

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2023

or

☐ 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	90-0031917
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
800 S. Gay Street, Suite 1610 Knoxville, Tennessee	37929
(Address of principal executive offices)	(Zip Code)

866-594-5999
(Registrant’s telephone number, including area code)

Not Applicable
(Former name, former address, and former fiscal year, if changed since last report)

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

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

The number of shares outstanding of the registrant’s common stock, par value \$0.001 per share, as of November 13, 2023, was 419,522,119.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q 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. Forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to materially differ from those described in the forward-looking statements. Readers should not place undue reliance on forward-looking statements. Such statements are made as of the date of this Quarterly Report on Form 10-Q, and we undertake no obligation to update such statements after this date, unless otherwise required by law.

Risks and uncertainties that could cause our actual results to materially differ from those described in forward-looking statements include those discussed in our filings with the U.S. Securities and Exchange Commission (the “SEC”) (including those described in Item 1A of Part I of our Annual Report on Form 10-K for the year ended December 31, 2022), and:

- The uncertainty of generating (i) sales from rose bengal sodium-based drug product candidates, PV-10[®] and PH-10[®], and/or any other halogenated xanthene-based drug product candidates (if and when approved), (ii) licensing, milestone, royalty, and/or other payments related to these drug product candidates, and/or (iii) payments from the Company’s liquidation, dissolution, or winding up, or any sale, lease, conveyance, or other disposition of any intellectual property relating to these drug product candidates and/or rose bengal sodium- and other halogenated xanthene-based drug substances;
- The uncertainty of raising additional capital through the proceeds of private placement transactions of debt and/or equity securities, the exercise of existing warrants and outstanding stock options, and/or public offerings of debt and/or equity securities;
- The disruptions from the widespread outbreak of an illness or communicable/infectious disease, such as severe acute respiratory syndrome coronavirus 2, or another public health crisis to our business that could adversely affect our operations and financial condition; and
- The disruptions, shortages, and other supply chain-related issues that many companies across different industry sectors have reported and continue to report. In the biopharmaceutical sector, delays and interruptions in the supply chain have been particularly pronounced. During the first nine months of 2023, we were able to effectively manage our supply of drug product candidates and drug substance in a manner that avoided any significant interruptions to our clinical development and drug discovery programs.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

**PROVECTUS BIOPHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS**

	September 30, 2023	December 31, 2022
	(Unaudited)	
Assets		
Current Assets:		
Cash	\$ 367,250	\$ 21,605
Restricted cash	1,042,957	1,410,102
Short-term receivables	947	394
Prepaid expenses and other current assets	181,180	467,081
Total Current Assets	1,592,334	1,899,182
Equipment and furnishings, less accumulated depreciation of \$108,764 and \$102,073, respectively	14,250	20,941
Operating lease right-of-use asset	83,509	117,123
Total Assets	\$ 1,690,093	\$ 2,037,246
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	\$ 1,785,322	\$ 2,094,258
Unearned grant revenue	1,074,358	1,510,958
Other accrued expenses	3,057,678	2,404,012
Accrued interest	13,867	30,844
Accrued interest - related parties	122,646	40,992
Notes payable	78,066	239,394
Convertible notes payable	775,000	625,000
Convertible notes payable - related parties	2,217,500	1,202,500
Operating lease liability, current portion	47,146	44,422
Total Current Liabilities	9,171,583	8,192,380
Operating lease liability, non-current portion	37,714	73,376
Total Liabilities	9,209,297	8,265,756
Commitments, contingencies, and litigations (Note 12)		
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 September 30, 2023 and December 31, 2022; aggregate liquidation preference of \$14,164,889 at September 30, 2023 and December 31, 2022	12,373	12,373
Series D-1 Convertible Preferred Stock; 11,241,000 shares designated; 10,146,818 and 9,746,626 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively; aggregate liquidation preference of \$116,160,245 and \$111,578,880 at September 30, 2023 and December 31, 2022, respectively	10,146	9,747
Common stock; par value \$0.001 per share; 1,000,000,000 shares authorized; 419,522,119 and 419,497,119 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	419,522	419,497
Additional paid-in capital	244,101,958	242,954,193
Accumulated other comprehensive loss	(36,207)	(35,679)
Accumulated deficit	(252,026,996)	(249,588,641)
Total Stockholders' Deficit	(7,519,204)	(6,228,510)
Total Liabilities and Stockholders' Deficit	\$ 1,690,093	\$ 2,037,246

See accompanying notes to condensed consolidated financial statements.

PROVCTUS BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Grant Revenue	\$ 69,733	\$ 314,890	\$ 436,600	\$ 824,205
Operating Expenses:				
Research and development	350,792	580,390	1,333,399	2,068,154
General and administrative	433,089	400,689	1,399,765	1,500,278
Total Operating Expenses	783,881	981,079	2,733,164	3,568,432
Total Operating Loss	(714,148)	(666,189)	(2,296,564)	(2,744,227)
Other Income/(Expense):				
Research and development tax credit	(167)	(638)	15,798	37,621
Interest expense, net	(61,524)	(46,440)	(157,589)	(115,424)
Total Other Income (Expense), Net	(61,691)	(47,078)	(141,791)	(77,803)
Net Loss	\$ (775,839)	\$ (713,267)	\$ (2,438,355)	\$ (2,822,030)
Basic and Diluted Loss Per Common Share	\$ (0.00)	\$ (0.00)	\$ (0.01)	\$ (0.01)
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	419,515,869	419,489,239	419,503,438	419,461,313

See accompanying notes to condensed consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	2022	2023	2022
Net Loss	\$ (775,839)	\$ (713,267)	\$ (2,438,355)	\$ (2,822,030)
Other Comprehensive Loss:				
Foreign currency translation adjustments	-	(1,241)	(441)	(2,285)
Total Comprehensive Loss	<u>\$ (775,839)</u>	<u>\$ (714,508)</u>	<u>\$ (2,438,796)</u>	<u>\$ (2,824,315)</u>

See accompanying notes to condensed consolidated financial statements.

PROVCTUS BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' DEFICIT
(Unaudited)

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2023

	Preferred Stock Series D		Preferred Stock Series D-1		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Total
Balance at January 1, 2023	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)
Conversion of 2021 Note to Series D1 Preferred Stock	-	-	18,872	18	-	-	53,992	-	-	54,010
Comprehensive loss:										
Net loss	-	-	-	-	-	-	-	-	(827,454)	(827,454)
Other comprehensive income	-	-	-	-	-	-	-	191	-	191
Balance at March 31, 2023	12,373,247	12,373	9,765,498	9,765	419,497,119	419,497	243,008,185	(35,488)	(250,416,095)	(7,001,763)
Conversion of 2021 Note to Series D1 Preferred Stock	-	-	188,757	189	-	-	540,033	-	-	540,222
Comprehensive loss:										
Net loss	-	-	-	-	-	-	-	-	(835,062)	(835,062)
Other comprehensive loss	-	-	-	-	-	-	-	(278)	-	(278)
Balance at June 30, 2023	12,373,247	12,373	9,954,255	9,954	419,497,119	419,497	243,548,218	(35,766)	(251,251,157)	(7,296,881)
Common stock issued for services	-	-	-	-	25,000	25	2,825	-	-	2,850
Conversion of 2021 Note to Series D1 Preferred Stock	-	-	122,725	122	-	-	351,110	-	-	351,232
Conversion of 2022 Note to Series D1 Preferred Stock	-	-	69,838	70	-	-	199,805	-	-	199,875
Comprehensive loss:										-
Net loss	-	-	-	-	-	-	-	-	(775,839)	(775,839)
Other comprehensive loss	-	-	-	-	-	-	-	(441)	-	(441)
Balance at September 30, 2023	<u>12,373,247</u>	<u>\$ 12,373</u>	<u>10,146,818</u>	<u>\$ 10,146</u>	<u>419,522,119</u>	<u>\$419,522</u>	<u>\$244,101,958</u>	<u>\$ (36,207)</u>	<u>\$(252,026,996)</u>	<u>\$(7,519,204)</u>

FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2022

	Preferred Stock Series D		Preferred Stock Series D-1		Common Stock		Additional Paid-In	Accumulated Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Total

Balance at January 1, 2022	12,373,247	\$ 12,373	9,218,449	\$ 9,219	419,447,119	\$ 419,447	\$ 241,440,106	\$ (34,467)	\$(246,033,958)	\$(4,187,280)
Series D-1 Preferred Stock issued for cash	-	-	52,411	52	-	-	149,948	-	-	150,000
Comprehensive loss:										
Net loss	-	-	-	-	-	-	-	-	(1,030,922)	(1,030,922)
Other comprehensive loss	-	-	-	-	-	-	-	(716)	-	(716)
Balance at March 31, 2022	12,373,247	12,373	9,270,860	9,271	419,447,119	419,447	241,590,054	(35,183)	(247,064,880)	(5,068,918)
Comprehensive loss:										
Net loss	-	-	-	-	-	-	-	-	(1,077,841)	(1,077,841)
Other comprehensive loss	-	-	-	-	-	-	-	(328)	-	(328)
Balance at June 30, 2022	12,373,247	12,373	9,270,860	9,271	419,447,119	419,447	241,590,054	(35,511)	(248,142,721)	(6,147,087)
Stock-based compensation:										
Common Stock	-	-	-	-	50,000	50	2,975	-	-	3,025
Comprehensive loss:										
Net loss	-	-	-	-	-	-	-	-	(713,267)	(713,267)
Other comprehensive income	-	-	-	-	-	-	-	(1,241)	-	(1,241)
Balance at September 30, 2022	<u>12,373,247</u>	<u>\$ 12,373</u>	<u>9,270,860</u>	<u>\$ 9,271</u>	<u>419,497,119</u>	<u>\$ 419,497</u>	<u>\$ 241,593,029</u>	<u>\$ (36,752)</u>	<u>\$(248,855,988)</u>	<u>\$(6,858,570)</u>

See accompanying notes to condensed consolidated financial statements.

PROVCTUS BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	For the Nine Months Ended September 30,	
	2023	2022
Cash Flows From Operating Activities:		
Net loss	\$ (2,438,355)	\$ (2,822,030)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	2,850	3,025
Non-cash lease expense	33,613	41,947
Depreciation	6,691	8,857
Changes in operating assets and liabilities		
Short term receivables	(553)	4,351
Prepaid expenses and other current assets	359,572	142,129
Accounts payable	(308,728)	654,017
Unearned grant revenue	(436,600)	(824,205)
Other accrued expenses	653,664	442,355
Operating lease liability	(32,938)	(47,664)
Accrued interest	150,017	110,536
Net Cash Used In Operating Activities	(2,010,767)	(2,286,682)
Cash Flows From Financing Activities:		
Proceeds from issuance of convertible notes payable	700,000	550,000
Proceeds from issuance of convertible notes payable - related parties	1,525,000	510,000
Repayment of short-term note payable	(234,997)	(166,317)
Net Cash Provided By Financing Activities	1,990,003	893,683
Effect of exchange rates on cash and restricted cash	(736)	(2,592)
Net Decrease In Cash and Restricted Cash	(21,500)	(1,395,591)
Cash and Restricted Cash, Beginning of Period	1,431,707	3,106,942
Cash and Restricted Cash, End of Period	\$ 1,410,207	\$ 1,711,351
Cash and restricted cash consisted of the following:		
Cash and cash equivalents	\$ 367,250	\$ 67,030
Restricted cash	1,042,957	1,644,321
	\$ 1,410,207	\$ 1,711,351
Non-cash investing and financing activities:		
For purchase of Series D-1 Preferred Stock	\$ -	\$ (150,000)
Right-of-use assets obtained in exchange for operating lease liabilities	\$ -	\$ 130,422
Conversion of 2021 Notes and related accrued interest to Series D-1 Preferred Stock	\$ 804,533	\$ -
Conversion of 2022 Notes and related accrued interest to Series D-1 Preferred Stock	\$ 170,126	\$ -
Purchase of insurance policies financed by short-term note payable	\$ (73,669)	\$ (57,146)

See accompanying notes to condensed consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1. Business Organization, Nature of Operations and Basis of Presentation

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-catalysts called halogenated xanthenes (“HXs”). Our lead HX molecule is named rose bengal sodium (“RBS”).

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

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

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

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

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

Risks and Uncertainties

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.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“GAAP”) for interim financial information pursuant to Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements and should be reviewed in conjunction with the Company’s audited consolidated financial statements included in the Company’s Form 10-K for the year ended December 31, 2022 filed with the SEC on March 30, 2023. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2023 are not necessarily indicative of the results that may be expected for the year ending December 31, 2023.

2. Liquidity and Going Concern

To date, the Company has not generated any revenues or profits from planned principal operations.

The Company’s cash and restricted cash were \$1,410,207 at September 30, 2023 which includes \$1,042,957 of restricted cash resulting from a grant received from the State of Tennessee. The Company’s working capital deficit was \$7,579,249 and \$6,293,198 as of September 30, 2023 and December 31, 2022, respectively, net loss for the nine months ended September 30, 2023 and 2022 was \$2,438,355 and \$2,822,030, respectively, and cash used in operations was \$2,010,767 and \$2,286,682 for the nine months ended September 30, 2023 and September 30, 2022, respectively. 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 unaudited condensed 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 (see 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 offerings, although there can be no assurance 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, there can be no assurance 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, there can be no assurance that it will be able to complete additional financing in a timely manner. Any such financing may result in significant dilution to stockholders.

3. Significant Accounting Policies

Since the date the Company's December 31, 2022 consolidated financial statements were issued in its 2022 Annual Report on March 30, 2023, there have been no material changes to the Company's significant accounting policies.

Principles of Consolidation

Intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

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

Restricted Cash

Restricted cash consists of a grant award received from the State of Tennessee. Restricted cash available as of September 30, 2023 is \$1,042,957. See Note 10, Grants.

Cash Concentrations

Cash and restricted cash are maintained at financial institutions and, at times, balances may exceed federally insured limits of \$250,000, although the Company seeks to minimize this through treasury management. The Company has never experienced any losses related to these balances although there can be no assurance that it will not experience any losses in the future. As of September 30, 2023 and December 31, 2022, the Company had cash and restricted cash balances in excess of FDIC insurance limits of \$1,160,207 and \$1,181,707, respectively.

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:

	September 30,	
	2023	2022
Warrants	437,500	487,500
Options	3,225,000	3,425,000
Convertible preferred stock	113,841,427	105,081,847
2021 unsecured convertible notes	817,766	8,602,376
2022 unsecured convertible notes	10,115,192	646,952
Total potentially dilutive shares	128,636,885	118,243,675

Recently Adopted Accounting Pronouncements

In August 2020, the FASB issued ASU 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*, to clarify the accounting for certain financial instruments with characteristics of liabilities and equity. The amendments in this update reduce the number of accounting models for convertible debt instruments and convertible preferred stock by removing the cash conversion model and the beneficial conversion feature model. Limiting the accounting models will result in fewer embedded conversion features being separately recognized from the host contract. Convertible instruments that continue to be subject to separation models are (1) those with embedded conversion features that are not clearly and closely related to the host contract, that meet the definition of a derivative, and that do not qualify for a scope exception from derivative accounting and (2) convertible debt instruments issued with substantial premiums for which the premiums are recorded as paid-in-capital. In addition, this ASU improves disclosure requirements for convertible instruments and earnings-per-share guidance. The ASU also revises the derivative scope exception guidance to reduce form-over-substance-based accounting conclusions driven by remote contingent events. The amendments in this update are effective for our fiscal years beginning after December 15, 2023, and interim periods within those fiscal years. Early adoption will be permitted, but no earlier than for fiscal years beginning after December 15, 2020. The Company early adopted ASU 2020-06 effective January 1, 2023 which eliminated the need to assess whether a beneficial conversion feature needs to be recognized upon the issuance of new convertible instruments.

4. Other Accrued Expenses

The following table summarizes the other accrued expenses at September 30, 2023 and December 31, 2022:

	September 30, 2023	December 31, 2022
Accrued payroll and taxes	\$ 611,646	\$ 314,160
Accrued vacation	88,691	69,077
Accrued directors’ fees	2,234,339	1,945,589
Accrued other expenses	123,002	75,186
Total Other Accrued Expenses	\$ 3,057,678	\$ 2,404,012

5. Convertible Notes Payable

2021 Financing

	Non-Related Party Face Amount	Related Party Face Amount	Total
Balance as of January 1, 2023	\$ 550,000	\$ 525,000	\$ 1,075,000
Conversion	(50,000)	-	(50,000)
Balance as of March 31, 2023	500,000	525,000	1,025,000
Conversion	(500,000)	-	(500,000)
Balance as of June 30, 2023	-	525,000	525,000
Conversion	-	(325,000)	(325,000)
Balance as of September 30, 2023	\$ -	\$ 200,000	\$ 200,000

Through September 30, 2023, the Company issued 2021 Notes with aggregate proceeds of \$1,075,000 of which \$525,000 was from related party investors (an officer and a director of the Company).

2022 Financing

	Non-Related Party Face Amount	Related Party Face Amount	Total
Balance as of January 1, 2023	\$ 75,000	\$ 677,500	\$ 752,500
Issued	-	600,000	600,000
Balance as of March 31, 2023	75,000	1,277,500	1,352,500
Issued	-	725,000	725,000
Balance as of June 30, 2023	75,000	2,002,500	2,077,500
Issued	700,000	200,000	900,000
Conversion	-	(185,000)	(185,000)
Balance as of September 30, 2023	\$ 775,000	\$ 2,017,500	\$ 2,792,500

Through September 30, 2023, the Company issued 2022 Notes with aggregate proceeds of \$2,977,500 of which \$2,202,500 is from a related party investor (a director of the Company) in connection with the 2022 Financing.

For further details on the terms of the 2021 and 2022 Notes, refer to our Form 10-K as filed with the SEC on March 30, 2023.

2023 Conversions of 2021 Notes into Preferred Stock

The following summarizes the conversion activity during the nine months ended September 30, 2023:

	Series D-1 Preferred Stock
Principal converted	\$ 875,000
Accrued interest converted	70,466
Total converted	\$ 945,466
Conversion price	\$ 2.862
Total shares	330,354

During the three months ended September 30, 2023, principal and interest in the aggregate amount of \$351,239, owed in connection with the 2021 Notes were converted into 122,725 shares of Series D-1 Preferred Stock at the Conversion Price of \$2.862.

During the nine months ended September 30, 2023, principal and interest in the aggregate amount of \$945,466, owed in connection with the 2021 Notes were converted into 330,354 shares of Series D-1 Preferred Stock at the Conversion Price of \$2.862. Any fractional shares issuable pursuant to the formula were rounded up to the next whole share of Series D-1 Preferred Stock. See Note 8, Stockholders' Deficit for additional information on the Series D-1 Preferred Stock.

2023 Conversions of 2022 Notes into Preferred Stock

The following summarizes the conversion activity during the nine months ended September 30, 2023:

	Series D-1 Preferred Stock
Principal converted	\$ 185,000
Accrued interest converted	14,875
Total converted	\$ 199,875
Conversion price	\$ 2.862
Total shares	69,838

During the three and nine months ended September 30, 2023, principal and interest in the aggregate amount of \$199,875, owed in connection with the 2022 Notes were converted into 69,838 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 Stock. See Note 8, Stockholders' Deficit for additional information on the Series D-1 Preferred Stock.

6. Notes Payable

The Company obtained short-term financing from AFCO Insurance Premium Finance for our commercial insurance policies. As of September 30, 2023 and December 31, 2022, the balance of the note payable was \$78,066 and \$239,394, respectively.

7. Related Party Transactions

During the three months ended September 30, 2023 and 2022, the Company had consulting fees of \$63,600 each to Mr. Bruce Horowitz (Capital Strategists) for services rendered. Director fees for Mr. Horowitz for the three months ended September 30, 2023 and 2022 were \$18,750 each.

During the nine months ended September 30, 2023 and 2022, the Company had consulting fees of \$190,800 each to Mr. Bruce Horowitz (Capital Strategists) for services rendered. Director fees for Mr. Horowitz for the nine months ended September 30, 2023 and 2022 were \$56,250 each.

Accrued director fees for Mr. Bruce Horowitz as of September 30, 2023 and December 31, 2022 were \$412,500 and \$356,250, respectively. Total amounts owed to Capital Strategists for consulting fees as of September 30, 2023 and December 31, 2022 were \$381,600 and \$212,000, respectively. Mr. Horowitz serves as both Chief Operating Officer (“COO”) and a Company director.

See Note 5 for details of other related party transactions.

Director fees during the three and nine months ended September 30, 2023 and 2022 were \$96,250 and \$288,750, respectively. Accrued directors’ fees as of September 30, 2023 and December 31, 2022 were \$2,234,339 and \$1,945,589, respectively.

8. Stockholders’ Deficit

Preferred Stock

During the nine months ended September 30, 2023, the Company issued 330,354 shares of Series D-1 Convertible Preferred Stock upon the conversion of \$875,000 of principal and \$70,466 accrued interest outstanding on the 2021 Notes.

During the nine months ended September 30, 2023, the Company issued 69,838 shares of Series D-1 Convertible Preferred Stock upon the conversion of \$185,000 of principal and \$14,875 accrued interest outstanding on the 2022 Notes.

Options

During the three and nine months ended September 30, 2023 and 2022, the Company did not have any issuances, grants, or exercises of options.

The following table summarizes option activities during the nine months ended September 30, 2023:

	<u>Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Weighted Average Remaining Life in Years</u>	<u>Aggregate Intrinsic Value</u>
Outstanding and exercisable at January 1, 2023	3,425,000	\$ 0.29		\$ -
Forfeited	(200,000)	0.67		
Outstanding and exercisable at September 30, 2023	<u>3,225,000</u>	<u>0.27</u>	<u>2.11</u>	<u>\$ -</u>

The following table summarizes information about options outstanding and exercisable at September 30, 2023:

Exercise Price	Outstanding and Exercisable	Weighted Average Remaining Contractual Life	Intrinsic Value
\$ 0.12	2,425,000	2.10	\$ -
\$ 0.29	100,000	2.10	\$ -
\$ 0.75	550,000	2.20	\$ -
\$ 0.88	150,000	0.80	\$ -
	<u>3,225,000</u>	<u>2.11</u>	<u>\$ -</u>

Warrants

During the three and nine months ended September 30, 2023 and 2022, the Company did not have any issuances, grants, or exercises of warrants.

The following table summarizes warrant activities during the nine months ended September 30, 2023:

	Number of Warrants	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Aggregate Intrinsic Value
Outstanding and exercisable at January 1, 2023	475,000	\$ 0.97		
Forfeited	(37,500)	0.29		
Outstanding and exercisable at September 30, 2023	<u>437,500</u>	<u>\$ 1.03</u>	<u>0.60</u>	<u>\$ -</u>

The following table summarizes information about warrants outstanding and exercisable at September 30, 2023:

Exercise Price	Outstanding and Exercisable	Weighted Average Remaining Contractual Life	Intrinsic Value
\$ 0.29	50,000	0.29	\$ -
\$ 1.00	18,000	0.64	\$ -
\$ 1.12	366,000	0.64	\$ -
\$ 2.00	3,500	0.64	\$ -
	<u>437,500</u>	<u>0.60</u>	<u>\$ -</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.

Annual Stockholder Meeting Proposals

The Company held its annual meeting of stockholders on June 21, 2023. Stockholders authorized the Company's board of directors (the "Board") to amend the Company's Certificate of Incorporation, as amended by the Certificate of Designation of Series D Convertible Preferred Stock and Certificate of Designation of Series D-1 Convertible Preferred Stock (the "Certificates of Designation"), to effect a reverse stock split of the Company's common stock, Series D Convertible Preferred Stock, and Series D-1 Convertible Preferred Stock at a ratio of between 1-for-10 and 1-for-50, where the ratio would be determined by the Board at its discretion, and to make corresponding amendments to the Certificates of Designation to provide for the proportional adjustment of certain terms upon a reverse stock split, consistent with the Board's recommendation. The Company's stockholders also authorized the Board to amend the Company's Certificate of Incorporation, as amended by the Certificates of Designation, to decrease the number of authorized shares of the Company's common stock and preferred stock by the same reverse stock split ratio determined by the Board, consistent with the Board's recommendation. The Board has not acted on these stockholder authorizations as of the filing date.

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

Total operating lease expense for the three months ended September 30, 2023 was \$12,560, of which, \$8,373 was included within research and development and \$4,187 was included within general and administrative expenses on the condensed consolidated statements of operations. Total operating lease expense for the three months ended September 30, 2022 was \$12,497 of which, \$8,331 was included within research and development and \$4,166 was included within general and administrative expenses on the condensed consolidated statements of operations.

Total operating lease expense for the nine months ended September 30, 2023 was \$38,739, of which, \$25,826 was included within research and development and \$12,913 was included within general and administrative expenses on the condensed consolidated statements of operations. Total operating lease expense for the nine months ended September 30, 2022 was \$50,548, of which, \$33,698 was included within research and development and \$16,850 was included within general and administrative expenses on the condensed consolidated statements of operations.

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

	For the Nine Months Ended September 30,	
	2023	2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used in operating leases	\$ 32,938	\$ 50,784
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	\$ -	\$ 130,422
Weighted Average Remaining Lease Term		
Operating leases	1 year 9 months	2 years 9 months
Weighted Average Discount Rate		
Operating leases	5.0%	5.0% - 8.0%

Future minimum payments under the Company's non-cancellable lease obligations as of September 30, 2023 were as follows:

Future Minimum Payments

Years	Amount
2023	\$ 12,497
2024	50,663
2025	25,668
Total lease payments	88,828
Less: amount representing imputed interest	(3,968)
Present value of lease liability	84,860
Less: current portion	(47,146)
Lease liability, non-current portion	\$ 37,714

10. 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 whereby grant revenue is recognized as qualifying costs are incurred and there is reasonable assurance that the conditions of the grant have been met. Qualifying costs are presented as research and development expenses included in the Company’s statement of operations, in the period that such costs are incurred.

As of September 30, 2023 and December 31, 2022, \$1,074,358 and \$1,510,958 has been recorded as unearned Grant revenue liability on the accompanying condensed consolidated balance sheets, respectively. The Company recorded grant revenue of \$69,733 and \$436,600 during the three and nine months ended September 30, 2023, respectively, and \$314,890 and \$824,205 during the three and nine months ended September 30, 2022, respectively.

11. License Transactions

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 Bascom Palmer Eye Institute (“BPEI”) that included the use of OBC’s ophthalmic photodynamic antimicrobial therapy (“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 (i) paid \$5,000 for the option to obtain an exclusive worldwide, royalty-bearing license that had an option expiration date of May 31, 2023, (ii) agreed to pay up to \$10,000 of new UM patent expenses for this IP during the period of the option, (iii) agreed to pay up to \$25,000 of past UM patent expenses for this IP, and (iv) 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. The Company exercised the option to negotiate a license agreement with a negotiating period that ended on November 2, 2023, when negotiating exclusivity and right of first refusal no longer apply. UM’s Office of Technology Transfer and the Company are currently in negotiations to potentially finalize a full license agreement. If UM and the Company are unable to reach an agreement, UM may offer its patent rights to any third party.

12. Commitments, Contingencies and Litigation

The Company may, from time to time, be involved in litigation arising from the ordinary course of business. 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 condensed consolidated financial position, results of operations or cash flows.

13. Subsequent Events

The Company has evaluated events that have occurred after the balance sheet 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 September 30, 2023, the Company entered into a 2022 Note with a non-related party investor in the aggregate principal amount of \$50,000 in connection with 2022 Loans received by the Company for the same amount.

Series D-1 Preferred Stock

Subsequent to September 30, 2023, principal and interest in the aggregate amount of \$289,101, owed in connection with 2022 Notes was converted into 101,061 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 Stock.

ITEM 2. 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 unaudited condensed financial statements and our Annual Report on Form 10-K for the year ended December 31, 2022 filed with the SEC on March 30, 2023 (“2022 Form 10-K”), which includes additional information about our critical accounting policies and practices and risk factors. Historical results and percentage relationships set forth in the consolidated statement of operations, including trends which might appear, are not necessarily indicative of future operations.

Clinical Development and Drug Discovery

The Company’s small molecule HX medical science platform, which comprises several different drug product candidates and preclinical formulations made from pharmaceutical-grade RBS using different concentrations and delivered by different routes of administration specific to each disease area and/or indication, 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 clinical monotherapy and combination therapy mechanism of action and mechanism of immune response study for melanoma, metastatic uveal melanoma, and metastatic neuroendocrine tumors at Moffitt Cancer Center (“Moffitt”) 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 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.

Preclinical In Vivo Proof-of-Concept Programs

- **Oncology:** ITU PV-10 has undergone and is undergoing preclinical monotherapy and combination therapy study for the treatment of pancreatic cancer and human papillomavirus-positive and negative head and neck squamous cell carcinoma at Moffitt. ITU PV-10 has undergone preclinical monotherapy study for the treatment of penile squamous cell carcinoma at an academic medical center. 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, Canada ("Ucal"). The Company believes that the Ucal researchers have achieved *in vivo* monotherapy 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 *in vivo* monotherapy POC of PO administration, that the Company has achieved *in vivo* monotherapy POC of PO administration in both prophylactic and therapeutic settings, and that the Company has achieved *in vivo* monotherapy 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* monotherapy 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 *in vivo* monotherapy 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 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 canine soft tissue sarcomas 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.

Preclinical In Vitro Drug Discovery Programs

- **Immune vaccine adjuvant:** Different formulations have undergone and are undergoing preclinical study as a vaccine adjuvant to enhance T cell responses for anti-viral and anti-cancer vaccines.
- **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 have undergone preclinical monotherapy study for the treatment of oral bacterial infections at UTHSC.

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

- **Tissue Regeneration and Repair:** Different formulations are undergoing preclinical monotherapy study for vertebrate development, wound healing, and tissue regrowth at the University of Nevada, Las Vegas in Las Vegas, Nevada.

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 U.S. Food and Drug Administration ("FDA"), take an initial systemic drug product candidate into an early-stage clinic 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 clinic 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 active pharmaceutical ingredient (“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 World Health Organization (“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 International Nonproprietary Names (“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.

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 unaffiliated with the Company for preclinical study of the rose bengal molecule for potential biomedical therapeutic applications.

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

Diagnostic-Grade

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

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

Chemical Analytical Comparison

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

Potential Barriers to Entry

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

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

Components of Operating Results

Grant Revenue

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

Research and Development Expenses

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

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

We expense research and development costs as incurred.

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

General and Administrative Expenses

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

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and September 30, 2022

Overview

Grant revenue was \$69,733 for the three months ended September 30, 2023, a decrease of \$245,157 or 77.9% compared to the three months ended September 30, 2022. Total operating expenses were \$783,881 for the three months ended September 30, 2023, a decrease of \$197,198 or 20.1% compared to the three months ended September 30, 2022. The decrease was driven primarily by (i) decreased clinical trial costs, partially offset by (ii) higher payroll and taxes, (iii) higher legal costs related to patents, and (iv) higher professional fees related to the start of year-end audit work. Net loss for the three months ended September 30, 2023 was \$775,839, an increase of \$62,572 or 8.8% compared to the three months ended September 30, 2022. The increase is primarily attributable to lower grant revenue recognized in the current quarter.

	For the Three Months Ended September 30,			
	2023	2022	Increase/(Decrease)	% Change
Grant Revenue	\$ 69,733	\$ 314,890	\$ (245,157)	-77.9%
Operating Expenses:				
Research and development	350,792	580,390	(229,598)	-39.6%
General and administrative	433,089	400,689	32,400	8.1%
Total Operating Expenses	783,881	981,079	(197,198)	-20.1%
Total Operating Loss	(714,148)	(666,189)	(47,959)	7.2%
Other Income/(Expense):				
Research and development tax credit (deficit)	(167)	(638)	471	-73.8%
Interest expense, net	(61,524)	(46,440)	(15,084)	32.5%
Total Other (Expense), Net	(61,691)	(47,078)	(14,613)	31.0%
Net Loss	<u>\$ (775,839)</u>	<u>\$ (713,267)</u>	<u>\$ (62,572)</u>	<u>8.8%</u>

Grant Revenue

For the three months ended September 30, 2023 and September 30, 2022, there was \$69,733 and \$314,890, respectively, of grant revenue recognized related to qualifying expenses that were incurred and included within research and development expenses on the condensed consolidated statements of operations.

Research and Development Expenses

Research and development expenses were \$350,792 for the three months ended September 30, 2023, a decrease of \$229,598 or 39.6% compared to \$580,390 for the three months ended September 30, 2022. The decrease was primarily due to (i) lower costs of clinical trials, partially offset by (ii) higher payroll and taxes.

	For the Three Months Ended September 30,			
	2023	2022	Increase/(Decrease)	% Change
Operating Expenses:				
Research and development:				
Clinical trial and research expenses	\$ 198,002	\$ 449,638	\$ (251,636)	-56.0%
Depreciation/amortization	1,764	1,765	(1)	-0.1%
Insurance	57,409	57,620	(211)	-0.4%
Payroll and taxes	85,244	62,457	22,787	36.5%
Rent and utilities	8,373	8,910	(537)	-6.0%
Total research and development	<u>\$ 350,792</u>	<u>\$ 580,390</u>	<u>\$ (229,598)</u>	<u>39.6%</u>

General and Administrative Expenses

General and administrative expenses were \$433,089 for the three months ended September 30, 2023, an increase of \$32,400 or 8.1% compared to \$400,689 for the three months ended September 30, 2022. The increase was primarily due to (i) higher legal fees related to patents and (ii) higher professional fees related to the start of year-end audit work.

	For the Three Months Ended September 30,			
	2023	2022	Increase/(Decrease)	% Change
Operating Expenses:				
General and administrative:				
Depreciation	\$ 466	\$ 1,054	\$ (588)	-55.8%
Directors fees	96,250	96,250	-	0.0%
Insurance	45,302	45,272	30	0.1%
Legal	71,222	65,602	5,620	8.6%
Other general and administrative cost	15,724	14,991	733	4.9%
Payroll and taxes	60,829	61,554	(725)	-1.2%
Professional fees	138,620	111,310	27,310	24.5%
Rent and utilities	4,676	4,656	20	0.4%
Total general and administrative	\$ 433,089	\$ 400,689	\$ 32,400	8.1%

Other Income/(Expense)

Research and development tax credit decreased from \$(638) for the three months ended September 30, 2022 to \$(167) for the three months ended September 30, 2023. The decrease was mainly due to lower clinical trial activities in Australia resulting in a lower research and development tax refund.

Net interest expense increased by \$15,084 from \$46,440 for the three months ended September 30, 2022 to \$61,524 for the three months ended September 30, 2023. The increase was mainly due to the interest expense costs incurred in connection with the higher note balances.

	For the Three Months Ended September 30,			
	2023	2022	Increase/(Decrease)	% Change
Other Income/(Expense):				
Research and development tax credit (deficit)	\$ (167)	(638)	471	-73.8%
Interest expense, net	\$ (61,524)	(46,440)	\$ (15,084)	32.5%
Total Other Income (Expenses), Net	\$ (61,691)	\$ (47,078)	\$ (14,613)	31.0%

Comparison of the Nine Months Ended September 30, 2023 and September 30, 2022

Overview

Grant revenue was \$436,600 for the nine months ended September 30, 2023, a decrease of \$387,605 or 47.0% compared to the nine months ended September 30, 2022. Total operating expenses were \$2,733,164 for the nine months ended September 30, 2023, a decrease of \$835,268 or 23.4% compared to the nine months ended September 30, 2022. The decrease was driven primarily by (i) decreased clinical trial costs, (ii) lower rent and utilities cost, (iii) lower legal fees, (iv) lower insurance cost, and (v) lower general and administrative cost due to receipt of employee retention credit and lower professional fees. Net loss for the nine months ended September 30, 2023 was \$2,438,355, a decrease of \$383,675, or 13.6% compared to the nine months ended September 30, 2022. The decrease is primarily attributable to lower operating expenses offset by lower grant revenue recognized in the current year.

	For the Nine Months Ended September 30,		Increase/(Decrease)	% Change
	2023	2022		
Grant Revenue	\$ 436,600	\$ 824,205	\$ (387,605)	-47.0%
Operating Expenses:				
Research and development	1,333,399	2,068,154	(734,755)	-35.5%
General and administrative	1,399,765	1,500,278	(100,513)	-6.7%
Total Operating Expenses	2,733,164	3,568,432	(835,268)	-23.4%
Total Operating Loss	(2,296,564)	(2,744,227)	(447,633)	16.3%
Other Income/(Expense):				
Research and development tax credit	15,798	37,621	(21,823)	-58.0%
Interest expense, net	(157,589)	(115,424)	(42,165)	36.5%
Total Other Expense, Net	(141,791)	(77,803)	(63,988)	82.2%
Net Loss	\$ (2,438,355)	\$ (2,822,030)	\$ (383,675)	13.6%

Grant Revenue

For the nine months ended September 30, 2023 and September 30, 2022, there was \$436,600 and \$824,205, respectively, of grant revenue recognized related to qualifying expenses that were incurred and included within research and development on the condensed consolidated statements of operations.

Research and Development Expenses

Research and development expenses were \$1,333,399 for the nine months ended September 30, 2023, a decrease of \$734,755 or 35.5% compared to \$2,068,154 for the nine months ended September 30, 2022. The decrease was primarily due to (i) lower costs of clinical trials, (ii) lower rent and utilities, and (iii) lower insurance cost, partially offset by an increase in (iv) payroll and taxes.

	For the Nine Months Ended September 30,		Increase/(Decrease)	% Change
	2023	2022		
Operating Expenses:				
Research and development:				
Clinical trial and research expenses	913,881	1,655,623	\$ (741,742)	-44.8%
Depreciation/amortization	5,294	5,694	(400)	-7.0%
Insurance	172,065	173,510	(1,445)	-0.8%
Payroll and taxes	216,333	196,932	19,401	9.9%
Rent and utilities	25,826	36,395	(10,569)	-29.0%
Total research and development	\$ 1,333,399	\$ 2,068,154	\$ (734,755)	-35.5%

General and Administrative Expenses

General and administrative expenses were \$1,399,765 for the nine months ended September 30, 2023, a decrease of \$100,513 or 6.7% compared to \$1,500,278 for the nine months ended September 30, 2022. The decrease was primarily due to (i) lower legal fees relating to patents, (ii) reduced rent and utilities cost, (iii) slightly lower insurance cost, (iv) lower other general and administrative cost related to receipt of employee retention credit, and (v) lower professional fees.

	For the Nine Months Ended September 30,		Increase/(Decrease)	% Change
	2023	2022		
Operating Expenses:				
General and administrative:				
Depreciation	\$ 1,397	\$ 3,163	\$ (1,766)	-55.8%
Directors fees	288,750	288,750	-	0.0%
Insurance	134,390	138,162	(3,772)	-2.7%
Legal	278,819	304,223	(25,404)	-8.4%
Other general and administrative cost	28,634	72,326	(43,692)	-60.4%
Payroll and taxes	189,262	189,428	(166)	-0.1%
Professional fees	464,122	486,343	(22,221)	-4.6%
Rent and utilities	14,391	18,522	(4,131)	-22.3%
Foreign currency translation	-	(639)	639	-100.0%
Total general and administrative	<u>\$ 1,399,765</u>	<u>\$ 1,500,278</u>	<u>\$ (100,513)</u>	<u>-6.7%</u>

Other Income/(Expense)

Research and development tax credit decreased from \$37,621 for the nine months ended September 30, 2022 to \$15,798 for the nine months ended September 30, 2023. The decrease was mainly due to lower clinical trial activities in Australia resulting in a lower research and development tax refund.

Net interest expense increased by \$42,165 from \$115,424 for the nine months ended September 30, 2022 to \$157,589 for the nine months ended September 30, 2023. The increase was mainly due to the interest expense costs incurred in connection with the higher note balances.

	For the Nine Months Ended September 30,		Increase/(Decrease)	% Change
	2023	2022		
Other Income/(Expense):				
Research and development tax credit	\$ 15,798	\$ 37,621	\$ (21,823)	-58.0%
Interest expense, net	(157,589)	(115,424)	(42,165)	36.5%
Total Other Expense, Net	<u>\$ (141,791)</u>	<u>\$ (77,803)</u>	<u>\$ (63,988)</u>	<u>82.2%</u>

Liquidity and Capital Resources

The Company's cash and restricted cash were \$1,410,207 at September 30, 2023 which includes \$1,042,957 of restricted cash resulting from a grant received from the State of Tennessee, compared to \$1,431,707 at December 31, 2022, which included \$1,410,102 of restricted cash. The Company's working capital deficit was \$7,579,249 and \$6,293,198 as of September 30, 2023 and December 31, 2022, respectively. The condensed consolidated financial statements and notes thereto included in this Quarterly Report on Form 10-Q have been prepared on a basis that contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. We have continuing net losses and negative cash flows from operating activities. In addition, we have an accumulated deficit of \$252,026,996 as of September 30, 2023. These conditions raise substantial doubt about our ability to continue as a going concern for a period within one year from the date that the financial statements included elsewhere in this Quarterly Report on Form 10-Q 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.

As of September 30, 2023, cash required for our current liabilities included approximately \$4,890,146 for accounts payable and other accrued expenses (including operating lease liabilities) and a \$78,066 note payable related to our short-term financing of our commercial insurance policies. Also, if not converted prior to maturity, convertible debt in the amount of \$2,992,500 plus accrued interest will mature one year from the date of the notes. As of September 30, 2023, cash required for our long-term liabilities consists of \$37,714 for our operating lease. The Company intends to meet these cash requirements from its current cash balance and from future financing.

Management's plans include selling our equity securities and obtaining other financing, including the issuance of 2022 unsecured convertible notes (the "2022 Financing"), to fund our capital requirements and on-going operations; however, there can be no assurance that the Company will be successful in these efforts. Significant funds will be needed to continue and complete our ongoing and planned clinical trials.

Access to Capital

Management plans to access capital resources through possible public or private equity offerings, including the 2022 Financing, equity financings, 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.

The primary business objective of management is to build the Company into a commercial-stage biotechnology company; however, there can be no assurance that management will be successful in implementing the Company's business plan of developing, licensing, and/or commercializing our prescription drug product 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, 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, there can be no assurance 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.

Critical Accounting Estimates and Policies

Since the date the Company's December 31, 2022 consolidated financial statements were issued in its 2022 Annual Report, there have been no material changes to the Company's significant accounting policies. Refer to our Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 30, 2023 and Note 3 to the condensed consolidated financial statements of this Quarterly Report on Form 10-Q, for a discussion of our significant accounting policies and use of estimates.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements, financings, or other relationships with unconsolidated entities or other persons, also known as special purpose entities ("SPEs").

Available Information

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

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

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

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

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our 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 Securities Exchange Act of 1934, as amended (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 the SEC’s 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 fiscal quarter covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

The information required by this item is incorporated by reference from Part I, Item 1. Financial Statements, Notes to Condensed Consolidated Financial Statements, Note 12.

ITEM 1A. RISK FACTORS.

There have been no material changes to the risk factors that were disclosed in the 2022 Form 10-K.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

2022 Financing

During the three and nine months ended September 30, 2023, the Company received aggregate proceeds of \$900,000 and \$2,225,000, respectively, pursuant to certain unsecured convertible notes (the “2022 Notes”). Through September 30, 2023, the Company had drawn down \$2,977,500 under the 2022 Notes.

For further details on the terms of the 2022 Notes, refer to our Form 10-K as filed with the SEC on March 30, 2023.

Preferred Convertible Stock

During the three months ended September 30, 2023, the Company issued 122,725 shares of restricted Series D-1 Convertible Preferred Stock upon the conversion of \$325,000 of principal and \$26,232 accrued interest outstanding on the 2021 Notes.

During the nine months ended September 30, 2023, the Company issued 330,354 shares of restricted Series D-1 Convertible Preferred Stock upon the conversion of \$875,000 of principal and \$70,466 accrued interest outstanding on the 2021 Notes.

During the three and nine months ended September 30, 2023, the Company issued 69,838 shares of restricted Series D-1 Convertible Preferred Stock upon the conversion of \$185,000 of principal and \$14,875 accrued interest outstanding on the 2022 Notes.

The Company believes that such transactions were exempt from the registration requirements of the Securities Act of 1933, as amended, (the “Securities Act”), in reliance on Section 4(a)(2) of the Securities Act (or Rule 506(b) of Regulation D promulgated thereunder) as transactions by an issuer not involving a public offering.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

Exhibit No.	Description
31.1**	<u>Certification of Principal Executive Officer Pursuant to Rule 13a-14(a) (Section 302 Certification).</u>
31.2**	<u>Certification of Chief Financial Officer Pursuant to Rule 13a-14(a) (Section 302 Certification).</u>
32***	<u>Certification of Principal Executive Officer and Chief Financial Officer Pursuant to 18 U.S.C. Section 1350 (Section 906 Certification).</u>
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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

PROVECTUS BIOPHARMACEUTICALS, INC.

November 14, 2023

By: /s/ Bruce Horowitz

Bruce Horowitz

Chief Operating Officer (Principal Executive Officer)

By: /s/ Heather Raines

Heather Raines, CPA

Chief Financial Officer (Principal Financial Officer)

CERTIFICATION

I, Bruce Horowitz, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 14, 2023

By: /s/ Bruce Horowitz

Bruce Horowitz

Chief Operating Officer (Principal Executive Officer)

CERTIFICATION

I, Heather Raines, CPA, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 14, 2023

By: /s/ Heather Raines

Heather Raines, CPA

Chief Financial Officer (Principal Financial Officer)

**CERTIFICATION 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, the Chief Operating Officer (principal executive officer) of Provectus Biopharmaceuticals, Inc. (the “Company”), and Heather Raines, CPA, the Chief Financial Officer (principal financial officer) of the Company, 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 Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, 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 November 14, 2023.

By: /s/ Bruce Horowitz

Bruce Horowitz
Chief Operating Officer (Principal Executive Officer)

By: /s/ Heather Raines

Heather Raines, CPA
Chief Financial Officer (Principal Financial Officer)
