UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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, 2023

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

For the transition period from _____ to _____

Commission file number 001-36457

PROVECTUS BIOPHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**90-0031917**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

800 S Gay St, Suite 1610, Knoxville, TN 37929
(Address of principal executive offices) (Zip Code)

866-594-5999
(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
None	N/A	N/A

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

Common Stock, par value $0.001 per share
(Title of class)

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 registrant (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 (§ 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 standards 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 Act). ☐ Yes ☒ No

The aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of June 30, 2023 was $45,528,616 (computed on the basis of $0.113 per share).

The number of shares outstanding of the registrant's common stock, par value $0.001 per share, as of March 27, 2024 was 419,522,119.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III is incorporated by reference to portions of the definitive proxy statement to be filed within 120 days after December 31, 2023, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the 2024 annual meeting of stockholders.

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" as defined under U.S. federal securities laws. These statements reflect management's current knowledge, assumptions, beliefs, estimates, and expectations. These statements also express management's current views of future performance, results, and trends and may be identified by their use of terms such as "anticipate," "believe," "could," "estimate," "expect," "goal," "intend," "may," "plan," "predict," "project," "should," "strategy," "will," and other similar terms. While we believe that the expectations reflected in our forward-looking statements are reasonable, we can give no assurance that such expectations will prove correct. Forward-looking statements are subject to risks and uncertainties that could cause our actual results to differ materially from the future results, performance, or achievements expressed in or implied by any forward-looking statement we make. Some of the relevant risks and uncertainties that could cause our actual performance to differ materially from the forward-looking statements contained in this report are discussed below under the heading "Risk Factors" and elsewhere in this Annual Report on Form 10-K. We caution investors that these discussions of important risks and uncertainties are not exclusive, and our business may be subject to other risks and uncertainties which are not detailed there. Investors are cautioned not to place undue reliance on our forward-looking statements. We make forward-looking statements as of the date on which this Annual Report on Form 10-K is filed with the U.S. Securities and Exchange Commission (the "SEC"), and we assume no obligation to update the forward-looking statements after the date hereof whether as a result of new information or events, changed circumstances, or otherwise, except as required by law.

Risks and uncertainties that could cause our actual results to materially differ from those described in forward-looking statements:

- The uncertainty of generating (i) sales from rose bengal sodium-based drug product candidates PV-10® and PH-10®, and/or any other halogenated xanthene-based drug product candidates (if and when approved), (ii) licensing, milestone, royalty, and/or other payments related to these drug product candidates, and/or (iii) payments from the Company's liquidation, dissolution, or winding up, or any sale, lease, conveyance, or other disposition of any intellectual property relating to these drug product candidates and/or rose bengal sodium- and other halogenated xanthene-based drug substances;

- The uncertainty of raising additional capital through the proceeds of private placement transactions of debt and/or equity securities, the exercise of existing warrants and outstanding stock options, and/or public offerings of debt and/or equity securities;

- The disruptions from the widespread outbreak of an illness or communicable/infectious disease, such as severe acute respiratory syndrome coronavirus 2, or another public health crisis to our business that could adversely affect our operations and financial condition; and

- The disruptions, shortages, and other supply chain-related issues that many companies across different industry sectors have reported and continue to report. In the biopharmaceutical sector, delays and interruptions in the supply chain have been particularly pronounced. During 2023, we were able to effectively manage our supply of drug product candidates and drug substance in a manner that avoided any significant interruptions to our clinical development and drug discovery programs.

PART I

ITEM 1. BUSINESS.

General

Provectus Biopharmaceuticals, Inc., a Delaware corporation incorporated in 2002 (together with its subsidiaries, "Provectus" or "the Company"), is a clinical-stage biotechnology company developing immunotherapy medicines for different diseases that are based on a class of synthetic small molecule immuno-catalysts called halogenated xanthenes ("HXs"). Our lead HX molecule is named rose bengal sodium ("RBS").

The Company's proprietary, patented, pharmaceutical-grade RBS is the active pharmaceutical ingredient in the drug product candidates of our current clinical development programs and the preclinical formulations of our current drug discovery programs. Importantly, our pharmaceutical-grade RBS displays different therapeutic effects at different concentrations and can be formulated for delivery by different routes of administration.

The Company believes that RBS targets disease in a bifunctional manner. First, direct contact may lead to cell death or repair, depending on the disease being treated and the concentration of the RBS utilized in the treatment. Second, multivariate immune signaling, activation, and response may follow that may manifest as stimulatory, inhibitory, or both.

The Company believes that it is the first entity to advance an RBS formulation into clinical trials for the treatment of a disease, such as those trials reported on the clinical trials registry at ClinicalTrials.gov.

The Company believes that it is the first and only entity to date to make pharmaceutical-grade RBS successfully, reproducibly, and consistently at a purity of nearly 100%.

The Company's small molecule HX medical science platform comprises several different drug product candidates and preclinical pharmaceutical-grade RBS formulations using different concentrations delivered by different routes of administration specific to each disease area and/or indication. The Company's HX medical science platform includes clinical development programs in oncology, dermatology, and ophthalmology; *in vivo* proof-of-concept programs in oncology, hematology, wound healing, and animal health; and *in vitro* drug discovery programs in infectious diseases and tissue regeneration and repair.

Intellectual Property

U.S. Patents

We hold patents covering the HX medical science platform that we have developed and are continuing to develop for drug product candidates and drug formulations in different disease areas. All patents awarded by the U.S. Patent and Trademark Office ("USPTO") that are material to an understanding of the Company are listed in the table below:

U.S. Patent No.	Title	Issue Date	Expiration Date
7,201,914	Combination antiperspirant and antimicrobial compositions	April 10, 2007	May 15, 2024
8,530,675	Process for the synthesis of rose bengal and related xanthenes	September 10, 2013	April 21, 2031
9,107,887	Combination therapy for cancer	August 15, 2015	March 9, 2032
9,273,022	Process for the synthesis of rose bengal and related xanthenes	March 1, 2016	September 17, 2030
9,422,260	Process for the synthesis of rose bengal and related xanthenes	August 23, 2016	September 26, 2030
9,808,524	Combination of local and systematic immunomodulative therapies for melanoma and liver cancer	November 7, 2017	March 9, 2032

9,839,688	Combination of rose bengal and systemic immunomodulative therapies for enhanced treatment of cancer	December 12, 2017	March 9, 2032
10,130,658	Method of *ex vivo* enhancement of immune cell activity for cancer immunotherapy with a small molecule ablative compound	November 20, 2018	December 18, 2035
10,471,144	Combination of local rose bengal and systemic immunomodulative therapies for enhanced treatment of cancer	November 12, 2019	November 12 2034
11,058,664	*In vitro* and xenograft anti-tumor activity of a halogenated-xanthene against refractory pediatric solid tumors	July 13, 2021	May 15, 2039
11,071,781	Combination of local and systemic immunomodulative therapies for enhanced treatment of cancer	July 27, 2021	March 9, 2032
11,419,844	Composition and Methods for Treating Hematologic Cancers	August 23, 2022	December 3, 2040
11,426,379	Combination of Local and Systemic Therapies for Enhanced Treatment of Dermatologic Conditions	August 30, 2022	November 29, 2038

We received one patent allowance from the USPTO in 2023, U.S. patent application number 17/488,430 titled "Halogenated Xanthenes as Vaccine Adjuvants." Two patent applications were also published on the USPTO's website:

- Photodynamic Anti-Gram-Positive Bacterial Activity of Pharmaceutical-Grade Rose Bengal (USPTO application number 18/089,011), and
- Halogenated Xanthene-Containing Topical Anti-Gram-Positive Bacterial Ophthalmic Composition and Method (18/089,134).

International Patents

In 2023, the Company received a patent award for Mexico for "Method of Ex Vivo Enhancement of Immune Cell Activity for Cancer Immunotherapy With A Small Molecule Ablative Compound," patent awards for Australia and Mexico for "Combination of Local And Systemic Therapies for Enhanced Treatment of Dermatologic Conditions," and patent awards for Australia, China, Europe, Hong Kong, and Mexico for "In Vitro And Xenograft Anti-Tumor Activity Of A Halogenated-Xanthene Against Refractory Pediatric Solid Tumors."

Clinical Development and Drug Discovery

The Company's small molecule HX medical science platform includes:

Clinical Development Programs

- *Oncology:* Intratumoral ("ITU") formulation PV-10® ("ITU PV-10") has undergone and is undergoing multiple, monotherapy and combination therapy, early- to late-stage clinical trials, expanded access programs ("EAPs") for groups of and individual patients, and/or quality of life ("QOL") study at multiple clinical sites in Australia, Europe, and the U.S. for the treatments of Stage III and IV melanoma and different types of liver cancers. ITU PV-10 has undergone and is undergoing clinical monotherapy and combination therapy mechanism of action and mechanism of immune response study for melanoma, metastatic uveal melanoma, and metastatic neuroendocrine tumors at and/or with Moffitt Cancer Center in Tampa, Florida, The Queen Elizabeth Hospital in Adelaide, Australia, and MD Anderson Cancer Center in Houston, Texas.

- *Dermatology:* Topical ("TOP") formulation PH-10® ("TOP PH-10") has undergone multiple mid-stage, monotherapy clinical trials for the treatments of psoriasis and atopic dermatitis at different clinical sites in the U.S. TOP PH-10 has undergone clinical monotherapy mechanism of action and mechanism of immune response study for psoriasis at The Rockefeller University in New York, New York ("TRU").

Different formulations have undergone preclinical combination therapy study for psoriasis and are undergoing preclinical monotherapy study for skin inflammation at TRU.

- *Ophthalmology:* The Company believes that clinical monotherapy proof-of-concept ("POC") of TOP administration of non-pharmaceutical grade rose bengal for the treatment of infectious keratitis has been shown by clinicians and researchers at the University of Miami's ("UM's") Bascom Palmer Eye Institute ("BPEI") in Miami, Florida, who are now collaborating with the Company to evaluate the potential use of our pharmaceutical-grade RBS.

  TOP PV-305 has undergone preclinical monotherapy study for diseases and disorders of the eye, such as infectious keratitis at BPEI.

In Vivo Proof-of-Concept Drug Discovery Programs

- *Oncology:* ITU PV-10 has undergone preclinical monotherapy and combination therapy study for the treatment of relapsed and refractory pediatric solid tumor cancers at the University of Calgary's Cumming School of Medicine in Calgary, Alberta, Canada ("UCal"). The Company believes that the UCal researchers have achieved monotherapy *in vivo* POC of ITU administration.

- Oral ("PO") formulations are undergoing preclinical monotherapy study for high-risk and refractory adult solid tumor cancers at UCal. The Company believes that the UCal researchers and the Company have both achieved monotherapy *in vivo* POC of PO administration, that the Company has achieved monotherapy *in vivo* POC of PO administration in prophylactic and therapeutic settings, and that the Company has achieved monotherapy *in vivo* POC of intravenous ("IV") administration.

- *Hematology:* PO formulations are undergoing preclinical monotherapy study for the treatment of refractory and relapsed pediatric and other blood cancers, including leukemias, at UCal. The Company believes that the UCal researchers have achieved *in vivo* POC of PO administration.

- *Wound Healing:* Different formulations are undergoing preclinical monotherapy study for the healing of full-thickness cutaneous wounds. The Company believes that monotherapy *in vivo* POC of TOP administration of non-pharmaceutical grade rose bengal for the treatment of this indication has been shown by researchers at the University of Texas Medical Branch ("UTMB") in Galveston, Texas, who are now collaborating with the Company to use our pharmaceutical-grade RBS.

- *Animal Health:* Different formulations are undergoing preclinical monotherapy study for the treatment of cutaneous canine cancers at the University of Tennessee's College of Veterinary Medicine in Knoxville, Tennessee. The Company believes that it has achieved monotherapy POC in canines of ITU administration.

In Vitro Drug Discovery Programs

- *Infectious Diseases:* PO and intranasal ("IN") formulations have undergone preclinical monotherapy study for the treatment of SARS-CoV-2 at UCal, another Canadian academic research center, the University of Tennessee Health Science Center ("UTHSC") in Memphis, Tennessee, and a U.S. contract research organization.

- Different formulations have undergone preclinical monotherapy and combination therapy study for the treatment of gram-positive and gram-negative bacterial infections (including multi-drug resistant strains) and have undergone preclinical monotherapy study for the treatment of oral bacterial infections at UTHSC.

- Different formulations have undergone preclinical monotherapy study for the treatment of fungal infections at UTHSC.

- *Tissue Regeneration and Repair*: Different formulations have undergone preclinical monotherapy study for vertebrate development, wound healing, and tissue regrowth at the University of Nevada, Las Vegas ("UNLV") in Las Vegas, Nevada.

2023 Activity

In April, preclinical research on the Company's pharmaceutical-grade rose bengal sodium drug substance against colistin-resistant gram-negative bacteria was published in The Journal of Antibiotics, a medical periodical by Nature Portfolio for the Japan Antibiotics Research Association: "Antibacterial effect of rose bengal against colistin-resistant gram-negative bacteria."

In June, the Company initiated a new sponsored research program with the University of Tennessee College of Veterinary Medicine to assess the safety and preliminary efficacy of intralesional injection of a formulation of the Company's pharmaceutical-grade RBS for canine soft tissue sarcomas.

The Company's stockholders approved the proposals of the Board of Directors ("Board") to seek the authority to undertake a reverse stock split and an authorized share reduction.

In July, the USPTO published the Company's patent application entitled "Photodynamic Anti-Gram-Positive Bacterial Activity of Pharmaceutical-Grade Rose Bengal" (publication no. 18/089,011).

In August, the USPTO published the Company's patent application entitled "Halogenated Xanthene-Containing Topical Anti-Gram-Positive Bacterial Ophthalmic Composition and Method" (publication no. 18/089,134).

In November, preclinical data from ongoing research on the potential use of PV-10 as an adjuvant in vaccines to help them work better was the subject of a poster presentation at the Society for Immunotherapy of Cancer (SITC) 2023 annual meeting, held in San Diego, CA from November 1-5: "The iodinated fluorescein derivative PV-10 enhances the antiviral activity of CD8+ T-Cells by inducing STING dimerization: Implications for enhanced vaccine applications."

The Company provided updated data from an ongoing Phase 1 clinical trial of PV-10 for the treatment of uveal melanoma (UM) metastatic to the liver (mUM) (NCT00986661).

The Company also provided updated data from an ongoing Phase 1b/2 clinical trial of PV-10 in combination with standard of care immune checkpoint blockade for the treatment of advanced cutaneous melanoma (NCT02557321).

In December, the USPTO allowed patent application 17/488,430, titled "Halogenated Xanthenes as Vaccine Adjuvants." The allowed patent application covers the use of Provectus's pharmaceutical-grade rose bengal sodium (RBS) drug substance as an adjuvant in anticancer, antiviral, and possibly other vaccines to potentially make them work better by enhancing T-cell response.

Competition

In general, the pharmaceutical and biotechnology industries are competitive, characterized by steady and sometimes disruptive advances in products and technology. A number of companies have developed and continue to develop products that address the areas we have targeted. Some of these companies are pharmaceutical companies and biotechnology companies that are international in scope and very large in size, while others are small companies that have been successful in one or more areas we are targeting. Existing or future pharmaceutical, device, or other competitors may develop products that accomplish similar functions to our technologies in ways that may be less expensive, receive faster regulatory approval, or receive greater market acceptance than our products. Many of our competitors have been in existence longer than we have, have greater capital resources, broader internal structure for research, development, manufacturing, and marketing, and may be further along in their respective product cycles.

Supply Chain

During 2023, we undertook extensive validation testing of our supply of prescription drug candidate PV-10.

Federal Regulation of Therapeutic Products

All the prescription drug candidates that we currently contemplate developing will require approval by the U.S. Food and Drug Administration ("FDA") prior to sales within the U.S. and by comparable international governmental healthcare regulatory agencies prior to sale outside the U.S. The FDA and comparable international agencies impose substantial requirements on the manufacturing and marketing of pharmaceutical products. These agencies and other entities regulate, among other things, research and development activities and the testing, manufacturing, quality control, safety and effectiveness claims, labeling, storage, record keeping, approval, advertising, and promotion of our prescription drug candidates. While we attempt to minimize and avoid significant regulatory bars when formulating our products, some degree of regulation from these regulatory agencies is unavoidable.

The regulatory process required by the FDA, through which our prescription drug candidates must successfully pass before they may be marketed in the U.S., generally involves pre-clinical laboratory and animal testing, submission of an application that must become effective before clinical trials may begin, adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication, and FDA approval to market a given product for a given indication after the appropriate application has been filed. For pharmaceutical products, pre-clinical tests include laboratory evaluation of the product, its chemistry, formulation, and stability, as well as *in vitro* and animal studies to assess the potential safety and efficacy of the product. We will require sponsored work to be conducted in compliance with pertinent local and international regulatory requirements, including those providing for Institutional Review Board approval, national governing agency approval, and patient informed consent, using protocols consistent with ethical principles stated in the Declaration of Helsinki and other internationally recognized standards and delineated by The International Conference on Harmonisation ("ICH") Good Clinical Practice standards.

If the FDA is satisfied with the results and data from pre-clinical tests, it will authorize human clinical trials. Human clinical trials traditionally are conducted in three sequential phases which may overlap. Each of the three phases involves testing and study of specific aspects of the effects of the investigational product on human subjects, including testing for safety, dosage tolerance, side effects, absorption, metabolism, distribution, excretion, and clinical efficacy.

Phase 1 clinical trials include the initial introduction of an investigational new drug into humans, or via a new route of administration or new organ system if previously investigated in humans. These studies are closely monitored and may be conducted in patients but may also be conducted in healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. While the FDA can cause us to end clinical trials at any phase due to safety concerns, Phase 1 clinical trials are primarily concerned with safety issues. We also attempt to obtain sufficient information about the drug candidate's pharmacokinetics and pharmacological effects during Phase 1 clinical trials to permit the design of scientifically valid, Phase 2 studies.

Phase 1 studies also evaluate drug metabolism, structure-activity relationships, and the mechanism of action in humans. These studies also determine which investigational drugs are used as research tools to explore biological phenomena or disease processes. The total number of subjects included in Phase 1 studies varies with the drug but is generally in the range of 10 to 80.

Phase 2 clinical trials include early controlled clinical studies conducted to obtain preliminary data on the effectiveness of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine the common short-term side effects and risks associated with the drug. Phase 2 studies are often randomized controlled studies that are closely monitored and conducted in a relatively small number of patients, usually involving up to several hundred people.

Phase 3 studies are expanded controlled and uncontrolled trials. They are performed after preliminary evidence suggesting effectiveness of the drug has been obtained in Phase 2 and are intended to gather definitive information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug. Phase 3 studies also provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labeling. Phase 3 studies usually include several hundred to several thousand people.

We have established a core clinical development team and have been working with external and FDA-experienced consultants to assist us in developing product-specific development and approval strategies, preparing the required submittals, guiding us through the regulatory process, and providing input into the design and site selection of human clinical studies.

The testing and approval process requires substantial time, effort, and financial resources, and we may not obtain FDA approval on a timely basis, if at all. Success in preclinical or early-stage clinical trials does not assure success in later-stage clinical trials. The FDA or research institution conducting the trials may suspend clinical trials or may not permit trials to advance from one phase to another at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Once issued, the FDA may withdraw a prescription drug approval if we do not comply with pertinent regulatory requirements and standards or if problems are identified after the product reaches the market. If the FDA grants approval of a prescription drug candidate, the approval may impose limitations, including limits on the indicated uses for which we may market a drug product. In addition, the FDA may require additional testing and surveillance programs to monitor the safety and/or effectiveness of approved drug products that have been commercialized, and the agency has the power to prevent or limit further marketing of a product based on the results of these post-marketing programs. Further, later discovery of previously unknown problems with a drug product may result in restrictions on the product, including withdrawal from the market.

Marketing our prescription drug candidates abroad will require similar regulatory approvals by equivalent national authorities and is subject to similar risks. To expedite development, we may pursue some or all of our initial clinical testing and approval activities outside the U.S., and in particular in those countries where our prescription drug candidates may have substantial medical and commercial relevance. In some such cases, any resulting drug products may be brought to the U.S. after substantial offshore experience is gained. Accordingly, we intend to pursue any such development in a manner consistent with U.S. and ICH standards so that the resultant development data is maximally applicable for potential global approval.

Additional Regulation

We are subject to various federal, state, and local laws and regulations relating to the protection of the environment, human health, and safety in the U.S. and in other jurisdictions in which we operate. If we violate these laws and regulations, we could be fined, criminally charged, or otherwise sanctioned by regulators. Environmental laws and regulations are complex, change frequently and have become more stringent over time. We believe that our operations currently comply in all material respects with applicable environmental laws and regulations.

Human Capital Resources

We have four full-time employees who currently serve as CFO, CTO, senior scientist, and controller. We also engage independent contractors, who currently serve as chief operations consultant, director of clinical operations, clinical research associates, and information technology manager.

We believe the Company's success depends on its ability to attract, develop, and retain key personnel. The skills, experience, and industry knowledge of key members of our Board of Directors, employees, and contractors significantly benefit our operations and performance. The Company's Board of Directors and management oversee various employee and contractor initiatives.

Available Information

Our website is located at www.provectusbio.com. We make available free of charge through this website our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed with or furnished to the SEC pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Reference to our website does not constitute incorporation by reference of the information contained on the site and should not be considered part of this document.

The SEC maintains an Internet site that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC as we do. The website is http://www.sec.gov.

The Company also intends to use press releases, the Company's website and certain social media accounts as a means of disclosing information and observations about the Company and its business, and for complying with the Company's disclosure obligations under Regulation FD: the Provectus Substack account (provectus.substack.com), the @ProvectusBio X account (twitter.com/provectusbio), and the Company's LinkedIn account (linkedin.com/company/provectus-biopharmaceuticals). The information and observations that the Company posts through these social media channels may be deemed material. Accordingly, investors should monitor these social media channels in addition to following the Company's press releases, SEC filings, and website. The social media channels that the Company intends to use as a means of disclosing the information described above may be updated from time to time.

The contents of the websites provided above are not intended to be incorporated by reference into this Annual Report on Form 10-K or in any other report or document we file with the SEC. Further, our references to the URLs for these websites are intended to be inactive textual references only.

ITEM 1A. RISK FACTORS.

Our business and its future performance may be affected by various factors, the most significant of which are discussed below.

Risks Related to Our Business

We are a clinical-stage drug company, have no prescription drug products approved for commercial sale, have incurred substantial losses, and expect to incur substantial losses and negative operating cash flow for the foreseeable future.

We are a clinical-stage drug company that has no prescription drug products approved for commercial sale. We have never generated any substantial revenues and may never achieve substantial revenues or profitability. As of December 31, 2023, we have incurred net losses of approximately $253 million in the aggregate since inception in January 2002. We may never achieve or maintain profitability, even if we succeed in developing and commercializing one or more of our prescription drug candidates. We also expect to continue to incur significant operating expenditures and anticipate that our operating and capital expenses may increase substantially in the foreseeable future as we continue to develop and seek regulatory approval for our prescription drug candidates, develop our prescription drug formulation candidates, implement additional internal systems and infrastructure, and hire additional personnel.

We also expect to experience negative operating cash flow for the foreseeable future as we fund our operating losses and any future capital expenditures. As a result, we will need to generate significant revenues 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 could negatively impact the value of our common stock.

We need additional capital to conduct our operations and commercialize and/or further develop our prescription drug candidates and prescription drug formulation candidates in 2024 and beyond, and our ability to obtain the necessary funding is uncertain.

We need additional capital in 2024 and beyond to continue developing and seeking to commercialize our drug product candidates. We intend to continue with the development of our prescription drug candidates and prescription drug formulation candidates on the basis of historical, ongoing, and prospective clinical and preclinical study results.

We have based our estimate of capital needs on assumptions that may prove to be wrong, and we cannot assure you that estimates and assumptions will remain unchanged. On August 13, 2021, the Board approved a Financing Term Sheet (the "2021 Term Sheet"), which sets forth the terms under which the Company will use its best efforts to arrange for financing of a maximum of $5,000,000 (the "2021 Financing"), which amounts will be obtained in several tranches and evidenced by convertible promissory notes (collectively, the "2021 Notes"). As of December 31, 2023, the Company had received 2021 Notes proceeds of $1,460,000, of which $200,000 is from a related party investor.

On September 20, 2022, the Board approved the closure of the 2021 Financing. Through December 31, 2023, the Company had received 2021 Notes proceeds of $2,335,000, of which $525,000 is from a related party investor (a Company officer and Company director), however $1,260,000 of these notes were converted to Series D-1 Preferred Shares during the 4th quarter 2022 and $875,000 of these notes were converted to Series D-1 Preferred Shares during the year ended December 31, 2023. As of December 31, 2023, the remaining 2021 Note balance was $200,000. See Note 5.

On September 20, 2022, the Board approved a Financing Term Sheet (the "2022 Term Sheet"), which set forth the terms under which the Company will use its best efforts to arrange for financing of a maximum of $5,000,000 (the "2022 Financing"), which amounts will be obtained in several tranches. Through December 31, 2023, the Company had received 2022 Notes proceeds of $3,227,500, as defined below, of which $2,352,500 is from a related party investor (a Company director), however, $752,500 of these notes were converted to Series D-1 Preferred Shares during the year ended December 31, 2023. As of December 31, 2023, the remaining 2022 Notes balance was $2,475,000. See Note 5.

Such additional financing may not be available on acceptable terms, or at all. As discussed in more detail below, additional equity financing could result in significant dilution to stockholders. Further, in the event that additional funds are obtained through licensing or other arrangements, these arrangements may require us to relinquish rights to some of our products, product candidates, and technologies that we would otherwise seek to develop and commercialize ourselves. If sufficient capital is not available, we may be required to delay, reduce the scope of, or eliminate one or more of our programs, any of which could have a material adverse effect on our business.

There is substantial doubt as to our ability to continue as a going concern.

The Company's cash balance was $1,026,799 at December 31, 2023, which includes $950,223 of restricted cash resulting from a grant received from the State of Tennessee. The Company's working capital deficiency was $7,652,098 and $6,293,198 as of December 31, 2023 and December 31, 2022, respectively. The Company continues to incur significant operating losses and management expects that significant on-going operating expenditures will be necessary to successfully implement our business plan and develop and market our products. These circumstances raise substantial doubt about our ability to continue as a going concern for a period of one year from the date that the consolidated financial statements included elsewhere in this Annual Report on Form 10-K are issued. Implementation of our plans and our ability to continue as a going concern will depend upon our ability to develop our prescription drug candidates and prescription drug formulation candidates, and to raise additional capital.

Management believes that we may have access to capital resources through possible public or private equity offerings, including the 2022 Financing, exchange offers, debt financings, corporate collaborations, or other means. If we are unable to raise sufficient capital, we will not be able to pay our obligations as they become due.

Our prescription drug product candidates are at early- to mid-stages of development and may never obtain U.S. or international regulatory approvals required for us to commercialize our investigational drug product candidates.

We will need approval of the FDA to commercialize our prescription drug product candidates in the U.S. and approvals from FDA-equivalent regulatory authorities in international jurisdictions to commercialize our investigational drug product candidates there.

We are continuing to pursue clinical development of our most advanced drug product candidates, PV-10 and PH-10, for use as treatments for specific disease indications. The continued and further development of these drug product candidates will require significant additional research, formulation and manufacturing development, and pre-clinical and extensive clinical testing prior to their regulatory approval and commercialization. Pre-clinical and clinical studies of our drug product candidates may not demonstrate the safety and efficacy necessary to obtain regulatory approvals. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after experiencing promising results in earlier trials. Pharmaceutical products that appear to be promising at early stages of development may not reach the market or be marketed successfully for a number of reasons, including a product may be found to be ineffective or have harmful side effects during subsequent pre-clinical testing or clinical trials, a product may fail to receive necessary regulatory clearance, a product may be too difficult to manufacture on a large scale, a product may be too expensive to manufacture or market, a product may not achieve broad market acceptance, others may hold proprietary rights that will prevent a product from being marketed, and others may market equivalent or superior products.

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 research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional nonclinical and clinical testing or to perform post-marketing studies. The approval process may also 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 delay commercialization of, and our ability to derive revenues from, our prescription drug candidates, impose costly procedures on us, and diminish any competitive advantages that we may otherwise enjoy.

Our research and product development efforts may not be successfully completed and may not result in any successfully commercialized drug products. Further, after commercial introduction of a new drug product, discovery of problems through adverse event reporting could result in restrictions on the product, including withdrawal from the market and, in certain cases, civil or criminal penalties.

Even if we comply with all FDA requests, we cannot be sure that we will ever obtain regulatory clearance for any of our drug product candidates. Failure to obtain FDA approval of any of our prescription drug candidates will severely undermine our business by reducing our number of salable drug products and, therefore, corresponding revenues.

In international jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our prescription drug candidates. International regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above.

Before obtaining regulatory approval for the sale of our drug product candidates, including PV-10 and PH-10, we must conduct additional clinical trials to demonstrate the safety and efficacy of our drug product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to timing and outcome. Competition in clinical development has made it difficult to enroll patients at an acceptable rate in some of our clinical trials. Advances in medical technology could make our prescription drug candidates obsolete prior to completion of clinical testing. A failure of one or more of our clinical trials may occur at any stage of testing. The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy characteristics despite having progressed satisfactorily through pre-clinical studies and initial clinical testing. A number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience, have suffered significant setbacks in Phase 3 clinical development, even after seeing promising results in earlier clinical trials.

Our research and development expenses may increase in connection with expanding clinical trials of our product candidates in existing indications and undertaking clinical trials of our product candidates in new indications. Because successful development of our drug product candidates is uncertain, we are unable to estimate the actual funds required to complete research and development and commercialize our products under development.

Negative or inconclusive results of our future clinical trials of PV-10 and PH-10, or any other clinical trial we conduct, could cause the FDA to require that we repeat or conduct additional clinical studies. Despite the results reported in earlier clinical trials for PV-10 and PH-10, we do not know whether any clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates. If later stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates may be adversely impacted.

Delays in clinical trials are common and have many causes, and any delay could result in increased costs to us and jeopardize or delay our ability to obtain regulatory approval.

Our planned or ongoing clinical trials may not begin on time, have an effective design, enroll a sufficient number of subjects, or be completed on schedule, if at all. Events which may result in delays or unsuccessful completion of clinical trials, including our future clinical trials, include inability to raise funding, initiate or continue a trial, delays in obtaining regulatory approval to commence a trial, delays in reaching agreement with the FDA or other regulatory authorities on final trial design, imposition of a clinical hold following an inspection of our clinical trial operations or trial sites by the FDA or other regulatory authorities, delays in reaching agreement on acceptable terms with prospective contract research organizations and clinical trial sites, delays in obtaining required institutional review board approval at each site, delays in recruiting suitable patients to participate in a trial, delays in having subjects complete participation in a trial or return for post-treatment follow-up, delays caused by subjects dropping out of a trial, delays caused by clinical sites dropping out of a trial, time required to add new clinical sites or to obtain regulatory approval and open sites in geographic regions beyond the sites initially planned, and delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

In addition, we may experience a number of unforeseen events during clinical trials for our prescription drug candidates, including PV-10 and PH-10, that could delay or prevent the commencement and/or completion of our clinical trials, including regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site, the clinical study protocol may require one or more amendments delaying study completion, clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us to conduct additional clinical trials or abandon product development programs, the number of subjects required for clinical trials of our product candidates may be larger than we anticipate, subjects may drop out of these clinical trials at a higher rate than we anticipate and enrollment in these clinical trials may be significantly slower than we anticipated requiring us to expand the geographic scope of enrollment of patients, clinical investigators or study subjects may fail to comply with clinical study protocols, trial conduct and data analysis errors may occur, including, but not limited to, data entry and/or processing errors, our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, we might have to suspend or terminate clinical trials of our prescription drug candidates for various reasons, including a finding that the subjects are being exposed to unacceptable health risks, regulators or institutional review boards may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, the cost of clinical trials of our prescription drug candidates may be greater than we anticipate, the supply or quality of our clinical trial materials or other materials necessary to conduct clinical trials of our prescription drug candidates may be insufficient or inadequate, and our prescription drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators to suspend or terminate the trials.

Moreover, we or the FDA may suspend our clinical trials at any time if it appears we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our submissions or the conduct of these trials. If initiation or completion of any of our clinical trials for our product candidates, are delayed for any of the above reasons or other reasons, our development costs may increase, the approval process could be delayed, any periods during which we may have the exclusive right to commercialize our prescription drug candidates may be reduced and our competitors may bring drug products to market before us. Any of these events could impair our ability to generate revenues from drug product sales and impair our ability to generate regulatory and commercialization milestones and royalties, all of which could have a material adverse effect on our business.

The results of our clinical trials may not support acceptable label claims concerning our prescription drug candidates.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support acceptable label claims concerning our drug product candidates. Success in pre-clinical 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 pre-clinical testing. The clinical trial process may fail to demonstrate that our prescription drug candidates are safe for humans or effective for indicated uses.

This failure could cause us to abandon a prescription drug candidate and may delay development of other prescription drug candidates. Any delay in, or termination of, our clinical trials will delay our ability to commercialize our prescription drug candidates and generate product revenues. In addition, we anticipate that our clinical trials will involve only a small patient population. Accordingly, the results of such trials may not be indicative of future results over a larger patient population.

Physicians and patients may not accept and use our prescription drug candidates.

Even if the FDA approves our drug product candidates, physicians and patients may not accept and use them. Acceptance and use of our drug products will depend upon a number of factors including perceptions by members of the healthcare community, including physicians, about the safety and effectiveness of our drug products, availability of reimbursement for our drug 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 sales or licensure of our prescription drug candidates, if approved, to generate substantially all of our revenues if they are approved, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

We have no sales, marketing, or distribution capabilities for our prescription drug candidates.

We currently have no sales, marketing, or distribution capabilities. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships, the collaborator's strategic interest in the prescription drug products under development and such collaborator's ability to successfully market and sell any such drug products. There can 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 market and sell our prescription drug candidates in the U.S. or internationally.

Competition in the prescription pharmaceutical and biotechnology industries is intense.

Other pharmaceutical and biotechnology companies and research organizations currently engage in or have in the past engaged in research efforts related to treatment of cancer and dermatological conditions, which may compete with our clinical trials for patients and investigator resources, cause lower enrollment than anticipated, and could lead to the development of drug products or treatment therapies that could compete directly with our drug product candidates that we are seeking to develop and market.

Many companies are also developing novel therapies to treat cancer and dermatological conditions and, in this regard, are our competitors. Many of the pharmaceutical companies developing and marketing these competing products have greater financial resources and expertise than we do in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals, and marketing.

Smaller companies may also prove to be competitors, particularly through collaborative arrangements with larger and more established companies that may compete with our efforts to establish similar collaborative arrangements. Academic institutions, government agencies, and other public and private research organizations may also conduct research, seek patent protection, and establish collaborative arrangements for research, clinical development, and marketing of prescription drug candidates similar to ours. These companies and institutions compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to our drug development programs.

In addition to the above factors, we expect to face competition in product efficacy and safety, the timing and scope of regulatory consents, availability of resources, reimbursement coverage, price, and patent position, including potentially dominant patent positions of others.

Since our prescription drug candidates PV-10 and PH-10 have not yet been approved by the FDA or introduced to the marketplace, we cannot estimate what competition these prescription drug candidates might face when they are finally introduced, if at all. We cannot assure you that these prescription drug candidates will not face significant competition for other approved drug products, investigational drug products, and generic equivalents.

If we lose any of our key personnel, we may be unable to successfully execute our business plan.

Our business is presently managed by key Board members, employees, and independent contractors: (i) Ed Pershing, who is chairman of the Board, (ii) Dominic Rodrigues, who is vice chairman of the Board and chief operations consultant, (iii) Eric Wachter, Ph.D., our Chief Technology Officer ("CTO"), who is an employee, and (iv) Heather Raines, CPA, our CFO, who is an employee.

In order to successfully execute our business plan, our management and Board must succeed in all of the following critical areas: researching diseases and possible therapies in the areas of oncology and dermatology, developing our prescription drugs candidates, marketing and selling developed prescription drug candidates, obtaining additional capital to finance research and development production, and marketing of our drug products, and managing our business as it grows.

Disruption resulting from management transition may have a detrimental impact on our ability to implement our strategy. The reduction in role and/or loss of key employees, contractors, and/or Board members could have a material adverse effect on our operations, and limit or constrain our ability to execute our business plan.

Our business and operations are subject to risks related to climate change.

The long-term effects of global climate change present risks to our business. Extreme weather or other conditions caused by climate change could adversely impact our supply chain and the operation of our business. Such conditions could also result in physical damage to our leased property, clinical trial materials, clinical sites, or the facilities of our contract manufacturers. These events could adversely affect our operations and our financial performance.

Our business and operations are vulnerable to computer system failures, cyber-attacks, or deficiencies in our cyber-security, which could increase our expenses, divert the attention of our management and key personnel away from our business operations and adversely affect our results of operations.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from: computer viruses; malware; natural disasters; terrorism; war; telecommunication and electrical failures; cyber-attacks or cyber-intrusions over the Internet; attachments to emails; persons inside our organization; or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach was to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims and liability, and damage to our reputation, and the further development of our product candidates could be delayed. We could be forced to expend significant resources in response to a cyber security breach, including repairing system damage, increasing cyber security protection costs by deploying additional personnel and protection technologies, paying regulatory fines, and resolving legal claims and regulatory actions, all of which would increase our expenses, divert the attention of our management and key personnel away from our business operations and adversely affect our results of operations.

Risks Related to Our Intellectual Property ("IP")

If we are unable to secure or enforce patent rights, trademarks, trade secrets or other IP, our business could be harmed.

We may not be successful in securing or maintaining proprietary patent protection for our prescription drug candidates and technologies we develop or license. In addition, our competitors may develop prescription drug candidates similar to ours using methods and technologies that are beyond the scope of our IP protection, which could reduce our anticipated sales. While some of our drug product candidates have proprietary patent protection, a challenge to these patents can subject us to expensive litigation. Litigation concerning patents, other forms of IP, and proprietary technology is becoming more widespread and can be protracted and expensive and can distract management and other personnel from performing product development duties.

We also rely upon trade secrets, unpatented proprietary knowledge and continuing technological innovation to develop a competitive position. We cannot assure you that others will not independently develop substantially equivalent proprietary technology and techniques or otherwise gain access to our trade secrets and technology, or that we can adequately protect our trade secrets and technology.

If we are unable to secure or enforce patent rights, trademarks, trade secrets, or other IP, our business, financial condition, results of operations and cash flows could be materially adversely affected. If we infringe on the IP of others, our business could be harmed.

We could be sued for infringing patents and other IP that purportedly cover prescription drug candidates and/or methods of using such prescription drug candidates held by persons other than us. Litigation arising from an alleged infringement could result in removal from the market, or a substantial delay in, or prevention of, the introduction of our prescription drug candidates, any of which could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

If we do not update and enhance our technologies, they will become obsolete.

The pharmaceutical market is characterized by technological change, and our future success will depend on our ability to conduct successful research in our fields of expertise, discover new technologies as a result of that research, develop products based on our technologies, and commercialize those products. While we believe that our current technology is adequate for our present needs, if we fail to stay at the forefront of technological development, we will be unable to compete effectively. Our competitors may use greater resources to develop new pharmaceutical technologies and to commercialize products based on those technologies. Accordingly, our technologies may be rendered obsolete by advances in existing technologies or the development of different technologies by one or more of our current or future competitors.

Risks Related to Our Governing Documents and Securities

Anti-takeover provisions in our organizational documents and Delaware law may discourage or prevent a change of control, even if an acquisition would be beneficial to our stockholders, which could affect our stock price adversely and prevent attempts by our stockholders to replace or remove our current management.

Our certificate of incorporation, as amended, and bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Among other things, these provisions will (i) permit our Board to issue up to 25,000,000 shares of preferred stock which can be created and issued by the Board without prior stockholder approval, with rights senior to those of the common stock, (ii) provide that all vacancies on our Board, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum, (iii) require that any action to be taken by our stockholders must be affected at a duly called annual or special meeting of stockholders and not be taken by written consent, (iv) provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice, (v) not provide for cumulative voting rights, and (vi) provide that special meetings of our stockholders may be called only by the Board or by such person or persons requested by a majority of the Board to call such meetings.

These and other provisions in our certificate of incorporation, as amended, and bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our Board or initiate actions that are opposed by our then-current Board, including delaying or impeding a merger, tender offer, or proxy contest involving our company. Any delay or prevention of a change of control transaction or changes in our Board could cause the market price of our common stock to decline.

Our stock price is below $5.00 per share and is treated as a "penny stock," which places restrictions on broker-dealers recommending the stock for purchase.

Our common stock is defined as "penny stock" under the Exchange Act and its rules. The SEC has adopted regulations that define "penny stock" to include common stock that has a market price of less than $5.00 per share, subject to certain exceptions. These rules include the following requirements: (i) broker-dealers must deliver, prior to the transaction, a disclosure schedule prepared by the SEC relating to the penny stock market, (ii) broker-dealers must disclose the commissions payable to the broker-dealer and its registered representative, (iii) broker-dealers must disclose current quotations for the securities, and (iv) a broker-dealer must furnish its customers with monthly statements disclosing recent price information for all penny stocks held in the customer's account and information on the limited market in penny stocks.

Additional sales practice requirements are imposed on broker-dealers who sell penny stocks to persons other than established customers and accredited investors. For these types of transactions, the broker-dealer must make a special suitability determination for the purchaser and must have received the purchaser's written consent to the transaction prior to sale. If our common stock remains subject to these penny stock rules these disclosure requirements may have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result, fewer broker-dealers may be willing to make a market in our stock, which could affect a shareholder's ability to sell their shares.

Future sales by our stockholders may adversely affect our stock price and our ability to raise funds in new stock offerings.

Sales of our common stock in the public market following any prospective offering could lower the market price of our common stock. Sales may also make it more difficult for us to sell equity securities or equity-related securities in the future at a time and price that our management deems acceptable.

It is our general policy to retain any earnings for use in our operation.

We have never declared or paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, for use in our business and therefore do not anticipate paying any cash dividends on our common stock in the foreseeable future.

In the event of the liquidation, winding-up or dissolution of the Company or certain mergers, corporate reorganizations or sales of our assets, holders of Series D and Series D-1 Preferred Stock will be entitled to a preference of a multiple of their investment amount, which will reduce the proceeds to be received by holders of our common stock.

In connection with the 2022, 2021, 2020 and 2017 Financings, we have issued convertible notes that converted or are convertible into shares of Series D and Series D-1 Preferred Stock. The Series D and Series D-1 Preferred Stock will have a first priority right to receive proceeds from the liquidation, winding-up or dissolution of us or certain mergers, corporate reorganizations, or sales of our assets (each, a "Company Event"). If a Company Event occurs within two (2) years of the date of issuance of the Series D and Series D-1 Preferred Stock (the "Date of Issuance"), the holders of Series D and Series D-1 Preferred Stock will receive a preference of four times (4x) their respective investment amount. If a Company Event occurs after the second (2nd) anniversary of the Date of Issuance, the holders of the Series D and Series D-1 Preferred Stock will receive a preference of six times (6x) their respective investment amount. As a result, upon the occurrence of a Company Event, the holders of Series D and Series D-1 Preferred Stock would have the right to receive proceeds from any such transaction before our common stockholders. The payment of this preference could result in our common stockholders not receiving any consideration in connection with a Company Event.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 1C. CYBERSECURITY.

Provectus Biopharmaceuticals understands the importance of managing risks from cybersecurity threats and maintains a comprehensive cybersecurity program developed with reference to the National Institute of Standards and Technology ("NIST") cybersecurity framework. Our cybersecurity program includes administrative, organizational, technical, and physical safeguards reasonably designed to protect the confidentiality, integrity, and availability of our data. We devote significant resources to network, operations, and product security, data encryption, business continuity/disaster recovery, vulnerability management, event monitoring and incident response, and other measures to protect our systems and data from unauthorized external access or internal misuse.

Our use of information systems for accessing, transmitting, and storing data is a vital aspect of our business operations. Information systems can be vulnerable to a range of cybersecurity threats that could potentially have a material impact on our business, results of operations, and financial condition.

Cybersecurity is a key category within our risk management efforts, and our cybersecurity risk management is intended to assist in assessing, identifying, and managing material risks from cybersecurity threats to the Company's information systems. Our cybersecurity risk management and strategy are based upon utilizing systems that are cloud-based which require multifactor authentication to access. Due to our small size, we partner with a third-party service provider which utilizes multiple security operations centers. The security operations centers maintain, monitor, mitigate, and alert on threats against the cloud systems that we utilize. If a risk is identified, the security operations center has the ability to shut down access to any user in the Company.

The Audit Committee of our Board of Directors is responsible for oversight of the Company's cybersecurity risk management. Management's role is to assist the Audit Committee in identifying and considering material cybersecurity risks, ensure implementation of management- and employee-level cybersecurity practices and training, and provide the Audit Committee with unrestricted access to Company personnel and documents regarding any cybersecurity attacks or vulnerabilities.

We also require our employees to participate in cybersecurity training and awareness programs. The Company's employees are expected to help safeguard the Company's information systems and to assist in the discovery and reporting of cybersecurity incidents. These programs are intended to decrease cybersecurity risks associated with human error and foster a culture of cybersecurity consciousness.

To date, the risks from cybersecurity threats, including because of any previous immaterial cybersecurity incidents, have not materially affected nor are reasonably likely to materially affect our business strategy, results of operations, or financial condition. While our insurance covers certain cybersecurity-related matters, the costs related to cybersecurity threats or disruptions may not be fully insured.

ITEM 2. PROPERTIES.

On June 18, 2022, the Company moved into 2,700 square feet of leased corporate office space in Knoxville, Tennessee through an operating lease agreement for a term of three years ending June 30, 2025. The monthly base rent ranges from $4,053 to $4,278 over the term on the lease.

ITEM 3. LEGAL PROCEEDINGS.

The information required by this item is incorporated by reference from Part II, Item 8. Financial Statements and Supplementary Data, Notes to Consolidated Financial Statements, Note 16 – Commitments, contingencies, and litigation.

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 and Holders

Our common stock trades on the OTCQB Marketplace under the symbol "PVCT".

As of March 27, 2024, we had 820 active stockholders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently plan to retain future earnings, if any, to finance the growth and development of our business and do not anticipate paying any cash dividends in the foreseeable future. We may incur indebtedness in the future which may prohibit or effectively restrict the payment of dividends, although we have no current plans to do so. Any future determination to pay cash dividends will be at the discretion of our Board of Directors. The holders of our Series D and Series D-1 Preferred Stock are entitled to receive dividends, if any, that are declared and paid to common stockholders.

Recent Issuances of Unregistered Securities

During the year ended December 31, 2023, the Company issued 25,000 shares of common stock as incentive compensation with a value of $2,850.

The issuances of the securities were exempt from the registration requirements of the Securities Act of 1933 by virtue of Section 4(a)(2) and Rule 506 promulgated under Regulation D thereunder as transactions not involving a public offering.

Securities Authorized for Issuance under Equity Compensation Plans

Information about the securities authorized for issuance under our equity compensation plans will be set forth under the heading "Equity Compensation Plan Information" in the definitive Proxy Statement for our 2024 Annual Meeting of Stockholders, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act, incorporated by reference in Part III, Item 12 of this Annual Report on Form 10-K.

ITEM 6. [RESERVED].

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion is intended to assist in the understanding and assessment of significant changes and trends related to our results of operations and our financial condition together with our consolidated subsidiaries. This discussion and analysis should be read in conjunction with the accompanying consolidated financial statements and notes thereto included in the Annual Report on Form 10-K. Historical results and percentage relationships set forth in the statements of operations, including trends which might appear, are not necessarily indicative of future operations.

Business Strategy

The Company is selectively continuing ongoing and planning to initiate new monotherapy and combination therapy ITU PV-10 clinical trials in melanoma and liver cancer indications to generate more and/or new clinical data and appropriately utilizing clinical data from historical ITU PV-10 trials, EAPs, and/or QOL study of these oncology indications. Our goals are to pursue drug approval pathways and/or co-development relationships with commercial pharmaceutical companies for ITU PV-10 based on these indications and data.

The Company is developing a systemically administered formulation of pharmaceutical-grade RBS for the treatment of cancer. Our goals, when this work is complete, are to file an investigational new drug application ("IND") with the FDA, take an initial systemic drug product candidate into an early-stage clinical trial for an initial oncology or hematology indication, and/or pursue a co-development collaboration or out-license arrangement for this route of administration and disease area.

The Company is developing different formulations of pharmaceutical-grade RBS using different concentrations and different routes of administration (e.g., PO, IV, IN) for other disease areas by endeavoring to show preclinical activity and lack of toxicity. Our goals, when each task of this work is completed, are to file an IND with the FDA, take an initial drug product candidate into an early-stage clinical trial for an initial indication, and/or pursue a co-development collaboration or out-license arrangement for the respective disease area and route of administration.

The Company is endeavoring to fully elucidate the traits and characteristics of the RBS molecule using different academic medical centers under sponsored research and testing agreements. Our goal is to gain and communicate additional knowledge of the RBS molecule's targeting, mechanism, signaling, immune response, and other features that are common to and/or different from each disease area and indication under research.

The Company is doing rigorous, chemical analytical comparisons of non-pharmaceutical grades of rose bengal from specialty chemical suppliers against the Company's pharmaceutical-grade RBS. Our goal is to demonstrate the proprietary nature of the Company's pharmaceutical-grade RBS and that our pharmaceutical-grade RBS meets the necessary uniformity and purity requirements for commercial pharmaceutical use.

RBS Drug Substance and Drug Product Candidate Manufacturing

Our pharmaceutical-grade RBS resulted from the Company's innovation of a proprietary, patented, commercial-scale process to synthesize and utilize the RBS molecule into a viable API for commercial pharmaceutical use; the development of unique chemistry, manufacturing, and control ("CMC") specifications for drug substance and drug product candidate manufacturing processes; the production and multi-year stability testing of multiple drug substance and drug product candidate lots; the comprehensive documentation of lot composition and reproducibility; and the review and acceptance of CMC data from these lots by seven different national drug regulatory agencies for use in a prior, multi-country, multi-center Phase 3 randomized control trial of the Company.

The Company's drug substance and drug product candidate manufacturing processes employ Quality-by-Design principles, current good manufacturing practice ("cGMP") regulations, and the guidelines of The International Council for Harmonization (ICH) of Technical Requirements for Pharmaceuticals for Human Use. These processes utilize controls that eliminate the formation of historical impurities and avoid the introduction of potentially hazardous impurities that the Company believes may have been and could be present in uncontrolled and unreported amounts in non-pharmaceutical grades of rose bengal.

The Company's processes of synthesizing the RBS molecule into pharmaceutical-grade RBS and manufacturing RBS drug substance and ITU PV-10 drug product candidate, the processes' CMC specifications, and the CMC data from the production of stability lots of drug substance and drug product candidate have been reviewed by multiple national drug regulatory agencies prior to granting clinical trial authorizations for the Company to commence a historical Phase 3 study of ITU PV-10 for the treatment of locally advanced cutaneous melanoma, including the U.S. FDA, Germany's Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Australia's Therapeutic Goods Administration (TGA) under a clinical trial notification, France's Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), Italy's Agenzia Italiana del Farmaco (AIFA), Mexico's Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS), and Argentina's Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT).

RBS Non-proprietary Name

The RBS name for the Company's pharmaceutical-grade API was selected by and passed the review of the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations after the Company applied for the non-proprietary name in the third quarter of 2020 and reached the status of recommended INN. INN Recommended List 88, which includes the RBS name, was published with the No. 3 issue of the WHO Drug Information, Volume 36 in the fourth quarter of 2022.

The aim of the INN system since inception has been to provide health professionals with a unique and universally available designated name to identify each pharmaceutical substance or API, according to the WHO. The existence of an international nomenclature, in the form of INN, is important for the accurate identification, prescribing, and dispensing of medicines to patients, and for communication and exchange of information among health professionals and scientists worldwide.

Prior Medical Diagnostic Use of Rose Bengal

FDA-Approved Liver Diagnostic Use

In 1971, ^{131}I rose bengal (Robengatope® [rose bengal sodium ^{131}I injection USP]) was approved by the FDA (NDA 016224) for use as a diagnostic aid to determine liver function. In 2009, manufacturer Bracco Diagnostics Inc. withdrew Robengatope from the U.S. market because of the emergence of newer liver imaging methods, such as computed tomography.

Historic Ophthalmic Diagnostic Use

In 1974, Barnes-Hind Pharmaceuticals, Inc. ("Barnes-Hind") introduced a medical device product of 1% rose bengal in an aqueous solution for the diagnosis of corneal injury, diagnosis of keratitis, keratoconjunctivitis, and sicca, and detection of foreign bodies in the eye. In 1981, Barnes-Hind introduced ophthalmic strips of the same concentration for the same indications. While both the solution and strip medical device products were accepted by the FDA for marketing, the Company does not believe that the devices or their respective claims were approved by the FDA because their introductions predated formal FDA review and approval of medical devices.

Non-Pharmaceutical Grades of Rose Bengal

Commercial-Grade

This material may be purchased from specialty chemical suppliers in the U.S. and from other parts of the world; however, the Company believes that the material itself is almost exclusively made in China and India under non-cGMP conditions. Commercial grade rose bengal appears to have reported purity that may vary between approximately 80% and 95%, and that may contain substantial amounts of unreported impurities and/or gross contaminants. Commercial grade rose bengal is typically used by researchers for preclinical study of the rose bengal molecule for potential biomedical therapeutic applications.

We believe that commercial grade rose bengal is still manufactured using the historical process (or a variant thereof) that was developed by the synthetic molecule's Swiss creator Rudolph Gnehm in 1881. Some manufacturers may, however, apply purification techniques that the Company believes still result in material that may possess questionable purity and contaminants and may also be subject to substantial lot-to-lot manufacturing variability.

Diagnostic-Grade

The Company coined this phrase to describe non-approved rose bengal that is used as an ingredient in historical or current ophthalmic solutions and strips, has been historically or is presently compounded by pharmacists for ophthalmic use, and has been or is in other non-ophthalmic diagnostic tests such as the rose bengal test in human brucellosis.

We presume, but have not yet confirmed, that diagnostic-grade rose bengal is derived from commercial-grade rose bengal that may have undergone a form of purification and/or may have been compounded under cGMP regulations by a pharmacist, academic medical researcher, or commercial entity. Here too, the Company believes that purification may not sufficiently improve the amounts and accuracy of rose bengal purity and lot contents and may not adequately reduce or eliminate lot-to-lot manufacturing variability.

Chemical Analytical Comparison

In the first quarter of 2022, the Company began work with a U.S. contract development and manufacturing organization to assess rigorously and methodically three lots of commercial-grade rose bengal, one each from three different specialty chemical suppliers, and compare and contrast these non-pharmaceutical grade materials with the Company's pharmaceutical-grade RBS. This chemical analytical work was substantially completed by the end of the third quarter of 2022. The Company believes that the preliminary results of these analyses indicate that all three lots of commercial grade rose bengal had rose bengal purity that was drastically different from what was represented on their respective certificates of analysis ("CofAs"), and that one of the three lots contained gross contaminants that were not represented on its CofA.

Potential Barriers to Entry

The Company believes that the Company's proprietary, patented, pharmaceutical-grade RBS possesses several competitive advantages over non-pharmaceutical-grades of rose bengal that researchers, clinicians, and academic, business, and/or governmental competitors have used, are using, and/or may attempt to use for potential biomedical applications. The Company believes that non-pharmaceutical-grades of rose bengal may suffer from the uncontrolled presence of substance-related impurities and/or gross contaminants, substantial lot-to-lot manufacturing variability, inaccurately reported and/or misrepresented purity and contents, and the lack of reproducible, consistent, and fulsome CMC specifications and documentation.

The Company believes that historical and potentially hazardous impurities and other manufacturing and handling issues facing non-pharmaceutical grades of rose bengal may pose significant scientific, technological, and economic challenges to overcome and validate for compliance with modern drug regulatory standards.

Components of Operating Results

Grant Revenue

Grant revenue is recognized when qualifying costs are incurred and there is reasonable assurance that the conditions of the grant have been met. Cash received from grants in advance of incurring qualifying costs is recorded as unearned grant revenue and recognized as grant revenue when qualifying costs are incurred.

Research and Development Expenses

A large component of our total operating expenses is the Company's investment in research and development activities, including the clinical development of our product candidates. Research and development expenses represent costs incurred to conduct research and undertake clinical trials to develop our drug product candidates. These expenses consist primarily of:

- costs of conducting clinical trials, including amounts paid to clinical centers, clinical research organizations and consultants, among others;
- salaries and related expenses for personnel, including stock-based compensation expense;
- other outside service costs including cost of contract manufacturing;
- the costs of supplies and reagents; and
- occupancy and depreciation charges.

We expense research and development costs as incurred.

Research and development activities are central to our business model. We expect our research and development expenses to increase in the future as we advance our existing product candidates through clinical trials and pursue their regulatory approval. Undertaking clinical development and pursuing regulatory approval are both costly and time-consuming activities. As a result of known and unknown uncertainties, we are unable to determine the duration and completion costs of our research and development activities, or if, when, and to what extent we will generate revenue from any subsequent commercialization and sale of our drug product candidates.

General and Administrative Expenses

General and administrative expense consists primarily of salaries, stock-based compensation expense and other related costs for personnel in executive, finance, accounting, business development, legal, information technology and corporate communication functions. Other costs include facility costs not otherwise included in research and development expense, insurance, and professional fees for legal, patent and accounting services.

Comparison of the Years Ended December 31, 2023 and 2022

Overview

Refer to tables below for year over year comparison of revenues and expenses.

	For the Years Ended December 31,			
	2023	2022	Increase/(Decrease)	% Change
Grant Revenue	$ 557,710	$ 989,042	$ (431,332)	-43.6%
Operating Expenses:				
Research and development	1,749,240	2,389,360	(640,120)	-26.8%
General and administrative	1,709,720	2,027,628	(317,908)	-15.7%
Total Operating Expenses	3,458,960	4,416,988	(958,028)	-21.7%
Total Operating Loss	(2,901,250)	(3,427,946)	526,696	-15.4%
Other Income/(Expense):				
Research and development tax credit	15,696	36,954	(21,258)	-57.5%
Interest expense, net	(216,214)	(163,691)	(52,523)	-32.1%
Total Other Expense, Net	(200,518)	(126,737)	(73,781)	-58.2%
Net Loss	$ (3,101,768)	$ (3,554,683)	$ 452,915	-12.7%

Grant Revenue

For the years ended December 31, 2023 and 2022, there was $557,710 and $989,042 respectively, of grant revenue recognized related to qualifying expenses that were incurred and included within research and development on the consolidated statements of operations.

Research and Development

Research and development expenses were $1,749,240 for the year ended December 31, 2023, a decrease of $640,120 or 26.8% compared to $2,389,360 for the year ended December 31, 2022. The decrease was due to lower clinical trial costs associated with full enrollment of open trials, write-off of old accounts payable, and lower rent expense, partially offset by increased payroll taxes.

The following table summarizes our research and development expenses incurred during the years ended December 31, 2023 and 2022:

	For the Years Ended December 31,			
	2023	2022	Increase/(Decrease)	% Change
Operating Expenses:				
Research and development:				
Clinical trial and research expenses	$ 1,193,529	$ 1,833,037	$ (639,508)	-34.9%
Depreciation/amortization	7,059	7,458	(399)	-5.3%
Insurance	229,774	230,947	(1,173)	-0.5%
Payroll and taxes	284,616	273,177	11,439	4.2%
Rent and utilities	34,262	44,741	(10,479)	-23.4%
Total research and development	$ 1,749,240	$ 2,389,360	$ (640,120)	-26.8%

General and Administrative

General and administrative expenses were $1,709,720 for the year ended December 31, 2023, a decrease of $317,908 or 15.7% compared to $2,027,628 for the year ended December 31, 2022. The decrease was due to (i) lower legal cost relating to patent application and general business fees, (ii) lower rent expense, (iii) lower professional fees, (iv) write off of old accounts payable, and (v) more favorable foreign currency translation cost, partially offset by (vi) higher other general and administrative costs.

The following table summarizes our general and administrative expenses incurred during the years ended December 31, 2023 and 2022:

	For the Years Ended December 31,			
	2023	2022	Increase/(Decrease)	% Change
Operating Expenses:				
General and administrative:				
Depreciation	$ 1,862	$ 3,437	$ (1,575)	-45.8%
Directors fees	385,000	385,000	-	0.0%
Insurance	179,846	182,897	(3,051)	-1.7%
Legal and litigation	387,189	521,632	(134,443)	-25.8%
Other general and administrative cost	40,793	12,288	28,505	232.0%
Payroll and taxes	250,685	249,777	908	0.4%
Professional fees	469,438	649,834	(180,396)	-27.8%
Rent and utilities	19,134	23,196	(4,062)	-17.5%
Foreign currency translation	(24,227)	(433)	(23,794)	-5495.2%
Total general and administrative	$ 1,709,720	$ 2,027,628	$ (317,908)	-15.7%

Other Income/(Expense)

Research and development tax credits were $15,696 for the year ended December 31, 2023, a decrease of $21,258, compared to $36,954 for the year ended December 31, 2022.

Interest expense increased by $52,523 from $163,691 for the year ended December 31, 2022 to $216,214 for the year ended December 31, 2023. The increase was due to the issuance of new 2022 Notes, partially offset by the impact of the conversion of the 2021 and 2022 Notes into shares of Series D-1 Preferred Stock.

The following table summarizes our Other Income/(Expenses) incurred during the years ended December 31, 2023 and 2022:

	For the Years Ended December 31,			
	2023	2022	Increase/(Decrease)	% Change
Other Income/(Expense):				
Research and development tax credit	$ 15,696	$ 36,954	$ (21,258)	-57.5%
Interest expense, net	(216,214)	(163,691)	(52,523)	-32.1%
Total Other Income/(Expense), Net	$ (200,518)	$ (126,737)	$ (73,781)	-58.2%

Liquidity and Going Concern

Our cash, and restricted cash were $1,026,799 at December 31, 2023, which includes the $950,223 of restricted cash associated with the grant received from the State of Tennessee. The consolidated financial statements and notes thereto included in this Annual Report on Form 10-K have been prepared on a basis that contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. We have continuing net losses and negative cash flows from operating activities. In addition, we have an accumulated deficit of $252,690,409 as of December 31, 2023. These conditions raise substantial doubt about our ability to continue as a going concern for a period of at least one year from the date that the consolidated financial statements included elsewhere in this Annual Report on Form 10-K are issued. Our financial statements do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern depends on our ability to obtain additional financing as may be required to fund current operations.

Management's plans include selling our equity securities and obtaining other financing to fund our capital requirement and on-going operations, including the 2022 Financing discussed above; however, there can be no assurance we will be successful in these efforts. Significant funds will be needed to continue and complete our ongoing and planned clinical trials.

Cash requirements for our current liabilities include approximately $4,964,404 for accounts payable and accrued expenses (including lease liabilities) and a $277,815 note payable related to our short-term financing of our commercial insurance policies. Also, if not converted prior to maturity, convertible debt in the amount of $2,675,000 plus accrued interest will mature one year from the date of the notes. The 2022 Notes are only subject to repayment in the event of a change of control or event of default. Cash requirements for long-term liabilities include $25,299 for operating lease liabilities. The Company intends to meet these cash requirements from its current cash balance and from future financing.

Access to Capital

Management plans to access capital resources through possible public or private equity offerings, including the 2022 Financing, exchange offers, debt financings, corporate collaborations, or other means. If we are unable to raise sufficient capital through the 2022 Financing or otherwise, we will not be able to pay our obligations as they become due.

The primary business objective of management is to build the Company into a commercial-stage biotechnology company; however, we cannot assure you that management will be successful in implementing the Company's business plan of developing, licensing, and/or commercializing our prescription drug candidates. Moreover, even if we are successful in improving our current cash flow position, we nonetheless plan to seek additional funds to meet our current and long-term requirements in 2024 and beyond. We anticipate that these funds will otherwise come from the proceeds of private placement transactions, including the 2022 Financing, the exercise of existing warrants and outstanding stock options, or public offerings of debt or equity securities. While we believe that we have a reasonable basis for our expectation that we will be able to raise additional funds, we cannot assure you that we will be able to complete additional financing in a timely manner. In addition, any such financing may result in significant dilution to stockholders.

During the years ended December 31, 2023 and 2022, our sources and uses of cash were as follows:

Net Cash Used in Operating Activities

We experienced negative cash flows from operating activities for the years ended December 31, 2023 and 2022 in the amounts of $2,571,978 and $3,041,472, respectively. The net cash used in operating activities for the year ended December 31, 2023 was primarily due to cash used to fund a net loss of $3,101,768, adjusted for non-cash items in the aggregate amount of $56,869, plus $472,922 of cash generated from changes in the levels of operating assets and liabilities. The net cash used in operating activities for the year ended December 31, 2022 was primarily due to cash used to fund a net loss of $3,554,683, adjusted for non-cash expenses in the aggregate amount of $66,803, plus $446,408 of cash generated from changes in the levels of operating assets and liabilities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities during the years ended December 31, 2023 and 2022 was $2,207,371 and $1,367,841, respectively. During the year ended December 31, 2023, we received $2,475,000 of proceeds from the issuance of convertible notes payable and paid $267,629 for the repayment of the short-term note payable. During the year ended December 31, 2022, we received $1,627,500 proceeds from the issuance of convertible notes payable and paid $259,659 for the repayment of the short-term note payable.

Critical Accounting Estimates

We prepare our consolidated financial statements in accordance with U.S. GAAP, which require our management to make estimates that affect the reported amounts of assets, liabilities and disclosures of contingent assets and liabilities at the balance sheet dates, as well as the reported amounts of revenues and expenses during the reporting periods. To the extent that there are material differences between these estimates and actual results, our financial condition or results of operations would be affected. We base our estimates on our own historical experience and other assumptions that we believe are reasonable after taking account of our circumstances and expectations for the future based on available information. We evaluate these estimates on an ongoing basis.

We consider an accounting estimate to be critical if: (i) the accounting estimate requires us to make assumptions about matters that were highly uncertain at the time the accounting estimate was made, and (ii) changes in the estimate that are reasonably likely to occur from period to period or use of different estimates that we reasonably could have used in the current period, would have a material impact on our financial condition or results of operations. There are items within our financial statements that require estimation but are not deemed critical, as defined above.

Critical Accounting Policies

The following is not intended to be a comprehensive list of all of our accounting policies or estimates. Our accounting policies are more fully described in Note 3 – Summary of Significant Accounting Policies, in our financial statements included at the end of this Annual Report. The following represent our most critical accounting policies:

Stock-Based Compensation

We measure the cost of services received in exchange for an award of equity instruments based on the fair value of the award on the date of grant. The fair value amount of the shares expected to ultimately vest is then recognized over the period for which services are required to be provided in exchange for the award, usually the vesting period. The estimation of stock-based awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from original estimates, such amounts are recorded as a cumulative adjustment in the period that the estimates are revised. We account for forfeitures as they occur.

Research and Development

Research and development expenses consist of expenses incurred in performing research and development activities, including compensation and benefits for research and development employees and consultants, facilities expenses, overhead expenses, cost of laboratory supplies, manufacturing expenses, fees paid to third parties and other outside expenses. We accrue for costs incurred as the services are being provided by monitoring the status of the clinical trial or project and the invoices received from our external service providers. We adjust our accrual as actual costs become known.

Income Taxes

The Company accounts for income taxes under the liability method in accordance with Accounting Standards Codification ("ASC") 740 "Income Taxes". Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established if it is more likely than not that all, or some portion, of deferred income tax assets will not be realized. The Company has recorded a full valuation allowance to reduce its net deferred income tax assets to zero. In the event the Company were to determine that it would be able to realize some or all its deferred income tax assets in the future, an adjustment to the deferred income tax asset would increase income in the period such determination was made.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained upon an examination. Any recognized income tax positions would be measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement would be reflected in the period in which the change in judgment occurs. The Company would recognize any corresponding interest and penalties associated with its income tax positions in income tax expense.

Convertible Instruments

The Company evaluates its convertible instruments to determine if those contracts or embedded components of those contracts qualify as derivative financial instruments to be separately accounted for in accordance with ASC Topic 815: *Derivatives and Hedging*. The accounting treatment of derivative financial instruments requires that the Company record qualifying embedded conversion options and any related freestanding instruments at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification. Embedded conversion options classified as derivative liabilities and any related equity classified freestanding instruments are recorded as a discount to the host instrument.

Preferred Stock

The Company applies the accounting standards for distinguishing liabilities from equity when determining the classification and measurement of its preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified as temporary equity. At all other times, preferred shares are classified as stockholders' deficiency.

Grant Revenue

Grant revenue is recognized when qualifying costs are incurred and there is reasonable assurance that the conditions of the grant have been met. Cash received from grants in advance of incurring qualifying costs is recorded as unearned grant revenue and recognized as grant revenue when qualifying costs are incurred.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the accompanying statements of operations and comprehensive loss.

Recent Accounting Pronouncements

Recently issued accounting standards are included in Note 3 – Significant Accounting Policies of our consolidated financial statements included within this annual report.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Provectus Biopharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Provectus Biopharmaceuticals, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, changes in stockholders' deficit, and cash flows for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 2, the Company has a working capital deficit, has incurred losses from operations, and needs to raise additional funds to meet its obligations and sustain its operations. These conditions 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 financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 audits to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the 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 financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2016.

Los Angeles, CA
March 28, 2024

PROVECTUS BIOPHARMACEUTICALS, INC.

CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
Assets		
Current Assets:		
Cash	$ 76,576	$ 21,605
Restricted cash	950,223	1,410,102
Short-term receivables	476	394
Prepaid expenses and other current assets	337,522	467,081
Total Current Assets	1,364,797	1,899,182
Equipment and furnishings, less accumulated depreciation of $110,994 and $102,073, respectively	12,020	20,941
Operating lease right-of-use asset	72,026	117,123
Total Assets	$ 1,448,843	$ 2,037,246
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	$ 1,675,891	$ 2,094,258
Unearned grant revenue	953,248	1,510,958
Other accrued expenses	3,240,436	2,404,012
Accrued interest	22,600	30,844
Accrued interest - related parties	123,828	40,992
Notes payable	277,815	239,394
Convertible notes payable	800,000	625,000
Convertible notes payable - related parties	1,875,000	1,202,500
Operating lease liability, current portion	48,077	44,422
Total Current Liabilities	9,016,895	8,192,380
Operating lease liability, non-current portion	25,299	73,376
Total Liabilities	9,042,194	8,265,756
Commitments, contingencies, and litigations (Note 16)		
Stockholders' Deficit:		
Preferred stock; par value $0.001 per share; 25,000,000 shares authorized; Series D Convertible Preferred Stock; 12,374,000 shares designated; 12,373,247 shares issued and outstanding at December 31, 2023 and 2022; aggregate liquidation preference of $14,164,889 at December 31, 2023 and 2022	12,373	12,373
Series D-1 Convertible Preferred Stock; 11,241,000 shares designated; 10,361,097 and 9,746,626 shares issued and outstanding at December 31, 2023 and 2022, respectively; aggregate liquidation preference of $118,613,136 and $111,578,880 at December 31, 2023 and 2022, respectively	10,361	9,747
Common stock; par value $0.001 per share; 1,000,000,000 shares authorized; 419,522,119 and 419,447,119 shares issued and outstanding at December 31, 2023 and 2022, respectively	419,522	419,497
Additional paid-in capital	244,714,967	242,954,193
Accumulated other comprehensive loss	(60,165)	(35,679)
Accumulated deficit	(252,690,409)	(249,588,641)
Total Stockholders' Deficit	(7,593,351)	(6,228,510)
Total Liabilities and Stockholders' Deficit	$ 1,448,843	$ 2,037,246

See accompanying notes to consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2023	**2022**
Grant Revenue	$ 557,710	$ 989,042
Operating Expenses:		
Research and development	1,749,240	2,389,360
General and administrative	1,709,720	2,027,628
Total Operating Expenses	3,458,960	4,416,988
Total Operating Loss	(2,901,250)	(3,427,946)
Other Income/(Expense):		
Research and development tax credit	15,696	36,954
Interest expense, net	(216,214)	(163,691)
Total Other Expense, Net	(200,518)	(126,737)
Net Loss	$ (3,101,768)	$ (3,554,683)
Basic and Diluted Loss Per Common Share	$ (0.01)	$ (0.01)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	419,508,146	419,470,338

See accompanying notes to consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	For the Years Ended December 31,	
	2023	**2022**
Net Loss	$ (3,101,768)	$ (3,554,683)
Other Comprehensive Loss:		
Foreign currency translation adjustments	(24,486)	(1,212)
Total Comprehensive Loss	$ (3,126,254)	$ (3,555,895)

See accompanying notes to consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
FOR THE YEARS ENDED DECEMBER 31, 2023 AND 2022

	Preferred Stock Series D		Preferred Stock Series D-1		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Total
Balance at January 1, 2022	12,373,247	$ 12,373	9,218,449	$ 9,219	419,447,119	$419,447	$241,440,106	$ (34,467)	$(246,033,958)	$(4,187,280)
Series D-1 Preferred Stock issued for cash	-	-	52,411	52	-	-	149,948	-	-	150,000
Stock-based compensation:										
Common stock	-	-	-	-	50,000	50	2,975	-	-	3,025
Conversion of 2021 Notes to Series D-1 Preferred Stock	-	-	475,766	476	-	-	1,361,164	-	-	1,361,640
Comprehensive loss:										
Net loss	-		-	-	-	-	-	-	(3,554,683)	(3,554,683)
Other comprehensive loss	-	-	-	-	-	-	-	(1,212)	-	(1,212)
Balance at December 31, 2022	12,373,247	12,373	9,746,626	9,747	419,497,119	419,497	242,954,193	(35,679)	(249,588,641)	(6,228,510)
Stock-based compensation:										
Common stock	-	-	-	-	25,000	25	2,825	-	-	2,850
Conversion of 2021 Notes to Series D-1 Preferred Stock	-	-	330,354	329	-	-	945,135	-	-	945,464
Conversion of 2022 Notes to Series D-1 Preferred Stock	-		284,117	285	-	-	812,814	-	-	813,099
Comprehensive loss:										
Net loss	-		-	-	-	-	-	-	(3,101,768)	(3,101,768)
Other comprehensive loss	-	-	-	-	-	-	-	(24,486)	-	(24,486)
Balance at December 31, 2023	12,373,247	$ 12,373	10,361,097	$ 10,361	419,522,119	$419,522	$244,714,967	$ (60,165)	$(252,690,409)	$(7,593,351)

See accompanying notes to consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2023	**2022**
Cash Flows From Operating Activities:		
Net loss	$ (3,101,768)	$ (3,554,683)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,850	3,025
Non-cash lease expense	45,097	52,883
Depreciation	8,921	10,895
Changes in operating assets and liabilities		
Short term receivables	(82)	4,481
Prepaid expenses and other current assets	451,425	122,914
Accounts payable	(418,370)	807,073
Unearned grant revenue	(557,710)	(989,042)
Other accrued expenses	836,426	402,390
Operating lease liability	(44,422)	(58,262)
Accrued interest	205,655	156,854
Net Cash Used In Operating Activities	(2,571,978)	(3,041,472)
Cash Flows From Financing Activities:		
Proceeds from issuance of convertible notes payable	800,000	625,000
Proceeds from issuance of convertible notes payable - related parties	1,675,000	1,002,500
Repayment of short-term note payable	(283,445)	(259,659)
Net Cash Provided By Financing Activities	2,191,555	1,367,841
Effect of exchange rates on cash and restricted cash	(24,485)	(1,604)
Net Decrease In Cash and Restricted Cash	(404,908)	(1,675,235)
Cash and Restricted Cash, Beginning of Period	1,431,707	3,106,942
Cash and Restricted Cash, End of Period	$ 1,026,799	$ 1,431,707
Cash and restricted cash consisted of the following:		
Cash	$ 76,576	$ 21,605
Restricted cash	950,223	1,410,102
	$ 1,026,799	$ 1,431,707
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the year for:		
Interest	$ -	$ -
Income taxes	$ -	$ -
Non-cash investing and financing activities:		
Deposit applied to equity issuances	$ -	$ (150,000)
Right-of-use assets obtained in exchange for operating lease liabilities	$ -	$ 130,443
Conversion of 2021 Notes and related accrued interest to Series D-1 Preferred Stock	$ 945,467	$ 1,361,640
Conversion of 2022 Notes and related accrued interest to Series D-1 Preferred Stock	$ 813,098	$ -
Purchase of insurance policies financed by short-term note payable	$ (306,050)	$ (203,175)

See accompanying notes to consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Business Organization and Nature of Operations

Provectus Biopharmaceuticals, Inc., a Delaware corporation (together with its subsidiary Provectus Biopharmaceuticals Australia Pty Ltd, "Provectus" or "the Company"), is a clinical-stage biotechnology company developing immunotherapy medicines for different diseases that are based on a class of synthetic small molecule immuno-catalysts called halogenated xanthenes ("HXs"). Our lead HX molecule is named rose bengal sodium ("RBS").

The Company's proprietary, patented, pharmaceutical-grade RBS is the active pharmaceutical ingredient in the drug product candidates of our current clinical development programs and the preclinical formulations of our current drug discovery programs. Importantly, our pharmaceutical-grade RBS displays different therapeutic effects at different concentrations and can be formulated for delivery by different routes of administration.

The Company believes that RBS targets disease in a bifunctional manner. First, direct contact may lead to cell death or repair, depending on the disease being treated and the concentration of the RBS utilized in the treatment. Second, multivariate immune signaling, activation, and response may follow that may manifest as stimulatory, inhibitory, or both.

The Company believes that it is the first entity to advance an RBS formulation into clinical trials for the treatment of a disease, such as those trials reported on the clinical trials registry at ClinicalTrials.gov.

The Company believes that it is the first and only entity to date to make pharmaceutical-grade RBS successfully, reproducibly, and consistently at a purity of nearly 100%.

The Company's small molecule HX medical science platform comprises several different drug product candidates and preclinical pharmaceutical-grade RBS formulations using different concentrations delivered by different routes of administration specific to each disease area and/or indication. The Company's HX medical science platform includes clinical development programs in oncology, dermatology, and ophthalmology; *in vivo* proof-of-concept programs in oncology, hematology, wound healing, and animal health; and *in vitro* drug discovery programs in infectious diseases and tissue regeneration and repair.

Risks and Uncertainties

To date, the Company has not generated any revenues or profits from planned principal operations. The Company's activities are subject to significant risks and uncertainties, including failing to successfully develop and license or commercialize the Company's prescription drug candidates.

2. Liquidity and Going Concern

The Company's cash and restricted cash were $1,026,799 at December 31, 2023 which includes $950,223 of restricted cash resulting from a grant received from the State of Tennessee. The Company's working capital deficiency was $7,652,098 and $6,293,198 as of December 31, 2023 and 2022, respectively. The decline in working capital is primarily driven by lower cash on hand and higher convertible notes outstanding. The Company continues to incur significant operating losses. Management expects that significant on-going operating expenditures will be necessary to successfully implement the Company's business plan and develop and market its products. These circumstances raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that these consolidated financial statements are issued. Implementation of the Company's plans and its ability to continue as a going concern will depend upon the Company's ability to develop PV-10, PH-10, and/or any other halogenated xanthene-based drug products, and to raise additional capital.

The Company plans to access capital resources through possible public or private equity offerings, including the 2022 Financing (as defined in Note 5), exchange offers, debt financings, corporate collaborations, or other means. In addition, the Company continues to explore opportunities to strategically monetize its lead drug candidates, PV-10 and PH-10, through potential co-development and licensing transactions, although there can be no assurance that the Company will be successful with such plans. The Company has historically been able to raise capital through equity and debt offerings, although no assurance can be provided that it will continue to be successful in the future. If the Company is unable to raise sufficient capital, it will not be able to pay its obligations as they become due.

Under ASC Subtopic 205-40, Presentation of Financial Statements—Going Concern ("ASC 205-40"), the Company has the responsibility to evaluate whether conditions and/or events raise substantial doubt about its ability to meet future financial obligations as they become due within one year after the date that these financial statements are issued. The accompanying consolidated financial statements have been prepared on the basis that we will continue as a going concern, which contemplates realization of assets and the satisfaction of liabilities in the normal course of business. However, since the Company's inception we have had a history of recurring net losses from operations, recurring use of cash in operating activities and declining working capital.

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"), which contemplate continuation of the Company as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The financial statements do not include any adjustment that might become necessary should the Company be unable to continue as a going concern.

The primary business objective of management is to build the Company into a commercial-stage biotechnology company; however, the Company cannot assure that it will be successful in co-developing, licensing, and/or commercializing PV-10, PH-10, and/or any other halogenated xanthene-based drug candidate developed by the Company or entering into any financial transaction. Moreover, even if the Company is successful in improving its current cash flow position, the Company nonetheless plans to seek additional funds to meet its long-term requirements in 2023 and beyond. The Company anticipates that these funds will otherwise come from the proceeds of private placement transactions, the exercise of existing warrants and outstanding stock options, or public offerings of debt or equity securities. While the Company believes that it has a reasonable basis for its expectation that it will be able to raise additional funds, the Company cannot provide assurance that it will be able to complete additional financing in a timely manner. In addition, any such financing may result in significant dilution to stockholders.

These factors raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of liabilities that may be necessary should we be unable to continue as a going concern.

Our consolidated financial statements included elsewhere in this Annual Report on Form 10-K have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"), which contemplate our continuation as a going concern and the realization of assets and satisfaction of liabilities in the normal course of business. The carrying amounts of assets and liabilities presented in the consolidated financial statements do not necessarily purport to represent realizable or settlement values.

3. Significant Accounting Policies

Principles of Consolidation

Intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States ("GAAP") requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company's significant estimates and assumptions include the recoverability and useful lives of long-lived assets, stock-based compensation, accrued liabilities and the valuation allowance related to the Company's deferred tax assets.

Restricted Cash

Restricted cash consists of a grant award of $2,500,000 received in cash from the State of Tennessee less payments to vendors for expenses and deposits in the amount of $1,549,777. See Note 14, Grants.

Cash Concentrations

Cash and restricted cash are maintained at financial institutions and, at times, balances may exceed federally insured limits of $250,000, although the Company seeks to minimize this through treasury management. The Company has never experienced any losses related to these balances although no assurance can be provided that it will not experience any losses in the future. As of December 31, 2023 and 2022, the Company had cash and restricted cash balances in excess of FDIC insurance limits of $776,799 and $1,181,707, respectively.

Equipment and Furnishings, net

Equipment and furnishings are stated at cost less accumulated depreciation. Depreciation of equipment is provided for using the straight-line method over the estimated useful lives of the assets. Computers and office equipment are being depreciated over five years; furniture and fixtures are being depreciated over ten years. Leasehold improvements are amortized over the lesser of (a) the useful life of the asset; or (b) the remaining lease term. Maintenance and repairs are charged to operations as incurred. The Company capitalizes cost attributable to the betterment of property and equipment when such betterment extends the useful life of the assets.

Long-Lived Assets

The Company reviews the carrying values of its long-lived assets for possible impairment whenever an event or change in circumstances indicates that the carrying amount of the assets may not be recoverable. Any long-lived assets held for disposal are reported at the lower of their carrying amounts or fair value less cost to sell. Management has determined there to be no impairment during the years ended December 31, 2023 and 2022.

Short-term Receivables

Management estimates expected credit losses immediately based on existing economic conditions in addition to current and future economic conditions and events. Receivables are considered past due if full payment is not received by the contractual date. Past due amounts are generally written off against the reserve for uncollectibility only after all collection attempts have been exhausted. As of December 31, 2023 and 2022, there was no allowance for uncollectible amounts.

Grant Revenue

Grant revenue is recognized when qualifying costs are incurred and there is reasonable assurance that the conditions of the grant have been met. Cash received from grants in advance of incurring qualifying costs is recorded as unearned grant revenue and recognized as grant revenue when qualifying costs are incurred.

Research and Development

Research and development costs are charged to expense when incurred. An allocation of payroll expenses to research and development is made based on a percentage estimate of time spent. The research and development costs include the following: payroll, consulting and contract labor, lab supplies and pharmaceutical preparations, insurance, rent and utilities, and depreciation and amortization.

Patent Costs

The Company expenses all costs as incurred in connection with patent applications (including direct application fees, and the legal and consulting expenses related to making such applications) and such costs are included in general and administrative expenses in the accompanying statements of operations and comprehensive loss.

Leases

The Company leases properties under operating leases. For leases in effect upon adoption of Accounting Standards Update ("ASU") 2016-02, "Leases (Topic 842)" at January 1, 2020 and for any leases commencing thereafter, the Company recognizes a liability to make lease payments, the "lease liability", and an asset representing the right to use the underlying asset during the lease term, the "right-of-use asset". The lease liability is measured at the present value of the remaining lease payments, discounted at the Company's incremental borrowing rate. The right-of-use asset is measured at the amount of the lease liability adjusted for the remaining balance of any lease incentives received, any cumulative prepaid or accrued rent if the lease payments are uneven throughout the lease term, any unamortized initial direct costs, and any impairment of the right-of-use-asset. Operating lease expense consists of a single lease cost calculated so that the remaining cost of the lease is allocated over the remaining lease term on a straight-line basis, variable lease payments not included in the lease liability, and any impairment of the right-of-use asset.

Income Taxes

The Company accounts for income taxes under the liability method in accordance with Accounting Standards Codification ("ASC") 740 "Income Taxes". Under this method, deferred income tax assets and liabilities are determined based on differences between financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established if it is more likely than not that all, or some portion, of deferred income tax assets will not be realized. The Company has recorded a full valuation allowance to reduce its net deferred income tax assets to zero. In the event the Company were to determine that it would be able to realize some or all its deferred income tax assets in the future, an adjustment to the deferred income tax asset would increase income in the period such determination was made.

The Company recognizes the effect of income tax positions only if those positions are more likely than not of being sustained upon an examination. Any recognized income tax positions would be measured at the largest amount that is greater than 50% likely of being realized. Changes in recognition or measurement would be reflected in the period in which the change in judgment occurs. The Company would recognize any corresponding interest and penalties associated with its income tax positions in income tax expense. There were no income taxes, interest or penalties incurred in 2023 or 2022.

Convertible Instruments

The Company evaluates its convertible instruments to determine if those contracts or embedded components of those contracts qualify as derivative financial instruments to be separately accounted for in accordance with ASC Topic 815: *Derivatives and Hedging*. The accounting treatment of derivative financial instruments requires that the Company record qualifying embedded conversion options and any related freestanding instruments at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification. Embedded conversion options classified as derivative liabilities and any related equity classified freestanding instruments are recorded as a discount to the host instrument.

Preferred Stock

The Company applies the accounting standards for distinguishing liabilities from equity when determining the classification and measurement of its preferred stock. Preferred shares subject to mandatory redemption are classified as liability instruments and are measured at fair value. Conditionally redeemable preferred shares (including preferred shares that feature redemption rights that are either within the control of the holder or subject to redemption upon the occurrence of uncertain events not solely within the Company's control) are classified as temporary equity. At all other times, preferred shares are classified as stockholders' deficit.

Basic and Diluted Loss Per Common Share

Basic loss per common share is computed by dividing net loss by the weighted average number of vested common shares outstanding during the period. Diluted earnings per share reflects the potential dilution that could occur if securities or other instruments to issue common stock were exercised or converted into common stock. The following securities are excluded from the calculation of weighted average dilutive common shares because their inclusion would have been anti-dilutive:

	December 31,	
	2023	**2022**
Warrants	412,500	475,000
Options	3,225,000	3,425,000
Convertible preferred stock	115,984,217	109,839,507
2021 unsecured convertible notes	831,742	3,973,871
2022 unsecured convertible notes	9,858,239	2,662,523
Total potentially dilutive shares	130,311,698	120,375,901

Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on the guidance of ASC 820 "Fair Value Measurements and Disclosures" ("ASC 820") which defines fair value, establishes a framework for measuring fair value, and expands disclosures about fair value measurements. The Company determines the estimated fair value of amounts presented in these consolidated financial statements using available market information and appropriate methodologies. However, considerable judgment is required in interpreting market data to develop the estimates of fair value. The estimates presented in the financial statements are not necessarily indicative of the amounts that could be realized in a current exchange between buyer and seller. The use of different market assumptions and/or estimation methodologies may have a material effect on the estimated fair value amounts. These fair value estimates were based upon pertinent information available as of December 31, 2023 and 2022. The carrying amounts of the Company's financial assets and liabilities, such as cash and cash equivalents, restricted cash, receivables, other current assets, accounts payable, unearned grant income, and accrued expenses approximate fair value due to the short-term nature of these instruments.

The carrying amounts of our credit obligations approximate fair value because the effective yields on these obligations, which include contractual interest rates are comparable to rates of returns for instruments of similar credit risk.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

Level 1 Inputs use quoted prices in active markets for identical assets or liabilities that the Company has the ability to access.

Level 2 Inputs use directly or indirectly observable inputs. These inputs include quoted prices for similar assets and liabilities in active markets as well as other inputs such as interest rates and yield curves that are observable at commonly quoted intervals.

Level 3 Inputs are unobservable inputs, including inputs that are available in situations where there is little, if any, market activity for the related asset or liability.

In instances where inputs used to measure fair value fall into different levels in the above fair value hierarchy, fair value measurements in their entirety are categorized based on the lowest level input that is significant to the valuation. The Company's assessment of the significance of particular inputs to these fair value measurements requires judgment and considers factors specific to each asset or liability.

Both observable and unobservable inputs may be used to determine the fair value of positions that are classified within the Level 3 category. As a result, the unrealized gains and losses for assets within the Level 3 category may include changes in fair value that were attributable to both observable (e.g., changes in market interest rates) and unobservable (e.g., changes in historical company data) inputs. Financial assets are considered Level 3 when their fair values are determined using pricing models, discounted cash flow methodologies or similar techniques and at least one significant model assumption or input is unobservable.

Foreign Currency Translation

The Company's reporting currency is the United States Dollar. The functional currencies of the Company's operating subsidiaries are their local currencies (United States Dollar and Australian Dollar). Australian Dollar denominated assets and liabilities of $13,916 and $389,540 at December 31, 2023 and $17,373 and $383,447 at December 31, 2022, respectively) are translated into the United States Dollar at the balance sheet date, and net expense accounts of $9,763 and $4,503 for the years ended December 31, 2023 and 2022, respectively) are translated at a weighted average exchange rate for the years then ended. Equity is translated at historical rates and the resulting foreign currency translation adjustments are included as a component of accumulated other comprehensive loss ("AOCL"), which is a separate component of stockholders' deficit. Therefore, the U.S. dollar value of the non-equity translated items in the Company's consolidated financial statements will fluctuate from period to period, depending on the changing value of the U.S. dollar versus these currencies.

The Company engages in foreign currency denominated transactions with its Australian subsidiary. At the date that the transaction is recognized, each asset, liability, revenue, expense, gain, or loss arising from the transaction is measured and recorded in the functional currency of the recording entity using the exchange rate in effect at that date. At each balance sheet date, recorded monetary balances denominated in a currency other than the functional currency are adjusted using the exchange rate at the balance sheet date, with gains or losses recorded in other income or other expense.

Stock-Based Compensation

The Company measures the cost of services received in exchange for an award of equity instruments based on the fair value of the award. The fair value of the award is measured on the grant date and then is recognized over the period during which services are required to be provided in exchange for the award, usually the vesting period. The Company computes the fair value of equity-classified warrants and options granted using the Black-Scholes option pricing model. Option valuation models require the input of highly subjective assumptions including the expected volatility factor of the market price of the Company's common stock which is determined by reviewing its historical public market closing prices.

Recently Issued Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07 "Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures." These amendments require a public entity to disclose significant segment expenses and other segment items on an annual and interim basis and to provide in interim periods all disclosures about a reportable segment's profit or loss and assets that are currently required annually. Public entities with a single reporting segment are required to provide both the new disclosures and all of the existing disclosures required under ASC 280. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. Since this new ASU addresses only disclosures, the Company does not expect the adoption of this ASU to have any material effects on its financial condition, results of operations or cash flows. The Company is currently evaluating any new disclosures that may be required upon adoption of ASU 2023-07.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures. The amendments in this update address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This update also includes certain other amendments to improve the effectiveness of income tax disclosures. The amendments in ASU 2023-09 are effective for the Company on December 15, 2024, with early adoption permitted. Since this new ASU addresses only disclosures, the Company does not expect the adoption to have any material effects on its financial condition, results of operation or cash flows. The Company is currently evaluating any new disclosures that may be required upon adoption of ASU 2023-09.

Recently Adopted Accounting Pronouncements

In August 2020, FASB issued Accounting Standards Update ("ASU") No. 2020-06, *"Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*" ("ASU 2020-06"). Under ASU 2020-06, the embedded conversion features are no longer separated from the host contract for convertible instruments with conversion features that are not required to be accounted for as derivatives under Topic 815, or that do not result in substantial premiums accounted for as paid-in capital. Consequently, a convertible debt instrument will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The new guidance also requires the if-converted method to be applied for all convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, including interim periods within those fiscal years, with early adoption permitted. Adoption of the standard requires using either a modified retrospective or a full retrospective approach. The Company adopted ASU 2020-06 on January 1, 2023, using the modified retrospective approach and it did not have a material impact on its consolidated financial statements and disclosures.

4. Other Accrued Expenses

The following table summarizes the other accrued expenses at December 31, 2023 and 2022:

	For the Years Ended December 31,	
	2023	**2022**
Accrued payroll and taxes	$ 719,460	$ 314,160
Accrued vacation	92,985	69,077
Accrued directors' fees	2,330,589	1,945,589
Accrued other expenses	97,402	75,186
Total Other Accrued Expenses	$ 3,240,436	$ 2,404,012

5. Convertible Notes Payable

The following summarizes convertible note activity during the years ended December 31, 2023 and 2022:

2021 Financing

	Non-Related Party Face Amount	Related Party Face Amount	Total
Balance as of January 1, 2022	$ 1,260,000	$ 200,000	$ 1,460,000
Issuance	550,000	325,000	875,000
Conversion	(1,260,000)	-	(1,260,000)
Balance as of December 31, 2022	550,000	525,000	1,075,000
Conversion	(550,000)	(325,000)	(875,000)
Balance as of December 31, 2023	$ -	$ 200,000	$ 200,000

2022 Financing

	Non-Related Party Face Amount	Related Party Face Amount	Total
Balance as of January 1, 2022	$ -	$ -	$ -
Issuance	75,000	677,500	752,500
Balance as of December 31, 2022	75,000	677,500	752,500
Issuance	800,000	1,675,000	2,475,000
Conversion	(75,000)	(677,500)	(752,500)
Balance as of December 31, 2023	$ 800,000	$ 1,675,000	$ 2,475,000

2021 Financing

On August 13, 2021, the Board approved a Financing Term Sheet (the "2021 Term Sheet"), which set forth the terms under which the Company will use its best efforts to arrange for financing of a maximum of $5,000,000 (the "2021 Financing"), which amounts will be obtained in several tranches.

Pursuant to the 2021 Term Sheet, the 2021 Notes will either be paid back, convert into shares of the Company's Series D-1 Preferred Stock, or convert into Company equity securities and/or debt instruments of certain future financings on or before twelve months after the issue date of a 2021 Note, subject to certain exceptions.

The 2021 Financing is in the form of unsecured convertible loans from the investors and evidenced by convertible promissory notes (individually, a "2021 Note" and collectively, the "2021 Notes"). In addition to customary provisions, the 2021 Notes will contain the following provisions:

(i) The 2021 Notes bear interest at the rate of eight percent (8%) per annum on the outstanding principal amount of the loan that has been funded to the Company;

(ii) In the event there is a change of control of the Board, the term of the 2021 Notes will be accelerated and all amounts due under the 2021 Notes may be immediately due and payable at the investors' option;

(iii) The outstanding principal amount and interest payment under the 2021 Notes may be paid back at maturity at the investors' option;

(iv) The outstanding principal amount and interest payable under the 2021 Notes are convertible at the investors' option into shares of Series D-1 Preferred Stock at a price per share equal to $2.862. The Series D-1 Preferred Stock is convertible into ten (10) shares of common stock; and

(v) In the event the Company conducts a qualified equity or debt financing and the Company receives gross proceeds in the aggregate amount of $20 million, the 2021 Notes may be converted into the equity securities and/or debt instruments of such financing at the same terms as those investors.

The embedded conversion options associated with the 2021 Notes do not require bifurcation and treatment as a derivative liability.

On September 20, 2022, the Board approved the closure of the 2021 Financing. Through December 31, 2023, the Company received aggregate proceeds of $2,335,000, of which $525,000 is from related party investors (an officer and director of the Company), in connection with the 2021 Notes. For the years ended December 31, 2023 and 2022, the Company recorded interest expense of $46,189 and $147,340, respectively, related to the 2021 Notes.

2022 Financing

On September 20, 2022, the Board approved a Financing Term Sheet (the "2022 Term Sheet"), which set forth the terms under which the Company will use its best efforts to arrange for financing of a maximum of $5,000,000 (the "2022 Financing"), which amounts will be obtained in several tranches. Through December 31, 2023, the Company received proceeds of $3,227,500, of which $2,352,500 was from a related party investor (a Company director) in connection with the 2022 Notes. For the years ended December 31, 2023 and 2022, the Company recorded interest expense of $159,466 and $9,514, respectively, related to the 2022 Notes.

Pursuant to the 2022 Term Sheet, the 2022 Notes (defined below) will convert into shares of the Company's Series D-1 Preferred Stock twelve months after the issue date of a 2022 Note, subject to certain exceptions.

The 2022 Financing will be in the form of unsecured convertible loans from the investors (the "2022 Note Investors") and evidenced by convertible promissory notes (individually, a "2022 Note" and collectively, the "2022 Notes"). In addition to customary provisions, the 2022 Notes will contain the following provisions:

(i) The 2022 Notes will bear interest at the rate of eight percent (8%) per annum on the outstanding principal amount of the Loan that has been funded to the Company;

(ii) In the event there is a change of control of the Board, the term of the 2022 Notes will be accelerated and all amounts due under the 2022 Notes may be immediately due and payable at the 2022 Note Investors' option;

(iii) The outstanding principal amount and interest payable under the 2022 Notes may be convertible at the 2022 Note Investors' option into shares of Series D-1 Preferred Stock at a price per share equal to $2.862. The Series D-1 Preferred Stock is convertible into ten (10) shares of common stock; and

(iv) The outstanding principal amount and interest payable under the 2022 Notes will be automatically convertible into shares of the Company's Series D-1 Preferred Stock twelve (12) months after the issue date of a 2022 Note.

The embedded conversion options associated with the 2022 Notes do not require bifurcation and treatment as a derivative liability.

2022 Conversions of 2021 Notes into Preferred Stock

The following summarizes the conversion activity during the year ended December 31, 2022:

	Series D-1 Preferred Stock
Principal converted	$ 1,260,000
Accrued interest converted	101,640
Total converted	$ 1,361,640
Conversion price	$ 2.862
Total shares	475,766

During the year ended December 31, 2022, principal and interest in the aggregate amount of $1,361,640, representing two 2021 Notes were converted into 475,766 shares of Series D-1 Preferred Stock at the Conversion Price of $2.862. Any fractional shares issuable pursuant to the formula were rounded up to the next whole share of Series D-1 Preferred Shares. See Note 9, Stockholders' Deficit for additional information on the Series D-1 Preferred Stock.

2023 Conversions of 2021 Notes into Preferred Stock

The following summarizes the conversion activity during the year ended December 31, 2023:

	Series D-1 Preferred Stock
Principal converted	$ 875,000
Accrued interest converted	70,464
Total converted	$ 945,464
Conversion price	$ 2.862
Total shares	330,354

During the year ended December 31, 2023, principal and interest in the aggregate amount of $945,464, owed in connection with the 2021 Notes were converted into 330,354 shares of Series D-1 Preferred Stock at the Conversion Price of $2.862 per share. Any fractional shares issuable pursuant to the formula were rounded up to the next whole share of Series D-1 Preferred Shares. See Note 9, Stockholders' Deficit for additional information on the Series D-1 Preferred Stock.

2023 Conversions of 2022 Notes into Preferred Stock

The following summarizes the conversion activity during the year ended December 31, 2023:

	Series D-1 Preferred Stock
Principal converted	$ 752,500
Accrued interest converted	60,598
Total converted	$ 813,098
Conversion price	$ 2.862
Total shares	284,117

During the year ended December 31, 2023, principal and interest in the aggregate amount of $813,098, owed in connection with the 2022 Notes were converted into 284,117 shares of Series D-1 Preferred Stock at the Conversion Price of $2.862 per share. Any fractional shares issuable pursuant to the formula were rounded up to the next whole share of Series D-1 Preferred Shares. See Note 9, Stockholders' Deficit for additional information on the Series D-1 Preferred Stock.

6. Notes Payable

The Company obtained short-term financing from AFCO Insurance Premium Finance for our commercial insurance policies. As of December 31, 2023 and December 31, 2022, the balance of the note payable was $277,815 and $239,394, respectively. For the years ended December 31, 2023 and 2022, the Company recorded interest expense of $5,650 and $3,409, respectively, related to the notes payable.

7. Related Party Transactions

During the years ended December 31, 2023 and 2022, the Company accrued Capital Strategists consulting fees of $254,400 and $254,400, respectively, for services rendered. The total amount owed to Capital Strategists as of December 31, 2023 and 2022 were $445,200 and $212,000, respectively. Bruce Horowitz, the Managing Director of Capital Strategists, previously served as both the Chief Operating Officer and a director of the Company until March 25, 2024.

Director fees for Mr. Horowitz for the years ending December 31, 2023 and 2022 were $75,000 and $75,000, respectively. Accrued director fees for Mr. Horowitz as of December 31, 2023 and 2022 were $431,250 and $356,250, respectively.

See Note 5 for details of other related party transactions.

Director fees during the years ended December 31, 2023 and 2022 were $385,000 and $385,000, respectively. Accrued directors' fees as of December 31, 2023 and 2022 were $2,330,589 and $1,945,589, respectively.

8. Short-term Receivables

Receivables at December 31, 2023 and 2022, include the Australian VAT tax credit and approximately $2,100,000 that is owed from Peter Culpepper, the former Interim Chief Executive Officer of the Company. The Company has established a reserve of approximately $2,100,000 as of December 31, 2023 and 2022, which represents the amount Culpepper owes to the Company in connection with a derivative lawsuit settlement (excluding the amount of attorneys' fees incurred in enforcing the terms of the derivative lawsuit settlement).

9. Stockholders' Deficit

Authorized Capital

As of December 31, 2023, the Company was authorized to issue 1,000,000,000 shares of common stock, $0.001 par value, and 25,000,000 shares of preferred stock, $0.001 par value. The holders of the Company's common stock are entitled to one vote per share. The preferred stock is designated as follows: 12,374,000 shares to Series D Convertible Preferred Stock (the "Series D Preferred Stock"), and 11,241,000 shares of Series D-1 Convertible Preferred Stock (the "Series D-1 Preferred Stock") and 1,385,000 shares undesignated.

Series D and Series D-1 Preferred Stock

The preferred stock is designated as follows: 12,374,000 shares are designated as Series D Convertible Preferred Stock (the "Series D Preferred Stock"), 11,241,000 shares are designated as Series D-1 Convertible Preferred Stock (the "Series D-1 Preferred Stock").

The rights, preferences and privileges of the Series D Preferred Stock and Series D-1 Preferred Stock (collectively, the "D-Series Preferred Stock") are set forth in their respective Certificates of Designation.

Rank

The Series D Preferred Stock and the Series D-1 Preferred Stock rank *pari passu* with each other. The D-Series Preferred Stock rank senior to the Common Stock and any other class or series of the Company's capital stock, the terms of which do not provide that shares of such class rank senior to, or *pari passu* with, the D-Series Preferred as to dividends and distributions upon a change of control transaction, or the liquidation, winding-up and dissolution of the Company.

Dividends

The D-Series Preferred Stock does not have any dividend preference but are entitled to receive, on a *pari passu* basis, dividends, if any, that are declared and paid on the common stock and any other class of the Company's capital stock that ranks junior or on par to the D-Series Preferred Stock.

Liquidation Preference

Upon the occurrence of the liquidation, winding-up or dissolution of the Company or certain mergers, corporate reorganizations, or sales of the Company's assets (each, a "Company Event"), holders of D-Series Preferred Stock will be entitled to receive a liquidation preference before any distributions are made to holders of any other class or series of the Company's capital stock junior to the D-Series Preferred Stock. If a Company Event occurs within two years of June 20, 2021 (the "Date of Issuance"), the holders of D-Series Preferred Stock will receive, for each share of D-Series Preferred Stock, an amount in cash equal to the Original Issue Price (as defined in the respective Certificates of Designation) multiplied by four. If a Company Event occurs from and after the second anniversary of the Date of Issuance, the holders of D-Series Preferred Stock will receive, for each share of D-Series Preferred Stock, an amount in cash equal to the Original Issue Price multiplied by six. The Original Issue Price for the Series D Preferred Stock is $0.2862, and the Original Issue Price for the Series D-1 Preferred Stock is $2.862.

Voting Rights

Holders of shares of D-Series Preferred Stock will vote together with the holders of common stock as a single class. Each share of Series D Preferred Stock carries the right to one vote per share. Each share of Series D-1 Preferred Stock carries the right to ten votes per share.

The Company is not permitted to amend, alter or repeal its Certificate of Incorporation or bylaws in a manner adverse to the relative rights, preferences, qualifications, limitations or restrictions of the D-Series Preferred Stock without the affirmative vote of a majority of the votes entitled to be cast by holders of outstanding shares of D-Series Preferred Stock, voting together as a single class with each share of D-Series Convertible Preferred Stock having a number of votes equal to the number of shares of common stock then issuable upon conversion of such share of D-Series Preferred Stock.

Conversion

The Series D Preferred Stock is convertible at the option of the holders thereof into shares of common stock based on a one-for-one conversion ratio. The Series D-1 Preferred Stock is convertible at the option of the holders thereof into shares of common stock based on a one-for-ten conversion ratio. The conversion ratio of the D-Series Preferred Stock is subject to adjustment for stock splits and combinations, recapitalizations, reclassifications, reorganizations, mergers, and consolidations. The D-Series Preferred Stock will automatically convert into shares of common stock upon the fifth anniversary of the date of issuance.

During the year ended December 31, 2021, the Company received consideration of $150,000 from an investor in exchange for an aggregate of 52,411 shares of restricted Series D-1 Preferred Stock that were issued during the first quarter of 2022.

During the year ended December 31, 2022, the Company issued 475,766 shares of Series D-1 Preferred Stock upon the automatic conversion of $1,260,000 of principal and $101,640 accrued interest outstanding on the 2021 Notes.

During the year ended December 31, 2023, the Company issued 330,354 shares of Series D-1 Preferred Stock upon the automatic conversion of $875,000 of principal and $70,464 accrued interest outstanding on the 2021 Notes.

During the year ended December 31, 2023, the Company issued 284,117 shares of Series D-1 Preferred Stock upon the automatic conversion of $752,500 of principal and $60,598 accrued interest outstanding on the 2022 Notes.

Common Stock Issuances

During the year ended December 31, 2022, the Company issued an aggregate of 50,000 shares of immediately vested restricted common stock with a grant date fair value of $3,025 for services.

During the year ended December 31, 2023, the Company issued an aggregate of 25,000 shares of immediately vested restricted common stock with a grant date fair value of $2,850 for services.

10. Stock Incentive Plan and Warrants

The 2017 Amendment and Restatement of the Provectus Biopharmaceuticals, Inc. 2014 Equity Compensation Plan (the "2017 Equity Compensation Plan") provides for the issuance of up to 20,000,000 shares of common stock pursuant to stock options for the benefit of eligible employees and directors of the Company. Options granted under the 2017 Equity Compensation Plan are either "incentive stock options" within the meaning of Section 422 of the Internal Revenue Code or options which are not incentive stock options. Vested stock options are exercisable over a period determined by the Board of Directors (through its Compensation Committee), but generally no longer than 10 years after the date they are granted. As of December 31, 2023, there were 16,587,500 shares available for issuance under the 2017 Equity Compensation Plan.

There were no stock options granted during the years ended December 31, 2023 and 2022.

The following table summarizes option activity during the years ended December 31, 2023 and 2022:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Life in Years
Outstanding and exercisable at January 1, 2022	3,625,000	$ 0.32	
Forfeited	(200,000)	0.86	
Outstanding and exercisable at December 31, 2022	3,425,000	$ 0.29	
Forfeited	(200,000)	0.67	
Outstanding and exercisable at December 31, 2023	3,225,000	0.27	2.11

As of December 31, 2023, the intrinsic value of outstanding and exercisable options was $0.

The following table summarizes information about stock options outstanding at December 31, 2023:

Options Outstanding				Options Exercisable
Exercise Price		Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options
$	0.12	2,425,000	1.90	2,425,000
$	0.29	100,000	1.90	100,000
$	0.75	550,000	1.90	550,000
$	0.88	150,000	0.60	150,000
		3,225,000	1.90	3,225,000

Warrants

There were no warrants granted during the years ended December 31, 2023 and 2022.

The following table summarizes warrant activity during the years ended December 31, 2023 and 2022:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life in Years
Outstanding and exercisable at January 1, 2022	512,500	$ 0.92	
Forfeited	(37,500)	0.29	
Outstanding and exercisable at December 31, 2022	475,000	$ 0.97	
Forfeited	(62,500)	0.29	
Outstanding and exercisable at December 31, 2023	412,500	$ 1.07	0.38

As of December 31, 2023, the intrinsic value of outstanding and exercisable warrants was $0.

The following table summarizes information about warrants outstanding at December 31, 2023:

Warrants Outstanding			Warrants Exercisable	
Exercise Price		Outstanding Number of Warrant	Weighted Average Remaining Life In Years	Exercisable Number of Warrants
$	0.29	25,000	0.25	25,000
$	1.00	18,000	0.39	18,000
$	1.12	366,000	0.39	366,000
$	2.00	3,500	0.39	3,500
		412,500	0.38	412,500

Holders of the outstanding warrants are not entitled to vote and the exercise prices of such warrants are subject to customary anti-dilution provisions.

11. Income Taxes

The domestic and foreign components of loss before income taxes from operations for the years ended December 31, 2023 and 2022 are as follows:

	Years ended December 31	
	2023	**2022**
Domestic	$ (3,116,233)	$ (3,550,182)
Foreign	(9,762)	(4,501)
Net Pre-Tax Loss	$ (3,125,995)	$ (3,554,683)

The income tax provision (benefit) consists of the following:

		Years ended December 31	
		2023	2022
Federal:			
Current		$ -	$ -
Deferred	21.00%	(566,183)	538,915
State:			
Current		-	-
Deferred	5.14%	(138,445)	131,778
	26.14%	(704,628)	670,693
Change in valuation allowance		704,628	(670,693)
Income tax provision (benefit)		$ -	$ -

The reconciliations between the statutory federal income tax rate and the Company's effective tax rate are as follows:

	Years Ended December 31	
	2023	2022
Tax benefit at federal statutory rate	(21.0)%	(21.0)%
State income taxes, net of federal benefit	(5.1)%	(5.1)%
Permanent differences	(2.9)%	(3.7)%
Change in valuation allowance	22.5%	(18.6)%
Prior year true-up	(3.8)%	(2.3)%
Expiration of federal and state net operating loss carryforwards	10.2%	49.1%
Expiration of warrants and options	1.1%	1.0%
Miscellaneous	(1.0)%	0.6%
Effective income tax rate	0.0%	0.0%

The components of the Company's deferred income taxes are summarized below:

	December 31	
	2023	2022
Deferred Tax Assets:		
Net operating loss carryforwards	$ 41,888,685	$ 42,012,057
Research and development credit carryovers	3,350,278	3,229,869
Stock-based compensation	118,855	152,813
Intangible assets	425,259	337,558
Capitalized R&D expenditures	817,239	358,897
Contribution carryovers	-	10,062
Accrued liabilities	833,876	628,265
Gross deferred tax assets	47,434,192	46,729,521
Deferred Tax Liabilities:		
Depreciation	(2,622)	(3,915)
Prepaid expenses	(87,794)	(86,459)
Gross deferred tax liabilities	(90,416)	(90,374)
Valuation allowance	(47,343,776)	(46,639,147)
Deferred tax asset, net of valuation allowance	$ -	$ -
Change in valuation allowance	$ (704,628)	$ 670,693

A valuation allowance against deferred tax assets is required if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. The Company is in the early stages of development and realization of the deferred tax assets is not considered more likely than not. As a result, the Company has recorded a full valuation allowance for the net deferred tax asset.

Since inception of the Company on January 17, 2002, the Company has generated federal, state, and Australian tax net operating losses of approximately $164 million, $143 million, and $158 thousand, respectively. Under the Tax Cuts and Jobs Act, federal net operating losses incurred after December 31, 2017 may be carried forward indefinitely. The tax loss carryforwards of the Company may be subject to limitation by Section 382 of the Internal Revenue Code with respect to the amount utilizable each year. This limitation could reduce the Company's ability to utilize net operating loss carryforwards. Federal net operating losses ("NOLs") totaling $144.1 million expire in various amounts between 2024 and 2037. Federal NOLS totaling $20.1 million do not expire.

Year Generated	Year of Expiration	Amount
2004	2024	$ 3,571,227
2005	2025	5,530,815
2006	2026	7,192,407
2007	2027	10,218,952
2008	2028	7,017,372
2009	2029	9,573,948
2010	2030	10,344,298
2011	2031	11,225,047
2012	2032	11,193,882
2013	2033	10,273,181
2014	2034	9,075,738
2015	2035	17,455,417
2016	2036	19,710,699
2017	2037	11,703,175
2018	N/A	6,255,067
2019	N/A	4,085,063
2020	N/A	4,167,397
2021	N/A	3,167,687
2022	N/A	1,336,826
2023	N/A	1,116,173
Total NOLS		$164,214,371

State NOLS totaling $143.4 million expire in various years between 2024 and 2039.

Year Generated	Year of Expiration	Amount
2008	2024	$ 7,106,425
2009	2025	9,680,770
2010	2026	10,440,651
2011	2027	11,362,120
2012	2028	11,311,394
2013	2029	10,381,763
2014	2030	9,278,510
2015	2031	18,547,287
2016	2032	20,166,661
2017	2033	12,131,850
2018	2034	6,455,113
2019	2035	4,211,210
2020	2036	4,234,755
2021	2037	3,232,081
2022	2038	3,758,942
2023	2039	1,116,173
Total NOLS		$143,415,705

Australia NOLS totaling $157,966 do not expire.

Year Generated	Year of Expiration	Amount
2017	N/A	$ 861
2018	N/A	54,101
2019	N/A	13,843
2020	N/A	13,384
2021	N/A	56,351
2022	N/A	4,830
2023	N/A	14,596
Total NOLS		$ 157,966

The Company has determined that there are no uncertain tax positions as of December 31, 2023 or 2022.

We file income tax returns in the U.S., Tennessee, and Australia. As of December 31, 2023, the U.S. federal and Tennessee tax years open to examination are 2020 through 2023. The Australia income tax return remains open to examination for 2021 through 2023.

To date, the Company's operations conducted by its Australian subsidiary consist primarily of research and development activities. As of December 31, 2023, there were no accumulated earnings and profits in the Company's foreign subsidiary. At current tax rates, no additional federal income taxes (net of available tax attributes) would be payable if such earnings were to be repatriated.

12. Leases

Leases

The Company leased 4,500 square feet of corporate office space in Knoxville, Tennessee through an operating lease agreement for a term of five years ending on June 30, 2022. Payments were approximately $6,100 per month due to the Company negotiating a continued reduced rent from January 1, 2022 through June 30, 2022.

On June 30, 2022, the lease expired and was not renewed. On June 18, 2022, the Company moved into 2,700 square feet of leased corporate office space in Knoxville, Tennessee through an operating lease agreement for a term of three years ending June 30, 2025. The monthly base rent ranges from $4,053 to $4,278 over the term on the lease.

Total expense for operating leases for the year ended December 31, 2023 was $51,393, of which, $34,262 was included within research and development and $17,131 was included within general and administrative expenses on the consolidated statements of operations. Total expense for operating leases for the year ended December 31, 2022 was $63,066, of which, $42,044 was included within research and development and $21,022 was included within general and administrative expenses on the consolidated statements of operations.

As of December 31, 2023, the Company had no leases that were classified as a financing lease. As of December 31, 2023, the Company did not have additional operating and financing leases that have not yet commenced.

A summary of the Company's right-of-use assets and liabilities is as follows:

	For The Years Ended December 31,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used in operating leases	$ 44,422	$ 62,944
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	$ -	$ 130,422
Weighted Average Remaining Lease Term		
Operating leases	1.50 Years	2.50 Years
Weighted Average Discount Rate		
Operating leases	5.0%	5.0%-8.0%

Future minimum payments under the non-cancellable lease as of December 31, 2023 were as follows:

Years	Amount
2024	$ 50,663
2025	25,669
Total lease payments	76,332
Less: amount representing imputed interest	(2,955)
Present value of lease liability	73,377
Less: current portion	(48,077)
Lease liability, non-current portion	$ 25,299

13. 401(K) Profit Sharing Plan

The Company maintains a retirement plan under Section 401(k) of the Internal Revenue Code, which covers all eligible employees. All employees with U.S. source income are eligible to participate in the plan immediately upon employment. There was no contribution made by the Company in 2023 or 2022.

14. Grants

On October 25, 2021, the Company received a grant award of $2,500,000 from the State of Tennessee for the study of animal cancers and dermatological disorders for the period October 15, 2021 to June 30, 2022 (the "Tennessee Grant" or "Grant"). The Tennessee Grant was pre-funded; therefore, the funds do not need to be used in full by June 30, 2022. The Tennessee Grant was provided as reimbursement of research and development expenses related to the development of animal health drug products. The Company has elected gross presentation of the Tennessee Grant income earned and the related research and development expenses, with Grant income presented as Grant revenue in the period in which it is earned, and qualifying costs presented as research and development expenses included in the Company's statement of operations in the period that such costs are incurred. As of December 31, 2023, $953,248 has been recorded as unearned Grant revenue liability on the accompanying audited consolidated balance sheets. The Company recorded $557,710 and $989,042 of Grant revenue during the years ended December 31, 2023 and 2022, respectively. As of December 31, 2022, $1,510,958 has been recorded as unearned Grant revenue liability on the accompanying audited consolidated balance sheets.

15. License Transactions

In the third quarter of 2019, the Company entered into a dialog with Bascom Palmer Eye Institute ("BPEI") regarding collaboration on BPEI's ophthalmic photodynamic antimicrobial therapy ("PDAT") using the Company's pharmaceutical-grade RBS. On February 16, 2022, and later amended on May 11, 2022, the Company entered into an option agreement with the University of Miami ("UM") for an exclusive worldwide license of intellectual property ("IP") developed by the Ophthalmic Biophysics Center ("OBC") of BPEI that included the use of OBC's PDAT medical device in combination with formulations of the Company's pharmaceutical-grade RBS for the treatment of bacterial, fungal, and viral infections of the eye. The Company completed the arrangements of this collaboration during the third quarter of 2022, whereby the Company paid $5,000 for the option that expires on May 31, 2023; agreed to pay up to $10,000 of new UM patent expenses for this IP during the period of the option and up to $25,000 of past UM patent expenses for this IP; and entered into a sponsored research agreement with UM on September 16, 2022 to study the combination of OBC's PDAT and TOP PV-305, a formulation of the Company's pharmaceutical-grade RBS, for the treatment of infectious keratitis.

16. Commitments, Contingencies and Litigation

The Company may, from time to time, be involved in litigation arising in the ordinary course of business which may be expected to be covered by insurance. The Company is not aware of any pending or threatened litigation that, if resolved against the Company, would have a material adverse effect on the Company's consolidated financial position, results of operations or cash flows.

17. Subsequent Events

The Company has evaluated events that have occurred after the balance sheet date and through the date the financial statements were issued. Based upon the evaluation, the Company did not identify any recognized or non-recognized subsequent events that would have required adjustment or disclosure in the financial statements, except as disclosed below.

Convertible Notes Payable

Subsequent to December 31, 2023, the Company entered into 2022 Notes with non-related party investors in the aggregate principal amount of $153,000.

Subsequent to December 31, 2023, the Company entered into a 2022 Note with a related party investor (a director of the Company) in the aggregate principal amount of $815,000.

Subsequent to December 31, 2023, the Company paid back $75,000 against a 2021 Note with a related party investor (an officer of the Company).

Preferred Stock

Subsequent to December 31, 2023, principal and interest in the aggregate amount of $648,162 representing 2022 Notes were converted into 226,474 shares of Series D-1 Convertible Preferred Stock upon automatic conversion of the 2022 Notes.

Bruce Horowitz – Resignation and Termination Agreement

On March 25, 2024, Bruce Horowitz resigned from the Board and as the Company's Chief Operating Officer. Mr. Horowitz, through counsel, had requested that the Company pay him $977,000, representing $508,000 for amounts owed under the Independent Contractor Agreement, dated as of April 19, 2017, by and between Mr. Horowitz and the Company, as amended by Amendment No. 1, dated as of May 9, 2017, and Amendment No. 2, dated as of May 8, 2019 (the "Horowitz Agreement"), and $469,000 for accrued director fees. On March 25, 2024, the Company and Mr. Horowitz entered into an Independent Contractor and Director Fee Termination Agreement and Release (the "Termination Agreement") to resolve Mr. Horowitz's claims and terminate the Horowitz Agreement. The Termination Agreement provides, among other things, for the Company to pay Mr. Horowitz an initial payment of $250,000 within two business days of the Termination Agreement and a discounted second payment in the amount of $258,000 so long as it is paid prior to June 30, 2024, after which the amount of the second payment is $500,000. The Company has paid the initial payment of $250,000.

Dominic Rodrigues – Appointment and Independent Contractor Agreement

On March 25, 2024, the Board retained Dominic Rodrigues as the Company's chief operations consultant pursuant to an Independent Contractor Agreement entered into with Mr. Rodrigues. In this role, Mr. Rodrigues will serve as the Company's principal executive officer and will be paid $20,000 per calendar month.

License Transactions

On March 21, 2024, the Company entered into an exclusive worldwide license for UM's IP. Details of the license agreement are reported in the Company's Current Report on Form 8-K filed with the Commission on March 27, 2024.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external purposes in accordance with GAAP. Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures by us are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the consolidated financial statements.

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting as of the period covered by this report based on the criteria for effective internal control described in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Based on the results of management's assessment and evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2023.

Evaluation of Disclosure Controls and Procedures

Management, with the participation of our principal executive officer and principal financial officer, carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on this evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered in this report, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Inherent Limitations on Effectiveness of Controls

Even assuming the effectiveness of our controls and procedures, our management, including our principal executive officer and principal financial officer, does not expect that our disclosure controls or our internal control over financial reporting will prevent or detect all error or all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. In general, our controls and procedures are designed to provide reasonable assurance that our control system's objective will be met, and our principal executive officer and principal financial officer has concluded that our disclosure controls and procedures are effective at the reasonable assurance level. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Controls can also be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the controls. The design of any system of controls is based in part on certain assumptions about the likelihood of future events and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Projections of any evaluation of the effectiveness of controls in future periods are subject to risks. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures.

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during the fourth quarter of 2023 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.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our 2024 Annual Meeting of Stockholders, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

ITEM 11. EXECUTIVE COMPENSATION.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our 2024 Annual Meeting of Stockholders, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our 2024 Annual Meeting of Stockholders, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our 2024 Annual Meeting of Stockholders, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our 2024 Annual Meeting of Stockholders, which will be filed with the SEC pursuant to Regulation 14A under the Exchange Act.

PART IV

ITEM 15. EXHIBIT AND FINANCIAL STATEMENT SCHEDULES.

Financial Statements

All financial statements are set forth under Part II, Item 8 of this report.

Financial Statement Schedules

None

Exhibits

Exhibit No.	Description
3.1	Certificate of Incorporation of Provectus Biopharmaceuticals, Inc., as amended (incorporated by reference to Exhibit 3.1 of the Company's annual report on Form 10-K filed with the SEC on March 31, 2017).
3.2	Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's current report on Form 8-K filed with the SEC on June 24, 2021).
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series D-1 Convertible Preferred Stock (as amended by the Certificate of Amendment, dated March 30, 2022) (incorporated by reference to Exhibit 3.4 of the Company's quarterly report on Form 10-Q filed with the SEC on May 12, 2022).
3.4	Bylaws of Provectus Biopharmaceuticals, Inc. (incorporated by reference to Exhibit 3.4 of the Company's annual report on Form 10-K filed with the SEC on March 13, 2014).
4.1	Specimen certificate for the Common Stock, par value $0.001 per share, of the Company (incorporated by reference to Exhibit 4.1 of the Company's annual report on Form 10-KSB filed with the SEC on April 15, 2003).
4.2	Specimen certificate for the Common Stock, par value $0.001 per share, of the Company (incorporated by reference to Exhibit 4.1 to the Company's registration statement on Form S-4, Commission File No. 333-208816, filed with the SEC on December 31, 2015).
4.3	Form of Unsecured Convertible Promissory Note under the 2021 Financing Term Sheet (incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K filed with the SEC on August 18, 2021).
4.4	Form of Unsecured Convertible Promissory Note under the 2022 Financing Term Sheet (incorporated by reference to Exhibit 4.1 of the Company's current report on Form 8-K filed with the SEC on September 26, 2022).
4.5†	Description of Securities.
10.1*	Confidentiality, Inventions and Non-Competition Agreement dated as of November 26, 2002 between the Company and Timothy C. Scott (incorporated by reference to Exhibit 10.9 of the Company's annual report on Form 10-KSB filed with the SEC on April 15, 2003).
10.2*	Confidentiality, Inventions and Non-Competition Agreement dated as of November 26, 2002, between the Company and Eric A. Wachter (incorporated by reference to Exhibit 10.10 of the Company's annual report on Form 10-KSB filed with the SEC on April 15, 2003).
10.3	Material Transfer Agreement dated as of July 31, 2003 between Schering-Plough Animal Health Corporation and the Company (incorporated by reference to Exhibit 10.15 of the Company's quarterly report on Form 10-QSB filed with the SEC on August 14, 2003).

Exhibit No.	Description
10.4	Controlled Equity Offering[SM] Sales Agreement, dated April 30, 2014, by and between Provectus Biopharmaceuticals, Inc. and Cantor Fitzgerald & Co. (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on April 30, 2014).
10.5	Stipulated Settlement Agreement and Mutual Release, dated June 6, 2014, by and among the Company as nominal defendant, H. Craig Dees, Timothy C. Scott, Eric A. Wachter, Peter R. Culpepper, Stuart Fuchs, Kelly M. McMasters, and Alfred E. Smith, IV, as defendants, and Glenn Kleba and Don B. Dale, as plaintiffs (Exhibits Omitted) (incorporated by reference to Exhibit 10.6 of the Company's quarterly report on Form 10-Q filed with the SEC on August 7, 2014).
10.6	Definitive Financing Commitment Term Sheet dated March 19, 2017 (incorporated by reference to Exhibit 10.2 of the Company's quarterly report on Form 10-Q filed with the SEC on May 10, 2017).
10.7	2020 Definitive Financing Term Sheet (incorporated by reference to Exhibit 10.39 to the Company's annual report on Form 10-K filed with the SEC on March 5, 2020).
10.8	2021 Financing Term Sheet (incorporated by reference to Exhibit 10.1 to the Company's quarterly report on Form 10-Q filed with the SEC on November 10, 2021).
10.9	2022 Financing Term Sheet (incorporated by reference to Exhibit 10.1 to the Company's quarterly report on Form 10-Q filed with the SEC on November 9, 2022).
10.10*	Provectus Pharmaceuticals, Inc. 2012 Stock Plan (incorporated herein by reference to Appendix A of the Company's definitive proxy statement filed with the SEC on April 30, 2012).
10.11*	2017 Amendment and Restatement of the Provectus Biopharmaceuticals, Inc. 2014 Equity Compensation Plan (incorporated herein by reference to Appendix A of the Company's definitive proxy statement filed with the SEC on April 27, 2017).
10.12*	Independent Contractor Agreement, dated April 19, 2017, between the Company and Bruce Horowitz (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed with the SEC on April 20, 2017).
10.13*	Amendment No. 1 to the Independent Contractor Agreement, dated May 9, 2017, between the Company and Bruce Horowitz (incorporated by reference to Exhibit 10.6 of the Company's quarterly report on Form 10-Q filed with the SEC on August 9, 2017).
10.14*	Amendment No. 2 to the Independent Contractor Agreement dated April 19, 2017, between the Company and Bruce Horowitz, dated May 8, 2019 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed May 9, 2019).
10.15*	Employment Agreement between the Company and Heather Raines, CPA, dated March 25, 2019 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on March 25, 2019).
10.16*	Executive Employment Agreement between the Company and Eric A. Wachter, Ph.D., dated May 17, 2019 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed May 20, 2019).
10.17	Indemnification Agreement between the Company and Dominic Rodrigues, dated April 3, 2017 (incorporated by reference to Exhibit 10.3 of the Company's current report on Form 8-K filed with the SEC on April 4, 2017).
10.18	Indemnification Agreement between the Company and Bruce Horowitz, dated April 3, 2017 (incorporated by reference to Exhibit 10.4 of the Company's current report on Form 8-K filed with the SEC on April 4, 2017).
10.19	Indemnification Agreement between the Company and Ed Pershing, dated April 19, 2018 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on April 24, 2018).

Exhibit No.	Description
10.20	Indemnification Agreement between the Company and Jack Lacey, MD, dated April 19, 2018 (incorporated by reference to Exhibit 10.2 of the Company's current report on Form 8-K filed on April 24, 2018).
10.21	Indemnification Agreement between the Company and Webster Bailey, effective as of July 20, 2020 (incorporated by reference to Exhibit 10.1 of the Company's current report on Form 8-K filed on July 16, 2020).
14	Code of Ethics (incorporated by reference to Exhibit 14 of the Company's annual report on Form 10-K filed with the SEC on March 16, 2011).
21	Subsidiaries of the Company (incorporated by reference to Exhibit 21 of the Company's annual report on Form 10-K filed with the SEC on March 31, 2017).
31.1†	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) of the Securities Exchange Act of 1934.
31.2†	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) of the Securities Exchange Act of 1934.
32††	Certification Pursuant to 18 U.S.C. Section 1350.
101.INS†	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH†	Inline XBRL Taxonomy Extension Schema Document.
101.CAL†	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.LAB†	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE†	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
101.DEF†	Inline XBRL Taxonomy Extension Definition Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

† Filed herewith.
†† Furnished herewith.
* Indicates a management contract or compensatory plan or arrangement.

ITEM 16. FORM 10-K SUMMARY.

None.

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.

March 28, 2024

PROVECTUS BIOPHARMACEUTICALS, INC.

By: */s/ Dominic Rodrigues*
Dominic Rodrigues
Chief Operations Consultant (principal executive officer)

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

Signature	Title	Date
/s/ Heather Raines Heather Raines, CPA	Chief Financial Officer (principal financial officer and principal accounting officer)	March 28, 2024
/s/ Dominic Rodrigues Dominic Rodrigues	Director, Vice Chairman of the Board and Chief Operations Consultant (principal executive officer)	March 28, 2024
/s/ Webster Bailey Webster Bailey	Director	March 28, 2024
/s/ John W. Lacey, III, MD John W. Lacey, III, MD	Director	March 28, 2024
/s/ Ed Pershing Ed Pershing	Director and Chairman of the Board	March 28, 2024

Exhibit 4.5

DESCRIPTION OF SECURITIES

REGISTERED UNDER SECTION 12 OF THE EXCHANGE ACT

Provectus Biopharmaceuticals, Inc. (the "Company," "Provectus," "we" or "our") has one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"): our Common Stock.

Description of Common Stock

The following description of our Common Stock is a summary and does not purport to be complete. It is subject to and qualified in its entirety by reference to our Certificate of Incorporation, as amended (the "Certificate of Incorporation"), and our Bylaws, as amended (the "Bylaws"), each of which is incorporated by reference as an exhibit to the Annual Report on Form 10-K, of which this Exhibit is a part. We encourage you to read our Certificate of Incorporation, our Bylaws, and the applicable provisions of the Delaware General Corporation Law, for additional information.

Authorized Shares of Capital Stock

Our authorized capital stock consists of 1,000,000,000 shares of common stock, $0.001 par value per share ("Common Stock"), and 25,000,000 shares of preferred stock, $0.001 par value per share ("Preferred Stock"). As of December 31, 2023, 419,522,119 shares of Common Stock were issued and outstanding. The outstanding shares of our Common Stock are duly authorized, validly issued, fully paid, and nonassessable.

Voting Rights

Holders of Common Stock are entitled to one vote per share on all matters voted on by the stockholders, including the election of directors. Our Common Stock does not have cumulative voting rights.

Dividend Rights

Subject to the rights of holders of outstanding shares of Preferred Stock, if any, the holders of Common Stock are entitled to receive dividends, if any, as may be declared from time to time by the Company's Board of Directors (the "Board") in its discretion out of funds legally available for the payment of dividends.

Liquidation Rights

In the event of our dissolution, liquidation or winding up, holders of our Common Stock are entitled to share ratably in any assets remaining after the satisfaction in full of the prior rights of creditors and the aggregate liquidation preference of any Preferred Stock then outstanding.

Other Rights and Preferences

Holders of our Common Stock do not have any conversion, redemption, sinking fund or preemptive rights.

Certain Anti-Takeover Effects

Provisions of our Certificate of Incorporation and Bylaws may delay or discourage transactions involving an actual or potential change of control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our Common Stock. Among other things, our Certificate of Incorporation and Bylaws will:

- permit our Board to issue up to 25,000,000 shares of Preferred Stock, with any rights, preferences, and privileges as they may designate;

- provide that all vacancies on our Board, including as a result of newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;

- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide advance notice in writing, and also specify requirements as to the form and content of a stockholder's notice;

- not provide for cumulative voting rights, thereby allowing the holders of a majority of the shares of Common Stock entitled to vote in any election of directors to elect all of the directors standing for election; and

- provide that special meeting of our stockholders may be called only by the Board or by such person or persons requested by a majority of the Board to call such meetings.

Preferred Stock

The rights, preferences, and privileges of the holders of our Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of Preferred Stock that we have designated and issued or may designate and issue in the future. Under our Certificate of Incorporation, we are authorized to issue up to 25,000,000 shares of Preferred Stock, from time to time in one or more series, in any manner permitted by law, as determined from time to time by our Board, and stated in the resolution or resolutions providing for the issuance of such shares adopted by our Board. Without limiting the generality of the foregoing, shares in such series shall have voting powers, full or limited, or no voting powers, and shall have such designations, preferences and relative, participating, optional, or other special rights, and qualifications, limitations, or restrictions thereof, permitted by law, as shall be stated in the resolution or resolutions providing for the issuance of such shares adopted by our Board. The number of shares of any such series so set forth in the resolution or resolutions may be increased (but not above the total number of authorized shares of Preferred Stock) or decreased (but not below the number of shares thereof then outstanding) by further resolution or resolutions adopted by the Board. As of December 31, 2023, 12,373,247 and 10,361,097 shares of Series D and D-1 Preferred Stock were issued and outstanding, respectively.

Series D and Series D-1 Preferred Stock

The rights, preferences and privileges of the Series D Convertible Preferred Stock are set forth in a Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock (the "Series D Certificate of Designation"), a copy of which is attached as Exhibit 3.2 to this Annual Report on Form 10-K. The rights, preferences and privileges of the Series D-1 Convertible Preferred Stock are set forth in a Certificate of Designation of Preferences, Rights and Limitations of Series D-1 Convertible Preferred Stock (the "Series D-1 Certificate of Designation"), a copy of which is attached as Exhibit 3.3 to this Annual Report on Form 10-K.

The Board of Directors of the Company approved each of the Series D Certificate of Designation and Series D-1 Certificate of Designation on June 16, 2021, and each of the Series D Certificate of Designation and Series D-1 Certificate of Designation were filed with the Delaware Secretary of State on June 17, 2021. The Series D Certificate of Designation and Series D-1 Certificate of Designation are the same, other than certain key differences to account solely for the different conversion ratios for the holders of 2017 Notes who did not execute an Amendment compared to the holders of Amended 2017 Notes and the holders of 2020 Notes.

The Series D Certificate of Designation established and designated 12,374,000 shares of Series D Convertible Preferred Stock. The Series D-1 Certificate of Designation (as amended by the Certificate of Amendment, dated March 30, 2022) established and designated 11,241,000 shares of Series D-1 Convertible Preferred Stock.

The Series D Convertible Preferred Stock and the Series D-1 Convertible Preferred Stock rank *pari passu* with each other. The Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock rank senior to the Common Stock and any other class or series of the Company's capital stock, the terms of which do not provide that shares of such class rank senior to, or *pari passu* with, the Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock as to dividends and distributions upon a change of control transaction, or the liquidation, winding-up and dissolution of the Company.

The Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock do not have any dividend preference but are entitled to receive, on a *pari passu* basis, dividends, if any, that are declared and paid on the Common Stock and any other class of the Company's capital stock that ranks junior or on par to the Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock.

Upon the occurrence of the liquidation, winding-up or dissolution of the Company or certain mergers, corporate reorganizations or sales of the Company's assets (each, a "Company Event"), holders of Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock will be entitled to receive a liquidation preference before any distributions are made to holders of any other class or series of the Company's capital stock junior to the Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock. If a Company Event occurs within two years of June 20, 2021 (the "Date of Issuance"), the holders of Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock will receive for each share of Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock, respectively, an amount in cash equal to the Original Issue Price (as defined in the Series D Certificate of Designation and Series D-1 Certificate of Designation, respectively) multiplied by four. If a Company Event occurs from and after the second anniversary of the Date of Issuance, the holders of Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock will receive for each share of Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock, respectively, an amount in cash equal to the Original Issue Price multiplied by six. The Original Issue Price for the Series D Convertible Preferred Stock is $0.2862, and the Original Issue Price for the Series D-1 Convertible Preferred Stock is $2.862.

Holders of shares of Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock will vote together with the holders of Common Stock as a single class. Each share of Series D Convertible Preferred Stock carries the right to one vote per share. Each share of Series D-1 Convertible Preferred Stock carries the right to 10 votes per share.

The Company is not permitted to amend, alter or repeal its Certificate of Incorporation or Bylaws in a manner adverse to the relative rights, preferences, qualifications, limitations or restrictions of the Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock without the affirmative vote of a majority of the votes entitled to be cast by holders of outstanding shares of Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock, voting together as a single class with each share of Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock having a number of votes equal to the number of shares of Common Stock then issuable upon conversion of such share of Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock.

The Series D Convertible Preferred Stock is convertible at the option of the holders thereof into shares of Common Stock based on a one-for-one conversion ratio. The Series D-1 Convertible Preferred Stock is convertible at the option of the holders thereof into shares of Common Stock based on a one-for-10 conversion ratio. The conversion ratio of the Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock is subject to adjustment for stock splits and combinations, recapitalizations, reclassifications, reorganizations, mergers, and consolidations. The Series D Convertible Preferred Stock and Series D-1 Convertible Preferred Stock will automatically convert into shares of Common Stock upon the fifth anniversary of the Date of Issuance.

Transfer Agent and Registrar

Broadridge Financial Solutions, Inc. is the transfer agent and registrar for our Common Stock.

Listing

Our Common Stock is traded on the OTCQB Marketplace under the trading symbol "PVCT."

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934

I, Dominic Rodrigues, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 of Provectus Biopharmaceuticals, 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 28, 2024

By: */s/ Dominic Rodrigues*
Dominic Rodrigues
Chief Operations Consultant (principal executive officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO RULE 13a-14(a) UNDER
THE SECURITIES EXCHANGE ACT OF 1934

I, Heather Raines, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 of Provectus Biopharmaceuticals, 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 28, 2024

By: */s/ Heather Raines*
Heather Raines, CPA
Chief Financial Officer (principal financial officer)

Exhibit 32

CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13a-14(b) UNDER THE SECURITIES EXCHANGE ACT OF 1934 AND SECTION 1350 OF CHAPTER 63 OF TITLE 18 OF THE UNITED STATES CODE

Each of the undersigned, Dominic Rodrigues and Heather Raines, certifies, pursuant to Rule 13a-14(b) under the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code, that (1) this Annual Report on Form 10-K for the year ended December 31, 2023 of Provectus Biopharmaceuticals, Inc. (the "Company") fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act, and (2) the information contained in this report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This Certification is signed on March 28, 2024.

/s/ Dominic Rodrigues

Dominic Rodrigues
Chief Operations Consultant (principal executive officer)

/s/ Heather Raines

Heather Raines, CPA
Chief Financial Officer (principal financial officer)