

PROVCTUS BIOPHARMACEUTICALS, INC.

FORM 10-Q (Quarterly Report)

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Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

The number of shares outstanding of the registrant's common stock, par value \$0.001 per share, as of August 13, 2025, was 420,279,879.

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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, 2024), and:

- The uncertainty of generating (i) sales from rose bengal sodium-based drug product candidates PV-10[®] and PH-10, PV-305, and/or any rose bengal sodium-based or 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, and outstanding stock options, and/or public offerings of debt and/or equity securities; and
- The disruptions from a public health crisis, such as severe acute respiratory syndrome coronavirus 2, or an economic predicament, such as tariffs, or another macro upheaval to our business that could adversely affect our operations and financial condition.

PART I - FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS.

PROVECTUS BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS

	June 30, 2025	December 31, 2024
	(Unaudited)	
Assets		
Current Assets:		
Cash	\$ 385,929	\$ 307,442
Restricted cash	30,542	182,284
Prepaid expenses and other current assets	151,849	487,046
Total Current Assets	568,320	976,772
Equipment and furnishings, less accumulated depreciation of \$119,082 and \$118,151, respectively	3,931	4,863
Operating lease right-of-use asset	150,133	24,624
Total Assets	\$ 722,384	\$ 1,006,259
Liabilities and Stockholders' Deficit		
Current Liabilities:		
Accounts payable	\$ 1,311,038	\$ 1,106,551
Unearned grant revenue	-	336,108
Accrued interest	26,344	27,774
Accrued interest - related parties	121,868	144,913
Other accrued expenses	2,623,420	2,175,376
Notes payable	54,337	206,463
Convertible notes payable	650,000	853,000
Convertible notes payable - related parties	1,660,000	2,100,000
Operating lease liability, current portion	46,232	25,299
Total Current Liabilities	6,493,239	6,975,484
Operating lease liability, non-current portion	103,900	-
Total Liabilities	6,597,139	6,975,484
Commitments, contingencies, and litigations (Note 13)		
Stockholders' Deficit:		
Preferred stock; par value \$0.001 per share; 25,000,000 shares authorized;		
Series D Convertible Preferred Stock; 957,100 shares designated at June 30, 2025 and December 31, 2024; 956,985 shares issued and outstanding at June 30, 2025 and December 31, 2024; aggregate liquidation preference of \$1,643,333 at June 30, 2025 and December 31, 2024	957	957
Series D-1 Convertible Preferred Stock; 23,042,900 shares designated at June 30, 2025 and December 31, 2024; 13,724,563 and 13,106,223 shares issued and outstanding at June 30, 2025 and December 31, 2024, respectively; aggregate liquidation preference of \$219,120,053 and \$150,040,045 at June 30, 2025 and December 31, 2024, respectively	13,724	13,106
Common stock; par value \$0.001 per share; 1,000,000,000 shares authorized; 420,279,879 shares issued and outstanding at June 30, 2025 and December 31, 2024	420,280	420,280
Additional paid-in capital	254,131,964	251,090,027
Accumulated other comprehensive loss	(60,361)	(60,741)
Accumulated deficit	(260,377,489)	(257,422,961)
Total stockholders' deficit attributable to Provectus Biopharmaceuticals, Inc., stockholders	(5,870,925)	(5,959,332)
Non-controlling interest in subsidiary	(3,830)	(9,893)
Total Stockholders' Deficit	(5,874,755)	(5,969,225)
Total Liabilities and Stockholders' Deficit	\$ 722,384	\$ 1,006,259

See accompanying notes to condensed consolidated financial statements.

PROVCTUS BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Three Months Ended		For the Six Months Ended	
	June 30,		June 30,	
	2025	2024	2025	2024
Grant Revenue	\$ 57,480	\$ 254,991	\$ 336,108	\$ 493,063
Operating Expenses:				
Research and development	867,345	472,927	1,256,155	1,028,462
General and administrative	990,863	576,918	1,978,622	706,720
Total Operating Expenses	1,858,208	1,049,845	3,234,777	1,735,182
Total Operating Loss	(1,800,728)	(794,854)	(2,898,669)	(1,242,119)
Other Income (Expense):				
Research and development credit	-	9,301	-	9,301
Interest expense	(51,353)	(61,295)	(115,014)	(118,072)
Net Loss	(1,852,081)	(846,848)	(3,013,683)	(1,350,890)
Net Loss attributable to noncontrolling interest	(37,661)	-	(59,155)	-
Net Loss attributable to common stockholders	<u>\$ (1,814,420)</u>	<u>\$ (846,848)</u>	<u>\$ (2,954,528)</u>	<u>\$ (1,350,890)</u>
Basic and Diluted Loss Per Common Share	<u>\$ (0.00)</u>	<u>\$ (0.00)</u>	<u>\$ (0.01)</u>	<u>\$ (0.00)</u>
Weighted Average Number of Common Shares Outstanding - Basic and Diluted	<u>420,279,879</u>	<u>419,522,119</u>	<u>420,279,879</u>	<u>419,522,119</u>

See accompanying notes to condensed consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(Unaudited)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Net Loss	\$ (1,852,081)	\$ (846,848)	\$ (3,013,683)	\$ (1,350,890)
Other Comprehensive Income (Loss):				
Foreign currency translation adjustments	328	126	380	(289)
Comprehensive Loss, net	(1,851,753)	(846,722)	(3,013,303)	(1,351,179)
Comprehensive Loss attributed to non-controlling interest	(37,661)	-	(59,155)	-
Comprehensive Loss attributed to controlling interest	<u>\$ (1,814,092)</u>	<u>\$ (846,722)</u>	<u>\$ (2,954,148)</u>	<u>\$ (1,351,179)</u>

See accompanying notes to condensed consolidated financial statements.

(Unaudited)

(Unaudited)											
	Preferred Stock Series D		Preferred Stock Series D-1		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Noncontrolling Interest	Total
	Shares	Amount	Shares	Amount	Shares	Amount					
Balance at January 1, 2025	956,985	\$ 957	13,106,223	\$ 13,106	420,279,879	\$420,280	\$251,090,027	\$ (60,741)	\$(257,422,961)	\$ (9,893)	\$(5,969,225)
Issuance of common stock of majority owned subsidiary	-	-	-	-	-	-	634,782	-	-	65,218	700,000
Conversion of 2022 Notes and interest to Series D-1 Preferred Stock	-	-	365,400	365	-	-	1,046,329	-	-	-	1,046,694
Stock-based compensation:											-
Amortization of stock options	-	-	-	-	-	-	315,100	-	-	-	315,100
Comprehensive loss:											-
Net loss	-	-	-	-	-	-	-	-	(1,140,108)	(21,494)	(1,161,602)
Other comprehensive income	-	-	-	-	-	-	-	52	-	-	52
Balance at March 31, 2025	956,985	957	13,471,623	13,471	420,279,879	420,280	253,086,238	(60,689)	(258,563,069)	33,831	(5,068,981)
Conversion of 2022 Notes and interest to Series D-1 Preferred Stock	-	-	252,940	253	-	-	723,656	-	-	-	723,909
Stock-based compensation:											
Amortization of stock options	-	-	-	-	-	-	322,070	-	-	-	322,070
Comprehensive loss:											
Net loss	-	-	-	-	-	-	-	-	(1,814,420)	(37,661)	(1,852,081)
Other comprehensive income	-	-	-	-	-	-	-	328	-	-	328
Balance at June 30, 2025	956,985	\$ 957	13,724,563	\$ 13,724	420,279,879	\$420,280	\$254,131,964	\$ (60,361)	\$(260,377,489)	\$ (3,830)	\$(5,874,755)

comprehensive loss	-	-	-	-	-	-	-	(415)	-	-	(415)
Balance at March 31, 2024	12,373,247	12,373	10,587,571	10,587	419,522,119	419,522	245,362,902	(60,580)	(253,194,451)	-	\$(7,449,647)
Forfeited shares of Series D Preferred Stock	(11,416,262)	(11,416)	-	-	-	-	11,416	-	-	-	-
Issuance of Series D-1 Preferred Stock for forfeited shares of Series D Preferred Stock	-	-	1,141,626	1,141	-	-	(1,141)	-	-	-	-
Conversion of 2022 Notes and interest to Series D-1 Preferred Stock	-	-	273,691	274	-	-	783,022	-	-	-	783,296
Comprehensive loss:											-
Net loss	-	-	-	-	-	-	-	-	(846,848)	-	(846,848)
Other comprehensive income	-	-	-	-	-	-	-	126	-	-	126
Balance at June 30, 2024	<u>956,985</u>	<u>\$ 957</u>	<u>12,002,888</u>	<u>\$ 12,003</u>	<u>419,522,119</u>	<u>\$419,522</u>	<u>\$246,156,198</u>	<u>\$ (60,454)</u>	<u>\$(254,041,299)</u>	<u>\$ -</u>	<u>\$(7,513,073)</u>

See accompanying notes to condensed consolidated financial statements.

PROVECTUS BIOPHARMACEUTICALS, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	For the Six Months Ended June 30,	
	2025	2024
Cash Flows From Operating Activities:		
Net loss	\$ (3,013,683)	\$ (1,350,890)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	637,170	-
Non-cash operating lease expense	24,623	23,402
Depreciation	932	4,461
Changes in operating assets and liabilities		
Short term receivables	-	(299)
Prepaid expenses and other current assets	335,198	127,328
Accounts payable	204,488	(353,763)
Unearned grant revenue	(336,108)	(493,063)
Accrued interest	108,128	111,134
Other accrued expenses	447,980	148,011
Operating lease liability	(25,299)	(23,401)
Net Cash Used In Operating Activities	<u>(1,616,571)</u>	<u>(1,807,080)</u>
Cash Flows From Financing Activities:		
Proceeds from issuance of convertible notes payable	-	353,000
Proceeds from issuance of convertible notes payable - related parties	995,000	1,285,000
Proceeds from issuance of common stock of majority-owned subsidiary	700,000	-
Repayment of short-term note payable	(152,126)	(167,953)
Repayment of 2021 convertible note payable - related party	-	(100,000)
Net Cash Provided By Financing Activities	<u>1,542,874</u>	<u>1,370,047</u>
Effect of exchange rates on cash and restricted cash	442	(483)
Net Decrease In Cash and Restricted Cash	(73,255)	(437,516)
Cash and Restricted Cash, Beginning of Period	489,726	1,026,799
Cash and Restricted Cash, End of Period	<u>\$ 416,471</u>	<u>\$ 589,283</u>
Cash and restricted cash consisted of the following:		
Cash	\$ 385,929	\$ 29,581
Restricted cash	<u>30,542</u>	<u>559,702</u>
	<u>\$ 416,471</u>	<u>\$ 589,283</u>
Supplemental Disclosures of Cash Flow Information:		
Cash paid during the period for:		
Interest	<u>\$ 4,305</u>	<u>\$ 5,439</u>
Income taxes	<u>-</u>	<u>\$ -</u>
Non-cash investing and financing activities:		
Conversion of 2022 Notes and related accrued interest to Series D-1 Preferred Stock	<u>\$ 1,770,603</u>	<u>\$ 1,431,457</u>
Forfeited shares of Series D Preferred Stock	<u>\$ -</u>	<u>\$ (11,416)</u>
Issuance of Series D-1 Preferred Stock for forfeited shares of Series D Preferred Stock	<u>\$ -</u>	<u>\$ 1,141</u>
Right-of-use assets obtained in exchange for operating lease liabilities	<u>\$ 150,133</u>	<u>\$ -</u>

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. Our drug product candidates are based on bioactive, synthetic, small molecule rose bengal sodium (“RBS”), which is a member of a class of molecules called halogenated xanthenes (“HXs”).

The Company’s proprietary, patented, pharmaceutical-grade RBS is the active pharmaceutical ingredient (“API”) in all our clinical development and non-clinical research programs. The Company is the first entity to advance RBS into clinical trials for the treatment of disease. The Company is also the first entity, and currently the only one, to date to make pharmaceutical-grade RBS API consistently at a purity of nearly 100%.

RBS can be delivered by different routes of administration. RBS may concurrently display stimulatory and inhibitory effects and may target disease in a bifunctional multi-modal manner. Direct contact by RBS with disease may lead to cell death or repair by one or more targeting mechanisms, depending on the disease being treated and the concentration of RBS being utilized in the formulation. Multivariate innate and adaptive immune activation, signaling, and response may follow.

The Company’s RBS drug platform and pipeline comprise drug product candidates and non-clinical formulations that use different amounts of RBS and are delivered by different routes of administration specific to each disease area, including:

- Clinical: Development programs in oncology (intratumoral administration), dermatology (topical), and ophthalmology (topical),
- *In vivo*: Proof-of-concept programs in oncology (oral), hematology (oral), wound healing (topical), and canine cancers (intratumoral),
- *In vitro*: Early discovery programs in infectious diseases and tissue regeneration and repair, and
- *In silico*: Computer modeling of amyotrophic lateral sclerosis and other disease targets.

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.

Changes in U.S. Trade Policies Could Adversely Affect Our Operations

Ongoing uncertainty around U.S. trade policies, tariffs, and international agreements may impact the cost and availability of materials, supplies, and equipment used in our operations or those of our partners. Any disruptions or increased costs resulting from these changes could negatively affect our business, financial condition, results of operations, and the market price of our common stock.

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, 2024 filed with the SEC on March 28, 2025. 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 six months ended June 30, 2025 are not necessarily indicative of the results that may be expected for the year ending December 31, 2025.

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 \$416,471 at June 30, 2025 which includes \$30,542 of restricted cash resulting from a grant received from the State of Tennessee. The Company's working capital deficit was \$5,924,919 and \$5,998,712 as of June 30, 2025 and December 31, 2024, respectively, net loss for the six months ended June 30, 2025 and 2024 was \$3,013,683 and \$1,350,890, respectively, and cash used in operations was \$1,616,571 and \$1,807,080 for the six months ended June 30, 2025 and 2024, 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 HX-based drug products, and to raise additional capital.

The Company plans to access capital resources through possible public or private equity offerings, including the 2025 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 clinical-stage drug candidates, PV-10, PH-10, and PV-305 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, we cannot assure you that management will be successful in implementing the Company's business plan of developing, licensing, and/or commercializing our prescription drug candidates. Moreover, even if we are successful in improving our current cash flow position, we nonetheless plan to seek additional funds to meet our current and long-term requirements in 2025 and beyond. We anticipate that these funds will otherwise come from the proceeds of private placement transactions, including the 2025 Financing, exercise of outstanding stock options, or public offerings of debt or equity securities. While we believe that we have a reasonable basis for our expectation that we will be able to raise additional funds, we cannot assure you that we will be able to complete additional financing in a timely manner. In addition, any such financing may result in significant dilution to stockholders.

As of June 30, 2025, cash requirements for our current liabilities include approximately \$3,980,690 for accounts payable and other accrued expenses (including lease liabilities) and \$54,337 for a 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 \$2,310,000 plus \$148,212 of accrued interest will mature one year from the date of the notes. The 2021, 2024, and 2025 Notes are only subject to repayment in the event of a change of control or event of default. The Company intends to meet these cash requirements from its current cash balance and from future financing.

The aforementioned factors indicate that management's plans do not alleviate the substantial doubt about the Company's ability to continue as a going concern for a period of one year from the issuance of these financial statements.

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

3. Significant Accounting Policies

Since the date the Company's December 31, 2024 consolidated financial statements were issued in its 2024 Annual Report on March 28, 2025, there have been no material changes to the Company's significant accounting policies.

Basis of Presentation

The condensed consolidated financial statements include the consolidated results of Provectus, its wholly owned subsidiaries, and its majority-owned subsidiary, VisiRose (see Note 12). The interests of non-controlling shareholders in VisiRose are presented as net loss attributable to noncontrolling interest in the condensed consolidated statements of operations and as noncontrolling interest in the condensed consolidated balance sheets. 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 June 30, 2025 is \$30,542.

Cash Concentrations

Cash and restricted cash are maintained at financial institutions and, at times, balances may exceed federally insured limits of \$250,000, although the Company seeks to minimize this through treasury management. The Company has never experienced any losses related to these balances although no assurance can be provided that it will not experience any losses in the future. As of June 30, 2025 and December 31, 2024, the Company had cash and restricted cash balances in excess of FDIC insurance limits of \$166,471 and \$239,726, respectively.

Equipment and Furnishings, net

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

Long-Lived Assets

The Company reviews the carrying values of its long-lived assets for possible impairment whenever an event or change in circumstances indicates that the carrying amount of the assets may not be recoverable. Any long-lived assets held for disposal are reported at the lower of their carrying amounts or fair value less cost to sell. Management has determined there to be no impairment of the Company's long-lived assets during the six months ended June 30, 2025 and 2024.

Grant Revenue

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

Research and Development

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

Patent Costs

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

Leases

The Company leases properties under operating leases. The Company recognizes a liability to make lease payments, the “lease liability”, and an asset representing the right to use the underlying asset during the lease term, the “right-of-use asset” upon the commencement of a lease. The lease liability is measured at the present value of the remaining lease payments, discounted at the Company’s incremental borrowing rate. The right-of-use asset is measured at the amount of the lease liability adjusted for the remaining balance of any lease incentives received, any cumulative prepaid or accrued rent if the lease payments are uneven throughout the lease term, any unamortized initial direct costs, and any impairment of the right-of-use-asset. Operating lease expense consists of a single lease cost calculated so that the remaining cost of the lease is allocated over the remaining lease term on a straight-line basis, variable lease payments not included in the lease liability, and any impairment of the right-of-use asset.

Convertible Instruments

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

Preferred Stock

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

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:

	June 30,	
	2025	2024
Options	53,873,102	3,225,000
Convertible preferred stock	138,202,615	120,985,865
2021 unsecured convertible notes and accrued interest	543,133	505,746
2022 unsecured convertible notes and accrued interest	-	10,113,074
2024 unsecured convertible notes and accrued interest	4,503,941	-
2025 unsecured convertible notes and accrued interest	3,542,069	-
Total potentially dilutive shares	200,664,860	134,829,685

Stock-Based Compensation

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

Segment

The Company has one operating and reporting segment (namely, clinical stage biotechnology), namely, for the development of immunotherapy medicines. The accounting policies of the segment are the same as those described in the summary of significant accounting policies. The chief operating decision maker ("CODM"), who is the Company's chief executive officer, utilizes the Company's financial information on a consolidated basis for purposes of making operating decisions, allocating resources and assessing financial performance, as well as for making strategic operations decisions and managing the organization. The CODM is not regularly provided with disaggregated expense information, other than the expense information included in the condensed consolidated statements of operations and comprehensive loss. The measure of segment assets is reported on the condensed balance sheet as total assets.

Recently Issued Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. The amendments in this update address investor requests for more transparency about income tax information through improvements to income tax disclosures primarily related to the rate reconciliation and income taxes paid information. This update also includes certain other amendments to improve the effectiveness of income tax disclosures. The amendments in ASU 2023-09 are effective for the Company for annual periods beginning after December 15, 2024, with early adoption permitted. The Company expects that additional income tax disclosures will be required upon adoption of ASU 2023-09.

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures*. ASU 2024-03 is intended to improve disclosures about a public business entity's expenses and provide more detailed information to investors about the types of expenses in commonly presented expense captions. The amendments in this ASU will be applied retrospectively and are effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact of implementing this guidance.

In November 2024, the Financial Accounting Standards Board ("FASB"), issued Accounting Standards Update ("ASU") 2024-04, *Debt-Debt with Conversions and Other Options*. ASU 2024-04 is intended to clarify requirements for determining whether certain settlements of convertible debt instruments, including convertible debt instruments with cash conversion features or convertible debt instruments that are not currently convertible, should be accounted for as an induced conversion. This ASU is effective for all entities for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods, with early adoption permitted. The Company is currently evaluating the potential impact of this guidance on its financial statements.

4. Other Accrued Expenses

The following table summarizes the other accrued expenses at June 30, 2025 and December 31, 2024:

	June 30, 2025	December 31, 2024
Accrued payroll and taxes	\$ 1,935,826	\$ 1,501,449
Accrued vacation	165,030	131,099
Accrued directors' fees	232,500	77,500
Accrued other expenses	290,064	465,328
Total Other Accrued Expenses	\$ 2,623,420	\$ 2,175,376

5. Convertible Notes Payable

The following summarizes convertible notes payable activity during the six months ended June 30, 2025:

	2021 Financing		2022 Financing		2024 Financing		2025 Financing		Total	
	Non-Related Party	Related Party	Non-Related Party	Related Party	Non-Related Party	Related Party	Non-Related Party	Related Party	Non-Related Party	Related Party
Balance as of January 1, 2025	\$ -	\$ 100,000	\$ 353,000	\$ 1,285,000	\$ 500,000	\$ 715,000	\$ -	\$ -	\$ 853,000	\$ 2,100,000
Notes issued	-	-	-	-	-	-	-	455,000	-	455,000
Principal converted	-	-	(153,000)	(815,000)	-	-	-	-	(153,000)	(815,000)
Balance as of March 31, 2025	-	100,000	200,000	470,000	500,000	715,000	-	455,000	700,000	1,740,000
Notes issued	-	-	-	-	-	-	150,000	390,000	150,000	390,000
Principal converted	-	-	(200,000)	(470,000)	-	-	-	-	(200,000)	(470,000)
Balance as of June 30, 2025	<u>\$ -</u>	<u>\$ 100,000</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 500,000</u>	<u>\$ 715,000</u>	<u>\$ 150,000</u>	<u>\$ 845,000</u>	<u>\$ 650,000</u>	<u>\$ 1,660,000</u>

The 2021 Notes, 2022 Notes, 2024 Notes and 2025 Notes, are together, the “Convertible Notes”. The embedded conversion options associated with the Convertible Notes do not require bifurcation and treatment as a derivative liability.

Related party investors in the Company’s convertible notes consist of an officer and an officer/director of the Company.

2025 Financing Note

On January 15, 2025, the Board approved a Financing Term Sheet (the “2025 Term Sheet”), which set forth the terms under which the Company will use its best efforts to arrange for financing of a maximum of \$10,000,000 (the “2025 Financing”), which amounts will be obtained in several tranches.

Pursuant to the 2025 Term Sheet, the 2025 Notes (defined below) will convert into shares of the Company’s Series D-1 Preferred Stock twelve months after the issue date of a 2025 Note.

The 2025 Financing will be in the form of unsecured convertible loans from the investors (the “2025 Note Investors”) and evidenced by convertible promissory notes (individually, a “2025 Note” and collectively, the “2025 Notes”). In addition to customary provisions, the 2025 Notes will contain the following provisions:

- (i) The 2025 Notes will bear interest at the rate of eight percent (8%) per annum on the outstanding principal amount of the Loan that has been funded to the Company;
- (ii) In the event there is a change of control of the Board, the term of the 2025 Notes will be accelerated and all amounts due under the 2025 Notes may be immediately due and payable at the 2025 Note Investors’ option;
- (iii) The outstanding principal amount and interest payable under the 2025 Notes may be converted early at the 2025 Note Investors’ option into shares of Series D-1 Preferred Stock at a price per share equal to \$2.862. The Series D-1 Preferred Stock is convertible into ten (10) shares of common stock; and
- (iv) The outstanding principal amount and interest payable under the Loan will automatically convert into shares of the Company’s Series D-1 Preferred Stock twelve (12) months after the issue date of a 2025 Note. The Series D-1 Preferred Stock shall be convertible into ten (10) shares of the Company’s Common Stock.

During the three months ended June 30, 2025, the Company received 2025 Notes proceeds in the aggregate amount of \$540,000, of which \$150,000 was from a non-related party and \$390,000 was from an officer and director of the Company. During the six months ended June 30, 2025, the Company received 2025 Notes proceeds in the aggregate amount of \$995,000, of which \$150,000 was from a non-related party and \$845,000 was from an officer and director of the Company.

As of June 30, 2025, principal and interest in the amount of \$995,000 and \$18,740, respectively, remains outstanding on the 2025 Notes.

2024 Financing

On January 15, 2025, the Board approved the closure of the 2024 Financing.

As of June 30, 2025, principal and interest in the amount of \$1,215,000 and \$74,028, respectively, remains outstanding on the 2024 Notes.

2022 Financing

On July 11, 2024, the Board approved the closure of the 2022 Financing.

During the three months ended June 30, 2025, principal and interest in the aggregate amount of \$723,909, owed in connection with the 2022 Notes were converted into 252,940 shares of Series D-1 Preferred Stock at the Conversion Price of \$2.862 per share. Any fractional shares issuable pursuant to the formula were rounded up to the next whole share of Series D-1 Preferred Stock. See Note 9, Stockholders' Deficit for additional information on the Series D-1 Preferred Stock.

During the six months ended June 30, 2025, principal and interest in the aggregate amount of \$1,770,603, owed in connection with the 2022 Notes were converted into 618,340 shares of Series D-1 Preferred Stock at the Conversion Price of \$2.862 per share. Any fractional shares issuable pursuant to the formula were rounded up to the next whole share of Series D-1 Preferred Stock. See Note 9, Stockholders' Deficit for additional information on the Series D-1 Preferred Stock.

2021 Financing

On September 20, 2022, the Board approved the closure of the 2021 Financing.

As of June 30, 2025, principal and interest in the amount of \$100,000 and \$55,444, respectively, remains outstanding on the 2022 Note. For the three months ended June 30, 2025, the Company recorded interest expense of \$2,000, related to the 2021 Notes. For the six months ended June 30, 2025, the Company recorded interest expense of \$4,000, related to the 2021 Notes.

Interest Expense on Convertible Notes Payable

During the three months ended June 30, 2025, the Company incurred an aggregate of \$49,976 in interest expense on outstanding 2021, 2022, 2024, and 2025 Notes. During the three months ended June 30, 2024, the Company incurred an aggregate of \$53,308 in interest expense on outstanding 2021 and 2022 Notes. No 2024 Notes or 2025 Notes were outstanding during the three months ended June 30, 2024.

During the six months ended June 30, 2025, the Company incurred an aggregate of \$108,128 in interest expense on outstanding 2021, 2022, 2024, and 2025 Notes. During the six months ended June 30, 2024, the Company incurred an aggregate of \$111,134 in interest expense on outstanding 2021 and 2022 Notes. No 2024 Notes or 2025 Notes were outstanding during the six months ended June 30, 2024.

As of June 30, 2025 and December 31, 2024, aggregate interest accrued on the Convertible Notes was \$148,212 and \$172,687, respectively.

6. Notes Payable

The Company obtained short-term financing for our commercial insurance policies. As of June 30, 2025 and December 31, 2024, the balance of the note payable was \$54,337 and \$206,463, respectively.

7. Related Party Transactions

During the six months ended June 30, 2025 and 2024, the Company incurred consulting fees of \$0 and \$63,600, respectively, for services rendered by Bruce Horowitz (Capital Strategists) a former member of the Board and former Chief Operating Officer (“COO”). As of March 25, 2024, Mr. Horowitz resigned as COO and member of the Board. On March 26, 2024, the Company paid Mr. Horowitz \$250,000 and on June 27, 2024, the Company paid \$258,000 for outstanding consulting fees.

Directors’ fees for Mr. Horowitz for the six months ended June 30, 2025 and 2024 were \$0 and \$18,750, respectively. Mr. Horowitz waived the amount of \$450,000 due to him in directors’ fees upon his resignation.

See Note 5 for details of other related party transactions.

Directors’ fees incurred during the three months ended June 30, 2025 and 2024, were \$77,500 and \$77,500, respectively. Directors’ fees incurred during the six months ended June 30, 2025 and 2024, were \$155,000 and \$173,750, respectively. Accrued directors’ fees as of June 30, 2025 and December 31, 2024 were \$232,500 and \$77,500, respectively.

8. Prepaid Expenses and Other Current Assets

The following table summarizes the prepaid expenses and other current assets at June 30, 2025 and December 31, 2024:

	June 30, 2025	December 31, 2024
Deferred tax asset	\$ 1,596	\$ 1,596
Prepaid insurance	121,979	209,320
Prepaid rent	8,106	8,106
Prepaid subscriptions	14,380	27,418
Prepaid other	2,977	4,223
Other current assets	2,811	236,383
Total Prepaid Expenses and Other Current Assets	<u>\$ 151,849</u>	<u>\$ 487,046</u>

Other current assets at December 31, 2024 include a refund due from the University of Tennessee College of Veterinary Medicine upon termination of contract which was received on February 19, 2025.

9. Stockholders’ Deficit

Preferred Stock

During the three months ended June 30, 2025, the Company issued 252,940 shares of Series D-1 Convertible Preferred Stock upon the conversion of \$670,000 of principal and \$53,909 of accrued interest outstanding on the 2022 Notes.

During the six months ended June 30, 2025, the Company issued 618,340 shares of Series D-1 Convertible Preferred Stock upon the conversion of \$1,638,000 of principal and \$132,603 of accrued interest outstanding on the 2022 Notes.

On June 21, 2024, the Board of Directors approved the conversion of 11,416,242 Series D Preferred Shares held by Dominic Rodrigues (a Company officer and director) into 1,141,626 shares of Series D-1 Preferred shares.

Number of Preferred Shares

On June 24, 2024, the Company filed an amended Series D Certificate of Designation to decrease the authorized shares from 12,374,000 to 957,100 shares of Series D Convertible Preferred Stock. The Series D-1 Certificate of Designation was also amended to increase the authorized shares from 9,441,000 to 23,042,900 shares of Series D-1 Convertible Preferred Stock.

See Note 15 for details on issuances of 2025 Notes subsequent to June 30, 2025.

Stock Options

On April 1, 2025, the Company granted 5-year options for the purchase of 480,000 shares of the Company's common stock at an exercise price of \$.30 to a consultant (the "Consultant Options"). The Consultant Options had a grant date value of \$13,876 and vest 25% at date of grant, and 25% on the first day of each quarter following the date of grant.

The grant date value of the stock options was calculated using the Black Sholes valuation model with the following assumptions:

Risk free interest rate	3.86%
Expected term (years)	2.5
Expected volatility	90%
Expected dividends	0.00%

No stock options were exercised during the three and six months ended June 30, 2025 or the three and six months ended June 30, 2024.

The following table summarizes stock option activities during the six months ended June 30, 2025:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Life in Years	Aggregate Intrinsic Value
Options outstanding at January 1, 2025	53,393,102	\$ 0.2834	9.3	\$ -
Options exercisable at January 1, 2025	20,881,145	0.2791	8.5	\$ -
Options outstanding at June 30, 2025	53,873,102	0.2836	8.9	\$ -
Options exercisable at June 30, 2025	21,001,145	\$ 0.2793	8.0	\$ -

The following table summarizes information about outstanding and exercisable options at June 30, 2025:

Options Outstanding		Options Exercisable		Intrinsic Value
Exercise Price	Outstanding Number of Options	Weighted Average Remaining Life In Years	Exercisable Number of Options	
\$ 0.1200	2,425,000	0.40	2,425,000	\$ -
\$ 0.2862	814,681	4.30	271,562	\$ -
\$ 0.2862	49,503,421	9.40	17,534,583	\$ -
\$ 0.2900	100,000	0.40	100,000	\$ -
\$ 0.3000	480,000	4.80	120,000	\$ -
\$ 0.7500	550,000	0.40	550,000	\$ -
	<u>53,873,102</u>		<u>21,001,145</u>	<u>\$ -</u>

During the three months ended June 30, 2025 and 2024, the Company recognized stock-based compensation expense of \$322,070 and \$0, respectively, in connection with the amortization of stock options. During the six months ended June 30, 2025 and 2024, the Company recognized stock-based compensation expense of \$637,170 and \$0, respectively, in connection with the amortization of stock options.

As of June 30, 2025, there was \$1,830,984 of unrecognized stock-based compensation related to the above stock options, which will be recognized over the weighted average remaining vesting period of 1.4 years.

10. Leases

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.

On April 24, 2025, the Company entered into the first amendment to its operating lease agreement, extending the lease term by an additional three years through June 30, 2028. Pursuant to the amendment, monthly base rent will range from \$4,391 to \$4,616 over the extended term.

Total operating lease expense for the three months ended June 30, 2025 was \$12,675, of which \$8,450 was included within research and development and \$4,225 was included within general and administrative expenses on the condensed consolidated statements of operations. Total operating lease expense for the three months ended June 30, 2024 was \$13,002 of which \$8,668 was included within research and development and \$4,334 was included within general and administrative expenses on the condensed consolidated statements of operations.

Total operating lease expense for the six months ended June 30, 2025 was \$24,894, of which \$16,596 was included within research and development and \$8,298 was included within general and administrative expenses on the condensed consolidated statements of operations. Total operating lease expense for the six months ended June 30, 2024 was \$25,844 of which \$17,229 was included within research and development and \$8,615 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 Six Months Ended	
	June 30,	
	2025	2024
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows used in operating leases	\$ 25,299	\$ 23,402
Right-of-use assets obtained in exchange for lease obligations:		
Operating leases	\$ 150,133	\$ -
Weighted Average Remaining Lease Term		
Operating leases	3 years	1 year
Weighted Average Discount Rate		
Operating leases	5.0%	5.0%

Future minimum payments under the Company's non-cancellable lease obligations as of June 30, 2025 were as follows:

Future Minimum Payments

Years	Amount
Remainder of 2025	26,345
2026	53,364
2027	54,716
2028	27,695
Total lease payments	162,120
Less: amount representing imputed interest	(11,988)
Present value of lease liability	150,132
Less: current portion	(46,232)
Lease liability, non-current portion	\$ 103,900

11. Grants

On October 25, 2021, the Company received a grant award of \$2,500,000 from the State of Tennessee for the study of animal cancers and dermatological disorders for the period October 15, 2021 to June 30, 2022 (the "Tennessee Grant" or "Grant"). The Tennessee Grant was pre-funded; therefore, the funds do not need to be used in full by June 30, 2022. The Tennessee Grant was provided as reimbursement of research and development expenses related to the development of animal health drug products. The Company has elected gross presentation of the Tennessee Grant income earned and the related research and development expenses, with Tennessee Grant income presented as grant revenue in the period in which it is earned, and qualifying costs presented as research and development expenses included in the Company's statement of operations in the period that such costs are incurred. As of June 30, 2025 and December 31, 2024, the Company recorded \$0 and \$336,108, respectively, as unearned grant revenue liability on the accompanying condensed consolidated balance sheets. The Company recorded grant revenue of \$57,480 and \$336,108 during the three and six months ended June 30, 2025, respectively, and \$254,991 and \$493,063 during the three and six months ended June 30, 2024, respectively.

12. License Transactions

VisiRose

On January 3, 2025, the Company's majority-owned subsidiary, VisiRose, received investments totaling \$700,000 in exchange for the issuance of 3,694 shares of VisiRose common stock. In accordance with the licensing agreement, VisiRose also issued an additional 188 shares of common stock to the University of Miami to maintain the University's 5% ownership interest.

As of June 30, 2025, Provectus holds a majority ownership interest in its subsidiary, VisiRose, with a 90% stake, while the University of Miami retains a 5.0% ownership interest, and two additional investors each hold approximately 2.5%. In accordance with U.S. Generally Accepted Accounting Principles (GAAP), the Company consolidates VisiRose's financial results within its condensed consolidated financial statements.

During the three and six months ended June 30, 2025, the Company recorded a net loss attributable to VisiRose noncontrolling interest of \$37,661 and \$59,155, respectively, reflecting the noncontrolling interests' proportionate share of the VisiRose losses.

13. Commitments, Contingencies and Litigation

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

14. Segment Reporting

The Company's only segment is Clinical Stage Biotechnology. The CODM reviews profit and loss information on a consolidated basis in order to assess performance and make decisions about the allocation of operating and capital resources.

The following table presents disaggregated financial information with respect to the Company's Clinical Stage Biotechnology segment for the three and six months ended June 30, 2025 and 2024, respectively:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2025	2024	2025	2024
Grant Revenue	\$ 57,480	\$ 254,991	\$ 336,108	\$ 493,063
Operating Expenses:				
Research and development				
Clinical trial and research expense	733,295	339,441	983,791	758,821
Depreciation / amortization	-	1,765	-	3,530
Insurance	51,827	57,540	99,816	115,087
Payroll and taxes	73,773	65,513	155,952	133,795
Rent and utilities	8,450	8,668	16,596	17,229
Total research and development	867,345	472,927	1,256,155	1,028,462
General and administrative				
Stock-based compensation	322,070	-	637,170	-
Payroll and taxes	224,404	170,772	441,117	235,621
Professional fees	178,303	117,992	336,930	294,122
Legal fees	125,133	136,660	246,155	313,480
Directors' fees	77,500	77,500	155,000	(276,250)
Insurance	26,194	41,684	52,954	87,263
Donations	-	-	50,000	-
Rent and utilities	4,333	4,846	8,984	9,697
Depreciation / amortization	465	465	931	931
Foreign currency translation	(48)	363	-	509
Other segment expenses	32,509	26,636	49,381	41,347
Total general and administrative	990,863	576,918	1,978,622	706,720
Total Operating Loss	(1,800,728)	(794,854)	(2,898,669)	(1,242,119)
Other Income (Expense):				
Research and development credit	-	9,301	-	9,301
Interest expense	(51,353)	(61,295)	(115,014)	(118,072)
Net Loss	\$ (1,852,081)	\$ (846,848)	\$ (3,013,683)	\$ (1,350,890)

Other segment expenses primarily include costs associated with office expenses, travel, bank charges, computer-related expenses, dues and subscriptions, and taxes. These expenses are incurred as part of the day-to-day operations and general administration of the Company's segments.

15. Subsequent Events

The Company has evaluated events that have occurred after the balance sheet and through the date the condensed consolidated 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 June 30, 2025, the Company entered into 2025 Notes with non-related party investors in the aggregate principal amount of \$250,000.

Series D-1 Preferred Stock

Subsequent to June 30, 2025, principal and interest in the aggregate amount of \$232,343, owed in connection with 2024 Notes was converted into 81,183 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 consolidated financial statements and our Annual Report on Form 10-K for the year ended December 31, 2024 filed with the SEC on March 28, 2025 (“2024 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 platform, which comprises different drug candidates and non-clinical formulations made from pharmaceutical-grade RBS using different concentrations and delivered by different routes of administration specific to each disease and/or disease indication, includes:

Clinical Development Programs

- *Oncology:* Intratumoral 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, different types of liver cancers, and breast cancer.

PV-10 has undergone clinical monotherapy and combination therapy study of mechanisms of action and immune response 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.

The Company’s co-lead indication for intratumoral PV-10 is FOLRINOX-refractory pancreatic ductal adenocarcinoma (“PDAC”) metastatic to the liver (“mPDAC”), where patients would receive the combination therapy of PV-10 and systemically administered gemcitabine and nab-paclitaxel at a single-site early-stage clinical trial at Moffitt.

The Company’s other co-lead indication is pre-operative penile squamous cell carcinoma (“penile SCC”), where patients would receive monotherapy PV-10 at a single-site early-stage clinical trial at Moffitt.

- *Dermatology:* Topical PH-10, a formulation of PV-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.

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 PV-10 formulations have undergone non-clinical combination therapy study for psoriasis and are undergoing non-clinical monotherapy study for skin inflammation and skin aging at TRU.

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

Topical formulation PV-305, a formulation of PV-10, has undergone non-clinical combination therapy study (i.e., drug and device) for diseases and disorders of the eye, such as infectious keratitis, at BPEI.

The Company launched a clinical-stage start-up biotechnology company named VisiRose, Inc. (“VisiRose”), a collaboration between the Company and UM to commercialize BPEI’s ocular research using PV-305.

Proof-of-Concept Programs

- *Oncology*: Intratumoral PV-10 has undergone non-clinical monotherapy and combination therapy study for the treatment of relapsed and refractory pediatric solid tumor cancers at the University of Calgary's Cumming School of Medicine in Calgary, Alberta, Canada ("UCal"). The Company believes that the UCal researchers have achieved monotherapy *in vivo* POC of intratumoral administration for pediatric solid tumor cancers.
- Oral ("PO") formulations of PV-10 have undergone non-clinical monotherapy study for high-risk and refractory adult solid tumor cancers at UCal. The Company believes that the UCal researchers and the Company have both achieved monotherapy *in vivo* POC of PO administration, that the Company has achieved monotherapy *in vivo* POC of PO administration in both prophylactic and therapeutic settings, and that the Company has achieved monotherapy *in vivo* POC of PO administration for adult solid tumors.
- *Hematology*: PO formulations of PV-10 have undergone non-clinical monotherapy study for the treatment of refractory and relapsed pediatric and other blood cancers, including leukemias, at UCal. The Company believes that the UCal researchers have achieved *in vivo* POC of PO administration for blood cancers.
- *Wound Healing*: The Company believes that monotherapy *in vivo* POC of topical administration of non-pharmaceutical grade rose bengal for the treatment of this indication has been shown by researchers at the University of Texas Medical Branch ("UTMB") in Galveston, Texas, who are now collaborating with the Company to use our pharmaceutical-grade RBS.

Topical formulations of PV-10 are undergoing non-clinical monotherapy study for the healing of full-thickness cutaneous wounds at UTMB.

- *Animal Health*: PV-10 formulations have undergone non-clinical monotherapy study for the treatment of cutaneous canine cancers at the University of Tennessee's College of Veterinary Medicine in Knoxville, Tennessee. The Company believes that it has achieved monotherapy POC of intratumoral administration for canine cancers.

Early Drug Discovery Programs

- *Immune vaccine adjuvant*: Different formulations of PV-10 have undergone non-clinical study as a vaccine adjuvant to enhance T cell responses for anti-viral and anti-cancer vaccines.
- *Infectious Diseases*: PO and intranasal ("IN") formulations of PV-10 have undergone non-clinical 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 of PV-10 have undergone non-clinical monotherapy and combination therapy study for the treatment of gram-positive and gram-negative bacterial infections (including multi-drug-resistant strains) and have undergone non-clinical monotherapy study for the treatment of oral bacterial infections at UTHSC. Different formulations of PV-10 have undergone non-clinical monotherapy study for the treatment of fungal infections at UTHSC.
- *Tissue Regeneration and Repair*: Different formulations of PV-10 have undergone non-clinical monotherapy study for vertebrate development, wound healing, and tissue regrowth at the University of Nevada, Las Vegas in Las Vegas, Nevada.
- *Proprietary*: Different formulations of PV-10 are undergoing non-clinical study for proprietary diseases at an academic medical center.

Computer Modeling Programs

- Computer-based molecular docking of RBS has been done and is being done for amyotrophic lateral sclerosis and other disease targets.

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 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 for other disease areas by endeavoring to show non-clinical 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 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 API and Drug 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 API and drug candidate manufacturing processes; the production and multi-year stability testing of multiple API and drug 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 API and drug 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 API and ITU PV-10 drug candidate, the processes’ CMC specifications, and the CMC data from the production of stability lots of API and drug 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 the Company’s former lead indication of locally advanced cutaneous melanoma, including the U.S. FDA, Germany’s Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), Australia’s Therapeutic Goods Administration (TGA) under a clinical trial notification, France’s Agence Nationale de Sécurité du Médicament et des Produits de Santé (ANSM), Italy’s Agenzia Italiana del Farmaco (AIFA), Mexico’s Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS), and Argentina’s Administración Nacional de Medicamentos, Alimentos y Tecnología Médica (ANMAT).

RBS Non-Proprietary Name

The RBS name for the Company's pharmaceutical-grade API was selected by and passed the review of the World Health Organization ("WHO") Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations after the Company applied for a non-proprietary name in the third quarter of 2020 and reached the status of recommended International Non-proprietary 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

Commercial grade rose bengal can be purchased from specialty chemical suppliers in the U.S. and in other parts of the world that manufacture it under non-cGMP conditions. Commercial grade rose bengal appears to have reported purities that may vary between 80% and 95% and 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 non-clinical study of the rose bengal molecule for potential biomedical therapeutic applications.

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

Diagnostic Grade

Diagnostic grade rose bengal describes non-approved rose bengal that is used as an ingredient in historical or current ophthalmic solutions, strips, and devices, 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 for 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 under cGMP regulations and/or may have been compounded by a pharmacist, academic medical researcher, or commercial entity under cGMP regulations. Here too, the Company believes that purification may not sufficiently improve the amounts and accuracy of diagnostic grade 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 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-grade rose bengal (i.e., commercial and diagnostic grades) 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-grade 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 grade rose bengal may pose significant scientific, technological, and economic challenges to overcome and validate for compliance with modern drug regulatory standards.

Recent Developments

Annual Stockholder Meeting Proposals

The Company held its annual meeting of stockholders on June 18, 2025. 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.

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 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;
- 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 candidates.

General and Administrative Expenses

General and administrative expenses consist 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 June 30, 2025 and June 30, 2024

	For the Three Months Ended June 30,		Increase/ (Decrease)	% Change
	2025	2024		
Grant Revenue	\$ 57,480	\$ 254,991	\$ (197,511)	(77.5%)
Operating Expenses:				
Research and development	867,345	472,927	394,418	83.4%
General and administrative	990,863	576,918	413,945	71.8%
Total Operating Expenses	1,858,208	1,049,845	808,363	77.0%
Total Operating Loss	(1,800,728)	(794,854)	(1,005,874)	(126.5%)
Other Income (Expense):				
Research and development credit	-	9,301	(9,301)	(100.0%)
Interest expense	(51,353)	(61,295)	(9,942)	(16.2%)
Net Loss	\$ (1,852,081)	\$ (846,848)	\$ (1,005,233)	(118.7%)

Overview

The Company's net loss increased by \$1,005,233 for the three months ended June 30, 2025 as compared to the three months ended June 30, 2024, primarily as the result of a decrease in grant revenue and an increase in operating expenses, described below.

Grant Revenue

Grant revenue recognized during the three months ended June 30, 2025, was \$57,480, compared to \$254,991 for the same period in 2024, representing a decrease of \$197,511, or 77.5%. The decrease was primarily due to lower qualifying research and development expenses eligible for reimbursement under the grant.

Operating Expenses:

Research and Development Expenses

Research and development expenses were \$867,345 for the three months ended June 30, 2025, an increase of \$394,418, or 83.4%, compared to \$472,927 for the same period in 2024. The increase was primarily driven by higher clinical trial and research expenses related to the manufacturing of a new drug.

The following table summarizes research and development expenses for the three months ended June 30, 2025 and 2024.

	For the Three Months Ended June 30,		Increase/ (Decrease)	% Change
	2025	2024		
Research and development:				
Clinical trial and research expenses	\$ 733,295	\$ 339,441	\$ 393,854	116.0%
Depreciation/amortization	-	1,765	(1,765)	(100.0%)
Insurance	51,827	57,540	(5,713)	(9.9%)
Payroll and taxes	73,773	65,513	8,260	12.6%
Rent and utilities	8,450	8,668	(218)	(2.5%)
Total research and development	\$ 867,345	\$ 472,927	\$ 394,418	83.4%

General and Administrative Expense

General and administrative expenses were \$990,863 for the three months ended June 30, 2025, compared to \$576,918 for the three months ended June 30, 2024, reflecting an increase of \$413,945 or 71.8%. The increase was primarily due to (i) higher payroll expenses and associated taxes resulting primarily from the addition of two officers hired in April 2024, (ii) increased professional fees related to the annual shareholders meeting, and (iii) higher stock-based compensation from stock options granted in December 2024.

The following table summarizes general and administrative expenses for the three months ended June 30, 2025 and 2024.

	For the Three Months Ended June 30,		Increase/ (Decrease)	% Change
	2025	2024		
General and administrative:				
Depreciation	\$ 465	\$ 465	\$ -	0.0%
Directors fees	77,500	77,500	-	0.0%
Insurance	26,194	41,684	(15,490)	(37.2%)
Legal and litigation	125,133	136,660	(11,527)	(8.4%)
Other general and administrative cost	32,509	26,636	5,873	22.0%
Payroll and taxes	224,404	170,772	53,632	31.4%
Professional fees	178,303	117,992	60,311	51.1%
Rent and utilities	4,333	4,846	(513)	(10.6%)
Stock based compensation	322,070	-	322,070	100.0%
Foreign currency translation	(48)	363	(411)	(113.2%)
Total general and administrative	<u>\$ 990,863</u>	<u>\$ 576,918</u>	<u>\$ 413,945</u>	<u>71.8%</u>

Other Expense, Net

Interest expense decreased by \$9,942 or 16.2% from \$61,295 for the three months ended June 30, 2024 to \$51,353 for the three months ended June 30, 2025, primarily as the result of lower convertible debt and notes payable balances outstanding during the period.

Research and development tax credit in Australia decreased by \$9,301 or 100.0% from \$9,301 for the three months ended June 30, 2024 to \$0 for the three months ended June 30, 2025. The decrease was due to the absence of active clinical trials in Australia during the 2025 period.

Comparison of the Six Months Ended June 30, 2025 and June 30, 2024

	For the Six Months Ended June 30,		Increase/ (Decrease)	% Change
	2025	2024		
Grant Revenue	\$ 336,108	\$ 493,063	\$ (156,955)	(31.8%)
Operating Expenses:				
Research and development	1,256,155	1,028,462	227,693	22.1%
General and administrative	1,978,622	706,720	1,271,902	180.0%
Total Operating Expenses	3,234,777	1,735,182	1,499,595	86.4%
Total Operating Loss	(2,898,669)	(1,242,119)	(1,656,550)	(133.4%)
Other Income (Expense):				
Research and development credit	-	9,301	(9,301)	(100.0%)
Interest expense	(115,014)	(118,072)	(3,058)	(2.6%)
Net Loss	\$ (3,013,683)	\$ (1,350,890)	\$ (1,662,793)	(123.1%)

Overview

The Company's net loss increased by \$1,662,793 or 123.1% for the six months ended June 30, 2025 as compared to the six months ended June 30, 2024, primarily due to a decline in grant revenue and higher operating expenses, as described below.

Grant Revenue

Grant revenue was \$336,108 for the six months ended June 30, 2025, compared to \$493,063 for the six months ended June 30, 2024, representing a decrease of \$156,955 or 31.8%. The decrease was primarily due to lower qualifying research and development expenses eligible for reimbursement under the grant.

Operating Expenses

Research and Development Expenses

Research and development expenses were \$1,256,155 for the six months ended June 30, 2025, representing an increase of \$227,693, or 22.1%, compared to \$1,028,462 for the same period in 2024. The increase was primarily driven by higher clinical trial and research costs related to the manufacturing of a new drug.

The following table summarizes research and development expenses for the six months ended June 30, 2025 and 2024.

	For the Six Months Ended June 30,		Increase/ (Decrease)	% Change
	2025	2024		
Operating Expenses:				
Research and development:				
Clinical trial and research expenses	\$ 983,791	\$ 758,821	\$ 224,970	29.6%
Depreciation/amortization	-	3,530	(3,530)	(100.0%)
Insurance	99,816	115,087	(15,271)	(13.3%)
Payroll and taxes	155,952	133,795	22,157	16.6%
Rent and utilities	16,596	17,229	(633)	(3.7%)
Total research and development	\$ 1,256,155	\$ 1,028,462	\$ 227,693	22.1%

General and Administrative Expenses

General and administrative expenses were \$1,978,622 for the six months ended June 30, 2025, compared to \$706,720 for the six months ended June 30, 2024, representing an increase of \$1,271,902, or 180.0%. The increase was primarily attributable to (i) higher directors' fees in 2025, driven by the reversal of \$469,000 previously accrued director fees for Mr. Bruce Horowitz, our former COO, following his resignation on March 25, 2024, (ii) increased professional fees related to audit and accounting fees, (iii) higher payroll and payroll taxes resulting from the addition of two new officers in April 2024, (iv) increased donations due to a contribution made to the University of Miami by the Company's majority-owned subsidiary, VisiRose, and (v) higher stock-based compensation from stock options granted in December 2024. These increases were partially offset by (vi) lower insurance costs following a change in insurance carrier and (vii) reduced legal costs associated with patents.

The following table summarizes general and administrative expenses for the six months ended June 30, 2025 and 2024.

	For the Six Months Ended June 30,		Increase/ (Decrease)	% Change
	2025	2024		
General and administrative:				
Depreciation	\$ 931	\$ 931	\$ -	0.0%
Directors fees	155,000	(276,250)	431,250	(156.1%)
Donations	50,000	-	50,000	100.0%
Insurance	52,954	87,263	(34,309)	(39.3%)
Legal and litigation	246,155	313,480	(67,325)	(21.5%)
Other general and administrative cost	49,381	41,347	8,034	19.4%
Payroll and taxes	441,117	235,621	205,496	87.2%
Professional fees	336,930	294,122	42,808	14.6%
Rent and utilities	8,984	9,697	(713)	(7.4%)
Stock based compensation	637,170	-	637,170	100.0%
Foreign currency translation	-	509	(509)	(100.0%)
Total general and administrative	<u>\$ 1,978,622</u>	<u>\$ 706,720</u>	<u>\$ 1,271,902</u>	<u>180.0%</u>

Other Expense, Net

Interest expense decreased by \$3,058 or 2.6% from \$118,072 for the six months ended June 30, 2024 to \$115,014 for the six months ended June 30, 2025, primarily as the result of lower convertible debt and notes payable balances outstanding during the period.

Research and development tax credit in Australia decreased by \$9,301 or 100.0% from \$9,301 for the six months ended June 30, 2024 to \$0 for the six months ended June 30, 2025. The decrease was due to the absence of active clinical trials in Australia during the 2025 period.

Liquidity and Going Concern

The Company's cash and restricted cash were \$416,471 at June 30, 2025, which includes \$30,542 of restricted cash resulting from a grant received from the State of Tennessee, compared to \$489,726 at December 31, 2024, which included \$182,284 of restricted cash. The Company's working capital deficit was \$5,924,919 and \$5,998,712 as of June 30, 2025 and December 31, 2024, respectively. We have continuing net losses and negative cash flows from operating activities. In addition, we have an accumulated deficit of \$260,377,489 as of June 30, 2025. 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. 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. 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 June 30, 2025, cash requirements for our current liabilities include approximately \$3,980,690 for accounts payable and other accrued expenses (including lease liabilities) and \$54,337 for a 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 \$2,310,000 plus \$148,212 of accrued interest will mature one year from the date of the notes. The 2021, 2024, and 2025 Notes are only subject to repayment in the event of a change of control or event of default. 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 2025 unsecured convertible notes (the "2025 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 2025 Financing, exchange offers, debt financings, corporate collaborations, or other means. If we are unable to raise sufficient capital through the 2025 Financing or otherwise, we will not be able to pay our obligations as they become due.

The primary business objective of management is to build the Company into a commercial-stage biotechnology company; however, we cannot assure you that management will be successful in implementing the Company's business plan of developing, licensing, and/or commercializing our prescription drug candidates. Moreover, even if we are successful in improving our current cash flow position, we nonetheless plan to seek additional funds to meet our current and long-term requirements in 2025 and beyond. We anticipate that these funds will otherwise come from the proceeds of private placement transactions, including the 2025 Financing, exercise of outstanding stock options, or public offerings of debt or equity securities. While we believe that we have a reasonable basis for our expectation that we will be able to raise additional funds, we cannot assure you that we will be able to complete additional financing in a timely manner. In addition, any such financing may result in significant dilution to stockholders.

Critical Accounting Estimates

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

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

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

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

Inherent Limitations on Effectiveness of Controls

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

Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting that occurred during the 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 13.

ITEM 1A. RISK FACTORS.

Except as noted below, there have been no material changes to the risk factors disclosed in our Annual Report on Form 10-K for the year ended December 31, 2024.

The following risk factor is provided as an update to our previously disclosed risk factors:

Changes in U.S. Trade Policies Could Adversely Affect Our Operations

Ongoing uncertainty around U.S. trade policies, tariffs, and international agreements may impact the cost and availability of materials, supplies, and equipment used in our operations or those of our partners. Any disruptions or increased costs resulting from these changes could negatively affect our business, financial condition, results of operations, and the market price of our common stock.

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

2025 Financing

During the three and six months ended June 30, 2025, the Company received aggregate proceeds of \$540,000 and \$995,000, respectively pursuant to certain unsecured convertible notes (the “2025 Notes”). Through June 30, 2025, the Company had drawn down \$995,000 under the 2025 Notes.

Preferred Convertible Stock

During the three months ended June 30, 2025, the Company issued 252,940 shares of restricted Series D-1 Convertible Preferred Stock upon the conversion of \$670,000 of principal and \$53,909 accrued interest, outstanding on the Company’s convertible notes. During the six months ended June 30, 2025, the Company issued 618,340 shares of restricted Series D-1 Convertible Preferred Stock upon the conversion of \$1,638,000 of principal and \$132,603 accrued interest, outstanding on the Company’s convertible 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.

August 14, 2025

By: /s/ Dominic Rodrigues

Dominic Rodrigues

President (Principal Executive Officer)

By: /s/ Heather Raines

Heather Raines, CPA

Chief Financial Officer (Principal Financial Officer)

CERTIFICATION

I, Dominic Rodrigues, 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: August 14, 2025

By: /s/ Dominic Rodrigues

Dominic Rodrigues

President (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: August 14, 2025

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, Dominic Rodrigues, the President (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 June 30, 2025, 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 August 14, 2025.

By: /s/ Dominic Rodrigues

Dominic Rodrigues
President (Principal Executive Officer)

By: /s/ Heather Raines

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