

**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, 2022

☐ **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

**PROVCTUS BIOPHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of incorporation or organization)

90-0031917  
(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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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, 2022 was \$22,587,552 (computed on the basis of \$0.056 per share).

The number of shares outstanding of the registrant's common stock, par value \$0.001 per share, as of March 28, 2023 was 419,497,119.

**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, 2022, pursuant to Regulation 14A under the Securities Exchange Act of 1934 in connection with the 2023 annual meeting of stockholders.

## TABLE OF CONTENTS

### PART I

ITEM 1.	BUSINESS.....	2
ITEM 1A.	RISK FACTORS .....	9
ITEM 1B.	UNRESOLVED STAFF COMMENTS.....	16
ITEM 2.	PROPERTIES .....	16
ITEM 3.	LEGAL PROCEEDINGS .....	16
ITEM 4.	MINE SAFETY DISCLOSURES.....	16

### PART II

ITEM 5.	MARKET FOR REGISTRANT’S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES .....	17
ITEM 6.	[RESERVED] .....	17
ITEM 7.	MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS .....	17
ITEM 7A.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK .....	25
ITEM 8.	FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.....	26
ITEM 9.	CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.....	27
ITEM 9A.	CONTROLS AND PROCEDURES .....	27
ITEM 9B.	OTHER INFORMATION .....	28
ITEM 9C.	DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS .....	28

### PART III

ITEM 10.	DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE .....	29
ITEM 11.	EXECUTIVE COMPENSATION .....	29
ITEM 12.	SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS .....	29
ITEM 13.	CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE .....	29
ITEM 14.	PRINCIPAL ACCOUNTANT FEES AND SERVICES .....	29

### PART IV

ITEM 15.	EXHIBIT AND FINANCIAL STATEMENT SCHEDULES .....	30
ITEM 16.	FORM 10-K SUMMARY .....	32

SIGNATURES .....	33
------------------	----

## 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<sup>®</sup> and PH-10<sup>®</sup>, 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 2022, 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 molecule is named rose bengal sodium (“RBS”).

The Company’s proprietary, patented, pharmaceutical-grade RBS is the active pharmaceutical ingredient (“API”) 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, such contact may catalyze multivariate immune signaling and 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 ClinicalTrials.gov.

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

The Company’s small molecule HX medical science platform comprises a number of different drug product candidates and preclinical pharmaceutical-grade RBS formulations using different concentrations and 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 drug discovery 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 a number of 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:

<b>U.S. Patent No.</b>	<b>Title</b>	<b>Issue Date</b>	<b>Expiration Date</b>
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

<b>U.S. Patent No.</b>	<b>Title</b>	<b>Issue Date</b>	<b>Expiration Date</b>
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 <i>ex vivo</i> 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	<i>In vitro</i> 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 two patent awards from the USPTO in 2022, U.S. patent numbers 11,419,844 and 11,426,379. Three patent applications were also published on the USPTO's website:

- Combination of local and systemic immunomodulative therapies for enhanced treatment of cancer (USPTO application number 17/382,943),
- Halogenated Xanthenes as Immune Adjuvants (17/488,430), and
- Combination of Local and Systemic Therapies for Enhanced Treatment of Dermatologic Conditions (17/466,600).

#### *International Patents*

In 2022, the Japanese Patent Office granted two of the Company's patent applications, "*In Vitro* And Xenograft Anti-Tumor Activity Of A Halogenated-Xanthene Against Refractory Pediatric Solid Tumors" and "Combination of Local and Systemic Therapies for Enhanced Treatment of Dermatologic Conditions."

### **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 is undergoing 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 and are undergoing 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 are undergoing preclinical monotherapy study for the treatment of oral bacterial infections at UTHSC.
- Different formulations are undergoing preclinical monotherapy study for the treatment of fungal infections at UTHSC.
- *Tissue Regeneration and Repair*: Different formulations are undergoing preclinical monotherapy study for vertebrate development, wound healing, and tissue regrowth at the University of Nevada, Las Vegas (“UNLV”) in Las Vegas, Nevada.

## 2022 Activity

In January, preclinical research on a formulation of the Company's pharmaceutical-grade rose bengal against Gram-positive bacteria was published in *Molecules*, an open-access journal of chemistry by UTHSC: "[Antibacterial Activity of Pharmaceutical-Grade Rose Bengal: An Application of a Synthetic Dye in Antibacterial Therapies.](#)"

The USPTO published the Company's patent application entitled "Halogenated Xanthenes as Vaccine Adjuvants" (publication no. 17/488,430) that contained, among other things, *in vitro* data that showed PV-10 was able to significantly increase numbers of interferon gamma-producing CD8 cells (compared to controls) for peptides representing various antigenic regions of the Hepatitis B virus ("HBV") core protein (HBcAg). These peptides were selected for their capability to raise CD4 and CD8 T cells against HBV.

In March, data from an ongoing clinical trial of PV-10 for the treatment of neuroendocrine tumors metastatic to the liver refractory to somatostatin analogs and peptide receptor radionuclide therapy (NCT02693067) were presented as an oral presentation at the annual conference of the European Neuroendocrine Tumor Society (ENETS), held from March 10-11, 2022 in a hybrid setting of Barcelona, Spain and online: "A phase 1 study of percutaneous autolytic rose bengal disodium for metastatic uveal melanoma patients with hepatic metastases."

The Company successfully developed and manufactured a second HX. The molecular name of the newly synthesized HX is 4,5,6,7-tetrabromo-3',6'-dihydroxy-2',4',5',7'-tetraiodo-3H-spiro[isobenz- ofuran-1,9'-xanthen]-3-one.

In April, preclinical research on systemic administration of PV-10 for the treatment of high-risk and refractory adult solid tumor cancers is being presented at the annual meeting of the American Association for Cancer Research (AACR), held April 8-13, 2022 in New Orleans, Louisiana: "[Identification and \*In Vivo\* Validation of Unique Anti-Oncogenic Properties and Mechanisms Involving Protein Kinase Signaling and Autophagy Mediated by the Investigational New Agent PV-10.](#)"

Aru Narendran, MD, PhD was added to the Company's Scientific Advisory Board. Dr. Narendran is a professor in the departments of Pediatrics, Oncology, and Biochemistry & Molecular Biology at UCal, and holds the Kids Cancer Care Foundation Endowed Chair in Clinical and Translational Research in pediatric oncology.

The USPTO allowed US patent application 16/688,319 (Patent No. 11,419,844), "Composition and Method for Treating Hematologic Cancers," covering the use of PV-10 for the treatment of hematologic diseases. *In vivo* data of mice with acute lymphoblastic leukemia receiving oral PV-10 showed increased survival compared to controls. This allowed patent application was the first patent awarded to the Company in hematology from the USPTO.

In May, the USPTO allowed US patent application 17/466,600 (Patent No. 11,426,379), "Combination of local and systemic therapies for enhanced treatment of dermatologic conditions," covering the use of topical PH-10 in combination with one or more systemic therapies for the treatment of various inflammatory dermatoses, such as psoriasis and atopic dermatitis, and various epithelial diseases. This allowed patent application was the first patent awarded to the Company in dermatology from the USPTO.

In June, updated data from the Company's initial expansion cohort of patients with uveal melanoma metastatic to the liver in its cancers-of-the-liver Phase 1 trial of PV-10 (NCT00986661) were presented at the 2022 American Society of Clinical Oncology (ASCO) annual meeting, held June 3-7 in Chicago, Illinois and online: "[Metabolic complete responses \(mCR\) in metastatic uveal melanoma \(mUM\) patients treated with image-guided injection \(IGI\) of PV-10.](#)"

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.

Updated data from the Company's initial expansion cohort of patients with uveal melanoma metastatic to the liver in its cancers-of-the-liver Phase 1 trial of PV-10 (NCT00986661) were part of two oral presentations at the 20<sup>th</sup> Congress of the International Society of Ocular Oncology (ISOO), held June 17-21, 2022 in Leiden, The Netherlands: "[A phase 1 study of percutaneous autolytic rose bengal disodium for metastatic uveal melanoma patients with hepatic metastases](#)" and "[Metabolic complete responses \(mCR\) in metastatic uveal melanoma \(mUM\) patients treated with image-guided injection of PV-10.](#)"

In July, the Company initiated a new sponsored research program with Kelly Tseng, PhD, Associate Professor of Pathology and Lab Medicine, School of Life Sciences at UNLV to characterize the effects of the Company's pharmaceutical-grade RBS on vertebrate tissue regeneration and repair. The Tseng Lab at UNLV will assess the effects of RBS on animal development and tissue repair using the African clawed frog (*Xenopus laevis*), an established vertebrate model organism, and *in vivo* assays to evaluate key biological processes: embryo development, wound healing, and tissue regeneration.

In August, the Company expanded its sponsored research program with Dr. Narendran at UCal to investigate systemic administration of Provectus' pharmaceutical-grade rose bengal for the treatment of pediatric leukemia. The Company's innovatively-assembled and proprietary rose bengal is the lead member of a class of small molecules called halogenated xanthenes. As part of this new sponsored research, the Narendran team plans to identify clinically-feasible drug combinations and synthetic lethality that have synergistic activity with Provectus' rose bengal, evaluate systemic drug administration routes for maximal tolerability, evaluate the modulation of WNK1 (lysine deficient protein kinase 1) and other related pathways induced by the Company's rose bengal, and complete demonstration of STING (stimulator of interferon genes) dimerization in leukemia cells.

The Company expanded its sponsored research program with Michio Kurosu, PhD, Professor, Department of Pharmaceutical Sciences at the College of Pharmacy of UTHSC to investigate the Company's pharmaceutical-grade RBS for the treatment of anti-fungal and anti-oral bacterial infections. As part of this new sponsored research, the Kurosu team plans to evaluate the in vitro activity of Provectus' rose bengal against different fungal strains and to conduct susceptibility tests against fungal and bacterial mouth microbes.

In September, the Company entered into an option agreement with UM for an exclusive worldwide license of intellectual property developed by the Ophthalmic Biophysics Center ("OBC") of BPEI, which is part of the UM Health System, for the use of OBC's photodynamic antimicrobial therapy (PDAT) medical device in combination with Provectus' proprietary pharmaceutical-grade rose bengal for the treatment of bacterial, fungal, and viral infections of the eye. The Company also initiated a sponsored research program with OBC to investigate the Company's pharmaceutical-grade RBS for the treatment of infectious keratitis.

The Company initiated a new sponsored research program with Amina El Ayadi, PhD, Assistant Professor, Surgical Sciences Division and Jayson Jay, PhD, Postdoctoral Research Fellow and Jeane B. Kempner Scholar of the Burn, Trauma, and Critical Care Research Laboratory in the Department of Surgery at UTMB to characterize the effects of Provectus' proprietary pharmaceutical-grade RBS on full-thickness cutaneous wounds and during the subsequent phases of wound healing.

In October, the Company expanded its sponsored research program with James G. Krueger, MD, PhD, Co-director, Center for Clinical and Translational Science, D. Martin Carter Professor in Clinical Investigation, Senior Attending Physician, and head of the Laboratory of Investigative Dermatology at TRU to investigate the potential for PH-10 to directly alter the growth and differentiation of human keratinocytes, and to block cytokine-mediated signaling that creates different inflammatory skin diseases and may also be important in skin neoplasms.

In November, the International Nonproprietary Names ("INN") Expert Committee of the World Health Organization ("WHO") selected "rose bengal sodium" (RBS) for the nonproprietary name of the Company's API. The RBS name was selected by the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations, reached the status of recommended INN after a period of public consultation, and was included in INN Recommended List 88 published with the No. 3 issue of the WHO Drug Information, Volume 36 in October 2022.

New data from the Company's ongoing, multi-cohort, Phase 1b/2 study of the combination of PV-10 and anti-PD-1 therapy Keytruda (pembrolizumab) for the treatment of immune checkpoint blockade-naïve Stage III cutaneous melanoma (NCT01223415) were presented as a poster presentation and an oral video communication at Melanoma Bridge 2022 in Naples, Italy and online from December 1-3, 2022: ["Response for combination of PV-10 autolytic immunotherapy and immune checkpoint blockade in stage III cutaneous melanoma,"](#)

On November 29, 2022, the Company's Board decided to not undertake the reverse stock split and authorized share reduction, which Company stockholders approved at the Company's 2022 Annual Meeting of Stockholders, by the expiration date of December 31, 2022.

## **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

In 2022, many companies across a variety of sectors were still having disruptions, shortages, and other supply chain-related issues. In the biopharmaceutical sector, delays and interruptions in the supply chain have been particularly pronounced. During 2022, we were able to effectively manage our supply of prescription drug candidates in a manner that avoided any significant interruptions to our clinical programs.

## Federal Regulation of Therapeutic Products

All of the prescription drug candidates 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 require 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 COO, director of clinical operations, clinical research associates, information technology manager, and patient advocacy 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.

Employee health and safety in the workplace is one of the Company's core values. The COVID-19 pandemic has underscored for us the importance of keeping our employees and contractors safe and healthy. In response to the pandemic, the Company has taken actions aligned with the WHO and the Centers for Disease Control and Prevention to protect its workforce so they can more safely and effectively perform their work. During the past three years, employees have worked remotely to ensure their safety, while continuing to perform their duties as they would have.

### **Available Information**

Our website is located at [www.provectusbio.com](http://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>.

## 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, 2022, we have incurred net losses of approximately \$250 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 2023 and beyond, and our ability to obtain the necessary funding is uncertain.***

We need additional capital in 2023 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, 2021, 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. As of December 31, 2022, 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 4<sup>th</sup> quarter 2022. The remaining 2021 notes is \$1,075,000.

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. As of December 31, 2022, the Company had received 2022 Notes proceeds of \$752,500, as defined below, of which \$677,500 is from a related party investor (a Company director) in connection with the 2022 Financing.

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 \$1,431,707 at December 31, 2022, which includes \$1,410,102 of restricted cash resulting from a grant received from the State of Tennessee. The Company's working capital deficiency was \$6,293,198 and \$4,258,679 as of December 31, 2022 and December 31, 2021, 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, (iii) Bruce Horowitz, our COO, who is an independent contractor, (iv) Eric Wachter, Ph.D., our Chief Technology Officer (“CTO”), who is an employee, and (v) 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.

## **Risks Related to SARS-CoV-2**

***We are subject to risks associated with a pandemic, epidemic or outbreak of a contagious disease, such as the ongoing SARS-CoV-2 pandemic, which may affect our future access to liquidity and materially adversely affect our business operations, results of operations and financial condition.***

SARS-CoV-2 was reportedly first identified in late-2019 and subsequently declared a global pandemic by the World Health Organization on March 11, 2020. As a result of the SARS-CoV-2 pandemic, many companies have experienced disruptions of their operations and the markets they serve. The Company has taken several temporary precautionary measures intended to help ensure the well-being of its employees and contractors and to minimize business disruption. The Company considered the impact of SARS-CoV-2 pandemic on its business and operational assumptions and estimates, and determined there were no material adverse impacts on the Company’s results of operations and financial position at December 31, 2022.

The full extent of the SARS-CoV-2 pandemic impacts on the Company's operations and financial condition is still uncertain. The Company has experienced slower than normal enrollment and treatment of patients, and a prolonged SARS-CoV-2 pandemic could have a material adverse impact on the Company's business and financial results, including the timing and ability of the Company to raise capital, initiate and/or complete current and/or future preclinical studies and/or clinical trials; disrupt the Company's regulatory activities; and/or have other adverse effects on the Company's clinical development.

**ITEM 1B. UNRESOLVED STAFF COMMENTS.**

None.

**ITEM 2. PROPERTIES.**

We 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.

**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 28, 2023, we had 821 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, 2022, the Company issued 50,000 shares of common stock as incentive compensation with a value of \$3,025.

During the year ended December 31, 2022, the Company did not issue any warrants.

During the year ended December 31, 2021, the Company issued an aggregate of 300,000 shares of immediately vested restricted common stock with a grant date value of \$23,199 for services.

During the year ended December 31, 2021, the Company issued three-year immediately vested warrants to a board member to purchase an aggregate of 25,000 shares of common stock with an exercise price of \$0.28620 per share.

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 2023 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 Nonproprietary 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, <sup>131</sup>I rose bengal (Robengatope® [rose bengal sodium <sup>131</sup>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 rigorously and methodically assess 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, 2022 and 2021

### Overview

Grant revenue was \$989,042 for the year ended December 31, 2022, compared to \$0 for the year ended December 31, 2021. The increase was driven by grant revenue recognized related to qualifying expenses that were incurred and included within research and development on the consolidated statements of operations. Total operating expenses were \$4,416,988 for the year ended December 31, 2022, a decrease of \$255,266 or 5.5% compared to the year ended December 31, 2021. The decrease was driven by our continued transformation and process improvement efforts within the Company, along with lower clinical trial and research expenses, reduced legal fees and lower rent expense. Net loss for the year ended December 31, 2022 was \$3,554,683, a decrease of \$1,984,860 or 35.8% compared to the year ended December 31, 2021, which resulted from reduced costs incurred in connection with our preclinical and clinical trial programs, general and administrative costs, and interest expense due to the conversion of the 2017 and 2020 Notes.

	For the Years Ended December 31,		Increase/ (Decrease)	% Change
	2022	2021		
Grant Revenue .....	\$ 989,042	\$ -	\$ 989,042	0.0%
Operating Expenses:				
Research and development .....	2,389,360	2,608,357	(218,997)	-8.4%
General and administrative .....	2,027,628	2,063,897	(36,269)	-1.8%
Total Operating Expenses .....	4,416,988	4,672,254	(255,266)	-5.5%
Total Operating Loss .....	(3,427,946)	(4,672,254)	1,244,308	-26.6%
Other Income/(Expense):				
Research and development tax credit .....	36,954	31,315	5,639	18.0%
Gain from forgiveness of PPP loan and interest .....	-	63,094	(63,094)	-100.0%
Interest expense, net.....	(163,691)	(961,698)	798,007	-83.0%
Total Other Expense, Net.....	(126,737)	(867,289)	740,552	-85.4%
Net Loss .....	\$ (3,554,683)	\$ (5,539,543)	\$ 1,984,860	-35.8%

### Grant Revenue

For the years ended December 31, 2022 and 2021, there was \$989,042 and \$0, 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 \$2,389,360 for the year ended December 31, 2022, a decrease of \$218,997 or 8.4% compared to \$2,608,357 for the year ended December 31, 2021. The decrease was due to lower clinical trial cost and lower rent expense, partially offset by increased insurance costs.

The following table summarizes our research and development expenses incurred during the years ended December 31, 2022 and 2021:

	For the Years Ended December 31,		Increase/(Decrease)	% Change
	2022	2021		
Research and development:				
Clinical trial and research expenses .....	1,833,037	2,064,125	\$ (231,088)	-11.2%
Depreciation/amortization .....	7,458	8,647	(1,189)	13.8%
Insurance.....	230,947	207,556	23,391	11.3%
Payroll and taxes.....	273,177	266,514	6,663	2.5%
Rent and utilities .....	44,741	61,515	(16,774)	-27.3%
Total research and development .....	\$ 2,389,360	\$ 2,608,357	\$ (218,997)	-8.4%

## General and Administrative

General and administrative expenses were \$2,027,628 for the year ended December 31, 2022, a decrease of \$36,269 or 1.8% compared to \$2,063,897 for the year ended December 31, 2021. The decrease was due to (i) lower legal fees, (ii) lower rent expense, and (iii) lower other general and administrative cost, partially offset by (iv) higher insurance cost, (v) higher professional fees, and (vi) higher payroll and related taxes due to an additional employee.

The following table summarizes our general and administrative expenses incurred during the years ended December 31, 2022 and 2021:

	For the Years Ended December 31,		Increase/(Decrease)	% Change
	2022	2021		
General and administrative:				
Depreciation.....	\$ 3,437	\$ 4,218	\$ (781)	-18.5%
Directors fees .....	385,000	385,000	-	0.0%
Insurance.....	182,897	161,992	20,905	12.9%
Legal fees.....	521,632	590,779	(69,147)	-11.7%
Other general and administrative cost.....	12,288	63,679	(51,391)	-80.7%
Payroll and taxes.....	249,777	230,898	18,879	8.2%
Professional fees .....	649,834	591,356	58,478	9.9%
Rent and utilities .....	23,196	31,055	(7,859)	-25.3%
Foreign currency translation .....	(433)	4,920	(5,353)	-108.8%
Total general and administrative.....	<u>\$ 2,027,628</u>	<u>\$ 2,063,897</u>	<u>\$ (36,269)</u>	<u>-1.8%</u>

## Other Income/(Expense)

Research and development tax credits were \$36,954 for the year ended December 31, 2022, an increase of \$5,639, compared to \$31,315 for the year ended December 31, 2021.

Gain from extinguishment decreased from \$63,094 for the year ended December 31, 2021 to \$0 for the year ended December 31, 2022 due to the forgiveness of the PPP Loan and interest in 2021.

Interest expense decreased by \$798,007 from \$961,698 for the year ended December 31, 2021 to \$163,691 for the year ended December 31, 2022. The decrease was due to the conversion of the 2017 and 2020 Notes into shares of Series D and Series D-1 Preferred Stock.

The following table summarizes our Other Income/(Expenses) incurred during the years ended December 31, 2022 and 2021:

	For the Years Ended December 31,		Increase/ (Decrease)	% Change
	2022	2021		
Other Income/(Expense):				
Research and development tax credit .....	\$ 36,954	\$ 31,315	\$ 5,639	-
Gain from extinguishment .....	-	63,094	(63,094)	0.0%
Interest income and interest expense .....	(163,691)	(961,698)	798,007	-83.0%
Total Other Expenses, Net .....	<u>\$ (126,737)</u>	<u>\$ (867,289)</u>	<u>\$ 740,552</u>	<u>-85.4%</u>

## Liquidity and Going Concern

Our cash, and restricted cash were \$1,431,707 at December 31, 2022, which includes the \$1,410,102 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 \$249,588,641 as of December 31, 2022. 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 \$4,614,528 for accounts payable and accrued expenses (including lease liabilities) and a \$239,394 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 \$1,827,500 plus accrued interest will mature one year from the date of the notes. Cash requirements for long-term liabilities include \$73,376 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 2023 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, 2022 and 2021, 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, 2022 and 2021 in the amounts of \$3,041,472 and \$1,013,304, respectively. 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 items in the aggregate amount of \$66,803, plus \$446,408 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, 2021 was primarily due to cash used to fund a net loss of \$5,539,543, adjusted for non-cash expenses in the aggregate amount of \$54,717, plus \$4,471,522 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, 2022 and 2021 was \$1,367,841 and \$4,024,046, respectively. During the year ended December 31, 2022, we received \$1,627,500 proceeds from the issuance of convertible notes payable and \$259,659 for the repayment of short-term note payable. During the year ended December 31, 2021, we received \$3,160,000 proceeds from the issuance of convertible notes payable, \$962,223 from the exercise of warrants and \$150,000 from the investment to purchase Series D-1 Preferred Stock, less \$248,177 for repayment of short-term note payable.

#### **Critical Accounting Estimates and Policies**

The preparation of financial statements and related disclosures must be in conformity with U.S. GAAP. These accounting principles require us to make estimates and judgments that can affect the reported amounts of assets and liabilities as of the date of the financial statements as well as the reported amounts of revenue and expense during the periods presented. We believe that the estimates and judgments upon which it relies are reasonably based upon information available to us at the time that it makes these estimates and judgments. To the extent that there are material differences between these estimates and actual results, our financial results will be affected. A critical accounting estimate to our financial statements include stock-based compensation, research and development expenses, grant, and valuation of income taxes. The accounting policies that reflect our more significant estimates and judgments and which we believe are the most critical to aid in fully understanding and evaluating our reported financial results are described below.

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.

### *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.

If the instrument is determined to not be a derivative liability, the Company then evaluates for the existence of a beneficial conversion feature by comparing the commitment date fair value to the effective conversion price of the 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.**

**INDEX TO FINANCIAL STATEMENTS**

	<u>Page</u>
Report of Independent Registered Public Accounting Firm (Marcum LLP, PCAOB ID No. 688).....	F-1
Consolidated Balance Sheets as of December 31, 2022 and 2021.....	F-2
Consolidated Statements of Operations for the Years Ended December 31, 2022 and 2021 .....	F-3
Consolidated Statements of Comprehensive Loss for the Years Ended December 31, 2022 and 2021 .....	F-4
Consolidated Statements of Changes In Stockholders' Deficit for the Years Ended December 31, 2022 and 2021 .....	F-5
Consolidated Statements of Cash Flows for the Years Ended December 31, 2022 and 2021 .....	F-6
Notes to Consolidated Financial Statements.....	F-7 – F-23

## **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. and Subsidiaries (the “Company”) as of December 31, 2022 and 2021, 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, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

### **Explanatory Paragraph – Going Concern**

The accompanying consolidated 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 significant working capital deficit, has incurred significant losses 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 consolidated 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 29, 2023

**PROVECTUS BIOPHARMACEUTICALS, INC.**

**CONSOLIDATED BALANCE SHEETS**

	<b>December 31, 2022</b>	<b>December 31, 2021</b>
<b>Assets</b>		
Current Assets:		
Cash and cash equivalents .....	\$ 21,605	\$ 682,984
Restricted cash .....	1,410,102	2,423,958
Short-term receivables.....	394	5,107
Prepaid expenses and other current assets .....	467,081	329,908
Total Current Assets .....	1,899,182	3,441,957
Equipment and furnishings, less accumulated depreciation of \$102,073 and \$91,178, respectively .....	20,941	31,836
Operating lease right-of-use asset .....	117,123	39,563
Total Assets .....	<u>\$ 2,037,246</u>	<u>\$ 3,513,356</u>
<b>Liabilities and Stockholders' Deficit</b>		
Current Liabilities:		
Accounts payable .....	\$ 2,094,258	\$ 1,287,459
Deposit for Series D-1 Preferred Stock .....	-	150,000
Unearned grant revenue.....	1,510,958	2,500,000
Other accrued expenses .....	2,404,012	2,002,486
Accrued interest .....	30,844	10,578
Accrued interest - related parties.....	40,992	6,044
Notes payable .....	239,394	238,452
Convertible notes payable .....	625,000	1,260,000
Convertible notes payable - related parties.....	1,202,500	200,000
Operating lease liability, current portion .....	44,422	45,617
Total Current Liabilities.....	8,192,380	7,700,636
Operating lease liability, non-current portion .....	73,376	-
Total Liabilities.....	<u>8,265,756</u>	<u>7,700,636</u>
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, 2022 and December 31, 2021; aggregate liquidation preference of \$14,164,889 at December 31, 2022 and December 31, 2021 .....	12,373	12,373
Series D-1 Convertible Preferred Stock; 11,241,000 shares designated; 9,746,626 and 9,218,449 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively; aggregate liquidation preference of \$111,578,880 and \$105,532,804 at December 31, 2022 and December 31, 2021, respectively .....	9,747	9,219
Common stock; par value \$0.001 per share; 1,000,000,000 shares authorized; 419,497,119 and 419,447,119 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively .....	419,497	419,447
Additional paid-in capital .....	242,954,193	241,440,106
Accumulated other comprehensive loss .....	(35,679)	(34,467)
Accumulated deficit .....	(249,588,641)	(246,033,958)
Total Stockholders' Deficit.....	<u>(6,228,510)</u>	<u>(4,187,280)</u>
Total Liabilities and Stockholders' Deficit .....	<u>\$ 2,037,246</u>	<u>\$ 3,513,356</u>

See accompanying notes to consolidated financial statements.

**PROVECTUS BIOPHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF OPERATIONS**

	<b>For the Years Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Grant Revenue .....	\$ 989,042	\$ -
Operating Expenses:		
Research and development .....	2,389,360	2,608,357
General and administrative .....	2,027,628	2,063,897
Total Operating Expenses .....	<u>4,416,988</u>	<u>4,672,254</u>
Total Operating Loss .....	<u>(3,427,946)</u>	<u>(4,672,254)</u>
Other Income/(Expense):		
Research and development tax credit .....	36,954	31,315
Gain from forgiveness of PPP loan and interest .....	-	63,094
Interest expense, net.....	<u>(163,691)</u>	<u>(961,698)</u>
Total Other Expense, Net.....	<u>(126,737)</u>	<u>(867,289)</u>
<b>Net Loss</b> .....	<u>\$ (3,554,683)</u>	<u>\$ (5,539,543)</u>
Basic and Diluted Loss Per Common Share .....	<u>\$ (0.01)</u>	<u>\$ (0.01)</u>
Weighted Average Number of Common Shares Outstanding - Basic and Diluted.....	<u>419,470,338</u>	<u>408,223,004</u>

See accompanying notes to consolidated financial statements.

**PROVECTUS BIOPHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

	<b>For the Years Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Net Loss .....	\$ (3,554,683)	\$ (5,539,543)
Other Comprehensive Loss:		
Foreign currency translation adjustments .....	(1,212)	(370)
Total Comprehensive Loss .....	<u>\$ (3,555,895)</u>	<u>\$ (5,539,913)</u>

See accompanying notes to consolidated financial statements.



**PROVCTUS BIOPHARMACEUTICALS, INC.**

**CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT  
FOR THE YEARS ENDED DECEMBER 31, 2022 AND 2021**

	Preferred Stock		Preferred Stock		Preferred Stock		Common Stock		Additional	Accumulated		
	Series B		Series D		Series D-1		Common Stock		Paid-In	Other	Accumulate	
	Share	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Comprehensiv	Deficit	Total
	s			t		t				e	d	
<b>Balance at January 1, 2021</b>	100	\$ -	-	\$ -	-	\$ -	398,807,037	398,808	209,923,347		(240,494,415)	(30,206,357)
Common stock issued upon exercise of warrants	-	-	-	-	-	-	18,052,966	18,053	944,170	-	-	962,223
Stock-based compensation:												
Common stock	-	-	-	-	-	-	300,000	300	22,899	-	-	23,199
Warrants	-	-	-	-	-	-	-	-	488	-	-	488
Conversion of Series B Preferred Stock to Common Stock	(100)	-	-	-	-	-	65,666	65	(65)	-	-	-
Conversion of PRH Notes to Series D Preferred Stock	-	-	12,373,247	12,373	-	-	-	-	3,528,849	-	-	3,541,222
Conversion of PRH Notes to Series D1 Preferred Stock	-	-	-	-	9,440,594	9,441	-	-	27,022,417	-	-	27,031,858
Conversion of Series D-1 Preferred Stock to Common stock	-	-	-	-	(222,145)	(222)	2,221,450	2,221	(1,999)	-	-	-
Comprehensive loss:												
Net loss	-	-	-	-	-	-	-	-	-	-	(5,539,543)	(5,539,543)
Other comprehensive loss	-	-	-	-	-	-	-	-	-	(370)	-	(370)
<b>Balance at December 31, 2021</b>	-	\$ -	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)
<b>Balance at December 31, 2022</b>	-	\$ -	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)

See accompanying notes to consolidated financial statements.

**PROVECTUS BIOPHARMACEUTICALS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	<b>For the Years Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>Cash Flows From Operating Activities:</b>		
Net loss.....	\$ (3,554,683)	\$ (5,539,543)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation.....	3,025	23,688
Non-cash lease expense .....	52,883	81,258
Depreciation.....	10,895	12,865
Gain on forgiveness of PPP Loan and interest .....	-	(63,094)
Changes in operating assets and liabilities		
Short term receivables.....	4,481	(1,449)
Prepaid expenses and other current assets.....	122,914	265,957
Accounts payable .....	807,073	331,148
Unearned grant revenue .....	(989,042)	2,500,000
Other accrued expenses.....	402,390	502,581
Operating lease liability .....	(58,262)	(83,549)
Accrued interest .....	156,854	956,834
<b>Net Cash Used In Operating Activities.....</b>	<b>(3,041,472)</b>	<b>(1,013,304)</b>
<b>Cash Flows From Financing Activities:</b>		
Proceeds from issuance of convertible notes payable.....	625,000	2,960,000
Proceeds from issuance of convertible notes payable - related parties .....	1,002,500	200,000
Repayment of short-term note payable .....	(259,659)	(248,177)
Deposit for purchase of Series D-1 Preferred Stock.....	-	150,000
Proceeds from exercise of warrants .....	-	962,223
<b>Net Cash Provided By Financing Activities .....</b>	<b>1,367,841</b>	<b>4,024,046</b>
<b>Effect of exchange rates on cash, cash equivalents, and restricted cash.</b>	<b>(1,604)</b>	<b>(1,031)</b>
<b>Net (Decrease) Increase In Cash, Cash Equivalents, and Restricted Cash.....</b>	<b>(1,675,235)</b>	<b>3,009,711</b>
<b>Cash, Cash Equivalents, and Restricted Cash, Beginning of Year .....</b>	<b>3,106,942</b>	<b>97,231</b>
<b>Cash, Cash Equivalents, and Restricted Cash, End of Year .....</b>	<b>\$ 1,431,707</b>	<b>\$ 3,106,942</b>
Cash, cash equivalents and restricted cash consisted of the following:		
Cash and cash equivalents.....	\$ 21,605	\$ 682,984
Restricted cash .....	1,410,102	2,423,958
	<b>\$ 1,431,707</b>	<b>\$ 3,106,942</b>
<b>Supplemental Disclosures of Cash Flow Information:</b>		
Cash paid during the year for:		
Interest .....	\$ -	\$ -
Income taxes .....	\$ -	\$ -
Non-cash investing and financing activities:		
Purchase of insurance policies financed by short-term note payable .....	\$ (203,175)	\$ (273,347)
Deposit applied to equity issuances .....	\$ (150,000)	\$ -
Conversion of non-amended 2017 Notes to Series D Preferred Stock .....	\$ -	\$ 3,541,222
Conversion of amended 2017 Notes and 2020 Notes to Series D-1 Preferred Stock .....	\$ -	\$ 27,031,858
Conversion of Series D-1 Preferred Stock to Common stock .....	\$ -	\$ 222
Conversion of 2021 Notes to Series D-1 Preferred Stock .....	\$ 1,361,640	\$ -
Right-of-use asset for lease liability .....	\$ (130,443)	\$ -

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 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-modulators called halogenated xanthenes (“HXs”). Our lead 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. Secondly, 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 ClinicalTrials.gov.

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

The Company’s small molecule HX medical science platform comprises a number of different drug product candidates and preclinical pharmaceutical-grade RBS formulations using different concentrations and 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; proof-of-concept *in vivo* drug discovery programs in oncology, hematology, wound healing, and animal health; and preclinical *in vitro* drug discovery programs in infectious diseases and tissue regeneration and repair.

#### *Risks and Uncertainties*

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.

Severe acute respiratory syndrome (“SARS”) coronavirus (“CoV”) 2 (“SARS-CoV-2”) was first identified in late-2019 and subsequently declared a global pandemic by the World Health Organization on March 11, 2020. As a result of the SARS-CoV-2 pandemic, many companies have experienced disruptions of their operations and the markets they serve. The Company has taken several temporary precautionary measures intended to help ensure the well-being of its employees and contractors and to minimize business disruption. The Company considered the impact of SARS-CoV-2 pandemic on its business and operational assumptions and estimates, and determined there were no material adverse impacts on the Company’s results of operations and financial position at December 31, 2022.

The full extent of the SARS-CoV-2 pandemic impacts on the Company’s operations and financial condition is uncertain. The Company has experienced slower than normal enrollment and treatment of patients, and a prolonged SARS-CoV-2 pandemic could have a material adverse impact on the Company’s business and financial results, including the timing and ability of the Company to raise capital, initiate and/or complete current and/or future preclinical studies and/or clinical trials, disrupt the Company’s regulatory activities, and/or have other adverse effects on the Company’s clinical development.

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 \$1,431,707 at December 31, 2022 which includes \$1,410,102 of restricted cash resulting from a grant received from the State of Tennessee. The Company's working capital deficiency was \$6,293,198 and \$4,258,679 as of December 31, 2022 and 2021, respectively. The decline in working capital is primarily driven by lower cash on hand and higher accounts payable. 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.

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.

## ***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.

### Cash and Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. As of December 31, 2022 and 2021, the Company's cash equivalents consisted of Treasury bills of \$0 and \$42,594, respectively.

### 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 \$1,089,898. See Note 14, Grants.

### Cash Concentrations

Cash, cash equivalents, 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, 2022 and 2021, the Company had cash, cash equivalent, and restricted cash balances in excess of FDIC insurance limits of \$1,181,707 and \$2,856,942, 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, 2022 and 2021.

### Related Party Receivables

Management estimates the reserve for uncollectibility based on existing economic conditions, the financial conditions of the current and former employees, and the amount and age of past due receivables. Receivables are considered past due if full payment is not received by the contractual due date. Past due amounts are generally written off against the reserve for uncollectibility only after all collection attempts have been exhausted. See Note 8, Short-term Receivables.

### 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 adopted ASC 842 effective January 1, 2019 and applied the available practical expedients to the existing lease which expired on June 30, 2022. The Company applied the standard to the current lease agreement in the same manner. The most significant impact upon adoption was the recognition of ROU assets and lease liabilities for operating leases.

## 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 2022 or 2021.

## 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.

If the instrument is determined to not be a derivative liability, the Company then evaluates for the existence of a beneficial conversion feature by comparing the commitment date fair value to the effective conversion price of the 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:

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Warrants.....	475,000	512,500
Options.....	3,425,000	3,625,000
Convertible preferred stock .....	109,839,507	104,557,737
2021 unsecured convertible notes.....	3,973,871	-
2022 unsecured convertible notes.....	2,662,523	-
Total potentially dilutive shares.....	<u>120,375,901</u>	<u>108,695,237</u>

## 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, 2022 and 2021. 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 \$17,373 and \$383,447 at December 31, 2022 and \$22,053 and \$407,851 at December 31, 2021, respectively) are translated into the United States Dollar at the balance sheet date, and net expense accounts of \$4,503 and \$85,052 for the years ended December 31, 2022 and 2021, 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 Standards

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 plans to adopt ASU 2020-06 on January 1, 2023 and does not believe the adoption will have a material impact on the Company's consolidated financial statements or disclosures.

## Recently Adopted Accounting Pronouncements

In October 2020, the FASB issued ASU 2020-10 "*Codification Improvements*", which improves consistency by amending the Codification to include all disclosure guidance in the appropriate disclosure sections and clarifies application of various provisions in the Codification by amending and adding new headings, cross referencing to other guidance, and refining or correcting terminology. The guidance is effective for the Company beginning in the first quarter of fiscal year 2022 with early adoption permitted. The Company adopted this standard on January 1, 2022 and it did not have a material effect on its consolidated financial statements.

On May 3, 2021, the FASB issued ASU 2021-04, *Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options*. This new standard provides clarification and reduces diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (such as warrants) that remain equity classified after modification or exchange. This standard is effective for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Issuers should apply the new standard prospectively to modifications or exchanges occurring after the effective date of the new standard. Early adoption is permitted, including adoption in an interim period. If an issuer elects to adopt the new standard early in an interim period, the guidance should be applied as of the beginning of the fiscal year that includes that interim period. The Company adopted this standard on January 1, 2022 and it did not have a material effect on its consolidated financial statements.

In November 2021, the FASB issued ASU 2021-10, *Government Assistance (Topic 832)*, which increases the transparency of government assistance including the disclosure of (1) the type of assistance, (2) an entity's accounting for the assistance, and (3) the effect of the assistance on an entity's financial statements. The amendments in this update are effective for the Company in the financial statements issued for annual periods beginning after December 15, 2021. The Company adopted this standard on January 1, 2022 and it did not have a material effect on its consolidated financial statements.

## **4. Other Accrued Expenses**

The following table summarizes the other accrued expenses at December 31, 2022 and 2021:

	<b>For the Years Ended</b>	
	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Accrued payroll and taxes.....	\$ 314,160	\$ 174,533
Accrued vacation .....	69,077	42,871
Accrued directors' fees .....	1,945,589	1,560,589
Accrued other expenses .....	75,186	224,493
Total Other Accrued Expenses .....	<u>\$ 2,404,012</u>	<u>\$ 2,002,486</u>



## 5. Convertible Notes Payable

The following summarizes convertible note activity during the years ended December 31, 2022 and 2021:

	<b>2017 Notes</b>	<b>Amended 2017 Notes</b>	<b>2020 Notes</b>	<b>2021 Notes</b>	<b>2022 Notes</b>	<b>Total</b>
Balance at January 1, 2021 .....	\$ 2,712,000	\$ 17,355,000	\$ 3,325,000	\$ -	\$ -	\$ 23,392,000
Issuance .....	-	-	1,700,000	1,460,000	-	3,160,000
Conversions .....	(2,712,000)	(17,355,000)	(5,025,000)	-	-	(25,092,000)
Balance at December 31, 2021 .....	-	-	-	1,460,000	-	1,460,000
Issuance .....	-	-	-	875,000	752,500	1,627,500
Conversions .....	-	-	-	(1,260,000)	-	(1,260,000)
Balance at December 31, 2022 .....	\$ -	\$ -	\$ -	\$ 1,075,000	\$ 752,500	\$ 1,827,500

### 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 and they do not represent a beneficial conversion feature because the effective conversion price is not at a discount to the commitment date market price.

On September 20, 2022, the Board approved the closure of the 2021 Financing. As of December 31, 2022, the Company had received 2021 Notes (defined above) aggregate proceeds of \$2,335,000, of which \$525,000 is from related party investors (an officer and director of the Company).

### 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. As of December 31, 2022, the Company had received proceeds of \$752,500 from 2022 Notes, (defined below), of which \$677,500 was from a related party investor (a Company director) in connection with the 2022 Financing.

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 an 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 and they do not represent a beneficial conversion feature because the effective conversion price is not at a discount to the commitment date market price.

#### 2021 Conversions of 2017 and 2020 Notes into Preferred Stock

The following summarizes the conversion activity during the year ended December 31, 2021:

	<b>2021 Conversions Into Preferred Stock</b>			
	<b>Series D</b>	<b>Series D-1</b>		<b>Total</b>
	<b>2017 Notes</b>	<b>Amended 2017 Notes</b>	<b>2020 Notes</b>	
Principal converted .....	\$ 2,712,000	\$ 17,355,000	\$ 5,025,000	\$ 25,092,000
Accrued interest converted .....	829,222	4,332,286	319,572	5,481,080
Total converted .....	\$ 3,541,222	\$ 21,687,286	\$ 5,344,572	\$ 30,573,080
Conversion price .....	\$ 0.2862	\$ 2.862	\$ 2.862	
Total shares .....	<u>12,373,247</u>	<u>7,573,157</u>	<u>1,867,437</u>	<u>21,813,841</u>

Any fractional shares issuable pursuant to the formula were rounded up to the next whole share of Series D and Series D-1 Preferred Shares.

The 2017 Notes originally provided that they were convertible into a new series of preferred stock at a price per share equal to \$0.2862 (the "Original Conversion Price"). In order to ensure that the Company had sufficient authorized shares of preferred stock into which the 2017 Notes would convert, yet keep the economic terms of the 2017 Notes substantially equivalent, on February 26, 2019, the Company entered into amendments (the "Amendments") to the 2017 Notes (as amended, the "Amended 2017 Notes") with a large majority of the holders of 2017 Notes to increase the conversion price by 10 times from \$0.2862 to \$2.862 (the "New Conversion Price") and to change the conversion ratio by providing that one share of Preferred Stock would be convertible into 10 shares of common stock (the "New Conversion Ratio"). The impact of the Amendments was to reduce by 10 times the number of shares of preferred stock into which the 2017 Notes would convert, while keeping the economic terms the same.

The 2020 Notes had substantially similar terms to the Amended 2017 Notes, including being convertible into preferred stock at the New Conversion Price, with the Preferred Stock being convertible into Common Stock at the New Conversion Ratio.

In order to (i) address the fact that a small minority of the holders of 2017 Notes did not execute the Amendments and (ii) ensure economic fairness for all of the holders of the 2017 Notes and 2020 Notes, on June 17, 2021, the Company designated two separate series of preferred stock into which the 2017 Notes and 2020 Notes would convert: (i) the Company's Series D Convertible Preferred Stock, par value \$0.001 per share was designated for the holders of 2017 Notes who did not execute the Amendments and (ii) the Company's Series D-1 Preferred Stock, par value \$0.001 per share was designated for issuance upon the conversion of Amended 2017 Notes, 2020 Notes, 2021 Notes, and 2022 Notes.

On June 20, 2021, principal and interest in the aggregate amount of \$3,541,222, representing all of the outstanding non-amended 2017 Notes, was converted into 12,373,247 shares of Series D Convertible Preferred Stock at the Original Conversion Price of \$0.2862. Further on June 20, 2021, principal and interest in the aggregate amount of \$27,031,858, representing all of the outstanding Amended 2017 Notes and outstanding 2020 Notes was converted into 9,440,594 shares of Series D-1 Convertible Preferred Stock at the New Conversion Price of \$2.862. Any fractional shares issuable pursuant to the formula were rounded up to the next whole share of Series D and Series D-1 Preferred Shares. See Note 9, Stockholders' Deficit for additional information on the Series D and Series D-1 Preferred Stock.

As a result of the conversion of the 2017 Notes and 2020 Notes into convertible preferred stock, all the security interests of these Notes in the Company's intellectual property were released.

#### 2022 Conversions of 2021 Notes into Preferred Stock

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

	<b>Series D-1 Preferred Stock</b>
Principal converted .....	\$ 1,260,000
Accrued interest converted .....	101,640
Total converted .....	\$ 1,361,640
Conversion price .....	\$ 2.862
Total shares .....	<u>475,766</u>

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.

#### **6. Notes Payable**

On April 20, 2020, the Company received a \$62,500 loan under the CARES Act PPP (the "PPP Loan"). The PPP provides for loans to qualifying businesses for amounts of up to 2.5 times certain of the borrower's average monthly payroll expenses. On May 20, 2021, the Company applied for forgiveness of the PPP Loan. On June 2, 2021, the Company was awarded full forgiveness of the PPP Loan and accrued interest. During the year ended December 31, 2021, the Company recognized a gain on forgiveness of the PPP loan of \$62,500 and interest of \$594.

The Company obtained short-term financing from AFCO Insurance Premium Finance for our commercial insurance policies. As of December 31, 2022 and December 31, 2021, the balance of the note payable was \$239,394 and \$238,452, respectively.

#### **7. Related Party Transactions**

During the years ended December 31, 2022 and 2021, the Company paid Mr. Bruce Horowitz (Capital Strategists) consulting fees of \$169,600 and \$169,600, respectively, for services rendered. Director fees for Mr. Horowitz for the year ending December 31, 2022 and 2021 were \$75,000 and \$75,000, respectively. Accrued director fees for Mr. Horowitz as of December 31, 2022 and 2021 were \$356,250 and \$281,250, respectively. Total amount owed to Capital Strategists as of December 31, 2022 and 2021 were \$212,000 and \$127,200, respectively. Mr. Horowitz serves as both COO and a Director.

See Note 5 and Note 8 for details of other related party transactions.

Director fees during the years ended December 31, 2022 and 2021 were \$385,000 and \$385,000, respectively. Accrued directors' fees as of December 31, 2022 and 2021 were \$1,945,589 and \$1,560,589, respectively.

## **8. Short-term Receivables**

Receivables at December 31, 2022 and 2021, 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, 2022 and 2021, which represents the amount Culpepper owes to the Company under the 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, 2022, 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 B Preferred Stock

On August 25, 2016, the Company filed the Series B Certificate of Designation with the Delaware Secretary of State. The Series B Certificate of Designation provides for the issuance of the Series B Preferred Stock with a par value of \$0.001 per share and a stated value of \$25.00 per share. The Series B Preferred Stock has no voting rights. The holders of Series B Preferred Stock are entitled to receive cumulative dividends at the rate of 8% per annum of the stated value per share, until the fifth anniversary of the date of issuance of the Series B Preferred Stock, at which time the Series B Preferred Stock automatically converts into common stock at the adjusted conversion price of \$0.0533.

During the year ended December 31, 2021, 100 shares of outstanding Series B Preferred Stock automatically converted, at the fifth-year anniversary of their issuance, into 65,666 shares of common stock, which represents \$3,500 (\$2,500 of stated value plus \$1,000 of cumulative dividends) divided by the adjusted conversion price. On March 30, 2022, the Company filed a Certificate of Elimination with the State of Delaware eliminating the Series B Preferred Stock.

### Series D and 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. The Board of Directors of the Company approved each of the Certificates of Designation on June 14, 2021, and each Certificate of Designation was filed with the Delaware Secretary of State on June 17, 2021. The Series D Certificate of Designation established and designated 12,374,000 shares of Series D Preferred Stock. The Series D-1 Certificate of Designation was established and initially designated 9,441,000 shares of Series D-1 Preferred Stock.

On June 20, 2021, the Company issued 12,373,247 shares of Series D Preferred Stock upon the conversion of all of the outstanding 2017 Notes at the Original Conversion Price of \$0.2862 and issued 9,440,594 shares of Series D-1 Preferred Stock upon the conversion of all outstanding Amended 2017 Notes and 2020 Notes at the New Conversion Price of \$2.862. See Note 5, Convertible Notes Payable for additional information on the conversion.

During the year ended December 31, 2021, a holder of 222,145 shares of Series D-1 Preferred Stock voluntarily converted the Preferred Stock into 2,221,450 shares of common stock.

On March 30, 2022, the Company amended the Certificate of Designation filed with the Delaware Secretary of State to increase the authorized shares of Series D-1 Preferred Stock to 11,241,000 shares.

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 fourth quarter of 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.

### *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.

### Common Stock Issuances

During the year ended December 31, 2021, the Company issued an aggregate of 300,000 shares of immediately vested restricted common stock with a grant date fair value of \$23,199 for services.

During the year ended December 31, 2021, the Company issued 2,221,450 shares of common stock upon the voluntary conversion of Series D-1 Preferred Stock.

During the year ended December 31, 2021, the Company issued 65,666 shares of common stock upon automatic conversion of Series B Preferred Stock.

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.

## 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. The stock options are exercised 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, 2022, 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, 2022 and 2021.

The following table summarizes option activity during the year ended December 31, 2022 and 2021:

	Shares	Weighted Average Exercise Price
Outstanding and exercisable at January 1, 2021 .....	4,800,000	\$ 0.46
Forfeited.....	(1,175,000)	0.89
Outstanding and exercisable at December 31, 2021 .....	3,625,000	\$ 0.32
Forfeited.....	(200,000)	0.86
Outstanding and exercisable at December 31, 2022 .....	3,425,000	\$ 0.29

As of December 31, 2022, the intrinsic value of outstanding and exercisable options was \$0.

The following table summarizes information about stock options outstanding at December 31, 2022:

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	2.90	2,425,000
\$ 0.29	100,000	2.90	100,000
\$ 0.67	200,000	0.60	200,000
\$ 0.75	550,000	2.90	550,000
\$ 0.88	150,000	1.60	150,000
	3,425,000	2.75	3,425,000

### Warrants

During the year ended December 31, 2022, the Company did not issue any warrants. On August 30, 2021, a total of 68,723,698 of August 2016 warrants expired.

During the year ended December 31, 2021, holders of warrants exercised warrants to purchase 18,052,966 shares of common stock at a price of \$0.053 per share. In connection with the exercises, the Company received cash proceeds of \$962,223 and issued 18,052,966 shares of common stock.

During the year ended December 31, 2021, the Company issued 25,000 three-year immediately vested warrants to an advisory board member to purchase an aggregate of 25,000 shares of common stock with exercise price of \$0.28620 per share. The warrants had an aggregate grant date fair value of \$488, which was recognized immediately within stock compensation in general and administrative expenses.

In applying the Black-Scholes option pricing model to warrants granted, the Company used the following assumptions:

	<b>For the Years Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Contractual terms (years).....	n/a	3.00
Expected volatility .....	n/a	92%
Risk-free interest rate.....	n/a	0.35%
Expected dividend .....	n/a	0.00%

The following table summarizes warrant activity during the year ended December 31, 2022 and 2021:

	<b>Number of Warrants</b>	<b>Weighted Average Exercise Price</b>
Outstanding and exercisable at January 1, 2021 .....	87,264,164	\$ 0.02
Granted .....	25,000	0.29
Exercised .....	(18,052,966)	0.05
Forfeited .....	(68,723,698)	0.05
Outstanding and exercisable at December 31, 2021 .....	512,500	\$ 0.92
Forfeited .....	(37,500)	0.29
Outstanding and exercisable at December 31, 2022 .....	475,000	\$ 0.97

As of December 31, 2022, the intrinsic value of outstanding and exercisable warrants was \$0.

The following table summarizes information about warrants outstanding at December 31, 2022:

<b>Warrants Outstanding</b>		<b>Warrants Exercisable</b>	
<b>Exercise Price</b>	<b>Outstanding Number of Warrant</b>	<b>Weighted Average Remaining Life In Years</b>	<b>Exercisable Number of Warrants</b>
\$ 0.290	87,500	0.85	87,500
\$ 1.00	18,000	1.39	18,000
\$ 1.12	366,000	1.39	366,000
\$ 2.00	3,500	1.39	3,500
	<u>475,000</u>	<u>1.29</u>	<u>475,000</u>

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, 2022 and 2021 are as follows:

	<b>Years ended December 31</b>	
	<b>2022</b>	<b>2021</b>
Domestic .....	\$ (3,550,182)	\$ (5,454,489)
Foreign.....	(4,501)	(85,053)
Net Pre-Tax Loss .....	<u>\$ (3,554,683)</u>	<u>\$ (5,539,542)</u>

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

		<b>Years ended December 31</b>	
		<b>2022</b>	<b>2021</b>
Federal:			
Current .....		\$ -	\$ -
Deferred .....	21.00%	538,915	295,524
State:			
Current .....		-	-
Deferred .....	5.14%	131,778	72,262
	<u>26.14%</u>	<u>670,693</u>	<u>367,786</u>
Change in valuation allowance .....		(670,693)	(367,786)
Income tax provision (benefit) .....		<u>\$ -</u>	<u>\$ -</u>

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

		<b>Years Ended December 31</b>	
		<b>2022</b>	<b>2021</b>
Tax benefit at federal statutory rate .....	(21.0)%	(21.0)%	(21.0)%
State income taxes, net of federal benefit .....	(5.1)%	(5.1)%	(5.1)%
Permanent differences .....	(3.7)%	(0.9)%	(0.9)%
Change in valuation allowance .....	(18.6)%	(7.2)%	(7.2)%
Prior year true-up .....	2.3%	2.4%	2.4%
Expiration of federal and state net operating loss carryforwards .....	49.1%	6.8%	6.8%
Expiration of warrants and options .....	1.0%	3.6%	3.6%
Conversion of accrued interest to preferred stock .....	0.00%	21.4%	21.4%
Miscellaneous .....	(0.7)%	0.0%	0.0%
Effective income tax rate .....	<u>0.0%</u>	<u>0.0%</u>	<u>0.0%</u>

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

		<b>December 31</b>	
		<b>2022</b>	<b>2021</b>
Deferred Tax Assets:			
Net operating loss carryforwards .....	\$	42,012,057	\$ 43,453,746
Research and development credit carryovers .....		3,229,869	3,049,608
Stock-based compensation .....		152,813	186,772
Intangible assets .....		337,558	227,397
Capitalized R&D expenditures .....		358,897	-
Contribution carryovers .....		10,062	10,062
Accrued liabilities .....		628,265	505,038
Gross deferred tax assets .....		<u>46,729,521</u>	<u>47,432,623</u>
Deferred Tax Liabilities:			
Depreciation .....		(3,915)	-
Prepaid expenses .....		(86,459)	(82,179)
Other .....		-	(40,604)
Gross deferred tax liabilities .....		<u>(90,374)</u>	<u>(122,783)</u>
Valuation allowance .....		<u>(46,639,147)</u>	<u>(47,309,840)</u>
Deferred tax asset, net of valuation allowance .....	\$	<u>-</u>	<u>\$ -</u>
Change in valuation allowance .....	\$	<u>670,693</u>	<u>\$ 367,786</u>



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 \$165 million, \$141 million, and \$143 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 \$145.6 million expire in various amounts between 2023 and 2037. Federal NOLS totaling \$19.9 million do not expire.

Year Generated	Year of Expiration	Amount
2003	2023	\$ 1,520,649
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	2,207,092
Total NOLS		<u>\$ 165,489,113</u>

State NOLS totaling \$140.7 million expire in various years between 2023 and 2037.

Year Generated	Year of Expiration	Amount
2008	2023	\$ 7,106,425
2009	2024	9,680,770
2010	2025	10,440,651
2011	2026	11,362,120
2012	2027	11,311,394
2013	2028	10,381,763
2014	2029	9,278,510
2015	2030	18,547,287
2016	2031	20,166,661
2017	2032	12,131,850
2018	2033	6,455,113
2019	2034	4,211,210
2020	2035	4,234,755
2021	2036	3,232,081
2022	2037	2,207,092
Total NOLS		<u>\$ 140,747,682</u>

Australia NOLS totaling \$143,370 do not expire.

<b>Year Generated</b>	<b>Year of Expiration</b>	<b>Amount</b>
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
Total NOLS		<u>\$ 143,370</u>

The Company has determined that there are no uncertain tax positions as of December 31, 2022 or 2021.

We file income tax returns in the U.S., Tennessee, and Australia. As of December 31, 2022, the U.S. federal and Tennessee tax years open to examination are 2019 through 2022. The Australia income tax return remains open to examination for 2020 through 2022.

To date, the Company's operations conducted by its Australian subsidiary consist primarily of research and development activities. As of December 31, 2022, 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, 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. Total expense for operating leases for the year ended December 31, 2021 was \$86,545, of which, \$57,697 was included within research and development and \$28,848 was included within general and administrative expenses on the consolidated statements of operations.

As of December 31, 2022, the Company had no leases that were classified as a financing lease. As of December 31, 2022, 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:

	<b>For The Years Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used in operating leases.....	\$ 62,944	\$ 82,678
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases.....	\$ 130,422	\$ -
<b>Weighted Average Remaining Lease Term</b>		
Operating leases.....	2.50 Years	0.50 Years
<b>Weighted Average Discount Rate</b>		
Operating leases.....	5.0% - 8.0%	8.0%

Future minimum payments under the non-cancellable lease as of December 31, 2022 were as follows:

Years	Amount
2023 .....	\$ 49,311
2024 .....	50,663
2025 .....	25,669
Total future minimum lease payments.....	125,643
Less: amount representing imputed interest.....	(7,845)
Total.....	<u>\$ 117,798</u>

### **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 2022 or 2021.

### **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, 2022, \$1,510,958 has been recorded as unearned Grant revenue liability on the accompanying audited consolidated balance sheets. The Company recorded \$989,042 and \$0 of Grant revenue during the years ended December 31, 2022 and 2021, respectively.

### **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 or 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, 2022, the Company entered into a 2022 Note with a related party investor (a Company Director) in the aggregate principal amount of \$600,000.

#### **Preferred Stock**

Subsequent to December 31, 2022, the Company issued an aggregate of 18,872 shares of Series D-1 Convertible Preferred Stock upon automatic conversion of a 2021 Note.

## **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, 2022.

### *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 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION.**

None.

**ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS.**

Not applicable.

### **PART III**

#### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE.**

The information called for by this item is incorporated herein by reference to the definitive Proxy Statement for our 2023 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 2023 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 2023 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 2023 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 2023 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).

<b>Exhibit No.</b>	<b>Description</b>
10.4	Controlled Equity Offering <sup>SM</sup> 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).



<b>Exhibit No.</b>	<b>Description</b>
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 29, 2023

PROVECTUS BIOPHARMACEUTICALS, INC.

By: /s/ Bruce Horowitz

Bruce Horowitz

Chief Operating Officer (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.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Heather Raines</u> Heather Raines, CPA	Chief Financial Officer (principal financial officer and principal accounting officer)	March 29, 2023
<u>/s/ Bruce Horowitz</u> Bruce Horowitz	Director and Chief Operating Officer (principal executive officer)	March 29, 2023
<u>/s/ Webster Bailey</u> Webster Bailey	Director	March 29, 2023
<u>/s/ John W. Lacey, III, MD</u> John W. Lacey, III, MD	Director	March 29, 2023
<u>/s/ Ed Pershing</u> Ed Pershing	Director and Chairman of the Board	March 29, 2023
<u>/s/ Dominic Rodrigues</u> Dominic Rodrigues	Director and Vice Chairman of the Board	March 29, 2023

## 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, 2022, 419,497,119 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, 2022, 12,373,247 and 9,746,626 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."

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

I, Bruce Horowitz, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 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 29, 2023

By: /s/ Bruce Horowitz.

Bruce Horowitz

Chief Operating Officer (principal executive officer)

**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, 2022 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 29, 2023

By: /s/ Heather Raines

Heather Raines, CPA

Chief Financial Officer (principal financial officer)

**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, Bruce Horowitz 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, 2022 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 29, 2023.

/s/ Bruce Horowitz

Bruce Horowitz  
Chief Operating Officer (principal executive officer)

/s/ Heather Raines

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