

Summary of Risk Factors

Our business faces significant risks and uncertainties of which investors should be aware before making a decision to invest in our common stock. If any of the following risks are realized, our business, financial condition and results of operations could be materially and adversely affected. The following is a summary of the more significant risks relating to the Company. A more detailed description of our risk factors is set forth below under the caption "Risk Factors" in Item 1A in Part I of this Annual Report.

Risks Relating to Financial Position and Capital Requirements

- To date, we have not generated significant revenue.
- Our consolidated financial statements have been prepared assuming that we will continue as a going concern.
- We have a limited operating history in our current lines of business.
- We have incurred net losses every year since our inception and expect this to continue.
- We will need to raise additional capital to support our long-term business plans.
- We face risks related to the restatement of our previously issued financial statements.
- We identified a material weakness in our internal control over financial reporting.
- In order to develop ANTHIM®, we will have to devote significant resources to ANTHIM®.

Risks Relating to Our Company

- We have a limited operating history conducting commercial development of bioanalytics, process development and manufacturing activities.
- We depend on spending and demand from our customers for our services.
- To date, our revenues have come from a limited number of customers.
- Our ability to generate product revenues from sales of ANTHIM® is dependent upon government spending.
- We generally do not have long-term CDMO customer contracts.

- Elusys has been manufacturing ANTHIM® with one manufacturer.
- We are substantially dependent on the success of ANTHIM®.
- All of our manufacturing operations are conducted at our facility situated in San Antonio, Texas,.
- The operations of our CROs and suppliers could also be subject to business interruptions.
- We rely on third parties to supply most of the necessary raw materials.
- If we are unable to provide quality and timely services, our business could suffer.
- Our customers' failure to receive or maintain regulatory approval for their product candidates could negatively impact our revenues and profitability.
- Our use of hazardous and biological materials could result in us being liable for damages.
- Impairment of acquired intangible assets could result in a significant charge to earnings.

Risks Relating to Regulatory Approval and Commercialization

- Failure to comply with existing and future regulatory requirements for our CDMO and sales of ANTHIM® could adversely affect our business, financial condition, and results of operations.
- If we do not obtain the necessary regulatory approvals, we will not be able to sell our product candidates.
- Our product candidates will require extensive testing and funding.
- Clinical trials are very expensive, time-consuming, and difficult to design and implement.
- There is uncertainty as to market acceptance of our technology and product candidates.
- We may not be able to compete successfully for market share against other drug companies.
- Our development program partially depends upon third-party researchers who are outside our control.
- We rely significantly on third parties to formulate and manufacture our product candidates.
- We have and will in the future rely on third parties to conduct, supervise and monitor our clinical trials.
- We will continue to be subject to ongoing and extensive regulatory requirements.
- Adverse effects resulting from other drugs could negatively affect our product candidates.
- We will continue to be subject to ongoing and extensive regulatory requirements.
- We have no experience selling, marketing or distributing products, and have no internal capability to do so.
- We may not be successful in establishing and maintaining strategic partnerships.
- Our dependence on licensing or collaboration agreements may adversely affect our business
- Our revenue will be diminished if our products sell for inadequate prices or reimbursement is not available.
- Legislative and regulatory changes affecting the health care industry could adversely affect our business.
- We may be exposed to liability claims associated with the use of biological and hazardous materials.
- We may incur substantial liabilities.
- International expansion of our business exposes us to risks.
- We may acquire other businesses that could adversely impact us.
- There is uncertainty regarding health care reform and declining general economic or business conditions.
- We are vulnerable to any failure to maintain the security of information.
- Failure to maintain the security of information could expose us to litigation.
- We may face particular data protection, data security and privacy risks in connection with the European Union's Global Data Protection Regulation and other privacy regulations.
- Our operating results may be adversely affected by fluctuations in foreign currency exchange rates.
- We could be adversely affected by violations of the U.S. and other worldwide anti-bribery laws.

Intellectual Property Risk Factors

- We have limited protection for our intellectual property, which could impact our competitive position.
- The technology we license or our products be found to infringe third-party rights.
- We rely on a license to use various technologies that are material to our business.
- The U.S. government may have "march-in rights" to certain of our intellectual property.

General Risk Factors

- Changes in general economic conditions and geopolitical conditions may adversely impact our business and operating results.

- We may not successfully effect our intended expansion, which would harm our business prospects.
- Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future.
- We rely on key executive officers and scientific, regulatory, and medical advisors.
- If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.
- Reduced reporting requirements applicable to smaller reporting companies may make our common stock less attractive.
- Our failure to meet the continued listing requirements of NYSE American could result in a de-listing of our common stock.
- The possible issuance of common stock may dilute the interests of stockholders.
- The issuance of additional securities could adversely affect the rights of the holders of our common stock.
- Certain provisions of the General Corporation Law of the State of Delaware, our bylaws and stockholder rights plan may have anti-takeover effects.
- Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain types of state actions that may be initiated by our stockholders.
- Future sales of our common stock by our existing stockholders could cause our stock price to decline.
- Our shares of common stock are from time to time thinly traded.
- Holders of our warrants will have no rights as a common stockholder until they acquire our common stock.
- There is no established market for the warrants that we previously issued.
- The shares of common stock offered under any at the market offering that we may engage in, and investors who buy shares at different times will likely pay different prices.
- Reports published by securities or industry analysts, including projections in those reports that exceed our actual results, could adversely affect our common stock price and trading volume.

Item 1. *Business*

Overview

We are 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. Our ecosystem is driven by the discovery efforts of our subsidiary, Skunkworx Bio, Inc. ("Skunkworx"), the clinical and commercial biodefense expertise of our subsidiary, Elusys Therapeutics, Inc. ("Elusys"), and the bioanalytical, process development and biomanufacturing capabilities of our subsidiary, Scorpius Biomanufacturing, Inc. ("Scorpius"). The coordination of this ecosystem potentiates the streamlined development and delivery of life-saving medical countermeasures, including our anthrax antitoxin ANTHIM® (obiltoxaximab).

The monoclonal antibody ANTHIM® (obiltoxaximab) received FDA approval and orphan drug exclusivity in 2016 for the treatment of inhalational anthrax in combination with antibiotics, and as a prophylaxis when alternative therapies are not available or are not appropriate. Additionally, ANTHIM® was approved in 2020 as the only licensed anthrax antitoxin treatment in the European Union ("EU") and Canada, and in 2021 in the United Kingdom. Working closely with Biomedical Advanced Research and Development Authority ("BARDA"), the National Institute of Allergy and Infectious Disease ("NIAID"), and the Department of Defense ("DoD"), Elusys has successfully advanced ANTHIM® to the commercial stage and provides the therapeutic for inclusion in both the US Strategic National Stockpile ("SNS") and the Public Health Agency of Canada Office of Emergency Response Services Depot.

Scorpius pairs cGMP biomanufacturing and quality control expertise with cutting edge capabilities in immunoassays, molecular assays, and bioanalytical methods to support cell- and gene-based therapies as well as large molecule biologics. Scorpius decreases our dependence on third-party contract research and development biomanufacturing organizations (CDMOs) for the manufacture of ANTHIM® (obiltoxaximab) and other assets and allows us to be opportunistic in offering excess capacity to third parties as a fee-for-service model. Our lead facility commenced operations in October 2022 in San Antonio, Texas. Planning and development efforts are underway on a potential commercial manufacturing facility to be built in Manhattan, Kansas in the coming years.

During the past year, our priorities have shifted to our biodefense and biomanufacturing capabilities resulting in a refocusing of our resources and efforts towards biodefense and biomanufacturing and away from our clinical-stage oncology assets including HS-110 and PTX-35.

OUR BIOMANUFACTURING, PROCESS DEVELOPMENT, AND BIOMANUFACTURING CAPABILITIES: SCORPIUS BIOMANUFACTURING, INC.

Manufacturing

Scorpius (formerly known as Scorpion Biological Services, Inc.) provides process development and biomanufacturing services to support our biotherapeutics and discovery pipeline. Scorpius also supports the biomanufacturing needs of third parties who use its excess biomanufacturing capacity as a fee-for-service model. Scorpius couples cGMP biomanufacturing and quality control expertise with cutting edge capabilities in immunoassays, molecular assays, and bioanalytical methods to support cell- and gene-based therapies as well as large molecule biologics using American-made equipment, reagents, and materials. The subsidiary expects to decrease our dependence on third-party CDMOs for the manufacture of ANTHIM®, assuming receipt of necessary regulatory approvals, and other assets as well as allow us to be opportunistic in offering excess capacity to third parties on a fee-for-service model. We are in the process of completing the technology transfer of ANTHIM® to Scorpius for future production. We anticipate the prioritization of Scorpius on American-made equipment, reagents, and materials paired with domestic sourcing of biomanufacturing expertise will make us competitive for U.S. government contracts and biodefense assets. We anticipate this will successfully support our expansion within the growing CDMO market.

We commenced operations of the leased San Antonio facility in September 2022 and are planning to begin development efforts on a commercial manufacturing facility expected to be built in Manhattan, Kansas in the coming years. We have historically relied on third-party manufacturers to produce and store our product candidates for clinical use and currently do not operate our own manufacturing facilities. In order to promote efficiency and reduce our reliance on third-party vendors, we have enhanced our in-house development of bioanalytic, process development and manufacturing capabilities and offer such services to third parties for fees. We expect to fill production capacity by transitioning our outsourced manufacturing and development in-house following validation activities and then contracting with external customers. However, there can be no assurance that we will be successful in these new operations.

We intend to meet our financing needs for the operations of the facility through multiple alternatives, including, but not limited to, cash on hand, grant funding and incentives, additional equity financings, debt financings and/or funding from partnerships or collaborations, and potential revenue, if any, from our planned development and manufacturing facility.

In April 2022, we announced a planned partnership of Scorpius, a private developer, the State of Kansas, and local and university affiliates to support the development of a 500,000+ square foot biodefense-focused large molecule and biologics biomanufacturing phased, multi-building facility in Manhattan, Kansas. Scorpius intends to utilize the new facility for large molecule and biologics manufacturing, with a particular focus on biodefense. In addition to servicing our own pipeline, Scorpius plans to operate and utilize the facility as a full-service CDMO to provide third-party manufacturing services on a fee-for-service basis. Scorpius and the developer have applied for over $300 million in funding, incentives, and tax relief to support the development of the facility. In April 2022, the City Commission of Manhattan, Kansas, passed a resolution supporting the proposed commercial manufacturing facility and its intent to offer an Economic Development Package that includes the issuance of approximately $567 million in industrial revenue bonds with proposed sales tax exemptions, an anticipated 10-year 100% property tax abatement plan, and an expected $8 million forgivable loan that will be tied to the realized capital investment and employee jobs, wages, and benefits. The Economic Development Package is conditioned upon successful negotiation and future action by the City Commission and upon Scorpius meeting certain negotiated performance and hiring goals.

We plan to manufacture CGMP pharmaceutical-grade products for our customers in our San Antonio facility. To date Scorpius has three customers for which it has not recognized any revenue. The deposits from these customer are in deferred revenue and will be converted to revenue once we meet our performance obligations for these contracts. The process for manufacturing generally uses commercially available raw materials from multiple suppliers, and in some instances, from a single source supplier. We rely on third parties to supply most of the necessary raw materials and supplies for the products

we manufacture on behalf of our customers and our inability to obtain such raw materials or supplies may adversely impact our business, financial condition, and results of operations. See "Risk Factors—Risks Related to Our Business" for additional discussion of raw materials supplied by third party vendors for the products we manufacture for our customers.

Biodefense

In 2022, we acquired ANTHIM® (obiltoxaximab) when we consummated the transaction contemplated by the Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with our wholly owned subsidiary ("Merger Sub"), Elusys and Fortis Advisors LLC, pursuant to which we acquired Elusys through the merger (the "Merger") of Merger Sub with Elusys. ANTHIM® is a monoclonal antibody antitoxin for anthrax. Our biodefense discovery and preclinical efforts remain focused on identifying novel assets to combat emerging biological threats. To date, all revenue that Elusys received for the sale of ANTHIM®, subsequent to our acquisition of Elusys, has been $6.0 million in procurement contracts to provide ANTHIM® (obiltoxaximab) to the Canada Office of Emergency Response Services Depot.

Anthrax

Anthrax is a disease caused by Bacillus anthracis. While it is primarily a disease of animals, cases of anthrax in humans occur through contact with infected animals or animal products or through intentional spread of Bacillus anthracis ("B. Anthracis") spores as a biowarfare or bioterrorism agent. Due to its virulence, high mortality, and ease to produce and disseminate, B. anthracis is considered a potent and dangerous "Category A" biowarfare or bioterrorism agent. Inhalational anthrax (i.e., when infection occurs via inhalation of bacterial spores) is particularly deadly. Untreated, the mortality rate is 97% and remains high (~50%) for individuals that are not administered aggressive antimicrobial treatment at the earliest stages of the disease. Once the disease has progressed to the fulminant stage, accumulated anthrax toxins drive progression of disease despite antibiotic therapy, resulting in death. In addition, antibiotics may be ineffective in infections with multi-drug-resistant B. anthracis or contraindicated in certain patient populations.) Bacillus anthracis is recognized by Public Health Emergency Medical Countermeasures Enterprise as a high-priority threat.

About ANTHIM® (obiltoxaximab)

ANTHIM® (obiltoxaximab) is a monoclonal antibody that binds the protective antigen (PA) component of the anthrax. Obiltoxaximab'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® (obiltoxaximab) is supplied as single-dose vials for IV infusion.

The development of ANTHIM® (obiltoxaximab) was supported by ~$250M USD in non-dilutive development contracts from the National Institutes of Health ("NIH"), Department of Defense ("DoD"), and Biomedical Advanced Research and Development Authority "("BARDA") to Elusys. To date, Elusys has received ~$151M USD and ~$6M USD in procurement contracts to provide ANTHIM® (obiltoxaximab) to the U.S. SNS and the Public Health Agency of Canada Office of Emergency Response Services Depot. NightHawk Biosciences acquired Elusys in April 2022 and is committed to expanding domestic and international sales of ANTHIM® (obiltoxaximab).

ANTHIM® (obiltoxaximab) was approved in the U.S. in 2016 in adults and pediatric patients for the treatment of inhalational anthrax in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not appropriate or available. Furthermore, it was licensed as ANTHIM® (obiltoxaximab) in Canada in 2020, and as NYXTHRACIS® (formerly Obiltoxaximab SFL) in the EU in 2020 in adults and pediatric patients for the treatment of inhalational anthrax in combination with appropriate antibacterial drugs and for the post-exposure prophylaxis of inhalational anthrax when alternative therapies are not appropriate or available. ANTHIM® (obiltoxaximab) 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® (obiltoxaximab) 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® (obiltoxaximab) in the pediatric population. Dosing in pediatric patients was derived using a population PK approach. ANTHIM® (obiltoxaximab) does not have direct antibacterial activity. As such, ANTHIM® (obiltoxaximab) should be used in combination with appropriate antibacterial drugs. ANTHIM® (obiltoxaximab) is not expected to cross the blood-brain barrier and does not prevent or treat meningitis.

Acquisition of Elusys

On April 18, 2022, we closed the Merger contemplated by the Merger Agreement (the "Closing"). Pursuant to the Merger Agreement, as merger consideration ("Merger Consideration") we 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. We have also paid to the Sellers (i) $2,000,000 and (ii) agreed to pay 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 shareholders' are to receive an additional payment of approximately $6.0 million, net from the fulfillment of an existing U.S. Government contract which we have 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. We 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 us, Elusys and the Merger Sub. Subject to certain customary limitations, the Sellers have agreed to indemnify us and our 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.

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 was filed with the 8-K on April 18, 2022 .

Biothreat Advisory Board

In August 2021, we announced the formation of our Biothreat Advisory Board to support the development of our biosecurity/biodefense initiatives. The advisory board includes Greg Burel, David Lasseter, Former Deputy Asst. Sec. of Defense for Countering Weapons of Mass Destruction, Andrew Webber, Former Asst. Sec. of Defense for Nuclear, Chemical & Biological Defense Programs, Jack Kingston, Former US Representative, Secretariat of the Alliance for Biosecurity (current), Gregor Koblentz, PhD, Professor of Biodefense at George Mason University, Expert on Chemical and Biological Weapons, and Former US Senator (AR) Mark Pryor. This panel was assembled to provide ongoing guidance on the development and commercialization of our biodefense assets and platforms.

RapidVax®: Preclinical Stage

Development Programs

Our biodefense efforts remain focused on identifying, manufacturing, and commercializing novel assets to combat emerging and existing biological threats through in-house discovery as well as external partnership and in-licensing opportunities such as Lytic Solutions, LLC.

In November 2018, we formed the discovery subsidiary Skunkworx (formerly known as Delphi Therapeutics, Inc.) to support in-house nomination of biologics for preclinical and clinical development. Our approach utilizes "Pocket Biologics" derived from diverse proprietary antibody and small protein libraries to identify and differentiate

pharmacologically active “HotSpot” sites on proteins relevant to disease. Coupled with the integration of computational and bioinformatic analysis, the goal is to “improve” candidate selection and accelerate validation of innovative therapeutics and biodefense assets from discovery into preclinical development.

Skunkworx is designing RapidVax® as a flexible “plug-and-play” vaccine platform designed to leverage our vast experience developing gp96-based vaccines and couples the immune-activating properties of heat shock protein gp96 and the T-cell co-stimulator OX40L with a flexible antigen expression system to promote antigen-specific T-cell activation, the generation of long-lasting memory cells, and neutralizing antibody production via the interaction of T follicular helper cells with B cells. RapidVax is designed to utilize a common unprogrammed vaccine base that can be manufactured in bulk, stockpiled, and rapidly customized upon identification of a biological threat to enable an accelerated time to clinic and to harness shared development, clinical safety, and manufacturing synergies.

Oncology

Prior to 2022, our focus was on the development of our oncology product candidates. More specifically, we were evaluating the potential of the gp96 platform immunotherapy HS-110 (viagenpumatucel-L) in patients with advanced non-small cell lung cancer (“NSCLC”) and completed the enrollment of our Phase 2 trial evaluating the safety and efficacy of HS-110 in combination with either nivolumab (Opdivo®), a Bristol-Myers Squibb anti-PD 1 checkpoint inhibitor, or Merck’s anti-PD1 checkpoint inhibitor, pembrolizumab (KEYTRUDA®), for the treatment of patients with advanced NSCLC. In addition, we completed an open-label, single arm, Phase 1 clinical trial assessing safety and tolerability of PTX-35, a monoclonal antibody which was part of our TNF receptor superfamily member 25 (TNFRSF25) platform, in patients with advanced solid tumors refractory to, or ineligible for, or who refuse available standard of care.

In our third quarter 2022 10-Q, we deprioritized our oncology program and the activities of our Heat Biologics I, Inc. and Pelican Therapeutics, Inc. (“Pelican”) subsidiaries to streamline operations to support the discovery, development, and commercialization of innovative medical countermeasures. In January 2023, we terminated all of our license agreements with the University of Miami, including all agreements associated with the gp96 and TNFRSF25 platforms. We are not pursuing further development of the gp96 based HS-110 (viagenpumatucel-L) and RapidVax programs.

Terminated License Agreements with University of Miami

From 2008 through 2020, we entered into the following eight (8) license agreements with the University of Miami, all of which notice of termination was provided by us to the University of Miami in January 2023, pursuant to which we or one of our subsidiaries was granted an exclusive, worldwide right to make, use or sell licensed materials based upon the patent-related rights set forth in the license agreements. Under the Agreements set forth in clauses (i)-(v) below, the licensees obtained exclusive rights to different patent families each directed to therapeutic compositions and methods related to targeting gp96. Under Agreements pursuant to which Pelican is the licensee, as set forth in (vi)-(viii) below, Pelican obtained exclusive rights to six different patent families each directed to therapeutic compositions and methods related to targeting DR3/TNFRSF25/TL1A for the purpose of modulating immune responses. No products that received regulatory approval for commercialization were developed under the license agreements.

i. License Agreement (UMSS-114 (previously UM97-14), concerning certain patents and patent applications related to a cell-based gp96 vaccine for treating cancer) between the University of Miami and Heat Biologics, Inc. (now known as Nighthawk Biosciences, Inc.) effective July 11, 2008, as amended (“UMSS-114 Agreement”);
ii. License Agreement ((UMSS114A), concerning certain patents and patent applications related to allogeneic cancer cell-based immunotherapy methods and regimens) between the University of Miami and Heat Biologics I, Inc. effective February 18, 2011, as amended (“UMSS114A Agreement”); and
iii. License Agreement ((UMD-107), concerning certain patents and patent applications related to heat shock protein gp96 vaccination) between the University of Miami Heat Biologics I, Inc. effective February 18, 2011, as amended (“UMD-107 Agreement”);
iv. Exclusive License Agreement ((UMIP-114/Strbo), concerning certain patents and patent applications related to a gp96-based cell vaccine for Zika infections) between the University of Miami and Zolovax, Inc., effective October 24, 2016 (“UMIP-114 Agreement”);

v. Exclusive License Agreement ((UMPIP-510), concerning certain patents and patent applications related to a gp96-based cell vaccine for coronavirus infections) between the University of Miami and Zolovax, Inc. dated as of December 31, 2020 ((“UMPIP-510 Agreement”);

vi. Exclusive License Agreement, concerning certain patents and patent applications related to modulating regulatory T cell (Treg) proliferation by targeting DR3/TNFRSF25/TL1A signaling, between the University of Miami and Pelican Therapeutics, Inc. f/k/a Heat Biologics II, Inc., effective July 11, 2008, as amended ((“UM03-31 UM05-39 Agreement”);

vii. Exclusive License Agreement, concerning certain patents and patent applications related to methods of modulating CD8 T cells and treating cancer by targeting DR3/TNFRSF25/TL1A signaling, between the University of Miami and Pelican Therapeutics, Inc. f/k/a Heat Biologics II, Inc., effective December 12, 2010 ((“UMI-176 Agreement”); and

viii. Exclusive License Agreement, concerning certain patents and patent applications related to certain TL1A fusion proteins, between the University of Miami and Pelican Therapeutics, Inc., effective November 19, 2013 ((“UMM-143 Agreement”).

All of the license agreements provided that the licensee had the right to terminate the license agreement upon providing ninety days written notice of termination, which notice was provided on January 27, 2023. Any termination is without prejudice to the University of Miami’s right to recover all amounts accruing to it prior to such termination and cancellation, which we believe that no amounts were owed or accruing. Upon termination, we or the licensee have no rights, express or implied, under any patent property which is the subject matter of the license

Strategy

Our objective is to become a market leader in the development of innovative medical countermeasures, prioritizing American-made equipment, reagents, materials, and in-house biomanufacturing to streamline the commercialization and delivery of novel biodefense biologics to the U.S. and allied partners. We believe our integrated end-to-end ecosystem provides a strategic advantage by reducing dependency on external third-parties and accelerating our development programs.

We consider expanded U.S. and international sales of our monoclonal antibody anthrax antitoxin ANTHIM® (obiltoxaximab) a driver of future company growth. To date, Elusys has received ~$151M USD and ~$6M USD in procurement contracts to provide ANTHIM® (obiltoxaximab) to the U.S. SNS and the Public Health Agency of Canada Office of Emergency Response Services Depot, respectively. We are actively engaging with new and existing government programs and considering potential investments with business partners to create and expand ANTHIM® (obiltoxaximab) deliveries.

We believe there is a growing market need and deficient availability for large molecule biomanufacturing. Scorpius is expected to decrease our dependence on third-party CDMOs for the manufacture of ANTHIM® (obiltoxaximab) and other assets, and allows us to be opportunistic in offering excess capacity to third parties as a fee-for-service model to fill this market gap. Additionally, we anticipate Scorpius prioritization of American-made equipment, reagents, and materials paired with domestic sourcing of biomanufacturing expertise will make the organization competitive for U.S. government contracts and biodefense assets.

The key elements of our strategy are:

- *Establish a fully integrated biopharmaceutical company specializing in end-to-end development and delivery of medical countermeasures and specialty immune-stimulating products:* The coordinated efforts of our subsidiaries Skunkworx, Elusys, and Scorpius form a drug development ecosystem designed to fuel innovation, from discovery to commercialization, with minimal reliance on external vendors. This capability offers the potential to translate our discoveries into therapeutics with increased efficiency and quality and without compromising our agility to pursue new innovations.

- *Maximize commercial opportunities for ANTHIM® (obiltoxaximab):* We believe that ANTHIM® (obiltoxaximab) will continue to be a critical biodefense asset for stockpiling by the U.S. SNS and Public Health

Agency of Canada Office of Emergency Response Services Depot. We intend to be opportunistic in seeking strategic partnerships that maximize the economic potential of this asset and are in the process of completing the technology transfer to Scorpius for future biomanufacturing.

- *Maximize commercial opportunities for Scorpius Biomanufacturing, Inc:* We launched Scorpius in October 2022 as a CDMO focused on developing bioanalytic, process development, and biomanufacturing capabilities to support our clinical and commercial pipeline. We are opportunistic in offering excess biomanufacturing capacity to third parties as a fee-for-service model and believe our prioritization of American-made equipment, reagents, and materials paired with domestic sourcing of biomanufacturing expertise will make the organization competitive for U.S. government contracts and biodefense assets.

- *Develop and obtain regulatory approval for our product candidates*: Our biodefense efforts remain focused on identifying, manufacturing, and commercializing novel assets to combat unmet and emerging biological threats through in-house discovery, external partnership, and in-licensing opportunities. We anticipate future announcements related to ongoing discovery and development efforts as these programs progress.

- *Enhance our partnering efforts:* We are continually exploring partnerships for licensing and other collaborative relationships and remain opportunistic in seeking strategic partnerships that maximize our economic potential and align with our objective to become a market leader in the development and commercialization of innovative medical countermeasures.

- *Further expand our broad patent portfolio*: We have made a significant investment in the development of our patent portfolio to protect our technologies and programs, and we intend to continue to expand our portfolio. Our Elusys subsidiary owns or exclusively licenses a patent estate that covers our ANTHIM® product. We are also developing a patent estate for various new pre-clinical biodefense-related technologies developed by NightHawk or our Skunkworx subsidiary. We also maintain some legacy patent assets relating to gp96 and TNFRSF25 that are owned or co-owned by us and Pelican.

- *Manage our business with efficiency and discipline*: We believe we have efficiently utilized our capital and human resources to develop and acquire our product candidates and programs and create a broad intellectual property portfolio. These resources form our drug development ecosystem. We use project management techniques to assist us in making disciplined strategic program decisions and to attempt to limit the risk profile of our product pipeline.

- *Obtain additional non-dilutive grant funding*: To develop our technologies and assets more fully, we continually seek and access external sources of grant funding on our own behalf and in conjunction with our external partners to support the development of our pipeline.

Intellectual Property

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies; preserve our trade secrets and exclusive rights in our unique biological materials; and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the strongest intellectual property protection possible for our current product candidates and any future product candidates and our subsidiaries' proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. However, even patent protection may not always afford us with complete protection against competitors who seek to circumvent our patents. See "Risk Factors – Risks Related to Intellectual Property."

We will continue to depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that

prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Elusys Intellectual Property

Elusys has an exclusive, fully paid up, worldwide patent license, dated June 30, 2003, from the Board of Regents of the University of Texas which grants Elusys the right to use for the manufacture, offer and sale of antibodies that bind immunologically to anthrax antigens under the patent rights held by the University of Texas under the U.S. patent application entitled "Neutralization of the Anthrax Toxin", serial number 10/288,269 filed on November 5, 2001 (and subsequently issued by the U.S. Patent and Trademark Office on November 4, 2008, serial number 7,446,182) and the U.S. patent application entitled "Antibodies With Increased Affinities For Anthrax Antigens", serial number 10/620,049 filed on July 15, 2003 (and subsequently issued by the U.S. Patent and Trademark Office on March 8, 2011, serial number 7,902,344). The term of agreement continues until all patent rights have expired, unless terminated automatically due to bankruptcy or insolvency of Elusys or by mutual written agreement. ANTHIM® is covered by 5 US patents which are owned by Elusys or exclusively licensed from the Board of Regents of the University of Texas.

Elusys is the assignee of the U.S. patent application entitled "Antibodies that bind B. anthracis exotoxin, formulations thereof, and methods of use", serial number 11/904,882 filed on September 28, 2007 (and subsequently issued by the U.S. Patent and Trademark Office on January 10, 2012, serial number 8,093,360) and the U.S. patent application entitled "Methods of preventing or treating anthrax using anti-anthrax antibodies", serial number 13/076,082 filed on March 30, 2011 (and subsequently issued by the U.S. Patent and Trademark Office on December 31, 2013, serial number 8,617,548).

Emerging and Legacy Intellectual Property

NightHawk and Skunkworx hold 5 non-provisional, international (PCT) applications and approximately 10 U.S. provisional applications which covering emerging, pre-clinical biodefense-related technologies, including antibody-based assets related to the "Pocket Biologics" concepts. We also own approximately 30 patents and 30 patent applications, in the U.S., Europe, China, Japan, and other countries, which cover historical gp96 assets. Pelican owns about 20 patents and 20 patent applications, in the U.S., Europe, China, Japan, and other countries, which cover historical TNFRSF25 assets, including coverage of PTX35.

License Agreement with Shattuck Labs

In June 2016, we entered into an exclusive license agreement with Shattuck Labs, Inc. ("Shattuck") pursuant to which we licensed to Shattuck certain provisional patent applications and know-how related to fusion proteins to treat cancer and other diseases that were not being developed by us. Shattuck paid us an initial license fee of $50,000 and is obligated to pay us fees upon its receipt of sublicensing income, achievement of certain milestones and royalties upon sales of commercial products. The technology that was out-licensed to Shattuck is in the early stages of development and there is a low likelihood of success for any technology at such stage, and there can be no assurance that any products will be developed by Shattuck or that we will derive any revenue from Shattuck. In February 2023, we were notified by Shattuck that a milestone was met and we received an additional $100,000 in milestone payments.

External Manufacturing

We have historically relied on third-party manufacturers to produce and store our product candidates for clinical use and currently do not operate our own manufacturing facilities. In order to promote efficiency and reduce our reliance on third-party vendors, we have enhanced our in-house development of bioanalytic, process development and manufacturing capabilities and offer such services to third parties for fees. We have entered into a lease for a 20,144 square foot facility in San Antonio, TX to conduct such services. Our expansion in Texas is part of a company-wide-growth strategy to enhance efficiency and decrease our dependence on third-party vendors as we advance our commercial pipeline. Operations at the facility commenced in October 2022, and we expect to fill production capacity by transitioning our outsourced manufacturing and development in-house immediately, followed by contracting with external customers. However, there can be no assurance that we will be successful in these new operations.

ANTHIM® (obiltoxaximab) is a best-in-class monoclonal antibody antitoxin for anthrax. ANTHIM® (obiltoxaximab) received FDA approval and orphan drug exclusivity in 2016 for the treatment of inhalational anthrax, in combination with antibiotics, and as a prophylaxis when alternative therapies are not available or are not appropriate. ANTHIM® (obiltoxaximab) was also approved in 2020 and 2021 as the only licensed anthrax anti-toxin treatment in the EU, UK, and Canada. ANTHIM® (obiltoxaximab) is being manufactured by an external vendor, Lonza Sales AG ("Lonza") and we are in the process of completing the tech transfer of this asset to Scorpius for future production. In 2015, Elusys entered into a bulk ordering agreement with Lonza for the commercial production of ANTHIM®. Under the agreement Lonza will manufacture ANTHIM® pursuant to purchase orders issued in accordance with forecasts that we provide. We will purchase ANTHIM® that meets agreed specifications in batches, with the price per batch varying according to the total number of batches ordered for serial production in a single manufacturing campaign. Once we agree to a schedule of services and pricing terms, we are obligated to purchase a minimum number of batches which may be reduced under certain circumstances. On March 31, 2022, we became obligated to purchase batches of ANTHIM® from Lonza. We may be obligated to pay certain fees to Lonza upon cancellation of purchase orders within a certain specified period of time prior to projected commencement of the applicable batch.

Competition

The pharmaceutical, biologics and diagnostic industry is highly competitive and characterized by several established large companies, mid-sized companies, as well as smaller companies like ours. If our competitors market products that are less expensive, safer, or more effective than any future products developed from our product candidates, or that reach the market before our approved product candidates, we may not achieve commercial success. Technological developments in our field of research and development occur at a rapid rate and we expect competition to intensify as advances in this field are made. We will be required to continue to devote substantial resources and efforts to our research and development activities. If we fail to stay at the forefront of technological change, we may be unable to compete effectively.

Biodefense Competition

We anticipate our most significant competitor for ANTHIM® (obiltoxaximab) will be Emergent BioSolutions, Inc. ("Emergent"). Emergent is the provider of the anthrax antitoxin raxibacumab. Raxibacumab received FDA approval on December 14, 2012, while ANTHIM® (obiltoxaximab) received FDA approval on March 18, 2016. ANTHIM® (obiltoxaximab) and raxibacumab both inhibit the binding of anthrax toxin PA to its cellular receptors, preventing the intracellular entry of the anthrax lethal factor and edema factor, the enzymatic toxin components responsible for the pathogenic effects of anthrax toxin. Package inserts indicate that ANTHIM® (obiltoxaximab) has an affinity equilibrium dissociation constant (Kd) of 0.33 nM compared to 2.78 nM for raxibacumab, and a potentially longer shelf life of 7 years compared to 5 years for raxibacumab. ANTHIM® (obiltoxaximab) and raxibacumab have both been supplied to the CDC's strategic national stockpile. We are fulfilling a delivery order for the U.S. SNS this year and anticipate based on previous delivery orders and option agreements that ANTHIM® (obiltoxaximab) will continue to fulfill delivery orders as part of the Office of the Assistant Secretary for Preparedness & Response's (ASPR) objective to diversify and acquire products with a longer shelf-life.

Internationally, ANTHIM® (obiltoxaximab) was approved as the only licensed anthrax antitoxin treatment in the EU and Canada in 2020 and in the UK in 2021. In Canada, the approval of ANTHIM® (obiltoxaximab) blocks future purchases of raxibacumab without Canadian Extraordinary-Use New Drug (EUND) approval. Furthermore, we completed delivery of an initial order of ANTHIM® (obiltoxaximab) to the Public Health Agency of Canada Office of Emergency Response Services Depot in 2022 and anticipate discission of future orders. Similarly, in the EU, orphan drug exclusivity (10 year) at the time of approval provides an advantage to ANTHIM® (obiltoxaximab) as we seek to support HERA's (the European Health Emergency Preparedness and Response Authority) Chemical, Biological, Radiological and Nuclear (CBRN) stockpile initiatives in France, Finland, and Poland. We believe these approvals position ANTHIM® (obiltoxaximab) for increasing biosecurity preparedness in commercially approved ex-U.S. ally territories and we will be opportunistic in seeking strategic partnerships that maximize economic potential of this asset.

Contract Development Biomanufacturing Organization (CDMO) Competition

We formed Scorpius to develop bioanalytic, process development, and biomanufacturing capabilities for our clinical and commercial pipeline as well as to offer excess biomanufacturing capacity to third parties as a fee-for-service CDMO model. Scorpius is focused on cell- and gene-based therapies as well as large molecule biologics and provides a broad array of services prioritizing American-made equipment, reagents, and materials when possible. Scorpius pairs cGMP biomanufacturing and quality control expertise with cutting edge capabilities in immunoassays, molecular assays, and bioanalytical methods to support the advancement of clinical and commercial programs.

We anticipate providing competition to established biomanufacturers including Lonza Group, Ltd and WuXi AppTec as well as recently announced biomanufacturing efforts from ThermoFisher Scientific, Inc. The COVID-19 pandemic revealed a critical shortage in U.S. biomanufacturing capacity. Historically, therapies could often take ~10 years to commercialize. However, with the implementation of Emergency Use Authorization, complex, effective vaccines can now advance through pipelines at record speed, contributing to new expectations for time to market, cost reduction, regulatory compliance, and good manufacturing performance. Considering the global cell and gene therapy clinical trials market size was valued at $9.2 billion in 2020 and is expected to expand at a compound annual growth rate (CAGR) of 22.3% from 2021 to 2028 per Grand View Research, we anticipate that a shortage of industry capacity may minimize the risk of direct competition. Additionally, we anticipate Scorpius prioritization of American-made equipment, reagents, and materials paired with domestic sourcing of biomanufacturing expertise will make the organization competitive for U.S. government contracts and biodefense assets. We formed the subsidiary Scorpius to focus on developing bioanalytic, process development and biomanufacturing capability to support our biotherapeutics and discovery pipeline. We plan to offer excess biomanufacturing capacity to third parties as a fee-for-service CDMO model. Scorpius is focused on cell- and gene-based therapies and large molecule biologics. We provide a broad array of biologics manufacturing, analytical and R&D services, offering services using American-made equipment, reagents, and materials. Scorpius couples cGMP biomanufacturing and quality control expertise with cutting edge capabilities in immunoassays, molecular assays, and bioanalytical methods to support the advancement of our development and commercial programs.

Government Regulation

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, (the "FDC Act"), and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Biological products used for the prevention, treatment, or cure of a disease or condition of a human being are subject to regulation under the FDC Act, except the section of the FDC Act that governs the approval of new drug applications, or NDAs. Biological products are approved for marketing under provisions of the Public Health Service Act, or PHSA, via a Biologics License Application, or BLA. However, the application process and requirements for approval of BLAs are very similar to those for NDAs, and biologics are associated with similar approval risks and costs as drugs. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs or BLAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties, and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the U.S. typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are

submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30 day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30 day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug or biologic to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (1) in compliance with federal regulations; (2) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (3) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions.

Clinical trials to support NDAs or BLAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug or biologic into healthy human subjects or patients, the product is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to evaluate the effectiveness of the drug or biologic for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug or biologic and to provide adequate information for the labeling of the product. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug or biologic. A single Phase 3 trial with other confirmatory evidence may be sufficient in rare instances where the study is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

After completion of the required clinical testing, an NDA or BLA is prepared and submitted to the FDA. FDA approval of the NDA or BLA is required before marketing of the product may begin in the United States. The NDA or BLA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA or BLA is substantial. The submission of most NDAs and BLAs is additionally subject to a substantial application user fee and the manufacturer and/or sponsor under an approved new drug application are also subject to an annual program fee. These fees are typically increased annually.

The FDA undertakes to perform an initial filing review within 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs and BLAs. Most such applications for standard review drug or biologic products are reviewed within ten to twelve months; most applications for priority review drugs or biologics are reviewed in six to eight months. The FDA can extend these reviews by three months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited to products intended to treat a serious or life-threatening

disease relative to the currently approved products. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug or biologic products, or drug or biologic products that present difficult questions of safety or efficacy, to an advisory committee – typically a panel that includes clinicians and other experts – for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. FDA will not approve the product unless compliance with current good manufacturing practice, or cGMP, is satisfactory and the NDA or BLA contains data that provide substantial evidence that the drug or biologic is safe and effective in the indication studied.

After the FDA evaluates the NDA or BLA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA or BLA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or nine months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug or biologic with specific prescribing information for specific indications. As a condition of NDA or BLA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug or biologic outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained, or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA or NDA or BLA supplement before the change can be implemented. In order for Scorpius to manufacture ANTHIM® we will be required to obtain FDA approval for the change in manufacturing facility. An NDA or BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA or BLA supplements as it does in reviewing NDAs or BLAs.

Post-Approval Requirements

Any products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among others, standards for direct-to-consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product's approved uses, known as 'off-label' use, limitations on industry-sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available products for off-label uses if the physician deems that use to be appropriate in their professional medical judgment, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval to ensure the long-term stability of the product. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Manufacturers and other entities involved in the

manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money, and effort on production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

The FDA also may require post-marketing testing, known as Phase 4 testing, and surveillance to monitor the effects of an approved product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product candidates under development.

Additional Controls for Biologics

To help reduce the increased risk of the introduction of adventitious agents, the PHSA emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSA also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the U.S. and between states.

After a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer. In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biologics, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

Cell and Tissue-Based Biologics

Establishments that manufacture cell and tissue-based products must comply with the FDA's current good tissue practices, or cGTP, which are FDA regulations that govern the methods used in, and the facilities and controls used for, the manufacture of such products. The primary intent of the cGTP requirements is to ensure that T-cell and tissue-based products are manufactured in a manner designed to prevent the introduction, transmission and spread of communicable disease. FDA regulations also include requirements for a unified registration and listing system, donor screening and testing, adverse reaction reporting, and labeling.

Cell and tissue-based products may also be subject to the same approval standards, including demonstration of safety and efficacy, as other biologic and drug products if they meet certain criteria such as if the cells or tissues are more than minimally manipulated or if they are intended for a non-homologous use. Marketing of these products in the U.S. will require FDA approval under the BLA pathway as discussed above.

CDMO Regulatory Approval

We are required to comply with the regulatory requirements of various local, state, national and international regulatory bodies having jurisdiction in the countries or localities where we manufacture products or where our customers' products are distributed. In particular, we are subject to laws and regulations concerning research and development, testing, manufacturing processes, equipment and facilities, including compliance with CGMPs, labeling and distribution, import and export, and product registration and listing. As a result, our facilities are subject to regulation by the FDA, as well as regulatory bodies of other jurisdictions where our customers have marketing approval for their products including, but not limited to, the EMA, ANVISA, Health Canada, and the Australian Department of Health. Scorpius is subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, Scorpius must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved BLA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented. Other types of changes to the approved product, such as adding new indications and claims, are also subject to further FDA review and approval.

We are also required to comply with environmental, health and safety laws and regulations, as discussed in "Environmental and Safety Matters" below. These regulatory requirements impact many aspects of our operations, including manufacturing, developing, labeling, packaging, storage, distribution, import and export and record keeping related to customers' products. Noncompliance with any applicable regulatory requirements can result in government refusal to approve facilities for manufacturing products or products for commercialization.

Our customers' products must undergo pre-clinical and clinical evaluations relating to product safety and efficacy before they are approved as commercial therapeutic products. The regulatory authorities having jurisdiction in the countries in which our customers intend to market their products may delay or put on hold clinical trials, delay approval of a product or determine that the product is not approvable. The FDA or other regulatory agencies can delay approval of a drug if our manufacturing facilities are not able to demonstrate compliance with CGMPs, pass other aspects of pre-approval inspections (i.e., compliance with filed submissions) or properly scale up to produce commercial supplies. The FDA and comparable government authorities having jurisdiction in the countries in which our customers intend to market their products have the authority to withdraw product approval or suspend manufacture if there are significant problems with raw materials or supplies, quality control and assurance or the product is deemed adulterated or misbranded. If new legislation or regulations are enacted or existing legislation or regulations are amended or are interpreted or enforced differently, we may be required to obtain additional approvals or operate according to different manufacturing or operating standards or pay additional fees. This may require a change in our manufacturing techniques or additional capital investments in our facilities.

The costs associated with complying with the various applicable local, state, national and international regulations could be significant and the failure to comply with such legal requirements could have an adverse effect on our financial condition and results of operations. See "Risk Factors—Risks Related to Our Business" for additional discussion of the costs associated with complying with the various regulations. Failure to comply with existing and future regulatory requirements could adversely affect our business, financial condition and results of operations.

Environmental and Safety Matters

Certain products manufactured by us involve the use, storage and transportation of toxic and hazardous materials. Our operations are subject to extensive laws and regulations relating to the storage, handling, emission, transportation and discharge of materials into the environment and the maintenance of safe working conditions. We maintain environmental and industrial safety and health compliance programs and training at our facilities.

Prevailing legislation tends to hold companies primarily responsible for the proper disposal of their waste even after transfer to third party waste disposal facilities. Other future developments, such as increasingly strict environmental, health and safety laws and regulations, and enforcement policies, could result in substantial costs and liabilities to us and could

subject the handling, manufacture, use, reuse or disposal of substances or pollutants at our facilities to more rigorous scrutiny than at present.

Other U.S. Healthcare Laws and Compliance Requirements

In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services, for instance the Office of Inspector General, the U.S. Department of Justice ("DOJ"), and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the physician payment transparency laws, the privacy and security provisions of HIPAA, as amended by HITECH, and similar state laws, each as amended.

The federal anti-kickback statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The anti-kickback statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor, however, does not make the conduct per se illegal under the anti-kickback statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Violations of this law are punishable by imprisonment, criminal fines, administrative civil money penalties and exclusion from participation in federal healthcare programs.

Additionally, the intent standard under the anti-kickback statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act., as discussed below.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Although we would not submit claims directly to payors, drug manufacturers can be held liable under the federal civil False Claims Act, which imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities (including manufacturers) for, among other things, knowingly presenting, or causing to be presented to federal programs (including Medicare and Medicaid) claims for items or services, including drugs, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services; making a false statement or record material to payment of a false claim; or avoiding, decreasing or concealing an obligation to pay money to the federal government. Penalties for a False Claims Act violation include three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal healthcare programs and, although the federal False Claims Act is a civil statute, conduct that results in a False Claims Act violation may also implicate various federal criminal statutes. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. Claims which include items or services resulting from a violation of the federal Anti-Kickback Statute are false or fraudulent claims for purposes of the False Claims Act. Our future marketing and activities relating to the reporting of wholesaler or estimated retail prices for our products, if

approved, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state and third-party reimbursement for our products, and the sale and marketing of our product and any future product candidates, are subject to scrutiny under this law. Pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal anti-kickback statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct business. HIPAA, as amended by the HITECH Act, and their respective implementing regulations. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, defined as independent contractors or agents of covered entities, which include health care providers, health plans, and healthcare clearinghouse, that create, receive, or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities and business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in specified circumstances, some of which are more stringent and many of which differ from each other in significant ways, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and criminal penalties.

Additionally, the Federal Physician Payments Sunshine Act under the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to annually report to the Centers for Medicare and Medicaid, or CMS, information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately, and completely the required information may result in civil monetary penalties. Certain states also mandate implementation of compliance programs, impose restrictions on pharmaceutical manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to healthcare providers and entities.

In order to distribute products commercially, we must also comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to it, we may be subject to penalties, including without limitation, significant civil,

criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, or refusal to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of operations, any of which could adversely affect our ability to operate our business and our results of operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Strict data privacy laws regulating the collection, transmission, storage and use of employee data and consumers' personally-identifying information are evolving in the EU, U.S. and other jurisdictions in which we operate. Outside of the U.S., the laws, regulations and standards in many jurisdictions apply broadly to the collection, use, and other processing of personal information. For example, in the EU, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation (the "GDPR"). The GDPR, together with national legislation, regulations and guidelines of the EU member states governing the processing of personal data, impose strict obligations on entities subject to the GDPR, including but not limited to: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent from data subjects; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with the data protection rights of data subjects; and (iv) obligations to report certain personal data breaches to governmental authorities and individuals. Data protection authorities from the different E.U. member states and other European countries may enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing European personal data. Failure to comply with the requirements of the GDPR and the related national data protection laws may result in significant monetary fines and other administrative penalties (the GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater) as well as civil liability claims from individuals whose personal data was processed. Additionally, expenses associated with compliance could reduce our operating margins.

The GDPR also prohibits the transfer of personal data from the E.U. to countries outside of the E.U. unless made to a country deemed by the European Commission to provide adequate protection for personal data or accomplished by means of an approved data transfer mechanism (e.g., standard contractual clauses). Data protection authority guidance and enforcement actions that restrict companies' ability to transfer data may increase risk relating to data transfers or make it more difficult or impossible to transfer E.U. personal data to the U.S.

Coverage, Pricing and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. In the U.S. and markets in other countries, sales of any products for which we receive regulatory approval for commercial sale will depend, in part, on the extent to that third-party payors provide coverage, and establish adequate reimbursement levels for such products. In the U.S., third-party payors include federal and state healthcare programs, private managed care providers, health insurers and other organizations. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost- effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy. We may need to conduct expensive pharmaco-economic studies in order to demonstrate the medical necessity and cost-effectiveness of our product candidates, in addition to the costs required to obtain the FDA approvals. Our product candidates may not be considered medically necessary or cost-effective. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on investment in product development.

Different pricing and reimbursement schemes exist in other countries. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. Other countries allow companies to fix their own prices for medicines but monitor and control company profits. The downward pressure on health care costs has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross-border imports from low-priced markets exert a commercial pressure on pricing within a country.

The marketability of any product candidate for which we receive regulatory approval for commercial sale may suffer if the government and third-party payors fail to provide adequate coverage and reimbursement. In addition, emphasis on managed care in the U.S. has increased and we expect the pressure on healthcare pricing will continue to increase. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

U.S. Healthcare Reform

In the U.S. and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. It is unclear how these challenges and other efforts to repeal and replace the ACA will impact our business in the future.

Other legislative changes have been proposed and adopted in the U.S. since the ACA was enacted. Additionally, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates and may affect our overall financial condition and ability to develop product candidates.

We anticipate that current and future U.S. legislative healthcare reforms may result in additional downward pressure on the price that we receive for any approved product, if covered, and could seriously harm our business. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors.

Non-U.S. Regulation

Before our products can be marketed outside of the U.S., they are subject to regulatory approval of the respective authorities in the country in which the product should be marketed. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary widely from country to country. No action can be taken to market any product in a country until an appropriate application has been approved by the regulatory authorities in that country. The current approval process varies from country to country, and the time spent in gaining approval varies from that required for FDA approval. In certain countries, the sales price of a product must also be approved. The pricing review period often begins after market approval is granted. Even if a product is approved by a regulatory authority, satisfactory prices might not be approved for such product.

In Europe, marketing authorizations may be submitted at a centralized, a decentralized or national level; however, the centralized procedure is mandatory for the approval of biotechnology products and provides for the grant of a single

marketing authorization that is valid in all EU member states. There can be no assurance that the chosen regulatory strategy will secure regulatory approval on a timely basis or at all.

While we intend to market our products outside the U.S. in compliance with our respective license agreements, we have not made any applications with non-U.S. authorities and have no timeline for such applications or marketing.

Research and Development

We have built an internal and external research and development organization that includes expertise in discovery research, preclinical development, product formulation, analytical chemistry, manufacturing, clinical development, and regulatory and quality assurance. Sponsors of clinical trials of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Our cancer trials have been registered on clinicaltrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the progress of development. Research and development expenses were $23.5 million and $16.5 million during the years ended December 31, 2022 and 2021, respectively.

Our Corporate Background and Information

We were incorporated under the laws of the State of Delaware on June 10, 2008. Our principal offices are located at 627 Davis Drive, Suite 300, Morrisville NC 27560. Our website address is www.nighthawkbio.com. The information contained in, and that can be accessed through our website, is not incorporated into and is not a part of this report. We make available on our website our Annual Reports on Form 10 K, Quarterly Reports on Form 10 Q and Current Reports on Form 8 K as soon as reasonably practicable after those reports are filed with the U.S. Securities and Exchange Commission (the "SEC"). The following Corporate Governance documents are also posted on our website: Code of Business Conduct and Ethics and the Charters for the following Committees of the Board of Directors: Audit Committee, Compensation Committee, and Nominating Committee. Our phone number is (919) 240-7133 and our facsimile number is (919) 869-2128. Our filings may also be read and copied at the SEC's Public Reference Room at 100 F Street NE, Room 1580 Washington, DC 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. The address of that website is www.sec.gov.

References to Nighthawk Biosciences also include references to our subsidiaries Pelican Therapeutics, Inc. ("Pelican"), Heat Biologics I, Inc. ("Heat I"), Heat Biologics III, Inc. ("Heat III"), Heat Biologics IV, Inc. ("Heat IV"), Heat Biologics GmbH, Heat Biologics Australia Pty Ltd., Zolovax, Inc., Skunkworx Bio, Inc. (formerly known as Delphi Therapeutics, Inc.), Scorpius BioManufacturing, Inc. (formerly Scorpion Biological Services, Inc), Blackhawk Bio, Inc., Abacus Biotech, Inc., and Elusys Therapeutics, Inc. ("Elusys") unless otherwise indicated. On May 30, 2012, we formed two wholly-owned subsidiaries, Heat Biologics III, Inc. and Heat Biologics IV, Inc. We formed Heat Biologics GmbH (Heat GmbH), a wholly-owned limited liability company, organized in Germany on September 11, 2012 and Heat Biologics Australia Pty LTD, a wholly-owned company, registered in Australia on March 14, 2014. On October 25, 2016, we formed a wholly-owned subsidiary, Zolovax, Inc., to focus on the development of gp96 based vaccines targeting Zika, HIV, West Nile, dengue, yellow fever, and SARS-CoV-2. In June 2012, we divested our 92.5% interest in Pelican (formerly known as Heat Biologics II, Inc.). On April 28, 2017, we completed the acquisition of an 80% controlling interest in Pelican, a related party prior to acquisition. In October 2018, we entered into an agreement with UM whereby UM exchanged its shares of stock in Heat's subsidiaries, Heat I and Pelican, resulting in us owning 100% of Heat I and increasing our controlling ownership in Pelican from 80% to 85%. We assigned our proprietary rights related to the development and application of our ImPACT® therapy platform to Heat Biologics I, Inc. In November 2018, we formed Skunkworx (formerly known as Delphi Therapeutics, Inc.) which uses a unique and proprietary platform to generate new biological entities that we may rapidly advance into clinical development. Also, in November 2018, we formed Scorpius BioManufacturing, Inc. ("Scorpius") (formerly known as Scorpion Biological Services, Inc.), to focus on developing bioanalytic, process development and manufacturing capability to service our in-house requirements as well as potentially those of others. In February 2021, we formed Abacus Biotech, Inc., a wholly-owned subsidiary to pursue additional

opportunities related to our business. In April 2022, we formed Elusys to focus on commercializing ANTHIM® and developing additional biodefense product candidates.

We are a "smaller reporting company", as defined in Regulation S-K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will cease to be a smaller reporting company if we have (i) more than $250 million in market value of our shares held by non-affiliates as of the last business day of our most recently completed second fiscal quarter or (ii) more than $100 million of annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter and a market value of our shares held by non-affiliates more than $700 million as of the last business day of our second fiscal quarter.

Human Capital

We believe that our success depends upon our ability to attract, develop, retain and motivate key personnel. Our management and scientific teams possess considerable experience in drug discovery, research and development, manufacturing, clinical and regulatory affairs and believe we directly benefit from this experience and industry knowledge. Our research team comprises B.S., M.S. and Ph.D.-level scientists with expertise in oncology, immunology, and molecular biology.

As of December 31, 2022, we had a total of 77 full-time employees, of which 29 are part of our research team located in San Antonio, Texas, 16 are part of our research team located in Morrisville, North Carolina, 5 are part of our research team located in New Brunswick, New Jersey, 3 are part of our research team located in Parsippany, New Jersey and 24 are part of our corporate team. We consider our relationships with our employees to be good. None of our employees is represented by a labor union. We anticipate that we will need to identify, attract, train and retain other highly skilled personnel to pursue our development program. Hiring for such personnel is competitive, and there can be no assurance that we will be able to retain our key employees or attract, assimilate or retain the qualified personnel necessary for the development of our business.

Although, management continually seeks to add additional talent to its work force, management believes that it has sufficient human capital to operate its business successfully.

Our compensation programs are designed to align the compensation of our employees with our performance and to provide the proper incentives to attract, retain and motivate employees to achieve superior results. The structure of our compensation programs balances incentive earnings for both short-term and long-term performance. Specifically:

- we provide employee wages that are competitive and consistent with employee positions, skill levels, experience, knowledge and geographic location;
- we engage nationally recognized outside compensation and benefits consulting firms to independently evaluate the effectiveness of our executive compensation and benefit programs and to provide benchmarking against our peers within the industry;
- we align our executives' long-term equity compensation with our shareholders' interests by linking realizable pay with stock performance;
- annual increases and incentive compensation are based on merit, which is communicated to employees at the time of hiring and documented through our talent management process as part of our annual review procedures and upon internal transfer and/or promotion; and
- all employees are eligible for health insurance, paid and unpaid leaves, a 401K retirement plan with employer matching contributions (maximum of 4% match) and life and disability/accident coverage. We also offer a variety of voluntary benefits that allow employees to select the options that meet their needs.

Item 1A. ***Risk Factors***

Investors should carefully consider the risks described below before deciding whether to invest in our securities. If any of the following risks actually occur, our business, financial condition or results of operations could be adversely affected. In such case, the trading price of our common stock could decline and you could lose all or part of your investment. Our actual results could differ materially from those anticipated in the forward-looking statements made throughout this Annual Report a result of different factors, including the risks we face described below.

Risks Relating to our Financial Position and Capital Requirements

To date, we have not generated significant revenue and we do not anticipate generating significant revenue in the near future.

To date, we have not generated any revenue from product sales and substantially all of our revenue to date has been revenue from one order of ANTHIM®, grant revenue that Pelican has received from CPRIT and a small amount of revenue from a research funding agreement. We do not anticipate generating any significant revenue from product sales for several years as to date we have only one product, ANTHIM®, approved for commercial sale and it will take several years for us to manufacture additional quantity of ANTHIM® for sale and receive any necessary regulatory approvals. Although we acquired inventory of ANTHIM®, we did not acquire a significant amount of inventory for sale. Therefore, we do not anticipate generating significant revenue from ANTHIM® sales for several years and in fact anticipate to incur additional expenses associated with such product before generating significant revenue from sales of ANTHIM®. Even if we generate revenue from product sales, which is not anticipated for several years, if at all, there can be no assurance that we will be profitable. In addition, we have entered into a new line of business, the provision of contract development and manufacturing services and no assurance can be given that we will be able to generate significant revenue as a contract development and manufacturing organization ("CDMO") or that we will be able to consummate our business strategy and plans. Financial, technological, market, or other limitations may force us to modify, alter, significantly delay, or significantly impede the implementation of such plans. The operation of the manufacturing facility required us to incur significant expenses before we realize any revenue from such facility. We have insufficient results for investors to use to identify historical trends. Investors should consider our prospects in light of the risk, expenses and difficulties we will encounter as an early-stage company. Our revenue and income potential is unproven and our business model is continually evolving. We are subject to the risks inherent to the operation of a new business enterprise and cannot assure you that we will be able to successfully address these risks.

Our consolidated financial statements have been prepared assuming that we will continue as a going concern

We have an accumulated deficit of $209.2 million as of December 31, 2022 and a net loss of approximately $43.9 million for the year ended December 31, 2022 and have not generated significant revenue or positive cash flows from operations. The Company expects to incur significant expenses and continued losses from operations for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we ramp up operations in our in-house bioanalytic, process development and manufacturing facility in San Antonio, TX, expand our infectious disease/biological threat program, and continue to support the development of, and commencement of operations at, a new biodefense-focused large molecule and biologics biomanufacturing facility in Manhattan, Kansas. Our audited financial statements for the fiscal year ended December 31, 2022 were prepared under the assumption that we will continue as a going concern; however, we have incurred significant losses from operations to date and we expect our expenses to increase in connection with our ongoing activities. These factors raise substantial doubt about our ability to continue as a going concern for one year after the financial statements are issued. Our auditors also included an explanatory paragraph in its report on our financial statements as of and for the year ended December 31, 2022 with respect to this uncertainty. There can be no assurance that funding will be available on acceptable terms on a timely basis, or at all. The various ways that we could raise capital carry potential risks. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business. If we raise funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or tests or grant licenses on terms that are not favorable to us. If we do not succeed in raising additional funds on acceptable terms or at all, we may be unable to complete planned build out of our Kansas facility or develop any new product candidates that we acquire. As

such, we cannot conclude that such plans will be effectively implemented within one year after the date that the financial statements included in this Annual Report are filed with the SEC and there is uncertainty regarding our ability to maintain liquidity sufficient to operate our business effectively, which raises substantial doubt about our ability to continue as a going concern.

We have a limited operating history in our current lines of business.

Our success is dependent upon our ability to obtain regulatory approval for commercial sale of our products and to sell such products. We have not yet demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any product candidates. To date, we have not obtained approval for commercialization of any of the products we have developed and, due to our limited time owning ANTHIM®, we have not proven that we can successfully commercialize any product. In addition, we have recently shifted our focus to the development and commercialization of biodefense products and provision of CDMO services. To date, we have generated $6.0 million from new sales of ANTHIM® subsequent to our acquisition of Elusys. To date, we have provided limited manufacturing services as a contract development and manufacturing organization and we have not proven that we can successfully operate a CDMO facility. The successful commercialization of any product candidates will require us to perform a variety of functions, including:

- undertaking preclinical development and successfully enrolling patients in clinical trials;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Until the last few years, our operations have been limited primarily to organizing and staffing, acquiring, developing and securing our proprietary technology and undertaking preclinical trials and preparing for and conducting our Phase 1 and Phase 2 clinical and preclinical trials of our product candidates for cancer and related indications. These operations provide a limited basis for you to assess our ability to successfully commercialize ANTHIM® and any other biodefense product we develop or acquire or to provide CDMO services.

We have incurred net losses every year since our inception and expect to continue to incur increased expenses and generate operating losses and experience negative cash flows and it is uncertain whether we will achieve profitability.

For the years ended December 31, 2022 and 2021, we incurred a net loss of $43.9 million and $35.4 million, respectively. We have an accumulated deficit of $209.2 million through December 31, 2022. We expect to continue to incur operating losses until such time, if ever, as we are able to achieve sufficient levels of revenue from operations. As stated above, we do not anticipate generating significant revenue from sales of our products for several years or from our manufacturing facility until such time as it is fully operational and operating at full capacity. Our ability to achieve profitability will depend on us successfully manufacturing and receiving regulatory approval for ANTHIM® and our other product candidates and market acceptance of our product offerings and services and our capacity to develop, introduce and sell our products and services to our targeted markets. There can be no assurance that future manufacturing of ANTHIM® will be approved or any of our product candidates that are under development will be approved for commercial sale, or even product candidates and products that are approved for commercial sale we will ever generate significant sales or achieve profitability. Furthermore, there can be no assurance that we generate sufficient revenue from manufacturing services to support the expenses anticipated to be incurred by the manufacturing facility. Accordingly, the extent of future losses and the time required to achieve profitability, if ever, cannot be predicted at this point.

Even if we succeed in developing and commercializing one or more product candidates, and are successful in selling ANTHIM® or are successful in generating revenue as a CDMO, we expect to incur substantial losses for the foreseeable future and may never become profitable. We also expect to continue to incur significant operating expenses and anticipate that our expenses will increase substantially in the foreseeable future as we:

- continue to undertake preclinical development and conduct clinical trials for product candidates;
- seek regulatory approvals for product candidates;
- implement additional internal systems and infrastructure;

- devote resources to constructing a facility for the development of bioanalytics, process development and manufacturing activities;
- sell ANTHIM® and engage in commercial scale manufacturing of ANTHIM®; and
- hire additional personnel.

We also expect to experience negative cash flows for the foreseeable future as we fund our operating losses. As a result, we will need to generate significant revenues or raise additional financing in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability would likely negatively impact the value of our securities and financing activities.

We will need to raise additional capital to support our long-term business plans and our failure to obtain funding when needed may force us to delay, reduce or eliminate our development programs or commercialization efforts.

During the year ended December 31, 2022, our operating activities used net cash of approximately $5.7 million and as of December 31, 2022, our cash and cash equivalents and short-term investments were approximately $44.3 million. During the year ended December 31, 2021, our operating activities used net cash of approximately $38.1 million and as of December 31, 2021 our cash and cash equivalents and short-term investments were approximately $96.4 million. We have experienced significant losses since inception and have a significant accumulated deficit. As of December 31, 2022, our accumulated deficit totaled $209.2 million and as of December 31, 2021, our accumulated deficit totaled $165.7 million on a consolidated basis. We expect to incur additional operating losses in the future and therefore expect our cumulative losses to increase. We do not expect to derive significant revenue from our CDMO services, any of our product candidates currently in development in the near future until we or our potential partners successfully commercialize our products and in order to generate significant revenue from ANTHIM® sales we will need to engage in full scale manufacturing of ANTHIM® which will take several years. We expect our expenses to increase if and when commence full scale manufacturing of ANTHIM®. Our agreement with Lonza obligates us to pay for certain services upon placement of an order and only allows us to cancel manufacturing of batches for which we have placed orders under certain circumstances and based upon the order that we placed on March 31, 2023, we anticipate being obligated to pay over a two year period to Lonza approximately $34 million and and an additional $19 million for resins and other raw materials required for production. In addition, we expect our expenses to increase due to the operation of the manufacturing facility in San Antonio and the build out and purchase of equipment for the facility in Kansas.

We will need to raise additional capital to fund our long-term operations and we cannot be certain that funding will be available to us on acceptable terms on a timely basis, or at all. To meet our financing needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, which we expect will include sales of common stock through at the market issuances, debt financings and/or funding from partnerships or collaborations. Our ability to raise capital through the sale of securities may be limited by our number of authorized shares of common stock and various rules of the SEC and the NYSE American that place limits on the number and dollar amount of securities that we may sell. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders, assuming we are able to sufficiently increase our authorized number of shares of common stock. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution. Any debt financing, if available, may involve restrictive covenants that may impact our ability to conduct our business. If we fail to raise additional funds on acceptable terms, we may be unable to complete planned preclinical and clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities or continue to maintain our listing on the NYSE American. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

We face risks related to the restatement of our previously issued financial statements for the quarters ended June 30, 2022 and September 30, 2022.

As discussed in the Explanatory Note and in Note 17 to the consolidated financial statements in this Annual Report, we reached a determination to restate our unaudited consolidated financial statements included in the quarterly reporting periods during fiscal year 2022, consisting of June 30, 2022 and September 30, 2022 and that such interim financial

statements should no longer be relied upon. As a result, we have incurred unanticipated costs for accounting and legal fees in connection with or related to the restatement, and have become subject to a number of additional risks and uncertainties, which may affect investor confidence in the accuracy of our financial disclosures and may raise reputational issues for our business. we expect to continue to face many of the risks and challenges related to the restatement, including the following:

- we may fail to remediate material weaknesses in our internal control over financial reporting and other material weaknesses may be identified in the future, which would adversely affect the accuracy and timing of our financial reporting;
- the processes undertaken to effect the restatement may not have been adequate to identify and correct all errors in our historical financial statements and, as a result, we may discover additional errors and our financial statements remain subject to the risk of future restatement;
- the incurrence of restatement-related expenses; and
- diversion of management and other human resources attention from the operation of our business.

We cannot assure that all of the risks and challenges described above will be eliminated and that lost business opportunities can be recaptured or that general reputational harm will not persist. If one or more of the foregoing risks or challenges persist, our business, operations and financial condition are likely to be materially and adversely affected

We identified a material weakness in our internal control over financial reporting and determined that our disclosure controls and procedures were ineffective as of June 30, 2022 and September 30, 2022 as well as of December 31, 2022. As a result, we restated our quarterly financial results for the periods ending June 30, 2022 and September 30, 2022. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations.

Management and our Audit Committee, in consultation with BDO USA LLP ("BDO"), our independent registered public accounting firm, determined that our previously issued interim financial statements filed on the Form 10-Q, as of June 30, 2022, and for the three and six months ended June 30, 2022 and three and nine months ended September 30, 2022 should no longer be relied upon. Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for evaluating and reporting on the effectiveness of our system of internal control. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with accounting principles generally accepted in the United States of America. As a public company, we are required to comply with the Sarbanes-Oxley Act and other rules that govern public companies. In particular, we are required to certify our compliance with Section 404 of the Sarbanes-Oxley Act, which requires us to furnish annually a report by management on the effectiveness of our internal control over financial reporting.

Management has concluded that in light of the errors described above, a material weakness in the Company's internal controls over financial reporting existed and management's assessment of the effectiveness of the Company's disclosure controls and procedures as of June 30, 2022 and September 30, 2022 set forth in it Quarterly Reports on Form 10-Q for the quarters ended June 30, 2022 and September 30, 2022 need to be modified to include a material weakness in its controls over financial reporting. The material weakness identified relates to the the ineffective design of management review controls over the computation and disclosure of income taxes. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of a company's annual or interim financial statements will not be prevented or detected on a timely basis. The existence of one or more material weaknesses precludes a conclusion by management that the Company's disclosure controls and procedures and internal control over financial reporting are effective. As a result of the material weakness, the Company believes that its internal control over financial reporting was not effective and its disclosure controls and procedures were not effective for the Non-Reliance Periods.

If we are not able to comply with the requirements of the Sarbanes-Oxley Act or if we are unable to maintain effective internal control over financial reporting, we may not be able to produce timely and accurate financial statements or guarantee that information required to be disclosed by us in the reports that we file with the SEC, is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms. Any failure of our internal control

over financial reporting or disclosure controls and procedures could cause our investors to lose confidence in our publicly reported information, cause the market price of our stock to decline, expose us to sanctions or investigations by the SEC or other regulatory authorities, or impact our results of operations.

In order to develop ANTHIM®, we will have to devote significant resources to ANTHIM®.

Pursuant to the terms of the Merger Agreement, we have agreed to use reasonable efforts to commercialize ANTHIM®. Obtaining requisite regulatory approvals for the manufacture and sale of ANTHIM® and manufacturing costs are anticipated to be significant. Our agreement with Lonza obligates us to pay for certain services upon placement of an order and only allows us to cancel manufacturing of batches for which we have placed orders under certain circumstances. Based upon the order that we placed in March 2023, we anticipate being obligated to pay over a two year period to Lonza approximately $34 million and an additional $19 million for resins and other raw materials required for production. We have incurred significant losses from operations to date and expect our expenses to increase in connection with our ongoing activities, and the addition of Elusys' activities. There can be no assurance that funding will be available on acceptable terms on a timely basis, or at all.

Risks Related to Our Company

We have a limited operating history conducting commercial development of bioanalytics, process development and manufacturing activities, which may limit the ability of investors to make an informed investment decision.

To date, we have limited experience manufacturing products for third parties and ourselves. Because of the numerous risks and uncertainties associated with development and manufacturing, we are unable to predict if we will be successful in providing such services to ourselves or third parties. Although we plan to use our anticipated facility to service our internal manufacturing needs, we also intend to generate revenue to offset the expenses we incur in operating the facility as well as the initial start-up expenses from third parties. Our ability to generate this revenue will depend, in part, on our ability to attract and maintain customers for our development, manufacturing and technology transfer services and on the amount spent by the customers on such services. If our anticipated facility fails to attract customers and operate at sufficient capacity, our margins will suffer, and we may not be able to fund the costs we incur to operate the facility. Our bioanalytics, process development and manufacturing activities will also depend, in part, on our ability to attract and retain an appropriately skilled and sufficient workforce to operate our development and manufacturing facility and our ability to comply with various quality standards and environmental, health and safety laws and regulations.

We depend on spending and demand from our customers for our contract manufacturing and development services and any reduction in spending or demand could have a material adverse effect on our business.

The amount that our customers spend on the development and manufacture of their products or product candidates, particularly the amount our customers choose to spend on outsourcing these services to us, substantially impacts our revenue. For ANTHIM®, the U.S government's spending budget and allocations for defense spending significantly impacts our revenue from sales of ANTHIM®. The outcomes of our customers' research, development and marketing also significantly influence the amount that our customers choose to spend on our services and offerings. Our customers determine the amounts that they will spend on our services based upon, among other things, the clinical and market success of their products, available resources, access to capital and their need to develop new products which, in turn, depend upon a number of other factors, including their competitors' research, development and product initiatives and the anticipated market for any new products, as well as clinical and reimbursement scenarios for specific products and therapeutic areas. Further, increasing consolidation in the pharmaceutical industry may impact such spending, particularly in the event that any of our customers choose to develop or acquire integrated manufacturing operations. Any reduction in customer spending on biologics development and related services as a result of these and other factors could have a material adverse effect on our business, financial condition, and results of operations. Available resources, the need to develop new products, and consolidation in the industries in which our customers operate may have an impact on such spending. Our customers finance their research and development spending from private and public sources. A reduction in spending by our customers, which may be influenced by the recent sharp downturn in available private and public funding for small and emerging biotechnology companies, could have a material adverse effect on our business, financial condition, and

results of operations. If our customers are not successful in attaining or retaining product sales due to market conditions, reimbursement issues, or other factors, our results of operations may be materially adversely affected.

To date, our revenues have come from a limited number of customers, making us dependent on those few customers.

For the year ended December 31, 2022, all of our revenue was derived from one ANTHIM® purchase order and one customer for CDMO services. Prior to our acquisition of Elusys, ANTHIM® sales were made solely by the prior management team of Elusys to U.S. Governmental agencies. If the U.S. government were to cut its healthcare spending and in particular its biodefense spending, our ability to generate revenue if we cannot compete successfully for market share against other drug companiesfrom ANTHIM® sales will be adversely impacted.

Our strategy is to expand the number of sales to such agencies as well as expand the customer base outside of the United States. To date, we have not had any experience with distribution and sales of commercial products. There can be no assurance that there will be additional demand for ANTHIM® or that we will be successful in our distribution and sale efforts Although we continue to expand our customer base, we remain dependent on a limited number of customers for a substantial majority of our revenues. The loss of, or a significant reduction of business from the U.S government for ANTHIM® or any of our current CDMO customers could have a material adverse effect on our business, financial condition, and results of operations.

Our ability to generate product revenues from sales of ANTHIM® is dependent upon government spending and compliance with the government contracts.

To date, substantially all of Elusys' revenue has been derived from the sale of ANTHIM® to U.S. Governmental agencies. If the U.S. government were to cut its healthcare spending and in particular its biodefense spending, our ability to generate revenue after consummation of the Merger from ANTHIM® sales will be adversely impacted.

We generally do not have long-term CDMO customer contracts and our backlog cannot be relied upon as a future indicator of revenues.

We generally do not have long-term contracts with our CDMO customers, and existing contracts and purchase commitments may be canceled under certain circumstances. As a result, we are exposed to market and competitive price pressures on every order, and our agreements with customers do not provide assurance of future revenues. Our customers are not required to make minimum purchases and, in certain circumstances, may cease using our services at any time without penalty. Our backlog should not be relied on as a measure of anticipated demand or future revenue, because the orders constituting our backlog may be subject to changes in delivery schedules or cancellation without significant penalty to the customer. Any reductions, cancellations or deferrals in customer orders would negatively impact our business.

Elusys has been manufacturing ANTHIM® with one manufacturer.

To date, all ANTHIM® bulk drug substance has been manufactured by one manufacturer, Lonza, at a 5,000 liter scale pursuant to the terms of an exclusive manufacturing agreement. Elusys' ability to manufacture additional batches of bulk drug substance will be dependent upon the slotting availability of the manufacturer. In addition, the manufacturer has decommissioned its 5,000 liter assets and therefore any further manufacturing by the manufacturer will be at a 6,000 liter scale. This new scale will require new regulatory approval from the FDA, timing of approval, if obtained, cannot be certain. In addition, there is no assurance that the bulk drug substance can be successfully manufactured at a 6,000 liter scale in a cost efficient manner.

We are substantially dependent on the success of ANTHIM®.

To date, a significant portion of our efforts and financial resources has been in the development of our product candidate, HS-110, HS-130 and PTX-35 which were our only products for which we had clinical trials. We terminated our license with respect to those products and therefore currently our only product from which we have derived revenue is ANTHIM®. Our future success depends heavily on our ability to successfully manufacture and sell ANTHIM®.

The ANTHIM® product, although approved for commercial sale, will not be manufactured at the facility that manufactured ANTHIM® previously sold by Elusys and therefore the facility where it will be manufactured will require regulatory approval. We and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, marketing, adverse event reporting and recordkeeping of our product candidates. Until, and unless, we receive approval from the FDA and other regulatory authorities for our product candidates, we cannot commercialize our product candidates and will not have product revenues. In addition, the technology that we out-licensed is in the early stages of development and there is a low likelihood of success for any such technology at that stage, therefore there can be no assurance that any products will be developed by such licensee or that we will derive any revenue from such licensee. In addition, changes may occur that would consume our available capital at a faster pace than expected, including changes in and progress of our development activities, acquisitions of additional candidates and changes in regulation. Moreover, preclinical studies and clinical trials may not start or be completed as we forecast and may not achieve the desired results. Therefore, we expect that we will seek additional sources of funding, such as additional financing or grant funding, and additional financing may not be available on favorable terms, if at all. Our ability to raise capital through the sale of equity may be limited by the various rules of the Securities and Exchange Commission and the NYSE American that place limits on the number of shares of stock that may be sold. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned preclinical work or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to delay, discontinue or curtail product development, forego sales and marketing efforts, and forego licensing in attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity or debt securities, which will have a dilutive effect on our stockholders.

All of our manufacturing services are conducted at our facility situated in San Antonio, Texas, which increases our exposure to significant disruption to our business as a result of unforeseeable developments in a single geographic area.

We operate one manufacturing facility in one location, San Antonio, Texas. It is possible that we could experience prolonged periods of reduced production due to unforeseen catastrophic events occurring in or around our facilities. It is also possible that operations could be disrupted due to other unforeseen circumstances such as power outages, explosions, fires, floods, earthquakes or accidents. As a result, we may be unable to shift manufacturing capabilities to alternate locations, accept materials from suppliers, meet customer shipment needs or address other severe consequences that may be encountered, and we may suffer damage to our reputation. Our financial condition and results of our operations could be materially adversely affected were such events to occur.

The operations of our CROs and suppliers could also be subject to business interruptions.

Our business and the business of the raw material suppliers could be materially and adversely affected by the risks, or the public perception of the risks, related to a pandemic or other health crisis, such as the recent outbreak of novel coronavirus (COVID-19). A significant outbreak of contagious diseases in the human population could result in a widespread health crisis that could adversely affect our planned operations. Such events could result in the complete or partial closure of one or more manufacturing facilities. In addition, it could impact economies and financial markets, resulting in an economic downturn that could impact our ability to raise capital or slow down potential partnering relationships.

We rely on third parties to supply most of the necessary raw materials and supplies for the products we manufacture on behalf of our customers and our inability to obtain such raw materials or supplies may adversely impact our business, financial condition, and results of operations.

Our operations require various raw materials, including proprietary media, resins, buffers, and filters, in addition to numerous additional raw materials supplied primarily by third parties. We or our customers specify the raw materials and other items required to manufacture their product and, in some cases, specify the suppliers from whom we must purchase these raw materials. In certain instances, the raw materials and other items can only be supplied by a limited number of suppliers and, in some cases, a single source, or in limited quantities. If third-party suppliers do not supply raw materials or other items on a timely basis, it may cause a manufacturing run to be delayed or canceled which would adversely impact our financial condition and results of operations. Additionally, we do not have long-term supply contracts with any of our single source suppliers. If we experience difficulties acquiring sufficient quantities of required materials or products from

our existing suppliers, or if our suppliers are found to be non-compliant with the FDA's quality system regulation, CGMPs or other applicable laws or regulations, we would be required to find alternative suppliers. If our primary suppliers become unable or unwilling to perform, any resulting delays or interruptions in the supply of raw materials required to support our manufacturing of CGMP pharmaceutical-grade products would ultimately delay our manufacture of products for our customers, which could materially and adversely affect our financial condition and operating results. Furthermore, third-party suppliers may fail to provide us with raw materials and other items that meet the qualifications and specifications required by us or our customers. If third-party suppliers are not able to provide us with raw materials that meet our or our customers' specifications on a timely basis, we may be unable to manufacture their product or it could prevent us from delivering products to our customers within required timeframes. Any such delay in delivering our products may create liability for us to our customers for breach of contract or cause us to experience order cancellations and loss of customers. In the event that we manufacture products with inferior quality components and raw materials, we may become subject to product liability claims caused by defective raw materials or components from a third-party supplier or from a customer, or our customer may be required to recall its products from the market.

Our manufacturing services are highly complex, and if we are unable to provide quality and timely services to our customers, our business could suffer.

The manufacturing services we offer are highly complex, due in part to strict regulatory requirements. A failure of our quality control systems in our facility could cause problems to arise in connection with facility operations for a variety of reasons, including equipment malfunction, viral contamination, failure to follow specific manufacturing instructions, protocols and standard operating procedures, problems with raw materials or environmental factors. Such problems could affect production of a single manufacturing run or a series of runs, requiring the destruction of products, or could halt manufacturing operations altogether. In addition, our failure to meet required quality standards may result in our failure to timely deliver products to our customers which, in turn, could damage our reputation for quality and service. Any such incident could, among other things, lead to increased costs, lost revenue, reimbursement to customers for lost drug substance, damage to and possibly termination of existing customer relationships, time and expense spent investigating the cause and, depending on the cause, similar losses with respect to other manufacturing runs. With respect to our commercial manufacturing, if problems are not discovered before the product is released to the market, we may be subject to regulatory actions, including product recalls, product seizures, injunctions to halt manufacture and distribution, restrictions on our operations, civil sanctions, including monetary sanctions, and criminal actions. In addition, such issues could subject us to litigation, the cost of which could be significant.

Our customers' failure to receive or maintain regulatory approval for their product candidates could negatively impact our revenues and profitability.

Our success depends upon the regulatory approval of the products we manufacture. As such, if our customers experience a delay in, or failure to receive, approval for any of their product candidates or fail to maintain regulatory approval of their products and we are not able to manufacture these products, our revenue and profitability could be adversely affected. Additionally, if the FDA or a comparable foreign regulatory authority does not approve of our facilities for the manufacture of a customer product or if it withdraws such approval in the future, our customers may choose to identify alternative manufacturing facilities and/or relationships, which could significantly impact our ability to expand our manufacturing capacity and capabilities and achieve profitability.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our contract manufacturing operations involve the controlled use of hazardous materials and chemicals. We are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of hazardous materials and chemicals. Although we believe that our procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we may incur significant additional costs to comply with applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials or chemicals. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the

liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our contract manufacturing operations, which could materially harm our business, financial condition and results of operations.

If our acquired intangible assets become impaired, we may be required to record a significant charge to earnings.

We regularly review acquired intangible assets for impairment when events or changes in circumstances indicate that the carrying value may not be recoverable. We test goodwill and indefinite-lived intangible assets for impairment at least annually. Factors that may be considered a change in circumstances, indicating that the carrying value of the intangible assets may not be recoverable, include: macroeconomic conditions, such as deterioration in general economic conditions; industry and market considerations, such as deterioration in the environment in which we operate; cost factors, such as increases in labor or other costs that have a negative effect on earnings and cash flows; our financial performance, such as negative or declining cash flows or a decline in actual or planned revenue or earnings compared with actual and projected results of relevant prior periods; other relevant entity-specific events, such as changes in management, key personnel, strategy, or customers; and sustained decreases in share price. During the year ended December 31, 2022 we recorded a indefinite-lived intangible assets impairment charge of $3.5 million. During the year ended December 31, 2021 we recorded a indefinite-lived intangible assets impairment charge totaling $2.4 million and goodwill impairment charge of $1.5 million.

Risks Related to Regulatory Approval and Commercialization

Failure to comply with existing and future regulatory requirements for our CDMO and sales of ANTHIM® could adversely affect our business, financial condition, and results of operations.

Our industry is highly regulated. We are required to comply with the regulatory requirements of various local, state, provincial, national and international regulatory bodies having jurisdiction in the countries or localities in which we manufacture products or in which our customers' products are distributed. In particular, our CDMO is subject to laws and regulations concerning development, testing, manufacturing processes, equipment and facilities, including compliance with CGMPs, import and export, and product registration and listing, among other things. As a result, our facility is subject to regulation by the FDA, as well as regulatory bodies of other jurisdictions where our customers have marketing approval for their products including, but not limited to, the EMA, ANVISA and/or Health Canada, depending on the countries in which our customers market and sell the products we manufacture on their behalf. As we expand our operations, including building our facility in Kansas, we may be exposed to more complex and new regulatory and administrative requirements and legal risks, any of which may require expertise in which we have little or no experience. It is possible that compliance with new regulatory requirements could impose significant compliance costs on us. Such costs could have a material adverse effect on our business, financial condition and results of operations.

These regulatory requirements impact many aspects of our operations, including manufacturing, developing, storage, distribution, import and export and record keeping related to customers' products. Noncompliance with any applicable regulatory requirements can result in government refusal to approve: (i) facilities for testing or manufacturing products or (ii) products for commercialization. The FDA and other regulatory agencies can delay, limit or deny approval for many reasons, including:

- changes to the regulatory approval process, including new data requirements for product candidates in those jurisdictions, including the United States, in which our customers may be seeking approval;
- that a customer's product candidate may not be deemed to be safe or effective; and
- the inability of the regulatory agency to provide timely responses as a result of its resource constraints;
- that the manufacturing processes or facilities may not meet the applicable requirements.

In addition, if new legislation or regulations are enacted or existing legislation or regulations are amended or are interpreted or enforced differently, we may be required to obtain additional approvals or operate according to different manufacturing or operating standards. This may require a change in our development and manufacturing techniques or additional capital investments in our facilities. Any related costs may be significant. If we fail to comply with applicable regulatory requirements in the future, then we may be subject to warning letters and/or civil or criminal penalties and fines, suspension

or withdrawal of regulatory approvals, product recalls, seizure of products, restrictions on the import and export of our products, debarment, exclusion, disgorgement of profits, operating restrictions and criminal prosecution and the loss of contracts and resulting revenue losses. Inspections by regulatory authorities that identify any deficiencies could result in remedial actions, production stoppages or facility closure, which would disrupt the manufacturing process and supply of product to our customers. In addition, such failure to comply could expose us to contractual and product liability claims, including claims by customers for reimbursement for lost or damaged active pharmaceutical ingredients or recall or other corrective actions, the cost of which could be significant.

In addition, certain products we manufacture must undergo pre-clinical and clinical evaluations relating to product safety and efficacy before they are approved as commercial therapeutic products. The regulatory authorities having jurisdiction in the countries in which our customers intend to market their products may delay or put on hold clinical trials or delay approval of a product or determine that the product is not approvable. The FDA or other regulatory agencies can delay approval of a drug if our manufacturing facility, including any newly commissioned facility, is not able to demonstrate compliance with CGMPs, pass other aspects of pre-approval inspections or properly scale up to produce commercial supplies. The FDA and comparable government authorities having jurisdiction in the countries in which we or our customers intend to market their products have the authority to withdraw product approval or suspend manufacture if there are significant problems with raw materials or supplies, quality control and assurance or the product we manufacture is adulterated or misbranded. If our manufacturing facilities and services are not in compliance with FDA and comparable government authorities, we may be unable to obtain or maintain the necessary approvals to continue manufacturing products for our customers, which would materially adversely affect our financial condition and results of operations.

If we do not obtain the necessary regulatory approvals in the United States and/or other countries, we will not be able to sell our product candidates.

We cannot assure you that we will receive the approvals necessary to commercialize any of our product candidates, including obtaining necessary approvals for the sale of ANTHIM® in light of the fact that the manufacturing of the ANTHIM® will not be at the facility that manufactured ANTHIM® previously sold by Elusys and therefore the facility where it will be manufactured will require regulatory approval. We will need FDA approval to commercialize our product candidates in the United States and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA a BLA, demonstrating that the product candidate is safe, pure and potent, or effective for its intended use. This demonstration requires significant research including preclinical studies, as well as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of our product candidates or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA. We also cannot predict whether our research and clinical approaches will result in drugs or therapeutics that the FDA considers safe and effective for the proposed indications. The FDA has substantial discretion in the drug approval process. The approval process may be delayed by changes in government regulation, future legislation or administrative action or changes in FDA policy that occur prior to or during our regulatory review. Delays in obtaining regulatory approvals may:

- prevent or delay commercialization of, and our ability to derive product revenues from, our product candidates; and
- diminish any competitive advantages that we may otherwise believe that we hold.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our BLAs. We may never obtain regulatory clearance for any of our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate.

In addition, the FDA may require us to conduct additional preclinical and clinical testing or to perform post-marketing studies, as a condition to granting marketing approval of a product. Regulatory approval of oncology products often requires that patients in clinical trials be followed for long periods to assess their overall survival. The results generated

after approval could result in loss of marketing approval, changes in product labeling, and/or new or increased concerns about the side effects or efficacy of a product. The FDA has significant post-market authority, including the explicit authority to require post-market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA-approved risk evaluation and mitigation strategies. The FDA's exercise of its authority has in some cases resulted, and in the future, could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products.

In foreign jurisdictions, we must also receive approval from the appropriate regulatory authorities before we can commercialize any vaccines. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. There can be no assurance that we will receive the approvals necessary to commercialize our product candidates for sale outside the United States.

Our product candidates are in early stages of development, and therefore they will require extensive preclinical and clinical testing.

Because our product candidates are in early stages of development, they will require extensive preclinical and clinical testing. All of the products being developed by Skunkworx are in the preclinical stage of development. We cannot predict with any certainty if or when we might submit a BLA for regulatory approval for any of our product candidates or whether any such BLA will be accepted for review by the FDA, or whether any BLA will be approved upon review.

Even if we perform our clinical trials on any of those product candidates, we cannot be certain that their results will support our proposed indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. The clinical trial process may fail to demonstrate that our product candidates are safe and effective for their proposed uses. This failure could cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any BLAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues.

Clinical trials are very expensive, time-consuming, and difficult to design and implement.

As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities. The number and design of the clinical trials that will be required varies depending upon product candidate, the condition being evaluated and the trial results themselves. Therefore, it is difficult to accurately estimate the cost of the clinical trials. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of our product candidates will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed or prevented by several factors, including:

- unforeseen safety issues;
- failure to determine appropriate dosing;
- greater than anticipated cost of our clinical trials;
- failure to demonstrate effectiveness during clinical trials;
- slower than expected rates of patient recruitment or difficulty obtaining investigators;
- patient drop-out or discontinuation;
- inability to monitor patients adequately during or after treatment;
- third party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner;
- insufficient or inadequate supply or quality of product candidates or other necessary materials to conduct our trials;
- potential additional safety monitoring, or other conditions required by FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, or other studies requested by regulatory agencies;

- problems engaging IRBs to oversee trials or in obtaining and maintaining IRB approval of studies;
- imposition of clinical hold or suspension of our clinical trials by regulatory authorities; and
- inability or unwillingness of medical investigators to follow our clinical protocols.

In addition, we or the FDA may suspend or terminate our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our IND submissions or the conduct of these trials. Therefore, we cannot predict with any certainty when, if ever, future clinical trials will commence or be completed.

There is uncertainty as to market acceptance of our technology and product candidates.

There can be no assurance that ANTHIM® or any product we develop in the future, even if approved by the FDA will gain broad market acceptance among governments, physicians, healthcare payers, patients, and the medical community. In addition, there can be no assurance that our CDMO services will gain market acceptance. We have conducted our own research into the markets for ANTHIM® and CDMO services generally; however, we cannot guarantee market acceptance. Our industry is susceptible to rapid technological developments and there can be no assurance that we will be able to match any new technological advances. If we are unable to match the technological changes in the needs of our customers the demand for our products will be reduced. Acceptance and use of any products or services we market will depend upon a number of factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our products;
- limitation on use or warnings required by FDA in our product labeling;
- cost-effectiveness of our products relative to competing products;
- convenience and ease of administration;
- potential advantages of alternative treatment methods;
- availability of reimbursement for our products from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect virtually all of our product revenues for the foreseeable future to be generated from sales of our current product candidates, if approved, the failure of these therapeutics to find market acceptance would substantially harm our business and would adversely affect our revenue.

If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. ANTHIM® competes with one other Anthrax therapeutic, the manufacturer of which is larger than we are and has more resources to enable it to market its product. If any of our product candidates receives FDA approval, it will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer. Our CDMO competes for customers with several other CDMOs that are well established and have a longer operating history than our company.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs, biologics and other therapies;
- undertaking preclinical testing and clinical trials;
- obtaining FDA and other regulatory approvals of drugs, biologics and other therapies;

- formulating and manufacturing drugs, biologics and other therapies; and
- launching, marketing and selling drugs, biologics and other therapies.

Our development program partially depends upon third-party researchers who are outside our control.

We are dependent upon independent investigators and collaborators, such as universities and medical institutions, to conduct our clinical trials under agreements with us. These collaborators are not our employees and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new product candidates, if any, will be delayed if obtained at all. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

We rely significantly on third parties to formulate and manufacture our product candidates.

We have developed certain expertise in the formulation, development and/or manufacturing of biologics; however to date we have relied on third parties for substantially all of our manufacturing needs. We have performed assay development work at our Texas laboratory to support our clinical needs as well as those of third parties. However, Scorpius does not have FDA approval to manufacture commercial quantities of ANTHIM®. Although there are other manufacturers that could manufacture ANTHIM®, including the manufacturer that to date has manufactured ANTHIM® and with whom we have an agreement to manufacture future batches of ANTHIM®, it will be several years before that manufacturer can manufacture ANTHIM® for us. To date, the manufacturer has only manufactured ANTHIM® at a 5,000 liter scale and the manufacturer plans to manufacture at a 6,000 liter scale at a new facility. In addition, there is no assurance that the bulk drug substance can be successfully manufactured at a 6,000 liter scale in a cost efficient manner.

Therefore, future manufacture of ANTHIM® by such manufacturer will require additional regulatory approvals for the new manufacturing site and new scale. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to renew or renegotiate current agreements on favorable terms or identify manufacturers on acceptable terms or at all because the number of potential manufacturers with appropriate expertise and facilities is limited.

- If we change manufacturers at any point during the development process or after approval we will be required to demonstrate comparability between the products made by the old and new manufacturers. If we are unable to do so, we may need to conduct additional clinical trials with product manufactured by the new manufacturer. Accordingly, it may be necessary to evaluate the comparability of our product candidates produced by the two different manufacturers at some point during the clinical development process.

- If we change the manufacturer of a product subsequent to the approval of the product, we will need to obtain approval from the FDA of the change in manufacturer. Any such approval would likely require significant testing and expense, and the new manufacturer may be subject to a cGMP inspection prior to approval. Our third-party manufacturers might be unable to formulate and manufacture our product candidates in the volume and with the quality required to meet our clinical needs and commercial needs, if any.

- Our third-party manufacturers might be unable to formulate and manufacture our product candidates in the volume and with the quality required to meet our clinical needs and commercial needs, if any.

- Our contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our product candidates.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, and corresponding state agencies to ensure compliance with cGMPs and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

- If any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

- Our contract manufacturers have in the past and may in the future encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. Our contract manufacturers are subject to inspections by the FDA and comparable agencies in other jurisdictions to assess compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, packaging, or storage of our products as a result of a failure of the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our products, including leading to significant delays in the availability of products for our clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we or our contract manufacturers are not able to maintain regulatory compliance, we may not be permitted to market our products and/or may be subject to product recalls, seizures, injunctions, or criminal prosecution.

- If we establish in-house development and manufacturing capabilities, there are a number of risks that could impact our financial condition, operating results and cash flows due to disruption of operations at the location or facility which may impede our ability to deliver assays or manufacture our products.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA or the commercialization of our product candidates or could also result in higher costs or deprive us of potential product revenues.

We have and will in the future rely on third parties to conduct, supervise and monitor any clinical trials we may conduct, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We have in the past and will in the future rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and we expect to have limited influence over their actual performance if we should conduct any future clinical trials.

We also expect to rely upon CROs to monitor and manage data for any future clinical programs we may have, as well as the execution of future nonclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our studies we may conduct is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with the Good Laboratory Practices and GCPs, which are regulations and guidelines enforced by the FDA and are also required by the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities in the form of International Conference on Harmonization of Technical Requirements for Pharmaceuticals for Human Use guidelines for any of our product candidates that are in preclinical and clinical development. The Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with GCPs, the clinical data generated in any clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that it develops would be harmed, its costs could increase, and our ability to generate revenues could be delayed.

If our relationship with these CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that it will not encounter challenges or delays in the future or that these delays or challenges will not have an adverse impact on our business, financial condition and prospects.

Even if we are able to obtain regulatory approval for our product candidates, we will continue to be subject to ongoing and extensive regulatory requirements, and our failure, or the failure of our contract manufacturers, to comply with these requirements could substantially harm our business.

If the FDA approves any of our product candidates, the labeling, manufacturing, packaging, adverse event reporting, storage, advertising, promotion and record keeping for our products will be subject to ongoing FDA requirements and continued regulatory oversight and review. As stated above, our manufacture of ANTHIM® will require additional regulatory approval. We may also be subject to additional FDA post-marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market our product candidates and/or may be subject to product recalls or seizures. The subsequent discovery of previously unknown problems with any marketed product, including AEs of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market.

We have minimal experience selling, marketing or distributing products, and have no internal capability to do so.

To date, we have not had any significant sales, marketing or distribution capabilities. Although we have hired some of the Elusys employees who have such experience and Scorpius has hired sales representatives, we do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our other proposed products, if approved. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator's strategic interest in ANTHIM® and the products under development and such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that our collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to successfully market and sell our products in the United States or overseas on our own.

We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products.

We may seek to enter into strategic partnerships in the future, including alliances with other biotechnology or pharmaceutical companies, to enhance and accelerate the development and commercialization of our products. We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and/or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy or return on investment. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing.

If we ultimately determine that entering into strategic partnerships is in our best interest, but either fail to enter into, are delayed in entering into or fail to maintain such strategic partnerships:

- the development of certain of our current or future product candidates may be terminated or delayed;
- our cash expenditures related to development of certain of our current or future product candidates may increase significantly and we may need to seek additional financing;
- we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted;
- we will bear all of the risk related to the development of any such product candidates; and
- the competitiveness of any product candidate that is commercialized could be reduced.

To the extent we elect to enter into licensing or collaboration agreements to partner our product candidates, our dependence on such relationships may adversely affect our business.

Our commercialization strategy for certain of our product candidates may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of these product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. We may determine that continuing collaboration under the terms provided is not in our best interest, and we may terminate the collaboration. Our collaborators could delay or terminate their agreements, and our product candidates subject to collaborative arrangements may never be successfully developed or commercialized.

Further, our future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or fewer resources than we would like, or they may be terminated altogether. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of any potential products or could result in time-consuming and expensive litigation or arbitration, which may not be resolved in our favor.

Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to commercialize our products, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;

- private health maintenance organizations and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Cost control initiatives could decrease the price that we would receive for any products in the future, which would limit our revenue and profitability. Government and other healthcare payers increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs and therapeutics. We might need to conduct post-marketing studies in order to demonstrate the cost-effectiveness of any future products to such payers' satisfaction. Such studies might require us to commit a significant amount of management time and financial and other resources. Our future products might not ultimately be considered cost-effective. Even if one of our product candidates is approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover such therapies. If government and other healthcare payers do not provide adequate coverage and reimbursement levels for one of our products, once approved, market acceptance of such product could be reduced.

Legislative and regulatory changes affecting the health care industry could adversely affect our business.

Political, economic and regulatory influences are subjecting the health care industry to potential fundamental changes that could substantially affect our results of operations. In many countries, the government controls the pricing and profitability of prescription pharmaceuticals. In the United States, we expect that there will continue to be federal and state proposals to implement similar governmental controls. In addition, recent changes in the Medicare program and increasing emphasis on managed care in the United States will continue to put pressure on pharmaceutical product pricing. It is uncertain whether or when any legislative proposals will be adopted or what actions federal, state, or private payers for health care treatment and services may take in response to any health care reform proposal or legislation. We cannot predict the effect health care reforms may have on our business and we can offer no assurances that any of these reforms will not have a material adverse effect on our business. These actual and potential changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective treatments. In addition, uncertainly remains regarding proposed significant reforms to the U.S. health care system.

In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our clinical product candidate, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidate for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements, (ii) additions or modifications to product labeling, (iii) the recall or discontinuation of our products or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect our business, financial condition and results of operations.

Among policy makers in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, The Patient Protection and Affordable Care Act (ACA), was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. It is unclear how these challenges and other efforts to replace the ACA will impact our business in the future.

Moreover, the Drug Supply Chain Security Act imposes obligations on manufacturers of prescription drugs in finished dosage forms. We have not yet adopted the significant measures that will be required to comply with this law. We are not sure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or what the impact of such changes on our business, if any, may be.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. Such reforms could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products, which could result in reduced demand for our clinical product candidate or additional pricing pressures. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

We may be exposed to liability claims associated with the use of biological and hazardous materials and chemicals.

Our research and development activities and CDMO services we provide may involve the controlled use of biological and hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. We currently operate one laboratory in North Carolina, one laboratory in New Jersey and Pelican operates a laboratory in Texas. In our laboratory in Texas, we will perform contract services for third parties that could involve the use of biological and hazardous materials and chemicals. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of drug and biological product candidates entail an inherent risk of product liability. Product liability claims might be brought against us by consumers, health care providers or others selling or otherwise coming into contact with our products. We currently operate one laboratory in North Carolina, one laboratory in New Jersey and Pelican operates a laboratory in Texas. In our laboratory in Texas we perform contract services for third parties. In addition, in our facility in San Antonio we perform CDMO services for third parties. We could incur liability in the performance of these services, including liability for damage to materials supplied to us. If any of the products or services we develop are used in clinical trials, clinical trial liability claims may be filed against us for damages suffered by clinical trial subjects or their families. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products which could impact our ability to continue as a going concern. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for any approved product candidates;
- impairment of our business reputation;
- withdrawal of clinical trial participants;

- costs of related litigation;
- distraction of management's attention;
- substantial monetary awards to patients or other claimants;
- loss of revenues; and
- the inability to successfully commercialize any approved drug candidates.

International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

Our business strategy incorporates international expansion, including establishing and maintaining clinician marketing and education capabilities outside of the United States, expanding our relationships with distributors and manufacturers and expanding sales of ANTHIM®. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- failure by us or our distributors to obtain regulatory approvals for the sale or use of our product candidates in various countries;
- difficulties in managing foreign operations;
- complexities associated with managing multiple payer-reimbursement regimes or self-pay systems;
- limits on our ability to penetrate international markets if our product candidates cannot be processed by a manufacturer appropriately qualified in such markets;
- financial risks, such as longer payment cycles, difficulty enforcing contracts and collecting accounts receivable and exposure to foreign currency exchange rate fluctuations;
- reduced protection for intellectual property rights;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- failure to comply with the Foreign Corrupt Practices Act, including its books and records provisions and its anti-bribery provisions, by maintaining accurate information and control over sales and distributors' activities.

Any of these risks, if encountered, could significantly harm our future international expansion and operations and, consequently, have a material adverse effect on our financial condition, results of operations and cash flows.

We may acquire other businesses or form joint ventures or make investments in other companies or technologies or new lines of business that could harm our operating results, dilute our stockholders' ownership, increase our debt or cause us to incur significant expense.

As part of our business strategy, we may pursue acquisitions of businesses and assets, such as we did with Pelican and Elusys. We may also make investments in other companies of technologies, new lines of business, or expansion of research bioanalytical development and manufacturing capacities. We also may pursue strategic alliances and joint ventures that leverage our core technology and industry experience to expand our offerings or distribution. Other than our acquisition of the equity of Pelican in 2017 and acquisition of Elusys in 2022, we have no experience with acquiring other companies and limited experience with forming strategic alliances and joint ventures. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. If we make any acquisitions, we may not be able to integrate these acquisitions successfully into our existing business, and we could assume unknown or contingent liabilities. Any future acquisitions or investments in other companies or technologies or new lines of business also could result in significant write-offs or the incurrence of debt and contingent liabilities, any of which could have a material adverse effect on our financial condition, results of operations and cash flows. Integration of an acquired company also may disrupt ongoing operations and require management resources that would otherwise focus on developing our existing business. We may experience losses related to investments in other companies, which could have a material negative effect on our results of operations. We may not identify or complete these transactions in a timely manner, on a cost-effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture.

To finance any acquisitions or joint ventures, we may choose to issue shares of our common stock as consideration, which would dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may not be able to acquire other companies or fund a joint venture project using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all.

Uncertainty regarding health care reform and declining general economic or business conditions may have a negative impact on our business.

Continuing concerns over U.S. health care reform legislation and energy costs, geopolitical issues, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. If the economic climate does not improve or continues to be uncertain, our business, as well as the financial condition of our suppliers and our third-party payors, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations.

We rely extensively on our information technology systems and are vulnerable to damage and interruption.

We rely on our information technology systems and infrastructure to process transactions, summarize results and manage our business, including maintaining client and supplier information. Additionally, we utilize third parties, including cloud providers, to store, transfer and process data. Our information technology systems, as well as the systems of our suppliers and other partners, whose systems we do not control, are vulnerable to outages and an increasing risk of continually evolving deliberate intrusions to gain access to company sensitive information. Likewise, data security incidents and breaches by employees and others with or without permitted access to our systems pose a risk that sensitive data may be exposed to unauthorized persons or to the public. A cyber-attack or other significant disruption involving our information technology systems, or those of our vendors, suppliers and other partners, could also result in disruptions in critical systems, corruption or loss of data and theft of data, funds or intellectual property. We may be unable to prevent outages or security breaches in our systems. We remain potentially vulnerable to additional known or yet unknown threats as, in some instances, we, our suppliers and our other partners may be unaware of an incident or its magnitude and effects. We also face the risk that we expose our vendors or partners to cybersecurity attacks. Any or all of the foregoing could adversely affect our results of operations and our business reputation.

Any failure to maintain the security of information relating to our customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation. We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

In connection with the sales and marketing of our products and services, we may from time to time transmit confidential information. We also have access to, collect or maintain private or confidential information regarding our clinical trials and the patients enrolled therein, employees, and suppliers, as well as our business. Cyberattacks are rapidly evolving and becoming increasingly sophisticated. In addition, as the manufacturer of biodefense product sold to the U.S. government, Elusys has access to highly confidential government information. It is possible that computer hackers and others might compromise our security measures, or security measures of those parties that we do business with now or in the future and obtain the personal information of patients in our clinical trials, vendors, employees and suppliers or our business information. A security breach of any kind, including physical or electronic break-ins, computer viruses and attacks by hackers, employees or others, could expose us to risks of data loss, litigation, government enforcement actions, regulatory penalties and costly response measures, and could seriously disrupt our operations. Any resulting negative publicity could significantly harm our reputation, which could cause us to lose market share and have an adverse effect on our results of operations.

We may face particular data protection, data security and privacy risks in connection with the European Union's Global Data Protection Regulation and other privacy regulations.

Outside of the United States, the laws, regulations and standards in many jurisdictions apply broadly to the collection, use, and other processing of personal information. If we should engage in business in the European Union, including selling products such as ANTHIM®, we will be subject to such laws. For example, in the European Union, the collection and use of personal data is governed by the provisions of the General Data Protection Regulation (the "GDPR"). The GDPR, together with national legislation, regulations and guidelines of the European Union member states governing the processing of personal data, impose strict obligations on entities subject to the GDPR, including but not limited to: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent from data subjects; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with the data protection rights of data subjects; and (iv) obligations to report certain personal data breaches to governmental authorities and individuals. Data protection authorities from the different E.U. member states and other European countries may enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing European personal data. Failure to comply with the requirements of the GDPR and the related national data protection laws may result in significant monetary fines and other administrative penalties (the GDPR authorizes fines for certain violations of up to 4% of global annual revenue or €20 million, whichever is greater) as well as civil liability claims from individuals whose personal data was processed. Additionally, expenses associated with compliance could reduce our operating margins.

The GDPR also prohibits the transfer of personal data from the E.U. to countries outside of the E.U. unless made to a country deemed by the European Commission to provide adequate protection for personal data or accomplished by means of an approved data transfer mechanism (e.g., standard contractual clauses). Data protection authority guidance and enforcement actions that restrict companies' ability to transfer data may increase risk relating to data transfers or make it more difficult or impossible to transfer E.U. personal data to the U.S.

Our operating results may be adversely affected by fluctuations in foreign currency exchange rates and restrictions on the deployment of cash across global operations.

Although we report operating results in U.S. dollars, if we engage in sales of products internationally, our revenues and expenses are or will be denominated in currencies other than the U.S. dollar, particularly in Europe. Fluctuations in foreign currency exchange rates can have a number of adverse effects on us. Because our consolidated financial statements are presented in U.S. dollars, we will be required to translate revenues, expenses and income, as well as assets and liabilities, into U.S. dollars at exchange rates in effect during or at the end of each reporting period. Therefore, changes in the value of the U.S. dollar against other currencies will affect revenues, income from operations, other income (expense), net and the value of balance sheet items originally denominated in other currencies. There is no guarantee that our financial results will not be adversely affected by currency exchange rate fluctuations. In addition, in some countries we could be subject to strict restrictions on the movement of cash and the exchange of foreign currencies, which could limit our ability to use these funds across our global operations.

We could be adversely affected by violations of the U.S. Foreign Corrupt Practices Act and other worldwide anti-bribery laws.

The FCPA and anti-bribery laws in other jurisdictions generally prohibit companies and their intermediaries from making improper payments for the purpose of obtaining or retaining business or other commercial advantage. Our policies mandate compliance with these anti-bribery laws, which often carry substantial penalties, including criminal and civil fines, potential loss of export licenses, possible suspension of the ability to do business with the federal government, denial of government reimbursement for products and exclusion from participation in government health care programs. We may operate in jurisdictions that have experienced governmental and private sector corruption to some degree, and, in certain circumstances, strict compliance with anti-bribery laws may conflict with certain local customs and practices. We cannot assure that the internal control policies and procedures always will protect us from reckless or other inappropriate acts committed by affiliates, employees or agents. Violations of these laws, or allegations of such violations, could have a material adverse effect on our business, financial position and results of operations.

Risks Related to Intellectual Property

We have limited protection for our intellectual property, which could impact our competitive position.

We intend to rely on a combination of common law copyright, patent, trademark, and trade secret laws and measures to protect our proprietary information. We have obtained exclusive rights to license the technology for which patent protection has been obtained; however, such protection does not prevent unauthorized use of such technology Trademark and copyright protections may be limited, and enforcement could be too costly to be effective. It may also be possible for unauthorized third parties to copy aspects of, or otherwise obtain and use, our proprietary information without authorization, including, but not limited to, product design, software, customer and prospective customer lists, trade secrets, copyrights, patents and other proprietary rights and materials. Other parties can use and register confusingly similar business, product and service names, as well as domain names, which could divert customers, resulting in a material adverse effect on our business, operating results and financial condition.

Intellectual property rights may also be unavailable or limited in some foreign countries, which could make it easier for competitors to capture market share. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. As a result, in response to the COVID-19 pandemic, it is possible that certain countries may take steps to facilitate compulsory licenses that permit the distribution of a COVID-19 vaccine in those countries. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of the relevant patent rights. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations, and prospects may be adversely affected.

If we fail to successfully enforce our intellectual property rights, our competitive position could suffer, which could harm our operating results. Competitors may challenge the validity or scope of our patents or future patents we may obtain. In addition, our licensed patents may not provide us with a meaningful competitive advantage. We may be required to spend significant resources to monitor and police our licensed intellectual property rights. We may not be able to detect infringement and our competitive position may be harmed. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, competitors may design around our technology or develop competing technologies.

The technology we license, our products or our development efforts may be found to infringe upon third-party intellectual property rights.

Third parties may in the future assert claims or initiate litigation related to their patent, copyright, trademark and other intellectual property rights in technology that is important to us. The asserted claims and/or litigation could include claims against us, our licensors or our suppliers alleging infringement of intellectual property rights with respect to our products or components of those products. Regardless of the merit of the claims, they could be time consuming, result in costly litigation and diversion of technical and management personnel, or require us to develop a non-infringing technology or enter into license agreements. We have not undertaken an exhaustive search to discover any third party intellectual patent rights, which might be infringed by commercialization of the product candidates described herein. Although we are not currently aware of any such third-party intellectual patent rights, it is possible that such rights currently exist or might be obtained in the future. In the event that a third party controls such rights and we are unable to obtain a license to such rights on commercially reasonable terms, we may not be able to sell or continue to develop our products, and may be liable for damages for such infringement. We cannot assure you that licenses will be available on acceptable terms, if at all.

Furthermore, because of the potential for significant damage awards, which are not necessarily predictable, it is not unusual to find even arguably unmeritorious claims resulting in large settlements. If any infringement or other intellectual property claim made against us by any third party is successful, or if we fail to develop non-infringing technology or license the proprietary rights on commercially reasonable terms and conditions, our business, operating results and financial condition could be materially adversely affected.

If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing drug or therapy candidate;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

We rely on licenses to use various technologies that are material to our business and if the agreements were to be terminated or if other rights that may be necessary or we deem advisable for commercializing our intended products cannot be obtained, it would halt our ability to market our products and technology, as well as have an immediate material adverse effect on our business, operating results and financial condition.

We have licensing agreements with certain universities granting us the right to use certain critical intellectual property. The terms of the licensing agreements continue until the end of the life of the last patent to expire. If we breach the terms of these licensing agreements, including any failure to make minimum royalty payments required thereunder or failure to reach certain developmental milestones, using best efforts to introduce a licensed product in certain territories by certain dates, the licensor has the right to terminate the license. If we were to lose or otherwise be unable to maintain these licenses on acceptable terms, or find that it is necessary or appropriate to secure new licenses from other third parties, it would halt our ability to market our products and technology, which would have an immediate material adverse effect on our business, operating results and financial condition.

The U.S. government may have "march-in rights" to certain of our intellectual property.

Because federal grant monies were used in support of the research and development activities that resulted in certain of our issued U.S. patents of pending U.S. patent applications, the federal government retains what are referred to as "march-in rights" to patents that are granted on these applications.

In particular, the U.S Army, which administered grant monies to the primary inventor of the technology we license, technically retain the right to require us, under certain specific circumstances, to grant the U.S. government either a nonexclusive, partially exclusive or exclusive license to the patented invention in any field of use, upon terms that are reasonable for a particular situation. Circumstances that trigger march-in rights include, for example, failure to take, within a reasonable time, effective steps to achieve practical application of the invention in a field of use, failure to satisfy the health and safety needs of the public and failure to meet requirements of public use specified by federal regulations. The U.S. Army can elect to exercise these march-in rights on their own initiative or at the request of a third-party.

General Risk Factors

Changes in general economic conditions, geopolitical conditions, domestic and foreign trade policies, monetary policies and other factors beyond our control may adversely impact our business and operating results.

Our operations and performance depend on global, regional and U.S. economic and geopolitical conditions. General worldwide economic conditions have experienced significant instability in recent years including the recent global economic uncertainty and financial market conditions. Russia's invasion and military attacks on Ukraine have triggered significant sanctions from U.S. and European leaders and financial markets around the world experienced volatility

following the invasion of Ukraine by Russia in February 2022. Resulting changes in U.S. trade policy could trigger retaliatory actions by Russia, its allies and other affected countries, including China, resulting in a "trade war." Furthermore, if other countries, including the U.S., become further involved in the conflict, we could face significant adverse effects to our business and financial condition.

The uncertain financial markets, disruptions in supply chains, mobility restraints, and changing priorities as well as volatile asset values could impact our business in the future. The COVID-19 outbreak and government measures taken in response to the pandemic have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, have spiked, while demand for other goods and services, such as travel, have fallen. The future progression of the pandemic and its effects on our business and operations are uncertain.

Further, although we have not experienced any material adverse effects on our business due to increasing inflation, it has raised operating costs for many businesses and, in the future, could impact demand or pricing manufacturing of our drug candidates or services providers, foreign exchange rates or employee wages. Inflation rates, particularly in the United States and United Kingdom, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital. In addition, the Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks.

Actual events involving reduced or limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market-wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we did not have any cash or cash equivalent balances on deposit with Silicon Valley Bank, uncertainty and liquidity concerns in the broader financial services industry remain and the failure of Silicon Valley Bank and its potential near- and long-term effects on the biotechnology industry and its participants such as our vendors, suppliers, and investors, may also adversely affect our operations and stock price.

We are actively monitoring the effects these disruptions and increasing inflation could have on our operations.

These conditions make it extremely difficult for us to accurately forecast and plan future business activities.

In addition, the outbreak of a pandemic could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. Pandemics could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs.

We may not successfully effect our intended expansion, which would harm our business prospects.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management, and on our administrative, operational and financial resources. To manage this growth, we must expand our facilities; augment our operational, financial and management systems; and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future, and as a result, investors in our common stock could incur substantial losses and our ability to raise funds may be impacted.

Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future. On January 3, 2022, the reported low sale price of our common stock was $3.05 per share and the reported high sales price was $3.59 per share. For comparison purposes, on December 30, 2022, the price of our common stock closed at $0.81 per share. We may incur rapid and substantial decreases in our stock price in the foreseeable future that are unrelated to our operating performance or prospects. The stock market generally and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may experience losses on their investment in our common stock. The market price for our common stock may be influenced by many factors, including the following:

- investor reaction to our business strategy;
- the success of competitive products or technologies;
- our continued compliance with the listing standards of the NYSE American;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our products;
- results of our clinical trials;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional products or product candidates;
- developments concerning our collaborations or partners;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our products;
- our ability to generate revenue from ANTHIM® sales;
- our ability to generate revenue from our CDMO facility;
- our ability or inability to raise additional capital and the terms on which we raise it;
- declines in the market prices of stocks generally;
- trading volume of our common stock;
- sales of our common stock by us or our stockholders;
- general economic, industry and market conditions; and
- other events or factors, including those resulting from suchevents, or the prospect of such events, including war, terrorism and other international conflicts, such as the recent Russian invasion of Ukraine as well as continued and new sanctions against Russia by, among others, the European Union and the Unites States, which restrict a wide range of trade and financial dealings with Russia and Russia parties, public health issues including health epidemics or pandemics, and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability.

These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance. Since the stock price of our common stock has fluctuated in the past, has been recently volatile and may be volatile in the future, investors in our common stock could incur substantial losses. In the past, following periods of volatility in the market, securities class-action litigation has often been instituted against companies. Such litigation, if instituted against us, could result in substantial costs and diversion of management's attention and resources, which could materially and adversely affect our business, financial condition, results of operations and growth prospects. There can be no guarantee that our stock price will remain at current prices or that future sales of our common stock will not be at prices lower than those sold to investors.

We rely on key executive officers and scientific and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace.

We are highly dependent on our principal scientific, regulatory and medical advisors and our chief executive officer. Other than a $2.0 million insurance policy we hold on the life of Jeffrey Wolf, we do not have "key person" life insurance policies for any of our officers or advisors. The loss of the technical knowledge, management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed

We will need to hire additional qualified personnel with expertise in preclinical and clinical research, government regulation, formulation and manufacturing, sales and marketing and accounting and financing. Over the next 12 months, we expect to hire additional new employees both in North Carolina and for Scorpius in Texas. We compete for qualified individuals with numerous biopharmaceutical companies, universities, and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful especially in light of the CPRIT Grant requirements, including the requirement that Pelican maintain its headquarters in Texas and use certain vendors, consultants and employees located in Texas. Attracting and retaining qualified personnel will be critical to our success.

We are a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors.

We are a smaller reporting company under Rule 12b-2 of the Exchange Act. For as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not smaller reporting companies, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on smaller reporting company exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

There can be no assurance that we will be able to comply with the applicable regulations in a timely manner, if at all.

Our failure to meet the continued listing requirements of the NYSE American LLC (the "NYSE American") could result in a de-listing of our common stock.

Our shares of common stock are currently listed on the NYSE American. If we fail to satisfy the continued listing requirements of the NYSE American, such as the corporate governance requirements, minimum bid price requirement or the minimum stockholder's equity requirement, NYSE American may take steps to de-list our common stock. Any de-listing would likely have a negative effect on the price of our common stock and would impair stockholders' ability to sell or purchase their common stock when they wish to do so. In the past our common stock was listed on the Nasdaq Capital Market and we received notices from the Listing Qualifications Department of Nasdaq Stock Market LLC ("Nasdaq") that we failed to comply with the stockholder's equity requirements and the minimum closing bid requirements. On June 21, 2019, we received written notice from the Listing Qualifications Department of the Nasdaq Stock Market LLC notifying us that for the preceding 30 consecutive business days (May 9, 2019 through June 20, 2019), our common stock did not maintain a minimum closing bid price of $1.00 per share ("Minimum Bid Price Requirement") as required by Nasdaq Listing Rule 5550(a)(2). On July 24, 2020, we received written notice from The Nasdaq Capital Market that from July 10, 2020 through July 23, 2020, the closing bid price of our common stock has been at $1.00 per share or greater and accordingly we had regained compliance with Nasdaq Listing Rule 5550(a)(2) and the matter was now closed. There can be no assurance given that we will be able to continue to satisfy our continued listing requirements and maintain the listing of our common stock on the NYSE American going forward.

The possible issuance of common stock subject to options, restricted stock units and warrants may dilute the interests of stockholders.

As of March 31, 2023, awards for 6,980,764 shares of common stock are outstanding under our equity compensation plans and 243,873 shares of common stock remain available for grants under the plans. In addition, as of March 31, 2023, we have warrants exercisable for 716,383 shares of our common stock to third parties in connection with our public offerings. To the extent that outstanding stock options and warrants are exercised, or additional securities are issued, dilution to the interests of our stockholders may occur. Moreover, the terms upon which we will be able to obtain additional equity capital may be adversely affected since the holders of the outstanding options can be expected to exercise them at a time when we would, in all likelihood, be able to obtain any needed capital on terms more favorable to us than those provided in such outstanding options.

We have additional securities available for issuance, which, if issued, could adversely affect the rights of the holders of our common stock.

Our certificate of incorporation authorizes the issuance of 250,000,000 shares of our common stock and 10,000,000 shares of preferred stock. In certain circumstances, the common stock, as well as the awards available for issuance under the incentive plans, can be issued by our Board of Directors, without stockholder approval. Any future issuances of such stock would further dilute the percentage ownership of us held by holders of preferred stock and common stock. Our Board of Directors is authorized to create and issue from time to time, only with stockholder approval, up to an aggregate of 10,000,000 shares of preferred stock of which 8,212,500 have been designated. The authority to designate preferred stock may be used to issue series of preferred stock, or rights to acquire preferred stock, that could dilute the interest of, or impair the voting power of, holders of the common stock or could also be used as a method of determining, delaying or preventing a change of control.

We have never paid dividends and have no plans to pay dividends in the future.

Holders of shares of our common stock are entitled to receive such dividends as may be declared by our Board of Directors. To date, we have paid no cash dividends on our shares of our preferred or common stock and we do not expect to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any return investors in our preferred or common stock may have will be in the form of appreciation, if any, in the market value of their shares of common stock.

Certain provisions of the General Corporation Law of the State of Delaware, our bylaws and stockholder rights plan may have anti-takeover effects that may make an acquisition of our company by another company more difficult.

We are subject to the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a Delaware corporation from engaging in any business combination, including mergers and asset sales, with an interested stockholder (generally, a 15% or greater stockholder) for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. The operation of Section 203 may have anti-takeover effects, which could delay, defer or prevent a takeover attempt that a holder of our common stock might consider in its best interest. Certain provisions of our bylaws including the ability of our Board of Directors to fill vacancies on our Board of Directors and advance notice requirements for stockholder proposals and nominations may prevent or frustrate attempts by our stockholders to replace or remove our management. In addition, the Rights issued pursuant to our stockholder rights plan that we implemented, if not redeemed or suspended, could result in the dilution of the stock ownership of a potential hostile acquirer, likely preventing acquisitions that have not been approved by our Board of Directors and therefore discouraging, delaying or preventing a change in control that stockholders may consider favorable.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for certain types of state actions that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our amended and restated bylaws provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on behalf of us, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders, (iii) any action arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws (as either may be amended from time to time), or (iv) any action asserting a claim governed by the internal affairs doctrine, except, in each case for claims arising under the Securities Act of 1933, as amended, the Exchange Act, or other federal securities laws for which there is exclusive federal or concurrent federal and state jurisdiction.

These exclusive-forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, employees, control persons, underwriters, or agents, which may discourage lawsuits against us and our directors, employees, control persons, underwriters, or agents. Additionally, a court could determine that the exclusive forum provision is unenforceable, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. If a court were to find these provisions of our amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition, or results of operations.

Future sales of our common stock by our existing stockholders could cause our stock price to decline.

On March 30, 2023, we had 26,049,209 shares of our common stock outstanding, all of which are currently eligible for sale in the public market, subject, in certain circumstances to the volume, manner of sale and other limitations under Rule 144 promulgated under the Securities Act. It is conceivable that stockholders may wish to sell some or all of their shares. If our stockholders sell substantial amounts of our common stock in the public market at the same time, the market price of our common stock could decrease significantly due to an imbalance in the supply and demand of our common stock. Even if they do not actually sell the stock, the perception in the public market that our stockholders might sell significant shares of our common stock could also depress the market price of our common stock.

A decline in the price of shares of our common stock might impede our ability to raise capital through the issuance of additional shares of our common stock or other equity securities, and may cause stockholders to lose part or all of their investment in our shares of common stock.

Our shares of common stock are from time to time thinly traded, so stockholders may be unable to sell at or near ask prices or at all if they need to sell shares to raise money or otherwise desire to liquidate their shares.

Our common stock has from time to time been "thinly-traded," meaning that the number of persons interested in purchasing our common stock at or near ask prices at any given time may be relatively small or non-existent. This situation is attributable to a number of factors, including the fact that we are a small company that is relatively unknown to stock analysts, stock brokers, institutional investors and others in the investment community that generate or influence sales volume, and that even if we came to the attention of such persons, they tend to be risk-averse and would be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. As a consequence, there may be periods of several days or more when trading activity in our shares is minimal or non-existent, as compared to a seasoned issuer that has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. We cannot give stockholders any assurance that a broader or more active public trading market for our common shares will develop or be sustained, or that current trading levels will be sustained.

Holders of our warrants will have no rights as a common stockholder until they acquire our common stock.

Until warrant holders acquire shares of our common stock upon exercise of their warrants, the warrant holders will have no rights with respect to shares of our common stock issuable upon exercise of their warrants. Upon exercise of the

warrants, the warrant holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

There is no established market for the warrants that we previously issued and our previously issued warrants may not have any value.

Our previously issued warrants to purchase shares of our common stock may not have any value. For example, we previously issued warrants in a public offering that have exercise prices of $11.55, $11.09 and $5.78 per share. In the event that our common stock price does not exceed the exercise price of our previously issued warrants during the period when the warrants are exercisable, the warrants may not have any value.

The shares of common stock offered under any at the market offering that we may engage in, and investors who buy shares at different times will likely pay different prices.

Investors who purchase shares that are sold under at-the-market-offerings at different times will likely pay different prices, and so may experience different outcomes in their investment results. We will have discretion, subject to market demand, to vary the timing, prices, and numbers of shares sold, and there is no minimum or maximum sales price. Investors may experience declines in the value of their shares as a result of share sales made at prices lower than the prices they paid.

Reports published by securities or industry analysts, including projections in those reports that exceed our actual results, could adversely affect our common stock price and trading volume.

Securities research analysts, including those affiliated with our underwriters from prior offerings, establish and publish their own periodic projections for our business. These projections may vary widely from one another and may not accurately predict the results we actually achieve. Our stock price may decline if our actual results do not match securities research analysts' projections. Similarly, if one or more of the analysts who writes reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business or if one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, our stock price or trading volume could decline. While we expect securities research analyst coverage to continue going forward, if no securities or industry analysts cover us, the trading price for our stock and the trading volume could be adversely affected.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Facilities

Our executive offices are located at 627 Davis Drive, Suite 300, Morrisville, North Carolina 27560. In November 2022, we commenced a lease that expires October 1, 2030 for 15,996 square feet of office and laboratory space for monthly rent of $43,655 exclusive of payments required for maintenance of common areas and utilities.

In January 2018, Pelican entered into a five-year lease for 5,156 square feet of office and laboratory space located in San Antonio, Texas for monthly rent of $9,668, exclusive of payments required for maintenance of common areas and utilities. This lease expired in February 2023.

In July 2020, and amended August 2022, we entered into a lease for our Skunkworx subsidiary in North Brunswick, New Jersey that is expected to expire July 1, 2023 for 2,725 square feet of laboratory space for monthly rent of $11,434 exclusive of payments required for utilities.

The lease for our Scorpius manufacturing facility commenced in September 2022 and is located at 1305 E. Houston Street, San Antonio, Texas 78205 for general office, laboratory, research, analytical, and/or biomanufacturing purposes for

monthly base rent starting at $50,360 and increasing at the rate of three percent (3%) on an annual basis up to a maximum monthly base rent of $76,174. This lease is set to expire in September 2037.

In April 2022, upon the completion of the merger of Elusys Therapeutics, we took over their lease of approximately 6,702 square feet of office space for monthly rent of $13,404 exclusive of payments required for maintenance of common areas and utilities. This lease is set to expire in July 2023.

We believe our existing properties are adequate for our current needs.

Item 3. Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, operating results, financial condition or cash flows. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Effective May 3, 2022, Heat Biologics, Inc. changed its name to NightHawk Biosciences, Inc. (the "Company") by filing a Certificate of Amendment (the "Certificate of Amendment") to its Third Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware. On May 3, 2022, our common stock commenced trading on the NYSE American under the symbol "NHWK." Between February 14, 2022 and May 2, 2022, our common stock was trading on the NYSE American under the symbol "HTBX". Prior to February 14, 2022, our common stock traded on the Nasdaq Capital Market under the symbol "HTBX".

Holders

As of March 30, 2023, there were approximately 28 stockholders of record of our common stock. The number of holders of record is based on the actual number of holders registered on the books of our transfer agent and does not reflect holders of shares in "street name" or persons, partnerships, associations, corporations or other entities identified in security position listings maintained by depository trust companies.

Dividend Policy

We have never paid any cash dividends on our common stock to date, and do not anticipate paying such cash dividends in the foreseeable future. Whether we declare and pay dividends is determined by our Board of Directors at their discretion, subject to certain limitations imposed under Delaware corporate law. The timing, amount and form of dividends, if any, will depend on, among other things, our results of operations, financial condition, cash requirements and other factors deemed relevant by our Board of Directors.

Equity Compensation Plan Information

Securities Authorized for Issuance Under Equity Compensation Plans

The following table contains information about our equity compensation plans as of December 31, 2022.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders			
2009 Stock Incentive Plan (1)	1,135	$ 403.80	—
2014 Stock Incentive Plan	17,385	181.11	20,603
2017 Stock Incentive Plan	31,018	18.29	26,227
2018 Stock Incentive Plan	6,955,758	3.11	465,256
2021 Abacus Subsidiary Stock Incentive Plan	10,526	0.01	9,474
2021 Blackhawk Subsidiary Stock Incentive Plan	10,526	0.01	9,474
2021 Scorpion Subsidiary Stock Incentive Plan	—	—	7,245
2021 Skunkworx Subsidiary Stock Incentive Plan	10,526	1.67	9,484
2021 Employee Stock Purchase Plan	—	—	488,336
Total	7,036,874	$ 3.67	1,036,099

(1) The 2009 Stock Incentive Plan terminated, such that no further awards are available for issuance under this plan. Outstanding awards under this plan continue in accordance with the respective terms of such grants.

Recent Sales of Unregistered Securities

Except as previously disclosed in our Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, we had no sales of unregistered equity securities during the year ended December 31, 2022.

Purchase of Equity Securities

We have not purchased any of our equity securities during the period covered by this Annual Report.

Item 6. ***[Reserved]***

Item 7. ***Management's Discussion and Analysis of Financial Condition and Results of Operations***

The following discussion of our financial condition and results of operations should be read in conjunction with the audited financial statements and notes thereto for the years ended December 31, 2022 and December 31, 2021 found in this Annual Report. In addition to historical information, the following discussion contains forward-looking statements that involve risks, uncertainties and assumptions. Where possible, we have tried to identify these forward-looking statements by using words such as "may," "should," "potential," "continue," "expects," "anticipates," "intends," "plans," "believes," "estimates," and similar expressions. Our actual results could differ materially from those anticipated by the forward-looking statements due to important factors and risks including, but not limited to, those set forth under "Risk Factors" in Part I, Item 1A of this Annual Report.

Company Overview

We are 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. Our ecosystem is driven by the discovery efforts of our subsidiary, Skunkworx, the clinical and commercial biodefense expertise of our subsidiary, Elusys, and the bioanalytical, process development and biomanufacturing capabilities of our subsidiary Scorpius. The coordination of this ecosystem potentiates the streamlined development and delivery of life-saving medical countermeasures, including our commercially available anthrax antitoxin ANTHIM® (obiltoxaximab).

The monoclonal antibody ANTHIM® (obiltoxaximab) received FDA approval and orphan drug exclusivity in 2016 for the treatment of inhalational anthrax in combination with antibiotics, and as a prophylaxis when alternative therapies are not available or are not appropriate. Additionally, ANTHIM® was approved in 2020 as the only licensed anthrax antitoxin treatment in the European Union ("EU") and Canada, and in 2021 in the United Kingdom. Working closely with Biomedical Advanced Research and Development Authority ("BARDA"), the National Institute of Allergy and Infectious Disease ("NIAID"), and the Department of Defense ("DoD"), Elusys has successfully advanced ANTHIM® to the commercial stage and provides the therapeutic for inclusion in both the US Strategic National Stockpile ("SNS") and the Public Health Agency of Canada Office of Emergency Response Services Depot.

Scorpius pairs cGMP biomanufacturing and quality control expertise with cutting edge capabilities in immunoassays, molecular assays, and bioanalytical methods to support cell- and gene-based therapies as well as large molecule biologics. Scorpius decreases our dependence on third-party contract research and development biomanufacturing organizations (CDMOs) for the manufacture of ANTHIM® (obiltoxaximab) and other assets and allows us to be opportunistic in offering excess capacity to third parties as a fee-for-service model. Our lead facility commenced operations in October 2022 in San Antonio, Texas. Planning and development efforts are underway on a potential commercial manufacturing facility to be built in Manhattan, Kansas in the coming years.

During the past year, our priorities have shifted to our biodefense and biomanufacturing capabilities resulting in a refocusing of our resources and efforts towards biodefense and biomanufacturing and away from our clinical-stage oncology assets including HS-110 and PTX-35.

Funding/Liquidity

We have incurred an accumulated deficit of $209.2 million through December 31, 2022. We have incurred negative cash flows from operations since we started our business. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials, and our research and discovery efforts.

We expect to incur significant expenses and continued losses from operations for the foreseeable future. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development and seek marketing approval for our product candidates and as we add to our product candidate pipeline including expansion of our infectious disease/biothreat programs.

We expect to incur significant additional expenses in connection with the planned development partnership of Scorpius with a private developer, the State of Kansas and local and university affiliates and the facility to be developed by a third-party developer and leased to Scorpius. We do not intend to finance the remaining costs that we will incur for the Kansas facility from working capital and instead anticipate raising financing through multiple alternatives, including, but not limited to, the sale of equity or debt of Scorpius.

The fair value of the purchase consideration for Elusys was $42.9 million pursuant to the terms of the Merger Agreement, we also paid an additional $2.0 million after having paid $3.0 million in cash consideration at closing, plus we may be required to pay an additional $1.6 million subject to adjustment upon attainment of certain milestones.

Furthermore, we anticipate increased costs associated with the manufacture of ANTHIM® and the increase in headcount due to the acquisition of Elusys. Our agreement with Lonza obligates us to pay for certain services upon placement of an

order and only allows us to cancel manufacturing of batches for which we have placed orders under certain circumstances. Based upon the order that we placed in March 2023, we anticipate being obligated to pay over a two year period to Lonza approximately $34 million and an additional $19 million for resins and other raw materials required for production.

In addition, if we obtain marketing approval for any of our other product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. We will need to obtain substantial additional future funding in connection with our manufacturing facility that we are building out in San Antonio, Texas and any new programs or ventures we pursue. While we are currently funding vaccine development and preclinical studies, we do not expect to use significant corporate resources to advance our COVID-19 program. We are applying for several large grants to support clinical development of this program and are engaged in collaboration discussions, which we believe may provide attractive and non-dilutive pathways to help accelerate development of our COVID-19 program; however, to date we have not received any grant funding for such program and there can be no assurance that we will receive such grant funding or if received, the amount of such grant funding. Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. These factors raise substantial doubt about our ability to continue as a going concern for one year after the financial statements are issued. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, which include sales of our common stock under at-the-market offerings, if available, debt financings, partnerships, collaborations and other funding transactions. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We will need to generate significant revenues to achieve profitability, and we may never do so. As of December 31, 2022, we had approximately $44.3 million in cash and cash equivalents and short-term investments.

We intend to meet our financing needs through multiple alternatives, including, but not limited to, cash on hand, additional equity financings, debt financings and/or funding from partnerships or collaborations and potential revenue, if any, from our planned development and manufacturing facility.

The uncertain financial markets, disruptions in supply chains, mobility restraints, and changing priorities as well as volatile asset values could impact our business in the future. The outbreak and government measures taken in response to the pandemic have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, have spiked, while demand for other goods and services, such as travel, have fallen. The future progression of the pandemic and its effects on our business and operations are uncertain. We may face difficulties performing services at our San Antonio facility if our workforce is impacted by the pandemic. Although we have increased manufacturing material levels in an attempt to mitigate supply chain issues, we may still face disruptions in procuring items that are essential to perform our services. In addition, we have experienced minor disruptions in equipment supply in the building of our San Antonio facility. These minor disruptions have had an immaterial effect on business, which we have been able to address with minimal impact to our business operations to date. Further, although we have not experienced any material adverse effects on our business due to increasing inflation, it has raised operating costs for many businesses and, in the future, could impact demand or pricing of our manufacturing services, the cost we incur to manufacture ANTHIM®, the costs required to build the manufacturing facility in Kansas, foreign exchange rates or employee wages. We are actively monitoring the effects these disruptions and increasing inflation could have on our operations.

CRITICAL ACCOUNTING POLICIES AND SIGNIFICANT JUDGMENTS AND ESTIMATES

We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as "critical" because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used, which would have resulted in different financial results.

Our management's discussion and analysis of financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities,

revenue and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates based on historical experience and make various assumptions, which management believes to be reasonable under the circumstances, which form the basis for judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

The notes to our audited consolidated financial statements contain a summary of our significant accounting policies. We consider the following accounting policies critical to the understanding of the results of our operations:

- Revenue;
- Deferred revenue;
- Leases;
- Intangible assets;
- Goodwill impairment;
- Income tax;
- Contingent consideration;
- Stock-based compensation;
- Research and development costs, including clinical and regulatory cost; and

Revenue and Deferred Revenue

Our 2022 revenue primarily consisted of product sales revenue of ANTHIM® and our 2021 revenue primarily consisted of research funding from our CPRIT Grant. Product sales revenue is recognized when its performance obligation with its customers has been satisfied. The performance obligation is satisfied at a point in time when the Company's customers obtain control of the product, which is typically upon acceptance of the product at the delivery site. Grant revenue is recognized when qualifying costs are incurred and there is reasonable assurance that the conditions of the award have been met for collection. Deferred revenue represent customer deposits for process development services billed and/or received in advance of our fulfillment of performance obligations. Deferred revenue will convert to revenue as we perform our obligations under the contract.

Leases

We determine if an arrangement is, or contains, a lease at inception. Operating and finance leases are included in right-of-use assets and lease liabilities in our consolidated balance sheets, representing our right to use an underlying asset for the lease term and the obligation to make lease payments arising from the lease. Right-of-use, or ROU, assets and lease liabilities are recognized at commencement based on the present value of lease payments over the lease term. We use our incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments. The ROU assets also include any lease payments made and is adjusted for lease incentives. Lease terms may include options to extend or terminate the lease which are recognized when it is reasonably certain that we will exercise that option. Lease expense is recognized on a straight-line basis over the lease terms. Lease and non-lease components are accounted for as a single lease component.

Goodwill and Intangible Assets

Intangible assets represent the fair value assigned to technologies that were acquired from Elusys, which at the time of acquisition have not reached technological feasibility and have no alternative future use. Intangible assets from the acquisition of Pelican were considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. During the third quarter of 2022, Pelican's intangible asset was fully written-off as the PTX-35 trial has been discontinued. The intangible asset acquired from the acquisition of Elusys is a definite-lived asset comprised of the ANTHIM® formulation. The asset is being amortized over 80 months, which is the approximate life of the patent.

Intangible assets are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the assets are less than their carrying amounts. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the asset, calculated as the excess of carrying value of the intangible assets over fair value. See Note 8 regarding impairment at December 31, 2022.

We test goodwill and intangible asset impairment each year as of April 1, or more frequently should a significant impairment indicator occur. As part of the impairment test, we may elect to perform an assessment of qualitative factors. If this qualitative assessment indicates that it is more likely than not that the fair value of a reporting unit, including goodwill, is less than its carrying amount, or if we elect to bypass the qualitative assessment, we would then proceed with the impairment test. The impairment test involves comparing the fair values of the reporting units to their carrying amounts. If the carrying amount of a reporting unit exceeds its fair value, we recognize a goodwill loss in an amount equal to any excess.

Determining the fair value of a reporting unit is judgmental in nature and involves the use of significant estimates and assumptions. We forecast discounted future cash flows at the reporting unit level using risk-adjusted discount rates and estimated future revenues and operating costs, which take into consideration expectations of competitive, business, and economic environments. We also identify similar publicly traded companies and develop a correlation, referred to as a multiple, to apply to the operating results of the reporting units.

Determining the fair value of intangible assets is judgmental in nature and involves the use of significant estimates and assumptions. We forecast discounted future cash flows, risk-adjusted discount rates and estimated future revenues and operating costs, which take into consideration expectations of competitive, business, and economic environments. The fair value is then compared to the carrying value and if the carrying value exceeds fair value an impairment charge is recognized.

Changes in market demand, fluctuations in the markets in which we operate, the volatility and decline in the worldwide equity markets, and a decline in our market capitalization could unfavorably impact the remaining carrying value of our goodwill and intangible assets, which could have a significant effect on our current and future results of operations and financial position.

Income Tax

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statements carrying amounts of assets and liabilities and their respective tax bases, operating loss carryforwards, and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

In accordance with FASB ASC 740, *Accounting for Income Taxes*, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of December 31, 2022, and 2021, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying consolidated statements of operations. As of December 31, 2022 and 2021, the Company had recorded no such amounts.

Contingent Consideration

Contingent consideration is recorded as a liability and is the estimate of the fair value of potential milestone and royalty payments related to business acquisitions. Contingent consideration is measured at fair value using a probability-weighted income approach utilizing significant unobservable inputs including the probability of achieving each of the potential milestone and royalty payments and an estimated discount rate associated with the risks of the expected cash flows

attributable to the various milestones. Significant increases or decreases in any of the probabilities of success or changes in expected timelines for achievement of any of these milestones would result in a significantly higher or lower fair value of these milestones, respectively, and commensurate changes to the associated liability. The contingent consideration is revalued at each reporting period and changes in fair value are recognized in the consolidated statements of operations and comprehensive loss.

Stock-Based Compensation

Calculating stock-based compensation expense requires the input of highly subjective assumptions. The fair value of restricted stock units is estimated based on the closing price of our stock on the date of grant, and for the purposes of expense recognition, the total new number of shares expected to vest is adjusted for as they occur. We apply the Black-Scholes-Merton option pricing model to determine the fair value of our stock options awards. Inherent in this model are assumptions related to expected stock-price volatility, expected option life, risk-free interest rate and dividend yield. We use an average historical stock price volatility of our own data plus an analysis of reported data for a peer group of comparable companies that have issued stock options with substantially similar terms. We estimate the expected life of our options using the simplified method. The risk-free interest rate is based on the U.S. Treasury zero-coupon yield curve on the grant date for a maturity similar to the expected life of the options. The dividend rate is based on our historical rate, which we anticipate remaining at zero. We account for forfeitures as they occur. The assumptions used in calculating the fair value of stock options represent our best estimates, however these estimates involve inherent uncertainties and the application of management judgment. As a result, if factors change and different assumptions are used, the stock-based compensation expense could be materially different in the future.

Research and Development Costs

We expense research and development costs associated with developmental products not yet approved by the FDA as well as costs associated with bringing our developmental products into advanced phase clinical trials as incurred. These costs consist primarily of pre-manufacturing and manufacturing drug costs, clinical trial execution, investigator payments, license fees, salaries, stock-based compensation, and related personnel costs. Other costs include fees paid to consultants and outside service providers related to the development of our product candidates, and other expenses relating to the design, development, and testing and enhancement of our product candidates.

RESULTS OF OPERATIONS

Years Ended December 31, 2022 and 2021

Revenues

For the year ended December 31, 2022, we recognized $6.0 million of product sales revenue, $0.1 million of contract revenue, and $0.3 million of CPRIT grant revenue. As of December 31, 2021 we recognized $2.1 million in 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 is due to the fact that we have recognized all $15.2 million of CPRIT grant revenue. For the year ended December 31, 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.

Cost of sales

For the year ended December 31, 2022, we 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® sale to the Canadian government. Cost of sales include $5.9 million of inventory, $0.3 million of pre-acquisition backlog, and $0.2 million of shipping and fulfillment expense.

Selling, general and administrative 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 our 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 expense

Research and development expenses increased to $23.5 million from $16.5 million for the years ended December 31, 2022 and 2021, respectively. The components of research and development expense are as follows, in millions:

	For the year Ended December 31,	
	2022	2021
Programs		
HS-110	$ 0.5	$ 1.7
HS-130	0.7	0.9
PTX-35	2.6	2.9
ANTHIM	1.2	—
Other programs	1.6	2.3
Unallocated research and development expenses	16.9	8.7
	$ 23.5	$ 16.5

- HS-110 decreased by $1.2 million primarily due to a decrease in manufacturing expenses and site and investigator fees as the result of the closing of our clinical trials.
- HS-130 expense decreased by $0.2 million primarily due to a decrease in site and investigator fees as the result of the closing of our clinical trials.
- PTX-35 expense decreased by $0.3 million primarily due to a decrease in site and investigator fees as the result of the closing of our clinical trials.
- ANTHIM® expense increased as a result of our acquisition of Elusys in April 2022.
- Other programs expenses decreased by $0.7 million and include preclinical costs associated with our 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 preclinical research, as well as increased clinical and CMC consulting expenses and Skunkworx lab and personnel costs.

Change in fair value of contingent consideration

We reassess the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. The change in the fair value of contingent consideration was ($3.4) million for the year ended December 31, 2022 compared to the change in fair value of contingent consideration of $0.4 million for the year ended December 31, 2021. The change in fair value for the year ended December 31, 2022 was primarily due to the write off of Pelican's contingent consideration of $3.3 million due to the discontinuation of the PTX-35 and the decrease of ($0.1) million in fair value of Elusys' contingent consideration due to the passage of time to milestone achievement as well as increased interest rates.

In-process research and development impairment

IPR&D impairment was $3.5 million and $2.4 million for the years ended December 31, 2022 and 2021, respectively. IPR&D was fully impaired during the third quarter of 2022 as the PTX-35 trial will not progress to Phase 2.

Total non-operating loss

Total non-operating loss was ($1.5) million for the years ended December 31, 2022 which primarily consisted of ($1.7) million of unrealized losses on short-term investment balances, ($0.2) million of unrealized loss on foreign currency, ($0.2) million of finance lease interest expense, ($0.4) million of loss on disposal of assets, offset by $1.0 million of interest and dividends income on short-term investment balances. Total non-operating loss was ($0.1) million for the year ended December 31, 2021 which primarily consisted of $0.9 million of interest income, and ($1.0) million of unrealized losses on short-term investment balances.

Income tax benefit

Income tax benefit was $3.3 million for the year ended December 31, 2022 compared to $0.1 million for the year ended December 31, 2021, primarily due to the recognition of Elusys' deferred tax liability ("DTL").

BALANCE SHEET AS OF DECEMBER 31, 2022 AND 2021

Short-term Investments. Short-term investments were $35.8 million as of December 31, 2022 compared to $88.3 million as of December 31, 2021. The decrease is primarily due the sale of investments and transferring the cash to fund the Scorpius facility build-out and other operations.

Prepaid Expenses and Other Current Assets. Prepaid expenses and other current assets were approximately $3.6 million as of December 31, 2022 and $2.9 million as of December 31, 2021. The $0.7 million increase is primarily attributable to our payments to certain vendors related to the close out process of our PTX-35 clinical trial.

Property, Plant & Equipment. Property, Plant and Equipment was approximately $20.5 million as of December 31, 2022, and $2.2 million as of December 31, 2021. The increase is attributed to a $18.3 million increase in lab equipment and leasehold improvements as a result of the Scorpius lease.

Grants Receivable. Grants receivable was $1.5 million as of December 31, 2022, and $1.3 million as of December 31, 2021. The CPRIT grant will award the remaining grant funds, on a reimbursement basis, after NightHawk has fulfilled every requirement of the grant and the grant has been approved to be finalized. The receivable relates to reimbursable costs incurred related to PTX-35.

Other Assets. Other assets were approximately $0.3 million and $12.2 million as of December 31, 2022 and 2021, respectively. The $11.9 million decrease is directly attributable to equipment purchases in 2021 for Scorpius's new facility in San Antonio, Texas, which commenced operations in the third quarter of 2022. Other assets were then transferred into property and equipment.

Intangible Assets. As of December 31, 2022 and 2021, we had intangible assets of $8.7 million and $3.5 million. The increase was due to the ANTHIM® formulation obtained from the Elusys acquisition offset by the write off of Pelican's in-process R&D of $3.5 million due to the termination of the development of PTX-35, Pelican's lead product candidate.

Goodwill. As of December 31, 2022 and December 31, 2021, we had goodwill of $3.3 million and $0.0 million, respectively. The carrying value of this asset increased by $3.3 million due to the acquisition of Elusys in April 2022.

Accounts Payable. Accounts payable was approximately $4.4 million and $0.9 million as of December 31, 2022 and December 31, 2021. The $3.5 million increase is due to payables related to increased operations with the opening of the Scorpius facility.

Deferred Revenue. Deferred revenue was $1.6 million and $0.0 million as of December 31, 2022 and December 31, 2021, respectively. This deferred revenue represents proceeds received for Scorpius contracts but for which the costs have not been incurred or the conditions of the contracts not yet met.

Accrued Expenses and Other Liabilities. Accrued expenses and other liabilities were approximately $4.3 million at December 31, 2022 compared to $2.4 million at December 31, 2021. The increase is primarily due to license fee accruals, sponsored research agreements and tax accruals related to our acquisition of Elusys.

Operating and Financing Lease Liabilities. Current and long term liabilities related to operating and finance leases were $9.4 million as of December 31, 2022 and $1.9 million as of December 31, 2021. These balances are related to our Scorpius facility lease, corporate office lease and equipment leases.

Deferred Tax Liability. Deferred tax liability was approximately $0.0 million and $0.2 million for the years ended December 31, 2022 and December 31, 2021, respectively. The decrease was primarily due to the recognition of Pelican's DTL in the third quarter of 2022 due to the abandonment of the PTX-35 trial.

Contingent Consideration. As of December 31, 2022, we had contingent consideration of $12.2 million compared to $3.3 million as of December 31, 2021. The increase is primarily related to our acquisition of Elusys. This amount represents the fair value of future milestone payments and royalities to Elusys shareholders which were discounted in accordance with ASC 820 – *Fair Value Measurement*. We perform an analysis on a quarterly basis and for the year ended December 31, 2022, we determined the change in the estimated fair value of the contingent consideration to be approximately ($3.5) million primarily due to the discontinuation of the PTX-35 clinical trial.

LIQUIDITY AND CAPITAL RESOURCES

Current and Future Financing Needs

Since our inception in June 2008, we have incurred significant losses and we have financed our operations with net proceeds from the private placement of our preferred stock, common stock and debt. Since our initial public offering, we have primarily financed our operations with net proceeds from the public offering of our securities and to a lesser extent, the proceeds from the exercise of warrants. During May 2018, we closed a public offering of shares of our common stock and warrants to purchase shares of our common stock in which we received net proceeds of approximately $18.8 million and after the closing of the offering, an additional $4.8 million from the exercise of 436,381 warrants issued in this offering. During November 2018, we closed a public offering of shares of our common stock and warrants to purchase shares of our common stock in which we received net proceeds of approximately $12.7 million. For the years ended December 31, 2018 and 2019, we received net proceeds of approximately $3.8 million from sales of our common stock in at-the-market offerings. On January 21, 2020, we closed an underwritten public offering of shares of our common stock and warrants to purchase shares of our common stock pursuant to which we received net proceeds of approximately $6.4 million. For the year ended December 31, 2021, we received net proceeds of $25.6 million from the sale of 2,106,027 shares of our common stock in at-the-market offerings. As of December 31, 2022, we had an accumulated deficit of approximately $209.2 million. We had net losses of $43.9 million and $35.4 million for the years ended December 31, 2022 and 2021, respectively.

We expect to incur significant commercialization expenses related to product sales, marketing, manufacturing, and distribution. We will need to obtain substantial additional future funding in connection with our manufacture of ANTHIM® and our manufacturing facility construction and set up.

However, the actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our research activities;
- our ability to attract customers for our CDMO services and ANTHIM®
- the number and scope of our research programs;
- the progress of our preclinical and clinical development activities;

- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our expansion plans and cash needs of any new projects;
- our ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights;
- the costs and timing of regulatory approvals;
- the receipt of grant funding if any;
- clinical laboratory development and testing;
- additional manufacturing facility construction costs and equipment costs; and
- manufacturing costs of ANTHIM®.

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of our equity or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock, such as through the Amended and Restated Common Stock Sales Agreement with B. Riley FBR, Inc. and Cantor Fitzgerald & Co., or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

Adequate additional financing may not be available to us on acceptable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. These factors raise substantial doubt about the Company's ability to continue as a going concern for one year after the financial statements are issued. To meet our capital needs, we are considering multiple alternatives, including, but not limited to, additional equity financings, which include sales of our common stock under at-the-market offerings, if available, debt financings, partnerships, collaborations and other funding transactions. This is based on our current estimates, and we could use our available capital resources sooner than we currently expect. We will need to generate significant revenues to achieve profitability, and we may never do so. As of December 31, 2022, we had approximately $44.3 million in cash and cash equivalents and short-term investments. The Company will need to generate significant revenues to achieve profitability, and it may never do so. Management has determined that there is substantial doubt about the Company's ability to continue as a going concern within one year after the consolidated financial statements are issued.

Cash Flows

Operating activities. The use of cash in both periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities during the year ended December 31 2022 was $5.7 million compared to $38.1 million during the same period in 2021. The decrease was primarily due to an increased net loss of $8.5 million, an increase in contract receivables of $24.5 million, and an increase in inventory of $5.8 million.

Investing activities. Net cash provided by investing activities was $11.0 million during the year ended December 31, 2022 compared to $9.8 million used during the same period in 2021. The decrease is from the change in net purchases of short-term investment purchases and sales of $39.1 million, the increase in purchase of property, plant and equipment of $18.2 million from 2021 to 2022 and the $22.8 million contingent consideration payment in 2022, offset by the increasea of $2.7 million from the acquisition of Elusys.

Financing activities. Net cash used in financing activities was $4.9 million during the year ended December 31, 2022 compared to net cash provided by financing activities of $25.5 million during the year ended December 31, 2021. The decrease of $30.4 million was primarily due to a $26.2 million net decrease in proceeds from the issuance of common

stock in 2021 that did not recur in 2022 offset by contingent consideration of $4.7 million paid out related to an Elusys milestone.

Additional In-Licensed Programs

We may enter into additional license agreements relating to new product candidates.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable because we are a smaller reporting company.

Item 8. Financial Statements and Supplemental Data

See pages F-1 through F-32.

Item 9. *Changes In and Disagreements with Accountants on Accounting and Financial Disclosures*

None.

Item 9A. *Controls and Procedures*

Disclosure Controls and Procedures

Under the direction and with the participation of management, including the Chief Executive Officer and Chief Financial Officer, we carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2022. We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in its periodic reports with the Securities and Exchange Commission is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and regulations, and that such information is accumulated and communicated to management, including its principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. Our disclosure controls and procedures are designed to provide a reasonable level of assurance of reaching its desired disclosure control objectives.

Our Chief Executive Officer and Chief Financial Officer has concluded that, due to the material weaknesses described below, our disclosure controls and procedures were not effective as of December 31, 2022.Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of the principal executive officer and principal financial officer and implemented by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements in accordance with U.S. generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of management, including the Chief Executive and Principal Financial Officer, we evaluated the effectiveness of our internal control over financial reporting as of December 31, 2022 based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or the COSO Framework. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls. Our Chief Executive and Financial Officer concluded that as of such date, our internal controls over financial reporting were not effective.

Material Weaknesses in Internal Control Over Financial Reporting

A material weakness (as defined in Rule 12b-2 under the Exchange Act) is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Our management concluded that the following material weaknesses existed as of December 31, 2022:

- We identified ineffective information technology general controls in the areas of user access and segregation of duties related to certain information technology systems that support our financial reporting process. As a result, certain activity level controls were also deemed to be ineffective that are dependent on information derived from these information technology systems.

- In March 2023, we determined that we had made certain errors in the manner in which we recognized the deferred tax asset valuation allowance related to the acquisition of Elusys Therapeutics, Inc, with the result that net loss had been overstated in our quarterly filings for the periods ending June 30, 2022 through September 30, 2022. As a result, we determined that there were material errors in the financial statements that required a restatement of our Forms 10-Q for the quarterly periods ended June 30, 2022 through September 30, 2022. This was due to the inadequate design and implementation of controls to evaluate and monitor the accounting for income taxes.

- We identified a material weakness related to the ineffective design of certain management review controls across a significant portion of the Company's financial statement areas, particularly with regard to the precision of the review and evidence of review procedures performed.

Remediation of Material Weaknesses

In order to remediate these material weaknesses, we will change certain control activities over financial reporting to include, but are not limited to, the following: (i) evaluating and implementing enhanced process controls around user access management and segregation of duties, (ii) expanding the documentation over user access and system controls and enhancing the level of evidence maintained in management review controls and (iii) enhancing the design of existing controls and are implementing new controls over the accounting, processing, and recording of income tax.

We are committed to maintaining a strong internal control environment and implementing measures designed to help ensure that control deficiencies contributing to the material weaknesses are remediated as soon as possible.

Notwithstanding the material weaknesses described above, management has concluded that the consolidated financial statements included in this Annual Report on Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows in conformity with GAAP.

Changes in Internal Control over Financial Reporting

Other than as described above, there have been no other changes in our internal control over financial reporting that have occurred during the quarter ended December 31, 2022, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. **Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

Not Applicable.

PART III

Item 10. ***Directors, Executive Officers and Corporate Governance***

Below is certain information regarding our directors and executive officers.

Name	Age	Position	Served as an Officer or Director Since
Jeffrey Wolf	59	Chairman of the Board of Directors, Chief Executive Officer and President	2008
William L. Ostrander	55	Chief Financial Officer and Secretary	2019
John Monahan, Ph.D.	76	Director	2009
John K.A. Prendergast, Ph.D.	69	Director	2016
Edward B. Smith, III	47	Director	2010

Jeffrey Wolf, ***Chairman of the Board of Directors, Chief Executive Officer and President***

Mr. Wolf has served as our Chairman of the Board of Directors, Chief Executive Officer and President since our inception. He founded Heat Biologics in August 2008. Mr. Wolf served from June 1997 to March 2011, as managing director at Seed-One Ventures, LLC a venture firm focused on launching and growing exceptional healthcare companies from the ground up. Since founding Seed-One, Mr. Wolf has founded and run several biomedical companies. Mr. Wolf's start-ups include Avigen, Inc., a gene therapy company where he was a co-founder and director; TyRx Pharma, a Princeton-based company focused on the development of bio-compatible polymers where he was a co-founder and Chairman and Elusys, where he was for several years a co-founder, Chairman and Chief Executive Officer; and Generation One, a company focused on mobile-based collaborative care, where he was the founder, Chairman and Chief Executive Officer. Mr. Wolf received his M.B.A. from Stanford Business School, his J.D. from New York University School of Law and his B.A. from the University of Chicago, where he graduated with honors in Economics. Mr. Wolf serves as a director of several Seed-One portfolio companies and serves as a director of Theriva Biologics, Inc. (formerly known as Synthetic Biologics, Inc.), a clinical stage company developing therapeutics to protect the gut microbiome.

We selected Mr. Wolf to serve on our Board as our Chairman because he brings to the board extensive knowledge of the pharmaceutical and biotechnology industries. Having served in senior corporate positions in several biomedical

companies, he has a vast knowledge of the industry and brings to the board significant executive leadership and operational experience. His business experience provides him with a broad understanding of the operational, financial and strategic issues facing public companies and his service on other public company boards provides him with extensive corporate governance knowledge.

William L. Ostrander, ***Chief Financial Officer and Secretary***

Mr. Ostrander currently serves as our Chief Financial Officer, a position he was appointed to on January 4, 2021 and has served as our Secretary since September 25, 2019 when he joined our company as Vice President of Finance. Mr. Ostrander has over 22 years of experience in financial management at public and private companies. From November 2014 until joining our company, Mr. Ostrander served as Executive Director of Finance at Liquidia Technologies, Corporation, a publicly-traded biopharmaceutical company. Prior to that, he served as Senior Director of Finance and Accounting at KBI Biopharma, a biopharmaceutical contract services company. He also served as Manager of Finance at LexisNexis Risk Solutions, a data analytics solutions company. Prior to that, he served as Controller of Seisint Inc., a private information products company that was acquired by LexisNexis. He also served as Senior Manager, Finance and held other accounting and finance positions for Boca Research, a data communications hardware manufacturer. Mr. Ostrander holds a B.S. in Finance from Central Michigan University.

John Monahan, Ph.D., ***Director***

Dr. Monahan has served on our Board of Directors since November 2009. Dr. Monahan co-founded Avigen Inc. in 1992, a pharmaceutical company. Over a 12 year period as CEO of Avigen he raised over $235 million in several private and public financings including its IPO. From 1989 to 1992, he was VP of R&D at Somatix Therapy Corp., and from 1985 to 1989 he was Director of Molecular & Cell Biology at Triton Biosciences Inc. Prior to that, from 1982 to 1985, he was Research Group Chief, Department of Molecular Genetics, Hoffmann-LaRoche AG. and from 1975 to 1977 he was an instructor at Baylor College of Medicine located in Houston, Texas. He received his Ph.D. in Biochemistry in 1974 from McMaster University in Canada and his B.Sc. from University College in Dublin, Ireland in 1969. Dr. Monahan is a Scientific Advisory Board member of Agilis Biotherapeutics, LLC. Dr. Monahan currently is a board member of Theriva Biologics, Inc., and served as a scientific advisory consultant to Theriva Biologics, Inc. (formerly known as Synthetic Biologics, Inc.) from 2015 to November 10, 2020, prior to his appointment as a board member, and from 2010 through 2015 he was the Senior Executive Vice President of Research & Development at Theriva Biologics, Inc. He is also a board member of a number of Irish biotech companies including Genable Technologies Ltd., Cellix Ltd., Luxcel Biosciences Ltd., and GK Technologies, Inc. and from August 2016 until May 2021, also was a board member of Anixa Biosciences, Inc. (formerly ITUS Corporation).

We selected Dr. Monahan to serve on our Board because he brings extensive knowledge of the pharmaceutical and biologics industry. Having served in senior corporate positions in many medical companies he has a vast knowledge of the industry.

John K. A. Prendergast, Ph.D., ***Lead Director***

Dr. Prendergast has served on our Board since April 2016. Dr. Prendergast is co-founder of Palatin Technologies, Inc. (“Palatin”), a biopharmaceutical company developing targeted, receptor-specific peptide therapeutics for the treatment of diseases with significant unmet medical need and commercial potential (NYSE MKT: PTN). Dr. Prendergast has been Chairman of the Board of Palatin since June 14, 2000, and a director since August 1996. Dr. Prendergast has been president and sole stockholder of Summercloud Bay, Inc., an independent consulting firm providing services to the biotechnology industry, since 1993. He was previously a member of the board of the life science companies AVAX Technologies, Inc., Avigen, Inc. and MediciNova, Inc and previously executive chairman of the Board of Directors of Antyra, Inc., a privately-held biopharmaceutical firm. From October 1991 through December 1997, Dr. Prendergast was a managing director of The Castle Group Ltd., a medical venture capital firm. Dr. Prendergast received his M.Sc. and Ph.D. from the University of New South Wales, Sydney, Australia and a C.S.S. in administration and management from Harvard University.

We selected Dr. Prendergast to serve on our Board because he brings extensive industry experience in corporate development and finance in the life sciences field. His prior service on other publicly traded company boards provides experience relevant to good corporate governance practices.

Edward B. Smith, III, *Director*

Mr. Smith has served on our Board since November 2010. Since January 1, 2015, Mr. Smith has also been Managing Member of Aristar Capital Management, LLC, a New York-based investment firm founded in 2015. From April 14, 2017 through July 14, 2017, Mr. Smith served as the interim Chief Executive Officer and interim Chief Financial Officer of Agritech Worldwide, Inc. ("Agritech," formerly Z Trim Holdings, Inc.), a manufacturer of environmentally friendly agricultural functional ingredients. From January 2015 until May 2016, Mr. Smith also served as the Chief Executive Officer of Agritech and from 2009 through July 2017 he served as a board member of Agritech. From April 2005 through December 2014, Mr. Smith served as the Managing Partner of Brightline Capital Management, LLC ("BCM"), a New York-based investment firm founded in 2005. Prior to founding BCM, Mr. Smith worked at Gracie Capital from 2004-2005, GTCR Golder Rauner from 1999-2001 and Credit Suisse First Boston from 1997-1999. Mr. Smith holds a Bachelor of Arts in Social Studies from Harvard College and a Masters in Business Administration from Harvard Business School.

We selected Mr. Smith to serve on our Board because he brings a strong business background to our company, and adds significant strategic, business and financial experience. Mr. Smith's business background provides him with a broad understanding of the issues facing us, the financial markets and the financing opportunities available to us. His past service on other public company boards provides him with extensive corporate governance knowledge and insight into issues faced by companies similar to ours.

Committees of the Board of Directors

The Board of Directors has a standing Audit Committee, Compensation Committee, and Nominating and Governance Committee. The following table shows the directors who are currently members or Chairman of each of these committees.

Board Members	Audit Committee	Compensation Committee	Nominating and Governance Committee
Jeffrey Wolf	—	—	—
John Monahan, Ph.D.	Member	Chairman	Member
Edward B. Smith, III	Chairman	Member	Chairman
John K.A. Prendergast, Ph.D.*	Member	Member	Member

* Dr. Prendergast serves as our independent Lead Director.

Audit Committee

Our common stock is listed on the NYSE American. Under the rules of NYSE American, independent directors must comprise a majority of a listed company's board of directors and all members of our audit, compensation and nominating and governance committees must be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Exchange Act. Under the rules of the NYSE American, a director will only qualify as an "independent director" if, in the opinion of that company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director.

In order to be considered to be independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee: (1) accept, directly or indirectly, any consulting, advisory or other compensatory fee from the listed company or any of its subsidiaries or (2) be an affiliated person of the listed company or any of its subsidiaries.

Our Board undertook a review of its composition, the composition of its committees and the independence of each director. Based upon information requested from and provided by each director concerning his background, employment and

affiliations, including family relationships, our Board has determined that Dr. Monahan, Mr. Smith and Dr. Prendergast, representing three of our four directors, do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the rules of the NYSE American. In making this determination, our Board considered the relationships that each non-employee director has with us and all other facts and circumstances our Board deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director. We intend to comply with the other independence requirements for committees within the time periods specified above.

Dr. Monahan, Mr. Smith, and Dr. Prendergast currently serve as members of the Audit Committee. The Board has determined that Dr. Monahan, Mr. Smith and Dr. Prendergast are each "independent" in accordance with the NYSE American definition of independence and each is an "audit committee financial expert", as defined by the SEC regulations, and each has the related financial management expertise within the meaning of the NYSE American rules. The primary purpose of the Audit Committee is to act on behalf of the Board of Directors in its oversight of all material aspects of our accounting and financial reporting processes, internal controls and audit functions, including our compliance with Section 404 of the Sarbanes-Oxley Act of 2002. Pursuant to its charter, our Audit Committee reviews on an on-going basis for potential conflicts of interest, and approves if appropriate, all our "Related Party Transactions." For purposes of the Audit Committee Charter, "Related Party Transactions" shall mean those transactions required to be disclosed pursuant to SEC Regulation S-K, Item 404. In addition, the Audit Committee reviews, acts on and reports to the Board of Directors with respect to various auditing and accounting matters, including the selection of the Company's independent registered public accounting firm, the scope of the annual audits, fees to be paid to the independent registered public accounting firm, the performance of the Company's independent registered public accounting firm and the accounting practices of the Company and the Company's internal controls and legal compliance functions. The Committee also reviews, prior to publication, our quarterly earnings releases and our reports to the Securities and Exchange Commission on Forms 10-K and 10-Q. The Audit Committee operates pursuant to a written charter adopted by the Board of Directors, which is available on the Company's website at *www.nighthawkbio.com*. The charter describes the nature and scope of responsibilities of the Audit Committee.

Compensation Committee

Our Compensation Committee is comprised of Dr. Monahan, Mr. Smith, and Dr. Prendergast, each of whom is deemed to be independent in accordance with the NYSE American definition of independence. Compensation Committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. This Committee determines, approves, and reports to the Board of Directors on all elements of compensation of our executive officers. The Compensation Committee also has the power to prescribe, amend, and rescind rules relating to our stock incentive plans, to recommend the grant of options and other awards under the stock incentive plans, and to interpret the stock incentive plans.

The Compensation Committee operates under a formal charter that governs its duties and standards of performance. A copy of the charter is available on our website at *www.nighthawkbio.com*.

Our Compensation Committee annually reviews the compensation program for our Chief Executive Officer and other members of senior management and then makes recommendations to the full board for determination. In each case, the Committee takes into account the results achieved by the executive, his or her future potential, and his or her scope of responsibilities and experience. During our fiscal year ended December 31, 2022, the Committee evaluated the performance of our executives and considered the compensation levels and equity programs at comparable companies and related industries and the analysis of its outside consultant before it made its compensation recommendations to the full board, including recommendations regarding salary increases, awards of cash bonuses and awards of stock options.

The Committee administers our equity incentive plans, including review and recommendation of long-term incentive compensation for each executive, director and employee, including grants of stock options. The Committee believes that this long-term incentive compensation aligns the interests of our executives with those of our stockholders and furthers executive retention.

The Committee also reviews and recommends to the Board of Directors appropriate director compensation programs for service as directors, committee chairs and committee members.

Nominating and Governance Committee

The Nominating and Governance Committee is comprised of Dr. Monahan, Mr. Smith, and Dr. Prendergast.

The functions performed by the Nominating and Governance Committee include:

- recommending to the Board of Directors individuals for appointment to vacancies on any committee of the Board of Directors;
- recommending to the Board of Directors regarding any changes to the size of the Board of Directors or any committee;
- reporting to the Board of Directors on a regular basis; and
- performing any other duties or responsibilities expressly delegated to the committee by the Board of Directors relating to board or committee members.

Candidates for director should have certain minimum qualifications, including the ability to understand basic financial statements, being over 21 years of age, having relevant business experience (taking into account the business experience of the other directors), and having high moral character. The Committee retains the right to modify these minimum qualifications from time to time.

In evaluating an incumbent director whose term of office is set to expire, the Nominating and Governance Committee reviews such director's overall service to the Company during such director's term, including the number of meetings attended, level of participation, quality of performance, and any transactions with the Company engaged in by such director during his term.

When selecting a new director nominee, the Committee first determines whether the nominee must be independent for NYSE American purposes or whether the candidate must qualify as an "audit committee financial expert." The Committee then uses its network of contacts to compile a list of potential candidates, but may also engage, if it deems appropriate, a professional search firm to assist in the identification of qualified director candidates. The Committee also will consider nominees recommended by our stockholders. The Nominating and Governance Committee does not distinguish between nominees recommended by our stockholders and those recommended by other parties. The Committee evaluates the suitability of potential nominees, taking into account the current board composition, including expertise, diversity and the balance of inside and independent directors. The Nominating and Governance Committee endeavors to establish a diversity of background and experience in a number of areas of core competency, including business judgment, management, accounting, finance, knowledge of our industry, strategic vision, research and development and other areas relevant to our business.

In considering any person recommended by one of our stockholders, the Committee will look for the same qualifications that it looks for in any other person that it is considering for a position on the Board of Directors. The Nominating and Governance Committee operates under a formal charter that governs its duties and standards of performance. A copy of the charter is available on our website at *www.nighthawkbio.com*.

Ad Hoc Committees

From time to time we establish ad hoc committees to address particular matters.

Board Leadership Structure

Mr. Wolf, the Company's Chief Executive Officer, also serves as Chairman of the Board of Directors. We have a separate, independent Lead Director. Although we do not have a formal policy addressing the topic, we believe that when the

Chairman of the Board is an employee of the Company or otherwise not independent, it is important to have a separate Lead Director, who is an independent director.

Dr. Prendergast serves as the Lead Director. In that role, he presides over the Board's executive sessions, during which our independent directors meet without management, and he serves as the principal liaison between management and the independent directors of the Board. The Lead Director also:

- confers with the Chairman of the Board regarding Board meeting agenda;
- chairs meetings of the independent directors including, where appropriate, setting the agenda and briefing the Chairman of the Board on issues discussed during the meeting;
- oversees the annual performance evaluation of the CEO;
- consults with the Nominating and Governance Committee and the Chairman of the Board regarding assignment of Board members to various committees; and
- performs such other functions as the Board may require.

We believe the combination of Mr. Wolf as our Chairman of the Board and an independent director as our Lead Director is an effective structure for our company. The division of duties and the additional avenues of communication between the Board and our management associated with this structure provide the basis for the proper functioning of our Board and its oversight of management.

Risk Oversight

The Board has an active role, as a whole and also at the committee level, in overseeing management of our company's risks. The Board regularly reviews information regarding our company's strategy, finances and operations, as well as the risks associated with each. The Audit Committee is responsible for oversight of Company risks relating to accounting matters, financial reporting, internal controls and legal and regulatory compliance. The Audit Committee undertakes, at least annually, a review to evaluate these risks. The members then meet separately with management responsible for such area, including our Chief Financial Officer, and report to the Audit Committee on any matters identified during such discussions with management. In addition, the Compensation Committee considers risks related to the attraction and retention of talent as well as risks relating to the design of compensation programs and arrangements. In addition, the Nominating and Governance Committee manages risks associated with the independence of the Board. While each committee is responsible for evaluating certain risks and overseeing the management of such risks, the entire Board is regularly informed through committee reports about such risks. The full Board considers strategic risks and opportunities and regularly receives detailed reports from the committees regarding risk oversight in their respective areas of responsibility.

Code of Business Conduct and Ethics

We have long maintained a Code of Business Conduct and Ethics that is applicable to all of our directors, officers and employees. We undertake to provide a printed copy of these codes free of charge to any person who requests. Any such request should be sent to our principal executive offices attention: Corporate Secretary. The code is posted on our website at www.nighthawkbio.com.

Item 11. Executive Compensation

We are a "smaller reporting company" and the following compensation disclosure is intended to comply with the requirements applicable to smaller reporting companies. Although the rules allow us to provide less detail about our executive compensation program, the Compensation Committee is committed to providing the information necessary to help stockholders understand its executive compensation-related decisions. Accordingly, this section includes supplemental narratives that describe the 2022 executive compensation program for our named executive officers.

Set forth below is the compensation paid or accrued to our Named Executive Officers during the years ended December 31, 2022 and 2021:

Summary Compensation Table

Name and Principal Position	Year	Salary	Bonus	Stock Awards (1)	Options	Other	Total
Jeffrey Wolf	2022	$ 561,600	$ 281,000	$ —	$ 2,328,529 (3)	$ —	$ 3,171,129
Chairman and Chief Executive Officer	2021	$ 539,623	$ 270,000	$ 2,633,525 (2)	$ 1,964,424 (4)	$ 500,000 (5)	$ 5,907,572
William L. Ostrander	2022	$ 350,000	$ 126,241	$ —	$ 401,471 (6)	$ —	$ 877,712
Chief Financial Officer	2021	$ 274,817	$ 96,250	$ —	$ 451,602 (7)	$ —	$ 822,669

(1) For all stock options and stock awards, the values reflect the aggregate grant date fair value computed in accordance with FASB ASC 718. Assumptions made in the calculation of these amounts are described in Note 12 to the Company's audited consolidated financial statements for the years ended December 31, 2022 and 2021.
(2) Mr. Wolf was issued 288,100 shares of restricted stock on January 4, 2021 and 246,305 shares of restricted stock on December 13, 2021.
(3) Mr. Wolf was issued 2,843,137 option awards on December 7, 2022.
(4) Mr. Wolf was issued 147,980 option awards on January 4, 2021 and 42,216 option awards on August 2, 2021 for the subsidiary plans as described in Note 12 to the Company's audited financial statements for the years ended December 31, 2021 and 2020, 161,774 option awards on December 13, 2021 and 231,987 option awards on December 30, 2021.
(5) This is a special bonus to cover the estimated taxes from the 246,305 restricted share award granted on December 13, 2021.
(6) Mr. Ostrander was issued 490,196 option awards on December 7, 2022.
(7) Mr. Ostrander was issued 51,487 option awards on January 4, 2021 and 2,127 option awards on August 2, 2021 for the subsidiary plans as described in Note 12, to the Company's audited financial statements for the years ended December 31, 2021 and 2020, and 68,807 option awards on December 13, 2021.

Narrative Disclosure To Summary Compensation Table

Overview of Our Compensation Program

A. Philosophy and Objectives

Our primary objective with respect to executive compensation is to design compensation programs that will align executives' compensation with our overall business strategies for the creation of stockholder value and attract, motivate and retain highly qualified executives.

Our executive compensation program is based on the following philosophies and objectives:

- *Compensation Should Align with Stockholders' Interests* — The Compensation Committee and our Board believes that executives' interests should be aligned with those of the stockholders. Executives are granted restricted stock and stock options so that the majority of their total compensation is tied directly to the value realized by our stockholders. Executive bonuses are tied directly to company strategy and operational execution which contributed to our success as a whole.

- *Compensation is Competitive* — The Compensation Committee and Board seek to provide a total compensation package that attracts, motivates and retains the executive talent that we need in order to maximize the return to stockholders and execute our operational and scientific strategy. To accomplish this objective, executive compensation is reviewed annually to ensure that compensation levels are competitive and reasonable in relation to comparable companies with which we compete for talent.

- *Compensation Motivates and Rewards the Achievement of Goals* —Our executive compensation program is designed to appropriately reward both individual and collective performance that meets and exceeds our annual and long-term strategic and operational goals. To accomplish this objective, a substantial percentage

of total compensation is variable and/or "at risk", both through annual incentive compensation and the granting of long-term incentive awards.

We seek to achieve these objectives through three key compensation elements:

- a base salary;
- a performance-based annual cash incentive (i.e., annual cash incentive compensation); and
- long term equity awards.

In order to enhance the Compensation Committee's ability to carry out its responsibilities effectively, as well as maintain strong links between executive pay and performance, the Compensation Committee reviews compensation information for each Named Executive Officer, which includes the following information:

- the annual compensation and benefit values that are being offered to each executive;
- the value of all outstanding equity awards; and
- discussions with our Chairman, Chief Executive Officer and other senior management in connection with compensation matters, as well as compensation consultants and other advisors from time to time.

B. Compensation Administration

Roles and Responsibilities of Compensation Committee

The primary purpose of the Compensation Committee is to conduct reviews of our general executive compensation policies and strategies and oversee and evaluate our overall compensation structure and programs. The Compensation Committee confirmed that total compensation paid to our Named Executive Officers during the year ended December 31, 2022, was reasonable and competitive. The following were our Named Executive Officers for the year ended December 31, 2022: Jeffrey Wolf, our Chief Executive Officer and William L. Ostrander, our Chief Financial Officer (collectively, our "Named Executive Officers"). Responsibilities of the Compensation Committee include, but are not limited to:

- Establishing on an annual basis performance goals and objectives for purposes of determining the compensation of our Chief Executive Officer and other senior executive officers, evaluating the performance of such officers in light of those goals and objectives, and setting the compensation level for those officers based on this evaluation.
- Recommending to the Board the compensation for independent Board members (including retainer, committee and committee chair's fees, stock options and components of compensation as appropriate).
- Reviewing the competitive position of, and making recommendations to the Board with respect to, the cash-based and equity-based compensation plans and other programs relating to compensation and benefits.
- Reviewing our financial performance and operations as well as our major benefit plans.
- Overseeing the administration of our equity and other executive compensation plans, including recommending to the Board of Directors the granting of equity awards under those plans, and the approval or disapproval of the participation of individual employees in those plans.
- Reviewing and approving for our Chief Executive Officer and other senior executive officers: (a) employment agreements; (b) severance agreements; (c) change in control agreements/provisions; and (d) any other material perquisites or other in-kind benefits.

Additional information regarding the Compensation Committee's responsibilities is set forth in its charter, which is posted on our website at *www.nighthawkbio.com*.

Use of Compensation Consultant

The Compensation Committee retained Meridian Compensation Partners, LLC ("Meridian"), a nationally-recognized global human resources consulting firm, as its independent compensation advisor in 2021 and 2022. Meridian principally provides analysis, advice and recommendations regarding named executive officer and non-employee director compensation as well as guidance and considerations on our long-term incentive program for all eligible employees including salary, bonus, benefits and equity awards for our executive officers and retainers, meeting fees and equity awards for our directors. Meridian reports to the Chairman of the Compensation Committee and has direct access to the other members of the Compensation Committee. Meridian does not provide any other services to the Company other than in its role as the Compensation Committee's independent advisor. The Compensation Committee has evaluated Meridian's reports and, as they considered appropriate to achieve the best interests of the Company and its stockholders, implemented the recommendations.

The Compensation Committee considered whether Meridian had any conflicts of interest in advising the Committee. In doing so, the Compensation Committee considered whether Meridian had been providing services of any other nature to us; the amount of fees received from us by Meridian; the policies and procedures adopted by Meridian that have been designed to prevent conflicts of interest; whether any business or personal relationships existed between the consultants employed by Meridian who worked on our matters and any member of the Compensation Committee; whether any business or personal relationship existed between such consultants and any of our executive officers; and whether Meridian or such consultants hold any of our common stock. Upon evaluating such considerations, the Committee found no conflicts of interest in Meridian advising the Compensation Committee.

Role of the Chief Executive Officer

Our Chief Executive Officer, Mr. Wolf, makes recommendations to the Compensation Committee regarding the compensation of our other named executive officers. Mr. Wolf does not participate in any discussions or processes concerning his own compensation and participates in a non-voting capacity in discussions or processes concerning the compensation of our Chief Financial Officer and other members of management.

Compensation Committee Consideration of Shareholder Advisory Votes

At our annual meeting of stockholders held on September 15, 2022, we submitted our executive compensation program that covers our Named Executive Officers to our stockholders for a nonbinding advisory vote. Our executive compensation program did not receive the support of holders of a majority of the shares that voted on this proposal at the annual meeting of stockholders (including abstentions but excluding broker non-votes). In response to the vote, with respect to 2022 compensation, we did not grant Mr. Wolf shares of restricted stock which in prior years resulted in a tax being required to be paid upon grant and resulted in a special bonus being granted to Mr. Wolf to cover taxes and instead we granted him options, which are not taxed upon grant and therefore we did not issue a special bonus to cover taxes. In addition, at our annual meeting of stockholders held on July 23, 2019, our stockholders voted on an advisory basis with respect to the frequency of future advisory votes on our executive compensation program. Holders of a majority of the shares that voted on this proposal at the meeting (including abstentions but excluding broker non-votes) expressed their preference for an advisory vote every three years. Accordingly, we intend to hold an annual advisory vote on executive compensation at our annual meeting of stockholders in 2023.

C. Competitive Considerations

In making compensation decisions with respect to each element of compensation for our Named Executive Officers, the Compensation Committee believes that it is important to be informed as to the competitive market practices at similarly situated public companies. In setting 2022 target total direct compensation levels for our Named Executive Officers, the Compensation Committee relied in part on reports prepared by Meridian effective December 7, 2022. Meridian conducted a comprehensive assessment of our Named Executive Officer's pay program relative to a peer group of 17 similarly-

situated public companies that were pre-revenue cancer therapeutics companies with market capitalizations between $150 million and $1.6 billion. The elements of the Named Executive Officer's pay programs assessed against peer group practices for 2022 included: (1) base salary, (2) target annual incentives (bonuses), (3) target total cash compensation, (4) long-term incentives and (5) target total direct compensation. In addition, Meridian also provided an analysis of our pay mix relative to peer group practices. Meridian's assessment included our Chief Executive Officer and Chief Financial Officer. The Compensation Committee considered the competitive market pay data of our peer group that was included in Meridian's analysis and relevant survey data when setting each Named Executive Officer's compensation.

The Compensation Committee's desired competitive positioning and its pay program decision-making (in terms of both compensation levels and overall mix of pay which is focused on variable or "at risk" compensation) is reflective of our pay for performance philosophy and provides alignment of executive interests with those of our stockholders.

We believe that, given the industry in which we operate and our compensation philosophy and objectives, our approach to executive compensation is sufficient to retain our current executive officers and to hire new executive officers when and as required.

D. Components of Compensation

The allocation between cash and non-cash named executive officer compensation is influenced by subjective and objective factors considered by the Compensation Committee and is intended to reflect the Compensation Committee's determination of the appropriate compensation mix among base pay, annual cash incentives and long-term equity incentives for each named executive officers.

1. Base Salaries

We provide our Named Executive Officers a competitive level base salary commensurate with their position, responsibilities and experience. In setting the base salary, the Compensation Committee considers a number of factors including, peer group market data, our company performance and each Named Executive Officer's role and responsibilities, experience and individual performance. We design base pay to be competitive in attracting and retaining top talent.

Initial base salaries for the Named Executive Officers were set by their initial respective employment contracts and are reviewed annually by the Compensation Committee. The Compensation Committee determined that our Chief Executive's Officer's and Chief Financial Officer's 2022 base salary levels were below market practice of our peer group; therefore the base salaries were increased in January 2022. The 2021, 2022, and 2023 base salaries for our current Named Executive Officers are as follows:

Named Executive Officer	Base Salary 2021	Base Salary 2022	Base Salary 2023
Jeffrey Wolf, Chief Executive Officer	$ 540,000	$ 561,600	$ 575,000
William L. Ostrander, Chief Financial Officer	$ 275,000	$ 350,000	$ 375,000

2. Bonuses

For 2022, the Compensation Committee recommended to the full Board of Directors the following bonus payouts to our Named Executive Officers:

- Jeffrey Wolf bonus. The Board approved the Compensation Committee's recommendation that Mr. Wolf receive a $281,000 cash bonus (50% of gross salary increased to 55% in December 2022).

- William Ostrander bonus. The Board approved the Compensation Committee's recommendation that Mr. Ostrander receive a $122,500 cash bonus (35% of gross base salary increased to 40% in December 2022).

The employment agreement with Jeffrey Wolf that was in effect during 2021 and 2022 provided that he was eligible for a cash performance bonus of up to fifty percent (50%) of his base salary which was increased to fifty five (55%) in December 2022 as well an equity bonus in the sole discretion of the Board of Directors, with the actual amount of any such bonus increased or decreased in the sole discretion of the Board of Directors. William L. Ostrander's employment agreement that was in effect for 2022 provided for an annual bonus of up to thirty-five percent (35%) of his base salary which was increased to forty (40%) in December 2022 as well as an equity bonus in the sole discretion of the Board of Directors, with the actual amount of any such bonus increased or decreased in the sole discretion of the Board of Directors. The Compensation Committee believes that the granting of a bonus is appropriate to motivate the Named Executive Officers. The Compensation Committee focuses on individual performance, which enables the Compensation Committee to differentiate among executives and emphasize the link between personal performance and compensation. Although the Compensation Committee does not use any fixed formula in determining bonuses, it does link them to financial objectives of importance to it.

3. Long-Term Incentives

A substantial portion of the Named Executive Officer's total compensation is in the form of equity-based compensation to encourage retention and better align the interests of the Named Executive Officers with the stockholders. The Compensation Committee determined to grant a combination of stock options and restricted stock awards to the current Named Executive Officers and other key employees as the primary long-term incentive vehicles.

In 2021 and 2022 the Compensation Committee determined the size of equity awards granted to the Named Executive Officers based on the following factors: accounting impact, peer group market data, our company performance and each Named Executive Officer's position, role and responsibilities, experience, tenure, individual performance and pro forma percent ownership. In addition, the Compensation Committee considered that there was a lack of realizable value from their prior awards since substantially all of the prior awards were of significant low value and/or underwater or held low value. The Compensation Committee also sought to better align the Chief Executive Officer's equity ownership interest in our company with that of other chief executive officers of our peer group companies. The Compensation Committee determined in December 2022 to grant a combination of options to the Chief Executive Officer and the Chief Financial Officer.

On December 7, 2022, Mr. Wolf and Mr. Ostrander were granted a ten-year option to purchase 2,843,137 and 490,196 shares of our common stock respectively of which one third vests on January 2023 and the balance vests pro-rata over 36 months.

In January 2021, Mr. Wolf was granted 288,100 restricted stock awards as part of his long-term incentive compensation for the year ended December 31, 2021. On December 13, 2021, Mr. Wolf was also awarded 246,305 shares of restricted common stock, half of which vested immediately and the remaining half vested on January 1, 2022. The 246,305 shares of restricted stock were awarded pursuant to the terms of an amended and restated restricted stock agreement. The restricted stock awards vested 50% immediately and 50% on the one-year anniversary of the grant date. The restricted stock agreements with respect to the foregoing grants, among other things, prohibit transfers of the restricted stock prior to the two-year anniversary of the grant date other than by will, laws of descent and distribution and in the event of death. In addition, sales or transfers made after the two year anniversary of the grant date are subject to the right of us to buy back the stock at any time that the holder desires to sell the restricted stock at a price equal to the lower of the closing price per share and 17 times the closing price per share on the date of grant with respect to the 2020 and 2021 grants and 10 times the closing price per share on the date of grant with respect to the 2021 grants. In January 2021, Mr. Wolf was also granted an option to purchase up to 147,980 shares of common stock that vest on the two-year anniversary of the grant date. On December 13, 2021 and December 31, 2021, Mr. Wolf was awarded an option to purchase 161,774 and 231,987 shares of our common stock, respectively.

On December 13, 2021, Mr. Ostrander was awarded a ten-year option to purchase 68,807 shares of our common stockMr. Ostrander was issued 51,487 option awards on January 4, 2021.

On August 2, 2021, the Board of Directors adopted the Heat Biologics, Inc. 2021 Subsidiaries Stock Incentive Plan (the "SSIP"). The SSIP is designed to compensate employees of our subsidiaries based on their responsibilities and for their

contributions to the successful achievement of certain corporate goals and objectives of such subsidiaries and to share the success and risks of such subsidiaries based upon achievement of business goals. In addition, in August we issued to Mr. Wolf options under the SSIP to purchase 10,526, 10,638, 10,526 and 10,526 shares of common stock of Skunkworx, Scorpius, Abacus, and Blackhawk, respectively and we issued Mr. Ostrander 2,127 shares of common stock of Scorpius, all subject to forfeiture if the Subsidiary Plan was not approved by our stockholders at our annual meeting so stockholders. At our Annual Meeting of Stockholders held on September 15, 2021, the SSIP was approved by our stockholders. Skunkworx, Scorpius, Abacus, and Blackhawk currently have 200,100, 200,100, 200,000 and 200,000 shares outstanding, respectively.

The Compensation Committee does not seek to time equity grants to take advantage of information, either positive or negative, about our company that has not been publicly disclosed. Option grants are effective on the date the award determination is made by the Compensation Committee, and the exercise price of options is the closing market price of our common stock on the business day of the grant or, if the grant is made on a weekend or holiday, on the prior business day.

Outstanding Equity Awards at Fiscal Year-End (December 31, 2022)

	Option Awards				Stock Awards	
Name and Principal Position	**Number of securities underlying unexercised options/ exercisable**	**Number of securities underlying unexercised options/ unexercisable**	**Option exercise price**	**Option expiration date**	**Number of shares or units of stock that have not vested**	**Market value of shares or units of stock that have not vested**
Jeffrey Wolf	1,428 (1)	—	$ 603.40	06/11/2024	—	—
Chairman and	178 (2)	—	$ 317.10	1/12/2025	—	—
Chief Executive Officer	1,343 (3)	—	$ 172.90	1/11/2026	—	—
	1,071 (4)	—	$ 60.20	12/30/2026	—	—
	1,785 (5)	—	$ 60.90	1/03/2027	—	—
	8,508 (6)	—	$ 27.79	1/07/2028	—	—
	114,285 (7)	—	$ 7.42	1/02/2029	—	—
	285,714 (8)	—	$ 14.49	7/28/2030	—	—
	201,728 (9)	—	$ 8.40	8/24/2030	—	—
	— (10)	147,980	$ 5.67	1/04/2031	—	—
	10,526 (11)	—	$ 1.67	8/02/2031	—	—
	10,526 (12)	—	$ 0.01	8/02/2031	—	—
	10,526 (13)	—	$ 0.01	8/02/2031	28,286 (14)	$ 22,912 (14)
	— (15)	161,774	$ 4.06	12/13/2031	—	—
	— (16)	231,987	$ 4.06	12/30/2031	—	—
	— (17)	2,843,137	$ 1.02	12/07/2032	—	—
William L. Ostrander	6,473 (18)	2,009	$ 3.64	9/25/2029	—	—
Chief Financial Officer	14,731 (19)	6,697	$ 4.20	3/12/2030	—	—
	34,324 (20)	17,163	$ 5.67	1/04/2031	—	—
	17,201 (21)	51,606	$ 4.06	12/13/2031	—	—
	— (22)	490,196	$ 1.02	12/07/2032	—	—

(1) All shares are fully vested as of January 2016.
(2) All shares are fully vested as of December 2018.
(3) All shares are fully vested as of December 2019.
(4) All shares are fully vested as of December 2020.
(5) All shares are fully vested as of January 2021.
(6) Issued January 7, 2018, these shares vest over a 46-month period and will be fully vested in January 2022.

(7) Issued January 2, 2019, 57,142 shares vested on January 2, 2019; 34,285 shares vested on January 2, 2020; 11,429 shares vested on January 2, 2021 and 11,429 shares vested on January 2, 2022.
(8) All shares vested on July 28, 2020.
(9) All shares vested on August 24, 2020.
(10) Issued January 4, 2021, these shares fully vested on January 4, 2023.
(11) All shares fully vested in August 2022.
(12) All shares fully vested in August 2022.
(13) All shares fully vested in August 2022.
(14) Issued January 2, 2020, 141,428 restricted stock units vested January 2, 2020; 84,858 vested January 2, 2021; 28,285 vested January 2, 2022; and 28,286 vested January 2, 2023. Amount represents the value of shares at December 31, 2022. Market value based on closing price of the common stock of $0.81 on December 31, 2022.
(15) Issued December 13, 2021, these shares fully vest on December 13, 2023.
(16) Issued December 30, 2021, these shares fully vest on December 30, 2023.
(17) Issued December 7, 2022, 947,712 vest on January 3, 2023 and 1,895,425 vest on a pro-rata basis over 36 months.
(18) Issued September 25, 2019, these shares vest over a 48-month period and will be fully vested in September 2023.
(19) Issued March 12, 2020, these shares vest over a 48-month period and will be fully vested in March 2024.
(20) Issued January 4, 2021, 17,162 shares vested on January 4, 2021; 17,162 vested on January 4, 2022; and 17,163 vested on January 4, 2023.
(21) Issued December 13, 2021, these shares vest over a 48-month period and will be fully vested in December 2025.
(22) Issued December 7, 2022, 163,398 vest on January 3, 2023 and 326,798 vest on a pro-rata basis over 36 months.

Employment Agreements

On December 18, 2009, we entered into an employment agreement with Jeffrey Wolf to act as our Chief Executive Officer, which agreement was amended on November 22, 2011, and further amended on each of January 20, 2014, January 11, 2016, January 1, 2017 and January 2, 2020 (the "Prior Agreement"). Pursuant to the employment agreement in effect during 2020, Mr. Wolf received an annual base salary of $540,000 per year. He was also eligible to receive, at the sole discretion of the board, an additional cash performance-based bonus equal to up to 50% of his then outstanding base salary at the end of each year and a discretionary equity award, with the actual amount of his bonus to be increased or decreased in the sole discretion of the Board of Directors. In addition, he was also eligible to receive certain options to purchase 2% of our fully diluted equity at an exercise price equal to the then current market price if our stock is traded on a nationally recognized exchange or Nasdaq and our market capitalization is at least $500 million for at least 15 business days, which milestone was achieved in July 2020.

On January 4, 2021, we entered into a new employment agreement with Jeffrey Wolf (the "Wolf Agreement") to continue to serve as our Chief Executive Office and President, which agreement replaces the Prior Agreement agreement. Pursuant to the terms of the Wolf Agreement, Mr. Wolf will receive an annual base salary of $540,000 per year which was amended in December 2022 to $575,000. He also may receive, at the sole discretion of the board, an additional cash performance-based bonus equal to up to fifty percent (50%) of his then outstanding base salary at the end of each year (which was amended to fifty five (55%) in December 2022) and a discretionary equity award, with the actual amount of his bonus to be increased in the sole discretion of the Board of Directors. In addition, he is to receive (i) an incentive cash bonus in an amount equal to 2% of the Transaction Consideration (as defined in the agreement) paid in connection with the consummation of a Change in Control (as defined in the agreement), provided that such Change in Control results in the stockholders of the Company receiving (or being entitled to receive, whether upon the consummation of the Change in Control or at a future date) transaction consideration worth at least 125% of the average closing trading price of the Company's common stock during the 20 trading-day period immediately preceding the consummation of the Change in Control and (ii) an equity bonus in the form of additional stock options or restricted stock units or shares of restricted stock equal to 2% of the total fully-diluted equity of the Company if the market capitalization of the Company is equal to or exceeds a valuation of $500 million or more for fifteen (15) business days or longer. In addition, subject to certain condition, Mr. Wolf may also be entitled to receive equity in newly formed subsidiaries of the Company. If the Wolf Agreement is terminated for death or disability (as defined in the Wolf Agreement), he (or his estate in the event of death) will receive any unpaid base salary through the date of death or disability, any unpaid target bonus earned through date of termination and he shall be entitled to exercise any vested awards for the shorter of 24 months after termination and the remaining term of the award. If Mr. Wolf's employment is terminated by us other than for Cause (as defined in the

agreement) or by him for Good Reason (as defined in the Wolf Agreement), he will receive a payment of an amount equal to one (1) times his annual base salary plus his annual target bonus amount for the year of termination assuming payment in full of the annual target bonus, accelerated vesting of all unvested equity awards, extension of the time period in which to exercise awards equal to the lesser of 24 months after termination or the remaining term of the award and payment of COBRA premiums for the earlier or twelve months, the date he becomes eligible for other group benefits or his rights to COBRA expire. In addition, in the event the Company terminates Mr. Wolf's employment upon or at any time in connection with a Change of Control Transaction (as defined in the Wolf Agreement), Mr. Wolf is entitled to a lump sum cash payment equal to 24 months of his current base pay, a cash payment equal to a pro-rated amount of his target annual target bonus for the year preceding termination, payment in full for COBRA for 12 months following termination and immediate vesting of the unvested portion of any outstanding equity awards and a period to exercise the awards equal to the lesser of 12 months after termination or the remaining term of the award. If within one year after the occurrence of a Change in Control, the Executive terminates his employment for Good Reason or the Company terminates his employment for any reason other than death, disability of cause Mr. Wolf is entitled to a lump sum cash payment equal to 24 months of his current base pay, a cash payment equal to his full target annual target bonus, payment in full for COBRA for 12 months following termination and immediate vesting of the unvested portion of any outstanding equity awards and a period to exercise the awards equal to the lesser of 24 months after termination or the remaining term of the award. Under the Wolf Agreement, Mr. Wolf has also agreed to non-competition provisions.

Effective September 24, 2019 we entered into an offer letter with Mr. Ostrander to serve as our Vice President of Finance and Secretary. Effective January 4, 2021, Mr. Ostrander, was promoted to Chief Financial Officer. In connection with Mr. Ostrander's new role as our Chief Financial Officer, effective January 4, 2021, we entered into an amendment (the "Ostrander Amendment") to the offer letter, dated September 23, 2019, which had been amended on January 1, 2020. Pursuant to the Ostrander Amendment, Mr. Ostrander's base salary was increased from $226,600 to $275,000 and his bonus target was increased to 30% of his base salary. Mr. Ostrander was also eligible for other benefits consistent with those received by our other executives.

On December 15, 2021, we entered into a four-year employment agreement, effective as of January 1, 2022, with William Ostrander (the "Ostrander Employment Agreement"), to continue to serve as our Chief Financial Officer and Corporate Secretary. The Ostrander Employment Agreement replaced the Offer Letter entered into by us with Mr. Ostrander, dated September 23, 2019, as amended on January 1, 2020 and January 4, 2021. Pursuant to the Ostrander Employment Agreement, Mr. Ostrander is entitled to an annual base salary of $350,000 which was amended in December 2022 to $375,000 and will be eligible for discretionary performance bonus payments of thirty-five percent (35%) (which was amended to forty (40%) in December 2022) of his annual base salary. If Mr. Ostrander's employment is terminated for any reason, he or his estate as the case may be, will be entitled to receive the accrued base salary, vacation pay, expense reimbursement and any other entitlements accrued by him to the extent not previously paid (the "Accrued Obligations"); provided, however, that if his employment is terminated by us without Just Cause (as defined in the Ostrander Employment Agreement) then in addition to paying the Accrued Obligations, (i) we shall continue to pay his then current base salary for a period of six (6) months; and (ii) the vesting on all unvested options shall be accelerated so that all options shall become fully vested. If his employment is terminated within one year of a Change of Control (as defined in the 2018 Stock Incentive Plan), he will be paid his then current base salary for a period of six (6) months.

2022 Director Compensation

Compensation of Directors

The following table sets forth information for the fiscal year ended December 31, 2022 regarding the compensation of our directors who at December 31, 2022 were not also named executive officers.

Name and Principal Position	Fees Earned or Paid in Cash	Option Awards	Stock Awards	Totals
John Monahan, Ph.D. (1)	$ 81,500	$ 82,486	$ —	$ 163,986
John K. A. Prendergast, Ph.D. (2)	$ 296,750	$ 164,972	$ —	$ 461,722
Edward B. Smith, III (1)	$ 92,500	$ 82,486	$ —	$ 174,986

1) The stock options are computed in accordance with FASB ASC 718 and reflect the value of an option to purchase 101,960 shares of common stock granted on December 7, 2022 to Dr. Monahan and Mr. Smith that vest pro-rata on a monthly basis over 12 months, subject to continued service as a board member through such date. The fair value of the options was calculated in accordance with FASB ASC 718, and the assumptions used are described in Note 11 to the Company's audited consolidated financial statements for the years ended December 31, 2022 and 2021.

2) The stock options are computed in accordance with ASC 718 and reflect the value of an option to purchase 203,921 shares of common stock granted on December 7, 2022 to Dr. Prendergast that vest pro-rata on a monthly basis over 12 months, subject to continued service as a board member through such date. The fair value of the options was calculated in accordance with ASC 718, and the assumptions used are described in Note 11 to the Company's audited consolidated financial statements for the years ended December 31, 2022 and 2021.

As of December 31, 2022, the following table sets forth the number of aggregate outstanding option awards held by each of our directors who were not also named executive officers:

Name	Aggregate Number of Option Awards	Aggregate Number of Stock Awards
John Monahan, Ph.D.	245,655	—
John K. A. Prendergast, Ph.D.	339,605	5,715
Edward B. Smith, III	245,655	—

Our Compensation Committee conducted an evaluation of the compensation of the members of our Board of Directors for 2022 with assistance from Meridian. Based on Meridian's review, the Compensation Committee determined that the director pay program was consistent with competitive market practices (relative to NightHawk's publicly traded peer group at that time), aligned with our overall philosophy and approach to director pay and reflective of desired competitive positioning. For 2022 after consultation with Meridian, it was determined that directors who are not employees will receive an annual cash fee of $55,000 as well as a cash fee of $8,000 for service on the Audit Committee and $5,000 for service on each of the Compensation Committee and the Nominating and Governance Committee. In addition, the Chairman of each of the Audit, Compensation and Nominating and Governance Committees will each receive an additional cash fee of $12,500, $8,500 and $7,000, respectively. The lead independent director receives a monthly fee of $14,000 for his services as lead independent director.

Item 12. ***Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.***

The following table sets forth information, as of March 30, 2023, or as otherwise set forth below, with respect to the beneficial ownership of our common stock (i) all persons known to us to be the beneficial owners of more than 5% of the outstanding shares of our common stock, (ii) each of our directors and our executive officer named in the Summary Compensation Table, and (iii) all of our directors and our executive officer as a group. As of March 30, 2023, we had 26,049,209 shares of common stock outstanding.

Security Ownership of Management and Certain Beneficial Owners

Unless otherwise indicated the mailing address of each of the stockholders below is c/o Heat Biologics, Inc., 627 Davis Drive, Suite 300, Morrisville, North Carolina 27560. Except as otherwise indicated, and subject to applicable community property laws, except to the extent authority is shared by both spouses under applicable law, the Company believes the

persons named in the table have sole voting and investment power with respect to all shares of common stock held by them.

Name of Beneficial Owner	Common Stock	Shares subject to Options (1)	Total Number of Shares Beneficially Owned	Percentage Ownership
Executive Officers & Directors				
Jeffrey Wolf (Chairman of the Board of Directors, Chief Executive Officer and President) (2)	1,094,045 (3)	1,953,913	3,047,958	10.9 %
William L. Ostrander (Chief Financial Officer and Secretary)	6,597	300,117	306,714	1.2 %
John K. A. Prendergast, Ph.D. (Director)	238,272 (4)	220,651	458,923	1.7 %
John Monahan, Ph.D. (Director)	73	186,178	186,251	*
Edward B. Smith, III (Director)	143	186,178	186,321	*
All Executive Officers and Directors, as a group (5 persons)	1,339,130	2,847,037	4,186,167	14.5 %

* less than 1%

(1) Represents shares subject to options that are currently vested and options that will vest and become exercisable within 60 days of March 30, 2023.

(2) Includes 11,025 shares of common stock held by Orion Holdings V, LLC and 10,231 shares of common stock held by Seed-One Holdings VI, LLC, entities for which Mr. Wolf serves as the managing member. Mr. Wolf is deemed to beneficially own the shares held by such entities as in his role as the managing member he has the control over the voting and disposition of any shares held by these entities. Does not include 26,468 shares of common stock beneficially owned by Mr. Wolf's children's trust of which Mr. Wolf is not the trustee. Mr. Wolf disclaims beneficial ownership of these shares except to the extent of any pecuniary interest (as defined in Rule 16a – 1(a)(2) promulgated under the Exchange Act) that he may have in such entities. In addition, if our company is traded on a recognized national exchange or Nasdaq while Mr. Wolf is employed by us and the market capitalization of our company is equal to or in excess of $500 million for at least fifteen consecutive trading days, then Mr. Wolf will be entitled to receive an additional stock option equal to 2% of the then outstanding shares of our common stock, at an exercise price equal to the then current market price as determined in good faith by the board.

(3) Includes 41,144 unvested shares received pursuant to restricted stock awards granted in December 2019 and January 2020 that are subject to forfeiture.

(4) Includes 5,715 unvested shares received pursuant to restricted stock awards granted in January 2020 that are subject to forfeiture.

The following table sets forth information, as of March 30, 2022, or as otherwise set forth below, with respect to the beneficial ownership of our directors and named executive officers of the common stock of each of our subsidiaries set forth below and (ii) each of our directors and our executive officer named in the Summary Compensation Table, and (iii) all of our directors and our executive officer as a group.

	Common Stock Beneficially Owned (%)				
Name of Beneficial Owner	**Pelican Therapeutics, Inc.(1)**	**Skunkworx Bio, Inc.(2)**	**Abacus Biotech, Inc.(2)**	**Scorpius BioManufacturing, Inc. (2)**	**Blackhawk Bio, Inc.(2)**
Jeffrey Wolf	3.1 %	5.0 %	5.0 %	5.0 %	5.0 %
William Ostrander	—	—	—	1.0 %	—
John K. A. Prendergast, Ph.D.	—	—	—	—	—
John Monahan, Ph.D.	— *	—	—	—	—
Edward B. Smith, III	0.3 %	—	—	—	—
Total	3.4 %	5.0 %	5.0 %	6.0 %	5.0 %

* less than 1%

(1) The shares of common stock of Pelican were issued to each individual prior to Pelican becoming a subsidiary of our company.
(2) Consists of options issued in each applicable subsidiary pursuant to The NightHawk Bioscience, Inc. 2021 Subsidiaries Stock Plan. Percent is the beneficial ownership percent for each individual in the applicable subsidiary.

Equity Compensation Plan Information

See Part II, Item 5, "Equity Compensation Plan Information" for certain information regarding our equity compensation plans.

Item 13. ***Certain Relationships and Related Transactions, and Director Independence***

Pursuant to our charter, our Audit Committee shall review on an on-going basis for potential conflicts of interest, and approve if appropriate, all our "Related Party Transactions" as required by Section 120 of the NYSE American Company Guide. For purposes of the Audit Committee Charter, "Related Party Transactions" shall mean those transactions required to be disclosed pursuant to SEC Regulation S-K, Item 404.

The following is a summary of transactions since January 1, 2021 to which we have been a party in which the amount involved exceeded $120,000 and in which any of our executive officers, directors or beneficial holders of more than five percent of our capital stock had or will have a direct or indirect material interest, other than compensation arrangements which are described under the sections of this Annual Report entitled Part III, Item 10. "Directors, Executive Officers and Corporate Governance—Director Compensation" and Part III, Item 11. "Executive Compensation:"

Compensation paid to our executive officers during 2021 and 2022 and equity awards granted to our executive officers and directors during 2021, 2022, 2023 and payments due to interests in Pelican, are disclosed under the sections of this Annual Report on Form 10-K entitled Part III, Item 10. "Directors, Executive Officers and Corporate Governance—2022 Director Compensation" and Part III, Item 11. "Executive Compensation" and Note 4 to the Company's audited consolidated financial statements for the years ended December 31, 2022 and 2021 "Acquisition of Pelican Therapeutics."

On December 20, 2021, we entered into the Merger Agreement with Merger Sub, Elusys and Fortis Advisors LLC pursuant to which, subject to certain conditions, we intend to acquire Elusys through the Merger. Elusys was formed in 1998 by Jeff Wolf, our President, Chief Executive Officer and Chairman of the Board of Directors, who is a director of Elusys and 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. 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. See" Business Recent Developments" for a more complete description of the Merger Agreement.

Indemnification agreements

Our third amended and restated certificate of incorporation contains provisions limiting the liability of directors and our amended and restated bylaws provide that we will indemnify each of our directors to the fullest extent permitted under Delaware law. In addition, we have entered and expect to continue to enter into agreements to indemnify our directors.

Independence of the Board of Directors

The Board of Directors undertook a review of the independence of the members of the Board of Directors and considered whether any director has a material relationship with our company that could compromise his or her ability to exercise independent judgment in carrying out his or her responsibilities. Based upon information requested from and provided by each director concerning their background, employment and affiliations, including family relationships, the Board of

Directors has determined that all of our current directors, except Mr. Wolf, due to his position as President and Chief Executive Officer of our company, are "independent" as that term is defined under the rules of NYSE American. As a result, Dr. Monahan, Dr. Prendergast and Mr. Smith are deemed to be "independent" as that term is defined under the rules of NYSE American. See the section of this Annual Report entitled "Item 10. Directors, Executive Officers and Corporate Governance."

Item 14. Principal Accountant Fees and Services

Independent Registered Public Accounting Firm Fees and Services

The following table sets forth the aggregate fees including expenses billed to us for the years ended December 31, 2022 and 2021 by BDO USA, LLP.

	December 31, 2022	December 31, 2021
Audit fees and expenses (1)	$ 605,349	$ 376,123

(1) Audit fees and expenses were for professional services rendered for the audit and reviews of the consolidated financial statements of the Company, professional services rendered for issuance of consents and assistance with review of documents filed with the SEC.

The Audit Committee has adopted procedures for pre-approving all audit and non-audit services provided by the independent registered public accounting firm, including the fees and terms of such services. These procedures include reviewing detailed back-up documentation for audit and permitted non-audit services. The documentation includes a description of, and a budgeted amount for, particular categories of non-audit services that are recurring in nature and therefore anticipated at the time that the budget is submitted. Audit Committee approval is required to exceed the pre-approved amount for a particular category of non-audit services and to engage the independent registered public accounting firm for any non-audit services not included in those pre-approved amounts. For both types of pre-approval, the Audit Committee considers whether such services are consistent with the rules on auditor independence promulgated by the SEC and the PCAOB. The Audit Committee also considers whether the independent registered public accounting firm is best positioned to provide the most effective and efficient service, based on such reasons as the auditor's familiarity with our business, people, culture, accounting systems, risk profile, and whether the services enhance our ability to manage or control risks, and improve audit quality. The Audit Committee may form and delegate pre-approval authority to subcommittees consisting of one or more members of the Audit Committee, and such subcommittees must report any pre-approval decisions to the Audit Committee at its next scheduled meeting. All of the services provided by the independent registered public accounting firm were pre-approved by the Audit Committee.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(a)(1) The following financial statements are included in this Annual Report for the fiscal years ended December 31, 2022 and 2021:

1. Report of Independent Registered Public Accounting Firm
2. Consolidated Balance Sheets as of December 31, 2022 and 2021
3. Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2022 and 2021
4. Consolidated Statements of Stockholders' Equity for the years ended December 31, 2022 and 2021
5. Consolidated Statements of Cash Flows for the years ended December 31, 2022 and 2021
6. Notes to Consolidated Financial Statements

(a)(2) All financial statement schedules have been omitted as the required information is either inapplicable or included in the Consolidated Financial Statements or related notes.

(a)(3) The exhibits set forth in the accompanying exhibit index below are either filed as part of this report or are incorporated herein by reference:

EXHIBIT INDEX

Exhibit No.	Description
1.1	Amended and Restated At Market Issuance Sales Agreement, dated August 24, 2020, by and among Heat Biologics, Inc., B. Riley Securities, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.1 of the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 24, 2020 (File No. 001-35994))
1.2	Amendment No. 1, dated December 10, 2020, to the Amended and Restated At Market Issuance Sales Agreement, dated August 24, 2020, by and among Heat Biologics, Inc., B. Riley Securities, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 1.2 to the Registration Statement on Form S-3 filed with the SEC on December 10, 2020 (File No. 001-35994))
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 Exhibit 2.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2021 (File No. 001-35994))
3.1	Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.5 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
3.2	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation filed on May 29, 2013 (incorporated by reference to Exhibit 3.6 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 30, 2013 (File No. 333-188365))
3.3	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on July 17, 2017 (File No. 001-35994))

Exhibit No.	Description
3.4	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 19, 2018 (File No. 001-35994))
3.5	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission March 23, 2020 (File No. 001 35994))
3.6	Amended and Restated Bylaws, dated October 17, 2019 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on October 18, 2019 (File No. 001-35994))
3.7	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation of Heat Biologics, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2020 (File No. 001 35994))
3.8	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2022 (File No. 001 35994))
3.9	Second Amended and Restated Bylaws, dated May 3, 2022 (incorporated by reference to Exhibit 3.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3,2022 (File No. 001 35994))
4.1#	2009 Stock Incentive Plan (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.2#	First Amendment of the 2009 Stock Incentive Plan (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.3#	Second Amendment of the 2009 Stock Incentive Plan (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.4#	Third Amendment of the 2009 Stock Incentive Plan (incorporated by reference to Exhibit 4.4to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.5#	Fourth Amendment of the 2009 Stock Incentive Plan (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.6	Specimen Common Stock Certificate of Heat Biologics, Inc. (incorporated by reference to Exhibit 4.8 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
4.7#	2014 Stock Incentive Plan (incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on June 13, 2014 (File No. 333-196763))
4.8#	Amended and Restated Heat Biologics, Inc. 2014 Stock Incentive Plan (incorporated by reference to Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on June 22, 2015))
4.9#	2017 Stock Incentive Plan (incorporated by reference as Exhibit 4.1 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on July 11, 2017 (File No. 333-219238))
4.10	Rights Agreement between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company dated March 11, 2018 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on March 12, 2018 (File No. 001-35994))
4.11#	2018 Stock Incentive Plan ((incorporated by reference to Exhibit 4.1 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
4.12	Warrant Agency Agreement between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company dated May 2, 2018 (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on May 7, 2018 (File No. 001-35994))

Exhibit No.	Description
4.13	Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K with the Securities and Exchange Commission on May 7, 2018 (File No. 001-35994))
4.14	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on November 21, 2018 (File No. 001-35994))
4.15	Amendment No. 1 to Rights Plan (incorporated by reference to Exhibit 4.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on March 12, 2019 (File No. 001-35994))
4.16	Amendment No. 2 to the Rights Agreement dated as of March 10, 2020 to the Rights Agreement dated March 11, 2018, as amended by Amendment No. 1 thereto, dated as of March 8, 2019, by and between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company, as rights agent (incorporated by reference to Exhibit 4.3 to the Form 8-A/A filed with the Securities and Exchange Commission on March 13, 2020 (File No. 001-35994))
4.17	Form of Warrant (incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 21, 2020 (File No. 001-35994))
4.18	Description of Securities of NightHawk Biosciences, Inc.
4.19	Amendment No. 3 to the Rights Agreement dated as of March 8, 2021 to the Rights Agreement dated March 11, 2018, as amended by Amendment No. 1 thereto, dated as of March 8, 2019, and Amendment No. 2 thereto, dated as of March 10, 2020, by and between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company, as rights agent (incorporated by reference to Exhibit 4.1 to the Form 8-K filed with the Securities and Exchange Commission on March 12, 2021 (File No. 001-35994))
4.20	Heat Biologics, Inc. 2021 Subsidiaries Stock Incentive Plan (incorporated by reference as Exhibit B to the Heat Biologics, Inc. Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on August 3, 2021 (File No. 001-35994))
4.21	Amendment No. 4 to the Rights Agreement dated as of March 8, 2021 to the Rights Agreement dated March 11, 2018, as amended by Amendment No. 1 thereto, dated as of March 8, 2019, Amendment No. 2 thereto, dated as of March 10, 2020, and Amendment No. 3 thereto dated as of March 8, 2021 by and between Heat Biologics, Inc. and Continental Stock Transfer & Trust Company, as rights agent (incorporated by reference to Exhibit 4.5 to the Form 8-K filed with the Securities and Exchange Commission on March 11, 2022 (File No. 001-35994)
10.1	License Agreement (97-14) between the University of Miami and its School of Medicine and Heat Biologics, Inc. effective July 11, 2008 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2021 (File No. 001-35994))
10.2	License Agreement (D-107) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 18, 2011 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2021 (File No. 333-001-35994))
10.3	License Agreement (SS114A) between the University of Miami and its School of Medicine and Heat Biologics I, Inc. effective February 18, 2011 (incorporated by reference to Exhibit 10.4 to the Current report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2021 (File No. 001-35994))
10.4#	Employment Agreement with Jeffrey Wolf dated December 18, 2009 (incorporated by reference to Exhibit 10.9 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.5#	Amendment to Employment Agreement with Jeffrey Wolf dated as of January 1, 2011 (incorporated by reference to Exhibit 10.10 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.6	Amendment to License Agreement (UM97-14) dated April 29, 2009 (incorporated by reference to Exhibit 10.18 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.7	Exclusive License between Heat Biologics, Inc. and the University of Michigan dated July 22, 2011 (incorporated by reference to Exhibit 10.21 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))

Exhibit No.	Description
10.8	Option Contract for Exclusive License between Heat Biologics, Inc. and the University of Miami dated April 1, 2013 (incorporated by reference to Exhibit 10.29 to the Registration Statement on Form S-1 with the Securities and Exchange Commission on May 6, 2013 (File No. 333-188365))
10.9#	Amendment to Employment Agreement, dated as of January 20, 2014, between the Company and Jeffrey Wolf (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K with the Securities and Exchange Commission on January 21, 2014 (File No. 001-35994))
10.10#	Form of Incentive Stock Option Agreement under the 2014 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K with the Securities and Exchange Commission on July 27, 2015 (File No. 001-35994))
10.11#	Form of Non-Statutory Stock Option Agreement under the 2014 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K with the Securities and Exchange Commission on July 27, 2015 (File No. 001-35994))
10.12#	Amendment to Employment Agreement between the Company and Jeffrey Wolf, dated January 11, 2016 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on January 15, 2016 (File No. 001-35994))
10.13#	Amendment to Employment Agreement between the Company and Jeffrey Wolf, dated April 1, 2016 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on April 7, 2016 (File No. 001-35994))
10.14	Amendment to License Agreement (UM97-14) between the University of Miami and Heat Biologics, Inc. effective July 26, 2016 (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q with the Securities and Exchange Commission on August 15, 2016 (File No. 001-35994))
10.15	Form of Indemnification Agreement by and between Heat Biologics, Inc. and its directors and officers (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q with the Securities and Exchange Commission on August 15, 2016 (File No. 001-35994))
10.16	Exclusive License Agreement (UMIP-114/Strbo) between the University of Miami and Zolovax, Inc., a wholly-owned subsidiary of Heat Biologics effective October 24, 2016 (incorporated by reference to Exhibit 10.5 to the Current report on Form 8-K filed with the Securities and Exchange Commission on August 11, 2021 (File No. 001-35994))
10.17#	Amendment to Employment Agreement between the Company and Jeffrey Wolf, dated January 1, 2017 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on January 4, 2017 (File No. 001-35994))
10.18#	Form of Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K with the Securities and Exchange Commission on January 4, 2017 (File No. 001-35994))
10.19	Stock Purchase Agreement by and among Heat Biologics, Inc., with Pelican Therapeutics, Inc. ("Pelican"), and certain stockholders in Pelican (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K with the Securities and Exchange Commission on March 8, 2017 (File No. 001-35994))
10.20	First Amendment to Exclusive License Agreement between The Regents of The University of Michigan and Heat Biologics, Inc. (UM File Number 3680) dated December 1, 2016 (incorporated by reference to Exhibit 10.67 to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 31, 2017 (File No. 001-35994))
10.21	First Amendment to Stock Purchase Agreement, dated March 29, 2017, by and among Heat Biologics, Inc., Pelican Therapeutics, Inc. and Josiah Hornblower as representative of the Stockholders (incorporated by reference to Exhibit 10.66 to the Annual Report on Form 10-K with the Securities and Exchange Commission on March 31, 2017 (File No. 001-35994))
10.22+	License Agreement by and between University of Miami and Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.), dated July 11, 2008, (UM03-31, UM05-39)
10.23+	License Agreement by and between University of Miami and Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.) dated December 12, 2010 (UMI176)
10.24+	Amendment to License Agreement between Heat Biologics, Inc. and University of Miami (UM03-31, UM05-39) dated April 20, 2009

Exhibit No.	Description
10.25+	Second Amendment to License Agreement between Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.) and University of Miami dated August 11, 2009 (UMC-131, UMC-139) (incorporated by reference to Exhibit 10.7 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on May 3, 2017 (File No. 001-35994))
10.26+	License Agreement by and between University of Miami and Pelican Therapeutics, Inc. (f/k/a Heat Biologics II, Inc.) dated November 19, 2013 (UMI143 and UMN 106)
10.27+	CPRIT Grant
10.28+	Assignment and Assumption Agreement between Heat Biologics, Inc. and Pelican Therapeutics, Inc.(f/k/a Heat Biologics II, Inc.) dated June 26, 2009 (UM131-31, UM139)
10.29#	Form of Incentive Stock Option Agreement under the 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.77 to the Heat Biologics, Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2018 (File No. 001-35994))
10.30#	Form of Non-Statutory Stock Option Agreement under the 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.78 to the Heat Biologics, Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2018 (File No. 001-35994))
10.31#	Form of Restricted Stock Unit Award Agreement under the 2017 Stock Incentive Plan (incorporated by reference to Exhibit 10.79 to the Heat Biologics, Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 2, 2018 (File No. 001-35994))
10.32#	Form of Incentive Stock Option Agreement under the 2018 Stock Incentive Plan (incorporated by reference to Exhibit 4.2 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
10.33#	Form of Non-Statutory Stock Option Agreement under the 2018 Stock Incentive Plan (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
10.34#	Form of Notice of Award under the 2018 Stock Incentive Plan (incorporated by reference to Exhibit 4.4 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
10.35#	Form of Restricted Stock Agreement under the 2018 Stock Incentive Plan (incorporated by reference to Exhibit 4.5 to the Registration Statement on Form S-8 with the Securities and Exchange Commission on October 4, 2018 (File No. 333-219238))
10.36#	Heat Biologics, Inc. Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2019 (File No. 001-35994))
10.37	Lease between Durham KTP Tech 7, LLC and Heat Biologics, Inc. dated April 17, 2019 (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 18, 2019 (File No. 001-35994))
10.38#	Amendment No. 1 to the Heat Biologics, Inc. 2018 Stock Incentive Plan (incorporated by reference to Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on June 4, 2019 (File No. 001-35994))
10.39	Offer Letter by and between Heat Biologics, Inc. and William L. Ostrander, dated September 23, 2019 (incorporated by reference to Exhibit 10.2 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on September 18, 2019 (File No. 001-35994))
10.40#	Amendment to Employment Agreement between Heat Biologics, Inc. and Jeffrey Wolf, effective as of January 1, 2020 (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2020 (File No. 001-35994))
10.41#	Amendment to Offer Letter between Heat Biologics, Inc. and William Ostrander, effective as of January 1, 2020 (incorporated by reference to Exhibit 10.3 to the Heat Biologics, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2020 (File No. 001-35994))
10.42#	Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.4 to the Heat Biologics, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on January 3, 2020 (File No. 001-35994))

Exhibit No.	Description
10.43#	Amendment no. 2 to the Heat Biologics 2018 Stock Incentive Plan (incorporated by reference to Exhibit 4.3 to the Registration Statement on Form S-8 filed with the Securities and Exchange Commission on March 12, 2020)
10.44	Form of Exchange Agreement (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on March 3, 2020 (File No. 001-35994))
10.45+	Attachment F to CPRIT Contract (incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 10, 2020)
10.46#	Amendment No. 3 to the Heat Biologics, Inc. 2018 Stock Incentive Plan (incorporated by reference to Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on July 27, 2020)
10.47	Amendment, dated December 7, 2020, to License Agreement (UMI-176) between the University of Miami and Heat Biologics, Inc. effective December 12, 2010 (incorporate by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2020 (File No. 001-35994))
10.48	Amendment, dated December 7, 2020, to License Agreement (UMSS-114) between the University of Miami and Heat Biologics, Inc. effective July 11, 2008 (incorporate by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2020 (File No. 001-35994))
10.49	Amendment, dated December 7, 2020, to License Agreement (D-107) between the University of Miami and Heat I, Inc. effective February 18, 2011 (incorporate by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on December 10, 2020 (File No. 001-35994))
10.50	Exclusive License Agreement between the University of Miami and Zolovax, Inc. dated as of December 31, 2020 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2021 (File No. 001-35994))
10.51#	Amendment to Offer Letter between Heat Biologics, Inc. and William Ostrander, dated as of January 4, 2021 (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2021 (File No. 001-35994))
10.52#	Employment Agreement between Heat Biologics, Inc. and Jeffrey Wolf, dated as of January 4, 2021 (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2021 (File No. 001-35994))
10.53#	Form of Restricted Stock Agreement (incorporated by reference to Exhibit 10.4 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2021 (File No. 001-35994))
10.54#	Separation Agreement dated December 31, 2020 between Heat Biologics, Inc. And Jeff Hutchins (incorporated by reference to Exhibit 10.5 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2021 (File No. 001-35994))
10.55	Lease between Durham Keystone Tech 7, LLC and Heat Biologics, Inc. dated June 21, 2021 (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 23, 2021 (File No. 001-35994))
10.56#	Form of Stock Option Agreement for the Heat Biologics 2021 Subsidiaries Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 3, 2021 (File No. 001-35994))
10.57#	Form of Restricted Stock Purchase Agreement for the Heat Biologics 2021 Subsidiaries Stock Incentive Plan (incorporated by reference to Exhibit 10.3 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on August 3, 2021 (File No. 001-35994))
10.58#	Heat Biologics, Inc. 2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit A to the Definitive Proxy Statement on Schedule A filed with the Securities and Exchange Commission on August 3, 2021) (File No. 001-35994))
10.59	Lease between Merchants Ice II, LLC and Heat Biologics, Inc. dated June October 5, 2021 (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 7, 2021 (File No. 001-35994))

Exhibit No.	Description
10.60#	Form of Amended and Restated Restricted Stock Agreement (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 15, 2021(File No.001-35994)
10.61#	Employment Agreement effective as of January 1, 2022 by and between Heat Biologics, Inc. and William Ostrander (incorporated by reference to Exhibit 10.2 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 15, 2021(File No.001-35994)
10.62*++	Ordering Agreement between Lonza Sales AG and Elusys Therapeutcs, Inc.
10.63*++	Ordering Agreement between Lonza Sales AG and Elusys Therapeutcs, Inc.
10.64	Form of New Incentive Stock Option Agreement under the 2018 Stock Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8 K with the Securities and Exchange Commission on January 3, 2022 (File No. 001 35994))
10.65	Form of New Non-Statutory Stock Option Agreement under the 2018 Stock Incentive Plan (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8 K with the Securities and Exchange Commission on January 3, 2022 (File No. 001 35994))
10.66	Patent License Agreement (UTA#03-005) between the University of Texas System and EluSys Therapeutics, Inc. effective July 11, 2008 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed with the Securities and Exchange Commission on April 18, 2022 (File No. 001-35994))
10.67	Amendment No. 4 to the Heat Biologics, Inc. 2018 Stock Incentive Plan (incorporated by reference to Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on July 28, 2022)
10.68	Amendment No. 4 to the NightHawk Biosciences, Inc. 2021 Subsidiaries Stock Incentive Plan (incorporated by reference to Appendix A to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on July 28, 2022)
10.69	Amendment No. 1 to Employment Agreement between NightHawk Biosciences, Inc. and Jeffrey Wolf, effective as of December 7, 2022 (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on December 9, 2022 (File No. 001-35994))
10.70	Amendment No. 1 to Employment Agreement between NightHawk Biosciences, Inc. and William Ostrander, effective as of December 7, 2022 (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc. Current Report on Form 8-K filed with the Securities and Exchange Commission on December 9, 2022 (File No. 001-35994))
10.71	Lease between TPB Merchants Ice LLC and Scorpion Biologics, Inc. dated December 31, 2022 (incorporated by reference to Exhibit 10.1 to the Heat Biologics, Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 25, 2023 (File No. 001-35994))
21.1*	List of Subsidiaries
23.1*	Consent of Independent Registered Public Accounting Firm (BDO USA, LLP)
31.1*	Certification of Jeffrey Wolf, Principal Executive Officer, pursuant to Rule 13a 14(a) or15d 14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of William Ostrander, Principal Financial Officer, pursuant to Rule 13a 14(a) or15d 14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1*	Certification of Jeffrey Wolf, Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of William Ostrander, Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document *
101.SCH	Inline XBRL Taxonomy Extension Schema Document *
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document *
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document *
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document *
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document *
104	Cover Page Interactive Data File (formatted in Inline XBRL in Exhibit 101)

* Filed herewith.
Management contract or compensatory plan or arrangement required to be identified pursuant to Item 15(a)(3) of this report.
\+ Confidential treatment has been requested as to certain portions of this exhibit pursuant to Rule 24b-2 of the Securities Exchange Act of 1934, as amended.
++ The Company has omitted certain portions of this exhibit in accordance with Item 601 (b)(10) of Regulation S-K. The Company agrees to furnish unredacted copies of these exhibits to the SEC upon request.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on the 31st day of March 2023.

NIGHTHAWK BIOSCIENCES, INC.

By: /s/ Jeffrey Wolf
Jeffrey Wolf
Chief Executive Officer and Chairman of the Board
(Principal Executive Officer)
Date: March 31, 2023

By: /s/ William L. Ostrander
William L. Ostrander
Chief Financial Officer, and Secretary
(Principal Financial and Principal Accounting Officer)
Date: March 31, 2023

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Jeffrey Wolf, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1934, this report has been signed by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Jeffrey Wolf Jeffrey Wolf	Chief Executive Officer, President and Chairman of the Board (Principal Executive Officer)	March 31, 2023
/s/ William L. Ostrander William L. Ostrander	Chief Financial Officer, and Secretary (Principal Financial and Principal Accounting Officer)	March 31, 2023
/s/ John Monahan, Ph.D. John Monahan, Ph.D.	Director	March 31, 2023
/s/ John K.A. Prendergast, Ph.D. John K.A. Prendergast, Ph.D.	Director	March 31, 2023
/s/ Edward B. Smith, III Edward B. Smith, III	Director	March 31, 2023

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Nighthawk Biosciences, Inc.
Morrisville, North Carolina

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Nighthawk Biosciences, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended**,** in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Company has suffered recurring losses from operations and not generated significant revenue or positive cash flows from operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Elusys Acquisition - Valuation of Developed Technology

As described in Note 5 to the Company's consolidated financial statements, the Company acquired Elusys Therapeutics, LLC ("Elusys") on April 18, 2022. The acquisition of Elusys was accounted for as a business combination and reflects the application of acquisition accounting in accordance with ASC 805, *Business Combinations.* The assets acquired from Elusys, including identifiable intangible assets, and liabilities assumed, were recorded at their preliminary estimated fair values with the excess purchase price assigned to goodwill. In connection with the acquisition of Elusys, the Company recorded a definite lived intangible asset of $9.7 million comprised of the ANTHIM® formulation. Determining the fair value of this intangible asset is judgmental in nature and involves the use of significant estimates and assumptions.

We identified the estimated fair value of the ANTHIM® formulation as a critical audit matter. The estimation of the fair value of the intangible asset acquired required management to make complex judgments with respect to the Company's forecast of future cash flows derived from ANTHIM® and a risk adjusted discount rate. Auditing these assumptions required increased auditor judgement and effort, including the use of valuation specialists.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the reasonableness of the cash flow assumptions used to estimate the acquisition date fair value of the ANTHIM® formulation by i) comparing forecasts of future revenues and operating expenses to historical performance of Elusys, and ii) assessing the likelihood of achieving the forecasted revenue.

- Utilizing professionals with specialized skills and knowledge in fair value measurements to assist in testing the accuracy of the Company's calculation and assessing the reasonableness of the discount rate selected.

Elusys Acquisition - Valuation of Elusys Earn Out

As described in Notes 2 and 5 to the Company's consolidated financial statements, the purchase consideration related to the acquisition of Elusys was approximately $42.9 million which included an earn out liability of $5.9 million. The earn out liability is measured at its estimated fair value as of the date of acquisition, with subsequent changes in fair value recorded in the consolidated statements of operations and comprehensive loss. The earn out liability is measured using a discounted cash flow model utilizing significant unobservable inputs including future revenue projections and an estimated discount rate. At December 31, 2022, the Elusys earn out liability was remeasured to fair value of $5.3 million and the Company recorded a $0.6 million gain on the change in fair value of the earn out liability.

We identified the estimation of the fair value of the Elusys earn out liability as of the acquisition date and the balance sheet date to be a critical audit matter. The estimation of the earn out liability at each date required management to make complex judgments with respect to future revenue projections derived from the ANTHIM® formulation and discount rates. Auditing these assumptions required increased auditor judgement and effort, including the use of valuation specialists.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the reasonableness of management's judgments with respect to future revenue projections derived from the ANTHIM® formulation used to estimate the value of the earnout liability at each date by i) comparing forecasts of future revenues to historical performance of Elusys and ii) assessing the likelihood of achieving the forecasted revenue.

- Utilizing professionals with specialized skills and knowledge in fair value measurements to assist in testing the accuracy of the Company's calculation and assessing the reasonableness of the discount rate selected.

Goodwill Impairment Testing – Elusys Reporting Unit

As described in Notes 2, 5 and 8 to the Company's consolidated financial statements, the Company recorded $3.6 million of goodwill in connection with the acquisition of Elusys. The Company tests goodwill for impairment at the reporting until level annually, or more frequently if events or changes in circumstances indicate that the asset might be impaired. The Company records a goodwill impairment charge if a reporting unit's carrying value exceeds its fair value. During the fourth quarter of 2022, due to a sustained a decline in quoted market price of its common stock, the Company performed an interim impairment analysis over the Elusys reporting unit using the income approach. Through quantitative analysis, the Company determined the carrying value was not in excess of its estimated fair value and therefore no impairment charge was recorded.

We identified the determination of the fair value of the Elusys reporting unit as a critical audit matter. The estimation of the fair value of the reporting unit required management to make complex judgments with respect to the Company's forecast of future cash flows within the reporting unit and a risk adjusted discount rate. Auditing these assumptions required increased auditor judgement and effort, including the use of valuation specialists.

The primary procedures we performed to address this critical audit matter included:

- Evaluating the reasonableness of the cash flow assumptions used to estimate the fair value of the reporting unit by i) comparing forecasts of future revenues and operating expenses to historical results, and ii) assessing the likelihood of achieving the forecasted revenue.

- Utilizing professionals with specialized skills and knowledge in fair value measurements to assist in testing the accuracy of the Company's calculation and assessing the reasonableness of the discount rate selected.

Scorpius Lease

As described in Note 14 of the consolidated financial statements, in October 2021, the Company, through its subsidiary Scorpius BioManufacturing, Inc. ("Scorpius"), entered into a lease agreement for a facility to be used for general office, laboratory, research, analytical, and/or biomanufacturing purposes. The facility is being leased from a nonprofit entity investing in the building such that investments made by both the landlord and Scorpius may qualify for certain tax credits. Scorpius agreed that all investments and expenditures qualifying under the relevant tax credit programs would be purchased by the landlord and Scorpius would reimburse the landlord for these payments. As of December 31, 2022, Scorpius had reimbursed the landlord $24.3 million. Scorpius recorded a finance lease right-of-use asset of $15.1 million and lease liability of $5.1 million for this lease.

We identified the accounting for the Scorpius lease as a critical audit matter. Accounting for the Scorpius lease required management to make significant judgements with respect to the fair value of the leased facility and its impact on lease classification, the identification of the accounting owner of investments made in the facility, the treatment of lease incentives related to the tax incentives received by the landlord, and the estimation of the incremental borrowing rate. Auditing these judgments required increased audit effort including involving professionals with specialized skills in technical lease accounting and valuation.

The primary procedures we performed to address this critical audit mater included:

- Evaluating the Company's accounting for the Scorpius lease based on the terms of the lease agreement, other relevant agreements related to the tax credits to be received by the landlord and the nature of the investments made in the facility.
- Utilizing professionals with specialized knowledge and experience in technical lease accounting to assist in the identification of the accounting owner of the investments made in the facility and evaluation of the impact of the lease incentives on the determination of lease classification and overall accounting for the lease.
- Utilizing professionals with specialized knowledge and skill in real estate valuations to assist in assessing the reasonableness of the Company's estimation of the fair value of the underlying assets used in determination of the lease classification.
- Utilizing professionals with specialized knowledge and skill in valuation to assist in assessing the reasonableness of the incremental borrowing rate estimated by management.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2012.

Raleigh, North Carolina
March 31, 2023

NIGHTHAWK BIOSCIENCES, INC.
Consolidated Balance Sheets

	December 31, 2022	December 31, 2021
Current Assets		
Cash and cash equivalents	$ 8,434,554	$ 8,053,879
Short-term investments	35,837,309	88,324,922
Accounts receivable	81,456	66,049
Grant receivable	1,524,522	—
Income tax refund receivable	600,877	—
Prepaid expenses and other current assets	3,575,541	2,886,520
Total Current Assets	50,054,259	99,331,370
Property and Equipment, net	20,480,375	2,158,479
Intangible assets, net	8,669,375	3,500,000
Goodwill	3,301,959	—
Grant receivable, net of current	—	1,318,359
Operating lease right-of-use asset	6,005,147	1,782,884
Finance lease right-of-use asset	15,329,075	470,700
Other assets	260,011	12,193,540
Deposits	296,711	205,901
Total Assets	$ 104,396,912	$ 120,961,233
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 4,424,053	$ 922,782
Deferred revenue, current portion	1,585,808	—
Operating lease liability, current portion	490,378	350,343
Finance lease liability, current portion	301,048	260,574
Accrued expenses and other liabilities	4,301,922	2,419,676
Contingent consideration, current portion	6,934,114	593,037
Contingent consideration, related party - current portion	—	174,333
Total Current Liabilities	18,037,323	4,720,745
Long Term Liabilities		
Other long-term liabilities	—	53,530
Derivative warrant liability	—	11,020
Deferred tax liability	—	215,937
Deferred revenue, net of current portion	32,500	35,000
Operating lease liability, net of current portion	3,079,887	1,060,856
Financing lease liability, net of current portion	5,520,034	255,429
Contingent consideration, net of current portion	5,290,500	1,990,118
Contingent consideration, related party	—	585,027
Total Liabilities	31,960,244	8,927,662
Commitments and Contingencies (Note 10 and Note 14)		
Stockholders' Equity		
Common stock, $0.0002 par value; 250,000,000 shares authorized, 25,661,488 and 25,649,824 shares issued and outstanding at December 31, 2022 and December 31, 2021	5,126	5,055
Additional paid-in capital	283,019,456	278,890,153
Accumulated deficit	(209,153,659)	(165,718,953)
Accumulated other comprehensive income (loss)	51,924	(67,941)
Total Stockholders' Equity - NightHawk Biosciences, Inc.	73,922,847	113,108,314
Non-Controlling Interest	(1,486,179)	(1,074,743)
Total Stockholders' Equity	72,436,668	112,033,571
Total Liabilities and Stockholders' Equity	$ 104,396,912	$ 120,961,233

See Notes to Consolidated Financial Statements

NIGHTHAWK BIOSCIENCES, INC.
Consolidated Statements of Operations and Comprehensive Loss

	Year ended December 31,	
	2022	2021
Revenue:		
Product sales	$ 5,980,993	$ —
Grant and contract revenue	402,176	2,112,806
Total revenue	6,383,169	2,112,806
Operating expenses:		
Product cost of sales	6,401,018	—
Research and development	23,461,400	16,455,278
General and administrative	21,130,879	16,828,229
Goodwill impairment loss	—	1,452,338
Amortization of intangible asset	1,030,625	—
In-process research and development impairment	3,500,000	2,366,000
Change in fair value of contingent consideration	(3,452,015)	430,000
Total operating expenses	52,071,907	37,531,845
Loss from operations	(45,688,738)	(35,419,039)
Change in fair value of warrant liability	11,020	22,758
Interest income	987,247	815,316
Unrealized loss on available-for-sale securities	(1,701,428)	(842,538)
Other expense, net	(759,235)	(123,278)
Total non-operating loss	(1,462,396)	(127,742)
Net loss before income taxes	(47,151,134)	(35,546,781)
Income tax benefit	3,288,937	145,974
Net loss	(43,862,197)	(35,400,807)
Net loss - non-controlling interest	(427,491)	(329,339)
Net loss attributable to NightHawk Biosciences, Inc.	$ (43,434,706)	$ (35,071,468)
Net loss per share, basic and diluted	$ (1.70)	$ (1.41)
Weighted-average common shares outstanding, basic and diluted	25,606,326	24,913,942
Comprehensive loss:		
Net loss	(43,862,197)	(35,400,807)
Unrealized gain on foreign currency translation	119,865	98,115
Total comprehensive loss	(43,742,332)	(35,302,692)
Comprehensive loss attributable to non-controlling interest	(427,491)	(329,339)
Comprehensive loss - NightHawk Biosciences, Inc.	$ (43,314,841)	$ (34,973,353)

See Notes to Consolidated Financial Statements

NIGHTHAWK BIOSCIENCES, INC.
Consolidated Statements of Stockholders' Equity

	Common Stock	APIC	Accumulated Deficit	Accumulated Other Comprehensive Gain (Loss)	Non-Controlling Interest	Total Stockholders Equity
Balance at December 31, 2020	$ 4,519	$ 247,048,349	$ (130,647,485)	$ (166,056)	$ (745,404)	$ 115,493,923
ATM raise	420	26,303,862	—	—	—	26,304,282
Issuance of common stock from vesting of restricted stock awards	110	(110)	—	—	—	—
Stock issuance costs	—	(658,184)	—	—	—	(658,184)
Stock based compensation	—	6,168,981	—	—	—	6,168,981
Cancellation and payout of fractional shares	(3)	3	—	—	—	—
Issuance of restricted stock	3	(3)	—	—	—	—
Exercise of options	6	27,255	—	—	—	27,261
Other comprehensive loss	—	—	—	98,115	—	98,115
Net loss	—	—	(35,071,468)	—	(329,339)	(35,400,807)
Balance at December 31, 2021	5,055	278,890,153	(165,718,953)	(67,941)	(1,074,743)	112,033,571
Issuance of common stock from vesting of restricted stock awards	65	(65)	—	—	—	—
Common Stock Issuance ESPP	6	43,631	—	—	—	43,637
Stock based compensation	—	4,085,737	—	—	—	4,085,737
Exercise of options	—	—	—	—	16,055	16,055
Other comprehensive loss	—	—	—	119,865	—	119,865
Net loss	—	—	(43,434,706)	—	(427,491)	(43,862,197)
Balance at December 31, 2022	$ 5,126	$ 283,019,456	$ (209,153,659)	$ 51,924	$ (1,486,179)	$ 72,436,668

See Notes to Consolidated Financial Statements

NIGHTHAWK BIOSCIENCES, INC.
Consolidated Statements of Cash Flows

	For the Year Ended December 31,	
	2022	**2021**
Cash Flows from Operating Activities		
Net loss	$ (43,862,197)	$ (35,400,807)
Adjustments to reconcile net loss to net cash used in operating activities:		
Goodwill impairment loss	—	1,452,338
In-process R&D impairment loss	3,500,000	2,366,000
Depreciation and amortization	2,115,015	607,667
Amortization of intangible asset	1,030,625	—
Noncash lease expense	116,583	83,809
Noncash interest expense	—	21,970
Stock-based compensation	4,085,737	6,168,981
Change in fair value of common stock warrants	(11,020)	(22,758)
Change in fair value of contingent consideration	(3,452,015)	430,000
Unrealized loss on investments	1,701,443	842,538
Deferred tax liability	(3,288,937)	(145,974)
Increase (decrease) in cash arising from changes in assets and liabilities, net of acquisitions:		
Accounts receivable	(15,967)	110,111
Grant receivable	(206,163)	(1,318,359)
Prepaid expenses and other current assets	58,656	(1,060,915)
Income tax refund receivable	443,968	—
Contract receivables	24,526,231	—
Inventory	5,844,000	—
Right-of-use assets	(12,158,238)	—
Other assets	12,233,529	(12,193,540)
Deposits	(64,560)	(83,122)
Accounts payable	3,299,326	(126,937)
Deferred revenue	1,583,308	(806,217)
Accrued expenses and other liabilities	(3,126,158)	929,023
Other long-term liabilities	(53,530)	17,286
Net Cash Used In Operating Activities	(5,700,364)	(38,128,906)
Cash Flows from Investing Activities		
Purchase of short-term investments	(2,457,348)	(66,960,279)
Sale of short-term investments	53,243,519	78,635,257
Purchase of property and equipment	(20,117,998)	(1,904,713)
Disposal of property and equipment	388,103	—
Acquisition of Elusys Therapeutics, net of cash paid	2,719,899	—
Payment of contingent consideration	(22,784,571)	—
Net Cash Provided By Investing Activities	10,991,604	9,770,265
Cash Flows from Financing Activities		
Proceeds from the issuance of common stock	59,692	26,304,282
Proceeds from the exercise of stock options	—	27,261
Stock issuance costs	—	(658,184)
Repayments of principal under finance lease	(231,633)	(183,010)
Payment of contingent consideration	(4,735,000)	—
Net Cash (Used In) Provided by Financing Activities	(4,906,941)	25,490,349
Effect of exchange rate changes on cash and cash equivalents	(3,624)	(9,719)
Net Increase (Decrease) in Cash and Cash Equivalents	380,675	(2,878,011)
Cash and Cash Equivalents – Beginning of the Year	8,053,879	10,931,890
Cash and Cash Equivalents – End of the Year	$ 8,434,554	$ 8,053,879
Supplemental Disclosure for Cash Flow Information:		
Right-of-use assets obtained upon operating lease commencements	$ 6,348,346	$ 88,596
Right-of-use assets obtained (surrendered) upon operating lease modifications	$ (81,752)	$ 37,767
Right-of-use assets obtained upon financing lease commencements	$ 15,477,515	$ 408,677
Right-of-use assets obtained due to financing lease modifications	$ 37,654	$ —
Supplemental disclosure of non-cash investing and financing activities:		
Purchases of property and equipment included in accounts payable	$ 288,807	$ —
Contingent and deferred cash consideration related to Elusys acquisition	$ 42,853,685	$ —

See Notes to Consolidated Financial Statements

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization

NightHawk Biosciences is a fully integrated biopharmaceutical company specializing in the end-to-end development and commercialization of innovative medical countermeasures that combat unmet and emerging biothreats. NightHawk's discovery subsidiary, Skunkworx Bio, enhances NightHawk's ability to identify candidates for drug development, while NightHawk's biomanufacturing subsidiary, Scorpius BioManufacturing, Inc. ("Scorpius"), provides internal bioanalytical, process development and biomanufacturing capabilities that support NightHawk's pipeline and commercial assets. Elusys Therapeutics, Inc. ("Elusys") supports NightHawk's goal of innovating in the biodefense sector by adding expertise in developing and delivering life-saving medical countermeasures, including our commercially available anthrax antitoxin ANTHIM® (obiltoxaximab). Collectively, this ecosystem is designed to increase the efficiency of drug development and accelerate the capability to combat infectious disease.

During the past year, NightHawk's priorities have shifted to biodefense and biomanufacturing capabilities resulting in a refocusing of resources and efforts towards biodefense and biomanufacturing and away from clinical-stage oncology assets including HS-110 and PTX-35.

Effective May 3, 2022, Heat Biologics, Inc. changed its name to NightHawk Biosciences, Inc. (the"Company") by filing a Certificate of Amendment (the "Certificate of Amendment") to its Third Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware

2. Summary of Significant Accounting Policies

Principles of Consolidation

The consolidated financial statements include the accounts of NightHawk Biosciences, Inc., and its subsidiaries ("the Company"), Pelican Therapeutics, Inc. ("Pelican"), Heat Biologics I, Inc. ("Heat I"), Heat Biologics III, Inc. ("Heat III"), Heat Biologics IV, Inc. ("Heat IV"), Heat Biologics GmbH, Heat Biologics Australia Pty Ltd., Zolovax, Inc., Skunkworx Bio, Inc. (formerly known as Delphi Therapeutics, Inc.), Scorpius BioManufacturing, Inc. ("Scorpius") (formerly Scorpion Biological Services, Inc), Blackhawk Bio, Inc., Abacus Biotech, Inc., and Elusys Therapeutics, Inc. ("Elusys"). The functional currency of the entities located outside the United States of America (the foreign entities) is the applicable local currency of the foreign entities. Assets and liabilities of the foreign entities are translated at period-end exchange rates. Statement of operations accounts are translated at the average exchange rate during the period. The effects of foreign currency translation adjustments are included in other comprehensive loss, which is a component of accumulated other comprehensive loss in stockholders' equity. All significant intercompany accounts and transactions have been eliminated in consolidation. The December 31, 2022 and 2021 year-end financials include an 85% controlling interest in Pelican. NightHawk accounts for its less than 100% interest in the consolidated financial statements in accordance with U.S. Generally Accepted Accounting Principles ("GAAP"). Accordingly, the Company presents non-controlling interest as a component of stockholders' equity on its consolidated balance sheets and reports non-controlling interest net loss under the heading "net loss – non-controlling interest" in the consolidated statements of operations and comprehensive loss.

Restatement of Prior Quarterly 2022 Financial Statements (Unaudited)

During the preparation and review of its annual tax provision for the year ended December 31, 2022, it was determined that the Company made certain errors in the manner in which it recognized a deferred tax asset valuation allowance related to the acquisition of Elusys Therapeutics, Inc. ("Elusys"). Under ASC 740 – Income Taxes, the release of an acquirer's valuation allowance on the acquirer's (i.e., the Company's) deferred tax assets in the amount of the acquired Elusys deferred tax liability ("DTL") should be recorded as an income tax benefit and be reported as a component of net loss in the unaudited consolidated statement of operations and comprehensive loss. The DTL was recorded in the unaudited consolidated balance sheet at June 30, 2022 and September 30, 2022, however the DTL was not and should have been recorded as an income tax benefit within the unaudited consolidated statement of operations and comprehensive loss for the quarter ending June 30, 2022. This error resulted in net loss being overstated by $3.3 million for the three and six months ended June 30, 2022 and the nine months ended September 30, 2022. In accordance with Staff Accounting Bulletin

("SAB") No. 99,Materiality, and SAB No. 108,Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements, the Company evaluated these misstatements, and based on an analysis of quantitative and qualitative factors, determined that the impact of these misstatements was material to its interim reporting periods ended June 30, and September 30, 2022.

Accordingly, the Company has restated its unaudited consolidated financial statements for the interim reporting periods for the three- and six-months ended June 30, 2022, and three- and nine- months ended September 30, 2022, respectively, and has included that restated unaudited financial information within this annual report. There is no cumulative impact to the Company's full-year 2022 financial statements as a result of this restatement. Restatement of amounts in previously filed unaudited quarterly financial statements are reflected in Note 17- Restatement of Interim Financial Statements. Because we are restating prior periods, we are also reflecting another immaterial adjustment related to an additional error that was identified during this process. The Company recorded a measurement period adjustment in the third quarter which reduced the acquired definite lived intangible asset value by approximately $1.5 million. Given that the DTL is calculated using the acquired intangible asset value, the Company should have also adjusted the purchase price allocation by recording a decrease to goodwill of $0.3 million. This also reduces the deferred tax assets utilized to offset the acquired DTL and thus increases the valuation allowance. This is adjusted through a decrease in the income tax benefit recognized for the three and nine-months ended September 30, 2022 of $0.3 million. This is adjusted in the restated unaudited consolidated balance sheet at September 30, 2022 and the restated unaudited statement of operations and comprehensive loss for the quarter ending September 30, 2022.

Going Concern Uncertainty

The Company has an accumulated deficit of $209.2 million as of December 31, 2022 and a net loss of approximately $43.9 million for the year ended December 31, 2022 and has not generated significant revenue or positive cash flows from operations. The Company expects to incur significant expenses and continued losses from operations for the foreseeable future. The Company expects its expenses to increase in connection with its ongoing activities, particularly as the Company ramps up operations in its in-house bioanalytic, process development and manufacturing facility in San Antonio, TX, expands its infectious disease/biological threat program, and continues to support the development of, and commencement of operations at, a new biodefense-focused large molecule and biologics biomanufacturing facility in Manhattan, Kansas. As of December 31, 2022, a lease has not been executed for this Kansas facility. In addition, any new business ventures that the Company may engage in are likely to require commitments of capital. Accordingly, the Company will in the future need to obtain substantial additional funding in connection with its planned operations. Adequate additional financing may not be available to the Company on acceptable terms, or at all. If the Company is unable to raise capital when needed or on attractive terms, it would be forced to delay, reduce or eliminate its research and development programs, any future commercialization efforts or the manufacturing services it plans to provide. To meet its capital needs, the Company intends to continue to consider multiple alternatives, including, but not limited to, additional equity financings such as sales of its common stock under at-the-market offerings, debt financings, partnerships, grants, funding collaborations and other funding transactions, if any are available. As of December 31, 2022, the Company had approximately $44.3 million in cash and cash equivalents and short-term investments. The Company will need to generate significant revenues to achieve profitability, and it may never do so. Management has determined that there is substantial doubt about the Company's ability to continue as a going concern within one year after the consolidated financial statements are issued.

Risk and Uncertainties

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty of results of clinical trials and reaching milestones, uncertainty of market acceptance of the Company's products, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers.

The Company depends on third-party suppliers for key materials and services used in research and development, as well as manufacturing processes, and is subject to certain risks related to the loss of these third-party suppliers or their inability

to supply adequate materials and services. The Company does not control the manufacturing processes of the contract development and manufacturing organizations, or CDMOs, with whom it contracts and is dependent on for the production of its therapeutic candidates in accordance with relevant regulations (such as current Good Manufacturing Practices, or cGMP), which include, among other things, quality control, quality assurance and the maintenance of records and documentation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Estimates are used for, but not limited to, useful lives of fixed assets, contingent consideration, valuation of goodwill and other intangible assets, income taxes, valuation of warrant liabilities, stock-based compensation, right-of-use assets and lease liabilities, and useful lives of intangible assets. Actual results may differ from those estimates.

Reclassification

Certain prior year amounts have been reclassified to conform to the current year presentation in the consolidated financial statements and accompanying notes to the consolidated financial statements including the IPR&D impairment, which was previously included in research and development expense and is now presented as a separate line item on the Company's consolidated statements of operations and comprehensive loss.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed the operations and managed the business as one segment.

Cash and Cash Equivalents

The Company considers all cash and other highly liquid investments with initial maturities from the date of purchase of three months or less to be cash and cash equivalents.

Short-term Investments

The Company’s short-term investments consist of equity securities and are carried at fair value. Unrealized gains and losses on securities are reported in the consolidated statements of operations and comprehensive loss. The Company classifies marketable equity investments available to fund current operations as current assets on its consolidated balance sheets.

Derivative Financial Instruments

The Company has issued common stock warrants in connection with the execution of certain equity financings. The fair value of the warrants, which were deemed to be derivative instruments, was recorded as a derivative liability under the provisions of ASC 815 *Derivatives and Hedging* because they are not considered indexed to the Company’s own stock. Subsequently, the liability is adjusted to fair value as of the end of each reporting period and the changes in fair value of derivative liabilities are recorded in the consolidated statements of operations and comprehensive loss under the caption “Change in fair value of warrant liability.”

The fair value of the warrants, including the warrants issued in connection with the January 2020 common stock offering and recorded as liability, was determined using the Monte Carlo simulation model, which is deemed to be an appropriate model due to the terms of the warrants issued.

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Concentration of Credit Risk

At times, cash balances may exceed the Federal Deposit Insurance Corporation ("FDIC") insurable limits. The Company has never experienced any losses related to these balances. As of December 31, 2022, and 2021, cash amounts in excess of $250,000 were not fully insured. The uninsured cash balance as of December 31, 2022 was $7.8 million. The Company does not believe it is exposed to significant credit risk on cash and cash equivalents.

Property and Equipment

Property and equipment are stated at cost and are capitalized. Depreciation is calculated using the straight-line method and is based on estimated useful lives of five years for lab equipment, three years for computer equipment, eight years for furniture and fixtures and vehicles, and five to eight years for leasehold improvements.

Leases

The Company leases office space and certain equipment under non-cancelable lease agreements. The Company applies the accounting guidance in ASC 842, *Leases.* As such, the Company assesses all arrangements that convey the right to control the use of property, plant and equipment at inception to determine if it is, or contains, a lease based on the unique facts and circumstances present in that arrangement. For those leases identified, the Company determines the lease classification, recognition, and measurement at the lease commencement date. For arrangements that contain a lease the Company: (i) identifies lease and non-lease components; (ii) determines the consideration in the contract; (iii) determines whether the lease is an operating or financing lease; and (iv) recognizes lease Right of Use ("ROU") assets and corresponding lease liabilities. Lease liabilities are recorded based on the present value of lease payments over the expected lease term. The corresponding ROU asset is measured from the initial lease liability, adjusted by (i) accrued or prepaid rents; (ii) remaining unamortized initial direct costs and lease incentives; and (iii) any impairments of the ROU asset.

Fixed lease payments on operating leases are recognized over the expected term of the lease on a straight-line basis. Variable lease expenses that are not considered fixed are expensed as incurred. Fixed and variable lease expense on operating leases is recognized within operating expenses within the accompanying consolidated statements of operations and comprehensive loss.

The interest rate implicit in the Company's lease contracts is typically not readily determinable and as such, the Company uses its incremental borrowing rate based on the information available at the lease commencement date, which represents an internally developed rate that would be incurred to borrow, on a collateralized basis, over a similar term, an amount equal to the lease payments in a similar economic environment.

Other Assets

In conjunction with a lease agreement further discussed in Note 14, Scorpius has made reimbursement payments to the lessor, Merchants Ice II, LLC, for costs incurred in conjunction with the leased site. Merchants Ice II, LLC is a nonprofit entity investing in the building with the intention to encourage development of emerging technologies. As a result, investments made to the building could generate tax incentives under the New Market Tax Credit ("NMTC") program. Scorpius agreed that all investments and expenditures qualifying under the NMTC (i.e., certain equipment and building improvements) would be purchased by Merchants Ice II, LLC to generate the largest possible tax incentive and Scorpius reimbursed Merchant Ice, LLC for these payments.

During the construction of the site, these payments were included in other assets on the consolidated balance sheets. On September 15, 2022, the lease commenced, and in accordance with ASC 842, the Company capitalized $13.2 million of payments to lab equipment and $10.2 million is included in the operating lease right-of-use asset.

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during each year. Fully diluted net loss per share is computed using the weighted average number of common shares and dilutive securities outstanding during each year. Dilutive securities having an anti-dilutive effect on diluted loss per share are excluded from the calculation.

Income Tax

Income taxes are accounted for using the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statements carrying amounts of assets and liabilities and their respective tax bases, operating loss carryforwards, and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

In accordance with ASC 740, *Accounting for Income Taxes*, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of December 31, 2022 and 2021, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying consolidated statements of operations. As of December 31, 2022 and 2021, the Company had no such accruals.

Stock-Based Compensation

The Company accounts for stock-based compensation arrangements with employees and non-employee directors using a fair value method that requires the recognition of compensation expense for costs related to all stock-based payments, including stock options and restricted stock units. The fair value method requires the Company to estimate the fair value of stock-based payment awards on the date of grant using an option pricing model. The fair value of restricted stock units is estimated based on the closing price of the Company's stock on the date of grant, and for the purposes of expense recognition, the total new number of shares expected to vest is adjusted for forfeitures as they occur. The Company settles exercises of stock options with newly issued shares of its common stock.

Stock-based compensation costs are based on the fair value of the underlying option calculated using the Black-Scholes-Merton option pricing model on the date of grant for stock options and are recognized as expense on a straight-line basis over the requisite service period, which is the vesting period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating stock price volatility, and expected term. The expected volatility rates are estimated based on average historical stock price volatility of its own data plus an analysis of reported data for a peer group of comparable companies that have issued stock options with substantially similar terms. The expected term for the years ended December 31, 2022 and 2021 represents the average time that options are expected to be outstanding based on the average of the vesting term and the contractual term of the option. We account for forfeitures as they occur. The Company has not paid dividends and does not anticipate paying a cash dividend in the foreseeable future and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards.

Net Loss Attributable to Non-controlling Interests

Net loss attributable to non-controlling interests is the result of the Company's consolidation of subsidiaries of which it does not own 100%. In October 2018, the Company entered into an agreement with the University of Miami ("UM") whereby UM exchanged its shares of stock in the Company's subsidiaries, Heat I, Inc. and Pelican, a related party prior to acquisition, for 35,000 shares of the Company's common stock. The stock exchange resulted in the Company owning

100% of Heat I, Inc. and increasing its controlling ownership in Pelican from80% to 85%. The Company's net loss attributable to non-controlling interests relates to the 15% ownership of Pelican that Heat does not own as of December 31, 2022 and 2021.

Deferred Revenue

Deferred revenue is comprised of an exclusive license agreement with Shattuck Labs, Inc. ("Shattuck") and process development customer deposits received in advance of our fulfillment of performance obligations.

License Agreements

The Company has licensed certain provisional patent applications and know-how related to fusion proteins to treat cancer and other diseases that were not being developed by the Company. Shattuck paid the Company an initial license fee of $50,000 in June 2016 and is obligated to pay the Company fees upon its receipt of sublicensing income, achievement of certain milestones, and royalties upon sales of commercial products. In-as-much as the technology that the Company out-licensed is in the early stages of development and there is a low likelihood of success for any technology at such stage, there can be no assurance that any products will be developed by Shattuck or that the Company will derive any revenue from Shattuck.

Process Development

Process development deferred revenue generally represents customer payments received in advance of the Company's fulfillment of performance obligations associated with the custom development of a manufacturing process and analytical methods for a customer's product. As of December 31, 2022 there was $1.6 million of deferred revenue related to process development.

Revenue Recognition

The Company applies ASC 606, *Revenue from Contracts with Customers.* Under ASC 606, revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price using the most likely method based on historical experience as well as applicable information currently available.

Product Sales

The Company recognizes revenue from product sales when its performance obligation with its customers has been satisfied. The performance obligation is satisfied at a point in time when the Company's customers obtain control of the product, which is typically upon acceptance of the product at the delivery site. The Company invoices its customers after acceptance of the product and invoice payments are generally due within 30 days of the invoice date. The Company records product sales net of any variable consideration, including refund rights. The Company uses the most likely amount method when estimating its variable consideration, unless terms are specified within contracts. The Company recognizes revenue to the extent that it is probable that a significant revenue reversal will not occur in a future period. These estimates may differ from actual consideration received. The Company evaluates these estimates to reflect known changes.

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Grant Revenue

The Company recognizes revenue related to the Cancer Prevention and Research Institute of Texas ("CPRIT") contract, which is being accounted for under Accounting Standards Update ("ASU") No. 2018-08*, Not-For-Profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made,* as a conditional non-exchange contribution.

The CPRIT grant covers the period from June 1, 2017 through May 31, 2022, for a total grant award of up to $15.2 million. CPRIT advances grant funds upon request by the Company consistent with the agreed upon amounts and schedules as provided in the contract. The first tranche of funding of $1.8 million was received in May 2017, a second tranche of funding of $6.5 million was received in October 2017, and the third tranche of funding of $5.4 million was received in December 2019. The remaining $1.5 million will be paid, on a reimbursement basis, after the Company has fulfilled every objective of the final goals of the grant. Funds received are reflected in deferred revenue as a liability until revenue is earned. Grant revenue is recognized when qualifying costs are incurred. When grant funds are received after costs have been incurred, the Company records revenue and a corresponding grants receivable until grant funds are received. As of December 31, 2022, all $15.2 million has been recognized.

On January 7, 2020, the Company was awarded a grant of up to $0.2 million from the National Institute of Allergy and Infectious Diseases, which is under the umbrella of the National Institutes of Health ("NIH"). The NIH grant provides funding for continued development of the Company's technologies for PTX-35. The grant funds will be made available by the NIH to the Company as allowable expenses are incurred. For the year ended December 31, 2022, the Company incurred $0.04 million of allowable expenses, respectively, under the NIH grant and recognized the corresponding revenue. For the year ended December 31, 2021, the Company incurred approximately $0.03 million of allowable expenses under the NIH grant and recognized a corresponding amount of grant revenues.

Process development revenue

Process development revenue generally represents revenue from services associated with the custom development of a manufacturing process and analytical methods for a customer's product. Process development revenue is recognized over time utilizing an output method by tracking the progress toward completion by measuring outputs to date relative to total estimated outputs needed to satisfy the performance obligation. Under a process development contract, the customer owns the product details and process, which has no alternative use. These process development projects are customized to each customer to meet its specifications and typically includes only one performance obligation. Each process represents a distinct service that is sold separately and has stand-alone value to the customer. The customer also retains control of its product as the product is being created or enhanced by our services and can make changes to its process or specifications upon request. Under these agreements, we are entitled to consideration for progress to date that includes an element of profit margin. As of December 31, 2022, the Company has not recognized any process development revenue.

Business Combinations

The accounting for our business combinations consists of allocating the purchase price to tangible and intangible assets acquired and liabilities assumed based on their estimated fair values, with the excess recorded as goodwill. We have up to one year from the acquisition date to use information as of each acquisition date to adjust the fair value of the acquired assets and liabilities, which may result in material changes to their recorded values with an offsetting adjustment to goodwill. Determining the fair value of assets acquired and liabilities assumed requires significant judgment, which includes, among other factors, analysis of historical performance and estimates of future performance. In some cases, we have used discounted cash flow analyses, which were based on our best estimate of future revenue, earnings and cash flows as well as our discount rate, adjusted for risk (see Note 5).

Goodwill and Intangible Assets

The Company classifies intangible assets into three categories: (1) intangible assets with definite lives subject to amortization, (2) intangible assets with indefinite lives not subject to amortization and (3) goodwill. The Company determines the useful lives of definite-lived intangible assets after considering specific facts and circumstances related to each intangible asset. Factors the Company considers when determining useful lives include the contractual term of any agreement related to the asset, the historical performance of the asset, and other economic facts; including competition and specific market conditions. Intangible assets that are deemed to have definite lives are amortized, primarily on a straight-line basis, over their estimated useful lives. Intangible assets that are deemed to have indefinite lives, including goodwill, are reviewed for impairment annually, or more frequently if events or changes in circumstances indicate that the asset might be impaired. The impairment test for indefinite-lived intangibles, other than goodwill, consists of a comparison of the fair value of the intangible asset with its carrying amount. If the carrying amount exceeds the fair value, an impairment charge is recognized in an amount equal to that excess. Indefinite-lived intangible assets, such as goodwill, are not amortized. The Company tests the carrying amounts of goodwill for recoverability on an annual basis or when events or changes in circumstances indicate a potential impairment exists, using a fair value-based test. The Company records a goodwill impairment charge if a reporting unit's carrying value exceeds its fair value.

In-process research and development ("IPR&D") assets are considered to be indefinite-lived until the completion or abandonment of the associated research and development projects. IPR&D assets represent the fair value assigned to technologies that the Company acquires, which at the time of acquisition have not reached technological feasibility and have no alternative future use. During the period that the assets are considered indefinite-lived, they are tested for impairment on an annual basis, or more frequently if the Company becomes aware of any events occurring or changes in circumstances that indicate that the fair value of the IPR&D assets are less than their carrying amounts. If and when development is complete, which generally occurs upon regulatory approval and the ability to commercialize products associated with the IPR&D assets, these assets are then deemed definite-lived and are amortized based on their estimated useful lives at that point in time. If development is terminated or abandoned, the Company may have a full or partial impairment charge related to the IPR&D assets, calculated as the excess of carrying value of the IPR&D assets over fair value. See Note 8 regarding impairment at December 31, 2022.

Contingent Consideration

Consideration paid in a business combination may include potential future payments that are contingent upon the acquired business achieving certain milestones in the future ("contingent consideration"). Contingent consideration liabilities are measured at their estimated fair value as of the date of acquisition, with subsequent changes in fair value recorded in the consolidated statements of operations and comprehensive loss. Contingent consideration is measured at fair value using a discounted cash flow model utilizing significant unobservable inputs including the probability of achieving each of the potential milestones, the estimated timing of milestone achievement, and an estimated discount rate associated with the risks of the expected cash flows attributable to the various milestones. The milestone payments will be made upon the achievement of milestones as well as royalty payments. Subsequent to the date of acquisition, the Company reassesses the actual consideration earned and the probability-weighted future earn-out payments at each balance sheet date. Any adjustment to the contingent consideration liability will be recorded in the consolidated statements of operations and comprehensive loss. Contingent consideration liabilities expected to be settled within 12 months after the balance sheet date are presented in current liabilities, with the non-current portion recorded under long term liabilities in the consolidated balance sheets. During the year ended December 31, 2022, $3.3 million of contingent consideration related to Pelican was written off as PTX-35 will not continue on to a Phase 2 trial (see Note 4).

Research and Development

Research and development costs associated with developmental products not yet approved by the FDA as well as costs associated with bringing developmental products into advanced phase clinical trials are expensed as incurred. These costs consist primarily of pre-manufacturing and manufacturing drug costs, clinical trial execution, investigator payments, license fees, salaries, stock-based compensation and related personnel costs. Other costs include fees paid to consultants

and outside service providers related to the development of the Company's product candidates and other expenses relating to the design, development, and testing and enhancement of its product candidates.

Impact of Recently Issued Accounting Standards:

The Company has evaluated issued ASUs not yet adopted and believes the adoption of these standards will not have a material impact on its consolidated financial statements.

3. ***Short-Term Investments***

Short-term investments consist of equity securities with a maturity of greater than three months and less than twelve months when acquired. The Company reports its securities at fair value as of December 31, 2022 and 2021. Unrealized losses on securities of $1.7 million and $0.8 million, respectively, are reported in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2022 and 2021. Short-term investments at December 31, 2022 and 2021 consisted of mutual funds with fair values of $35.8 million and $88.3 million, respectively.

4. ***Fair Value of Financial Instruments***

As a basis for determining the fair value of certain of the Company's financial instruments, the Company utilizes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level I – Observable inputs such as quoted prices in active markets for identical assets or liabilities.

Level II – Observable inputs, other than Level I prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level III – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the entire fair value measurement requires management to make judgments and consider factors specific to the asset or liability. The Company's cash equivalents are classified within Level I of the fair value hierarchy.

As of December 31, 2022 and 2021, the fair values of cash and cash equivalents, accounts payable, and accrued expenses approximated their carrying values because of the short-term nature of these assets or liabilities. The Company's short-term investments consist of Level I securities which are comprised of highly liquid money market funds. The estimated fair value of the short-term investments was based on quoted market prices. There were no transfers between fair value hierarchy levels during the years ended December 31, 2022 or 2021.

The fair value of financial instruments measured on a recurring basis is as follows:

	As of December 31, 2022			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Short-term investments	$ 35,837,309	$ 35,837,309	—	—
Liabilities:				
Contingent consideration	$ 12,224,614	—	—	$ 12,224,614
Warrant liability	—	—	—	—

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

	As of December 31, 2021			
Description	**Total**	**Level 1**	**Level 2**	**Level 3**
Assets:				
Short-term investments	$ 88,324,922	$ 88,324,922	—	—
Liabilities:				
Contingent consideration	3,342,515	—	—	3,342,515
Warrant liability	11,020	—	—	11,020

The following table summarizes the change in fair value, as determined by Level 3 inputs, for all assets and liabilities using unobservable Level 3 inputs for the years ended December 31, 2022 and 2021:

	Pelican Contingent Consideration	**Elusys Contingent Consideration**
Balance at December 31, 2020	$ 2,912,515	$ —
Change in fair value	430,000	—
Balance at December 31, 2021	$ 3,342,515	$ —
Acquisition of Elusys	—	39,853,685
Payment of receivable consideration	—	(20,784,571)
Payment of inventory consideration	—	(4,735,000)
Payment of deferred cash consideration		(2,000,000)
Change in fair value	(3,342,515)	(109,500)
Balance at December 31, 2022	$ —	$ 12,224,614

The change in the fair value of the contingent consideration of ($3,452,015) and $430,000 for the years ended December 31, 2022 and 2021, respectively, was primarily due to the effect of the change in discount rate, probability of achieving milestones, passage of time on the fair value measurement and discontinuation of the PTX-35 trial, thus leading to the write-off of the Pelican contingent consideration. Adjustments associated with the change in fair value of contingent consideration are included in the Company's consolidated statement of operations and comprehensive loss.

The following table presents quantitative information about the inputs and valuation methodologies used for the Company's fair value measurements of contingent consideration classified as Level 3 as of December 31, 2022 and 2021:

	As of December 31, 2022		
	Valuation Methodology	**Significant Unobservable Input**	**Weighted Average (range, if applicable)**
Elusys Revenue earn-out	Discounted cash flow analysis	Timing of expected payments	2025-2036
		Discount rate	24.5%
		Future revenue projections	$325.9 million
Elusys Contract deferred consideration	Discounted cash flow analysis	Timing of expected payments	2023
		Discount rate	15.5%
		Future revenue projections	$7.6 million

	As of December 31, 2021		
	Valuation Methodology	Significant Unobservable Input	Weighted Average (range, if applicable)
Contingent Consideration	Probability weighted income approach	Milestone dates	2022-2031
		Discount rate	7.51%
		Probability of occurrence	4.9% to 75%

The following table presents quantitative information about the inputs used in the valuation for the Company's fair value measurement of the warrant liability classified as Level 3 as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Current stock price	$ 0.81	$ 3.04
Estimated volatility of future stock price	80.94 %	133.13 %
Risk free interest rate	4.75 %	0.55 %
Contractual term	0.90 years	1.90 years

The Company measures certain non-financial assets on a non-recurring basis, including goodwill and in-process R&D and definite lived intangibles. As a result of those measurements, during the year ended December 31, 2022, in-process R&D with a total carrying value of $3.5 million was fully impaired with an impairment charge of $3.5 million. The full impairment of the in-process R&D was a result of the Company deciding to terminate any further development of PTX-35, Pelican's lead product candidate. During the year ended December 31, 2021, goodwill with a total carrying value of $1.5 million was written down and an impairment charge of $1.5 million was recorded. During the same period, in-process R&D with a total carrying value of $5.9 million was written down to its estimated fair value of $3.5 million and an impairment charge of $2.4 million. Impairment analysis requires significant judgments, including primarily the estimation of future development costs, the probability of success in various phases of its development programs, potential post-launch cash flows and a risk-adjusted weighted average cost of capital.

Assumptions related to future operating performance are based on management's annual and ongoing budgeting, forecasting and planning processes and represent our best estimate of the future results of our operations as of a point in time. These estimates are subject to many assumptions, such as the economic environments in which we operate, demand for the products and competitor actions. Estimated future cash flows are discounted to present value using a market participant, weighted average cost of capital, which considers the risk inherent in the probability adjusted future cash flows from each product. The financial and credit market volatility directly impacts certain inputs and assumptions used to develop the weighted average cost of capital such as the risk-free interest rate, industry beta, debt interest rate and our market capital structure. These assumptions are based on significant inputs not observable in the market and thus represent Level 3 measurements within the fair value hierarchy. The use of different inputs and assumptions could increase or decrease our estimated discounted future cash flows, the resulting estimated fair values and the amounts of related goodwill impairments, if any.

5. *Acquisitions*

Pelican Therapeutics

In 2017, the Company consummated the acquisition of 80% of the outstanding equity of Pelican, a related party, and Pelican became a majority owned subsidiary of the Company. During the quarter ended March 31, 2018, cash consideration of approximately $300,000 was distributed to the participating Pelican stockholders and the remainder of approximately $200,000 for certain Pelican liabilities not satisfied was recognized as other income in the statements of

operations and comprehensive loss for the period. In October 2018, the Company entered into an agreement with the University of Miami ("UM") whereby UM exchanged its shares of stock in the Company's subsidiaries, Heat I, Inc. and Pelican. The stock exchange resulted in Heat increasing its controlling ownership in Pelican from 80% to 85%.

Under the agreement, the Company was also obligated to make future payments based on the achievement of certain clinical and commercialization milestones, as well as low single digit royalty payments and payments upon receipt of sublicensing income. However, due to the discontinuation of PTX-35 no future milestone payments are expected to be made. The goodwill and in-process R&D resulting from the acquisiton were fully impaired as of December 31, 2022 (see Note 8).

Elusys Therapeutics

On April 18, 2022 ("Closing Date"), the Company closed on the acquisition of Elusys. NightHawk paid at the closing a cash upfront payment of $3,000,000 to the former owners ("Sellers") of Elusys. NightHawk is obligated to pay the Sellers $2,000,000 of deferred cash consideration ("Merger Consideration") at the same time that the payment of the receivable consideration is to be distributed to the Sellers as described below, which was paid in the second quarter of 2022. Earn out payments will be paid to the sellers for a period of 12 years from the date of the 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.

Per the Merger Agreement, upon collection of the Elusys contract receivables of $24.5 million, NightHawk will remit payment of $22.3 million (the "Receivable Consideration") to the Sellers. In April 2022, $20.8 million was remitted to the sellers less a hold back of $1.5 million related to future fulfillment cost. Elusys is expected to receive additional revenue from the future fulfillment of an existing U.S. Government contract, and NightHawk has agreed to fulfill the future obligations of Elusys under such contract and pass through and distribute to the Sellers the payments 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 "Contract Deferred Consideration"). The Merger Agreement further provides that 80% of any amounts paid to and received by Elusys (the "Additional Earn Out") after the Closing Date and prior to June 30, 2023, shall be paid to the Sellers, subject to certain adjustments specified in the Merger Agreement.

The Company acquired Elusys to expand its role in the biodefense space, complementing NightHawk's focus to target emerging biological threats. NightHawk plans to leverage Elusys' existing relationships and distribution channels. In addition, NightHawk expects to leverage the capabilities of its planned Scorpius biomanufacturing facility in Manhattan, Kansas, which will enable the Company to manufacture these therapies internally and therefore benefit from significant operating synergies, as well as enhanced oversight, quality control, and speed to market. The Company is also exploring opportunities to expand ANTHIM® distribution abroad. The acquisition is aligned with NightHawk's vision to establish a fully-integrated ecosystem to deliver medical innovations faster, better, and more efficiently.

The fair value of the purchase consideration was approximately $42.9 million. The purchase consideration consists of $3.0 million in cash and $2.0 million in deferred cash consideration, and the preliminary estimated fair value of the contingent and deferred consideration liabilities related to the receivable consideration, contract deferred consideration, earn out and additional earn out totaling $37.9 million. The preliminary valuation of the contract deferred consideration and earn out liabilities were valued using a discounted cash flow analysis that utilized discount rates of 24% and 14%, respectively. The preliminary value of the additional earn out liability was calculated as 80% of the estimated gross sales price of 1,500 pre-filled vials of ANTHIM®, less estimated fulfillment costs to be incurred. The value of the receivable consideration was equal to the value of the contract receivables acquired, less holdback expenses, as this liability was settled within 30 days of the Closing Date.

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The acquisition of Elusys was accounted for as a business combination and reflects the application of acquisition accounting in accordance with ASC 805, *Business Combinations*. The acquired Elusys' assets, including identifiable intangible assets and liabilities assumed, have been recorded at their estimated fair values with the excess purchase price assigned to goodwill. The recognition of goodwill is largely attributed to the value paid for Elusys' capabilities, which will broaden NightHawk's role in the biodefense space. The goodwill recorded for this transaction is valued at $3.3 million and will be deductible for tax purposes over 15 years.

The preliminary purchase price of $42.9 million has been allocated to the underlying assets and liabilities based on their estimated fair value at the date of acquisition. The excess of the purchase price over the fair value of assets acquired and liabilities assumed was recorded as goodwill. As we are still in the process of reviewing the fair value of the assets acquired and liabilities assumed, the purchase price allocation for Elusys is not complete as of December 31, 2022. In accordance with ASC 805, *Business Combinations*, we will finalize our purchase price allocation within one year of the acquisition date.

The following table highlights the components of the purchase consideration:

Aggregate consideration:	
Cash consideration	$ 3,000,000
Deferred cash consideration	2,000,000
Earn out	5,900,000
Additional earn out	4,735,000
Receivable consideration	22,318,685
Contract deferred consideration	4,900,000
Total purchase consideration	$ 42,853,685

The preliminary purchase price allocation resulted in the following amounts being allocated to the assets acquired and liabilities assumed as of the closing date based on their respective estimated fair values summarized below:

Purchase price allocation:	
Cash and cash equivalents	$ 5,719,899
Contract receivables	24,526,232
Prepaid expenses and other current assets	1,818,278
Inventory	5,844,000
Intangible asset – definite-lived (Note 8)	9,700,000
Property and equipment	50,224
Operating lease right of use assets	352,906
Other assets	326,249
Total assets acquired	48,337,788
Accounts payable	(204,794)
Accrued expenses and other current liabilities	(5,155,363)
Operating lease obligations	(352,906)
Deferred income tax liability	(3,073,000)
Total liabilities assumed	(8,786,063)
Net assets acquired and liabilities assumed	39,551,725
Goodwill	3,301,960
Total purchase consideration	$ 42,853,685

The above allocation of the purchase price is based upon certain preliminary valuations and other analyses that have not been finalized as of the date of this filing. Any changes in the estimated fair values of the purchase consideration and of the net assets recorded for this business combination upon the finalization of more detailed analyses of the facts and

circumstances that existed at the date of the transaction may change the amount and allocation of the purchase price. As such, the allocations for this transaction are preliminary estimates including deferred taxes, which may be subject to change within the measurement period.

During the three months ended September 30, 2022 the Company recognized a measurement period adjustment as a result of a change in forecast that related to the estimate of acquired assets resulting in a $1.5 million decrease in intangible assets, a $0.3 million decrease in the deferred tax liability and a $1.2 million decrease in goodwill. There were no other measurement period adjustments during the year.

In connection with the acquisition, the Company incurred one-time expenses consisting primarily of legal fees, accounting fees and consultant fees. For the year ended December 31, 2022, the Company incurred approximately $0.6 million of acquisition costs related to the Elusys transaction, which are included in general and administrative expenses in the consolidated statements of operations.

From the Elusys acquisition date through December 31, 2022, $6.0 million of total revenue and a net loss of $3.5 million associated with Elusys operations are included in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2022. Upon achievement of the next milestone payment event, contingent consideration of $5.4 million is expected to be paid to Elusys' shareholders by June 30, 2023.

The following unaudited pro forma financial information assumes the companies were combined as of January 1, 2021. The unaudited pro forma financial information as presented below is for informational purposes only and is based on estimates and assumptions that have been made solely for purposes of developing such pro forma information. This is not necessarily indicative of the results of operations that would have been achieved if the acquisition had taken place on January 1, 2021, nor is it necessarily indicative of future results. Consequently, actual results could differ materially from the unaudited pro forma financial information presented below. The following table presents the pro forma operating results as if Elusys had been included in the Company's consolidated statements of operations and comprehensive loss as of January 1, 2021 (unaudited):

	December 31,	
	2022	2021
	(unaudited)	(unaudited)
Revenue	$ 29,972,502	$ 55,511,592
Net loss	(33,433,608)	(10,084,749)
Net loss per share, basic and diluted	(1.31)	(0.40)

6. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following at:

	December 31, 2022	December 31, 2021
Prepaid manufacturing expense	$ 1,849,875	$ 563,280
Other prepaid expenses and current assets	1,432,242	460,030
Prepaid insurance	227,532	704,650
Prepaid preclinical and clinical expenses	65,892	1,158,560
	$ 3,575,541	$ 2,886,520

7. Property and Equipment

Property and equipment are recorded at cost and depreciated using the straight-line method over estimated useful lives ranging generally from three to eight years. Expenditures for maintenance and repairs are charged to expense as incurred.

Property and equipment consisted of the following at:

	December 31, 2022	December 31, 2021
Lab equipment	$ 18,060,058	$ 3,178,855
Leasehold improvements	2,495,585	22,563
Construction-in-process	2,053,335	309,620
Computers	502,084	85,071
Furniture and fixtures	286,739	66,106
Vehicles	44,562	—
Total	23,442,363	3,662,215
Accumulated depreciation	(2,961,988)	(1,503,736)
Property and equipment, net	$ 20,480,375	$ 2,158,479

Depreciation expense totaled $1.8 million and $0.4 million for the years ended December 31, 2022 and 2021, respectively.

8. Goodwill and other intangible assets

The Company performs an annual impairment test at the reporting unit level as of April 1st of each fiscal year or more frequently when an event occurs or circumstances change that indicate the carrying value may not be recoverable. As of April 1, 2022, the Company qualitatively assessed whether it is more likely than not that the respective fair value of the Company's reporting units (NightHawk, Pelican, Elusys and Scorpius) were less than its carrying amount, including goodwill.

Pelican Goodwill and In-Process R&D

Goodwill of $2.2 million and in-process R&D of $5.9 million were recorded in connection with the acquisition of Pelican, as described in Note 4 and have been allocated to the Pelican reporting unit. During the fourth quarter of 2021, due to a sustained decline in the quoted market price of its common stock, the Company performed an interim impairment analysis using the income approach and in-process R&D with a total carrying value of $5.9 million was written down to its estimated fair value of $3.5 million and an impairment charge of $2.4 million during the fourth quarter of 2021 was recorded and goodwill in the amount of $1.5 million was fully impaired. During the third quarter of 2022, the Company elected to terminate any further development of PTX-35. As a result of the termination, the in-process R&D affiliated with PTX-35, in the amount of $3.5 million, has been fully impaired.

Elusys Goodwill and Intangible Assets

Goodwill of $3.3 million and an intangible asset of $9.7 million was recorded in connection with the acquisition of Elusys which has been allocated to the Elusys reporting unit. During the fourth quarter of 2022, due to a sustained decline in the quoted market price of its common stock, the Company performed an interim goodwill impairment analysis using the income approach. However, through its quantitative analysis, the Company determined the carrying value was not in excess of its estimated fair value and therefore no impairment charge was recorded at December 31, 2022. Elusys' intangible asset relates to the ANTHIM® formulation and is amortized over its remaining patent life, approximately 80 months.

The following table provides the Company's goodwill, in-process R&D, and intangible assets as of December 31, 2022 and 2021.

	Goodwill	In-process R&D	Intangible Assets
Balance at December 31, 2020	$ 1,452,338	$ 5,866,000	$ —
Impairment	(1,452,338)	(2,366,000)	—
Balance at December 31, 2021	—	3,500,000	—
Impairment	—	(3,500,000)	—
Acquisition of Elusys Therapeutics	5,067,748	—	11,200,000
Measurement period adjustments	(1,765,789)		(1,500,000)
Amortization	—	—	(1,030,625)
Balance at December 31, 2022	$ 3,301,959	$ —	$ 8,669,375

9. Accrued Expenses and Other Liabilities

Accrued expenses and other liabilities consist of the following at:

	December 31, 2022	December 31, 2021
Compensation and related benefits	$ 1,176,963	$ 459,178
Income tax payable	1,092,560	—
Accrued preclinical and clinical trial expenses	959,992	955,013
Accrued manufacturing expenses	594,358	179,173
Other expenses	438,049	631,312
Accrued franchise tax	40,000	195,000
	$ 4,301,922	$ 2,419,676

10. Commitments and Contingencies

License Agreements

- *University of Miami*

  - Beginning in 2008, the Company has entered into various agreements with the University of Miami ("UM") for intellectual and tangible property rights relating to the *ImPACT*®, technology activities ("License Agreement 03-31, 05-39" and "License Agreement 97-14", or collectively "License Agreements"). These license agreements were subsequently assigned to the Company's subsidiary Heat Biologics I, Inc. ("Heat I") which issued to UM shares of its common stock representing 7.5% of its common stock. The term of the License Agreements is the length of the last to expire patent, unless terminated earlier.

  - The Company agreed to make minimum royalty payments of $10,000 for three years beginning in 2010 that are due on the anniversary date of the agreement for License Agreement 97-14. Beginning in 2013, and thereafter for the life of the agreement, the minimum royalty payment shall be $20,000 due on the same date. In July 2016, the Company and UM entered into an amendment which replaced the milestone payment of $250,000 by approval of a Biologics License Application ("BLA") for the lung cancer vaccine with a payment of $500,000 upon approval of a New Drug Application ("NDA") for a lung cancer vaccine covered by Patent Rights.

  - In August 2009, Heat I and UM entered into a second amendment ("Amendment 2") to License Agreement UMSS-114A to extend the foregoing payment due dates for all past due license fees and patent costs.

- On February 18, 2011, Heat I entered into a license agreement ("SS114A") with UM to obtain additional technology related to License Agreement 97-14. Heat I agreed to reimburse UM for all past patent costs of $37,381. As partial consideration for SS114A, Heat I agreed to grant back certain exclusive rights to UM.

- In addition, Heat entered into an agreement for "Modified Heat Shock Proteins-Antigenic Peptide Complex" with UM in September 2014 for a cancer cell line where UM agreed not to license the cell line to third parties while the Company is in good standing and in compliance of its patent license agreements with UM relating to our *ImPACT*® platform. There is no financial obligation on the Company's part under the arrangement.

- On October 25, 2016, the Company entered into an exclusive license agreement with UM for the license and development of intellectual property related to its gp96 platform to target the Zika virus and other infectious diseases. As consideration for the rights granted in this license agreement the Company is obligated to pay UM an upfront license fee of $20,000 and nominal annual maintenance fees over the initial ten years that total $82,000 and increasing thereafter. The Company is obligated to pay royalties equal to a percentage (mid-single digits) of net sales of products covered by the patent-related rights, subject to reduction if additional licenses from third parties are required to commercialize licensed products.

- On December 7, 2020, the Company entered into separate amendments to its existingthree license agreements with the University of Miami to extend to December 31, 2025, the date by which the University of Miami may terminate the license agreements if by such date the Company will not have introduced a licensed product into the commercial marketplace in one of the three major markets (European Union, Japan and the United States) or will not have made best efforts to achieve the same. The three license agreements so amended are: (i) License Agreement (UMSS-114 (previously UM 97-14)) between the University of Miami and Heat Biologics, Inc. effective July 11, 2008, (ii) License Agreement (D-107) between the University of Miami and Heat I, Inc. effective February 18, 2011, and (iii) License Agreement (UMSS-114A) between the University of Miami and Heat I, Inc. effective February 18, 2011.

- *University of Miami - Pelican*

  - For each agreement, the Company agreed to make minimum royalty payments of $10,000 for three years beginning in 2010 due on the anniversary date of the agreements to the University of Miami. Beginning in 2013, and thereafter for the life of the agreements, the minimum royalty payments shall be $20,000 due on the same date.

  License 0331, 0539:

  - Pelican is obligated to make milestone payments as follows: $150,000 due upon submission and approval of an IND and the completion of a Phase 1 clinical trial and $250,000 due upon the earlier of May 2024 or approval of an NDA. The Company has the right to terminate this Agreement without obligation for future unpaid milestones.

  - In August 2009, Pelican and UM entered into a second amendment ("Amendment 2") to License Agreement 0331, 0539 to extend the foregoing payment due dates for all past due license fees and patent costs.

  - In February 2010, Pelican and UM entered into a third amendment ("Amendment 3") to License Agreement 0331, 0539 to grant back to UM a certain nonexclusive license. In all other respects, the original agreement remained the same.

  - In October 2010, Pelican and UM entered into a fourth amendment ("Amendment 4") to License Agreement 0331, 0539 to grant to the licensor a nonexclusive license right for certain technology as research reagents and research tools.

License I176:

- On December 12, 2010, Pelican entered into another license agreement ("I176") with UM for one component of complimentary technology to the July 11, 2008 agreement. Pelican agreed to pay UM a license fee of $50,000 and a reimbursement of $15,797 for past patent fees. Pelican also agreed to make a minimum royalty payment of $10,000 during 2012 through 2014 and then $20,000 every year thereafter. Pelican is obligated to make milestone payments as follows: $150,000 due upon submission and approval of an IND and the completion of a Phase 1 clinical trial and $500,000 due upon the earlier of May 2024 or approval of an NDA. The Company has the right to terminate this Agreement without obligation for future unpaid milestones.

- In August 2012, Pelican and UM entered into a second amendment ("I176 Amendment 2") to License Agreement I176 to extend the foregoing payment due dates for all past due license fees and patent costs.

- On December 7, 2020, the Company entered into a separate amendment to License Agreement (UMI-176) between the University of Miami and Heat Biologics, Inc. effective December 12, 2010, to extend to December 31, 2025, the date by which the University of Miami may terminate the license agreements if by such date the Company will not have introduced a licensed product into the commercial marketplace in one of the three major markets (European Union, Japan and the United States) or will not have made best efforts to achieve the same.

- *Other License Agreements*

  - On April 12, 2011, the Company entered into a non-exclusive evaluation and biological material license agreement with a not-for-profit corporation for evaluation and production of vaccines. In consideration for the licenses, the Company agreed to pay the not-for-profit corporation a fee of $5,000 and $50,000, respectively. The Company has the option to renew the license once the original term has expired. Milestone payments are due upon certain events agreed upon by Heat and the not-for-profit corporation. In December 2015, the Company amended the evaluation and biological material license agreement to add additional cell lines in exchange for a one-time payment of $1,000.

  - On August 30, 2010, the Company entered into an option agreement with the University of Michigan ("University") to acquire the right to negotiate an exclusive license for certain materials which include cancer cells and all unmodified derivatives of these cells. An option fee of $2,000 was paid on September 8, 2010 to grant a period ofnine months for this consideration. In July 2011, the Company exercised the option to acquire the license for $10,000.

  - In June 2016, the Company entered into an exclusive license agreement with Shattuck Labs, Inc. ("Shattuck") pursuant to which the Company licensed certain provisional patent applications and know-how related to fusion proteins to treat cancer and other diseases that were not being developed by us. Shattuck paid the Company an initial license fee of $50,000 and is obligated to pay the Company fees upon its receipt of sublicensing income, achievement of certain milestones and royalties upon sales of commercial products. Inasmuch as the technology that the Company out-licensed is in the early stages of development and there is a low likelihood of success for any technology at such stage, there can be no assurance that any products will be developed by Shattuck or that the Company will derive any revenue from Shattuck.

  - On December 31, 2020, Zolovax, Inc. ("Zolovax"), a wholly-owned subsidiary of Heat Biologics, Inc. entered into an Exclusive License Agreement with the University of Miami for the license and development of a portfolio of patents leveraging its UMIP-510 platform to target the COVID-19 virus and other infectious diseases. The License Agreement grants Zolovax exclusive, worldwide rights to research, develop, make, use or sell Licensed Products (as defined in the License Agreement) based upon patent-related rights. The

term of the license is the later of the length of the last to expire patent orfifteen (15) years from the date of the first sale of a Licensed Product unless terminated earlier. As consideration for the rights granted in the License Agreement, Zolovax paid an upfront fee of $2,500, is obligated to pay certain annual payments and to pay royalties equal to a percentage (in the low-to-mid single digits) of net sales of Licensed Products. These royalty rates are subject to reduction if additional license rights from third parties are required to commercialize the Licensed Products.

Future minimum royalty payments by the Company for licenses as of December 31, 2022 are as follows (in thousands):

Year ended December 31,	
2023	$ 74,000
2024	775,000
2025	25,000
2026	50,000
Total	$ 924,000

Manufacturing Commitments

We rely on Lonza, a third party manufacturer, to produce our commercial quantities of our ANTHIM® substance requirements. We have firm orders with Lonza for future purchases of drug substance, with remaining total non-cancellable future commitments of approximately $53.0 million through 2025. If we terminate certain firm orders with Lonza without cause, we will be required to pay for drug substance scheduled for manufactureunder our arrangement.

11. Revenue

Product Sales

On April 19, 2022, Elusys entered into a contract with Public Works and Government Services of Canada to deliver3,000 vials of ANTHIM® for treatment of inhalational anthrax due to Bacillus anthrax. The total contract award is $6.0 million with a delivery date on or before September 30, 2022. This order was fulfilled on September 13, 2022 for the total contract amount of $6.0 million.

Grant Revenue

In June 2016, Pelican entered into a cancer research grant contract (“Grant Contract”) with CPRIT, under which CPRIT awarded a grant not to exceed $15.2 million for use in developing cancer treatments by targeting a novel T-cell costimulatory receptor (namely, DR3/TNFRSF25). The Grant Contract initially covered a period from June 1, 2016 through November 30, 2019, as amended, was extended to May 30, 2022. The first tranche of funding of $1.8 million was received in May 2017, a second tranche of funding of $6.5 million was received in October 2017, and a third tranche of funding of $5.4 million was received in December 2019. The remaining $1.5 million will be awarded on a reimbursement basis after we have fulfilled every requirement of the grant and the grant has been approved to be finalized. As of December 31, 2022, all $15.2 million has been recognized.

The grant is subject to customary CPRIT funding conditions including a matching funds requirement where Pelican will match $0.50 for every $1.00 from CPRIT. Consequently, Pelican is required to provide $7.6 million in matching funds over the life of the project. Upon commercialization of the product, the terms of the grant require Pelican to pay tiered royalties in the low to mid-single digit percentages. Such royalties reduce to less than one percent after a mid-single-digit multiple of the grant funds have been paid to CPRIT in royalties.

Through December 31, 2022, $15.2 million of grant funding received to date has been recognized as revenue. As of December 31, 2022, we had a grant 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. At the conclusion of the grant the Company will be subject to an audit by CPRIT before the final grant payment can be approved and distributed. The Company believes this will not be finalized until the end of 2023.

12. Stockholders' Equity

Authorized Capital

NightHawk has authorized 10,000,000 shares of Preferred Stock (par value $0.0001) as of December 31, 2022 and 2021. As of December 31, 2022 and 2021, there were no outstanding shares of Preferred Stock.

NightHawk had 250,000,000 shares of common stock (par value $0.0002) authorized as of December 31, 2022 and 2021. As of December 31, 2022 and 2021, 25,661,488 and 25,649,824 common stock shares wereissued and outstanding.

At-The-Market-Offering

From January 1, 2021 to December 31, 2021 the Company sold2,106,027 shares of common stock under the Common Stock Sales Agreement, and the Amended and Restated Common Stock Sales Agreement, at an average price of approximately $ 12.18 per share, raising aggregate net proceeds of approximately $25.6 million, after deducting an aggregate commission up to 3%. No shares of common stock were sold under the Common Stock Sales Agreement, or the Amended and Restated Common Stock Sales Agreement during the year ended December 31, 2022.

Common Stock Warrants

In connection with the November 26, 2018 public offering, the Company issued657,142 common stock warrants each of which are exercisable for one share of common stock. The common stock warrants have an exercise price of $11.55 per share and expire five years from the issuance date. The warrants have been accounted for as equity instruments.

In connection with the May 7, 2018 public offering, the Company issued1,357,142 pre-funded warrants and 1,026,785 common stock warrants each of which are exercisable for one share of common stock. The pre-funded warrants had an exercise price of $0.07 per share and as of December 31, 2019 all pre-funded warrants have been exercised. The common stock warrants have an exercise price of $11.09 per share and expire five years from the issuance date. The warrants have been accounted for as equity instruments.

In January 2021, the Company issued31,000 common stock warrants each of which are exercisable forone share of common stock. The common stock warrants have an exercise price of $5.78 per share and expire two years from the issuance date. The warrants have been accounted for as equity instruments.

During the year ended December 31, 2022, no common stock warrants have been issued, exercised, exchanged, or expired. During the year ended December 31, 2021, 31,000 warrants were issued and no common stock warrants were exercised orexchanged and 42,556 common stock warrants expired.

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The Company has a total of 747,383 warrants outstanding at a weighted average exercise price of $11.06 to purchase its common stock as of December 31, 2022. These warrants are summarized as follows:

Issuance Date	Number of Shares	Exercise Price	Expiration Date
5/7/2018	403,025	$ 11.09	5/8/2023
11/26/2018	313,358	$ 11.55	11/26/2023
1/28/2021	31,000	$ 5.78	1/28/2023

Equity Compensation Plans

2009 Stock Incentive Plan

In 2009, the Company adopted the Heat Biologics, Inc. 2009 Stock Option Plan (the "2009 Plan"), under which stock options to acquire 21,739 common shares could be granted to key employees, directors, and independent contractors. Under the 2009 Plan, both incentive and non-qualified stock options could be granted under terms and conditions established by the Board of Directors. The exercise price for incentive stock options was the fair market value of the related common stock on the date the stock option was granted. Stock options granted under the 2009 Plan generally have terms of 10 years and have various vesting schedules.

The Company amended the 2009 Stock Option Plan and all related addendum agreements in April 2011. This second amendment increased the number of shares available for issuance from 21,739 to 65,217. The Company amended the 2009 Plan to increase the number of shares available for issuance to 86,957. The 2009 Plan expired in September 2019, however all options outstanding at the time of expiration remained outstanding and exercisable by their term. As of December 31, 2022 and 2021, there were 1,135 and 2,622 stock options outstanding under the 2009 Plan, respectively.

2014 Stock Incentive Plan

In June 2014, the stockholders approved the Heat Biologics, Inc. 2014 Stock Option Plan (the "2014 Plan"), under which the Company is authorized to grant 50,000 awards in the form of both incentive and non-qualified stock options, restricted stock, stock appreciation rights and other stock-based awards with terms established by the Compensation Committee of the Board of Directors which has been appointed by the Board of Directors to administer the 2014 Plan. In 2015, the stockholders approved an amendment to the Plan to increase the number of shares by 60,000 and in 2016, the stockholders approved an amendment that allowed the Company to grant up to300,000 awards in total. As of December 31, 2022 and 2021, there were 17,385 and 21,368 stock options outstanding under the 2014 Plan, respectively.

2017 Stock Incentive Plan

In June 2017, the stockholders approved the Heat Biologics, Inc. 2017 Stock Incentive Plan (the "2017 Plan"), under which the Company is authorized to grant 500,000 awards in the form of both incentive and non-qualified stock options, restricted stock, stock appreciation rights and other stock-based awards with terms established by the Compensation Committee of the Board of Directors which has been appointed by the Board of Directors to administer the 2017 Plan. As of December 31, 2022 and 2021 there were 31,018 and 38,227 stock options outstanding under the 2017 Plan, respectively.

2018 Stock Incentive Plan

In October 2018, the stockholders approved the Heat Biologics, Inc. 2018 Stock Incentive Plan (the "2018 Plan"), under which the Company is authorized to grant 571,428 awards in the form of both incentive and non-qualified stock options, restricted stock, stock appreciation rights and other stock-based awards with terms established by the Compensation Committee of the Board of Directors which has been appointed by the Board of Directors to administer the 2018 Plan. At our 2019 Annual Meeting of Stockholders, the stockholders approved an amendment to the 2018 Plan to increase the number of shares by 571,428. As of December 31, 2022 and 2021 there were 6,955,758 and 2,847,755 stock options outstanding under the 2018 plan, respectively.

2021 Subsidiaries Stock Incentive Plan

In July 2021, the stockholders approved the Company's 2021 Subsidiaries Stock Incentive Plan (the "SSIP") which allows for the grant of equity interests in subsidiaries of the Company including Skunkworx, Scorpius, Abacus, Blackhawk and other newly formed subsidiaries of the Company that adopt the SSIP by resolution of their Board of Directors. On August 2, 2021, the Board of Directors, the Compensation Committee and the Boards of Directors of Skunkworx, Scorpius, Abacus and Blackhawk granted to Jeff Wolf, Chief Executive Officer, an option under the SSIP to purchase 10,526, 10,638, 10,526 and 10,526 shares of common stock of Skunkworx, Scorpius, Abacus and Blackhawk, respectively, and to William Ostrander, Chief Financial Officer, an option under the SSIP to purchase 2,127 shares of common stock of Scorpius. In addition, at its 2022 Annual Meeting for Stockholders, the stockholders approved adding Elusys as a participating subsidiary in the SSIP and increasing the numbers of shares that each participating subsidiary may issue under the SSIP. As of December 31, 2022 and 2021 there were 31,578 and 44,343 stock options outstanding under the 2021 SSIP plan, respectively.

2021 Employee Stock Option Plan

The ESPP was approved at the Company's annual meeting of stockholders in September 2021. The ESPP currently authorizes an aggregate of 500,000 shares of common stock to be purchased. The ESPP allows employees to purchase shares of common stock of the Company at each purchase date through payroll deductions of up to a maximum of 15% of their compensation, at 85% of the lesser of the market price of the shares at the time of purchase or the market price on the beginning date of an option period. At December 31, 2022, there were 488,336 shares available for issuance under the ESPP.

There are 547,763 stock options remaining available for grant under the 2014 Plan, 2017 Plan, 2018 Plan and 2021 Plans (collectively, the "Plans"). The following table summarizes the components of the Company's stock-based compensation included in net loss:

	For the years ended December 31,	
	2022	2021
Employee stock options	$ 2,782,694	$ 1,136,843
Non-employee stock options	1,114,894	1,294,279
Employee stock awards	169,571	2,903,463
Non-employee stock awards	18,578	834,396
	$ 4,085,737	$ 6,168,981

Accounting for Stock-Based Compensation:

Stock Compensation Expense - For the years ended December 31, 2022, and 2021, we recorded $4,085,737, and $6,168,981 of stock-based compensation expense, respectively. No compensation expense of employees with stock awards was capitalized during the years ended December 31, 2022 and 2021.

Stock Options - Under the Plans, we have issued stock options. A stock option granted gives the holder the right, but not the obligation to purchase a certain number of shares at a predetermined price for a specific period of time. We typically issue options that vest over four years in equal installments beginning on the first anniversary of the date of grant. Under the terms of the Plans, the contractual life of the option grants may not exceed ten years. During the years ended December 31, 2022, and 2021, we issued options that expire ten years from the date of grant.

Fair Value Determination - We have used the Black-Scholes-Merton option pricing model to determine fair value of our stock option awards on the date of grant.

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The following weighted-average assumptions were used for option grants during the years ended December 31, 2022 and 2021:

- ***Volatility*** – The Company used an average historical stock price volatility of its own data plus an analysis of reported data for a peer group of comparable companies that have issued stock options with substantially similar terms.

- ***Expected life of options*** – The expected term represents the period that the Company's stock option grants are expected to be outstanding. The Company elected to utilize the "simplified" method to estimate the expected term as the company does not have sufficient appropriate exercise data on which to base its estimate. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

- ***Risk-free interest rate*** – The rate is based on U.S. Treasury interest rates at the time of the grant whose term is consistent with the expected life of the stock options.

- ***Dividend yield*** – The expected dividend yield was considered to be0% in the option pricing formula since the Company had not paid any dividends and had no plan to do so in the future.

- ***Forfeitures*** – The Company's policy is to account for forfeitures as they occur.

The following table summarizes assumptions used in our calculations of fair value for the years ended December 31, 2022 and 2021:

	2022	2021
Dividend yield	— %	— %
Expected volatility	100.85-105.09 %	99.34-104.61 %
Risk-free interest rate	1.95-3.61 %	0.36-1.36 %
Expected lives (years)	5.3-6.1 years	5.0-6.1 years

Stock Option Activity - The weighted-average grant date fair value of options granted during the years ended December 31, 2022 and 2021 was $0.87 and $3.67, respectively.

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The following table summarizes stock option activity for the years ended December 31, 2022 and 2021:

	Shares	Weighted Average Exercise Price	Aggregate Intrinsic Value	Weighted Average Remaining Contractual Life
Stock options outstanding at December 31, 2020	1,480,139	$ 11.05	$ 403,743	
Granted	1,674,153	4.65		
Exercised	(70,967)	6.53	$ —	
Expired	(49,532)	14.26		
Forfeited	(79,478)	5.55		
Stock options outstanding at December 31, 2021	2,954,315	7.62	$ 100,419	
Granted	4,307,599	1.10		
Exercised	(12,765)	1.30	$ —	
Expired	(82,253)	10.20		
Forfeited	(130,022)	4.44		
Stock options outstanding at December 31, 2022	7,036,874	$ 3.67	$ 16,842	9.1 Years
Stock options exercisable at December 31, 2022	1,680,455	$ 9.63	$ 16,841	7.5 Years

Unrecognized compensation expense related to unvested stock options was $5.4 million as of December 31, 2022, which is expected to be recognized over a weighted-average period of 1.30 years and will be adjusted for forfeitures as they occur.

Restricted Stock - Under the Plans, the Company has issued restricted stock. A restricted stock award is an issuance of shares that cannot be sold or transferred by the recipient until the vesting period lapses. Restricted stock issued to members of our Board of Directors and Executives vest 50% on the grant date, 30% on the first anniversary and 10% each anniversary thereafter. The grant date fair value of the restricted stock is equal to the closing market price of the Company's common stock on the date of grant.

Restricted Stock Activity - The following table summarizes the restricted stock activity during the years ended December 31, 2022 and 2021:

	Shares	Weighted Average Fair Value
Restricted stock at December 31, 2020	239,928	$ 4.02
Granted	678,490	5.09
Vested	(548,248)	4.88
Restricted stock at December 31, 2021	370,170	4.71
Vested	(336,169)	4.86
Restricted stock at December 31, 2022	34,001	$ 3.22

The aggregate fair value of awards that vested during the years ended December 31, 2022 and 2021 was $1.6 million and $2.2 million.

RSUs - Under the Plans, the Company has time-based RSUs. RSUs are not actual shares, but rather a right to receive shares in the future. The shares are not issued and the employee cannot sell or transfer shares prior to vesting and has no voting rights until the RSUs vest. The employees' time-based RSUs will result in the delivery of shares in one-fourth increments commencing on the award date. The grant date fair value of the RSUs is equal to the closing market price of the Company's common stock on the grant date. The Company recognizes the grant date fair value of RSUs of shares it expects to issue as compensation expense ratably over the requisite service period.

The following table summarizes the RSU activity during the year ended December 31, 2021. There was no RSU activity during the year ended December 31, 2022.

	Shares	Weighted Average Fair Value
RSUs at December 31, 2020	1,900	$ 26.60
Vested	(1,900)	26.60
RSUs at December 31, 2021	—	$ —

13. Income Tax

The components of income tax benefit are as follows:

	2022	2021
Current Expense:		
Federal	$ —	$ —
State	—	—
Foreign	—	—
	—	—
Deferred Expense:		
Federal	$ (3,288,937)	$ (145,974)
State	—	—
Foreign	—	—
Total	$ (3,288,937)	$ (145,974)

The differences between the company's income tax benefit and the expense computed at the21% United States statutory income tax rate were as follows:

	2022	2021
Federal income tax expense at statutory rate:	$ (9,902,000)	$ (7,465,000)
Increase (reduction) in income tax resulting from:		
State income taxes	(198,000)	556,000
Foreign rate differential	(19,000)	(16,000)
Nondeductible expenses	1,000	1,000
Research and development credit	(1,312,000)	(836,000)
Stock based compensation	192,000	164,000
Excess executive compensation	9,000	259,000
Elusys acquisition	(41,000)	—
Goodwill impairment	—	305,000
Reserve for loss carryforwards limited by Sec. 382	8,000	8,000
Other	(99,937)	(32,974)
Increase in valuation allowance	8,073,000	6,911,000
	$ (3,288,937)	$ (145,974)

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The tax effects of temporary differences and operating loss carryforwards that gave rise to significant portions of the deferred tax assets and deferred tax liabilities were as follows at December 31, 2022 and 2021:

	2022	2021
Deferred tax assets:		
Net operating losses	$ 23,938,503	$ 17,830,889
R&D credits	4,132,625	2,538,168
Stock compensation	2,974,242	2,344,902
Contingent consideration	—	767,763
Deferred revenue	7,465	8,039
Section 174 costs	4,690,801	—
Unrealized gains/losses	584,079	210,300
Deferred tax assets	36,327,715	23,700,061
Deferred tax liabilities:		
Intangible assets	(1,991,789)	(803,937)
Property, plant and equipment, primarily due to differences in depreciation	(553,332)	(83,122)
Lease liability	(2,743,364)	(78,035)
Other	(99,272)	(83,931)
Deferred tax liabilities	(5,387,757)	(1,049,025)
Valuation allowance	(30,939,958)	(22,866,973)
Net deferred tax (liabilities)	$ —	$ (215,937)

At December 31, 2022 and December 31, 2021, the Company evaluated all significant available positive and negative evidence, including the existence of losses in recent years and management's forecast of future taxable income, and, as a result, determined it was more likely than not that federal and state deferred tax assets, including benefits related to net operating loss carryforwards, would not be realized. The company completed a 382 analysis to determine any limitations on the annual usage of their NOL carryforwards (discussed in further detail below). The allowance increased to $30,939,958 at December 31, 2022. Net Operating Losses created in years beginning after 2017 now only offset 80% of Taxable Income but no longer have a 20 year expiration. As such, NOL's created after 2017 can be used to offset indefinite lived liabilities up to 80%.

At December 31, 2022, the Company has federal net operating loss carryforwards of approximately $174,285,827, including $3,027,284 acquired from Pelican Therapeutics. However, due to Section 382 limitations (discussed in further detail below), only $116,493,744 of the NOLs are available to offset future taxable income. The federal net operating loss carryforwards begin to expire in 2029. The Company has various state net operating loss carryforwards totaling approximately $124,461,888 including $2,464,819 from Pelican Therapeutics, which are available to offset future state taxable income. State net operating losses begin to expire in 2024. On November 15, 2021, the North Carolina General Assembly passed Senate Bill 105 eliminating the current 2.5% corporate income tax by phased lowering of the rate from 2025 – 2030. A reserve has been set up for North Carolina NOLs that are not expected to be used by 2030. The Company has various foreign net operating loss carryforwards of $125,097. The foreign net operating loss carryforwards are carried forward indefinitely. Because the Company has incurred cumulative net operating losses since inception, all tax years remain open to examination by U.S. federal, state, and foreign income tax authorities.

In accordance with FASB ASC 740, Accounting for Income Taxes, the Company reflects in the financial statements the benefit of positions taken in a previously filed tax return or expected to be taken in a future tax return only when it is considered 'more-likely-than-not' that the position taken will be sustained by a taxing authority. As of December 31, 2022, and 2021, the Company had no unrecognized income tax benefits and correspondingly there is no impact on the Company's

effective income tax rate associated with these items. The Company's policy for recording interest and penalties relating to uncertain income tax positions is to record them as a component of income tax expense in the accompanying statements of income. As of December 31, 2022 and 2021, the Company had no such accruals

The Company files income tax returns in the United States, various state and foreign jurisdictions. The Company was subject to examination by taxing authorities for the tax years ended December 31, 2009 through 2021.

Potential 382 Limitation

The Company's ability to utilize its NOL and research and development (R&D) credit carryforwards may be substantially limited due to ownership changes that have occurred or that could occur in the future, as required by Section 382 of the Internal Revenue Code of 1986, as amended (the Code), as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change," as defined by Section 382 of the Code, results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50 percent of the outstanding stock of a company by certain stockholders or public groups.

The Company completed a Section 382 study during 2021. It was determined that the Company has experiencedfive ownership changes of over 50% since 2013, the latest occurring on June 30, 2020. Going forward, the utilization of loss carryforwards and tax credits generated before June 30, 2020 will be subject to an annual limitation. As a result of the ownership changes and limitations, $58,181,799 of federal NOLs and approximately $2,935,000 of federal R&D credits will expire unutilized, in addition to Section 382 limits on Pelican already in place.

14. Leases

The Company accounts for its leases under ASC 842, *"Leases"*. The Company has determined that its leases for office and laboratory space without optional terms or variable components are operating leases.

The Company conducts its operations from leased facilities in Morrisville, North Carolina; San Antonio, Texas; Parsippany, New Jersey and North Brunswick, New Jersey. The North Carolina lease will expire in 2030, the Texas lease will expire in 2037, the Parsippany and New Brunswick leases will expire in July 2023. The leases are for general office space, manufacturing space, and lab space and require the Company to pay property taxes, insurance, common area expenses and maintenance costs.

In June 2021, the Company entered into a lease agreement with Durham KTP Tech 7, LLC, to lease a15,996 square foot facility in Morrisville, North Carolina to expand its research and development activities. The lease has a term of eight years following the commencement date and provides the Company the option to extend the lease term for one five year term, however option to extend was not included in the ROU asset and liability. It is subject to fixed rate escalation increases and also provides up to $2.4 million for tenant improvements. NightHawk recorded an operating lease right-of-use asset of $5.6 million and lease liability of $3.2 million for this lease in the accompanying consolidated balance sheets.

In October 2021, Scorpius entered into a lease agreement with Merchants Ice II, LLC to lease a20,144 square foot facility in San Antonio, TX for general office, laboratory, research, analytical, and/or biomanufacturing purposes. Merchants Ice II, LLC is a nonprofit entity investing in the building with the intention to encourage development of emerging technologies. As a result, investments made by both Merchants Ice II, LLC and Scorpius into the building may qualify and share tax credits under the New Market Tax Credit ("NMTC") program. Scorpius agreed that all investments and expenditures qualifying under the NMTC (i.e., certain equipment and building improvements) would be purchased by Merchants Ice II, LLC to generate the largest possible tax incentive and Scorpius would reimburse Merchants Ice II, LLC for these payments. The lease officially commenced on September 15, 2022. As of December 31, 2022, Scorpius has reimbursed Merchants Ice II, LLC $24.3 million. Based on ASC 842, the Company has capitalized $13.2 million of the reimbursements as lab equipment, expensed $0.9 million as supplies and facilities, and $10.2 million has been included in the finance lease right-of-use asset. The lease has a term of fifteen years following the commencement date and provides

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

Scorpius the option to extend the lease term forone fifteen-year term, and one subsequent ten year term upon expiration of the first extended term. These options to extend were not included in the ROU asset and lease liability. It is subject to fixed rate escalation increases and also provides up to $2.4 million for tenant improvements. Scorpius recorded a finance lease right-of-use asset of $5.1 million and lease liability of $5.1 million for this lease in the accompanying consolidated balance sheets.

Total cash paid for operating leases during the years ended December 31, 2022 and 2021 was $0.8 million and $0.4 million and is included within cash flows from operating activities within the consolidated statements of cash flows.

The Company leases furniture and specialized lab equipment under finance leases. The related right-of-use assets are amortized on a straight-line basis over the lesser of the lease term or the estimated useful life of the asset. The effective interest rate was 5.80% and 5.30% for the years ended December 31, 2022 and 2021.

The Company's lease cost reflected in the accompanying statements of operations and comprehensive loss is as follows:

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Operating lease cost	$ 870,939	$ 474,135
Finance lease cost		
Amortization of lease assets	656,794	185,171
Interest on lease liabilities	181,667	21,970
Total finance lease cost	$ 838,461	$ 207,141

The weighted average remaining lease term and incremental borrowing rate as of December 31, 2022 and 2021 were as follows:

	For the Year Ended December 31, 2022	For the Year Ended December 31, 2021
Weighted average remaining lease term		
Operating leases	7.2 years	5.0 years
Finance leases	13.3 years	2.0 years
Weighted average incremental borrowing rate		
Operating leases	9.30 %	6.32 %
Finance leases	9.60 %	5.30 %

Maturities of operating and finance lease liabilities as of December 31, 2022 were as follows:

	Operating Leases	Finance Leases	Total
2023	791,502	769,621	1,561,123
2024	618,918	812,383	1,431,301
2025	635,180	715,782	1,350,962
2026	575,349	595,309	1,170,658
2027	592,572	615,269	1,207,841
2028	610,407	635,827	1,246,234
Thereafter	1,166,271	7,080,308	8,246,579
Total minimum lease payments	4,990,199	11,224,499	16,214,698
Less: imputed interest	(1,419,934)	(5,403,417)	(6,823,351)
Present value of lease liabilities	$ 3,570,265	$ 5,821,082	$ 9,391,347

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

15. Related Party Transactions

Prior to acquisition, Jeffrey Wolf, President, Chief Executive Officer and Chairman of the Board of Directors, was a director of Elusys and directly and through affiliated entities owned 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. Common stockholders are not expected to receive any future payments as presently it seems most, if not all, of such payments will also be paid to the preferred stockholders of Elusys.

16. Net Loss Per Share

Basic net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted-average number of common shares outstanding during the periods. Fully diluted net loss per common share is computed using the weighted average number of common and dilutive common equivalent shares outstanding during the periods. Common equivalent shares consist of stock options, restricted stock units, and warrants that are computed using the treasury stock method.

For the years ended December 31, 2022 and 2021, all of the Company's common stock options, unvested restricted stock units and warrants are anti-dilutive and therefore have been excluded from the diluted net loss per common share calculation.

The following table reconciles net loss to net loss attributable to NightHawk Biosciences, Inc.:

	For the Year Ended December 31,	
	2022	2021
Net loss	$ (43,862,197)	$ (35,400,807)
Net loss - Non-controlling interest	(427,491)	(329,339)
Net loss attributable to NightHawk	$ (43,434,706)	$ (35,071,468)
Weighted-average common shares outstanding, basic and diluted	25,606,326	24,913,942
Net loss per share, basic and diluted	$ (1.70)	$ (1.41)

The following potentially dilutive securities were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	2022	2021
Outstanding stock options	7,036,874	2,954,315
Restricted stock subject to forfeiture and restricted stock units	34,001	370,170
Outstanding common stock warrants	747,383	747,383

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

17. Quarterly Financial Data (Unaudited and restated)

The Company is providing restated quarterly unaudited consolidated financial information for interim periods June 30, 2022 and September 30, 2022.

The restated consolidated balance sheet line items for the second through third fiscal quarters of 2022 are as follows:

	June 30, 2022		
	As Previously Reported	Adjustments	As Restated
Deferred tax liability	$ 3,541,937	$ (3,326,000)	$ 215,937
Total Liabilities	36,467,130	(3,326,000)	33,141,130
Accumulated deficit	(183,996,826)	3,326,000	(180,670,826)
Total Stockholders' Equity - NightHawk Biosciences, Inc.	96,638,241	3,326,000	99,964,241
Total Stockholders' Equity	$ 95,387,663	$ 3,326,000	$ 98,713,663

	September 30, 2022		
	As Previously Reported	Adjustments	As Restated
Goodwill	$ 3,467,747	$ (253,000)	$ 3,214,747
Total Assets	120,164,913	(253,000)	119,911,913
Deferred tax liability	3,326,000	(3,326,000)	—
Total Liabilities	37,039,188	(3,326,000)	33,713,188
Accumulated deficit	(197,002,176)	3,073,000	(193,929,176)
Total Stockholders' Equity - NightHawk Biosciences, Inc.	84,465,725	3,073,000	87,538,725
Total Stockholders' Equity	$ 83,125,726	$ 3,073,000	$ 86,198,726

The restated line items of the consolidated statements of operations and comprehensive loss forthe second through third fiscal quarters of 2022 are as follows:

	Three Months Ended June 30, 2022	Six Months Ended June 30, 2022	Three Months Ended June 30, 2022	Six Months Ended June 30, 2022	Three Months Ended June 30, 2022	Six Months Ended June 30, 2022
	As Previously reported		Adjustments		As Restated	
Income tax benefit	$ —	$ —	$ 3,326,000	$ 3,326,000	$ 3,326,000	$ 3,326,000
Net loss	(10,263,910)	(18,453,708)	3,326,000	3,326,000	(6,937,910)	(15,127,708)
Net loss attributable to NightHawk Biosciences, Inc.	(10,157,286)	(18,277,873)	3,326,000	3,326,000	(6,831,286)	(14,951,873)
Net loss per share, basic and diluted	$ (0.40)	$ (0.71)	$ 0.13	$ 0.13	$ (0.27)	$ (0.58)
Total comprehensive loss	(10,114,055)	(18,359,122)	3,326,000	3,326,000	(6,788,055)	(15,033,122)
Comprehensive loss - NightHawk Biosciences, Inc.	$ (10,007,431)	$ (18,183,287)	$ 3,326,000	$ 3,326,000	$ (6,681,431)	$ (14,857,287)

	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022	Three Months Ended September 30, 2022	Nine Months Ended September 30, 2022
	As Previously reported		Adjustments		As Restated	
Income tax benefit	$ 215,937	$ 215,937	$ (253,000)	$ 3,073,000	$ (37,063)	$ 3,288,937
Net loss	(13,094,771)	(31,548,479)	(253,000)	3,073,000	(13,347,771)	(28,475,479)
Net loss attributable to NightHawk Biosciences, Inc.	(13,005,350)	(31,283,223)	(253,000)	3,073,000	(13,258,350)	(28,210,223)
Net loss per share, basic and diluted	$ (0.51)	$ (1.22)	$ (0.01)	$ 0.12	$ (0.52)	$ (1.10)
Total comprehensive loss	(12,979,112)	(31,338,234)	(253,000)	3,073,000	(13,232,112)	(28,265,234)
Comprehensive loss - NightHawk Biosciences, Inc.	$ (12,889,691)	$ (31,072,978)	$ (253,000)	$ 3,073,000	$ (13,142,691)	$ (27,999,978)

While the adjustments changed the deferred tax liability line item in the unaudited consolidated statements of cash flows, they did not have an impact on total net cash provided by operating activities, net cash used in investing activities, or net cash (used in) provided by financing activities for any of the applicable periods.

NIGHTHAWK BIOSCIENCES, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (CONTINUED)

The restated line items of the unaudited consolidated statements of cash flows for the second through third fiscal quarters of 2022 are as follows:

	For the Six Months Ended, June 30, 2022	For the Nine Months Ended, September 30, 2022	For the Six Months Ended, June 30, 2022	For the Nine Months Ended, September 30, 2022	For the Six Months Ended, June 30, 2022	For the Nine Months Ended, September 30, 2022
	As Previously Reported		Adjustments		As Restated	
Net loss	$ (18,453,708)	$ (31,548,479)	$ 3,326,000	$ 3,073,000	$ (15,127,708)	$ (28,475,479)
Adjustments to reconcile net loss to net cash used in operating activities:						
Deferred tax liability	$ —	$ (215,937)	$ (3,326,000)	$ (3,073,000)	$ (3,326,000)	$ (3,288,937)

18. Subsequent Events

On January 27, 2023, Nighthawk Biosciences, Inc. terminated its license agreements with the University of Miami as these assets will not be developed further. The following agreements have been terminated:

- License Agreement (UMIP-510) between the University of Miami and Zolovax, Inc. dated December 31, 2020.
- License Agreement (UMSS-114 (previously UM97-14)) between the University of Miami and Heat Biologics, Inc. effective July 11, 2008, as amended.
- License Agreement (UMSS114A) between the University of Miami and Heat Biologics I, Inc. effective February 18, 2011, as amended.
- License Agreement (UMD-107) between the University of Miami Heat Biologics I, Inc. effective February 18, 2011.
- License Agreement (UMIP-114/Strbo) between the University of Miami and Zolovax, Inc., effective October 24, 2016.
- License Agreement between the University of Miami and Pelican, effective November 19, 2013.
- License Agreement (I176) between the University of Miami and Heat Biologics II, Inc., effective December 12, 2010.
- License Agreement (0331, 0539) between the University of Miami and Heat Biologics II, Inc., effective July 11, 2008.

CERTAIN INFORMATION IN THIS EXHIBIT IDENTIFIED BY [*****] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

ORDERING AGREEMENT

between

LONZA SALES AG

and

ELUSYS THERAPEUTICS, INC.

The terms stated in this Agreement ("the Agreement") apply to orders by Elusys Therapeutics, Inc., located at 25 Riverside Drive, Unit 1, Pine Brook, New Jersey 07058 (hereinafter referred to as "Elusys", "Contractor" or "Elusys") to Lonza Sales AG, a Swiss corporation, with its principal office at Muenchensteinerstrasse 38, CH- 4002 Basel, Switzerland, (hereinafter referred to as "Subcontractor" or "Lonza"). Specifically, this Agreement shall govern orders of Bulk Drug Substance ("BDS") of Elusys' proprietary molecule designated ETI-204 ("Anthim"), which shall be manufactured in accordance with the current Good Manufacturing Practice ("cGMP") Regulations (21 C.F.R, §§ 210.1-211.208) and shall be manufactured at Lonza Portsmouth's Facility in Portsmouth, NH, USA.

Project Title: Anthim - BDS Ordering Agreement.

Order Funding: Orders submitted under this agreement may be made in support of Elusys' prime contracts **[*****].**

Materials and Services Provided by Subcontractor: Lonza shall provide all facilities, supplies, and staff necessary to manufacture and deliver Anthim BDS in accordance with the terms of this Agreement. Lonza shall perform the services as described in the attached Schedule 1.

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SCHEDULES

Schedule 1 – Services

Schedule 2 – Elusys Materials in Lonza's Possession

Schedule 3 – Elusys Patent Rights

Schedule 4 – Specifications

Schedule 5 – Quality Agreement

Schedule 6 – Federal Acquisition Regulations

NOW, THEREFORE, in consideration of the mutual promises and covenants contained herein, and other good and valuable consideration the receipt of which is hereby acknowledged, the Parties hereby agree as follows:

1. Definitions.

1.1 In this Agreement, the following terms have the meanings set forth below:

"Affiliate" means any corporation, partnership, limited liability company or other entity, which directly or indirectly controls, is controlled by or is under common control with the relevant Party to this Agreement, and "control" and its correlates means the ownership of more than fifty per cent (50%) of the issued voting shares, or the legal power to direct or cause the direction of the general management and policies, of the Party in question.

"Agreement" means this Agreement between Lonza and Elusys.

"Anthim BPS," "Anthim," or "ETI-204" means the BDS form of the high-affinity humanized and chimeric monoclonal antibody developed by Elusys, known as ETI-204, which targets the anthrax toxin protective antigen that is expressed by the pathogenic Anthrax cell.

"Batch" means the Anthim BDS product derived from a single run of the biologic manufacturing process, fermented at the 5.000L scale.

"Cell Line" means the [*****] cell line created by Elusys that is to be used in the manufacture of the Anthim BDS in accordance with this Agreement

"Certificate of Analysis" means the document certifying that the final Anthim BDS has met all Anthim BDS specifications and was manufactured according to the cGMP. For the avoidance of doubt, a Certificate of Analysis shall not be issued for any Batch of Anthim BDS that does not meet cGMP.

"Commencement" means, with respect to any Batch, production commencement, which begins upon the removal of the first ampoule of the Cell Line from the relevant frozen cell bank stocks for production of such Batch.

"cGMP" means current Good Manufacturing Practices (21 C.F.R. §§ 210.1-211.208) and the Guide to Good Manufacturing Practices for Medicinal Products as promulgated under European Commission Directive 2003/94/EC.

"Elusys Information" means all technical and other Information known to, controlled or owned by Elusys or its Affiliates from time to time, and not known to and not at the free disposal of Lonza prior to its disclosure by Elusys to Lonza and not in the public domain.

"Elusys Materials" means the materials supplied by Elusys to Lonza pursuant to this Agreement, including the Cell Line.

"Elusys Patent Rights" means all Patent Rights that are owned by or licensed to Elusys and are necessary or useful in the performance of the Services by Lonza as

contemplated hereby. The Elusys Patent Rights are listed in Schedule 3 and attached hereto.

"Facility" means the facility of Lonza Portsmouth located in Portsmouth, New Hampshire.

"Force Majeure" means causes beyond the reasonable control of a Party or its Affiliates including, without limitation, acts of God (including but not limited to earthquake), laws or regulations of any government or agency thereof (that could not reasonably have been expected or anticipated on the Effective Date following diligent inquiry into current and proposed federal, state, local and other regulatory requirements), war, terrorism, civil commotion, damage to or destruction of production facilities or materials, scientific or technical events, labor disturbances (whether or not any such labor disturbance is within the power of the affected Party to settle), epidemic, and failure of suppliers, public utilities or common carriers For the avoidance of doubt, a Stop Work Order permitted under FAR Clause 52.242-15, in and of itself, is not a Force Majeure event "Government" means the United States Government acting through BARDA.

"GS" means Lonza's glutamine synthetase expression system.

"GS License" means the license agreement between Lonza and Elusys, dated 8 April 2009, for use of GS.

"Lonza Patent Rights" means Patent Rights (i) owned or controlled by Lonza as of the Effective Date, (ii) acquired by Lonza from a third party after the Effective Date, or (iii) covering inventions made by Lonza outside the scope of this Agreement.

"Lonza Portsmouth" means Lonza's Affiliate, Lonza Biologics Inc., 101 International Drive, Portsmouth, NH 03801, USA.

"Lonza Information" means all technical and other Information, whether patented or unpatented, known to, owned or controlled by Lonza or its Affiliates from time to time, (and not known to and not at the free disposal of Elusys prior to its disclosure by Lonza to Elusys, or in the public domain), including, without limitation, the Process, GS and technical and other information, whether patented or unpatented developed, generated or created by Lonza or its Affiliates in the performance of this Agreement.

"Non-Production Services" means all Services except those performed directly in connection with Anthim BDS Batch production. For purposes of this definition, Services performed directly in connection with Anthim BDS Batch production shall mean the activities necessary to produce a Batch, beginning with Commencement and continuing through expansion of the culture to inoculate a 5.000L bioreactor and ending upon routine quality control analysis and the delivery of a Certificate of Analysis (if applicable) for such Batch, or such other endpoint as the Parties may agree upon in writing.

"Party" means one of Lonza or Elusys.

"Parties" means both Lonza and Elusys.

"Patent Rights" means all patents and patent applications of any kind throughout the world.

"Presidents" has the meaning ascribed to it by Section 8.3.

"Process" means the process operating parameters used for the production of Anthim BDS from the Cell Line and the methods of harvesting and purification of Anthim BDS

"Quality Agreement" means the most recent quality agreement entered into by the Parties relating to Anthim BDS.

"Raw Materials" means ingredients, additives (including media, feeds and supplements), disposables, including, but not limited to, bags and filters, purification resins, and reagents, which are purchased or used by Lonza in the performance of the Services and the related costs of virus testing, and other mutually agreed upon testing, conducted by Testing Laboratories. For purposes of clarity, it is currently contemplated that Lonza shall conduct all other tests included in the Specifications, and the mutually agreed upon testing described above shall exclude any such tests that are later sent by Lonza to third parties for completion.

"Raw Materials Fee" means that part of the Price which is payable to Lonza by Elusys for Raw Materials utilized in the performance of the Services, calculated in accordance with Section 13

"Release" means with respect to any Batch, issuance by Lonza of a Certificate of Analysis with respect to such Batch.

"Services" means all services to be provided by Lonza which are the subject of this Agreement as set out in Schedule 1.

"Specifications" means the specification for Anthim BDS, as agreed by the Parties, and attached hereto as Schedule 4 as such specifications may be modified from time pursuant to Section 9.2.

"Steering Committee" means the committee established pursuant to Section 8.

"Supply Deficiency" has the meaning ascribed to it by Section 6.3.

"Testing Laboratories" means any third party instructed by Lonza to carry out tests on the Elusys' Materials or the Anthim BDS.

"U.S. FDA" means the United States Food and Drug Administration or any successor governmental agency thereof.

1.2 Unless the context requires otherwise, references to the singular include the plural and vice versa, references to schedules are references to the Schedules to this Agreement, and references to sections are references to the Sections of this Agreement.

2. Term.

2.1 This Agreement shall take effect on the Effective Date and shall continue [*****], unless sooner terminated pursuant to Section 18 (the "Initial Term"). Following the Initial Term, this Agreement may be renewed for [*****] (each a "Renewal Term," and together with the Initial Term, the "Term") upon written agreement of both the Parties [*****], in each case subject to termination pursuant to Section 18.

3. Supply by Elusys.

3.1 Elusys shall supply to Lonza all Elusys Materials required by Lonza to perform the Services in accordance with agreed timelines as more fully set forth on Schedule 1. Lonza shall not be responsible for any delays arising out of Elusys* failure to provide such Elusys Materials, and Elusys shall be responsible for all additional costs and expenses arising out of such delay, including, if applicable, any idle Facility capacity costs. Lonza currently has possession of the Elusys Materials described on Schedule 2.

3.2 Rights in Elusys Information, Elusys Patent Rights and Elusys Materials.

3.2.1 Elusys hereby grants Lonza the non-exclusive right to use the Elusys Information, the Elusys Patent Rights and the Elusys Materials solely for the purpose of Lonza performing Services under this Agreement. Lonza and its Affiliates will not use the Elusys Information, Elusys Patent Rights or Elusys Materials (or any part thereof) for any other purpose without Elusys* prior written consent either during or after the Term of this Agreement Except as set forth in this Section 3.2, no licenses are granted to Lonza to use the Elusys Materials, the Elusys Patent Rights or the Elusys Information, and no licenses shall arise or be deemed to have arisen by default, estoppel or otherwise.

3.2.2 Lonza confirms that the Cell Line and all other cell lines and material generated by Lonza pursuant to all prior contracts with Elusys are owned by Elusys (subject to Lonza's retained rights in the Lonza Information), and are included in the Elusys Material.

3.3 Lonza Obligations regarding Elusys Materials. Lonza shall:

3.3.1 At all times use all reasonable endeavors to keep the Elusys Materials secure and safe from loss, damage, theft, misuse and unauthorized access in such manner as Lonza stores its own materials of similar nature;

3.3.2 Not part with possession of the Elusys Materials or the Anthim BDS, save for the purpose of tests at the Testing Laboratories or as directed by Elusys; and

3.3.3 Cause all Testing Laboratories to be subject to confidentiality and non-use obligations no less onerous than those confidentiality and non-use obligations imposed on Lonza under this Agreement.

3.4 No Other License. Without prejudice to Lonza's right to receive payment of the Price hereunder or to Lonza's own proprietary rights in the Process and the Lonza Information, Lonza agrees that, except as expressly provided in Section 3.2 above, Lonza shall not by virtue of this Agreement acquire any right, license or title in, or to, the Elusys Patent Rights, the Elusys Information, the Elusys Materials or the Anthim BDS.

4. Agreement to Supply and Perform Services.

4.1 cGMP Manufacture. Subject to Sections 15.1.5 and 15.1.6, Lonza shall, in accordance with the terms of this Agreement, manufacture and Deliver to Elusys Batches of Anthim BDS that meet the Specifications in accordance with cGMP using the Process.

4.2 Lonza Services. For each Batch of Anthim BDS ordered by Elusys hereunder, Lonza will perform the Services necessary to manufacture and Deliver the Anthim BDS, including:

4.2.1 Recover ampoules of the cell bank for the Cell Line and expand cultures to complete fermentation at the 5,000 liter scale, using the Process for the Anthim BDS.

4.2.2 Clarify culture supernatant and purify using the Process for the Anthim BDS.

4.2.3 Test the Anthim BDS against the Specifications.

4.2.4 Undertake cGMP review of lot documentation.

4.2.5 Issue a Certificate of Analysis.

4.2.6 Deliver the Anthim BDS and its Certificate of Analysis to Elusys.

4.2.7 Deliver electronic copies of the batch record documents to Elusys.

5. Forecasting and Order Procedures.

5.1 Forecasts. Elusys shall provide Lonza with rolling [*****] forecasts of the number of Batches to be ordered by Elusys (each a "Forecast"). Lonza will respond within [*****]of receiving a Forecast with a schedule of anticipated Commencement dates for the forecasted number of Batches (each a "Proposed Schedule"), which Lonza may update from time to time based on available capacity. Forecasts and Proposed Schedules are non-binding. Elusys understands and agrees that any Commencement date shown on a Proposed Schedule that is not reserved via a Binding Order [*****] prior to the Commencement date may be made available by Lonza to other customers. In that event, Lonza shall work with Elusys and shall exercise commercially reasonable efforts to schedule another mutually agreeable Commencement date.

5.2 Binding Order. From time to time, Customer shall notify Lonza in writing of the actual number of Batches it is ordering for manufacture. A "Binding Order" shall arise upon Lonza's acceptance of such notice and Lonza shall be committed to commence production of such Batches and Elusys shall be committed to pay for that number of Batches, or pay the Batch cancellation payments set forth in Section 5.3.

5.3 Batch Cancellation. Elusys may cancel any Batch (as all or part of a Binding Order) for any reason by giving written notice to Lonza. If such notice is delivered to Lonza [*****] before Lonza's then projected commencement date for such Batch, and subject to Section 18.3, Elusys shall pay Lonza a sum equal to [*****]of the Batch Price otherwise payable for such Batch, which payment to Lonza shall become due at [*****] and such payment shall satisfy in fall all payment obligations from Elusys to Lonza with respect to such cancelled Batch(es).

5.4 Lonza will use commercially reasonable efforts to secure a new project (but excluding any project then under contract with Lonza) for the cGMP manufacturing space, and for the same dates and duration that would have been occupied by Elusys, and then, in such case, the cancellation payment for each Batch cancelled that is replaced by a Batch of the new project shall be reduced by an amount equal to [*****] of the production fees associated with such replacement Batch.

In the event of cancellation in accordance with Sections 5.3, 6.3 and 18.3, [*****]. In the event that Elusys cancels a Batch at any time in accordance with Sections 6.3 and 18.3, the cancellation payment terms of Section 5.3 shall not apply; instead Lonza shall promptly return to Elusys any payments Elusys has made with respect to such Batch(es) including any payments made in accordance with Section 13.

5.5 Rescheduling. Lonza shall have the right to reasonably reschedule a Commencement date of any Batch or Campaign upon reasonable prior written notice to Elusys, [*****]. Requests to reschedule the Commencement date [*****] may be mutually agreed by parties.

5.6 Purchase Obligation. [*****].

5.7 Form of Purchase Order: Where Elusys issues any Purchase Order in respect of any Batches, any additional or inconsistent terms or conditions of any purchase order, acknowledgement or similar standardized form given or received pursuant to this Agreement shall have no effect and such terms and conditions are hereby excluded.

6. Provision of the Services.

6.1 Diligence: Lonza shall use commercially reasonable efforts to diligently carry out the Services as required pursuant to the terms of this Agreement, and may not Subcontract for the Services to be performed by a third-party without prior written consent by Elusys.

6.2 Safety Stock: Prior to the beginning of each Campaign, Lonza shall purchase (to the extent not in inventory) safety stock of Raw Materials (excluding resins) for the equivalent of [*****] Safety Stock will be purchased at Elusys' expense and invoiced upon use in the Process or expiry. Prior to the beginning of each Campaign, Safety Stock of resins (to the extent not in inventory) for the equivalent of [*****] shall be purchased at Elusys' expense and invoiced upon receipt of the resins by Lonza.

6.3 Procedure to Cure Supply Deficiencies. If Lonza fails to Deliver a Batch as set forth in the relevant Binding Order, or if a Batch does not meet the Specifications or was not manufactured in accordance with cGMP, such event shall constitute a "Supply Deficiency." If there is a Supply Deficiency, Lonza shall take one or more of the following steps to remedy the situation, as determined by the Steering Committee:

6.3.1 Utilize suitable production capacity (i.e., fully validated for production of Batches of the Anthim BDS) of Lonza or its Affiliates not then committed to third party customers; and

6.3.2 Coordinate and cooperate with Elusys, through the Steering Committee, to use reasonable commercial efforts to reschedule Batches of Anthim BDS ordered hereunder as quickly as possible in order to maximize Lonza's ability to rectify the Supply Deficiency while minimizing the disruption to any Binding Order then in force and any commitments to third party customers.

6.4 If, within [*****] of a Supply Deficiency, Lonza determines that it is unable (or the Parties agree that there is no reasonable likelihood that Lonza will be able) to deliver to Elusys the Binding Order [*****] of any such Supply Deficiency, Lonza shall, at Elusys' discretion:

6.4.1 Promptly return to Elusys all payments made by Elusys as to the affected Batch(es) pursuant to Section 13; or

6.4.2 Credit Elusys' account with all payments made by Elusys as to the affected Batch(es) and apply the credits toward a future Binding Order.

6.5 Exclusive Remedy. Except as provided in Section 5.3 and this Section 6, Elusys shall not be entitled to cancel any unfulfilled part of the Services, or to refuse to accept the Services, on grounds of late performance, late delivery or failure to produce. The provisions of this Section 6 shall be the sole liability of Lonza and sole remedy of Elusys with respect to any Supply Deficiency.

7. Delivery and Transportation of Anthim BDS.

7.1 Delivery. The Anthim BDS shall be delivered EXW (Ex Works, as defined by Incoterms 2010) the Facility ("Deliver," "Delivery," or "Delivered," as appropriate). Lonza shall issue to Elusys a Certificate of Analysis on the day of Delivery.

7.2 Packaging and Labeling. Unless otherwise agreed, Lonza will package and label Anthim BDS in accordance with its standard operating procedures. Elusys will inform Lonza in writing in advance of any special packaging and labeling requirements for the Anthim BDS. All additional costs and expenses incurred by Lonza in complying with such special requirements shall be charged to Elusys in addition to the Price.

7.3 Transportation and Insurance. Elusys agrees that it shall collect the Anthim BDS [*****] after notice of availability from Lonza, unless otherwise agreed between the Parties. At Elusys' request, Lonza will (acting as agent for Elusys) arrange for insurance to cover the Anthim BDS during such [*****] or other agreed period. At Elusys' request, Lonza will (acting as agent for Elusys) arrange for the transportation of Anthim BDS to a facility in USA designated by Elusys together with insurance for the then applicable Price for the number of Batches transported. All additional costs and expenses incurred by Lonza in arranging transportation and insurance, if applicable, shall be charged to Elusys in addition to the Price. Transportation of the Anthim BDS, whether or not under any arrangements made by Lonza on behalf of Elusys, shall be made at the sole risk and expense of Elusys. In cases where Elusys has not requested Lonza to arrange for transportation of Anthim BDS, Lonza will provide reasonable cooperation with Elusys' transportation agents in coordinating the collection of Anthim BDS from Lonza's Portsmouth, NH facility.

7.4 Inspection of Anthim BDS. Where Lonza has made arrangements for the transportation of Anthim BDS under Section 7.3, Lonza shall use its reasonable endeavors to notify Elusys of shipment by facsimile on the date of dispatch. Elusys shall diligently examine the Anthim BDS as soon as practicable after receipt Notice of all claims arising out of:

7.4.1 Damage to or total or partial loss of Anthim BDS in transit shall be given in writing to Lonza and the earner within [*****] of receipt; or

7.4.2 Failure of a shipment of Anthim BDS to arrive shall be given in writing within [*****] of the date on which the shipment was made, as stated in Lonza's notice of shipment provided on the date of dispatch to Elusys.

Elusys shall make damaged Anthim BDS available for inspection and shall comply with the requirements of any insurance policy covering the Anthim BDS. Lonza shall offer Elusys all reasonable assistance, at Elusys' cost, in pursuing any claims arising out of the transportation of Anthim BDS, but Lonza's responsibility shall otherwise be limited by the EXW (Incoterms 2000) shipping term.

7.5 Tests. Promptly following Delivery of a Batch of Anthim BDS, or any sample intended to be representative thereof, Elusys will determine if such Batch meets the applicable Specifications. If the Elusys determines that the Anthim BDS fails to meet the applicable Specifications, then Elusys shall give Lonza written notice thereof within [*****] from the date of the discovery of non-compliance and shall, unless otherwise directed by Lonza, return the Batch for further testing. In the absence of such written notice, the Batch shall be deemed to have been accepted by Elusys as meeting Specifications. If Lonza agrees, or it is

determined pursuant to Section 7.6, that the returned Batch fails to meet Specifications and, to the extent that such failure is not due (in whole or in part) to acts or omissions of Elusys or any third party after Delivery of such Batch, the Batch in question shall be regarded as not having been Delivered and shall constitute or contribute towards a Supply Deficiency and entitle Elusys to the rights set forth in Section 6, including those associated with a Supply Deficiency.

7.6 Disputes. If there is any dispute concerning whether a Batch meets the applicable Specifications and/or the reasons therefor, such dispute shall be referred for decision to an independent expert (acting as an expert and not as an arbitrator) to be appointed by agreement between Lonza and Elusys or, in the absence of agreement by operation of the provisions of Section 20.2. The costs of such independent expert shall be borne equally between Lonza and Elusys. The decision of such independent expert shall be in writing and, save for manifest error on the face of the decision, shall be binding on both Lonza and Elusys.

8. Steering Committee.

8.1 Composition of Steering Committee. Promptly following the Effective Date, Lonza and Elusys shall establish a Steering Committee. The Steering Committee shall be comprised of equal numbers of representatives of each Party (not to exceed four representatives of each Party)

8.2 Function of Steering Committee. Without limiting the functions of the Steering Committee set out elsewhere In this Agreement, the role of the Steering Committee shall be to:

8.2.1 Resolve disputes arising between the Parties under this Agreement, as provided in Section 20.2,

8.2.2 Monitor the progress of the Services;

8.2.3 Plan and assess needs for future supply of Anthim BDS;

8.2.4 Discuss and recommend any changes to the Process; and

8.2.5 Oversee the choice and qualification of vendors supplying Raw Materials;

8.2.6 Monitor and discuss the prices of Raw Materials.

8.3 Meetings. The Steering Committee shall meet at such times as the Steering Committee determines to resolve issues arising under and to perform its responsibilities under this Agreement, provided that the Steering Committee shall meet up to [*****] times per calendar year unless otherwise mutually agreed. If any issue to be determined by the Steering Committee is not resolved within [*****] days after submission of the relevant issue to the Steering Committee, such issue shall be referred for resolution to the President or Chief Operating Officer of Elusys and the senior officer of Lonza's Biopharmaceuticals division (together, the "Presidents'') as provided in Section 20.2.

8.4 Limitations. The Steering Committee is not empowered to amend the terms of this Agreement.

9. Process Changes.

9.1 Process. Lonza shall not unreasonably refuse any written request from Elusys to make changes to the Process (for example, changes to the Process which are required by an applicable regulatory authority or applicable laws), but no change to the Process shall be made except by an agreement in writing signed by the authorized representatives of the Parties.

9.2 Specifications. Lonza shall not unreasonably refuse any written request from Elusys to make changes to the Specifications (for example, changes to the Specifications that are required by an applicable regulatory authority or applicable laws), but no change to Specifications shall be made except by an agreement in writing signed by the authorized representatives of the Parties.

9.3 Procedure. Unless a Party has designated an authorized representative by notice to the Steering Committee, changes to Process or Specifications must be approved in writing by an officer of the Party in question.

9.4 Adjustments resulting from Process and Specification Changes. Any changes to a Process or to the Specifications shall be implemented on terms and conditions to be agreed, which may include, but not be limited to, additional development services (to be performed on terms to be agreed), and reasonable adjustments to the Batch Price payable for Services.

10. Facility.

10.1 On-site representative: Elusys shall be permitted to have, at no additional cost, up to [*****] Elusys employees, consultants or representatives visit a Facility (provided that: (i) Elusys shall provide Lonza with a list of any consultants and/or representatives at least [*****] in advance of such consultants and/or representatives' first visit to Lonza; (ii) Lonza may require such representative to enter into a confidentiality agreement with Lonza in a form reasonably acceptable to Lonza and (iii) Lonza shall not be required to permit access to any consultant and/or representative of Elusys who is also engaged by a third party biologics manufacturer reasonably determined by Lonza to be a competitor of Lonza), including [*****] Elusys employee, consultant or representative (subject to the proviso above) with reasonable access during the manufacture of the Anthim BDS from vial crack to bulk final fill, for the purpose of observing, reporting on, and consulting as to such manufacturing efforts, including without limitation access to the review of all batch records. Lonza shall reasonably cooperate in enabling such Elusys employee, consultant, representative or Government representative having full access to cany out his or her responsibilities and will make adequate office and desk space, access to computers, networks and phone systems, and other reasonable resources available to such person.

11. Regulatory Support and Quality Assurance.

11.1 Regulatory Support and Audits. Lonza shall provide regulatory support to Elusys, including annual updates to any drug master files, biologics licenses and other manufacturing or marketing applications and approvals applicable to the Anthim BDS held by Lonza or Elusys and the preparation for and hosting of inspections by the U.S. FDA (or other regulatory authorities) or Elusys (in the case of Elusys' inspections, at mutually convenient times). Elusys shall be entitled to conduct, and Lonza shall provide regulatory support for, [*****] audit (at mutually convenient times) by Elusys' personnel of up to [*****] each annually. Lonza agrees to allow [*****] to accompany Elusys on any such inspection or audit provided that: (i) Elusys shall provide Lonza with a list of any representatives at least [*****] in advance of such representatives' visit to Lonza; (ii) Lonza may require such representative to enter into a confidentiality agreement with Lonza in a form reasonably acceptable to Lonza and (iii) such representative shall act as observer of the audit (i.e., not an auditor) only. Lonza agrees to take and retain samples of Products during the manufacturing process as agreed to by the Parties, and to make such samples available to Elusys [*****] upon reasonable request.

11.2 Additional Regulatory Support. If regulatory support or ancillary development services are required by Elusys in addition to those described herein, an additional charge shall be made to Elusys at Lonza's standard rates for regulatory services and/or ancillary development services and for disbursements at the time the regulatory and/or ancillary development services are performed. Lonza shall inform Elusys of such charge and obtain Elusys' written consent to such charge before providing such additional support.

11.3 Regulatory Submissions. Elusys shall advise Lonza of any regulatory submissions regarding the Anthim BDS which may require responses from Lonza to questions from the regulatory authorities in a timely fashion, taking account of the amount of information Lonza is required to provide.

11.4 Amendments. If Lonza is required to amend the way it manufactures or tests the Anthim BDS as a result of a change in any statutory or regulatory requirement after the Effective Date, it shall use all reasonable efforts to comply with such requirement. In this event the Parties shall negotiate in good faith any appropriate revision to the Price to reflect additional costs incurred by Lonza and any appropriate revision to the time schedules for providing the Anthim BDS. Lonza shall not be required or entitled to amend the Services in any way unless and until the Parties have reached such agreement.

11.5 Additional Audits. If Elusys conducts an audit pursuant to its rights under Section 11.1 and,as a result of default on the part of Lonza, Elusys has just cause to conduct further audits in order to satisfy itself as to the matters of default in question, Elusys shall be entitled, without additional payment to Lonza, to conduct up to [*****] additional audits (at mutually convenient times) in order to satisfy itself of the matters in question. Any further audits beyond this number shall be performed on reasonable terms and conditions and at a price to be agreed, based on Lonza's standard rates.

11.6 Quality Agreement: Responsibility for quality assurance and quality control of Anthim BDS shall be allocated between the Parties as set forth in the Quality Agreement.

12. RESERVED.

12.1 RESERVED.

13. Price and Terms of Payment

13.1 Price for Services. In consideration for the performance of the Services, Elusys will pay Lonza the Price as set forth herein The Price for the Services in respect of each Batch shall consist of:

13.1.1 The Batch Price shall be:

(a) **[*****]** per Batch for Campaigns of **[*****]** batches other than such Campaigns that are included in subsection (b) below; and,

(b) **[*****]** per Batch for Campaigns of **[*****]** batches and for each Campaign ordered in 2015 wherein the earliest Commencement date for such Campaign is on or before **[*****]**,

in each case subject to adjustment as set forth in this Agreement. The Batch Price shall be established upon placement of the Binding Order. Thereafter, if the Campaign is divided into smaller campaigns at the discretion of Lonza, the Batch Price shall remain at the price established upon placement of the Binding Order. In the event Elusys requests Campaigns to be divided into smaller Campaigns the Batch Price shall be adjusted to reflect the actual Campaign size for each of the smaller Campaigns.

13.1.2 The Raw Materials Fee in respect of each Batch, as set forth in Sections 13.6 and 13.7, below

13.2 Annual Batch Price Adjustment. On or about **[*****]**, Lonza may, by written notice to Elusys, increase the Batch Price in accordance with the increase for the previous calendar year in the US Department of Labor's Bureau of Labor Statistics Pharmaceutical Preparations Index (ethical PCU 325414) or, if such index is no longer available, such index by which it is replaced; provided that Batch Prices shall not be increased pursuant to this Section 13.2 by more than **[*****]** for any single calendar year ("Batch Price Adjustment"). A Batch will be subject to a Batch Price Adjustment pursuant to this Section 13.2 if, (a) the Binding Order covering such Batch was accepted by Lonza after the date on which such Batch Price Adjustment was implemented; or (b) the Binding Order covering such Batch was accepted by Lonza prior to the date on which such Batch Price Adjustment was implemented and the Commencement date of such Batch was originally scheduled more than **[*****]** after such Binding Order was accepted by Lonza.

13.3 Batch Price Adjustments for Exceptional Items. The Batch Price shall be changed to reflect:

13.3.1 Additional costs Incurred by Lonza in the manufacture of Anthim BDS as a result of fluctuations of regional utility rates at Lonza's Portsmouth facility (including without limitation water, electricity, and natural gas prices) that cause Lonza's total utility costs for manufacture of Anthim BDS to increase by more than [*****] compared to such costs at the time the then current Batch Price was agreed. In the event that the Batch Price is increased to adjust for a fluctuation of the regional utilities cost, such increase will be reevaluated annually thereafter. If such annual review shows regional utilities cost decreases, then such increase shall be reduced or eliminated to reflect such decreased cost.

13.3.2 Changes in the Batch Price caused by mutually agreed alteration of a Process or Specifications, provided that, in each case, Elusys has received a written estimate of the change in costs and a reasonable demonstration of the items of cost or expense in question

13.4 Compliance with Regulatory Requirements. Lonza shall comply with all regulatory requirements from time to time applicable to the Services and in accordance with the other applicable legal requirements of the jurisdiction in which the Anthim BDS is manufactured. Such compliance shall be at Lonza's cost except to the extent that such requirements (that could not reasonably have been expected or anticipated as of the Effective Date following diligent inquiry into current and proposed federal, state, local and other regulatory requirements) cause Lonza to engage in significant modifications to the Facility; in such instances the Parties shall negotiate in good faith any appropriate revision to the Batch Price to reflect additional costs incurred by Lonza and any appropriate revision to the time schedules for providing the Anthim BDS. In this event the costs shall be allocated between Lonza, Elusys and any other customer for whom such regulatory requirements are also applicable. If Elusys requests Lonza to comply with any other legal or regulatory requirements, Lonza shall use reasonable commercial efforts to do so provided that.

13.4.1 Elusys shall be responsible for informing Lonza in writing of the precise requirements which Elusys is requesting Lonza to observe;

13.4.2 Such requirements do not conflict with any mandatory requirements under the laws of the location of the manufacture of the Anthim BDS;

13.4.3 Lonza shall be under no obligation to ensure that the information furnished by Elusys pursuant to Section 13 4.1 complies with the applicable requirements of any jurisdiction; and

13.4.4 All costs and expenses properly incurred by Lonza in complying with Elusys' requests regarding the requirements referred to in Sections 13.4.1 through 13.4.3 shall be charged to Elusys, in addition to the Price.

13.5 Payment of Batch Price. Elusys shall pay Lonza the Batch Price against Lonza's invoices therefor, as follows:

13.5.1 Lonza shall invoice Elusys [*****] of the Batch Price upon Commencement of work for such Batch; and

13.5.2 Lonza shall invoice Elusys [*****] of the Batch Price on the delivery of the Certificate of Analysis.

13.6 Raw Materials Fee. The Raw Materials Fee shall be equal to [*****] of the Raw Materials actually used in the Process, plus a handling charge of [*****] of such costs (except in respect of Raw Materials which are chromatography resins), plus freight, taxes and insurance. No handling charge shall be payable in respect of Raw Materials which are chromatography resins. Lonza shall maintain records pertaining to the calculation of the Raw Materials Fee. Elusys may audit such records, not more often than once in any calendar year, using independent auditors, provided such auditors have accepted the same obligations of confidentiality as Elusys hereunder in respect of such records.

13.7 Payment of Raw Materials Fee. The Raw Materials Fee for Safety Stock will be invoiced according to Section 6.2. Lonza shall invoice Elusys for the Raw Materials Fee in respect to all consumable Raw Materials (other than Safety Stock) to be used for the production of each Batch of Anthim BDS upon Release of such Batch. Lonza will invoice Elusys for the Raw Materials Fee in respect of chromatography resins, which are purchased for use in performing the Process at such time as the resins are received by Lonza.

13.8 Taxes. Unless otherwise indicated in writing by Lonza, all prices and charges are exclusive of any other taxes, levies, imposts, duties and fees of whatever nature imposed by or under the authority of any government or public authority in respect of the Services and delivery of Anthim BDS (other than taxes on Lonza's income), which shall be paid by Elusys.

13.9 Invoices. All invoices are strictly net and payment of undisputed items must be made within [*****] of date of invoice. Payment shall be made without deduction, set-off, lien or counterclaim of any nature. Lonza may defer production of further Batches if timely payment of outstanding invoices is not made within [*****] of a second written demand (i.e., a written demand issued after failure to settle an invoice which invoice shall count as the first written demand) for payment to Elusys. If Elusys reasonably believes it will not be able to pay Lonza within [*****] days of date of invoice, Elusys shall immediately advise Lonza and the Parties will discuss in good faith reasonable accommodations regarding the timing of such payment. If either Party disputes the validity of any item or part of an item included in an invoice, the matter may be referred to the Steering Committee who shall resolve such dispute and may determine whether, pending resolution, an extension of time for payment of such disputed item is appropriate.

13.10 Interest on Late Payments. Interest on late payments of invoices and other amounts from time to time owed by either Party to the other hereunder shall accrue at the annual rate of [*****] the U.S. prime rate from time to time as quoted in The Wall Street Journal (on the last business day of each calendar month).

14. Recalls.

14.1 Assistance of Lonza. Subject to Section 14.2, if Elusys recalls the Anthim BDS (voluntarily or by order of a regulatory body) or is required to respond to inquiries of regulatory bodies relating to the Services hereunder, Lonza agrees to provide reasonable assistance to Elusys at Elusys' sole expense. Any assistance to be provided by Lonza in response to inquiries of regulatory authorities shall be provided on terms to be agreed at Lonza's standard rates for providing such assistance.

14.2 Reimbursement by Lonza. Subject to the limitations of Lonza's liability to Elusys set out in this Agreement, Lonza agrees to reimburse Elusys for reasonable, direct, documented expenses incurred by Elusys as a result of recall of a Anthim BDS mandated by law or by an applicable regulatory body, but only to the extent Lonza's breach of this Agreement, negligence or willful misconduct in performing the Services has caused such recall to be required.

15. Representations and Warranties; Indemnification.

15.1 Lonza Representations and Warranties. Lonza represents and warrants that:

15.1.1 Lonza has the corporate power and authority to enter into this Agreement;

15.1.2 Lonza has, and subject to Section 15.1.9 below, shall at all times throughout the term of this Agreement have, the right to use the Process and the Lonza Information;

15.1.3 Any of the Processes used by Lonza, any related Patent Rights, and any Lonza Information not owned by Lonza are licensed to Lonza under a license which will permit their use by Lonza to perform the Services;

15.1.4 The Services shall be performed in accordance with this Agreement;

15.1.5 The Anthim BDS manufactured and Delivered to Elusys pursuant to Services performed under this Agreement shall be manufactured pursuant to cGMP and substantially in accordance with the relevant master batch record;

15.1.6 The Anthim BDS manufactured and Delivered to Elusys pursuant to the Services performed under this Agreement shall meet the relevant Specifications when Delivered;

15.1.7 Unencumbered title to all Anthim BDS will be conveyed to Elusys upon Delivery;

15.1.8 As of the Effective Date, the Lonza Information is owned by Lonza or Lonza is otherwise entitled to use it for the purposes of providing Services under this Agreement and during the term of this Agreement Lonza shall not do or cause anything to be done which would adversely affect their ownership or entitlement to use the same for those purposes;

15.1.9 To the best of Lonza's knowledge and belief, the use by Lonza of the Process (excluding any modifications or steps made or developed by

Elusys) and Lonza Information for the performance of the Services as provided herein will not infringe any rights (including without limitation any intellectual or industrial property rights) vested in any third party;

15.1.10 Lonza will promptly notify Elusys in writing if it receives a claim or allegation from a third party that the use by Lonza of the Process and/or the Lonza Information for Services infringes any intellectual property rights vested in such third party; and

15.1.11 Lonza has and shall maintain, during the term of this Agreement, all government permits, including but not limited to health, safety and environmental permits, necessary for the conduct of the Services.

15.1.12 As of the Effective Date, neither Lonza nor any of its principals have been debarred, suspended or proposed for debarment by the Federal Government;

15.1.13 The cost or pricing data (as defined in Section 15.401 of the Federal Acquisition Regulation (FAR) and required under FAR subsection 15.403-4) submitted to Elusys by Lonza contains certain estimates (by way of example, without limitation, in respect of Raw Materials provided by third parties). Accordingly, the cost and pricing data provided in this Agreement represents Lonza's good faith estimates, made using commercially reasonable efforts, but may be subject to change; and

15.1.14 Lonza will not use funds provided under this Agreement to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions: the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement.

15.1.15 Lonza acknowledges that U.S. Executive Orders and Laws, including but not limited to Executive Order 13224 and Public Law 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism, and shall ensure compliance with such Executive Orders and Laws.

15.1.16 THESE WARRANTIES ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND LONZA HEREBY EXPRESSLY DISCLAIMS AND NEGATES, ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE (EVEN IF THAT PURPOSE IS KNOWN TO LONZA), TITLE AND NON-INFRINGEMENT.

15.2 Elusys Representations and Warranties. Elusys represents and warrants that:

15.2.1 Elusys has the corporate power and authority to enter into this Agreement;

15.2.2 Elusys has, and subject to Section 15.2.4 below, shall at all times throughout the term of this Agreement have, the right to supply the Cell Line, the other Elusys Materials and the Elusys Information to Lonza;

15.2.3 Any of the Cell Line, the other Elusys Materials, Elusys Information and Elusys Patent Rights not owned by Elusys are licensed to Elusys under a license which will permit their use by Lonza to perform the Services;

15.2.4 To the best of Elusys' knowledge and belief, the use by Lonza of the inventions claimed in the Elusys Patent Rights, the Cell Line, other Elusys Materials and Elusys Information for the Services (including without limitation for the manufacture of the Anthim BDS but excluding any modifications to the Cell Line, other Elusys Materials or Elusys Information made or developed by Lonza) will not infringe any rights (including without limitation any intellectual or industrial property rights) vested in any third party;

15.2.5 Elusys will promptly notify Lonza in writing if it receives a claim or allegation from a third party that the Cell Line, other Elusys Materials, Elusys Information or the Elusys Patents, or that the use by Lonza of any of the foregoing for the provision of the Services, infringes any intellectual property rights of such third party; and

15.2.6 THESE WARRANTIES ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND ELUSYS HEREBY EXPRESSLY DISCLAIMS AND NEGATES, ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, ARISING BY OPERATION OF LAW OR OTHERWISE.

15.3 Indemnification by Elusys. Elusys shall indemnify, defend and hold Lonza and its Affiliates (the "Lonza Indemnified Parties") harmless against all claims, actions, costs, expenses (including reasonable legal fees and disbursements) or other liabilities whatsoever in respect of third party claims, demands or actions arising out of or relating to:

15.3.1 Elusys' breach of any of its representations and warranties set forth in Section 15.2;

15.3.2 Infringement of any intellectual property of a third party by the manufacture, use or sale of the Anthim BDS;

15.3.3 Any claims alleging Lonza's use of: (i) the Cell Line, (ii) other Elusys Materials, (iii) the Elusys Information, (iv) Elusys Patent Rights, or (v) any Process steps or components which are or become part of the Process by virtue of written requests by Elusys following the Effective Date that they should be included in the Process, in the course of performing the Services infringes or is alleged to infringe any rights

(including without limitation any intellectual property rights) of a third party or misappropriates or is alleged to misappropriate the trade secrets of a third party;

15.3.4 Any product liability (including personal injuries to or economic losses by a third party) in respect of the Anthim BDS, except to the extent that Lonza has indemnified Elusys under Section 15.4.5;

15.3.5 Any claims by employees, agents or vendors of Elusys unless such claim is caused by the gross negligence or willful misconduct of Lonza; and

15.3.6 Any gross negligence or willful misconduct of Elusys in relation to the use, processing, storage or sale of the Anthim BDS, or the marketing of the pharmaceutical product in which the Anthim BDS is used; provided, however, that the foregoing indemnification obligations shall not apply to the extent such claims, actions, costs, expenses or other liabilities are caused by the gross negligence, willful misconduct, or breach of this Agreement by Lonza.

15.4 Indemnification by Lonza. Lonza shall indemnify, defend and hold Elusys and its Affiliates harmless against all claims, actions, costs, expenses (including reasonable legal fees and disbursements) or other liabilities whatsoever in respect of third party claims, demands or actions arising out of or relating to:

15.4.1 Lonza's breach of any of its representations and warranties set forth in Section 15.1;

15.4.2 Lonza's violation of any applicable environmental law in connection with the performance of the Services unless such violation is proximately caused by the misrepresentation, gross negligence or willful misconduct, or express written instruction of Elusys;

15.4.3 Any claims alleging Lonza's use of: (i) the Lonza Information, or (ii) any Process, steps or components which are part of the Process on the Effective Date, or become part of the Process other than by virtue of written requests by Elusys following the Effective Date that they should be included in the Process, in the course of providing the Services infringes or is alleged to infringe any rights (including without limitation any intellectual property rights) of a third party or misappropriates or is alleged to misappropriate the trade secrets of a third party;

15.4.4 Any claims by employees, agents or vendors of Lonza, unless such claim is caused by the gross negligence or willful misconduct of Elusys; and

15.4.5 Any product liability suffered by a third party to the extent that such product liability arises as a result of a defect in the Anthim BDS Delivered by Lonza which defect arose from a negligent act, negligent omission or willful misconduct of Lonza in the performance of the Services, or a material breach of any of Lonza's representations, warranties, covenants or other obligations under this Agreement; and

provided, however, that the foregoing indemnification obligations shall not apply to the extent such claims, actions, costs, expenses or other liabilities are caused by the gross negligence, willful misconduct, or breach of this Agreement by Elusys.

15.5 Procedure for Indemnification. In the event of a Party seeking indemnification from the other Party, the Party seeking indemnification (the "Indemnified Party") shall promptly notify the other Party (the "Indemnitor") in writing of the claim and the Indemnitor shall manage and control, at its sole expense, the defense of the claim and its settlement. Upon timely notice, once the Indemnitor assumes responsibility for such defense, the Indemnitor shall not be liable for any litigation costs or expenses incurred by the Indemnified Party without the prior written consent of the Indemnitor, provided, however, that the Indemnified Party may: (i) engage counsel to review and comment on the actions undertaken by Indemnitor in the defense of any claim and Indemnitor shall pay the reasonable costs of such counsel; and (ii) may otherwise participate in the defense of any claim through its own counsel at its own expense. The Indemnified Party shall cooperate fully with the Indemnitor in the defense of any such claim. The Indemnitor shall not accept any settlement which imposes liability not covered by this indemnification or restrictions on the Indemnified Party without the prior written consent of the Indemnified Party. The Indemnified Party shall at the Indemnitor's cost take such action as the Indemnitor may reasonably and properly require to defend any such claim, unless such action conflicts with or prejudices the Indemnified Party's proper business interests, or might reasonably be expected to do so. Nothing contained in this Section 15.5 shall oblige the Indemnified Party to take any action or steps in its own name in defending any claim, action or proceedings. Notwithstanding any other rights of Lonza under this Agreement, in the event that any such claim against Elusys and for which Elusys is the Indemnitor results in the inability or prohibition of Lonza to manufacture the Anthim BDS, then any lost Batch Price in respect of Batches that were scheduled under a binding order for manufacture during the period of such inability or prohibition that cannot be later rescheduled for production without disruption to Lonza's obligations to Elusys or its other customers shall be included in the losses and damages resulting from such claim, in accordance with Section 5.3.

15.6 Insurance. Lonza shall obtain and maintain General Liability and Products Liability insurance coverage of the types and in the amounts customary and consistent with biopharmaceutical industry standards, but in any case not less than the amount of [*****] per event or directly connected series of events. Without limiting the foregoing, Lonza shall obtain and maintain insurance which covers business interruption. Elusys shall obtain and maintain General Liability and Products Liability insurance coverage which is customary and consistent with biopharmaceutical industry standards but in any case not less than the amount of [*****] per event or directly connected series of events, naming Lonza and its Affiliates as additional insured and providing that Lonza shall be notified at least [*****] in advance of any termination of such coverage.

16. Limitations of Liability

16.1 Lonza Limitation of Liability. WITH THE EXCEPTION OF CLAIMS AS A RESULT OF DEATH, PERSONAL INJURY, GROSS NEGLIGENCE, OR WILLFUL MISCONDUCT, THE LIABILITY OF LONZA TO ELUSYS FOR ANY LOSS SUFFERED BY ELUSYS AS A RESULT OF A BREACH OF THIS AGREEMENT BY LONZA, OR OF ANY OTHER LIABILITY ARISING OUT OF THIS AGREEMENT, AND THE SERVICES PROVIDED HEREUNDER SHALL BE LIMITED TO THE PAYMENT OF DAMAGES IN AN AMOUNT NOT TO EXCEED THE BATCH PRICE SET FORTH IN THIS AGREEMENT (INCLUDING THE ASSOCIATED RAW MATERIAL FEE FOR ALL RAW MATERIALS OTHER THAN RESIN).

16.2 Disclaimer of Consequential Damages. NEITHER PARTY HERETO SHALL BE LIABLE TO THE OTHER FOR THE FOLLOWING LOSSES OR DAMAGES HOWSOEVER CAUSED (EVEN IF FORESEEABLE OR IN THE CONTEMPLATION OF LONZA OR CUSTOMER SHOULD HAVE BEEN FORESEEABLE)

16.2.1 LOSS OF PROFITS, BUSINESS OR REVENUE, OR ANY SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES SUFFERED BY THE OTHER PARTY OR ANY OTHER PERSON; OR

16.2.2 PUNITIVE, EXEMPLARY, OR MULTIPLE DAMAGES WHETHER SUFFERED BY THE OTHER PARTY OR ANY OTHER PERSON.

17. Elusys Information, Lonza Information and Patent Rights.

17.1 Confidential Information. Elusys acknowledges that Lonza Information and Lonza acknowledges that Elusys Information delivered pursuant to this Agreement are delivered subject to obligations of confidentiality. Each agrees to keep the Lonza Information or the Elusys Information secret and confidential, respect the other's proprietary rights therein and to make use of and permit to be made use of such information only for the purposes of performing the Services hereunder, and not without the other Party's prior written consent disclose or permit the Lonza Information or such Elusys Information to be disclosed to any third party except as expressly provided herein.

17.2 Disclosure to Affiliates, employees, etc. Elusys and Lonza shall grant access to confidential Lonza Information or confidential Elusys Information only to Affiliates, employees, consultants, marketing collaborators and contractors who reasonably need to know such information for legitimate purposes and who are subject to the same obligations of confidentiality as Lonza and Elusys under appropriate secrecy agreements

17.3 Third Parties. Lonza and Elusys each undertake not to disclose or permit to be disclosed to any third party, or otherwise make use of or permit to be made use of, any trade secrets or confidential information relating to the technology, business affairs or finances of the other, any Affiliate of the other, or of any suppliers, agents, distributors, licensees or other customers of the other which come into its possession under this Agreement.

17.4 Exceptions. The confidentiality obligations under this Section 17 shall not extend to any information which:

17.4.1 Is or becomes generally available to the public otherwise than by reason of a breach by the receiving Party of the provisions of this Section 17;

17.4.2 Is known to the receiving Party, as evidenced by contemporaneous written records, prior to its receipt from the disclosing Party and free of any confidentiality obligation to any third party;

17.4.3 Is subsequently disclosed to the receiving Party without being made subject to an obligation of confidence by a third party;

17.4.4 Lonza or Elusys may be required to (or is advised by counsel that it is highly advisable to) disclose under any statutory, regulatory, stock exchange or similar legislative requirement or court order; provided however, that (i) the receiving Party gives the disclosing Party prior written notice, as practicable and allowable, of such required disclosure and assists the disclosing Party in its reasonable efforts to prevent or limit such disclosure; and (ii) the information so disclosed pursuant to this Section 17.4.4 otherwise remains Lonza Information or Elusys Information, as the case may be, for the purposes of this Section 17; or

17.4.5 The receiving Party can demonstrate by contemporaneous written records was independently discovered by the receiving Party or its employees without reference to any information received from the other Party hereto.

17.5 Lonza hereby acknowledges that, under the terms of Elusys' [*****] Contracts, Elusys may be required to disclose Lonza Information [*****]. Prior to any such disclosure, Elusys shall advise Lonza of the Lonza Information it wishes to disclose and Lonza shall have up to thirty (30) days during which to review the proposed disclosure and delete, disguise or generalize any Lonza Information that can reasonably be regarded as qualifying limited rights data [*****]. Following Lonza's review (and including any deletion or disguise made by Lonza), Elusys shall be entitled to disclose the Lonza Information [*****]. If there is any dispute between the Parties about any deletion or disguising of any information made by Lonza, the Parties shall negotiate in good faith and agree upon the content of the proposed disclosure, if Lonza and Elusys are unable to agree upon the content of such disclosure, Lonza shall provide such information directly [*****], subject to appropriate confidentiality protections being in place between Lonza [*****]. Notwithstanding the foregoing, at all times Elusys will take all legal and reasonable steps to protect Lonza Information, including but not limited to protecting qualifying Lonza information as limited rights data [*****]. Notwithstanding any provision of this Agreement to the contrary, and without limiting any other rights of Lonza with respect to qualifying limited rights data, it is acknowledged that Lonza policies and procedures generally applicable to production or quality operations in Lonza CMO facilities will be considered "qualifying limited rights data" under this Agreement [*****], and that Lonza may withhold such policies and procedures from Elusys [*****] notwithstanding any request for disclosure thereof In the event Lonza utilizes a

subcontractor to perform any of the Services, Lonza will use reasonable efforts to obtain from such subcontractors data required to be disclosed [*****] subject to the limitations set forth therein provided such data is identified by Elusys prior to performance of such Services by such subcontractor.

17.6 No License. Each Party acknowledges that, except as expressly provided herein or pursuant to a separate agreement between the Parties existing now or entered into in the future, such Party shall not at any time have any right, title, license or interest in or to the Lonza Information or Elusys Information as the case may be, Patent Rights or any other intellectual property rights relating to the Process which are owned by the other Party or its Affiliates or to which the other Party or its Affiliates is otherwise entitled

18. Termination.

18.1 Termination by Elusys. Elusys may in its sole discretion terminate this Agreement for any reason by giving not less than [*****] notice in writing to Lonza, provided that no such termination may become effective until the end of the Initial Term.

18.2 Termination by Lonza. Lonza may in its sole discretion terminate this Agreement for any reason by giving not less than [*****] notice in writing to Elusys, provided that no such termination may become effective until the end of the Initial Term.

18.3 Termination for Cause. Lonza and Elusys may each terminate this Agreement forthwith by notice in writing to the other upon the occurrence of any of the following events:

18.3.1 If the other materially breaches this Agreement, and (in the case of a breach capable of remedy) such breach is not remedied within [*****], or, if such breach is incapable of remedy within [*****], the other Party fails to commence actions within such [*****] to remedy such breach pursuant to a plan reasonably acceptable to the complaining Party; or

18.3.2 If the other ceases for any reason to carry on business, dissolves, liquidates, winds up, or files or is petitioned into bankruptcy, liquidation, rehabilitation or dissolution or becomes insolvent or fails generally to pay its debts or obligations or a petition is filed seeking the appointment of or the taking possession by a receiver custodian, trustee or similar official.

18.3.3 For the avoidance of doubt, in the case of termination of this Agreement by Elusys pursuant to this Section 18.3, the Batch cancellation payments set forth in Section 5.3 shall not be payable and any amounts paid by Elusys therefor shall be promptly returned by Lonza to Elusys.

18.4 Effect of Termination Generally. Upon the termination of the Agreement for whatever reason:

18.4.1 Lonza shall promptly return all Elusys Information to Elusys (to the extent legal or regulatory requirements permit) and shall dispose of, or return to Elusys the Elusys Materials and any materials derived therefrom, as directed by Elusys; and

18.4.2 Subject to any rights granted to Elusys pursuant to Section 18.5 or the GS License, Elusys shall promptly return to Lonza (to the extent legal and regulatory requirements permit) all Lonza Information it has received from Lonza; and

18.4.3 Subject to any rights granted to Elusys pursuant to Section 18.5 or the GS License, Elusys shall not thereafter use or exploit the Lonza information in any way whatsoever, except to the extent necessary to sell, transfer or otherwise dispose of Anthim BDS Delivered to Elusys prior to such termination. No licenses shall arise or be deemed to have arisen hereunder either by default, estoppel or otherwise except as expressly set forth herein; and

18.4.4 Lonza may thereafter use or exploit the Lonza Information in any way whatsoever without restriction; and

18.4.5 Lonza and Elusys shall do all such acts and things and shall sign and execute all such deeds and documents as the other may reasonably require to evidence compliance with this Section 18.4.

18.4.6 Binding Orders shall remain in effect unless cancelled by Elusys pursuant to Section 5. With respect to a termination pursuant to Section 18.1, Elusys shall (i) make the applicable payments to Lonza as set forth in Section 5.3 of this Agreement for any Batches that are cancelled, and (ii) pay Lonza for all Non-Production Services actually performed as of the date of such termination and expenses reasonably incurred by Lonza in giving effect to such termination, and (iii) pay Lonza for the reasonable expenses incurred by Lonza as a result of terminating any contractual commitments entered into under this Agreement with respect to unperformed Non-Production Services that are, at the time of termination, scheduled to be performed. Except as otherwise specifically set forth in this Section 18.4.6, Elusys shall have no obligation to pay for Non Production Services not actually performed as of the date of such termination.

18.5 Technology Transfer. In the event that during the term of or upon expiration or termination of this Agreement, Elusys notifies Lonza of its wish to obtain a license from Lonza (with the right to sublicense) to utilize the Lonza Information, Process, or any part thereof for the production of Anthim BDS either at its own facility or that of a third party, or any other intellectual property of Lonza or its Affiliates (whether or not patentable) reasonably necessary for the manufacture of the Anthim BDS, the Parties shall negotiate in good faith an agreement containing the commercially reasonable terms upon which such a license shall be granted and related technology shall be transferred, and shall thereafter enter into the same. Such negotiations shall be based on Lonza's standard terms for the grant of such licenses and the transfer of such technology

applying at the time in question. The Parties agree that prior to the incorporation of any patentable intellectual property a royalty, if any, which would be associated with such patentable intellectual property, shall be disclosed to Elusys and Elusys shall have the option to include or exclude such patentable intellectual property within the Process. In the event that Elusys agrees to incorporate any additional patentable intellectual property within the Process then the royalty associated with such patentable intellectual property shall be in addition to any other royalty payable by Elusys to Lonza.

18.6 Accrued Rights. The end of the term or prior termination of this Agreement for whatever reason shall not affect the accrued rights of either Lonza or Elusys arising under this Agreement. Notwithstanding the foregoing, upon termination of the Agreement and payment of all amounts accruing prior to and as of the date of termination (including those set forth in Section 18.4.6), Elusys shall have no further financial obligations to Lonza in respect of payment for the Services, and neither Party shall have any further financial obligation to the other in respect to such obligations accruing after the effective date of termination, other than to the extent required under the surviving provisions of the Agreement. The following provisions shall survive the expiration or termination of the Agreement 15.1.16 (Warranty disclaimer by Lonza), 15.2.6 (Warranty disclaimer by Elusys), 15.3 (Indemnification by Elusys), 15.4 (Indemnification by Lonza), 15.5 (Procedure for Indemnification), 16 (Limitations of Liability),17 (Elusys Information, Lonza Information and Patent Rights), 18.4 (Effect of Termination Generally), 18.5 (Technology Transfer). (Accrued Rights), 20.1 (Governing Law) and 20.2.(Arbitration).

19. Federal Acquisition Regulations.

[*****]

20. Governing Law, Jurisdiction and Enforceability.

20.1 Governing Law. The construction, validity, performance and enforcement of this Agreement shall be governed by the laws of State of Delaware, without giving effect to the principles of conflicts of law thereof.

20.2 Arbitration.

20.2.1 In the event of the failure on the part of any required representative of the Parties hereto or the Steering Committee to resolve any matter required by this Agreement to be agreed, or in the event of any other dispute or claim arising between the Parties under this Agreement, the Parties shall attempt by good faith negotiations to resolve such dispute or claim between them by reference to the Presidents, who shall negotiate in good faith during a period of not less than sixty (60) days to resolve such matter, dispute or claim. In the event the Parties are unable to resolve such dispute or claim within the required time, the dispute shall be submitted to binding arbitration. Whenever a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Any arbitration hereunder shall be conducted under the Commercial Arbitration Rules of the American Arbitration Association, except as modified herein. Each Party shall select one arbitrator and the two (2) arbitrators so selected shall choose a third arbitrator to resolve the dispute. All arbitrators shall be independent of the Parties and shall not have any present or past relationship with either Party. Prior to the commencement of arbitration, each Party shall certify that its chosen arbitrator is competent to decide such dispute and the two (2) arbitrators so certified shall jointly certify that their chosen third arbitrator is likewise competent to decide such dispute. Such competence may include the ability to understand disputes which are primarily scientific in nature or which require expertise and knowledge of processes related to the commercial development of a human therapeutic or diagnostic product which is peculiar to persons in the biotechnology or pharmaceutical industry The Parties shall allow and participate in discovery in accordance with the Federal Rules of Civil Procedure for a period of ninety (90) days after the commencement of the arbitration. In any such arbitration, the arbitrators will not have the right to modify the terms and conditions of this Agreement. As a result, the rights and obligations of the Parties will be determined only in accordance with the terms and conditions of this Agreement and any award will be only in accordance with the terms and conditions of this Agreement. A reasoned arbitration decision shall be rendered in writing and shall be binding and not be appealable to any court in any jurisdiction. The arbitration proceedings shall be conducted in the English language and shall be held in New York, New York. The arbitrators shall have the authority to grant specific performance, and to allocate between the Parties the costs of arbitration in such equitable manner as they determine. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made

to such court for judicial acceptance of any award and an order of enforcement, as the case may be.

20.2.2 Injunctive Relief. Notwithstanding the provisions of this Section 20.2, either Party will have the right to seek temporary injunctive relief in any court of competent jurisdiction as may be available to such Party under the laws and rules applicable in such jurisdiction.

20.3 No Waiver No failure or delay on the part of either Lonza or Elusys to exercise or enforce any rights conferred on it by the Agreement shall be construed or operate as a waiver thereof nor shall any single or partial exercise of any right, power or privilege or further exercise thereof operate so as to bar the exercise or enforcement thereof at any time or times thereafter.

20.4 Severability. The illegality or invalidity of any provision (or any part thereof) of this Agreement shall not affect the legality, validity or enforceability of the remainder of its provisions or the other parts of such provision, as the case may be

21. Miscellaneous.

21.1 Assignment. Neither Party shall be entitled to assign this Agreement without the prior written consent of the other, which consent shall not be unreasonably withheld or delayed, except that both Parties shall be entitled without the prior written consent of the other to assign this Agreement to an Affiliate or to any joint venture company of which that Party is the beneficial owner of more than fifty per cent (50%) of the issued voting share capital thereof or to any company to which that Party may transfer all or substantially all of its assets or capital stock relating to the activities contemplated under this Agreement, whether through purchase, merger, consolidation or otherwise. Any assignment not permitted by this Section 21 1 shall be void and of no effect whatsoever.

21.2 Ability to Direct Affiliates to Perform Services. Lonza has, and during the Term shall have, the right to and, during the Term, shall direct Lonza Biologics, Inc. (Portsmouth, NH) to perform the Services contemplated under and in accordance with this Agreement. Lonza hereby guarantees the performance by Lonza Biologics, Inc. of any of the Services performed on behalf of Lonza

21.3 Publicity. The text of any press release or other communication to be published by or in the media concerning the subject matter of this Agreement (not previously published pursuant to this Section 21.3) shall require the prior written approval of Lonza and Elusys, except to the extent required by law.

21.4 Entire Agreement. This Agreement embodies the entire agreement and understanding between Lonza and Elusys relating to the subject matter hereof and there are no promises, terms, conditions or obligations, oral or written, expressed or implied, with respect to its subject matter other than those contained in this Agreement. The terms of this Agreement supersede all previous agreements and understandings between Lonza and Elusys relating to the Services.

21.5 Independent Contractor. Each Party to this Agreement acts as an independent contractor and nothing in this Agreement shall be construed to create a relationship of partnership, principal and agent, or joint venture between the Parties.

21.6 Notices. Any notice or other communication to be given under this Agreement shall be delivered personally or sent by first class pre-paid registered or certified mail, return receipt requested, nationally recognized courier service or facsimile transmission addressed as follows:

If to Elusys, to:

Elusys Therapeutics, Inc.
25 Riverside Drive, Unit 1
Pine Brook, New Jersey 07058
For the attention of: Vice President, Corporate Development
Facsimile: 973-808-0322

If to Lonza, to:

Lonza Sales AG
Muenchensteinerstrasse 38
CH-4002, Basel
Switzerland
For the attention of General Counsel
Facsimile: +41 61 316 9111

with a copy to:

Lonza Biologics Inc.
101 International Drive
Portsmouth, NH 03801
For the attention of: Site Head
Facsimile: 603.601.5051

or to such other address as either Party hereto may hereafter notify the other in accordance with the provisions of this Section. All such notices or other communications shall be deemed to have been delivered as follows:

- If delivered personally, at the time of such delivery;
- If sent by registered or certified mail, five (5) business days (Saturdays, Sundays and public holidays excluded) after mailing, provided that a return receipt has been received by the sender;
- If sent by facsimile, upon receipt of the transmission confirmation slip showing completion of the transmission;
- If sent by courier service, two (2) days after being dispatched.

21.7 Headings. The headings in this Agreement are for convenience of reference only and shall not constitute part of this Agreement.

21.8 Counterparts. This Agreement may be executed in several counterparts, each of which is an original but all of which shall constitute one instrument.

21.9 Binding Effect. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns.

[next page is the signature page]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives as of the date first above written.

ELUSYS THERAPEUTICS, INC.

Signature:_____
Printed Name:_____
Title:_____

LONZA SALES AG

Signature:_____
Printed Name:_____
Title:_____

Signature_____
Printed Name:_____
Title:_____

SCHEDULE 1

Services

Upon Lonza's acceptance of a "Binding Order" Lonza shall execute such binding order to the current, effective versions of the following Process Descriptions and Records:

Process Descriptions:

USPO-9901	"IN5069 Inoculum Process Description H46"
USPO-9902	"FE5069 Fermentation Process Description H46"
USPO-9903	"PR509 Primary Recovery Process Description H46"
USPO-9924	"PP5069 Purification Process Description for 197377"

Process Records:

USPO-9908
USPO-9909
USPO-9910
USPO-9911
USPO-9912
USPO-9913
USPO-9914
USPO-9915
USPO-9916
USPO-9917
USPO-9918
USPO-9921
USPO-11666

With respect to each Batch, Elusys shall ensure that Lonza has adequate quantities of Cell Line and Product reference standard on hand **[*****]** prior to Commencement.

SCHEDULE 2

Elusys Materials in Lonza's Possession

[*****]

SCHEDULE 3

Elusys Patent Rights

US Pat. No. 7,446,182 B1	**Recombinant Antibodies for the Detection and Neutralization of Anthrax Toxin**	**G. Georgiou et al.**	**11/05/02**	**Issued 11/04/08**	**Ownership:** **Elusys Therapeutics**
AU Pat. No. 2002354047			**04/07/04**	**Issued 03/06/08**	
Can Pat. No. 2,465,891			**05/03/04**	**Issued 05/15/12**	
EP Pat. No. 1 451 338			**06/04/04**	**Issued 10/09/11**	
US Pat. No. 8,093,360 B2	**Antibodies That Bind B. *Anthracis* Exotoxin, Formulations Thereof, and Methods of Use**	**L. Casey et al.**	**09/28/07**	**Issued 01/10/12**	
US Patent Application No. 12/076,082	**Anti-Anthrax Antibody, Formulations and Methods of Use**	**L. Casey et al.**	**03/30/11**	**Notice of Allowance 09/10/2013**	

SCHEDULE 4

Specifications

Per current, effective USPO-10083 SN5069 Specification for Bulk Purified H46 Product P/N 197377.

SCHEDULE 5

Quality Agreement

Per current, effective UKSL-17080 Quality Agreement dated 28January2013 between Lonza and Elusys.

SCHEDULE 6

[*****]

* When applicable

[*****]

* When applicable

SPECIAL CONTRACT REQUIREMENTS

[*****]

EXPORT CONTROL
Subcontractor is responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and access to their proposed technologies, including compliance with the International Traffic in Arms Regulation (ITAR) and the Export Administration Regulations (EAR).

LABORATORY LICENSE REQUIREMENTS (May 1998)
The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended). This requirement shall also be included in any subcontract for services under the contract.

REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE
Anyone who becomes aware of the existence of apparent existence of fraud, waste and abuse in DHHS funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll-free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov.

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489 Washington, DC 20026

EXHIBIT 10.63

CERTAIN INFORMATION IN THIS EXHIBIT IDENTIFIED BY [*****] HAS BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL

AMENDMENT NO. 79

to the BULK DRUG SUBSTANCE ORDERING AGREEMENT

EFFECTIVE 5 FEBRUARY 2015

between

LONZA SALES AG

AND

ELUSYS THERAPEUTICS, INC.

THIS AMENDMENT 79 (this "Amendment") is made the 30th day of September 2022 ("Amendment Effective Date")

BETWEEN

1. LONZA SALES AG, of Muenchensteinerstrasse 38, Ch-4002 Basel, Switzerland ("Lonza")
and

2. ELUSYS THERAPEUTICS, INC., of 4 Century Drive, Suite 260, Parsippany, NJ 07054, USA ("Customer" or "Elusys").

WHEREAS

A. Customer and Lonza entered into that certain Anthim Bulk Drug Substance Ordering Agreement dated 5 February 2015 (as amended, the "Agreement"), under which Lonza is required to perform Services relating to the Cell Line and Bulk Drug Substance; and

B. The Parties wish to make certain changes to the Agreement to capture the transfer of the manufacturing process to the Lonza Portsmouth, NH 6,000L scale bioreactor suite, and to manufacture agreed Batches.

NOW THEREFORE it is agreed hereby by the parties as follows:

1. Capitalised terms used but not otherwise defined in this Amendment refer to those definitions in the Agreement.

2. Lonza will perform the additional Services in Stages 201-231 inclusive, as more fully set out in the Schedule below, provided however:

   a. the number of cGMP Pre-Approval Inspection (PAI) Batches at 6,000 Liter Scale as set out in Stage 228 may be reduced should the Customer receive regulatory agency approval to reduce the number of Batches required to demonstrate the Process upon inspection of the Lonza Portsmouth facility. Any PAI Batch campaign of less than six **[*****]** batches will be subject to a Batch price **[*****]**
   b. the **[*****]** commercial Batches referred to in Stage 229 are subject to Customer **[*****]** for additional Batches. Upon **[*****]** notice to Lonza, the Parties will proceed regarding such **[*****]** commercial Batches in Stage 229 in accordance with Section 5 of the Agreement. **[*****]**, then (a) Customer is not liable for the Batches in Stage 229, and (b) Lonza is not obliged to reserve any capacity for the Customer. Should **[*****]** additional Batches require additional production of Batches above the **[*****]** Batches listed in Stage 229, Customer shall submit this additional demand via the forecasting mechanism in Section 5 of the Ordering Agreement for Lonza review. Elusys is under no obligation to order Batches each calendar year beyond those Batches defined in Stage 229. The Batch campaign size in Stage 229 shall not be less than **[*****]** Batches per year subject to the Forecasting mechanism set forth in the Ordering Agreement.

3. Section 5.6 of the Agreement shall be deleted in its entirety and replaced with the following:

   "5.6 Purchase Obligation. Customer is not obliged to purchase exclusively from Lonza however, Customer does have the purchase obligations for Stages 201-231 as referred to in Section 2 above in this Amendment 79"

4. Save as herein provided , all other terms and conditions of the Agreement shall remain in full force and effect and are hereby ratified and confirmed in all respects. For further clarity, nothing in this Amendment 79 shall change the obligations of either Party in respect of 6K Batches except as set forth above, and all provisions and obligations (including the forecasting, ordering and cancellation provisions) in respect thereof shall continue.

5. This Amendment may be executed in two or more counterparts, each of which will be deemed an original but all of which together will constitute one and the same instrument. Delivery of executed copies (including by PDF) of this Amendment or counterparts thereof by facsimile, email or other electronic means will have the same legal validity as delivery of ink-signed copies. The Agreement, as previously amended and as amended by this Amendment, constitutes the entire agreement between the parties with respect to its subject and supersedes all contemporaneous and prior discussions and negotiations between the parties.

IN WITNESS WHEREOF, the parties have caused this Amendment No. 79 to be executed by their representatives thereunto duly authorised as of the day and year first written.

Signed for and on behalf of .....
LONZA SALES AG

..... TITLE
..... (DATE)

Signed for and on behalf of .....
LONZA SALES AG

..... TITLE
..... (DATE)

Signed for and on behalf of .....
ELUSYS THERAPEUTICS, INC.

..... TITLE
..... (DATE)

PRICE AND TERMS OF PAYMENT

1. Price

In consideration for Lonza performing the following Services, Elusys shall pay Lonza as follows:

Description	Price
Stage 201 – Internal Process Transfer to The Portsmouth Facility (6kL)	[*****]
Stage 202 – Process Characterization Risk assessment	[*****]
Stage 203 – Lab Scale Process Evaluation for Transfer to 6kL Scale	[*****]
Stage 204 – New Technology Implementation	[*****]
Stage 205 – cGMP Documentation and Automation (Portsmouth 6kL)	[*****]
Stage 206 – Production of one (1) Cell Simulation Batch at 6kL Scale	[*****]
Stage 207 – Process Validation Plan (PVP)	[*****]
Stage 208 – Biochemical Comparability	[*****]
Stage 209 – Evaluation of Protein A Resin Reuse at Small Scale	[*****]
Stage 210 – Virus Reduction Study (4 Viruses; Unused Resin)	[*****]
Stage 211 – Evaluation of DNA Reduction	[*****]
Stage 212 – Chromatography Resin Lifetime and Cleaning Protocol	[*****]
Stage 213 – Stability of Process Intermediates	[*****]
Stage 214 – DSP Mixing Study *Note: Price to be adjusted based on scope of mixing studies to be completed.*	[*****]
Stage 215 – Filtration Reprocessing Study	[*****]
Stage 216 – PPQ Protocols and Reports (Portsmouth)	[*****]
Stage 217 – PPQ Stability Study (60 Months)	[*****]
Stage 218 – PPQ Product Comparability Study	[*****]
Stage 219 – Risk Assessment of BDS Manufacturing Scale Extractables and Leachables	[*****]
Stage 220 – Final Filter Integrity Large Scale	[*****]

Stage 221 – Risk Assessment of Manufacturing Scale Bioburden and Endotoxin Data	**[*****]**
Stage 222 – Assessment of Reduced Scale Cumulative Hold Time Study for 6KL Scale	**[*****]**
Stage 223 – Media Feed Pre-Filtration Expiry Evaluation	**[*****]**
Stage 224 – UF Membrane Lifetime Protocol	**[*****]**
Stage 225 – Regulatory Filing & Support	**[*****]**
Stage 226 – cGMP Engineering Batch 6,000L	**[*****]**
Stage 227 – Production of **[*****]** Process Performance Qualification (PPQ) Batches at 6,000L Scale	**[*****]**
Stage 228 – Production of **[*****]** cGMP Pre-Approval Inspection (PAI) Batches at 6,000 Liter Scale	**[*****]**
Stage 229 – Production of **[*****]** cGMP Commercial Batches at 6,000 Liter Scale	**[*****]**
Stage 230 – Continuous Process Verification Plan	**[*****]**
Stage 231 – Global Data Mart	**[*****]**

Notes:

[*****]

Batch Description	Batch Price (per batch)	Rebate Amount per batch for Engineering Batch (per batch)	Adjusted Batch Price with Engineering Batch Rebate Included (per batch)
PPQ Batch (Stage 227)	**[*****]**	**[*****]**	**[*****]**
PAI Batch **[*****]** (Stage 228)	**[*****]**	**[*****]**	**[*****]**
Commercial Batches (Stage 229 **[*****]**)	**[*****]**	**[*****]**	**[*****]**

2. **Payment**

Payment by Elusys of the Price for each Stage shall be made against Lonza's invoices as follows:

2.1 Stage 226 – cGMP Batch Campaign – Engineering, **[*****]**.

2.2 Stage 227 – Production of **[*****]** Process Performance Qualification (PPQ) Batches at 6,000L Scale **[*****]**.

2.3 Stage 228 – Production of **[*****]** cGMP Pre-Approval Inspection (PAI) Batches at 6,000 Liter Scale **[*****]**.

2.4 Stage 229 Production of cGMP Commercial Batches at 6000 Liter Scale **[*****]**.

2.5 All other stages shall be paid **[*****]** upon initiation and **[*****]** on completion of the stage, where applicable.

2.6 Any External Laboratory testing charges will be invoiced separately as pass-through cost.

2.7 Stage 230 shall be paid **[*****]** upon initiation.

Schedule 1C

Services

[*****]

201. Internal Process Transfer to The Portsmouth Facility (6kL)

201.1. Objectives

[*****]

201.2. Activities

[*****]

Assumptions

[*****]

201.3. Estimated Duration

[*****]

202. Process Characterization Risk assessment

[*****]

203. Lab Scale Process Evaluation for Transfer to 6kL Scale

[*****]

204. New Technology Implementation

[*****]

205. cGMP Documentation and Automation (Portsmouth 6kL)

205.1. Objectives

[*****]

205.2. Activities

[*****]

205.3. Deliverables

[*****]

Assumptions

[*****]

205.4. Estimated Duration

[*****]

206. Production of one (1) Cell Simulation Batch at 6kL Scale

[*****]

207. Process Validation Plan (PVP)

207.1. Objectives

[*****]

207.2. Activities

[*****]

207.3. Deliverables

[*****]

Assumptions

[*****]

207.4. Estimated Duration

[*****]

208. Biochemical Comparability

208.1. Objectives

[*****]

208.2. Activities

[*****]

Assumptions

[*****]

208.3. Timescale

[*****]

209. Evaluation of Protein A Resin Re-Use at Small Scale

209.1. Objectives

[*****]

209.2. Activities

[*****]

Assumptions

[*****]

209.3. Timescale

[*****]

210. Virus Reduction Study (4 Viruses; Unused Resin)

210.1. Objectives

[*****]

210.2. Activities

[*****]

210.3. Deliverables

[*****]

Assumptions

[*****]

210.4. Estimated Duration

[*****]

211. Evaluation of DNA Reduction

211.1. Objectives

[*****]

211.2. Activities

[*****]

Assumptions

[*****]

211.3. Timescale

[*****]

212. Chromatography Resin Lifetime and Cleaning Protocol

212.1. Objective

[*****]

212.2. Activities

[*****]

212.3. Timescale

[*****]

213. Stability of In Process Intermediates

213.1. Objectives

[*****]

213.2. Activities

[*****]

213.3. Deliverables

[*****]

Assumptions

[*****]

213.4. Estimated Duration

[*****]

214. DSP Mixing Study

214.1. Objectives

[*****]

214.2. Activities

[*****]

214.3. Deliverables

[*****]

Assumptions

[*****]

214.4. Estimated Duration

[*****]

---

215. Filtration Reprocessing Study

215.1. Objectives

[*****]

215.2. Activities

[*****]

215.3. Deliverables

[*****]

Assumptions

[*****]

215.4. Estimated Duration

[*****]

216. PPQ Protocols and Reports (Portsmouth)

216.1. Objectives

[*****]

216.2. Activities

[*****]

[*****]

216.3. Deliverables

[*****]

Assumptions

[*****]

216.4. Estimated Duration

[*****]

217. PPQ Batch DS Stability Study (60 Months)

217.1. Objectives

[*****]

217.2. Activities

[*****]

217.3. Deliverables

[*****]

Assumptions

[*****]

217.4. Estimated Duration

[*****]

218. PPQ Product Comparability Study

218.1. Objectives

[*****]

218.2. Activities

[*****]

218.3. Deliverables

[*****]

218.4. Estimated Duration

[*****]

219. Risk Assessment of BDS Manufacturing Scale Extractables and Leachables

219.1. Objectives

[*****]

219.2. Activities

[*****]

219.3. Deliverables

[*****]

Assumptions

[*****]

219.4. Estimated Duration

[*****]

220. Final Filter Integrity Large Scale

220.1. Objectives

[*****]

220.2. Activities

[*****]

220.3. Deliverables

[*****]

Assumptions

[*****]

220.4. Estimated Duration

[*****]

---

221. Risk Assessment of Manufacturing Scale Bioburden and Endotoxin Data

221.1. Objectives

[*****]

221.2. Activities

[*****]

221.3. Deliverables

[*****]

Assumptions

[*****]

221.4. Estimated Duration

[*****]

---

222. Assessment of Reduced Scale Cumulative Hold Time Study for 6kL Scale

222.1. Objectives

[*****]

222.2. Activities

[*****]

222.3. Deliverables

[*****]

Assumptions

[*****]

222.4. Estimated Duration

[*****]

223. Media Feed Pre-Filtration Expiry Evaluation

223.1. Objectives

[*****]

223.2. Activities

[*****]

223.3. Deliverables

[*****]

Assumptions

[*****]

223.4. Estimated Duration

224. UF Membrane Lifetime Protocol

224.1. Objective

[*****]

224.2. Activities

[*****]

224.3. Timescale

[*****]

225. Preparation of Regulatory Documentation and Associated Regulatory Services

225.1. Objectives

225.2. Activities

[*****]

Assumptions

[*****]

[*****]

[*****]	[*****]
[*****]	[*****]
[*****]	[*****]

225.3. Estimated Duration

[*****]

226. cGMP Batch Campaign - Engineering 6,000L

226.1. Objectives

[*****]

226.2. Activities

[*****]

226.3. Deliverables

[*****]

Assumptions

[*****]

226.4. Estimated Duration

[*****]

227. Production of Process Performance Qualification (PPQ) Batches at 6,000L Scale Objectives

227.1. Objectives

[*****]

227.2. Activities

[*****]

227.3. Deliverables

[*****]

Assumptions

[*****]

227.4. Estimated Duration

[*****]

Production of [*****] cGMP Pre-Approval Inspection (PAI) Batches at 6,000 Liter Scale

227.5. Objectives

[*****]

227.6. Activities

[*****]

227.7. Deliverables

[*****]

Assumptions

[*****]

227.8. Estimated Duration

228. Production of cGMP Commercial Batches at 6,000 Liter Scale

228.1. Objectives

[*****]

228.2. Activities

[*****]

228.3. Deliverables

[*****]

Assumptions

[*****]

228.4. Estimated Duration

[*****]

229. Continued Process Verification

229.1. Objectives

[*****]

229.2. Activities

[*****]

229.3. Deliverables

[*****]

Assumptions

[*****]

229.4. Estimated Duration

[*****]

230. Global Data Mart

230.1. Objectives

[*****]

230.2. Activities

[*****]

230.3. Deliverables

[*****]

Assumptions

[*****]

230.4. Estimated Duration

[*****]

EXHIBIT 21.1

Subsidiaries

Name of Subsidiary	Jurisdiction
Heat Biologics, Inc	Delaware
Heat Biologics I, Inc	Delaware
Heat Biologics III, Inc.	Delaware
Heat Biologics IV, Inc.	Delaware
Heat Biologics GmbH.	Germany
Heat Biologics Australia Pty LTD	Australia
Zolovax, Inc.	Delaware
Pelican Therapeutics, Inc.	Delaware
Skunkworx Bio, Inc.	Delaware
Scorpius BioManufacturing, Inc.	Delaware
Abacus Biotech, Inc.	Delaware
Blackhawk Bio, Inc.	Delaware
Elusys Therapeutics, Inc.	Delaware

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

NightHawk Biosciences, Inc.
Morrisville, North Carolina

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (No. 333-224039 and No. 333-234105), Form S-3 (No. 333-214868, No. 333-237808, No. 333-251255, No. 333-251256 and No. 333-257051) and Form S-8 (No. 333-193453, No. 333-196763, No. 333-207108, No. 333-213133, No. 333-219238, No. 333-227699, No. 333-233352, No. 333-237137, No. 333-249466, No. 333-260120 and No. 333-267723) of Nighthawk Biosciences, Inc. of our report dated March 31, 2023, relating to the consolidated financial statements which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

Raleigh, North Carolina
March 31, 2023

EXHIBIT 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14 OR RULE 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey Wolf, certify that:

1. I have reviewed this annual report on Form 10-K of NightHawk Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 31, 2023

By: /s/ Jeffrey Wolf
Name: Jeffrey Wolf
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULE 13a-14 OR RULE 15d-14 OF THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, William Ostrander, certify that:

1. I have reviewed this annual report on Form 10-K of NightHawk Biosciences, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 31, 2023

By: /s/ William L. Ostrander
Name: William L. Ostrander
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

EXHIBIT 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of NightHawk Biosciences, Inc. (the "Registrant") hereby certifies, to such officer's knowledge, that:

(1) the accompanying Annual Report on Form 10-K of the Registrant for the year ended December 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 31, 2023

By: /s/ Jeffrey Wolf
Name: Jeffrey Wolf
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of NightHawk Biosciences, Inc. (the "Registrant") hereby certifies, to such officer's knowledge, that:

(1) the accompanying Annual Report on Form 10-K of the Registrant for the year ended December 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: March 31, 2023

By: /s/ William L. Ostrander
Name: William L. Ostrander
Title: Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)