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

FORM 10-Q

☒ Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the quarterly period ended: September 30, 2024

OR

☐ Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from ___ to ___

Commission File Number 001-38286

ENVERIC BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**95-4484725**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
4851 Tamiami Trail N , Suite 200 Naples , FL	**34103**
(Address of principal executive offices)	(Zip code)

(239) 302-1707
(Registrant's telephone number, including area code)

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

Title of Each Class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	ENVB	The Nasdaq Stock Market LLC

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

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

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

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

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

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

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

As of November 12, 2024, there were 9,944,920 shares outstanding of Registrant's Common Stock (par value $ 0.01 per share).

ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES

FORM 10-Q

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ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash	$ 3,111,683	$ 2,287,977
Prepaid expenses and other current assets	1,226,576	1,293,554
Total current assets	**4,338,259**	**3,581,531**
Other assets:		
Property and equipment, net	367,689	507,377
Intangible assets, net	84,368	210,932
Total other assets	**452,057**	**718,309**
Total assets	**$ 4,790,316**	**$ 4,299,840**
LIABILITIES, MEZZANINE EQUITY, AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 576,324	$ 1,218,783
Accrued liabilities	253,150	1,075,643
Investment option liability	4,944	23,608
Warrant liability	4,748	25,470
Total current liabilities	**839,166**	**2,343,504**
Commitments and contingencies (Note 9)		
Mezzanine equity		
Series C redeemable preferred stock, $ 0.01 par value, 100,000 shares authorized, and 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Total mezzanine equity	—	—
Shareholders' equity		
Preferred stock, $ 0.01 par value, 20,000,000 shares authorized; Series B preferred stock, $ 0.01 par value, 3,600,000 shares authorized, 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, $ 0.01 par value, 100,000,000 shares authorized, 8,994,920 and 2,739,315 shares issued and outstanding as of September 30, 2024 and December 31, 2023	89,949	27,392
Additional paid-in capital	107,316,058	100,815,851
Stock subscription receivable	—	(1,817,640)
Accumulated deficit	(102,919,859)	(96,499,518)
Accumulated other comprehensive loss	(534,998)	(569,749)
Total shareholders' equity	**3,951,150**	**1,956,336**
Total liabilities, mezzanine equity, and shareholders' equity	**$ 4,790,316**	**$ 4,299,840**

See the accompanying notes to the unaudited condensed consolidated financial statements.

ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses				
General and administrative	$ 1,235,661	$ 2,080,644	$ 4,467,065	$ 8,273,344
Research and development	762,717	1,281,455	1,736,373	5,531,436
Depreciation and amortization	84,814	86,296	255,002	259,300

Total operating expenses	2,083,192	3,448,395	6,458,440	14,064,080
Loss from operations	(2,083,192)	(3,448,395)	(6,458,440)	(14,064,080)
Other income (expense)				
Change in fair value of warrant liabilities	(122)	67,822	20,722	(115,342)
Change in fair value of investment option liability	(501)	562,715	18,664	(399,921)
Change in fair value of derivative liability	—	—	—	727,000
Interest income (expense), net	(217)	2,237	444	3,142
Total other income (expense)	(840)	632,774	39,830	214,879
Net loss before income taxes	(2,084,032)	(2,815,621)	(6,418,610)	(13,849,201)
Income tax expense	—	(6,595)	(1,731)	(6,595)
Net loss	(2,084,032)	(2,822,216)	(6,420,341)	(13,855,796)
Less preferred dividends attributable to non-controlling interest	—	—	—	19,041
Less deemed dividends attributable to accretion of embedded derivative at redemption value	—	—	—	147,988
Net loss attributable to shareholders	(2,084,032)	(2,822,216)	(6,420,341)	(14,022,825)
Other comprehensive income				
Foreign currency translation	31,497	10,433	34,751	1,115
Comprehensive loss	$ (2,052,535)	$ (2,811,783)	$ (6,385,590)	$ (14,021,710)
Net loss per share - basic and diluted	$ (0.24)	$ (1.30)	$ (0.95)	$ (6.62)
Weighted average shares outstanding, basic and diluted	8,702,951	2,164,656	6,771,162	2,117,153

See the accompanying notes to the unaudited condensed consolidated financial statements.

ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023

	Common Stock						
	Shares	Amount	Additional Paid-In Capital	Subscription Receivable	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
Balance at January 1, 2024	2,739,315	27,392	100,815,851	(1,817,640)	(96,499,518)	(569,749)	1,956,336
Stock-based compensation	—	—	351,488	—	—	—	351,488
Common stock sold under the Equity Distribution Agreement, net of offering costs of $ 583,713	1,668,000	16,680	1,792,109	—	—	—	1,808,789
Issuance of direct offering shares (see Note 7)	228,690	2,287	320,166	—	—	—	322,453
Exercise of Inducement Warrants for common stock	1,954,000	19,540	2,657,440	—	—	—	2,676,980
Proceeds from the subscription receivable related to the issuance of Inducement Warrants, net of offering costs of $ 12,821	—	—	(12,821)	280,500	—	—	267,679
Proceeds from the subscription receivable related to the exercise of warrants and preferred investment options and issuance of common stock in abeyance	704,000	7,040	(7,040)	1,537,140	—	—	1,537,140
Foreign exchange translation gain	—	—	—	—	—	17,906	17,906
Net loss	—	—	—	—	(2,456,915)	—	(2,456,915)
Balance at March 31, 2024	7,294,005	$ 72,939	$105,917,193	$ —	$ (98,956,433)	$ (551,843)	$ 6,481,856
Stock-based compensation	—	—	369,614	—	—	—	369,614
Common stock sold under the Purchase Agreement, net of offering costs of $ 82,850	125,000	1,250	(1,250)	—	—	—	—
Issuance of direct offering shares (see Note 7)	458,000	4,580	444,260	—	—	—	448,840
Issuance of common shares for vested RSU	1,563	16	(16)	—	—	—	—
Foreign exchange translation loss	—	—	—	—	—	(14,652)	(14,652)
Net loss	—	—	—	—	(1,879,394)	—	(1,879,394)
Balance at June 30, 2024	7,878,568	$ 78,785	$106,729,801	$ —	($ 100,835,827)	$ (566,495)	$ 5,406,264
Stock-based compensation	—	—	369,614	—	—	—	369,614
Common stock sold under the Purchase Agreement, net of offering costs of $ 290,029	1,090,477	10,905	216,902	—	—	—	227,807

Issuance of common shares for vested RSU	25,875	259	(259)	—	—	—	—
Foreign exchange translation gain	—	—	—	—	—	31,497	31,497
Net loss	—	—	—	—	(2,084,032)	—	(2,084,032)
Balance at September 30, 2024	8,994,920	$ 89,949	$107,316,058	$ —	$ 102,919,859)	$ (534,998)	$ 3,951,150

See the accompanying notes to the unaudited condensed consolidated financial statements.

ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN MEZZANINE EQUITY AND SHAREHOLDERS' EQUITY
FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023

	Redeemable Non-controlling Interest			Common Stock					
	Shares	Amount	Total Mezzanine Equity	Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
Balance at January 1, 2023	1,000	$ 885,028	$ 885,028	2,078,271	$ 20,782	$94,395,662	$ (79,207,786)	$ (536,734)	$ 14,671,924
Stock-based compensation	—	—	—	—	—	532,835	—	—	532,835
Preferred dividends attributable to redeemable non-controlling interest	—	12,329	12,329	—	—	(12,329)	—	—	(12,329)
Accretion of embedded derivative to redemption value	—	110,991	110,991	—	—	(110,991)	—	—	(110,991)
Foreign exchange translation gain	—	—	—	—	—	—	—	1,968	1,968
Net loss	—	—	—	—	—	—	(4,677,527)	—	(4,677,527)
Balance at March 31, 2023	1,000	$1,008,348	$1,008,348	2,078,271	$ 20,782	$94,805,177	$ (83,885,313)	$ (534,766)	$ 10,405,880
Stock-based compensation	—	—	—	—	—	879,738	—	—	879,738
Preferred dividends attributable to redeemable	—	6,712	6,712	—	—	(6,712)	—	—	(6,712)
Accretion of embedded derivative to redemption value	—	36,997	36,997	—	—	(36,997)	—	—	(36,997)
Redemption of Series A preferred stock	(1,000)	(1,052,057)	(1,052,057)	—	—	—	—	—	—
Issuance of common shares in exchange for RSU conversions from the reduction in force	—	—	—	63,511	635	(635)	—	—	—
Foreign exchange translation loss	—	—	—	—	—	—	—	(11,286)	(11,286)
Net loss	—	—	—	—	—	—	(6,356,053)	—	(6,356,053)
Balance at June 30, 2023	—	$ —	$ —	2,141,782	$ 21,417	$95,640,571	$ (90,241,366)	$ (546,052)	$ 4,874,570
Stock-based compensation	—	—	—	—	—	372,859	—	—	372,859
Issuance of common shares for vested RSU	—	—	—	40,130	401	(401)	—	—	—
Foreign exchange translation gain	—	—	—	—	—	—	—	10,433	10,433
Net loss	—	—	—	—	—	—	(2,822,216)	—	(2,822,216)
Balance at September 30, 2023	—	$ —	$ —	2,181,912	$ 21,818	$96,013,029	$ (93,063,582)	$ (535,619)	$ 2,435,646

See the accompanying notes to the unaudited condensed consolidated financial statements.

ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Nine Months Ended September 30,	
	2024	2023
Cash Flows From Operating Activities:		
Net loss	$ (6,420,341)	$ (13,855,796)
Adjustments to reconcile net loss to cash used in operating activities		
Change in fair value of warrant liability	(20,722)	115,342
Change in fair value of investment option liability	(18,664)	399,921
Change in fair value of derivative liability	—	(727,000)

Stock-based compensation	1,090,716	1,785,432
Amortization of right of use asset	—	64,246
Amortization of intangibles	126,564	126,566
Depreciation expense	128,438	132,734
Gain on disposal of property and equipment	—	(4,219)
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,674)	(746,033)
Accounts payable and accrued liabilities	(1,296,907)	429,688
Right-of-use operating lease asset and obligation	—	(64,244)
Net cash used in operating activities	(6,414,590)	(12,343,363)
Cash Flows From Investing Activities:		
Purchases of property and equipment	—	(5,195)
Proceeds from disposal of property and equipment	—	16,900
Net cash provided by investing activities	—	11,705
Cash Flows From Financing Activities:		
Proceeds from the subscription receivable related to the issuance of Inducement Warrants and the exercise of warrants and preferred investment options	1,804,819	—
Proceeds from exercise of Inducement Warrants	2,676,980	—
Proceeds from common stock sold under the Equity Distribution Agreement, net of offering costs	2,290,186	—
Proceeds from common stock sold under the Purchase Agreement, net of offering costs	599,862	—
Payment for offering costs previously accrued	(161,461)	(105,000)
Redemption of Series A Preferred Stock	—	(1,052,057)
Net cash provided by (used in) financing activities	7,210,386	(1,157,057)
Effect of Foreign Exchange Rate on Changes on Cash	27,910	31,399
Net increase (decrease) in cash	823,706	(13,457,316)
Cash at beginning of period	2,287,977	17,723,884
Cash at end of period	$ 3,111,683	$ 4,266,568
Supplemental disclosure of cash and non-cash transactions:		
Cash paid for interest	$ —	$ —
Income taxes paid	$ 24,001	$ 6,595
Offering costs accrued not paid	$ 35,455	$ 20,800
Deferred offering costs charged to offering costs	$ 495,544	—
Issuance of common shares for offering costs	$ 771,293	$ —
Preferred dividends attributable to redeemable non-controlling interest	$ —	$ 19,041
Accretion of embedded derivative to redemption value	$ —	$ 147,988

See the accompanying notes to the unaudited condensed consolidated financial statements.

ENVERIC BIOSCIENCES, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1. BUSINESS AND LIQUIDITY AND OTHER UNCERTAINTIES

Nature of Operations

Enveric Biosciences, Inc. (“Enveric” or the “Company”) is a biotechnology company developing novel neuroplastogenic small-molecule therapeutics for the treatment of depression, anxiety, and addiction disorders. The head office of the Company is located in Naples, Florida. The Company has the following wholly-owned subsidiaries: Jay Pharma Inc. (“Jay Pharma”), 1306432 B.C. Ltd., MagicMed Industries, Inc. (“MagicMed”), Enveric Biosciences Canada Inc., Akos Biosciences, Inc. (“Akos”), and Enveric Therapeutics, Pty. Ltd. (“Enveric Therapeutics”).

Leveraging its unique discovery and development platform, The Psybrary™, Enveric has created a robust intellectual property portfolio of new chemical entities for specific mental health indications. Enveric’s lead program, the EVM201 Series, comprises next generation synthetic prodrugs of the active metabolite, psilocin. Enveric is developing the first product from the EVM201 Series – EB-002 (formerly EB-373) – for the treatment of psychiatric disorders. Enveric is also advancing its product EB-003, a non-hallucinogenic neuroplastogen from the EVM301 Series, which is expected to offer a first-in-class, new approach to the treatment of difficult-to-address mental health disorders, mediated by the promotion of neuroplasticity without also inducing hallucinations in the patient.

The Company has continued to pursue the development of MagicMed’s proprietary library, the Psybrary™ which the Company believes will help to identify and develop the right drug candidates needed to address mental health challenges. The Company synthesizes novel analogues of serotonin, using a mixture of chemistry and synthetic biology, resulting in the expansion of the Psybrary™, which includes 15 patent families with over a million potential variations and hundreds of synthesized molecules. The Company has created over 1,200 novel molecular compounds and derivatives that are housed in the Psybrary™. The Company’s current focus is to develop its lead molecules, EB-002 and EB-003, and to out license other molecules from the Psybrary™.

The Company screens newly synthesized molecules in the Psybrary™ through PsyAI™, a proprietary artificial intelligence (“AI”) tool. Leveraging AI systems is expected to reduce the time and cost of pre-clinical, clinical, and commercial development. The Company believes it streamlines pharmaceutical design by predicting ideal binding structures of molecules, manufacturing capabilities, and pharmacological effects to help determine ideal drug candidates, tailored to each indication. Each of these molecules that the Company believes are patentable can then be further screened to see how changes to its makeup alter its effects in order to synthesize additional new molecules. New compounds of sufficient purity are undergoing pharmacological screening, including non-clinical (receptors/cell lines), preclinical (animal), and ultimately clinical (human) evaluations. The Company intends to utilize the Psybrary™ and the AI tool to categorize and characterize the Psybrary™ substituents to focus on bringing more non-hallucinogenic neuroplastogen molecules from discovery to the clinical phase.

Going Concern, Liquidity and Other Uncertainties

The Company has incurred a loss since inception resulting in an accumulated deficit of $ 102,919,859 as of September 30, 2024, and further losses are anticipated in the development of its business. For the nine months ended September 30, 2024, the Company has operating cash outflows of $ 6,414,590 and had a loss from operations of $ 6,458,440 . Being a research and development company, since inception, the Company has not yet generated revenue and the Company has incurred continuing losses from its operations. The Company's operations have been funded principally through the issuance of equity. These factors raise substantial doubt about the Company's ability to continue as a going concern for a period of one year from the issuance of these unaudited condensed consolidated financial statements.

In assessing the Company's ability to continue as a going concern, the Company monitors and analyzes its cash and its ability to generate sufficient cash flow in the future to support its operating and capital expenditure commitments. At September 30, 2024, the Company had cash of $ 3,111,683 and working capital of $ 3,499,093 . The Company's current cash on hand is not sufficient to satisfy its operating cash needs for the 12 months from the filing of this Quarterly Report on Form 10-Q. These conditions raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date the financial statements are issued. Management's plan to alleviate the conditions that raise substantial doubt include raising additional working capital through public or private equity or debt financings or other sources, the Purchase Agreement with Lincoln Park (see Note 7), subject to registration, and may include additional collaborations with third parties as well as disciplined cash spending. Adequate additional financing may not be available to us on acceptable terms, or at all. Should the Company be unable to raise sufficient additional capital, the Company may be required to undertake further cost-cutting measures including delaying or discontinuing certain operating activities.

As a result of these factors, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern for a period of one year after the date of the unaudited condensed consolidated financial statements are issued. The Company's unaudited condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Inflation Risks

The Company considers the current inflationary trend existing in the North American economic environment reasonably likely to have a material unfavorable impact on results of continuing operations. Higher rates of price inflation, as compared to recent prior levels of price inflation, have caused a general increase in the cost of labor and materials. In addition, there is an increased risk of the Company experiencing labor shortages due to a potential inability to attract and retain human resources due to increased labor costs resulting from the current inflationary environment.

Nasdaq Notice

On November 21, 2023, the Company received a letter from the Listing Qualifications Department of the Nasdaq Stock Market ("Nasdaq") stating that as of September 30, 2023, the Company did not meet the minimum of $ 2,500,000 in stockholders' equity required for continued listing pursuant to Nasdaq Listing Rule 5550(b)(1). On February 6, 2024, the Company received a letter from Nasdaq, granting the Company an extension to regain compliance with the minimum stockholders' equity requirement by May 20, 2024. On May 21, 2024, the Company received a letter from Nasdaq notifying the Company that it regained compliance with the minimum stockholders' equity requirement for continued listing on the Nasdaq.

On May 16, 2024, the Company received a letter from Nasdaq's Listing Qualifications Department stating that because the closing bid price for the Company's common stock listed on Nasdaq was below $ 1.00 for 30 consecutive business days, the Company no longer meets the minimum bid price requirement for continued listing on the Nasdaq Capital Market (the "Minimum Bid Price Requirement"). The Company received an initial period of 180 calendar days from May 16, 2024, or until November 12, 2024, to regain compliance with the Minimum Bid Price Requirement and was unable to regain compliance during that time. The Company has applied for a second 180-day compliance period. As of the date hereof, the Company has not heard whether it will be granted the second compliance period. The Company anticipates conducting a reverse split during the first or second quarter of 2025 in order to regain compliance with the Minimum Bid Price Requirement if the bid price of the Company's common stock fails to close at or above $ 1.00 per share for a minimum of 10 consecutive business days prior the end of the second compliance period.

NOTE 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation and Principal of Consolidation

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") for interim financial information and Article 8 of Regulation S-X. Accordingly, they do not include all the information and footnotes required by U.S. GAAP for complete financial statements. Management's opinion is that all adjustments (consisting of normal accruals) considered necessary for a fair presentation have been included. Operating results for the three and nine months ended September 30, 2024 are not necessarily indicative of the results that may be expected for the year ending December 31, 2024. These unaudited condensed consolidated financial statements should be read in conjunction with the consolidated financial statements for the year ended December 31, 2023, and related notes thereto included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on March 26, 2024.

The Company's significant accounting policies and recent accounting standards are summarized in Note 2 of the Company's consolidated financial statements for the year ended December 31, 2023. There were no significant changes to these accounting policies during the three and nine months ended September 30, 2024.

Use of Estimates

The preparation of the unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amount of assets and liabilities at the date of the financial statements and expenses during the periods reported. By their nature, these estimates are subject to measurement uncertainty and the effects on the financial statements of changes in such estimates in future periods could be significant. Significant areas requiring management's estimates and assumptions include determining the fair value of transactions involving common stock, the valuation of warrants and preferred investment options, and the valuation of stock-based compensation and accruals associated with third party providers supporting research and development efforts. Actual results could differ from those estimates.

Reclassification

Certain reclassifications have been made to the prior period's unaudited condensed consolidated financial statements in order to conform to the current year presentation. In the prior year, the Company included certain investor related expenses within research and development on the unaudited condensed consolidated statements of operations. These expenses were reclassified to general and administrative expenses in the current year. This reclassification had no effect on the Company's previously reported results of operations, changes in equity, or cash flows.

Foreign Currency Translation

From inception through September 30, 2024, the reporting currency of the Company was the United States dollar while the functional currency of certain of the Company's subsidiaries was the Canadian dollar and Australian dollar. For the reporting periods ended September 30, 2024 and 2023, the Company engaged in a number of transactions denominated in Canadian dollars and Australian dollars. As a result, the Company is subject to exposure from changes in the exchange rates of the Canadian dollar and Australian dollar against the United States dollar.

The Company translates the assets and liabilities of its Canadian subsidiaries and Australian subsidiary into the United States dollar at the exchange rate in effect on the balance sheet date. Revenues and expenses are translated at the average exchange rate in effect during each monthly period. Unrealized translation gains and losses are recorded as foreign currency translation gain (loss), which is included in the unaudited condensed consolidated statements of shareholders' equity as a component of accumulated other comprehensive loss.

The Company has not entered into any financial derivative instruments that expose it to material market risk, including any instruments designed to hedge the impact of foreign currency exposures. The Company may, however, hedge such exposure to foreign currency exchange fluctuations in the future.

Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other comprehensive loss in the unaudited condensed consolidated statements of operations and comprehensive loss as incurred.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist of cash accounts in a financial institution, which at times, may exceed the federal depository insurance coverage of $ 250,000 in the United States and Australia and $ 100,000 in Canada. The Company has not experienced losses on these accounts, and management believes the Company is not exposed to significant risks on such accounts. As of September 30, 2024, the Company had greater than $ 250,000 at United States financial institutions, greater than $ 250,000 at Australian financial institutions, and less than $ 100,000 at Canadian financial institutions.

Research and Development

Research and development expenses are charged to operations as incurred. Research and development expenses include, among other things, internal and external costs associated with preclinical development, pre-commercialization manufacturing expenses, and clinical trials. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial or services provided and the invoices received from its external service providers. In the case of clinical trials, a portion of the estimated cost normally relates to the projected cost to treat a patient in the trials, and this cost is recognized based on the number of patients enrolled in the trial. As actual costs become known, the Company adjusts its accruals accordingly.

Income Taxes

The Company files U.S. federal and state returns. The Company's foreign subsidiary also files a local tax return in their local jurisdiction. From a U.S. federal, state, and Canadian perspective, the years that remain open to examination are consistent with each jurisdiction's statute of limitations. The Company receives no tax benefit from operating losses due to a full valuation allowance.

Research and Development Tax Incentive Receivable

The Company, through its wholly-owned subsidiary in Australia, participates in the Australian research and development tax incentive program, such that a percentage of the Company's qualifying research and development expenditures are reimbursed by the Australian government, and such incentives are reflected as a reduction of research and development expense. The Australian research and development tax incentive is recognized when there is reasonable assurance that the incentive will be received, the relevant expenditure has been incurred and the amount of the consideration can be reliably measured. At each period end, management estimates the reimbursement available to the Company based on available information at the time.

Net Loss per Share

Basic net loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the period. Diluted loss per share is computed using the weighted average number of common shares and, if dilutive, potential common shares outstanding during the period. Potential common shares consist of the incremental common shares issuable upon the exercise of stock options and warrants (using the treasury stock method). The computation of basic net loss per share for the three and nine months ended September 30, 2024 and 2023 excludes potentially dilutive securities. The computations of net loss per share for each period presented is the same for both basic and fully diluted. In accordance with ASC 260 "Earnings per Share" ("ASC 260"), penny warrants were included in the calculation of weighted average shares outstanding for the purposes of calculating basic and diluted earnings per share.

Potentially dilutive securities outlined in the table below have been excluded from the computation of diluted net loss per share for the three and nine months ended September 30, 2024 and 2023 because the effect of their inclusion would have been anti-dilutive.

	For the three and nine months ended September 30, 2024	For the three and nine months ended September 30, 2023
Warrants to purchase shares of common stock	844,628	609,893
Restricted stock units - vested and unissued	20,526	20,847
Restricted stock units - unvested	351,616	148,251
Investment options to purchase shares of common stock	70,000	1,070,000
Options to purchase shares of common stock	23,082	31,852
Total potentially dilutive securities	1,309,852	1,880,843

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* . ASU 2023-07 updates reportable segment disclosure requirements primarily through enhanced disclosures about significant segment expenses. ASU 2023-07 is effective for all entities for fiscal years beginning after December 15, 2023, and for interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. The amendments should be applied retrospectively to all prior periods presented in the financial statements. The Company is currently assessing the potential impacts of ASU 2023-07, however as the Company currently has one reportable segment, does not expect this guidance will not have a material impact on its unaudited condensed consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* , which amends the disclosure to 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 and includes certain other amendments to improve the effectiveness of income tax disclosures. The ASU is effective on a prospective basis for annual periods beginning after December 15, 2024, and early adoption and retrospective application are permitted. Early adoption is permitted. The Company is currently assessing potential impacts of ASU 2023-09 and does not expect the adoption of this guidance will have a material impact on its unaudited condensed consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement (Topic 220): Reporting Comprehensive Income - Expense Disaggregation Disclosures, Disaggregation of Income Statement Expenses*, that requires public companies to disclose, in interim and reporting periods, additional information about certain expenses in the financial statements. The ASU is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted and is effective on either a prospective basis or retrospective basis. The Company is currently assessing the potential impacts of ASU 2024-03.

NOTE 3. PREPAID EXPENSES AND OTHER CURRENT ASSETS

As of September 30, 2024 and December 31, 2023, the prepaid expenses and other current assets of the Company consisted of the following:

	September 30, 2024	December 31, 2023
Prepaid research and development	$ 106,138	$ 46,320
Prepaid value-added taxes	245,972	243,429
Prepaid insurance	249,048	149,559
Prepaid other	99,061	62,036
Deferred offering costs (see Note 7)	508,599	567,603
Franchise tax receivable	17,758	79,258
R&D tax incentive receivable	—	145,349
Total prepaid expenses and other current assets	$ 1,226,576	$ 1,293,554

NOTE 4. INTANGIBLE ASSETS

As of September 30, 2024, the Company's intangible assets consisted of:

Definite lived intangible assets	
Balance at January 1, 2024	$ 210,932
Amortization	(126,564)
Balance at September 30, 2024	$ 84,368

For identified definite lived intangible assets, there was no impairment expense during the three and nine months ended September 30, 2024 and 2023. For identified definite lived intangible assets, amortization expense amounted to $ 42,188 and $ 42,191 during the three months ended September 30, 2024 and 2023, respectively and $ 126,564 and $ 126,566 during each of the nine months ended September 30, 2024 and 2023, respectively.

NOTE 5. PROPERTY AND EQUIPMENT

Property and equipment consists of the following assets which are located in Calgary, Canada, with all amounts converted into U.S. dollars:

	September 30, 2024	December 31, 2023
Lab equipment	$ 819,784	$ 836,709
Computer equipment and leasehold improvements	27,804	28,379
Less: Accumulated depreciation	(479,899)	(357,711)
Property and equipment, net of accumulated depreciation	**$ 367,689**	**$ 507,377**

Depreciation expense was $ 42,626 and $ 44,105 for the three months ended September 30, 2024 and 2023, respectively and $ 128,438 and $ 132,734 for the nine months ended September 30, 2024 and 2023, respectively.

NOTE 6. ACCRUED LIABILITIES

As of September 30, 2024 and December 31, 2023, the accrued liabilities of the Company consisted of the following:

	September 30, 2024	December 31, 2023
Product development	$ 112,346	$ 139,981
Accrued salaries, wages, and bonuses	8,736	8,889
Professional fees	114,068	584,810
Accrued restructuring costs (see Note 9)	—	301,645
Accrued franchise taxes	—	22,318
Patent costs	18,000	18,000

Total accrued expenses	$ 253,150	$ 1,075,643

NOTE 7. SHARE CAPITAL AND OTHER EQUITY INSTRUMENTS

Equity Distribution Agreement

On September 1, 2023, the Company entered into the Equity Distribution Agreement (the "Distribution Agreement"), with Canaccord Genuity LLC ("Canaccord"), pursuant to which the Company may offer and sell from time to time, through Canaccord as sales agent and/or principal, shares of common stock of the Company, par value $ 0.01 per share having an aggregate offering price of up to $ 10.0 million. Due to the offering limitations applicable to the Company and in accordance with the terms of the Distribution Agreement, the Company may offer Common Stock having an aggregate gross sales price of up to $ 2,392,514 pursuant to the prospectus supplement dated September 1, 2023 (the "Prospectus Supplement"). Subject to the terms and conditions of the Distribution Agreement, Canaccord may sell the Common Stock by any method permitted by law deemed to be an "at-the-market offering". The Company will pay Canaccord a commission equal to 3.0 % of the gross sales price of the Common Stock sold through Canaccord under the Distribution Agreement and has also agreed to reimburse Canaccord for certain expenses. The Company may also sell Common Stock to Canaccord as principal for Canaccord's own account at a price agreed upon at the time of sale. Any sale of Common Stock to Canaccord as principal would be pursuant to the terms of a separate terms agreement between the Company and Canaccord.

During the nine months ended September 30, 2024, the Company issued 1,668,000 shares of common stock for gross proceeds of $ 2,392,502 under the Distribution Agreement, and charged offering costs of $ 583,713 to additional paid in capital on the unaudited condensed consolidated balance sheet. As of September 30, 2024 and December 31, 2023, there were deferred offering costs related to the Distribution Agreement of $ 0 and $ 171,944 , respectively. As of September 30, 2024, there is $ 0 available under the Distribution Agreement.

On December 28, 2023, the Company entered into warrant exercise inducement offer letters (the "Inducement Letters") with certain holders (the "Holders") of the February 2022 Post-Modification Warrants and RD and PIPE preferred investment options to purchase shares of the Company's common stock (the "Existing Warrants and Investment Options") pursuant to which the Holders agreed to exercise for cash their Existing Warrants and Investment Options to purchase 1,122,000 shares of the Company's common stock, in the aggregate, at a reduced exercised price of $ 1.37 per share (from an original exercise price of $ 7.78 per share), in exchange for the Company's agreement to issue new warrants (the "Inducement Warrants") to purchase up to 2,244,000 shares of the Company's common stock (the "Inducement Warrant Shares"), and the Holders to make a cash payment of $ 0.125 per Inducement Warrant share for total proceeds of $ 280,500 . In January 2024, the Company received aggregate gross proceeds of $ 1,817,640 from the exercise of the Existing Warrants and Investment Options by the Holders and the sale of the Inducement Warrants. Because the Existing Warrants and Investment Options by the Holders and the sale of the Inducement Warrants that exercised on December 28, 2023 and unsettled until January 2024, the proceeds are included in the condensed consolidated balance sheet as a subscription receivable as of December 31, 2023. As of December 31, 2023, 418,000 shares of the Existing Warrants and Investment Options exercised were considered issued as the Company had the enforceable right to the obtain the cash proceeds, which were in-transit, and the Holders were no longer able to rescind the exercise election. Due to the beneficial ownership limitation provisions, 704,000 shares of the Existing Warrants and Investment Options exercised were initially unissued and held in abeyance for the benefit of the Holder until notice is received from the Holder that the shares may be issued in compliance with such limitation. During the nine months ended September 30, 2024, the Company issued all 704,000 shares of common stock of the 704,000 shares of Existing Warrants and Investment Options exercised that were held in abeyance due to the beneficial ownership limitation provisions.

On December 28, 2023, the Company entered into warrant exercise inducement offer letters (the "Inducement Letters") with certain holders of warrants and preferred investment options. The Inducement Letters prohibit the Company from entering into any variable rate transaction as defined in the Inducement Letters, including the issuance of (1) any variable priced debt or equity securities or (2) transactions whereby the Company may issue securities at a future determined price, such as through an at-the-market offering or an equity line of credit. The variable rate transaction restriction would have expired after six-months from the closing date of December 28, 2023 for the Inducement Letters for an issuance through an at-the-market offering, and one-year for the remaining variable rate transactions, however the restriction was waived for the at-the-market offering on March 8, 2024 and the equity line on May 3, 2024.

On March 8, 2024, the Company entered into a series of common stock purchase agreements for the issuance in a registered direct offering of 228,690 shares of the Company's common stock to the Holders of the Inducement Warrants. The issuance was made in exchange for the permanent and irrevocable waiver of the variable rate transaction limitation solely with respect to the entry into and/or issuance of shares of common stock in an at the market offering contained in the Inducement Letters. The fair value of the shares issued for consideration of waiving the variable rate transaction limitation was $ 322,453 and was charged to additional paid in capital, as it is direct and incremental to the Distribution Agreement, on the unaudited condensed consolidated balance sheet as an offering cost related to the Distribution Agreement.

Lincoln Park Equity Line

On November 3, 2023, the Company entered into a Purchase Agreement (the "Purchase Agreement") and a registration rights agreement (the "Registration Rights Agreement"), with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which Lincoln Park has committed to purchase up to $ 10.0 million of the Company's common stock subject to certain limitations and satisfaction of the conditions set forth in the Purchase Agreement.

Under the terms and subject to the conditions of the Purchase Agreement, the Company has the right, but not the obligation, to sell to Lincoln Park, and Lincoln Park is obligated to purchase up to $ 10.0 million of the Company's Common Stock (the "Purchase Shares"). However, such sales of Common Stock by the Company, if any, will be subject to important limitations set forth in the Purchase Agreement, including limitations on number of shares that may be sold. Sales may occur from time to time, at the Company's sole discretion, over the 24-month period commencing on the date that the conditions to Lincoln Park's purchase obligation set forth in the Purchase Agreement are satisfied, including that a registration statement on Form S-1 covering the resale of the shares of the Company's Common Stock that have been and may be issued to Lincoln Park under the Purchase Agreement, which the Company has filed with the SEC pursuant to the Registration Rights Agreement, is declared effective by the SEC and a final prospectus relating thereto is filed with the SEC. As required under the Purchase Agreement, the Company registered a resale of 1,140,477 shares of our common stock, plus the 139,403 commitment shares, by Lincoln Park on a registration statement on Form S-1 dated November 8, 2023, which was declared effective by the SEC on December 5, 2023. As of July 30, 2024, there were no remaining shares available to be issued in connection with this registration statement. On September 4, 2024, the Company filed an amended Form S-1, which was declared effective by the SEC on September 11, 2024. The amended Form S-1 registered an additional 4,900,000 shares of common stock that are available to be issued to Lincoln Park in connection with this agreement.

Because the purchase price per share to be paid by Lincoln Park for the shares of Common Stock that the Company may elect to sell to Lincoln Park under the Purchase Agreement, if any, will fluctuate based on the market prices of the Company's Common Stock at the time the Company elects to sell shares to Lincoln Park pursuant to the Purchase Agreement, if any, it is not possible for us to predict the number of shares of Common Stock that the Company will sell to Lincoln Park under the Purchase Agreement, the purchase price per share that Lincoln Park will pay for shares purchased from us under the Purchase Agreement, or the aggregate gross proceeds that the Company will receive from those purchases by Lincoln Park under the Purchase Agreement.

On May 3, 2024, the Company entered into a series of common stock purchase agreements for the issuance in a registered direct offering of an aggregate of 458,000 shares of the Company's common stock, to certain institutional investors. The issuance was made in exchange for the permanent and irrevocable waiver of the variable rate transaction limitation with respect to any existing or future agreement by the Company to effect any issuance of shares and issue such shares thereunder, as contained in those certain Inducement Offer Letters, dated December 28, 2023, between the Company and those certain institutional investors. The Company will not receive any net proceeds in connection with the offering. The fair value of the shares issued for consideration of waiving the variable rate transaction limitation was $ 448,840 and was recorded as deferred offering costs, as direct and incremental to the Purchase Agreement, within prepaid expenses and other current assets on the unaudited condensed consolidated balance sheet related to the Purchase Agreement.

The common stock purchase agreements contain customary representations and warranties and certain indemnification obligations of the Company. The common stock purchase agreements also restrict the Company from issuing, entering into any agreement to issue, or announcing the issuance of the Company's common stock from the date of the common stock purchase agreements until the earlier of 30 days after entering into the agreements or at such time as fifteen million (15,000,000) shares of the Company's common stock have traded in the open market. The closing of the issuance of the Shares pursuant to the common stock purchase agreements closed on May 3, 2024.

During the three and nine months ended September 30, 2024, the Company had issued 1,090,477 and 1,215,477 shares of common stock, respectively, through the Purchase Agreement for gross cash proceeds of $ 517,836 and $ 600,686 , respectively. During the three and nine months ended September 30, 2024, the Company charged offering costs of $ 290,029 and $ 372,879 , respectively, to additional paid in capital on the unaudited condensed consolidated balance sheet. As of September 30, 2024 and December 31, 2023, the Company has capitalized deferred offering costs of $ 508,599 and $ 395,660 , respectively. As of September 30, 2024, there were 4,825,000 shares available to be issued in connection with the Purchase Agreement.

Stock Options

Amendment to 2020 Long-Term Incentive Plan

On November 2, 2023, the stockholders approved the amendments to the 2020 Long-Term Incentive Plan, which was approved by the Board on August 8, 2023 (the "Amended Incentive Plan"). The Amended Incentive Plan (i) increased the number of authorized shares reserved for issuance under the Amended Incentive Plan to a maximum of 350,000 , subject to equitable adjustment, and (ii) removed the Evergreen Provision implemented in the Plan Amendment. During the first quarter of 2024, the Board approved an equitable adjustment to increase the number of shares available under the Plan by 134,779 shares. As of September 30, 2024, the total number of shares available for grant under the Incentive Plan was 6,257 .

A summary of the stock option activity under the Company's incentive plan for the nine months ended September 30, 2024 is presented below:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Grant Date Fair Value	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at December 31, 2023	30,329	$ 57.17	$ 77.22	3.4	$ —
Granted	—	$ —	$ —		—
Forfeited	(7,247)	$ 39.35	$ 54.02		—
Outstanding at September 30, 2024	23,082	$ 62.77	$ 84.51	2.6	$ —
Exercisable at September 30, 2024	22,145	$ 65.30	$ 87.98	2.2	$ —

The Company's stock based compensation expense, recorded within general and administrative expense in the unaudited condensed consolidated statement of operations and comprehensive loss, related to stock options for the three months ended September 30, 2024 and 2023 was $ 414 and $ 44,606 , respectively.

The Company's stock-based compensation expense, recorded within general and administrative expense, related to stock options for the nine months ended September 30, 2024 and 2023 was $(5,854) and $ 147,067 , respectively.

As of September 30, 2024, the Company had $ 2,346 in unamortized stock option expense, which will be recognized over a weighted average period of 1.40 years.

Issuance of Restricted Stock Units

The Company's activity in restricted stock units was as follows for the nine months ended September 30, 2024:

	Number of shares	Weighted average fair value
Non-vested at December 31, 2023	140,491	$ 28.97
Granted	251,500	$ 0.85
Forfeited	(9,750)	$ 2.87
Vested	(30,625)	$ 22.22
Non-vested at September 30, 2024	351,616	$ 10.17

For the three months ended September 30, 2024 and 2023, the Company recorded $ 369,200 and $ 328,253 , respectively, in stock-based compensation expense related to restricted stock units, which is a component of both general and administrative and research and development

expenses in the unaudited condensed consolidated statement of operations and comprehensive loss. For the nine months ended September 30, 2024 and 2023, the Company recorded $ 1,096,570 and $ 1,638,365 , respectively, in stock-based compensation expense related to restricted stock units, which is a component of both general and administrative and research and development expenses in the condensed consolidated statement of operations and comprehensive loss. As of September 30, 2024, the Company had unamortized stock-based compensation costs related to restricted stock units of $ 1,109,526 which will be recognized over a weighted average period of 1.57 years. As of September 30, 2024, 20,526 restricted stock units are vested without shares of common stock being issued, with all of these shares due as of September 30, 2024.

The following table summarizes the Company's recognition of stock-based compensation for restricted stock units for the following periods:

	Three Months Ended September		Nine Months Ended September	
Stock-based compensation expense for RSUs:	2024	2023	2024	2023
General and administrative	$ 162,042	$ 101,607	$ 476,513	$ 946,851
Research and development	207,158	226,646	620,057	691,514
Total	$ 369,200	$ 328,253	$ 1,096,570	$ 1,638,365

Warrants and Preferred Investment Options

The following table summarizes information about shares issuable under warrants outstanding at September 30, 2024:

	Warrant shares outstanding	Weighted average exercise price	Weighted average remaining life	Intrinsic value
Outstanding at December 31, 2023	2,799,213	$ 11.79	4.6	$ —
Expired	(585)	160.00	—	$ —
Exercised	(1,954,000)	1.37	—	$ —
Outstanding at September 30, 2024	844,628	$ 35.78	3.0	$ —
Exercisable at September 30, 2024	844,628	$ 35.78	3.0	$ —

The following table summarizes information about investment options outstanding at September 30, 2024:

	Investment options outstanding	Weighted average exercise price	Weighted average remaining life	Intrinsic value
Outstanding at December 31, 2023	70,000	$ 10.00	4.1	$ —
Outstanding at September 30, 2024	70,000	$ 10.00	2.9	$ —
Exercisable at September 30, 2024	70,000	$ 10.00	2.9	$ —

NOTE 8. LICENSING AGREEMENTS

On July 10, 2024, Akos entered into an Exclusive License Agreement (the "License Agreement") with Aries Science and Technology, LLC, an Ohio limited liability company ("Aries"), pursuant to which Akos granted Aries a license of Akos's patented radiation dermatitis topical product. The license allows Akos to use the patented formulation to develop pharmaceutical or non-pharmaceutical products for treating radiation dermatitis suitable for administration to humans or animals. The license is exclusive (subject to certain exceptions contained in the License Agreement), worldwide, royalty-bearing, and includes the right to sublicense. Akos is entitled to potential license payments, milestone payments and royalties based on net revenues of the Licensed Product on a licensed product-by-licensed product and country-by-country basis pursuant to the terms of the Agreement. Aries has the option during the license term, to purchase the rights to each licensed product (on a licensed product-by-licensed product basis) in the form of an exclusive (as to the applicable licensed product), fully paid, transferable right and license to the licensed product.

The Company has not earned any revenue related to this agreement as of September 30, 2024.

NOTE 9. COMMITMENTS AND CONTINGENCIES

The Company is periodically involved in legal proceedings, legal actions and claims arising in the normal course of business. Management believes that the outcome of such legal proceedings, legal actions and claims will not have a significant adverse effect on the Company's financial position, results of operations or cash flows.

Australian Subsidiary Research and Development

On March 23, 2023, the Company issued a press release announcing the selection of Australian CRO, Avance Clinical, in preparation for Phase 1 Study of EB-002, the Company's lead candidate targeting the treatment of anxiety disorders. Under the agreement, Avance Clinical will manage the Phase 1 clinical trial of EB-002 in coordination with the Company's newly established Australian subsidiary, Enveric Therapeutics Pty, Ltd. The Phase 1 clinical trial is designed as a multi-cohort, dose-ascending study to measure the safety and tolerability of EB-002. EB-002, a next-generation proprietary psilocin prodrug, has been recognized as a New Chemical Entity (NCE) by Australia's Therapeutic Goods Administration and is currently in preclinical development targeting the treatment of anxiety disorder. The total cost of the Avance Clinical contract is approximately 3,400,000 AUD, which translates to approximately $ 2,329,000 USD as of September 30, 2024. As of September 30, 2024, the Company has paid 100% of the Avance Clinical contract costs and has $ 0 recorded as prepaid assets within prepaid and other current assets, accrued $ 0 recorded as accrued liabilities and $ 0 as accounts payable on the accompanying condensed consolidated balance sheet. For the three and nine months ended September 30, 2024 and 2023, the Company has expensed $ 264,385 and $ 508,774 , and $ 157,117 and $ 401,284 , respectively, in research and development expenses within the accompanying unaudited condensed consolidated statement of operations. As of September 30, 2024, all payments have been made and the project is substantially completed.

According to Australian tax law, the Company is allowed an R&D tax credit that reduces a company's tax bill in Australia for expenses incurred in R&D subject to certain requirements. The Company's Australian subsidiary submits R&D tax credit requests annually for research and development expenses incurred. At September 30, 2024 and December 31, 2023, the Company had a research and development tax credit receivable of $0 and $ 145,349 , respectively, for R&D expenses incurred in Australia, included in prepaid and other current assets within the accompanying unaudited condensed consolidated statement of operations. The Company received the amount due in relation to the research and development tax credit during the three months ended September 30, 2024.

Purchase agreement with Prof. Zvi Vogel and Dr. Ilana Nathan

On December 26, 2017, Jay Pharma entered into a purchase agreement with Prof. Zvi Vogel and Dr. Ilana Nathan (the "Vogel-Nathan Purchase Agreement"), pursuant to which Jay Pharma was assigned ownership rights to certain patents, which were filed and unissued as of the date of the Vogel-Nathan Purchase Agreement. The patent portfolio acquired and developed under the Vogel-Nathan Purchase Agreement was sold to undisclosed buyers for an amount not material to these financials in the first quarter of 2024. No additional financial or other obligations exist regarding the Vogel-Nathan Purchase Agreement.

Other Consulting and Vendor Agreements

The Company has entered into a number of agreements and work orders for future consulting, clinical trial support, and testing services, with terms ranging between one and 12 months. These agreements, in aggregate, commit the Company to approximately $ 0.1 million in future cash payments, inclusive of amounts in accounts payable.

Reduction in Force/Restructuring

In May 2023, the Company entered into a cost reduction plan, including a reduction in force ("RIF") of approximately 35 % of its full-time employees to streamline its operations and conserve cash resources. Additionally, contracts with seven consultants that were focused on the Akos cannabinoid spin-out were terminated. The plan included a focus on progressing the Company's existing non-cannabinoid pipeline while reducing the rate of spend and managing cash flow. In June 2023, the Company completed the reduction in force, with such severance expenses recorded in general and administrative accounts.

In June 2023, the Company entered into a separation agreement with Avani Kanubaddi, the Company's President and Chief Operating Officer (the "Kanubaddi Separation Agreement"). In accordance with the Kanubaddi Separation Agreement, Mr. Kanubaddi received salary and benefits that is paid out in twelve monthly installments beginning in July 2023, was eligible for his 2023 performance bonus, which was not achieved, and any outstanding restricted stock units retained their vesting conditions.

The following table summarizes the Reduction in Force/Restructuring activity and ending balance at September 30, 2024 for the remaining severance payments included in accrued expenses in the consolidated balance sheet:

	Accrued Restructuring Costs
January 1, 2024 beginning balance	$ 301,645
Restructuring costs paid	(301,645)
September 30, 2024 ending balance	$ —

NOTE 10. SUBSEQUENT EVENTS

Subsequent to September 30, 2024, the Company issued 950,000 shares of common stock through the Purchase Agreement with Lincoln Park for gross cash proceeds of $ 405,820 . As of November 12, 2024, there are 3,875,000 remaining registered shares available to be issued in connection with this agreement.

On October 9, 2024, the Company granted 386,633 restricted stock units to its officers and certain employees, which fully vest on October 9, 2028 and 218,776 restricted stock awards to its non-employee directors, which fully vest on December 31, 2024.

Effective October 9, 2024, the Board approved an equitable adjustment to increase the number of shares available under the Incentive Plan by 966,026 shares, which increased the total number of authorized shares under the Incentive Plan to 1,450,805 shares.

On November 7, 2024, the Company entered into an Out-Licensing Agreement (the "Agreement") with MycoMedica Life Sciences, PBC, a Delaware public benefit corporation ("MycoMedica"), pursuant to which the Company will out-license EB-002 and its EVM201 series to MycoMedica for further development and sales of the product in treatment of neuropsychiatric disorders. MycoMedica will receive an exclusive, global license to the formulations, drugs, method of use, and medical devices developed by Enveric to utilize the compound. As part of the Agreement, the Company will receive modest upfront payments, and if certain conditions are met, will receive development and sales milestone payments of up to $ 62 million and tiered single-digit royalties based on future sales. MycoMedica has the option during the license term to buyout its milestone and royalty payment obligations at a predetermined amount depending upon the stage of product development and commercialization at the time of the buyout. Further, MycoMedica has the right to purchase the licensed patents at a nominal amount upon a change of control of the Company, although doing so does not relieve MycoMedica of any of its payment obligations.

Item 2. Management's discussion and analysis of financial condition and results of operations

The information set forth below should be read in conjunction with the unaudited condensed consolidated financial statements and notes thereto included elsewhere in this Quarterly Report on Form 10-Q. Unless stated otherwise, references in this Quarterly Report on Form 10-Q to "us," "we," "our," or our "Company" and similar terms refer to Enveric Biosciences, Inc., a Delaware corporation, and its subsidiaries.

Cautionary Note Regarding Forward-Looking Statements

This Quarterly Report on Form 10-Q (this "Form 10-Q") contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements may be identified by the use of forward-looking terms such as "anticipates,"

“assumes,” “believes,” “can,” “could,” “estimates,” “expects,” “forecasts,” “guides,” “intends,” “may,” “plans,” “seeks,” “projects,” “targets,” and “would” or the negative of such terms or other variations on such terms or comparable terminology. Such forward-looking statements include, but are not limited to, future financial and operating results, the company’s plans, objectives, expectations and intentions and other statements that are not historical facts. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition, and results of operations. These forward-looking statements speak only as of the date of this Form 10-Q and are subject to a number of risks, uncertainties, and assumptions that could cause actual results to differ materially from our historical experience and our present expectations, or projections described under the sections in this Form 10-Q entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” These risks and uncertainties include, but are not limited to:

- our dependence on the success of our prospective product candidates, which are in the early stages of development and may not reach a particular stage in development, receive regulatory approval, or be successfully commercialized;
- potential difficulties that may delay, suspend, or scale back our efforts to advance additional early research programs through preclinical development and investigational new drug (“IND”) application filings and into clinical development;
- the limited study on the effects of medical psychedelics, and the chance that future clinical research studies may lead to conclusions that dispute or conflict with our understanding and belief regarding the medical benefits, viability, safety, efficacy, dosing, and social acceptance of psychedelics;
- the expensive, time-consuming, and uncertain nature of clinical trials, which are susceptible to change, delays, termination, and differing interpretations;
- the ability to establish that potential products are efficacious or safe in preclinical or clinical trials;
- the fact that our current and future preclinical and clinical studies may be conducted outside the United States, and the United States Food and Drug Administration may not accept data from such studies to support any new drug applications we may submit after completing the applicable developmental and regulatory prerequisites;
- our ability to effectively and efficiently build, maintain and legally protect our molecular derivatives library so that it can be an essential building block from which those in the biotech industry can develop new patented products;
- our ability to establish or maintain collaborations on the development of therapeutic candidates;
- our ability to obtain appropriate or necessary governmental approvals to market potential products;
- our ability to manufacture product candidates on a commercial scale or in collaborations with third parties;
- our significant and increasing liquidity needs and potential requirements for additional funding;
- our ability to obtain future funding for developing products and working capital and to obtain such funding on commercially reasonable terms;

- legislative changes related to and affecting the healthcare system, including, without limitation, changes and proposed changes to the Patient Protection and Affordable Care Act;
- the intense competition we face, often from companies with greater resources and experience than us;
- our ability to retain key executives and scientists;
- the ability to secure and enforce legal rights related to our products, including intellectual property rights and patent protection;
- political, economic, and military instability in Israel which may impede our development programs;
- our success at managing the risks involved in the foregoing; and
- the risk of loss in excess of insurance limitations on funds held in U.S Banking Institutions.

For a more detailed discussion of these and other factors that may affect our business and that could cause the actual results to differ materially from those projected in these forward-looking statements, see the risk factors and uncertainties set forth in our periodic reports, including Part I, Item IA of the Annual Report on Form 10-K for the year ended December 31, 2023, and Part II, Item IA of our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2024 and June 30, 2024. Any one or more of these uncertainties, risks and other influences could materially affect our results of operations and whether forward-looking statements made by us ultimately prove to be accurate. We undertake no obligation to publicly update or revise any forward-looking statements, whether from new information, future events or otherwise, except as required by law.

Business Overview

We are a biotechnology company dedicated to the development of novel neuroplastogenic small-molecule therapeutics for the treatment of depression, anxiety, and addiction disorders. Leveraging our unique discovery and development platform, the Psybrary™, we have created a robust intellectual property portfolio of new chemical entities for specific mental health indications. Our lead program, the EVM201 Series, comprises next generation synthetic prodrugs of the active metabolite, psilocin. We are developing the first product from the EVM201 Series – EB-002 – for the treatment of psychiatric disorders. We are also advancing its second program, the EVM301 Series – EB 003, a non-hallucinogenic neuroplastogen – expected to offer a first-in-class, new approach to the treatment of difficult-to-address mental health disorders, mediated by the promotion of neuroplasticity without also inducing hallucinations in the patient.

Psychedelics

We have continued to pursue the development of MagicMed’s proprietary library, the Psybrary™ which we believe will help us to identify and develop the right drug candidates needed to address mental health challenges, including anxiety. We synthesize novel analogues of serotonin using a mixture of chemistry and synthetic biology, resulting in the expansion of the Psybrary™, which includes 15 patent families with over a million potential variations and hundreds of synthesized molecules. The Company has created over 1,200 novel molecular compounds that are housed in the Psybrary™. Our current focus is develop our lead molecules EB-002 and EB-003, a non-hallucinogenic neuroplastogen, and to out-license other molecules from the Psybrary™.

Recent Developments

Equity Distribution Agreement

During the nine months ended September 30, 2024, the Company issued 1,668,000 shares of common stock for gross proceeds of $2,392,502 under the Distribution Agreement, and charged offering costs of $583,713 to additional paid in capital on the unaudited condensed consolidated balance sheet. As of September 30, 2024 and December 31, 2023, there were deferred offering costs related to the Distribution Agreement of $0 and $171,944, respectively.

On December 28, 2023, the Company entered into warrant exercise inducement offer letters (the "Inducement Letters") with certain holders (the "Holders") of the February 2022 Post-Modification Warrants and RD and PIPE preferred investment options to purchase shares of the Company's common stock (the "Existing Warrants and Investment Options") pursuant to which the Holders agreed to exercise for cash their Existing Warrants and Investment Options to purchase 1,122,000 shares of the Company's common stock, in the aggregate, at a reduced exercised price of $1.37 per share (from an original exercise price of $7.78 per share), in exchange for the Company's agreement to issue new warrants (the "Inducement Warrants") to purchase up to 2,244,000 shares of the Company's common stock (the "Inducement Warrant Shares"), and the Holders to make a cash payment of $0.125 per Inducement Warrant share for total proceeds of $280,500. In January 2024, the Company received aggregate gross proceeds of $1,817,640 from the exercise of the Existing Warrants and Investment Options by the Holders and the sale of the Inducement Warrants. Because the Existing Warrants and Investment Options by the Holders and the sale of the Inducement Warrants that exercised on December 28, 2023 and unsettled until January 2024, the proceeds are included in the condensed consolidated balance sheet as a subscription receivable as of December 31, 2023. As of December 31, 2023, 418,000 shares of the Existing Warrants and Investment Options exercised were considered issued as the Company had the enforceable right to the obtain the cash proceeds, which were in-transit, and the Holders were no longer able to rescind the exercise election. Due to the beneficial ownership limitation provisions, 704,000 shares of the Existing Warrants and Investment Options exercised were initially unissued and held in abeyance for the benefit of the Holder until notice is received from the Holder that the shares may be issued in compliance with such limitation. During the nine months ended September 30, 2024, the Company issued all 704,000 shares of common stock of the 704,000 shares of Existing Warrants and Investment Options exercised that were held in abeyance due to the beneficial ownership limitation provisions.

On December 28, 2023, the Company entered into warrant exercise inducement offer letters (the "Inducement Letters") with certain holders of warrants and preferred investment options. The Inducement Letters prohibit the Company from entering into any variable rate transaction as defined in the Inducement Letters, including the issuance of (1) any variable priced debt or equity securities or (2) transactions whereby the Company may issue securities at a future determined price, such as through an at-the-market offering or an equity line of credit. The variable rate transaction restriction would have expired after six-months from the closing date of December 28, 2023 for the Inducement Letters for an issuance through an at-the-market offering, and one-year for the remaining variable rate transactions, however the restriction was waived for the at-the-market offering on March 8, 2024 and the equity line on May 3, 2024.

On March 8, 2024, the Company entered into a series of common stock purchase agreements for the issuance in a registered direct offering of 228,690 shares of the Company's common stock, par value $0.01 per share to the Holders of the Inducement Warrants. The issuance was made in exchange for the permanent and irrevocable waiver of the variable rate transaction limitation solely with respect to the entry into and/or issuance of shares of common stock in an at the market offering contained in the Inducement Letters. The fair value of the shares issued for consideration of waiving the variable rate transaction limitation was $322,453 and was charged to additional paid in capital on the unaudited condensed consolidated balance sheet as an offering cost related to the Distribution Agreement.

Lincoln Park Equity Line

During the three and nine months ended September 30, 2024, the Company had issued 1,090,477 and 1,215,477 shares of common stock, respectively, through the Purchase Agreement for gross cash proceeds of $517,836 and $600,686, respectively. During the three and nine months ended September 30, 2024, the Company charged offering costs of $290,029 and $372,879, respectively, to additional paid in capital on the unaudited condensed consolidated balance sheet. As of September 30, 2024 and December 31, 2023, the Company has capitalized deferred offering costs of $508,599 and $395,660, respectively.

On May 3, 2024, the Company entered into a series of common stock purchase agreements for the issuance in a registered direct offering of an aggregate of 458,000 shares of the Company's common stock, to certain institutional investors. The issuance was made in exchange for the permanent and irrevocable waiver of the variable rate transaction limitation with respect to any existing or future agreement by the Company to effect any issuance of shares and issue such shares thereunder, as contained in those certain Inducement Offer Letters, dated December 28, 2023, between the Company and those certain institutional investors. The Company will not receive any net proceeds in connection with the offering. The fair value of the shares issued for consideration of waiving the variable rate transaction limitation was $448,840 and was recorded as deferred offering costs within prepaid expenses and other current assets on the unaudited condensed consolidated balance sheet related to the Purchase Agreement.

As of July 30, 2024, there were no remaining shares available to be issued in connection with the initial registration statement. On September 4, 2024, the Company filed an amended Form S-1, which registered an additional 4,900,000 shares of common stock that are available to be issued to Lincoln Park in connection with this agreement. From July through November 12, 2024, under the initial registration statement and the amended Form S-1, the Company issued 2,040,477 shares of common stock through the Purchase Agreement with Lincoln Park for gross cash proceeds of $923,656. As of November 12, 2024, there are 3,875,000 remaining shares available to be issued in connection with the amended Form S-1.

Inducement Warrants

On February 29, 2024, a Holder of the Inducement Warrants, exercised 1,954,000 Inducement Warrants at an exercise price of $1.37 per share for 1,954,000 shares of the Company's common stock for total gross proceeds of $2,676,980.

Results of Operations

The following table sets forth information comparing the components of net loss for the three months ended September 30, 2024 and 2023:

	For the Three Months Ended September 30,	
	2024	**2023**

Operating expenses		
General and administrative	$ 1,235,661	$ 2,080,644
Research and development	762,717	1,281,455
Depreciation and amortization	84,814	86,296
Total operating expenses	2,083,192	3,448,395
Loss from operations	(2,083,192)	(3,448,395)
Other income (expense)		
Change in fair value of warrant liabilities	(122)	67,822
Change in fair value of investment option liability	(501)	562,715
Interest income (expense), net	(217)	2,237
Total other income (expense)	(840)	632,774
Net loss before income taxes	$ (2,084,032)	$ (2,815,621)
Income tax expense	—	(6,595)
Net loss	$ (2,084,032)	$ (2,822,216)

General and Administrative Expenses

Our general and administrative expenses decreased to $1,235,661 for the three months ended September 30, 2024 from $2,080,644 for the three months ended September 30, 2023, a decrease of $844,983, or 41%. This change was primarily driven by decreases in consulting expenses of $138,778, salaries and wages of $263,764, and legal fees of $192,941, all a direct result of the second quarter 2023 reduction in force and no longer pursuing the transfer and spin-off its cannabinoid clinical development pipeline assets to Akos Biosciences, Inc.

Research and Development Expenses

Our research and development expense for the three months ended September 30, 2024 was $762,717 as compared to $1,281,455 for the three months ended September 30, 2023 with a decrease of $518,738, or approximately 40%. This decrease was primarily driven by a decrease in CRO expense of $4,206, salaries and wages of $212,377, and product development of $208,312.

Depreciation and Amortization Expense

Depreciation and amortization expense for the three months ended September 30, 2024 was $84,814 as compared to $86,296 for the three months ended September 30, 2023, with a decrease of $1,482, or approximately 2%.

Change in Fair Value of Warrant Liabilities

Change in fair value of warrant liabilities for the three months ended September 30, 2024 resulted in an expense of $122 as compared to income of $67,822 for the three months ended September 30, 2023. The change in fair value of warrant liabilities is due to the exercise of 122,000 of warrants on December 28, 2023, resulting in less warrants outstanding and re-valued at September 30, 2024, as well as, the change in the closing price of Common Stock at the end of each period, as compared to the closing price of Common Stock at the beginning of each period with a strong inverse relationship between changes in fair value of warrant liabilities and the trading price of Common Stock.

Change in Fair Value of Investment Option Liability

Change in fair value of investment option liability the three months ended September 30, 2024 resulted in an expense of $501 as compared to income of $562,715 during the three months ended September 30, 2023. The change in fair value is due to the exercise of 1,000,000 investment options on December 28, 2023, resulting in less investment options re-valued at September 30, 2024 and a significant decrease in the Company's stock price for the three months ended September 30, 2024.

The following table sets forth information comparing the components of net loss for the nine months ended September 30, 2024 and 2023:

	For the Nine Months Ended September 30,	
	2024	**2023**
Operating expenses		
General and administrative	$ 4,467,065	$ 8,273,344
Research and development	1,736,373	5,531,436
Depreciation and amortization	255,002	259,300
Total operating expenses	6,458,440	14,064,080
Loss from operations	(6,458,440)	(14,064,080)
Other income (expense)		
Change in fair value of warrant liabilities	20,722	(115,342)
Change in fair value of investment option liability	18,664	(399,921)
Change in fair value of derivative liability	—	727,000
Interest income, net	444	3,142
Total other income (expense)	39,830	214,879
Net loss before income taxes	$ (6,418,610)	$ (13,849,201)
Income tax expense	(1,731)	(6,595)
Net loss	$ (6,420,341)	$ (13,855,796)

General and Administrative Expenses

Our general and administrative expenses decreased to $4,467,065 for the nine months ended September 30, 2024 from $8,273,344 for the nine months ended September 30, 2023, a decrease of $3,806,279, or 46%. This change was primarily driven by decreases in consulting expenses of $836,437, salaries and wages of $1,305,710, stock compensation expense of $623,259, investor relations of $313,509, legal fees of $487,863, and accounting fees of $227,200, all a direct result of the second quarter 2023 reduction in force and no longer pursuing the transfer and spin-off its cannabinoid clinical development pipeline assets to Akos Biosciences, Inc., and Delaware franchise taxes of $246,144 partially offset by an increase in director fees of $107,186.

Research and Development Expenses

Our research and development expense for the nine months ended September 30, 2024 was $1,736,373 as compared to $5,531,436 for the nine months ended September 30, 2023 with a decrease of $3,795,063, or approximately 69%. This decrease was primarily driven by a decrease salaries and wages of $1,542,075, research costs of $1,056,511, product development costs of $532,063, CRO costs of $128,560 and the gain realized related to the Australian R&D tax incentive of $291,439.

Depreciation and Amortization Expense

Depreciation and amortization expense for the nine months ended September 30, 2024 was $255,002 as compared to $259,300 for the nine months ended September 30, 2023, with a decrease of $4,298, or approximately 2%.

Change in Fair Value of Warrant Liabilities

Change in fair value of warrant liabilities for the nine months ended September 30, 2024 resulted in income of $20,722 as compared to a loss of $115,342 for the nine months ended September 30, 2023. The change in fair value of warrant liabilities is due to the exercise of 122,000 of warrants on December 28, 2023, resulting in less warrants outstanding and re-valued at September 30, 2024, as well as, the change in the closing price of Common Stock at the end of each period, as compared to the closing price of Common Stock at the beginning of each period with a strong inverse relationship between changes in fair value of warrant liabilities and the trading price of Common Stock.

Change in Fair Value of Investment Option Liability

Change in fair value of investment option liability the nine months ended September 30, 2024 resulted in income of $18,664 as compared to a loss of $399,921 during the nine months ended September 30, 2023. The change in fair value is due to the exercise of 1,000,000 investment options on December 28, 2023, resulting in less investment options re-valued at September 30, 2024 and a significant decrease in the Company's stock price for the nine months ended September 30, 2024.

Change in Fair Value of Derivative Liability

The Company's change in fair value of derivative liability is due to the May 2023 redemption which ceased the probability of occurrence of the Akos spin-off and Akos Series A Preferred Stock redemption.

Going Concern, Liquidity and Capital Resources

The Company has incurred a loss since inception resulting in an accumulated deficit of $102,919,859 as of September 30, 2024 and further losses are anticipated in the development of its business. Further, the Company had operating cash outflows of $6,414,590 for the nine months ended September 30, 2024. For the nine months ended September 30, 2024, the Company had a loss from operations of $6,458,440. Since inception, being a research and development company, the Company has not yet generated revenue and the Company has incurred continuing losses from its operations. The Company's operations have been funded principally through the issuance of debt and equity. These factors raise substantial doubt about the Company's ability to continue as a going concern for a period of one year from the issuance of these unaudited condensed consolidated financial statements.

In assessing the Company's ability to continue as a going concern, the Company monitors and analyzes its cash and its ability to generate sufficient cash flow in the future to support its operating and capital expenditure commitments. At September 30, 2024, the Company had cash of $3,111,683 and working capital of $3,499,093. The Company's current cash on hand is insufficient to satisfy its operating cash needs for the 12 months following the filing of this Quarterly Report on Form 10-Q. These conditions raise substantial doubt regarding the Company's ability to continue as a going concern for a period of one year after the date the financial statements are issued. Management's plan to alleviate the conditions that raise substantial doubt include raising additional working capital through public or private equity or debt financings or other sources, and may include additional collaborations with third parties as well as disciplined cash spending. Adequate additional financing may not be available to us on acceptable terms, or at all. Should the Company be unable to raise sufficient additional capital, the Company may be required to undertake cost-cutting measures including delaying or discontinuing certain operating activities.

As a result of these factors, management has concluded that there is substantial doubt about the Company's ability to continue as a going concern for a period of one year after the date of the unaudited condensed consolidated financial statements. The Company's unaudited condensed consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Cash Flows

Since inception, we have primarily used our available cash to fund our product development and operations expenditures.

Cash Flows for the Nine Months Ended September 30, 2024 and 2023:

The following table sets forth a summary of cash flows for the years presented:

	For the Nine Months Ended September	
	2024	**2023**
Net cash used in operating activities	$ (6,414,590)	$ (12,343,363)
Net cash provided by investing activities	—	11,705
Net cash provided by (used in) financing activities	7,210,386	(1,157,057)
Effect of Foreign Exchange Rate on Changes on Cash	27,910	31,399
Net increase (decrease) in cash	$ 823,706	$ (13,457,316)

Operating Activities

Net cash used in operating activities was $6,414,590 during the nine months ended September 30, 2024, which consisted primarily of a net loss adjusted for non-cash items of $5,114,009 and an increase in prepaid expenses and other current assets of $3,674 and a decrease in accounts payable and accrued liabilities of $1,296,907.

Net cash used in operating activities was $12,343,363 during the nine months ended September 30, 2023, which consisted primarily of a net loss adjusted for non-cash items of $11,962,774, an increase in prepaid expenses and other current assets of $746,033, offset by an increase in accounts payable and accrued liabilities of $429,688.

Investing Activities

Net cash used in investing activities was $0 during the nine months ended September 30, 2024.

Net cash provided by investing activities was $11,705 during the nine months ended September 30, 2023, which consisted of proceeds from disposal of property and equipment of $16,900, offset by the purchase of property and equipment of $5,195.

Financing Activities

Net cash provided by financing activities was $7,210,386 during the nine months ended September 30, 2024, which consisted of $1,804,819 from the proceeds received from the stock subscription receivable, $2,676,980 for the exercise of the Inducement Warrants, $2,290,186 for the common stock sold under the Distribution agreement, net of offering costs, and $599,862 for the common stock sold under the Purchase Agreement, offset by $161,461 offering costs previously accrued for the Inducement Warrants.

Net cash used in financing activities was $1,157,057 during the nine months ended September 30, 2023, which consisted of the redemption of redeemable non-controlling interest and payment of deferred offering costs.

Critical Accounting Estimates

Our unaudited condensed consolidated financial statements have been prepared in accordance with U.S. GAAP, which requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, costs and expenses and related disclosures. Our critical accounting estimates are those estimates that involve a significant level of uncertainty at the time the estimate was made, and changes in them have had or are reasonably likely to have a material effect on our financial condition or results of operations. Accordingly, actual results could differ materially from our estimates. We base our estimates on past experience and other assumptions that we believe are reasonable under the circumstances, and we evaluate these estimates on an ongoing basis. Our most critical accounting estimate includes determining the accruals associated with third party providers supporting research and development efforts.

There have been no material changes to our critical accounting estimates as compared to the critical accounting estimates disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our primary market risk exposure is foreign currency exchange risk. From inception through September 30, 2024, the Company's reporting currency is the United States dollar while the functional currency of certain of the Company's subsidiaries is the Canadian dollar and Australian dollar. For the reporting periods ended September 30, 2024 and September 30, 2023, the Company engaged in a number of transactions denominated in Canadian dollars and Australian dollars. As a result, the Company is subject to exposure from changes in the exchange rates of the Canadian dollar and Australian dollar against the U.S. dollar.

The Company has not entered into any financial derivative instruments that expose it to material market risk, including any instruments designed to hedge the impact of foreign currency exposures. The Company may, however, hedge such exposure to foreign currency exchange fluctuations in the future.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures designed to ensure that the information we are required to disclose in reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified under the rules and forms of the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosures. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. The matters that management identified in our Annual Report for the year ended December 31, 2023, continued to exist and were still considered material weaknesses in our internal control over financial reporting at September 30, 2024.

As required by paragraph (b) of Rules 13a-15 and 15d-15 under the Exchange Act, our Chief Executive Officer (our principal executive) and Chief Financial Officer (our principal financial officer and principal accounting officer) carried out an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures as of September 30, 2024. Based on this evaluation, and in light of the material weaknesses found in our internal controls over financial reporting, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in paragraph (e) of Rules 13a-15 and 15d-15 under the Exchange Act) were not effective as of September 30, 2024.

Management's Remediation Plan

As previously discussed in our Annual Report on Form 10-K for the year ended December 31, 2023, management had concluded that our internal control over financial reporting was not effective as of December 31, 2023, because management identified inadequate segregation of duties to ensure the processing, review, and authorization of all transactions, including non-routine transactions resulting in deficiencies, which, in aggregate, amounted to a material weakness in the Company's internal control over financial reporting.

As of September 30, 2024, there were control deficiencies that constituted a material weakness in our internal control over financial reporting. Management has taken, and is taking steps to strengthen our internal control over financial reporting: we have conducted evaluation of the material weakness to determine the appropriate remedy and have established procedures for documenting disclosures and disclosure controls.

While we have taken certain actions to address the material weaknesses identified, additional measures may be necessary as we work to improve the overall effectiveness of our internal controls over financial reporting.

Changes in Internal Control over Financial Reporting

Other than the changes discussed above in the Company's remediation plan, there have been no other changes in our internal controls over financial reporting (as defined in Rule 13a-15(f) and 15d-(f) of the Exchange Act) that occurred during quarter ending September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

The Company may be periodically involved in legal proceedings, legal actions and claims arising in the ordinary course of business. We do not have any pending litigation that, separately or in the aggregate, would, in the opinion of management, have a material adverse effect on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

Factors that could cause our actual results to differ materially from those in this Quarterly Report are any of the risks described in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 as filed with the SEC on March 26, 2024 and the Company's Quarterly Reports on Form 10-Q for the quarters ended March 31, 2024 and June 30, 2024, as filed with the SEC on May 15, 2024 and August 12, 2024, respectively. Any of these factors could result in a significant or material adverse effect on our results of operations of financial condition. Additional risk factors not presently known to us or that we currently deem immaterial may also impair our business or results of operations. As of the date of this Quarterly Report, other than as described below, there have been no material changes to the risk factors disclosed in the Company's Annual Report.

In the event that we fail to regain compliance with the listing requirements of The Nasdaq Capital Market or satisfy any of the listing requirements of Nasdaq, our common stock may be delisted, which could affect our market price and liquidity.

Our common stock is listed on Nasdaq. For continued listing on Nasdaq, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the stockholders' equity requirement, the corporate governance requirements and the minimum closing bid price requirement, among other requirements. On May 16, 2024, the Company received a letter from the Listing Qualifications Department of the Nasdaq Stock Market stating that because the closing bid price for the Company's common stock listed on Nasdaq was below $1.00 for 30 consecutive business days, the Company no longer meets the minimum bid price requirement for continued listing on the Nasdaq Capital Market (the "Minimum Bid Price Requirement"). The Company received an initial period of 180 calendar days from May 16, 2024, or until November 12, 2024, to regain compliance with the Minimum Bid Price Requirement and was unable to regain compliance during that time. The Company has applied for a second 180-day compliance period. As of the date hereof, the Company has not heard whether it will be granted the second compliance period. The Company anticipates conducting a reverse split during the first or second quarter of 2025 in order to regain compliance with the Minimum Bid Price Requirement if the bid price of the Company's common stock fails to close at or above $1.00 per share for a minimum of 10 consecutive business days prior the end of the second compliance period.

In the event that we fail to receive a second compliance period, or to otherwise regain compliance with the Minimum Bid Price Requirement or satisfy any of the listing requirements of Nasdaq, our common stock may be delisted. We will have an opportunity to appeal the determination to a Hearings Panel, but we cannot guarantee that such appeal will be successful. If we are unable to list on Nasdaq, we would likely be more difficult to trade in or obtain accurate quotations as to the market price of our common stock. If our common stock is delisted from trading on Nasdaq, and we are not able to list our common stock on another exchange or to have it quoted on Nasdaq, our securities could be quoted on the OTC Bulletin Board or on the "pink sheets." As a result, we could face significant adverse consequences including, without limitation:

- a limited availability of market quotations for our securities;

- a determination that our common stock is a "penny stock" which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage for our Company; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3 or obtain additional financing in the future).

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

INDEX TO EXHIBITS

Exhibit No.	Description
10.1	Exclusive License Agreement, dated July 10, 2024, between Akos Biosciences, Inc. and Aries Science and Technology, LLC ***
31.1	Certification pursuant to Section 302 of the Sarbanes–Oxley Act of 2002 of Principal Executive Officer
31.2	Certification pursuant to Section 302 of the Sarbanes–Oxley Act of 2002 of Principal Financial and Accounting Officer
32.1	Certification pursuant to Section 906 of the Sarbanes–Oxley Act of 2002 of Principal Executive Officer, Principal Financial and Accounting Officer
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

*** Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("[***]") because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

SIGNATURES

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

ENVERIC BIOSCIENCES, INC.

November 14, 2024

By: */s/ Dr. Joseph Tucker*
Joseph Tucker, Ph.D
Chief Executive Officer
(Principal Executive Officer)

November 14, 2024

By: */s/ Kevin Coveney*
Kevin Coveney
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 10.1

CERTAIN INFORMATION IDENTIFIED BY "[***]" HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH NOT MATERIAL AND IS THE TYPE OF INFORMATION THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

EXCLUSIVE LICENSE AGREEMENT

Pharmaceutical and OTC Cannabinoid Compounds for Treatment of Radiation Dermatitis

THIS EXCLUSIVE LICENSE AGREEMENT (the "Agreement"), is made and entered on this 10th day of July 2024 (the " Effective Date"), by and between Akos Biosciences, Inc., a Delaware corporation (hereinafter "Company") and Aries Science and Technology, LLC, an Ohio limited liability company (hereinafter "Licensee"). Company and Licensee shall each be considered a " Party" and together the "Parties".

WHEREAS, Company owns or controls certain Intellectual Property, as defined herein, for purposes of research and clinical development, manufacture, use, distribution, and sale of the Company Intellectual Property, as defined herein, as well as for the general purposes developing, commercializing, distributing, marketing, and selling pharmaceuticals and other products;

WHEREAS, Licensee has been established to undertake the development (including obtaining applicable regulatory approvals), manufacture, use, commercialization, distribution, marketing and selling of certain pharmaceutical and non-pharmaceutical products; and

WHEREAS, Company desires to license to Licensee, and Licensee desires to obtain such a license from Company to, the Company Intellectual Property so that Licensee can Develop, Manufacture, use, and Commercialize Licensed Product(s).

NOW, THEREFORE, in consideration of the foregoing premises and the mutual promises and covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1 ARTICLE 1 – DEFINITIONS

The terms in this Agreement with initial letters capitalized, whether used in the singular or the plural, shall have the meaning set forth below or, if not listed below, the meaning designated in places throughout this Agreement.

1.1 "Affiliate" means, with respect to a Party, any specified Person, any other Person which (directly or indirectly) is controlled by, controls or is under common control with such specified Person.

1.2 "Ancillary Agreements" means any other agreements entered into after the Effective Date between the Parties (or their respective Affiliates) with respect to the Development or Manufacture of the Licensed Product.

1.3 "Claim" means any demand or any civil, criminal, administrative, or investigative claim, action, or proceeding (including arbitration) asserted, commenced, or threatened against a Person.

1.4 "Confidential Information" means, with respect to a Party, all non-public information of such Party or its Affiliates that is disclosed to the other Party under this Agreement, whether disclosed in oral, written, graphic, or electronic form.

1.5 "Commercialize", "Commercialization", or "Commercializing" means, with respect to any pharmaceutical or non-pharmaceutical product, any and/or all activities (whether occurring before (to the extent permitted by applicable Law) or after the regulatory approval for such product) pertaining to the marketing, market development, or promotion of such product for commercial sale, the commercial sale of such product, including advertising, market research, offering to commercially sell, distributing, importing, exporting, or transporting such product for commercial sale, and regulatory activities in connection with or in support of the foregoing, but, for clarity, not Development or Manufacture.

1.6 "Commercially Reasonable Efforts" means the active carrying out of obligations or tasks with a level of effort and resources consistent with the commercially reasonable practices used by a similarly situated company at a similar stage of commercialization and of similar market potential, profit potential and strategic value, taking into consideration safety and efficacy, cost, the competitiveness of alternative products, the proprietary position, and all other relevant factors as measured by the facts and circumstances at the time such efforts are due.

1.7 "Company Indemnified Parties" means Company and its respective equity holders, directors, officers, managers, employees, and agents.

1.8 "Company Intellectual Property / Company IP " means (i) all Company Patents (including associated Patents and other intellectual property rights) Controlled by Company on or prior to the Effective Date, and (ii) all Company Technology, that are acquired, conceived, discovered, developed, reduced to practice, or otherwise made after the Effective Date solely by Company (or Third Parties acting on Company's behalf).

1.9 "Company Patents" means the Patents set forth in Schedule A , attached hereto, and any others Company identifies, and any continuations, continuations-in-part, divisionals, utility models, extensions (including extensions under the USA Patent Term Restoration Act, extensions of patents under the Japanese Patent Law and Supplementary Protection Certificates), renewals, substitutions and additions thereof and all reissues, revalidations and re-examinations thereof, including any and all foreign counterparts thereof, as well as any other patent rights Controlled by Company that contain at least one valid claim that would be infringed by the manufacture, import, use, offering for sale, or sale of Licensed Product(s) (if such activity were performed by a third party).

1.10 "Company Technology" means, collectively, all Know-How Controlled by Company that is directed to Licensed Products and which is necessary or useful for the research, development, manufacture, use, import, export, sale, offer for sale, transfer, or regulatory approval of Licensed Product(s), and other information that is necessary or reasonably useful to Develop, Manufacture, use, and/or Commercialize the Licensed Product, including, but not limited to: rights in unpatented subject matter, data (excluding protected health information as defined in the Health Insurance Portability and Accountability Act of 1996, codified as 42 U.S.C. 1320d or other personal protected information), and tangible materials that are: (a) directly related to or disclosed in the Company Intellectual Property; or (b) within the Field.

1.11 "Control" means, with respect to any Company Intellectual Property, possession of the right, whether directly or indirectly, and whether by ownership, license or otherwise, to assign, or grant a license, sublicense or other right to or under, such Company Intellectual Property as provided for herein without violating the terms of any written agreement with any Third Party.

1.12 "Develop", "Developed", "Developing", or "Development" means, with respect to any product, any and/or all activities relating to the development of such product and in obtaining the applicable regulatory approval for such product, including activities related to formulation, preclinical and other non-clinical testing, toxicology testing, human clinical studies, test method development and stability testing, process development, analytic development, statistical analysis and report writing, the preparation and submission of regulatory approval applications, regulatory affairs with respect to the foregoing (including communications with Regulatory Authorities), and all other activities necessary or reasonably useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining the applicable regulatory approval for such product, including development of packaging and labeling components for regulatory approval and manufacturing process development and associated quality assurance, quality control activities, scale-up and/or analytic process development. For clarity, Development activities do not include any Manufacturing or Commercialization activities.

1.13 "Development Costs" means, with respect to the Licensed Product, the sum of (i) all costs and expenses incurred by Licensee from the Effective Date through the date of calculation that directly relate to the Development conducted by or on behalf of Licensee with respect to such Licensed Product, including direct costs attributed to FTEs, out-of-pocket expenses, and any amounts paid to a Third Party; (ii) general overhead costs incurred by Licensee or its Affiliates related to the subject matter of this Agreement through the date of calculation that are allocable to such Licensed Product, where such general overhead costs are allocated as incurred on a monthly basis to such Licensed Product; and (iii) all license fees, milestones, and such other non-royalty payments due a Third Party under any option, license or covenant not to sue with respect to Development, Manufacture, use, or Commercialization of the Licensed Product, including without limitation, settlement of any IP Claim.

1.14 "Dispute" means any claim, dispute, or controversy arising out of, or relating to, this Agreement and/or an Ancillary Agreement, including any of the foregoing with respect to the interpretation and/or enforcement of, or any determinations under, any provision of this Agreement and/or an Ancillary Agreement and the performance of either Party of its obligations under this Agreement and/or an Ancillary Agreement.

1.15 "FDA" means the United States Food and Drug Administration or any successor entity thereto. For purposes of this Agreement, references to FDA shall include, as may be applicable, any foreign governmental agency having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products, delivery systems and devices within an applicable jurisdiction.

1.16 "Field" means the use of the Company Intellectual Property solely for the Licensed Product.

1.17 "First Commercial Sale" means, with respect to a Licensed Product, the first sale to a Third Party of such Licensed Product in a country after Regulatory Approval, if such is required, has been obtained in such country.

1.18 "GAAP" means the Generally Accepted Accounting Principles as issued by the Financial Accounting Standards Board.

1.19 "Governmental Authority" means any supra-national, federal, national, regional, state, provincial, local, or other governmental department, Regulatory Authority, judicial or administrative body, whether domestic or foreign, or international.

1.20 "Improvements" means, all Patents and Know-How related to the Licensed Product that are conceived, discovered, developed, reduced to practice or otherwise made in the conduct of Development activities by or on behalf of Licensee which are subject to a Valid Claim of the Company Patents.

1.21 "IND" means an investigational new drug application filed with the FDA for authorization to commence clinical trials, and its equivalent in other countries or regulatory jurisdictions in the Territory.

1.22 "Know-How" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data, results and other material, including, pre- clinical and clinical trial results, manufacturing procedures, test procedures, and purification and isolation techniques, (whether or not confidential, proprietary, patented, or patentable) in written, electronic or any other form, and all other discoveries, developments, information and inventions (whether or not confidential, proprietary, patented, or patentable), and tangible embodiments of any of the foregoing, including any discoveries, developments, information, or inventions relating to the stability, safety, efficacy, operation, manufacture, ingredients, preparation, indications, presentation, formulation, means of delivery, or dosage of any pharmaceutical or non-pharmaceutical composition or preparation, in all cases whether or not (i) confidential, proprietary, patented or patentable, (ii) reduced to written, electronic or any other form, and (iii) now known or hereinafter developed.

1.23 "Law" means all statutes, regulations, directives, ordinances, orders, rulings, agency or court interpretations (including common law), or other action or requirement of any Governmental Authority in any jurisdiction in the world whether currently in force or enacted during the Term applicable to the Development, Manufacture, use, and/or Commercialization of the Licensed Products, including any such rules, regulations, guidelines, guidance, or other requirements of all applicable Regulatory Authorities, that may be in effect from time to time in any country of the Territory.

1.24 "Licensed Product" means any pharmaceutical or non-pharmaceutical (e.g. over-the-counter) product suitable for administration to humans or animals where such product contains the formulation set forth in Schedule B or such product or its method of use is within the scope of the claims of the Company Patents, attached hereto in Schedule A.

1.25 "Licensee Indemnified Parties" means Licensee and its Affiliates and their respective equity holders, directors, officers, managers, employees, and agents.

1.26 "Licensee Intellectual Property / Licensee IP" means all Know-How (including associated Patents and other intellectual property rights): (i) owned or Controlled by Licensee on or prior to the Effective Date; or (ii) developed independently of the Company Intellectual Property.

1.27 "Loss" or "Losses" means all claims, losses, liabilities, damages, fines, penalties, and related costs, expenses, and other charges, including reasonable legal fees, costs of investigation, litigation, settlement, judgement, and appeal, remediation, obligations, and corrective actions required by Law, and any taxes imposed, interest, fines, and penalties with respect to the foregoing.

1.28 "Manufacture" and "Manufacturing" means any and/or all activities related to the manufacturing process development and associated validation, quality assurance, quality control activities, scale-up and/or analytic process development, actual production, manufacture, processing, filling, finishing, packaging, labeling, storing and shipping of a pharmaceutical or non-pharmaceutical product for pre- clinical, clinical and commercial use, including product characterization, quality assurance, and quality control but excluding those process development, qualification and validation, and scale-up activities included in Development activities.

1.29 "Net Revenues" means sales revenue received as reported in accordance with the GAAP standards applied on a consistent basis from the sale of Licensed Product by Licensee or its Affiliates, or in the case of Sublicensing by its Sublicensee, less the following deductions:

1.29.1 credits or allowances actually granted for damaged Licensed Product, returns or rejections of Licensed Product, price adjustments and billing errors;

1.29.2 normal and customary trade, cash and quantity discounts, allowances and credits actually allowed or paid, including the following:

1.29.2.1 those granted on account of price adjustments, billing errors, rejected goods, damaged goods, returns and rebates,

1.29.2.2 administrative and other fees and reimbursements and similar payments to wholesalers and other distributors, buying groups, specialty pharmacies, pharmacy benefit management organizations, health care insurance carriers and other institutions,

1.29.2.3 allowances and rebates paid to distributors, and

1.29.2.4 chargebacks;

1.29.3 commissions allowed or paid to Third Party distributors, brokers or agents with respect to the distribution of Licensed Product, other than sales personnel, sales representatives and sales agents employed by Licensee or its Affiliates;

1.29.4 transportation costs, including insurance, for outbound freight related to delivery of Licensed Product;

1.29.5 sales taxes, VAT taxes and other taxes directly related to the sales or delivery of the Licensed Product;

1.29.6 customs and excise duties and other duties related to the sales to the extent that such items are included in the gross amount invoiced; and

1.29.7 rebates and similar payments made with respect to sales paid for by any Governmental Authority or Regulatory Authority such as, by way of illustration and not in limitation of the Parties' rights hereunder, Federal or state Medicaid, Medicare or similar state program or equivalent foreign governmental program.

1.30 "Parties" means Company and Licensee, collectively.

1.31 "Party" means Company or Licensee, as applicable.

1.32 "Patent" means patents and patent applications, as well as any continuations, continuations-in-part, divisionals, utility models, extensions (including extensions under the USA Patent Term Restoration Act, extensions of patents under the Japanese Patent Law and Supplementary Protection Certificates), renewals, substitutions and additions thereof and all reissues, revalidations and re-examinations thereof, including any and all foreign counterparts thereof, as well as any other patent rights that contain at least one Valid Claim that would be infringed by the manufacture, import, use, offering for sale, or sale of Licensed Product(s) (if such activity were performed by a third party).

1.33 "Person" means an individual, a partnership, a limited liability company, a corporation, an association, a joint stock company, a trust, a joint venture, an unincorporated organization, or a sole proprietorship, or other similar entity or organization, including a government or political subdivision, department or agency of a government.

1.34 "Regulatory Approval" means, with respect to a country or regulatory jurisdiction in the Territory, any and all approvals, licenses, registrations or authorizations of any Regulatory Authority necessary to commercially import, distribute, sell or market a Licensed Product in such country and including, where applicable, (i) pricing or reimbursement approval in such country, (ii) pre- and post-approval marketing authorizations (including any prerequisite manufacturing approval or authorization related thereto), (iii) labeling approval, and (iv) technical, medical and scientific licenses.

1.35 "Regulatory Authority" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other Governmental Authorities regulating or otherwise exercising authority with respect to the Development, Manufacture, use, or Commercialization of the Licensed Products in the Territory.

1.36 "Sublicense" means a written agreement pursuant to which Licensee grants rights under the Company Intellectual Property to a Sublicensee to make, have made, offer to sell, and sell the Licensed Product in the Territory in compliance with, and subject to, the terms of this Agreement.

1.37 "Sublicensee" means any entity to which an express sublicense has been granted under the Patents. For clarity, a third party wholesaler or distributor who has no significant responsibility for marketing and promotion of the Licensed Product within its distribution territory or field (i.e., the third party simply functions as a reseller), and who does not pay any consideration to Licensee or an Affiliate for such wholesale or distributor rights, shall not be deemed a Sublicensee; and the resale by such a wholesaler or distributor shall not be treated as royalty bearing Net Revenues by a Sublicensee provided that a royalty is being paid by Licensee for the initial transfer to the wholesaler or distributor pursuant to this Agreement.

1.38 "Technical Failure" means the discontinuation of Development or Commercialization of a Licensed Product for technical, scientific, medical or regulatory reasons, including, but, not limited to, unacceptable preclinical toxicity, demonstration of a side effect profile significantly worse than currently marketed products, or inability to manufacture in an acceptable purity or for an acceptable price despite the Commercially Reasonable Efforts of Licensee.

1.39 "Term" has the meaning set forth in Section 7.1.

1.40 "Termination Notice" means a notice specifying that the non-breaching Party is electing to terminate the Agreement with immediate effect, specifying in detail the continuing nature of any breach and if applicable, why the terminating Party feels that any attempted cure was not adequate within such applicable cure period, if any.

1.41 "Territory" means worldwide.

1.42 "Third Party" means any Person other than Company or Licensee and their respective Affiliates.

1.43 "Valid Claim" means a claim of a pending or issued and unexpired patent which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal and that is not admitted to be invalid or unenforceable through reissue, disclaimer or otherwise (i.e., only to the extent the subject matter is disclaimed or is sought to be deleted or amended through reissue).

2 ARTICLE 2 – LICENSE GRANT; DEVELOPMENT, MANUFACTURE, USE, AND COMMERCIALIZATION

2.1 Grant of License Rights to Licensee. Subject to the terms and conditions of this Agreement, Company hereby grants to Licensee during the Term an exclusive (to the extent forth in Section 2.2, below), royalty-bearing, license with a right to sublicense (as set forth in Sections 2.4 and 2.5 below) under the Company Intellectual Property and within the Field, to Develop, have Developed, Manufacture, use, and Commercialize the Licensed Product in the Territory.

2.2 Exclusivity. During the Term of this Agreement, Company shall not grant rights to the Company Intellectual Property to any Third Party in the Field and Territory to Develop, Manufacture, use or Commercialize Licensed Product(s). During the Term, Company shall not Develop, Manufacture or Commercialize (or enter into any arrangement with any Person to Develop, Manufacture or Commercialize) the Licensed Product in the Field and Territory. During the Term, Licensee will use the Company Intellectual Property solely for Development, Manufacture, use, and/or Commercialization of the Licensed Product in the Field and Territory and shall not otherwise use or transfer to a Third Party any Company Intellectual Property outside of the Field or Territory or for any other purpose than the Development, Manufacture or Commercialization of the Licensed Product.

2.3 All Rights Reserved. Company hereby reserves all rights not expressly granted to Licensee under this Agreement, and without limiting the foregoing, all rights granted to Licensee under this Agreement are subject to Company's reserved right to use the Company Intellectual Property related to the Development, Manufacture, use, and/or Commercialization of any products or services which are not the Licensed Product(s), including within the Territory.

2.4 Subcontracting. Licensee may permit the use of Third Party subcontractors for purposes of conducting subcontracted obligations pursuant to the license granted herein by Company to Licensee pursuant to Section 2.1. Licensee will guarantee the performance of all subcontractors and shall remain primarily liable to Company for all of Licensee's duties and obligations contained in this Agreement, including the payments due pursuant to Article 4. Any act or omission of any subcontractor, whether permitted or not, that would be a breach of this Agreement if committed or omitted by Licensee shall be considered a breach by Licensee.

2.5 Sublicensing. Licensee has the right to grant Sublicenses to Sublicensees within the Territory. For the duration of the Term, each Sublicensee shall be a duly formed entity capable of selling Licensed Products within the Territory. Prior to any Sublicensee in connection with this Agreement on behalf of the Licensee, such Sublicensee shall have agreed in writing to be bound by the terms and conditions of this Agreement. Licensee and each Sublicensee hereby covenant and agree that (A) Sublicensee shall not exceed the scope and rights of the License granted to Licensee hereunder, (B) Licensee will remain fully responsible and liable to Company for any acts or omissions of a Sublicensee, including in respect of compliance with this Agreement, as if Licensee had committed such action or inaction itself, and (C) Company shall be entitled to enforce the terms and conditions of this Agreement that are applicable to a Sublicense against Licensee and/or such Sublicensee. Licensee shall deliver to Company a true, complete, and correct copy of each Sublicense granted by Licensee, and any modification or termination thereof, within thirty (30) days following the applicable execution, modification, or termination of such Sublicense.

2.6 Licensee Development Obligations.

2.6.1 Development. Subject to the terms and conditions of this Agreement, Licensee shall have the exclusive right to Develop, and shall be solely responsible for the Development of, the Licensed Product in the Field in the Territory during the Term.

2.6.2 Development Efforts. Except with respect to any termination of this Agreement in accordance with Article 7, upon Licensee's commencement of Development for any Licensed Product, Licensee shall use Commercially Reasonable Efforts in performing the Development for such Licensed Product.

2.7 Development Costs. Licensee shall bear all Development Costs to Develop the Licensed Product.

2.8 Manufacture. Licensee shall be solely responsible for the Manufacture of the Licensed Product in the Field in the Territory at its cost and expense. Company shall reasonably cooperate with Licensee in the technology transfer of the formulation and manufacturing process of Licensed Product to Licensee or its designee, including as may be more particularly described in any Ancillary Agreement(s) executed by the Parties for Company services.

2.9 Commercialization. Licensee shall have the exclusive right to control, and shall be solely responsible for, the Commercialization of the Licensed Product in the Field in the Territory at its cost and expense. Licensee will use Commercially Reasonable Efforts to Commercialize the Licensed Products in the Field in the Territory.

2.10 License Expiration. Subject to payment of outstanding amounts due to Company in accordance with this Agreement, upon expiration of the Term on a product-by-product, country-by-country basis, the rights granted to Licensee shall become paid-up and perpetual.

For avoidance of doubt and by way of example and not limitation under this Section 2.10, if the rights regarding Licensed Product A expire in country X where no Patent has issued and the Term expires as provided in Section 7.1(b) and outstanding amounts due to Company are paid as of the date the Term expires or, if thereafter, paid within the time provided for payment, then such rights in country X for Licensed Product A become paid-up and perpetual; however royalty-bearing rights remain for (i) Licensed Product A in country Z where a Patent remains in force and (ii) Licensed Product A in Country Y where a First Commercial Sale of Licensed Product A has not occurred and (iii) Licensed Product B in country X where a Patent remains in force.

By way of further example and not limitation, a Termination of this Agreement does not require Licensee to forfeit rights that have matured to paid up and perpetual on a product-by-product, country-by-country basis.

3 ARTICLE 3 - FURTHER COVENANTS AND AGREEMENTS

3.1 Compliance with Laws. Each Party shall perform its obligations under this Agreement and any Ancillary Agreement in accordance with all applicable Laws. Licensee hereby agrees that it shall not employ or otherwise use in any capacity for the purpose of performing Development for any Licensed Product, the services of any Person (including any employee or subcontractor): (i) that is currently excluded, debarred, suspended, or otherwise ineligible to participate in any governmental healthcare programs, (ii) that has been convicted of a criminal offense related to the provision of healthcare items or have been excluded, debarred, suspended, or otherwise declared ineligible to participate in any governmental healthcare programs, or (iii) that, to such Party's knowledge, is under investigation or involved in any dispute with a Governmental Authority that may result in such Person being excluded, debarred, suspended, or otherwise declared ineligible to participate in any governmental healthcare programs.

3.2 Regulatory Matters. Licensee shall have sole responsibility for preparing, filing, and prosecuting with Regulatory Authorities the application for the applicable Regulatory Approval for the Licensed Product, in its own name. Licensee shall provide any records, reports, or documentation.

3.3 Diligent Commercialization. Licensee shall use Commercially Reasonable Efforts to commercialize Licensed Products in the Field of Use within the Territory. In the event Licensee does not demonstrate Commercially Reasonable Efforts to develop the Licensed Product as defined herein, Company may terminate this Agreement in accordance with Section 7.2, and Licensee will no longer have any right to the Licensed Product or Company Intellectual Property related thereto.

4 ARTICLE 4 – PAYMENTS

4.1 License Payments. In partial consideration of the licenses and other rights granted herein, subject to the terms and conditions set forth in this Agreement, Licensee shall make the following non- refundable payments to Company on the applicable date or event:

PAYMENT EVENT	PAYMENT
1. License Execution Fee: upon full execution of this Agreement	$[***]
2. Annual Maintenance Fee, upon each anniversary of Agreement	$[***]

4.2 Milestone Fees. Licensee shall promptly inform Company of the achievement of each of the Development Milestone Events and Sales Milestone Events as set forth below by Licensee or any of its Affiliates or Sublicensees. In partial consideration of the licenses and other rights granted herein, and subject to the terms and conditions set forth in this Agreement, Licensee and applicable Sublicensees shall make the following non-refundable success fee payments to Company within thirty (30) days of such applicable event, on a Licensed Product-by-Licensed Product basis where Licensed Products are pharmaceutical products that require FDA (or the equivalent of FDA in non- US countries) Development Milestones Events:

DEVELOPMENT MILESTONE EVENT (per Licensed Product)	MILESTONE FEE (per Licensed Product)
1. IND or equivalent regulatory submission	$[***]
2. First in human patient dosed	$[***]
3. NDA Submission	$[***]

SALES MILESTONE EVENT (per Licensed Product)	MILESTONE FEE (per Licensed Product)
1. Reaching for the first time $70 Million in annual Net Revenue from sales of a Licensed Product	$[***]
2. Reaching for the first time $150 Million in annual Net Revenue from sales of a Licensed Product	$[***]
3. Reaching for the first time $300 Million in annual Net Revenue from sales of a Licensed Product	$[***]
4. Reaching for the first time $1 Billion in annual Net Revenue from sales of a Licensed Product	$[***]

4.3 Royalties. In partial consideration of the licenses and other rights granted herein, and subject to the terms and conditions set forth in this Agreement, Licensee shall pay to Company, and shall cause Sublicensees to pay to Company, on a quarterly basis, royalties based on Net Revenues, of the Licensed Product on a Licensed Product-by-Licensed Product and country-by-country basis in the Territory in accordance with the following:

LICENSED PRODUCT SALES (per Licensed Product)	ROYALTY RATE* (per Licensed Product)
1. Net Revenues from $[***] to $[***]	2.5%
2. Net Revenues from $[***] to $[***]	5%
3. Net Revenues from $[***] to $[***]	7.5%
4. Net Revenues from $[***] and above	10%

*Royalty rates shall be 50% of the above percentages following the last-to-expire of the Company Patents covering a Licensed Product, but prior to expiration of the Term.

4.3.1 Quarterly Royalty Reports. Licensee shall provide to Company a written report setting forth the date of First Commercial Sale of each Licensed Product in each country within thirty (30) days of the occurrence of such sale. Within sixty (60) days after the end of any calendar quarter during which there are sales of a Licensed Product in any country of the Territory, Licensee shall provide Company with a written report (the "Quarterly Royalty Report") setting forth (i) the amount of Net Revenues, specifying the gross sales and the deductions taken to arrive at the Net Revenues, listed by Licensed Product and by country, and any other credits or offsets; and (ii) the total royalty payments due to Company by Licensed Product and by country. Along with each such Quarterly Royalty Report, Licensee shall pay to Company the royalties due and payable under this Agreement. If no royalties or fees are due and payable, Licensee shall so report.

4.3.2 Records Pertaining to Sales or Other Disposition of Licensed Product. Licensee shall keep complete, true and accurate books and records relating to Development or Manufacturing activities conducted by Licensee, its Affiliates, or its designees under this Agreement for the period required by applicable laws. In addition, Licensee shall keep (and cause its Affiliates and Sublicensees to keep) complete and accurate records pertaining to the sale or other disposition of Licensed Products in sufficient detail to permit Company to confirm the accuracy of royalties and sales milestones due hereunder, for at least five (5) years following the calendar quarter to which the information relates.

4.3.3 Examination Rights Pertaining to Sales or Other Disposition of Licensed Product. During the Term and for five (5) years thereafter, Company shall have the right to appoint a certified public accountant that is, in its discretion, acceptable to Licensee to examine the applicable Net Revenue records of Licensee and its Affiliates to verify the accuracy of the relevant Quarterly Royalty Report and royalties and milestones payable, by inspection of relevant books of accounts and records, subject to the following terms:

4.3.3.1 Licensee and its Affiliates shall make their books and records available for inspection by the accountant solely to verify the accuracy of its Quarterly Royalty Report and royalties and sales milestones payable.

4.3.3.2 Company shall give at least thirty (30) days prior notice to Licensee of when its accountant shall visit Licensee and its Affiliates or Sublicensees.

4.3.3.3 Licensee and its Affiliates shall give access to the accountant to the relevant books and records during regular business hours at the place or places where the books and records are usually kept. While inspecting such accounts and records, the accountant shall abide by all of Licensee's (or its Affiliate's) standard rules and regulations.

4.3.3.4 The accountant shall prepare and deliver to each Party a report setting out its findings no later than thirty (30) days after the examination has been completed.

4.3.3.5 Company's examination right under this Section may not be exercised more than once every calendar year.

4.3.3.6 Company shall bear the examination costs, except where the examination shows that Licensee has underpaid Company by five percent (5%) or more of the total amount due for a calendar year, in which case Licensee shall bear the examination costs.

4.3.3.7 Where there has been an underpayment, Licensee shall pay to Company the underpayment with a monthly interest rate as set forth in Section 12.11 (together with reasonable and documentable examination costs if applicable) due within thirty (30) days of its receipt of the accountant's report. In the case of overpayment by Licensee, any future royalty payments payable to Company shall be offset by the amount of overpayment.

4.3.5 Payment Exchange Rate. In the case of sales by Licensee and its Affiliates outside the United States, the rate of exchange to be used in computing the amount of currency equivalent in U.S. Dollars due Company shall be made at the rate of exchange utilized by Licensee and its Affiliates in its worldwide accounting system, prevailing on the third to the last business day of the month prior to the month in which such sales are recorded by Licensee and its Affiliates.

By way of example and not limitation, when sales outside the United States are recorded by Licensee for the month of June, the exchange rate prevailing on the third to the last business day of May will be used in computing the amount of currency equivalent in U.S. Dollars due to Company.

4.4 [***].

4.5 Buyout Option. During the License Term, Licensee shall have the option to purchase the rights to each Licensed Product (on a Licensed Product-by-Licensed Product basis) in the form of an exclusive (as to the applicable Licensed Product), fully paid, transferable right and license to the Licensed Product, in accordance with the following, which shall be subject to the applicable Payment Multiplier:

BUYOUT EVENTS	**BUYOUT PAYMENT**
1. Upon Effective Date	$[***]
2. Upon IND Approval.	$[***]
3. Upon First Phase I Completion.	$[***]
4. Upon First Phase II Completion.	$[***]
5. Upon First Phase III Completion.	$[***]
6. Upon Regulatory Approval.	[***]% of Discounted Cash Flow (DCF) value calculated by independent Third Party
7. Upon Product Launch, where the Licensed Product is not a pharmaceutical product	Greater of $[***] or [***]% of Discounted Cash Flow (DCF) value calculated by independent Third Party

5 ARTICLE 5 - CONFIDENTIALITY

5.1 Confidentiality. Each Party shall, and shall cause its Affiliates, and each of its and their current and former respective officers, directors, employees and agents (collectively, Receiving Party's "Representatives") to, keep completely confidential and not publish or otherwise disclose and not use, directly or indirectly, by or on behalf the other Party for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by or on behalf of the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or such use is reasonably necessary for the performance of the Receiving Party's obligations, or the exercise by the Receiving Party of its rights, under this Agreement. "Confidential Information" means any information provided by or on behalf of one Party or its Affiliates (the "Disclosing Party") to the other Party or its Affiliates (the " Receiving Party") relating to the terms of this Agreement, the Licensed Product, the performance of Development activities, Manufacturing activities, Commercial activities or the scientific, regulatory, or business affairs or other activities of the Disclosing Party or the Disclosing Party's Affiliates. Each Receiving Party shall (and shall cause its Affiliates to) take reasonable actions to protect against any use or disclosure of the Confidential Information of the Disclosing Party except as expressly permitted under this Article 5. A Party's Representatives that receive or otherwise have access to the Disclosing Party's Confidential Information under this Article 5 shall have a need to know such information and shall be bound by obligations of confidentiality and non-use substantially similar to the Receiving Party's obligations hereunder. Notwithstanding the foregoing, Confidential Information shall not include any information that:

5.1.1 is or hereafter becomes part of the public domain by public use, publication, general knowledge or the like through no wrongful act, fault, or negligence on the part of Receiving Party or its Representatives;

5.1.2 can be demonstrated by documentation or other competent proof to have been in the Receiving Party's possession prior to disclosure by or on behalf of the Disclosing Party without any obligation of confidentiality with respect to said information;

5.1.3 is subsequently received by the Receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to said information; or

5.1.4 can be demonstrated by documentation or other competent evidence to have been independently developed by or for the Receiving Party without reference to the Disclosing Party's Confidential Information.

Specific aspects or details of Confidential Information shall not be deemed to be within the public domain or in the possession of the Receiving Party merely because the Confidential Information is embraced by more general information in the public domain or in the possession of the Receiving Party. Further, any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

5.2 Permitted Disclosures. Each Receiving Party may disclose Confidential Information disclosed to it by the Disclosing Party to the extent that such disclosure by the Receiving Party is:

5.2.1 made in response to a valid order of a court of competent jurisdiction or other Governmental Authority of competent jurisdiction or, if in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is otherwise required by applicable Law; provided, however, that the Receiving Party, where reasonably possible, shall first have given notice, to the extent legally permitted, to the Disclosing Party and given the Disclosing Party (at its sole expense) a reasonable opportunity to quash such order and to obtain a protective order requiring that the Confidential Information and documents that are the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided, further that if a disclosure order is not quashed or a protective order is not obtained, the Confidential Information disclosed in response to such court or governmental order shall be reasonably limited to the information that is legally required to be disclosed in response to such court or governmental order and such information disclosed shall be considered Confidential Information for all other purposes;

5.2.2 otherwise required by applicable Law or the requirements of a national securities exchange or stock market; provided that the Receiving Party shall (i) if not prohibited by applicable Law, provide the Disclosing Party with reasonable advance notice of, and an opportunity to comment on, any such required disclosure, to the extent such advance notice is legally permitted, (ii) if not prohibited by applicable Law, if requested by the Disclosing Party, seek confidential treatment with respect to any such disclosure to the extent available, and (iii) if not prohibited by applicable Law, consider the comments of the Disclosing Party in any such disclosure or request for confidential treatment;

5.2.3 made by the Receiving Party to a Regulatory Authority as required in connection with obtaining or maintaining any Regulatory Approval for the Licensed Product; provided, however, that reasonable measures shall be taken to seek confidential treatment of such information;

5.2.4 made by the Receiving Party as appropriate to file or prosecute Company Patents, prosecute or defend litigation, file Regulatory Approval applications, or otherwise establish rights or enforce obligations under this Agreement;

5.2.5 made by the Receiving Party or its Representative to its attorneys, auditors, advisors, consultants, contractors, licensees or other Third Parties in connection with the performance of its obligations or exercise of its rights as contemplated by this Agreement; provided, however, that such Persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential Information that are substantially similar to the Receiving Party's obligations hereunder; and

5.2.6 made by the Receiving Party or its Representative to actual or prospective acquirers, merger candidates, or investors (and to their respective Affiliates, representatives and financing sources); provided that (i) each such Third Party signs an agreement that contains obligations that are substantially similar to the Receiving Party's obligations hereunder, and (ii) each such representative or financing source to whom information is disclosed shall (a) be subject to reasonable obligations of confidentiality, (b) be informed of the confidential nature of the Confidential Information so disclosed, and (c) agree to hold such Confidential Information subject to the terms thereof.

5.3 Use of Name. Except as expressly provided in this Agreement, neither Party shall mention or otherwise use the corporate names or any other name or trademark of the other Party (or any abbreviation, acronym, adaptation, translation or transliteration thereof) in any publication, press release, marketing and promotional material, or other form of publicity without the prior written approval of such other Party in each instance. The restrictions imposed by this Section 5.3 shall not prohibit either Party from making any disclosure that is otherwise permitted under this Article 5 or with respect to which written consent has previously been obtained. Further, the restrictions imposed on each Party under this Section 5.3 are not intended, and shall not be construed, to prohibit a Party from identifying the other Party in its internal business communications, provided that any Confidential Information in such communications remains subject to this Article 5.

5.4 Press Releases. Neither Party shall issue any press release or other similar public communication relating to the execution of or the terms of this Agreement, its subject matter or the transactions covered by it, or the activities of the Parties under or in connection with this Agreement, without the prior written approval of the other Party, except for communications required by applicable Law or the requirements of a national securities exchange or stock market as reasonably advised by the issuing Party's counsel (provided, that, the issuing Party complies with the provision set forth in Section 5.2.2). Notwithstanding the above, the Parties acknowledge and agree that, upon and/or following the Effective Date, one or both of the Parties may desire to issue a press release announcing the execution of this Agreement with the prior written consent of the other Party, which consent may be granted or withheld in such other Party's sole discretion. The Parties agree in good faith with respect to the text and timing of such press releases prior to the issuance thereof. In addition, following any initial press release(s) announcing this Agreement or other public disclosure approved by both Parties, either Party shall be free to disclose, without the other Party's prior written consent, the existence of this Agreement, the identity of the other Party and those terms of the Agreement which have already been publicly disclosed in accordance herewith.

5.5 Return or Destruction of Confidential Information . Within ninety (90) days after the earlier of (i) the expiration of the Term, or (ii) the termination of this Agreement in its entirety, each Receiving Party shall, at the Disclosing Party's discretion and written request, promptly destroy or return to the Disclosing Party all documentary, electronic, or other tangible embodiments of the Disclosing Party's Confidential Information to which the Receiving Party does not retain rights hereunder and any and all copies thereof, and destroy those portions of any documents that incorporate or are derived from the Disclosing Party's Confidential Information to which the Receiving Party does not retain rights hereunder, and provide a written certification of such destruction, except that the Receiving Party may retain (a) one copy thereof for archival purposes, and (b) such additional copies of or any computer records or files containing such Confidential Information that have been created solely by the Receiving Party's automatic archiving and back-up procedures, to the extent created and retained in a manner consistent with the Receiving Party's standard archiving and back-up procedures, but not for any other use or purpose. Notwithstanding anything to the contrary in this Section 5.5, where Licensee's rights have become paid-up and perpetual as provided in Section 2.10, the Licensee may retain such Confidential Information as reasonably necessary to exercise rights granted under this Agreement.

5.6 Survival of Confidentiality Obligations . The confidentiality and non-use obligations imposed on each Party under this Article 5 shall continue with respect to a particular item of Confidential Information of the other Party until seven (7) years after termination or expiration of this Agreement; provided, however, that the confidentiality and non-use obligations imposed by this Agreement with respect to any of Company Technology, Improvements, or Licensee IP which comprises a trade secret shall continue for as long as such Company Technology, Improvements, or Licensee IP remains eligible for trade secret protection under applicable federal and state trade secret laws.

6 ARTICLE 6 - INTELLECTUAL PROPERTY

6.1 Company IP.

6.1.1 Ownership. As between the Parties, Company shall have sole and exclusive ownership of all right, title and interest on a worldwide basis in and to all Company IP and Improvements developed by Company. For any Improvements to Company IP, such Improvements shall automatically be subject to the license grants from Company to Licensee as set forth in this Agreement.

6.1.2 Company Patents. Company shall have the sole and exclusive right, but not the obligation, at its sole cost and expense, to prepare, file prosecute, and maintain (including with respect to (i) related interference, derivation, re-issuance, re-examination, opposition and other post- grant proceedings, and (ii) patent term extensions, including supplementary protection certificates and any other extensions or patent term adjustments that are now or become available in the future, wherever applicable) Patents with respect to Company IP and Improvements.

6.2 Licensee IP.

6.2.1 Licensee Ownership. As between the Parties, Licensee shall have the sole and exclusive ownership of all right, title and interest on a worldwide basis in and to any and all Licensee IP and any Improvements developed by Licensee. For any Improvements developed by Licensee, Licensee shall, and does hereby grant, Company a fully paid, perpetual, non- exclusive license to such Improvements for Company's use outside the Field.

6.2.2 Licensee Patents. Licensee shall have the sole and exclusive right, but not the obligation, at its sole cost and expense, to prepare, file, prosecute, and maintain (including with respect to (i) related interference, derivation, re-issuance, re-examination, opposition and other post- grant proceedings, and (ii) patent term extensions, including supplementary protection certificates and other extensions or patent term adjustments that are now or become available in the future, wherever applicable) Patents with respect to Licensee IP.

6.3 Disclosure of Inventions . To the extent relating to Improvements (including methods of making or using the Licensed Product), each Party will promptly disclose to the other Party all invention disclosures and know how related thereto ("Inventions") disclosed to such Party by its employees, contractors and/or agents within twenty (20) business days of receipt. Each Party will respond promptly to reasonable requests from the other Party for more information relating to such Inventions in order to determine whether such Inventions are Improvements. Each Party shall have the right to propose revisions to such invention disclosures to the other Party that owns Improvements, and the Party owning such Improvements shall take reasonable account of such proposed revisions in any resulting patent preparation.

6.4 Patent Extension. Each Party shall promptly notify the other if it becomes aware of Regulatory Approval for the Licensed Product for which an application for Patent term extension or supplemental protection certificate may be based, including any Third Party product, or any other event in any country that would enable Company or Licensee as appropriate to apply for Patent term extension, or supplemental protection certificate or other regulatory or marketing exclusivity in any country. The Parties hereto shall cooperate with each other, including without limitation to provide necessary information and assistance as the other Party may reasonably request, in obtaining patent term extension, supplemental protection certificate or their equivalents in any country in the Territory. In the event that elections with respect to obtaining such patent term extension, supplemental protection certificate or their equivalents are to be made, Company shall have the right to make the election when it concerns Company Intellectual Property, Improvements, and Licensee shall have the right to make the election when it comes to Licensee IP, and the other Party, as the case may be, agrees to abide by such election.

6.5 Infringement. In the event of any infringement by a Third Party of the Company Patents (" Infringement"), the Parties acknowledge that Company shall have the first right, but not the obligation, to bring and control, at its expense, an appropriate suit or other action before any government or private tribunal against any person or entity allegedly engaged in such Infringement (an "Infringement Action"). In the event that either Party becomes aware of any suspected Infringement or any Infringement Action, such Party shall promptly notify the other Party thereof. In the event such Infringement occurs within the Field, Licensee will have the right, at its own expense and by counsel of its choice, to be represented in any Infringement Action. At Company's request, Licensee will join any Infringement Action as a party. Company will have a period of ninety (90) days to elect to initiate an action to enforce any Patent in the applicable jurisdiction (or to settle or otherwise secure the abatement of such Infringement). In the event Company does not so elect (or settle or otherwise secure the abatement of such Infringement) within the aforementioned period of time or ten (10) days before the time limit, if any, for the filing of an Infringement Action, it will so notify Licensee in writing and Licensee will have the right to commence such a suit or take such action to enforce the applicable Company Patents, at Licensee's expense.

6.6 Third Party IP.

6.6.1 Notice of Potential Third Party Claims. If during the Term either Party obtains knowledge of any potential, alleged, or actual infringement, misappropriation, or other violation of a Third Party's patent rights or other intellectual property rights arising out of, or based upon, the Development, Manufacture, use, or intended Commercialization of any Licensed Product or any threatened or pending Claim relating thereto, or any threatened or pending action, suit or proceeding, then, such Party shall promptly notify the other Party thereof in writing thereof and provide all pertinent details with respect thereto that are reasonably available to such Party.

6.6.2 Newly Issued Third Party Patents. Following the Effective Date, if the Parties become aware that a patent has issued to a Third Party that either Party believes in good faith covers or claims the Licensed Product or its use or manufacture (a "New Third Party Patent"), Licensee may request that the Parties meet and discuss methods of addressing such New Third Party Patent, including determining whether, (i) it is commercially feasible to modify the features or attributes of such Licensed Product or its manufacturing process, or the indications for use of the Licensed Product, so as to avoid infringing the claims in such New Third Party Patent, and/or (ii) there is sufficient basis in fact and law to conclude that each relevant claim of such New Third Party Patent is invalid or unenforceable (any commercially feasible combination of options (i) and (ii) that addresses all relevant claims, a "New Work-Around"). Where Licensee determines, in its sole discretion, that no New Work-Around is commercially feasible in light of the costs, technical, or regulatory delays, risks, or legal or technical challenges associated therewith, such decision shall be deemed a decision that a Technical Failure has occurred with respect to such Licensed Product, and Licensee shall have the right to terminate this Agreement with respect to such Licensed Product in accordance with Sections 7.3 or 7.4. Alternatively, Licensee may, in its sole discretion, enter into a license with the Third Party for rights under the New Third Party Patent and will be solely responsible for payment of royalties, fees, costs, and other liabilities under such license.

6.7 Cooperation. Each Party shall cooperate with and assist the other Party, without additional compensation, to fully effect this Article 6, including by making any necessary assignments and licenses and executing such documents and taking such actions, and making its employees and using Commercially Reasonable Efforts to make independent contractors available to execute documents and provide information to such other Party or to such other Party's authorized attorneys, agents, or representatives, as necessary.

6.8 No Implied Licenses. Except as specifically set forth in this Agreement, neither Party shall acquire any license or other intellectual property interest, by implication or otherwise, in any information disclosed to it under this Agreement or under any patents, patent applications or other intellectual property owned or controlled by the other Party or its Affiliates.

6.9 Licensee Challenges to Company Patents. If, during the Term, Licensee or its Affiliate institutes or actively participates directly or indirectly as an adverse party in, or otherwise provides material support to, any action, suit, or other proceeding in the Territory to invalidate or limit the scope of any claim of Company Patents or obtain a ruling that any claim of Company Patents is unenforceable or not patentable or otherwise, Company has the right to immediately terminate this Agreement with notice to Licensee and with no opportunity for Licensee to cure.

7 ARTICLE 7 - TERM AND TERMINATION

7.1 Term. This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 7 shall continue until the longer of: (a) the last to expire of the Company Patents that Cover a Licensed Product; or (b) ten (10) years following First Commercial Sale, on a country-by-country basis (the "Term").

7.2 Termination for Breach. Either Party may terminate this Agreement by providing a Termination Notice in the event the other Party materially breaches this Agreement, in the following time periods:

7.2.1 if such material breach is a payment default and has continued for sixty (60) days after receipt of written notice by the allegedly breaching Party;

7.2.2 for material breaches that are capable of being cured within ninety (90) days, if such breach has continued for ninety (90) days after receipt of written notice by the allegedly breaching Party; and

7.2.3 for material breaches that are not capable of being cured within ninety (90) days, if such breach has continued for ninety (90) days after receipt of written notice by the allegedly breaching Party and such Party has not commenced good faith efforts to cure such breach within such ninety (90) day period.

For avoidance of doubt, any material default or breach of any Ancillary Agreement, shall not constitute breach of this Agreement.

7.3 Termination for Technical Failure. Either Party may terminate this Agreement in the event of Technical Failure by providing ninety (90) days written notice.

7.4 Termination for Convenience. Licensee may terminate this Agreement without cause, for convenience by providing ninety (90) days written notice to Licensor.

7.5 Termination for Insolvency. Company shall have the right to terminate this Agreement upon Termination Notice if Licensee:

7.5.1 passes a resolution for winding-up of all or a material part of its assets or business (other than a winding-up for the purpose of, or relating to, any solvent amalgamation or reconstruction) or a court enters an order to that effect;

7.5.2 has entered against it an order for relief recognizing it as a debtor under any insolvency or bankruptcy laws (or any equivalent order in any jurisdiction); or

7.5.3 enters into any composition or arrangement with its creditors with respect to all or a material part of its assets or business (other than relating to a solvent restructuring).

Notwithstanding the foregoing, in the case of any involuntary bankruptcy proceeding, such right to terminate shall only become effective if Licensee consents to the involuntary bankruptcy or if such proceeding is not dismissed or stayed within forty-five (45) days after the filing thereof.

7.6 Rights in Bankruptcy. All rights and licenses granted under or pursuant to this Agreement by a Party to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under the U.S. Bankruptcy Code. The Parties agree that each Party, as licensee of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of the commencement of a Bankruptcy proceeding by or against a Party under the U.S. Bankruptcy Code (the "Party subject to such proceeding"), the other Party (the "non-subject Party") shall be entitled to a complete duplicate of (or complete access to, as appropriate) all data relating to Development and Regulatory Approval of the Licensed Product, and all embodiments of such intellectual property related thereto, which shall be promptly delivered (i) upon any such commencement of a Bankruptcy proceeding upon the non-subject Party's written request therefor, unless the Party subject to such proceeding (x) elects to and does continue to perform all of its obligations under this Agreement, or (y) rejects this Agreement and the non-subject Party elects to treat this Agreement as terminated, or (ii) if not delivered under clause (i) above, following the rejection of this Agreement by or on behalf of the Party subject to such proceeding, upon written request therefor and the election by the non-subject Party to retain its rights under this Agreement. The provisions of this Section 7.6 are without prejudice to any rights that a Party may have arising under any applicable insolvency statute or other applicable law, including the right of a Party to assert that this Agreement is not an executory contract subject to rejection under Section 365 of the U.S. Bankruptcy Code.

7.7 Effects of Termination of this Agreement. Except as provided in Section 2.10, upon termination of this Agreement, (i) all rights licensed by Company to Licensee shall terminate, and all Improvements of Licensee, shall revert to Company in their entirety, and (ii) Licensee hereby grants to Company a non-exclusive, royalty free, worldwide license in all fields including the right to sublicense, all rights to Licensee Know-How not included in Improvements that is directly related to Licensed Products and developed depending on Company IP during the Term; provided that and notwithstanding this Section 7.7 (i) and (ii), where rights are paid-up and perpetual as provided in Section 2.10, Licensee retains the exclusive rights to Develop, Manufacture, use, and Commercialize Licensee IP, Improvements, and Licensee Know-How on a product-by-product, country-by-country basis. Notwithstanding the foregoing, Licensee, its Affiliates and Sublicensees shall be entitled to continue to sell (but not to actively promote after the effective date of termination) any existing inventory of Licensed Products in each terminated country of the Territory for which Regulatory Approval therefor has been obtained in accordance with the terms and conditions of this Agreement for a period of six (6) months following the effective date of such termination, and any Licensed Product sold or disposed of during this period shall be subject to the same consideration including without limitation the obligation to pay royalties for Licensed Product as would have applied had this Agreement otherwise remained in full force and effect. Following such period, Licensee, its Affiliates and Sublicensees shall not sell such terminated Licensed Products in such terminated country(ies).

7.8 Other Remedies. Termination or expiration of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to such expiration or termination, nor affect the survival of any provision hereof to the extent it is expressly stated to survive such termination. Subject to and without limiting the terms and conditions of this Agreement, expiration or termination of this Agreement shall not preclude any Party from (i) claiming any other damages, compensation or relief that it may be entitled to upon such expiration or termination, (ii) any right to receive any amounts accrued under this Agreement prior to the expiration or termination date but which are unpaid or become payable thereafter and (iii) any right to obtain performance of any obligation provided for in this Agreement which shall survive expiration or termination.

7.9 Survival. Termination or expiration of this Agreement shall not affect rights or obligations of the Parties under this Agreement that have accrued prior to the date of termination or expiration of this Agreement. Notwithstanding anything to the contrary, the following provisions shall survive and apply after expiration or termination of this Agreement: Sections 2.10 (to the extent applicable), 4.3.2, 4.3.3, 4.3.4, 6.2, 6.9, 7.7, 7.9, 8.4 and Articles 1 (to the extent necessary to interpret other surviving sections), 5, 9, 10, 11, and 12. All provisions not surviving in accordance with the foregoing shall terminate upon expiration or termination of this Agreement and be of no further force and effect.

8 ARTICLE 8 - REPRESENTATIONS, WARRANTIES AND COVENANTS; DISCLAIMER

8.1 Mutual Representations, Warranties and Covenants. Each Party represents and warrants to the other Party that:

8.1.1 Due Incorporation or Formation; Authorization of Agreement. Such Party is duly incorporated, organized or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation, organization or formation and has the corporate, company, or partnership power and authority to own its property and carry on its business as owned and carried on at the date hereof and as contemplated hereby. Such Party has the necessary power and authority to execute and deliver this Agreement and the Ancillary Agreements and to perform its obligations hereunder, and the execution, delivery and performance of this Agreement and the Ancillary Agreements by such Party has been duly authorized by all necessary corporate, company or partnership action of such Party. This Agreement and each Ancillary Agreement (when entered into) constitutes (and shall constitute) the legal, valid and binding obligation of such Party and is (and shall be) enforceable against it in accordance with its (and their) terms, subject to the effects of bankruptcy, insolvency, or other laws of general application affecting the enforcement of creditor rights and judicial principles affecting the availability of specific performance and general principles of equity.

8.1.2 No Conflicts. Neither the execution, delivery or performance of this Agreement and the Ancillary Agreements by such Party nor the consummation by such Party of the transactions contemplated hereby or thereby (i) conflicts with, violates, or will result in a breach in any material respect of any of the terms, conditions or provisions of any applicable Law, (ii) conflicts with, violates, or will result in a breach of or constitute a default under any of the terms, conditions or provisions of, where relevant, the articles of incorporation, bylaws, operating agreement, partnership agreement, or other organizational documents of such Party, (iii) conflicts with, violates, or will result in a breach of, constitute a default under (whether with notice or lapse of time or both), accelerate or permit the acceleration of the performance required by, give to others any material interests or rights within the Field or require any consent, authorization or approval under any agreement or instrument to which such Party is a party or by which such Party or any of their properties or assets is bound, in each case that would have a material adverse effect on such Party's ability to perform under this Agreement within the Field, or (iv) results or will result in the creation or imposition of any lien upon any of the properties or assets of such Party, in each case would have a material adverse effect on such Party's ability to perform under this Agreement or any Ancillary Agreement.

8.1.3 Governmental Authorizations; Consents. Any registration, declaration or filing with, or consent, approval, license, permit, or other authorization or order by, or exemption or other action of, any Governmental Authority, or any approval or consent of any other Person, that was or is required in connection with the valid execution, delivery, acceptance, and performance by such Party under this Agreement or any Ancillary Agreement were completed, made, or obtained on or before the Effective Date (other than with respect to (i) obtaining Regulatory Approval for the Licensed Product, which shall be sought in accordance with this Agreement, and (ii) post-Effective Date notifications to and/or consents from Governmental Authorities as required by applicable Law).

8.2 Company. Company represents and warrants to Licensee that:

8.2.1 Compliance with Laws. Company has not employed or otherwise used in any capacity the services of any Person (including any employee or subcontractor) in performing any activities with respect to such Company Intellectual Property: (i) that is currently excluded, debarred, suspended, or otherwise ineligible to participate in any governmental healthcare programs, (ii) that has been convicted of a criminal offense related to the provision of healthcare items or has been excluded, debarred, suspended, or otherwise declared ineligible to participate in any governmental healthcare programs, or (iii) that, to Company's knowledge, is under investigation or involved in any dispute with a Governmental Authority that may result in such Person being excluded, debarred, suspended, or otherwise declared ineligible to participate in any governmental healthcare programs.

8.2.2 Company Intellectual Property. Company: (i) has the authority to grant the licenses herein, and (ii) has not granted to any Third Party any right or license or option to practice for commercial purposes the Company Intellectual Property within the Field. As of the Effective Date, Company has granted no prior license, assignment, transfer, covenant not to sue, or other grant of rights under such Company Intellectual Property within the Field, in each case, that would materially impair the performance of the Development of the Licensed Product, or Licensee's ability to obtain Regulatory Approval for the Licensed Product.

8.2.3 Litigation. As of the Effective Date, there are no actions, suits, proceedings, or investigations pending, or, to the knowledge of Company, threatened against Company relating to any of the Licensed Product or the Development or Manufacture thereof before or by any Governmental Authority or any arbitrator, and there exist no facts or circumstances likely to give rise to any of the foregoing.

8.2.4 Other License Grants. Company has not granted, and will not grant after the Effective Date and during the Term, any right to any Third Party within the Field that would conflict with the rights granted to Licensee hereunder.

8.3 Licensee. Licensee represents and warrants to Company that:

8.3.1 Compliance with Laws. Licensed Products prepared and sold by Licensee shall be in compliance with all applicable Laws and that any Person (including any employee or subcontractor) in performing any activities with respect to Commercialization of the Company Intellectual Property, and all Licensed Products shall be Manufactured in accordance with Regulatory Approvals and all other applicable Laws, Manufacturing processes, and quality requirements, and shall not be adulterated or misbranded under any applicable Laws. Licensee has not employed or otherwise used in any capacity the services of any Person (including any employee or subcontractor) in performing any activities with respect to such Company Intellectual Property: (i) that is currently excluded, debarred, suspended, or otherwise ineligible to participate in any governmental healthcare programs, (ii) that has been convicted of a criminal offense related to the provision of healthcare items or has been excluded, debarred, suspended, or otherwise declared ineligible to participate in any governmental healthcare programs, or (iii) that, to Licensee's knowledge, is under investigation or involved in any dispute with a Governmental Authority that may result in such Person being excluded, debarred, suspended, or otherwise declared ineligible to participate in any governmental healthcare programs.

8.3.2 Commercialization. Licensee shall use Commercially Reasonable Efforts to Commercialize the Company Intellectual Property in accordance with Section 2.9.

8.3.3 Export Compliance. Licensee shall observe all applicable United States and foreign laws and regulations with respect to the research, development, manufacture, use, marketing and transfer of Licensed Products and related technical data, including, without limitation, the International Traffic in Arms Regulations (ITAR) and the Export Administration Regulation and hereby represents and covenants that Licensee: (a) is neither a national of, nor controlled by a national of, any country to which the United States prohibits the export or re-export of goods, services, or technology; (b) is not a Person specifically designated as ineligible to export from the United States or deal in U.S. origin goods, services, or technologies; (c) shall not export or re-export, directly or indirectly, any goods, services, or technology to any country or Person (including juridical Persons) to which the United States prohibits the export of goods, technology or services; and (d) in the event that a United States government license or authorization is required for an export or re-export of goods, services, or technology (including technical information acquired Company under this Agreement and/or any products created by using such technical information or any part thereof), shall obtain any necessary United States government license or other authorization prior to undertaking the export or re-export.

8.4 Disclaimer. EXCEPT AS OTHERWISE SET FORTH IN THIS ARTICLE 8, NEITHER COMPANY NOR LICENSEE MAKE ANY OTHER REPRESENTATIONS OR WARRANTIES WITH RESPECT TO THIS AGREEMENT OR ANY ANCILLARY AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY, AND EACH OF COMPANY AND LICENSEE EXPRESSLY DISCLAIMS ALL OTHER WARRANTIES WITH RESPECT TO THIS AGREEMENT AND THE ANCILLARY AGREEMENTS AND THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY, WHETHER EXPRESS, STATUTORY OR IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

9 ARTICLE 9 - INDEMNIFICATION

9.1 Indemnity by Company. Company shall indemnify and hold harmless the Licensee Indemnified Parties from and against any and all Losses (minus an amount equal to the amount of any insurance proceeds from insurance policies that Licensee is required to maintain pursuant to this Agreement that have been recovered (net of any collection costs) by such Indemnified Parties in connection with such Losses or the circumstances giving rise thereto) to the extent arising out of or relating to Third Party Claims asserted, brought, commenced, or threatened against any Licensee Indemnified Party arising from, out of, or in connection with bodily injury or death or property damage arising from or in connection with Company's willful misconduct, gross negligence, fraudulent acts or omissions of Company, or any violation of applicable Law by Company.

9.2 Indemnity by Licensee. Licensee shall indemnify and hold harmless the Company Indemnified Parties from and against any and all Losses (minus an amount equal to the amount of any insurance proceeds from insurance policies that any assignee of Company is required to maintain pursuant to this Agreement that have been recovered (net of any collection costs) by such Indemnified Parties in connection with such Losses or the circumstances giving rise thereto) to the extent arising out of or relating to Third Party Claims asserted, brought, commenced, or threatened against any Company Indemnified Party arising from, out of, or in connection with: (i) Licensee's breach of its representations, warranties, covenants or obligations under this Agreement or any Ancillary Agreement; (ii) any bodily injury or death or property damage arising from or in connection with the Development, Manufacture, use, or Commercialization of a Licensed Product (in each case excluding Claims for which Company is required to indemnify Licensee in accordance with Section 9.1, or in connection with Licensee's willful misconduct, gross negligence, fraudulent acts or omissions of Licensee, or any violation of applicable Law by Company); (iii) infringement, misappropriation, or other violation of another Person's patents or other intellectual property rights resulting from Licensee's Development, Manufacturing, use, or Commercialization of any Licensed Product; (iv) infringement, misappropriation, or other violation of another Person's patents or other intellectual property rights resulting from Licensee's development, manufacturing, use, or commercialization of any product which is not related to the actual Company Intellectual Property or which uses the Company Intellectual Property in a manner not authorized or contemplated by this Agreement.

9.3 Indemnification Procedures.

9.3.1 Notice of Claim. Any Licensee Indemnified Party or Company Indemnified Party asserting a right of indemnification under this Article 9 (an "Indemnitee") shall notify the indemnifying party (an " Indemnitor") in writing (the " Indemnity Notice") promptly after receiving written notice of any Third Party Claim against it, describing the Third Party Claim, the amount thereof (if known and quantifiable) and the basis thereof; provided, that, the failure to so notify an Indemnitor shall not relieve the Indemnitor of its obligations hereunder except to the extent that (and only to the extent that) the Indemnitor has been materially prejudiced thereby.

9.3.2 Defense of Third Party Non-IP Claims. Any Indemnitor shall be entitled to participate in the defense of any Claim brought by a Third Party giving rise to a right of indemnification ("Third Party Claim") at such Indemnitor's expense, and at such Indemnitor's option (subject to the limitations set forth below) shall be entitled to assume the defense thereof by promptly (but no less than thirty (30) days after receipt of the Indemnity Notice) notifying the Indemnitee in writing acknowledging its desire to defend such Third Party Claim (the "Indemnification Notice"). Upon providing the Indemnification Notice to the Indemnitee, the Indemnitor shall have the right, at the Indemnitor's expense and with counsel of its choosing, to conduct and control the defense and the disposition or, subject to Section 9.3.2.3, settlement of the Third Party Claim (including all decisions relative to litigation, appeal, and settlement), provided that:

9.3.2.1 the Indemnitee shall be entitled to participate in the defense of such Third Party Claim and to employ counsel of its choice for such purpose; provided that the fees and expenses of such separate counsel shall be borne by the Indemnitee (other than any reasonable fees and expenses of such separate counsel that are incurred prior to the date the Indemnitee receives the Indemnification Notice from the which, notwithstanding the foregoing, shall be borne by the Indemnitor, and except that the Indemnitor shall pay all of the fees and expenses of such separate counsel if the Indemnitee has been advised by counsel that a reasonable likelihood exists of a conflict of interest between the Indemnitor and the Indemnitee);

9.3.2.2 the Indemnitor shall not be entitled to assume control of such defense (unless otherwise agreed to in writing by the Indemnitee) and shall pay the reasonable fees and expenses of counsel retained by the Indemnitee if (i) the claim for indemnification relates to or arises in connection with any criminal or quasi-criminal proceeding, action, indictment, allegation or investigation; (ii) the Third Party Claim seeks an injunction or equitable relief against the Indemnitee; (iii) the Indemnitee has been advised by counsel that a reasonable likelihood exists of a conflict of interest between the Indemnitor and the Indemnitee; or (iv) upon petition by the Indemnitee, the appropriate court rules that the Indemnitor failed or is failing to vigorously prosecute or defend such Third Party Claim; and

9.3.2.3 the Party controlling the defense of the Third Party Claim shall obtain the prior written consent of the other Party before entering into any settlement of such Third Party Claim or ceasing to defend such Third Party Claim if, pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against such other Party or if such settlement does not expressly and unconditionally release such other Party from all liabilities and obligations with respect to such Third Party Claim, without prejudice.

9.3.3 Defense of Third Party IP Claims. If (i) either Party desires to initiate a declaratory judgment or similar action with respect to any Third Party Patent rights relating to the Development, Manufacture, use, or Commercialization of the Licensed Product, or (ii) a Claim (including any counterclaim to any declaratory judgment action) is brought by a Third Party giving rise to any Company Indemnified Party's right of indemnification under Section 9.2(iii) (in each case, an "IP Claim"), Licensee shall control the prosecution or defense, as applicable, of such IP Claim at Licensee's expense by appointing counsel of Licensee's choosing in connection with such IP Claim. Prior to Licensee assuming control of such prosecution or defense, Licensee shall verify to Company in writing that Licensee shall be fully responsible (with no reservation of any rights) for all liabilities and obligations relating to such IP Claim and that Licensee shall provide indemnification to the Company Indemnified Party(ies) with respect to such IP Claim, in each case in accordance with this Article 9 and Licensee shall obtain the prior written consent of Company before entering into any settlement of such IP Claim or ceasing to prosecute or defend such IP Claim if, pursuant to or as a result of such settlement or cessation, injunctive or other equitable relief will be imposed against Company or any other Company Indemnified Party or if such settlement does not expressly and unconditionally release the Company Indemnified Party(ies) from all liabilities and obligations with respect to such IP Claim, without prejudice.

10 ARTICLE 10 - LIMITATION OF LIABILITY

10.1 Limitation of Liability**.** EXCEPT WITH RESPECT TO PAYMENTS OWED OR THE INDEMNIFICATION OBLIGATIONS OF EACH PARTY SET FORTH IN ARTICLE 9, NEITHER PARTY NOR ITS AFFILIATES SHALL BE LIABLE FOR PUNITIVE, EXEMPLARY, CONSEQUENTIAL, OR SPECIAL DAMAGES, OR LOST PROFITS, LOST REVENUE, OR LOST SAVINGS, CONNECTED WITH, OR ARISING OR RESULTING FROM, ANY PERFORMANCE OR LACK OF PERFORMANCE UNDER THIS AGREEMENT OR ANY ANCILLARY AGREEMENT, EVEN IF SUCH DAMAGES WERE FORESEEABLE OR THE PARTY SOUGHT TO BE HELD LIABLE WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES, AND IN EACH CASE REGARDLESS OF WHETHER A CLAIM IS BASED ON CONTRACT, WARRANTY, TORT (INCLUDING NEGLIGENCE OR STRICT LIABILITY), OR ANY OTHER LEGAL OR EQUITABLE PRINCIPLE. NEITHER PARTY SHALL ALLEGE THAT ANY REMEDY OR ANY PROVISION OF THIS AGREEMENT OR ANY ANCILLARY AGREEMENT FAILS OF ITS ESSENTIAL PURPOSE.

10.2 Duty to Mitigate. EACH PARTY SHALL USE COMMERCIALLY REASONABLE EFFORTS TO MITIGATE LIABILITY, DAMAGES, AND OTHER LOSSES SUFFERED IN CONNECTION WITH, OR ARISING OR RESULTING FROM, ANY PERFORMANCE OR LACK OF PERFORMANCE UNDER THIS AGREEMENT.

11 ARTICLE 11 - DISPUTE RESOLUTION

Any Dispute shall be resolved as provided in this Article 11 and, to the extent applicable, Article 12.

11.1 Informal Dispute Resolution. The Parties shall attempt in good faith to resolve any Dispute in the first instance utilizing the dispute resolution procedures set forth in this Section 11.1. In the event of any Dispute, each Party may initiate the dispute resolution procedures set forth in this Section 11.1 by providing written notice of the Dispute to the other Party. The Parties shall first attempt to resolve any such Dispute in good faith by escalating the Dispute to an authorized representative of each Party. The authorized representatives of each Party shall work in good faith to develop a plan to resolve the Dispute. If such matters are not resolved within twenty (20) days ("Resolution Period") through such discussions, either Party may elect to seek resolution of the Dispute as provided in Section 11.2 hereof upon failure to timely agree upon a resolution.

11.2 Arbitration. If, in accordance with Section 11.1, the Parties have not reached a mutually acceptable resolution to the applicable Dispute following the informal dispute resolution process set forth in Section 11.1, either Party may submit such Dispute to final and binding arbitration in accordance with the Arbitration Rules of American Arbitration Association (" AAA") before a single arbitrator for the time being in force, which rules are deemed to be incorporated by reference in this clause. The arbitration shall be conducted, in English and the arbitration venue shall be in a location agreed to by the Parties and failing agreement within 10 business days of submitting such Dispute to final and binding arbitration, in Buffalo, NY. The arbitrator(s) shall not have the authority or power to act as an amicable compositeur or to fashion any relief or remedy that would have the effect of modifying or amending the terms of this Agreement or creating additional rights or obligations of a party. The decision of the arbitration tribunal shall be final and binding upon the parties and may be enforced in any court of competent jurisdiction, and no party shall seek redress against the other in any court or tribunal except solely for the purpose of obtaining execution of the arbitral award or of obtaining a judgment consistent with the award. Any monetary award made in arbitration shall be made and payable in U.S. Dollars. Subject to Section 11.1 and this Section 11.2, either Party may initiate litigation as outlined in Section 11.3 or seek equitable relief as outlined in Section 12.14.

11.3 Formal Proceedings; Equitable Relief. Notwithstanding anything to the contrary in this Article 11, each Party may institute formal court proceedings at any time in order to avoid the expiration of any applicable limitations period, to preserve a position with respect to creditors, or to seek equitable relief in accordance with Section 12.14.

12 ARTICLE 12 – MISCELLANEOUS

12.1 Assignment. This Agreement shall be binding on the Parties and their respective successors and permitted assigns. Except as expressly set forth in this Agreement, neither Party may assign this Agreement (including by operation of law, change of control, merger, or sale of assets) without the prior written consent of the other Party; provided, however, that: (i) either Party may, without such consent (a) collaterally assign, transfer or pledge its rights under this Agreement, in whole or in part, to any person for financing purposes, or (b) assign, delegate or otherwise transfer, in whole or in part, this Agreement or its rights or obligation hereunder, to an Affiliate, provided that such Party shall remain responsible and liable for the performance by such Affiliate of its obligations hereunder; and (ii) either Party may, without such consent, assign or otherwise transfer this Agreement in whole or in part, and its rights and obligations hereunder to any Third Party in connection with the transfer or sale of all or substantially all of its business, or in the event of its merger, consolidation, change in control or similar transaction, to or with such Third Party.

12.2 Complete Agreement. This Agreement and the Ancillary Agreements contain the complete agreement among the Parties and supersede any prior understandings, agreements or representations by or between the Parties, written or oral, which may have related to the subject matter hereof in any way. The Schedules and Exhibits to this Agreement shall be deemed incorporated into this Agreement by reference and shall form a part of this Agreement. The various parts of this Agreement and the Ancillary Agreements are intended to be complementary; however, unless explicitly stated otherwise in any Ancillary Agreement, any inconsistency, ambiguity, or conflict between this Agreement, its Attachments, Exhibits, and Schedules, any Ancillary Agreements and any Attachments, Exhibits, and Schedules thereto shall be resolved in the following order of precedence (with (i) having the highest priority): (i) the main body of this Agreement; (ii) Attachments, Exhibits, and Schedules to this Agreement; (iii) Ancillary Agreements; and (iv) Attachments, Exhibits, and Schedules to any Ancillary Agreement.

12.3 Amendment/Waiver. Except as expressly set forth in this Agreement, this Agreement (including any Attachments, Exhibits and Schedules) may be amended only in a writing executed by Licensee and Company. Except as expressly set forth in this Agreement, no provision of this Agreement may be waived except in a writing executed and delivered by the Party against whom such waiver is sought to be enforced. No course of dealing between or among any Persons having any interest in this Agreement shall be deemed effective to modify, amend, waive, or discharge any part of this Agreement or any rights or obligations of any Person under or by reason of this Agreement.

12.4 Consents and Approvals. Whenever any term of this Agreement requires any agreement, consent, permission, or approval of a Party, such Party will act reasonably and in good faith and will not unreasonably withhold, delay, or condition such agreement, consent, permission, or approval, unless this Agreement expressly establishes some other standard with respect thereto, such as exercise of a Party's sole discretion or the right to withhold any of the foregoing for any reason or no reason.

12.5 Governing Law. The internal law (and not the law of conflicts) of the State of New York, United States, shall govern all questions concerning the construction, validity and interpretation of this Agreement and the performance of the obligations imposed by this Agreement.

12.6 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable Law, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provisions or the remaining provisions of this Agreement.

12.7 Notices. All notices, demands and other communications to be given or delivered under or by reason of the provisions of this Agreement shall be in writing and shall be deemed to have been given (i) if personally delivered, on the date of delivery, (ii) if delivered by overnight courier service of national standing for next day delivery (with charges prepaid), on the business day following the date of delivery to such courier service, (iii) if deposited in the United States mail, first-class postage prepaid, on the fifth (5^{th}) business day following the date of such deposit, or (iv) if delivered by telecopy, provided the relevant transmission report indicates a full and successful transmission, (a) on the date of such transmission, if such transmission is completed at or prior to 5:00 p.m., local time of the recipient party, on the date of such transmission, and (b) on the next business day following the date of transmission, if such transmission is completed after 5:00 p.m., local time of the recipient party, on the date of such transmission. Notices, demands and communications to Company and Licensee shall, unless another address is specified in writing pursuant to the provisions of this Agreement, be sent to the following address:

Notices to Company:

Enveric Biosciences, Inc.
4851 Tamiami Trail N, Suite 200
Naples, FL 34103
Attention: Joseph Tucker

Phone: (508) 627-0485

Email: jtucker@enveric.com

with a copy to (which shall not constitute notice to Company):

Dickinson Wright PLLC
1850 N. Central Ave.
Attention: Bradley Wyatt
Phone: (734) 780-6517

Email: bwyatt@dickinsonwright.com

Notices to Licensee:

Aries Science and Technology LLC
8014 Lazelle Woods Dr.
Westerville, Ohio 43081

Attention: Ramanathan Lalgudi
Phone: (614) 592-1778
Email: lalgudir@ariesst.com

with a copy to (which shall not constitute notice to Licensee):

[NAME]
[ADDRESS]

Phone: [insert phone number]
Email: [ ]

Either Party may change its address(es) set forth in this Section 12.7 at any time by giving prior written notice to the other Party of such change as provided above.

12.8 Force Majeure. Neither Party shall be held liable or responsible to the other Party or be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement (other than an obligation to make any payment) to the extent such failure or delay directly results from events beyond the reasonable control of the non-performing Party, including fires, floods, earthquakes, or other similar natural disasters or acts of God, epidemics, quarantines, war, acts of war (whether war be declared or not), terrorist acts, insurrections, riots, or civil commotion (each, a "Force Majeure Event"). The non-performing Party shall notify the other Party of a Force Majeure Event promptly (but in any event within five (5) days) after the occurrence of such Force Majeure Event by giving written notice to the other Party stating the nature of such Force Majeure Event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance shall be of no greater scope and no longer duration than is necessary and the non-performing Party shall use Commercially Reasonable Efforts to promptly remedy its inability to perform and recommence performance.

12.9 Third Party Beneficiaries. Except as expressly stated in this Agreement or any Ancillary Agreement with respect to each Party's Affiliates and the indemnitees described in Article 9, the terms and provisions of this Agreement or any Ancillary Agreement are intended solely for the benefit of each Party and its respective successors or permitted assigns, and it is not the intention of the Parties to confer third-party beneficiary rights upon any other Person, including employees.

12.10 Relationship of the Parties**.** In no event shall this Agreement or any Ancillary Agreement be deemed to create: (i) a partnership, joint venture, or other joint business arrangement between Licensee or any of its Affiliates, on the one hand, and Company, on the other hand; (ii) any fiduciary duty owed by a Party or any of its Affiliates to the other Party or any of its Affiliates; (iii) a relationship of employer and employee between a Party or any of its Affiliates and the other Party or any of its Affiliates; or (iv) any basis for any employee of a Party to claim that he or she is an employee of the other Party.

12.11 Payments. All monetary amounts set forth in this Agreement or any Ancillary Agreement are in U.S. Dollars, and all payments to be made under this Agreement or any Ancillary Agreement shall be made by wire transfer of immediately available funds into an account designated by the receiving Party or otherwise pursuant to reasonable instructions set forth in the applicable invoice delivered by the receiving Party. Unless stated otherwise, all payments shall be due and payable within thirty (30) days of: (i) the applicable payment period, or (ii) receipt of an applicable invoice. All late payments under this Agreement or any Ancillary Agreement shall bear interest from the date due until paid at a rate equal to the lesser of (i) one-half percent (0.5%) per month, and (ii) the maximum amount permitted by applicable Law. The payment of such interest shall not limit the receiving Party from exercising any other right it may have as a consequence of the lateness of any payment.

12.12 Construction. Each of Licensee and Company confirm that it and its respective counsel have reviewed, negotiated, and adopted this Agreement as the joint agreement and understanding of the Parties and the language used in this Agreement shall be deemed to be the language chosen by the Parties to express their mutual intent, and no rule of strict construction shall be applied against any Person. The captions used in this Agreement are for convenience of reference only and do not constitute a part of this Agreement and shall not be deemed to limit, characterize, or in any way affect any provision of this Agreement, and all provisions of this Agreement shall be enforced and construed as if no such caption had been used in this Agreement. Except where the context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or) (for clarity, the use of the word either shall not mean "and/or"). The terms "include," "includes," and "including" as used herein are not limiting and shall be deemed to be followed (whether or not so followed) by "without limitation" so as not to limit the generality of any description preceding such term.

12.13 Further Assurances. Each Party agrees that from time-to-time, at the request of the other Party and without further consideration, it shall execute and deliver such other documents and take such other actions as the other Party may reasonably request to effectuate the transactions contemplated by this Agreement.

12.14 Specific Performance. The Parties agree that if any of the provisions of this Agreement are not performed in accordance with their specific terms or are otherwise breached, irreparable damage may occur, no adequate remedy at law may exist and damages would be difficult to determine, and that each Party shall be entitled to seek an injunction and/or specific performance of the terms of this Agreement, without the need to prove irreparable damage or otherwise post a bond or other security.

12.15 Counterparts. This Agreement may be executed in one or more counterparts with the same effect as if both Parties had signed the same document, each of which shall be deemed an original, shall be construed together and shall constitute one and the same instrument. This Agreement and any signed agreement or instrument entered into in connection with this Agreement, and any amendments hereto or thereto, to the extent delivered by means of a telecopy machine or electronic mail (any such delivery, an "Electronic Delivery") shall be treated in all manner and respects as an original agreement or instrument and shall be considered to have the same binding legal effect as if it were the original signed version thereof delivered in person. At the request of any Party hereto or to any such agreement or instrument, each other Party hereto or thereto shall re-execute original forms thereof and deliver them to all other Parties. No Party hereto or to any such agreement or instrument shall raise (i) the use of Electronic Delivery to deliver a signature or (ii) the fact that any signature or agreement or instrument was transmitted or communicated through the use of Electronic Delivery, as a defense to the formation of a contract, and each such Party forever waives any such defense, except to the extent such defense relates to lack of authenticity.

IN WITNESS WHEREOF, the Parties (in the case of Company and Licensee, through their duly authorized representatives) have executed this Agreement in multiple counterparts, to be effective as of the Effective Date.

AKOS BIOSCIENCES, INC.

DocuSigned by:
By: Joseph Tucker
248C860F46CF446...
Name: Joseph Tucker
Title: Chief Executive Officer
Date: 7/10/2024

ARIES SCIENCE AND TECHNOLOGY, LLC

DocuSigned by:
By: Ramanathan Lalgudi
B5C8D29E5F4A45F...
Name: Ramanathan Lalgudi
Title: Chief Executive Officer
Date: 7/10/2024

SCHEDULE A

LICENSED SUBJECT MATTER

[***]

SCHEDULE B

LICENSED PRODUCTS

[***]

EXHIBIT 31.1

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13A-14(A)/15D-14(A) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Dr. Joseph Tucker, Chief Executive Officer of Enveric Biosciences, Inc., certify that:

1. I have reviewed this report on Form 10-Q of Enveric Biosciences, Inc. (the "registrant");

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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2024

/s/ Dr. Joseph Tucker
Joseph Tucker, Ph.D.
Chief Executive Officer (Principal Executive Officer)

EXHIBIT 31.2

CERTIFICATION PURSUANT TO EXCHANGE ACT RULE 13A-14(A)/15D-14(A) AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Kevin Coveney, Chief Financial Officer of Enveric Biosciences, Inc., certify that:

1. I have reviewed this report on Form 10-Q of Enveric Biosciences, Inc. (the "registrant");

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 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 and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2024

/s/ Kevin Coveney
Kevin Coveney
Chief Financial Officer (Principal Financial and Accounting Officer)

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Enveric Biosciences, Inc. (the "Issuer") on Form 10-Q for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the "Form 10-Q"), each of the undersigned, in the capacities and on the dates indicated below, hereby certifies pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(i) the Form 10-Q fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(ii) the information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Issuer.

Dated: November 14, 2024

By: */s/ Dr. Joseph Tucker*
Joseph Tucker, Ph.D.
Chief Executive Officer
(Principal Executive Officer)

By: */s/ Kevin Coveney*
Kevin Coveney
Chief Financial Officer
(Principal Financial and Accounting Officer)