

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: 001-40804

**PASITHEA THERAPEUTICS CORP.**  
(Exact name of Registrant as specified in its charter)

<u>Delaware</u> (State or other jurisdiction of incorporation or organization)	<u>85-1591963</u> (I.R.S. Employer Identification No.)
<u>1111 Lincoln Road, Suite 500</u> <u>Miami Beach, Florida</u> (Address of principal executive offices)	<u>33139</u> (Zip Code)

Registrant's telephone number, including area code: (702) 514-4174

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

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
Common Stock, par value \$0.0001 per share	KTTA	The Nasdaq Capital Market
Warrants, to purchase shares of Common Stock, par value \$0.0001 per share	KTTAW	The Nasdaq Capital Market

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 and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).  Yes  No

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

Large Accelerated Filer	<input type="checkbox"/>	Accelerated Filer	<input type="checkbox"/>
Non-Accelerated Filer	<input checked="" type="checkbox"/>	Smaller Reporting Company	<input checked="" type="checkbox"/>
		Emerging Growth Company	<input checked="" type="checkbox"/>

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

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

As of November 11, 2024, there were 1,266,427 shares of the registrant's common stock outstanding.

**PASITHEA THERAPEUTICS CORP.**  
**FORM 10-Q**  
**For the Quarter ended September 30, 2024**

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

PASITHEA THERAPEUTICS CORP.  
CONDENSED CONSOLIDATED BALANCE SHEETS

	September 30, 2024	December 31, 2023
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 9,361,169	\$ 16,331,052
Amount due from sale of assets	-	40,500
Prepaid expenses	319,270	215,895
Other current assets	98,333	104,707
Total current assets	<u>9,778,772</u>	<u>16,692,154</u>
Property and equipment, net	127,060	141,208
Right of use asset- operating lease	-	79,271
Intangibles, net	7,468,691	7,941,314
Goodwill	1,262,911	1,262,911
Total assets	<u>\$ 18,637,434</u>	<u>\$ 26,116,858</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 660,397	\$ 2,552,360
Lease liability- short term portion	-	81,680
Total current liabilities	<u>660,397</u>	<u>2,634,040</u>
Non-current liabilities		
Warrant liabilities	163,578	84,366
Total non-current liabilities	<u>163,578</u>	<u>84,366</u>
Total liabilities	<u>823,975</u>	<u>2,718,406</u>
Stockholders' equity:		
Preferred stock, par value \$0.0001, 5,000,000 shares authorized; 0 issued and outstanding	-	-
Common stock, par value \$0.0001, 100,000,000 shares authorized; 1,044,914 and 1,041,582 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	104	104
Additional paid-in capital	64,253,789	58,721,538
Accumulated other comprehensive loss	(35,317)	(4,652)
Accumulated deficit	(46,405,117)	(35,318,538)
Total stockholders' equity	<u>17,813,459</u>	<u>23,398,452</u>
Total liabilities and stockholders' equity	<u>\$ 18,637,434</u>	<u>\$ 26,116,858</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

**PASITHEA THERAPEUTICS CORP.**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**  
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
General and administrative	\$ 1,423,228	\$ 2,164,560	\$ 5,301,934	\$ 6,081,362
Research and development	1,581,376	1,624,766	5,688,478	4,749,217
Loss from operations	<u>(3,004,604)</u>	<u>(3,789,326)</u>	<u>(10,990,412)</u>	<u>(10,830,579)</u>
Other income (expense):				
Change in fair value of warrant liabilities	(70,306)	44,996	(79,212)	111,552
Interest and dividends, net	75,076	131,740	342,701	242,543
Other income, net	4,770	176,736	263,489	354,095
Loss before income taxes	(2,999,834)	(3,612,590)	(10,726,923)	(10,476,484)
Provision for income taxes	-	-	-	-
Net loss from continuing operations	<u>\$ (2,999,834)</u>	<u>\$ (3,612,590)</u>	<u>\$ (10,726,923)</u>	<u>\$ (10,476,484)</u>
Net loss from discontinued operations, net of tax	-	-	-	(437,015)
Net loss	<u>\$ (2,999,834)</u>	<u>\$ (3,612,590)</u>	<u>\$ (10,726,923)</u>	<u>\$ (10,913,499)</u>
Weighted-average common shares outstanding, basic and diluted	1,044,144	1,258,050	1,043,315	1,289,201
Basic and diluted loss per share from continuing operations	<u>\$ (2.87)</u>	<u>\$ (2.87)</u>	<u>\$ (10.28)</u>	<u>\$ (8.13)</u>
Basic and diluted loss per share from discontinuing operations	\$ -	\$ -	\$ -	\$ (0.34)
Comprehensive loss:				
Net loss	\$ (2,999,834)	\$ (3,612,590)	\$ (10,726,923)	\$ (10,913,499)
Foreign currency translation	(27,133)	(4,256)	(30,665)	(7,056)
Comprehensive loss	<u>\$ (3,026,967)</u>	<u>\$ (3,616,846)</u>	<u>\$ (10,757,588)</u>	<u>\$ (10,920,555)</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

**PASITHEA THERAPEUTICS CORP.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY**  
(Unaudited)

	<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Other Comprehensive Loss</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>				
<b>Balance at January 1, 2024</b>	1,041,582	\$ 104	\$ 58,721,538	\$ (4,652)	\$ (35,318,538)	\$ 23,398,452
Stock-based compensation:						
-restricted stock units	1,666	-	48,088	-	-	48,088
-stock options	-	-	297,602	-	-	297,602
-warrants	-	-	787	-	-	787
Foreign currency translation	-	-	-	(620)	-	(620)
Net loss	-	-	-	-	(3,860,840)	(3,860,840)
<b>Balance at March 31, 2024</b>	<u>1,043,248</u>	<u>\$ 104</u>	<u>\$ 59,068,015</u>	<u>\$ (5,272)</u>	<u>\$ (39,179,378)</u>	<u>\$ 19,883,469</u>
Stock-based compensation:						
-restricted stock units	833	-	23,912	-	-	23,912
-stock options	-	-	134,680	-	-	134,680
-warrants	-	-	2,360	-	-	2,360
Foreign currency translation	-	-	-	(2,912)	-	(2,912)
Net loss	-	-	-	-	(3,866,249)	(3,866,249)
<b>Balance at June 30, 2024</b>	<u>1,044,081</u>	<u>\$ 104</u>	<u>\$ 59,228,967</u>	<u>\$ (8,184)</u>	<u>\$ (43,045,627)</u>	<u>\$ 16,175,260</u>
Stock-based compensation:						
-restricted stock units	833	-	24,175	-	-	24,175
-stock options	-	-	121,346	-	-	121,346
-warrants	-	-	2,360	-	-	2,360
Foreign currency translation	-	-	-	(27,133)	-	(27,133)
Issuance of September 2024 pre-funded and common warrants, net	-	-	4,517,285	-	-	4,517,285
Dividend - warrant modification	-	-	359,656	-	(359,656)	-
Net loss	-	-	-	-	(2,999,834)	(2,999,834)
<b>Balance at September 30, 2024</b>	<u>1,044,914</u>	<u>\$ 104</u>	<u>\$ 64,253,789</u>	<u>\$ (35,317)</u>	<u>\$ (46,405,117)</u>	<u>\$ 17,813,459</u>
<b>Balance at January 1, 2023</b>	1,301,921	\$ 130	\$ 61,855,659	\$ (661)	\$ (19,356,880)	\$ 42,498,248
Stock-based compensation:						
-restricted stock units	4,166	1	23,649	-	-	23,650
-stock options	-	-	153,372	-	-	153,372
Foreign currency translation	-	-	-	(2,483)	-	(2,483)
Net loss	-	-	-	-	(3,537,679)	(3,537,679)
<b>Balance at March 31, 2023</b>	<u>1,306,087</u>	<u>\$ 131</u>	<u>\$ 62,032,680</u>	<u>\$ (3,144)</u>	<u>\$ (22,894,559)</u>	<u>\$ 39,135,108</u>
Stock-based compensation:						
-restricted stock units	833	1	23,910	-	-	23,911
-stock options	-	-	194,722	-	-	194,722
Foreign currency translation	-	-	-	(317)	-	(317)
Net loss	-	-	-	-	(3,763,230)	(3,763,230)
<b>Balance at June 30, 2023</b>	<u>1,306,920</u>	<u>\$ 132</u>	<u>\$ 62,251,312</u>	<u>\$ (3,461)</u>	<u>\$ (26,657,789)</u>	<u>\$ 35,590,194</u>
Stock-based compensation:						
-restricted stock units	833	(1)	24,176	-	-	24,175
-stock options	-	-	102,499	-	-	102,499
Stock repurchase	(266,171)	(27)	(3,726,389)	-	-	(3,726,416)
Foreign currency translation	-	-	-	(4,256)	-	(4,256)
Net loss	-	-	-	-	(3,612,590)	(3,612,590)
<b>Balance at September 30, 2023</b>	<u>1,041,582</u>	<u>\$ 104</u>	<u>\$ 58,651,598</u>	<u>\$ (7,717)</u>	<u>\$ (30,270,379)</u>	<u>\$ 28,373,606</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

**PASITHEA THERAPEUTICS CORP.**  
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Unaudited)

**For the Nine Months Ended  
September 30,**

	<u>2024</u>	<u>2023</u>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss from continuing operations	\$ (10,726,923)	\$ (10,476,484)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	14,148	13,610
Amortization expense	472,623	472,623
Stock-based compensation	655,310	522,329
Change in fair value of warrant liabilities	79,212	(111,552)
Non-cash lease expense	-	2,880
Gain on sale of assets	-	(65,048)
Changes in operating assets and liabilities:		
Prepaid expenses	(103,375)	(422,692)
Other assets	46,874	156,481
Accounts payable and accrued liabilities	(1,915,862)	388,064
Lease liabilities	(2,409)	-
Net cash used in operating activities	<u>(11,480,402)</u>	<u>(9,519,789)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Purchase of property and equipment	-	(34,337)
Net cash proceeds from sale of assets	-	55,000
Net cash provided by investing activities	<u>-</u>	<u>20,663</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from sale of September 2024 Offering warrants	4,998,784	-
Payment of offering costs in connection with September 2024 Offering warrants	(457,600)	-
Note payable proceeds	-	392,354
Principal payments on note payable	-	(392,354)
Repurchase of common stock	-	(3,726,416)
Net cash provided by (used in) financing activities	<u>4,541,184</u>	<u>(3,726,416)</u>
Effect of foreign currency translation on cash	<u>(30,665)</u>	<u>(7,056)</u>
Net cash used in operating activities of discontinued operations	-	(594,383)
Net cash provided by investing activities of discontinued operations	-	323,807
<b>NET CHANGE IN CASH</b>	<b>\$ (6,969,883)</b>	<b>\$ (13,503,174)</b>
Cash - Beginning of period	<u>16,331,052</u>	<u>33,087,864</u>
Cash - End of period	<u>\$ 9,361,169</u>	<u>\$ 19,584,690</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for interest	<u>\$ -</u>	<u>\$ -</u>
Cash paid for taxes	<u>\$ -</u>	<u>\$ -</u>
<b>Supplemental disclosures of non-cash activity:</b>		
Amount due from sale of assets	<u>\$ -</u>	<u>\$ 95,000</u>
Dividend - warrant modification	<u>\$ (359,656)</u>	<u>\$ -</u>

See accompanying notes to the unaudited condensed consolidated financial statements.

**PASITHEA THERAPEUTICS CORP.**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**FOR THE THREE AND NINE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023**

**NOTE 1 – NATURE OF THE ORGANIZATION AND BUSINESS**

Pasithea Therapeutics Corp. (“Pasithea” or the “Company”) was incorporated in the State of Delaware on May 12, 2020 and completed an Initial Public Offering (the “Initial Public Offering”) on September 17, 2021. The Company is a biotechnology company focused on the discovery, research and development of innovative treatments for central nervous system (CNS) disorders and other diseases, including RASopathies. The Company is leveraging its expertise in the fields of neuroscience, translational medicine, and drug development to bring life-changing therapies to patients.

The Company’s primary operations (the “Therapeutics” segment) are focused on developing the Company’s lead product candidate, PAS-004, a next-generation macrocyclic mitogen-activated protein kinase, or MEK inhibitor that the Company believes may address the limitations and liabilities associated with existing drugs targeting a similar mechanism of action. In December 2023, the U.S. Food and Drug Administration (the “FDA”) cleared our Investigational New Drug application (the “IND”) for PAS-004 and the Company received a study may proceed letter from the FDA for the Company’s Phase 1 multicenter, open-label, dose escalation trial of PAS-004 in patients with MAPK pathway-driven advanced tumors with a documented RAS, NF1 or RAF mutation or patients who have failed BRAF/MEK inhibition. The Company is currently conducting the Phase 1 clinical trial at clinical sites in the United States and plans to open additional sites in Eastern Europe in the fourth quarter of 2024. The Company’s clinical development plan for PAS-004 is to begin a Phase 1/2a clinical trial in adult patients with neurofibromatosis type 1 (NF1)-associated plexiform and/or cutaneous neurofibromas followed by pediatric patients and ultimately seek FDA marketing approval in these patient populations.

Additionally, the Company has two programs that are in the discovery stage, which the Company believes address limitations in the treatment paradigm of the indications the Company plans to address with these programs, which are currently amyotrophic lateral sclerosis (“ALS”) for PAS-003 and schizophrenia for PAS-001. During the year ended December 31, 2023, we determined to cease further development of our PAS-002 program for multiple sclerosis due to several factors including the significant capital, resources and time required to develop the program, and the current and projected availability of effective treatment options for MS patients, among others.

During the year ended December 31, 2023, the Company discontinued providing business support services to anti-depression clinics (the “Clinics” segment) in the U.K. and in the United States, previously conducted through partnerships with healthcare providers. During the year ended December 31, 2023, the at home services in New York, NY as well as in the U.K were discontinued and the Company sold and disposed of the assets associated with the Clinics operations in Los Angeles, CA. The lease associated with the related property in Los Angeles was assumed by the buyer in the transaction.

Throughout this report, the terms “our,” “we,” “us,” and the “Company” refer to Pasithea Therapeutics Corp. and its subsidiaries, Pasithea Therapeutics Limited (U.K.), Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda, Pasithea Clinics Inc., Alpha-5 Integrin, LLC (“Alpha-5”), and AlloMek Therapeutics, LLC (“AlloMek”). Pasithea Therapeutics Limited (U.K.), legally dissolved as of January 2, 2024 was a private limited Company, registered in the United Kingdom (U.K.). Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda is a private limited Company registered in Portugal. Pasithea Clinics Inc. is incorporated in Delaware. Alpha-5 and AlloMek are both Delaware limited liability companies. The operations of Pasithea Therapeutics Limited (U.K.), Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda, and Pasithea Clinics Inc. have been discontinued.

*Basis of Presentation*

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”).

### *Emerging Growth Company*

The Company is an “emerging growth company,” as defined in Section 2(a) of the Securities Act, as modified by the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”), and it may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, reduced disclosure obligations regarding executive compensation in its periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and approval of any golden parachute payments not previously approved. Further, Section 102(b)(1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non-emerging growth companies but any such election to opt out is irrevocable. The Company has elected not to opt out of such extended transition period.

### *Liquidity and Capital Resources*

As of September 30, 2024, the Company had approximately \$9.4 million of cash and cash equivalents and working capital of approximately \$9.1 million. The Company’s major sources of cash have been comprised of proceeds from various private offerings, the Initial Public Offering and the exercise of warrants. The Company is dependent on obtaining additional working capital funding from the sale of equity and/or debt securities in order to continue to execute its development plans and continue operations. Based on the foregoing, management believes that the Company will not have sufficient working capital to meet its needs through twelve months from the date of these financial statements if additional funding cannot be obtained.

### *Going Concern Uncertainty*

The accompanying unaudited condensed consolidated financial statements have been prepared as if the Company will continue as a going concern. The Company has incurred significant operating losses and negative cash flows from operations since inception. On September 30, 2024, the Company had cash and cash equivalents of approximately \$9.4 million and an accumulated deficit of approximately \$46.4 million. The Company has incurred recurring losses, has experienced recurring negative operating cash flows, and requires significant cash resources to execute its business plans. Historically, the Company’s major sources of cash have been comprised of proceeds from various public and private offerings of its capital stock. The Company is dependent on obtaining additional working capital funding from the sale of equity and/or debt securities in order to continue to execute its development plans and continue operations. Without additional funding, there is substantial doubt about the Company’s ability to continue as a going concern through twelve months from the date of these financial statements.

## **NOTE 2 – SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

### *Principles of Consolidation*

The Company evaluates the need to consolidate affiliates based on standards set forth in Accounting Standards Codification (“ASC”) 810, “Consolidation,” (“ASC 810”). The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries, Alpha-5, AlloMek, Pasithea Therapeutics Limited (U.K.) (was legally dissolved as of January 2, 2024) and Pasithea Clinics Inc. All significant intercompany transactions and balances have been eliminated in consolidation.

These condensed consolidated financial statements are presented in U.S. Dollars.

### *Use of Estimates*

The preparation of financial statements in conformity with U.S. GAAP requires the Company’s management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statement and the reported amounts of revenues and expenses during the reporting period.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statements, which management considered in formulating its estimate, could change in the near term due to one or more future confirming events. Management regularly makes estimates related to the fair value of warrant liabilities; the recoverability of long-lived assets; the fair values and useful lives of intangible assets acquired in business combinations; the potential impairment of goodwill; and income taxes. The Company bases its estimates on historical experience and on various assumptions that are believed to be reasonable, the results of which form the basis for the amounts recorded in the consolidated financial statements. As appropriate, the Company obtains reports from third-party valuation experts to inform and support estimates related to fair value measurements.

### *Research and Development*

Research and development costs are charged to operations when incurred and are included in operating expense, except for goodwill related to intellectual property and patents. Our research and development costs consist principally of compensation of employees and consultants that perform the Company's research and development activities, payments to third parties for preclinical, clinical and regulatory activities, costs to acquire drug supply and drug product from contract development and manufacturing organizations and third-party contractors relating to chemistry, manufacturing and controls ("CMC") efforts, and research and development costs related to our discovery programs. Depending upon the timing of payments to the service providers, the Company recognizes prepaid expenses or accrued expenses related to these costs. These accrued or prepaid expenses are based on management's estimates of the work performed under service agreements, milestones achieved and experience with similar contracts. The Company monitors each of these factors and adjusts estimates accordingly.

### *General and Administrative*

Our general and administrative expenses primarily consist of personnel and related costs, including stock-based compensation, legal fees relating to both intellectual property and corporate matters, accounting and audit related costs, insurance, corporate communications and public company expenses, information technology, office and facility rents and related expenses, including depreciation, amortization and maintenance, and fees for consulting, business development and other professional services.

### *Grants*

In connection with the acquisition of Alpha-5, the Company legally assumed rights under a grant agreement with FightMND, which was entered into by Alpha-5 on September 23, 2021. FightMND supports pre-clinical research, development and assessment of therapeutics for motor neuron disease, including ALS. Under the grant agreement, the Company is entitled to reimbursements for costs incurred for research related to its monoclonal antibody targeting a5b1 integrin as a potential treatment for ALS. There was no grant income recognized for the nine months ended September 30, 2024 and 2023.

### *Cash and Cash Equivalents*

The Company considers all short-term investments with an original maturity of three months or less when purchased to be cash equivalents, classified as trading securities. The Company had cash equivalents of \$4.5 million and \$13.4 million as of September 30, 2024 and December 31, 2023, respectively.

### *Property and Equipment, net*

Property and equipment is recorded at cost, net of depreciation. Depreciation is computed using straight-line and accelerated methods over the estimated useful lives of the related assets which range from three to ten years. Expenditures that enhance the useful lives of the assets are capitalized and depreciated. Maintenance and repairs are expensed as incurred. When properties are retired or otherwise disposed of, related costs and related accumulated depreciation are removed from the accounts. Leasehold improvements are amortized over the shorter of the estimated useful life of those leasehold improvements and the remaining lease term.

### *Warrant Liability*

The Company accounts for the publicly traded warrants issued in its Initial Public Offering (the "Public Warrants") and the warrants issued as compensation to the underwriters in its Initial Public Offering (the "Representative Warrants" and together with the Public Warrants, the "IPO Warrants") in accordance with the guidance contained in ASC 815, "Derivatives and Hedging," under which the IPO Warrants do not meet the criteria for equity treatment and must be recorded as derivative liabilities. Accordingly, the Company classifies the IPO Warrants as liabilities at their fair value and adjusts the IPO Warrants to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until the IPO Warrants are exercised or expired, and any change in fair value is recognized in the Company's condensed consolidated statement of operations and comprehensive loss. The fair value of the IPO Warrants was initially measured using a Black Scholes pricing model. Currently, the fair value of the Public Warrants is measured using quoted market prices, and the fair value of the Representative Warrants is based on an estimate of the relative fair value to the Public Warrants, accounting for a small difference in the exercise price.

### *Concentration of Credit Risk*

Financial instruments that potentially subject the Company to concentrations of credit risk consist of a cash account in a financial institution, which, at times, may exceed the Federal Depository Insurance Coverage of \$250,000. As of September 30, 2024, the Company has not experienced losses on this account and management believes the Company is not exposed to significant risks on such account.

### *Fair Value of Financial Instruments*

With the exception of liabilities related to the IPO Warrants, described in the table below, the fair value of the Company's assets and liabilities, which qualify as financial instruments under ASC 820, "Fair Value Measurements and Disclosures," approximates the carrying amounts represented in the accompanying balance sheet, primarily due to their short-term nature.

## Fair Value Measurements

Fair value is defined as the price that would be received for sale of an asset or paid for transfer of a liability, in an orderly transaction between market participants at the measurement date. GAAP establishes a three-tier fair value hierarchy, which prioritizes the inputs used in measuring fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements). These tiers include:

- Level 1, defined as observable inputs such as quoted prices (unadjusted) for identical instruments in active markets;
- Level 2, defined as inputs other than quoted prices in active markets that are either directly or indirectly observable such as quoted prices for similar instruments in active markets or quoted prices for identical or similar instruments in markets that are not active; and
- Level 3, defined as unobservable inputs in which little or no market data exists, therefore requiring an entity to develop its own assumptions, such as valuations derived from valuation techniques in which one or more significant inputs or significant value drivers are unobservable.

The following table presents information about the Company's assets and liabilities that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

	<b>Fair value measurements at reporting date using:</b>			
	<b>Fair value</b>	<b>Quoted prices in active markets for identical liabilities (Level 1)</b>	<b>Significant other observable inputs (Level 2)</b>	<b>Significant unobservable inputs (Level 3)</b>
<b>Assets:</b>				
Cash equivalents, September 30, 2024	\$ 4,513,161	\$ 4,513,161	\$ -	\$ -
Cash equivalents, December 31, 2023	\$ 13,419,860	\$ 13,419,860	\$ -	\$ -
<b>Liabilities:</b>				
Public warrant liabilities, September 30, 2024	\$ 153,560	\$ 153,560	\$ -	\$ -
Representative warrant liabilities, September 30, 2024	\$ 10,018	\$ -	\$ -	\$ 10,018
<b>Liabilities:</b>				
Public warrant liabilities, December 31, 2023	\$ 79,200	\$ 79,200	\$ -	\$ -
Representative warrant liabilities, December 31, 2023	\$ 5,166	\$ -	\$ -	\$ 5,166

The following tables present a reconciliation of the Level 3 Representative Warrants liabilities:

	<b>Three Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
Representative warrant liabilities, July 1	\$ 5,712	\$ 4,535
Issuances	-	-
Exercises	-	-
Change in fair value	4,306	(2,757)
Representative warrant liabilities, September 30	<u>\$ 10,018</u>	<u>\$ 1,779</u>
	<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
Representative warrant liabilities, January 1	\$ 5,166	\$ 8,611
Issuances	-	-
Exercises	-	-
Change in fair value	4,852	(6,833)
Representative warrant liabilities, September 30	<u>\$ 10,018</u>	<u>\$ 1,779</u>

The change in fair value of the Representative Warrants liabilities is recorded in change in fair value of warrant liabilities on the condensed consolidated statement of operations and comprehensive loss.

The fair value of the cash equivalents is based on the fair value of marketable securities invested in U.S. government money market funds.

The fair value of the liability associated with the Public Warrants as of September 30, 2024 was based on the quoted closing price on The Nasdaq Capital Market and is classified as Level 1. The fair value of the liability associated with the Representative Warrants as of September 30, 2024 was based on an estimate of the relative fair value to the Public Warrants, accounting for a small difference in the exercise price, and is classified as Level 3.

In some circumstances, the inputs used to measure fair value might be categorized within different levels of the fair value hierarchy. In those instances, the fair value measurement is categorized in its entirety in the fair value hierarchy based on the lowest level input that is significant to the fair value measurement.

#### *Net Loss Per Share*

Net loss per share is computed by dividing net loss by the weighted average number of common shares outstanding during the reporting period. Diluted earnings per share is computed similarly to the basic earnings per share, except the weighted average number of common shares outstanding are increased to include additional shares from the assumed exercise of share options, if dilutive. The following outstanding shares issuable upon exercise of stock options and warrants and vesting of restricted stock units were excluded from the computation of diluted net loss per share for the periods presented because including them would have had an anti-dilutive effect:

	Nine Months Ended September 30,	
	2024	2023
Stock options	185,784	99,000
Warrants	3,293,693	767,800
Restricted stock units	1,669	4,167

#### *Foreign Currency Translations*

The Company's functional and reporting currency is the U.S. dollar. All transactions initiated in other currencies are translated into U.S. dollars using the exchange rate prevailing on the date of transaction. Monetary assets and liabilities denominated in foreign currencies are translated into the U.S. dollar at the rate of exchange in effect at the balance sheet date. Unrealized exchange gains and losses arising from such transactions are deferred until realization and are included as a separate component of stockholders' equity (deficit) as a component of comprehensive income or loss. Upon realization, the amount deferred is recognized in income in the period when it is realized.

#### *Translation of Foreign Operations*

The financial results and position of foreign operations whose functional currency is different from the Company's presentation currency are translated as follows:

- assets and liabilities are translated at period-end exchange rates prevailing at that reporting date;
- equity is translated at historical exchange rates; and
- income and expenses are translated at average exchange rates for the period.

Exchange differences arising from translation of foreign operations are transferred directly to the Company's accumulated other comprehensive loss in the condensed consolidated financial statements. Transaction gains and losses arising from exchange rate fluctuation on transactions denominated in a currency other than the functional currency are included in the condensed consolidated statements of operations and comprehensive loss.

The relevant translation rates are as follows:

	As of September 30, 2024	As of December 31, 2023
Closing rate, British Pound (GBP) to \$USD at period end	1.3413	1.2747
Average rate, GBP to \$USD for the period ended	1.2769	1.2434
Closing rate, Euro (EUR) to \$USD at period end	0.8962	0.9052
Average rate, EUR to \$USD for the period ended	0.9202	0.9251

*Comprehensive Income (Loss)*

ASC 220, “Comprehensive Income,” establishes standards for reporting and display of comprehensive income (loss) and its components in a full set of general-purpose financial statements. As of September 30, 2024 and December 31, 2023, the Company had no material items of other comprehensive income (loss) except for the foreign currency translation adjustment.

*Impairment of Long-Lived Assets and Goodwill*

Long-lived and amortizable intangible assets are assessed annually for impairment or sooner should impairment indicators exist. Significant events or changes in business circumstances indicate that the carrying value of the assets may not be recoverable. Such circumstances may include a significant decrease in the market price of an asset, a significant adverse change in the manner in which the asset is being used or in its physical condition or a history of operating or cash flow losses associated with the use of an asset. An impairment loss is recognized when the carrying amount of an asset exceeds the anticipated future undiscounted cash flows expected to result from the use of the asset and its eventual disposition. The amount of the impairment loss is the excess of the asset’s carrying value over its fair value. There were no charges related to impairments of long-lived assets for all periods presented.

Goodwill is assessed for impairment annually during the fourth quarter, or more frequently if impairment indicators exist. Impairment exists when the carrying amount of goodwill exceeds its implied fair value. The Company may elect to assess goodwill for impairment using a qualitative or a quantitative approach, to determine whether it is more likely than not that the fair value of goodwill is greater than its carrying value. There were no charges related to goodwill impairment for all periods presented.

*Leases*

The Company determines whether a contract is or contains a lease at the time of the contract’s inception based on the presence of identified assets and the Company’s right to obtain substantially all the economic benefit from or to direct the use of such assets. When the Company determines a lease exists, it records a right-of-use (“ROU”) asset and corresponding lease liability on its balance sheet. ROU assets represent the Company’s right to use an underlying asset for the lease term. Lease liabilities represent the Company’s obligation to make lease payments arising from the lease. ROU assets are recognized at the lease commencement date at the present value of the remaining future lease payments the Company is obligated for under the terms of the lease. Lease liabilities are recognized concurrently with the recognition of the ROU asset and represent the present value of lease payments to be made under the lease. These ROU assets and liabilities are adjusted for any prepayments, lease incentives received, and initial direct costs incurred. As the discount rate implicit in the lease is not readily determinable in most of the Company’s leases, the Company uses its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments. If the Company’s lease terms include an option to extend the lease for a set period, the Company evaluates the renewal option and should it be reasonably certain that the Company will exercise that option, adjusts the ROU asset and liability accordingly.

### Stock-Based Compensation

The Company accounts for its stock-based compensation awards to employees and members of its Board of Directors (the “Board”) in accordance with ASC Topic 718, Compensation—Stock Compensation (“ASC 718”). ASC 718 requires all stock-based payments to employees and Board members, including grants of employee stock options, to be recognized in the statements of operations by measuring the fair value of the award on the date of grant and recognizing this fair value as stock-based compensation using a straight-line method over the requisite service period, generally the vesting period.

### Recent Accounting Pronouncements

Management does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company’s condensed consolidated financial statements.

### NOTE 3 – PROPERTY AND EQUIPMENT, NET

Property and equipment, net consists of the following:

	As of September 30, 2024	As of December 31, 2023
Leasehold improvements	\$ 3,193	\$ 3,193
Medical equipment	155,363	155,363
Office equipment	6,140	6,140
Property and equipment, gross	164,696	164,696
Less: accumulated depreciation	(37,636)	(23,488)
Property and equipment, net	\$ 127,060	\$ 141,208

### NOTE 4 – LEASES

#### Laboratory Lease – South San Francisco, California

In August 2022, the Company, as a lessee, entered into an amended sublease agreement to sublease laboratory and office space in South San Francisco, California. The lease commenced on August 15, 2022. The term of this sublease is for a period of thirty-nine and one-fourth (39.25) months commencing on the effective date, until May 15, 2024. The lease had a gross monthly rent of \$15,700 per month to December 31, 2022. Starting January 1, 2023, the monthly rent increased by 3% annually, to \$16,171 per month in 2023. Starting January 1, 2024, the monthly rent increased to \$16,656. The Company had no remaining lease payments as of September 30, 2024.

This lease was accounted for as an operating lease under ASC 842, Leases, which resulted in the recognition of a right of use asset (“ROU asset”) and liability of approximately \$332,000 at inception. The ROU asset is recorded as a component of non-current assets and the liability a component of current and non-current liabilities on the Company’s consolidated balance sheets. The Company discounted the future lease payments of this lease using the prevailing collateralized lending rate which would be extended to the Company based on its credit profile relative to the period of inception, and the duration of the lease from inception. The interest rate used in calculating the fair value listed above was 7.8%.

As of September 30, 2024 and December 31, 2023, the Company recognized total ROU assets and lease liabilities as follows:

	As of September 30, 2024	As of December 31, 2023
Non-current leases - right of use assets	\$ -	\$ 79,271
Current liabilities - operating lease liabilities	\$ -	\$ 81,680
Non-current liabilities - operating lease liabilities	\$ -	\$ -
Operating lease expense	\$ 139,634	\$ 243,230
Cash paid for amounts included in the measurement of operating lease liabilities	\$ -	\$ -

## NOTE 5 – INTANGIBLE ASSETS

Intangible assets, net consists of the following:

	September 30, 2024			December 31, 2023		
	Gross Carrying Amount	Accumulated Amortization	Net	Gross Carrying Amount	Accumulated Amortization	Net
In-process research and development	\$ 2,900,000	\$ —	\$ 2,900,000	\$ 2,900,000	\$ —	\$ 2,900,000
Patents and intellectual property	5,671,478	(1,102,787)	4,568,691	5,671,478	(630,164)	5,041,314
Intangible assets, net	<u>\$ 8,571,478</u>	<u>\$ (1,102,787)</u>	<u>\$ 7,468,691</u>	<u>\$ 8,571,478</u>	<u>\$ (630,164)</u>	<u>\$ 7,941,314</u>

As of September 30, 2024, future expected amortization expense of Intangible assets was as follows:

2024 (remaining)	\$ 157,541
2025	630,164
2026	630,164
2027	630,164
2028	630,164
Thereafter	1,890,494
Remaining future amortization expense	<u>\$ 4,568,691</u>

There were no changes to goodwill for the nine months ended September 30, 2024.

## NOTE 6 – STOCKHOLDERS' EQUITY

The Company is authorized to issue an aggregate of 105,000,000 shares. The authorized capital stock is divided into: (i) 100,000,000 shares of Common Stock having a par value of \$0.0001 per share and (ii) 5,000,000 shares of preferred stock having a par value of \$0.0001 per share.

### Common Stock

The Company had 1,044,914 and 1,041,582 shares of its Common Stock issued and outstanding at September 30, 2024 and December 31, 2023, respectively.

Each holder of Common Stock is entitled to one vote for each share of Common Stock held on all matters submitted to a vote of the stockholders. Our Second Amended and Restated Certificate of Incorporation and Second Amended and Restated Bylaws do not provide for cumulative voting rights.

In addition, the holders of our Common Stock are entitled to receive ratably such dividends, if any, as may be declared by the Board out of legally available funds; however, the current policy of our Board is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the holders of our Common Stock will be entitled to share ratably in all assets that are legally available for distribution.

Holders of our Common Stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the Common Stock. The rights, preferences and privileges of the holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Effective January 2, 2024, the Company amended its Second Amended and Restated Certificate of Incorporation to effect a one-for-twenty (1:20) reverse stock split of our outstanding shares of Common Stock. No fractional shares were issued as a result of the reverse stock split. Any fractional shares resulting from the reverse stock split were paid in cash. The reverse stock split did not otherwise affect any of the rights currently accruing to holders of our Common Stock.

### 2023 Stock Incentive Plan

The Board and stockholders have adopted and approved the Company's 2023 Stock Incentive Plan (the "2023 Plan") which took effect on December 19, 2023. The 2023 Plan allows for the issuance of securities, including stock options, restricted stock, and restricted stock units ("RSUs") to employees, Board members and consultants. The initial number of shares of Common Stock available for issuance under the 2023 Plan was 125,000 shares plus 28,389 unused shares reserved under the Company's 2021 Stock Incentive Plan, which will, on January 1 of each calendar year, beginning on January 1, 2024 and ending on and including January 1, 2033, unless the Board decides otherwise, automatically increase to equal to the lesser of (A) three percent (3%) of the number of shares of Common Stock outstanding on the final day of the immediately preceding calendar year or (B) such smaller number of Shares as is determined by the Board.

On January 1, 2024, the number of shares of Common Stock available for issuance under the 2023 Plan automatically increased by 31,254 shares. As of September 30, 2024, a total of 197,393 shares of Common Stock were available under the 2023 Plan, of which 99,534 shares were issued and outstanding and 97,859 shares were available for potential issuances.

#### *Common Stock Issuances for the Three and Nine Months Ended September 30, 2024*

During the three and nine months ended September 30, 2024, the Company issued 833 and 3,332 shares of Common Stock, respectively, due to the vesting of restricted stock units (“RSUs”) and recognized approximately \$24,000 and \$96,000 of stock-based compensation expense, respectively, related to its outstanding RSUs. Stock-based compensation expense related to the Company’s RSUs is recognized within general and administrative expense on the condensed consolidated statements of operations and comprehensive loss.

As of September 30, 2024, the remaining unamortized RSU stock-based compensation expense was approximately \$21,000 with remaining three months of amortization.

#### *September 2024 Offering*

On September 26, 2024, the Company entered into a securities purchase agreement (the “September 2024 Offering”) with an institutional investor, pursuant to which the Company agreed to sell pre-funded warrants (“Pre-Funded Warrants”) to purchase up to an aggregate of 1,219,513 shares of common stock at an exercise price of \$0.001 per share, Series A warrants to purchase up to an aggregate of 1,219,513 shares of common stock at an exercise price of \$3.85 per share, and Series B warrants (together with the Series A Warrants, the “September 2024 PIPE Warrants”) to purchase up to an aggregate of 1,219,513 shares of common stock with an exercise price of \$3.85 per share. The combined purchase price per Pre-Funded Warrant and accompanying September 2024 PIPE Warrants was \$4.099. Aggregate gross proceeds from the September 2024 Offering were approximately \$4.5 million and the September 2024 Offering closed on September 30, 2024.

The Pre-Funded Warrants are exercisable immediately upon issuance and expire when exercised in full. The Series A Warrants are exercisable immediately upon issuance and have a term of exercise equal to five (5) years from the date of issuance. The Series B Warrants are exercisable immediately upon issuance and have a term of exercise equal to eighteen (18) months from the date of issuance.

A holder of the Pre-Funded Warrants and the September 2024 PIPE Warrants may not exercise any portion of such holder’s Pre-Funded Warrants or September 2024 PIPE Warrants to the extent that the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the Company’s outstanding shares of Common Stock immediately after exercise, except that upon at least 61 days’ prior notice from the holder to the Company, the holder may increase the beneficial ownership limitation to up to 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to the exercise. In the event of certain fundamental transactions, holders of the September 2024 PIPE Warrants will have the right to receive the Black Scholes Value of their Warrant calculated pursuant to a formula set forth in the Warrant, payable either in cash or in the same type or form of consideration that is being offered and being paid to the holders of Common Stock.

In connection with the September 2024 Private Placement, the Company entered into a registration rights agreement (the “Registration Rights Agreement”), dated as of September 26, 2024, with the investor, pursuant to which the Company agreed to prepare and file a registration statement with the Securities and Exchange Commission (the “SEC”) registering the resale of the shares of Common Stock underlying the Pre-Funded Warrants and the September 2024 PIPE Warrants no later than fifteen (15) days after the date of the Registration Rights Agreement (the “Registration Statement”), and to use its best efforts to have the registration statement declared effective as promptly as practical thereafter, and in any event no later than forty-five (45) days following the date of the Registration Rights Agreement (or ninety (90) days following the date of the Registration Rights Agreement in the event of a “full review” by the SEC). The Registration Statement was declared effective by the SEC on October 11, 2024.

The net proceeds to the Company from the September 2024 Private Placement were approximately \$4.5 million, after deducting placement agent fees and offering expenses payable by the Company. In addition, the Company issued to the placement agent or its designees warrants (the “Placement Agent Warrants”) to purchase up to an aggregate of 85,366 shares of Common Stock at an exercise price equal to \$5.125 per share. The Placement Agent Warrants have substantially the same terms as the September 2024 PIPE Warrants, are exercisable immediately upon issuance and have a term of exercise equal to five (5) years from the date of issuance. The Company intends to use the net proceeds received from the September 2024 Private Placement for working capital and general corporate purposes.

The September 2024 PIPE warrants met the requirement for equity classification. The Company computes the fair value of warrants and options using a Black-Scholes model. The expected term used for warrants is the contractual life. The Company is utilizing an expected volatility figure based on a review of the historical volatilities, over a period of time, equivalent to the expected life of the instrument being valued, of similarly positioned public companies within its industry. The risk-free interest rate was determined from the implied yields from U.S. Treasury zero-coupon bonds with a remaining term consistent with the expected term of the instrument being valued.

As of September 30, 2024, all 1,219,153 of the Pre-Funded Warrants are paid and issued but unexercised. In addition, the September 2024 PIPE Warrants have not been exercised as of September 30, 2024.

*Common Stock Issuances for the Three and Nine Months Ended September 30, 2023*

During the three and nine months ended September 30, 2023, the Company issued 833 and 5,832 shares of common stock, respectively, due to the vesting of restricted stock units (“RSUs”), and recognized approximately \$24,175 and \$71,736, respectively, of stock-based compensation expense related to its outstanding restricted stock units. Stock-based compensation expense related to the Company’s restricted stock units is recognized within selling, general and administrative expense.

As of September 30, 2023, the remaining unamortized RSU stock-based compensation expense was approximately \$117,000.

The Company did not grant any RSUs or restricted stock awards during the three and nine months ended September 30, 2023.

*Tender Offer (Common Stock Repurchase)*

On July 20, 2023, the Company announced that its Board of Directors authorized the repurchase, through a \$4.0 million tender offer of up to approximately 5.7 million shares of the Company’s outstanding common stock at a cash purchase price of \$0.70 per share (the “Tender Offer”). The Company launched the Tender Offer on August 9, 2023 and it expired on September 8, 2023.

On September 14, 2023, the Company disclosed the results of the Tender Offer. A total of 266,171 shares of the Company’s common stock (the “Tender Offer Shares”) were validly tendered and not properly withdrawn at a purchase price of \$0.70 per for an aggregate purchase price of \$3,726,416, including fees and expenses relating to the Tender Offer. The Company had 1,040,998 shares of common stock outstanding following payment for the shares of common stock purchased in the Tender Offer. The Tender Offer Shares were retired and cancelled following the closing of the Tender Offer.

*Warrants modification*

On November 29, 2021, the Company issued warrants to purchase up to 434,000 shares of Common Stock with an exercise price of \$70.00 per share (the “2021 PIPE Warrants”) in a private placement. Due to a certain anti-dilution provision, the exercise price of each 2021 PIPE Warrant was reduced to \$20.00 per share (the “Warrant Modification”) as a result of the September 2024 Offering. The Company recognized the effect of the Warrant Modification as a dividend of \$359,656.

**NOTE 7 – STOCK OPTIONS**

*Stock Options Issued, Vested and Cancelled*

During the three months ended September 30, 2024, the Company did not issue any stock options. During the three months ended September 30, 2024, 4,771 stock options subject to time-based milestone vesting conditions, vested.

During the nine months ended September 30, 2024, the Company granted stock options under the 2023 Plan to employees, to purchase an aggregate of 104,433 shares of Common Stock with a strike price equal to \$8.13 per share and a term of ten years. Of the stock options granted, stock options to purchase an aggregate of 37,433 shares of Common Stock were fully vested at issuance and the remaining stock options are subject to time-based vesting over a term ranging between one to three years. These stock options had a total fair value of approximately \$849,000, as calculated using the Black-Scholes pricing model with the following assumptions: volatility of 88.41%, discount rate of 4.20%, expected term of 6.5 years, and an exercise price of \$8.13.

During the nine months ended September 30, 2024, stock options to purchase an aggregate of 52,309 shares of Common Stock, subject to time-based milestone vesting conditions, vested.

During the nine months ended September 30, 2024, stock options to purchase an aggregate of 17,649 shares of Common Stock were cancelled in connection with the reduction in workforce related to the closure of our research laboratory.

### Stock-Based Compensation

For the three months ended September 30, 2024 and 2023, total stock-based compensation expense related to the Company's stock options was approximately \$121,000 and \$102,000, respectively. For the three months ended September 30, 2024, the Company recognized approximately \$107,000 of stock-based compensation related to its stock options within general and administrative expense, and approximately \$14,000 within research and development expense on the condensed consolidated statements of operations and comprehensive loss. For the three months ended September 30, 2023, all stock-based compensation expense was recorded within general and administrative expense on the condensed consolidated statements of operations and comprehensive loss.

For the nine months ended September 30, 2024 and 2023, total stock-based compensation expense related to the Company's stock options was approximately \$553,000 and approximately \$451,000, respectively. For the nine months ended September 30, 2024, the Company recognized approximately \$398,000 of stock-based compensation related to its options within general and administrative expense, and approximately \$155,000 within research and development expense. For the nine months ended September 30, 2023, all stock-based compensation expense was recorded within general and administrative expense.

The following table summarizes the activity related to the Company's stock options for the nine months ended September 30, 2024:

	Number of Options	Weighted average exercise price per share	Weighted average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding, January 1, 2024	99,000	\$ 32.38	8.55	\$ -
Granted	104,433	8.13	8.63	-
Expired/Cancelled	(17,649)	9.35	-	-
Exercised	-	-	-	-
Outstanding, September 30, 2024	<u>185,784</u>	<u>\$ 20.21</u>	<u>9.13</u>	<u>-</u>
Exercisable, September 30, 2024	95,514	\$ 30.27	8.24	\$ -

As of September 30, 2024, the remaining unamortized stock-based compensation expense related to the stock options was approximately \$476,000 with remaining 28 months of amortization.

## NOTE 8 – WARRANTS

As of September 30, 2024, the fair value of the Public Warrants was approximately \$0.698 per Public Warrant based on the closing price of the warrants on The Nasdaq Capital Market. The fair value of the Representative Warrants was approximately \$0.726 per Representative Warrant, which was based on the relative fair value to the Public Warrants.

The following table summarizes the Company's outstanding warrants:

Exercise Price	Number of warrants <sup>(1)</sup>	Weighted-average remaining contractual term (years)	Weighted average exercise price
\$ 3.85	2,439,026	3.26	
\$ 5.13	85,366	5.01	
\$ 8.13	1,500	9.42	
\$ 20.00	434,000	2.15	
\$ 37.60	100,001	2.88	
\$ 120.00	13,800	1.96	
\$ 125.00	220,000	1.96	
	<u>3,293,693</u>	<u>3.05</u>	<u>15.62</u>

(1) The number of warrants do not include 1,219,153 Pre-Funded Warrants that were issued but not exercised as of September 30, 2024.

During the three months ended September 30, 2024, the Company issued warrants to purchase an aggregate of 2,524,392 shares of Common Stock in connection with the September 2024 Offering as described in Note 6 above, excluding the Pre-Funded Warrants. This consisted of (i) Series A Warrants to purchase 1,219,513 shares of Common Stock, (ii) Series B Warrants to purchase 1,219,513 shares of Common Stock, and (iii) Placement Agent Warrants to purchase 85,366 shares of Common Stock

The Series A Warrants have an exercise price of \$3.85 per share and have a term of exercise equal to five (5) years from the date of issuance. The Series B Warrants have an exercise price of \$3.85 per share and have a term of exercise equal to eighteen (18) months from the date of issuance. The Placement Agent Warrants have an exercise price of \$5.13 per share and have a term of exercise equal to five (5) years from the date of issuance.

The exercise price of each 2021 PIPE Warrant was reduced from \$70.00 per share to \$20.00 per share in connection with the Warrant Modification. The Company recognized the effect of the Warrant Modification as a dividend of \$359,656.

For the three months ended September 30, 2024 and 2023, total stock-based compensation expense related to the Company's warrants was approximately \$2,360 and \$0, respectively, and is recognized within general and administrative expense on the condensed consolidated statements of operations and comprehensive loss.

During the nine months ended September 30, 2024, the Company issued warrants to purchase an aggregate of 2,525,892 shares of Common Stock in exchange for consulting services. The warrants were issued on March 1, 2024 and September 30, 2024 at \$8.13 per share, \$3.85 per share and \$5.13 per share. These warrants become exercisable in twelve equal monthly instalments commencing the day after issue date. The warrants expire ten years from the date of issuance.

For the nine months ended September 30, 2024 and 2023, total stock-based compensation expense related to the Company's warrants was approximately \$5,507 and \$0, respectively, and is recognized within general and administrative expense on the condensed consolidated statements of operations and comprehensive loss.

No warrants were expired/cancelled or exercised during the nine months ended September 30, 2024.

## NOTE 9 – COMMITMENTS AND CONTINGENCIES

### *Legal and Regulatory Environment*

The healthcare industry is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not limited to, matters such as licensure, accreditation, government healthcare program participation requirement, reimbursement for patient services and Medicare and Medicaid fraud and abuse. Government activity has increased with respect to investigations and allegations concerning possible violations of fraud and abuse statutes and regulations by healthcare providers.

Violations of these laws and regulations could result in expulsion from government healthcare programs, together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed. Management believes that the Company is in compliance with fraud and abuse regulations, as well as other applicable government laws and regulations. While no material regulatory inquiries have been made, compliance with such laws and regulations can be subject to future government review and interpretation, as well as regulatory actions unknown or unasserted at this time.

## NOTE 10 – DISCONTINUED OPERATIONS

During the year ended December 31, 2023, the Company sold and disposed of our assets associated with the Clinics operations in Los Angeles, CA and disposed of our services in the U.K. The lease associated with the related property in Los Angeles was assumed by the buyer in the transaction.

As of September 30, 2024 and December 31, 2023, the carrying amounts of the classes of assets and liabilities related to the discontinued operations of the Clinics operations were \$0.

The results of operations from discontinued operations for the three and nine months ended September 30, 2024 and 2023, have been reflected in the condensed consolidated statements of operations and consist of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues	\$ -	\$ -	\$ -	\$ -
Cost of services	-	-	-	-
Gross margin	-	-	-	-
Selling, general and administrative	-	-	-	502,063
Loss from discontinued operations	-	-	-	(502,063)
Gain on sale of assets	-	-	-	65,048
Loss from discontinued operations, before income tax	-	-	-	(437,015)
Income tax expense	-	-	-	-
Net loss from discontinued operations, net of tax	\$ -	\$ -	\$ -	\$ (437,015)
Weighted-average common shares outstanding, basic and diluted	1,044,144	1,258,050	1,043,315	1,289,201
Basic and diluted loss per share from discontinued operations	\$ -	\$ -	\$ -	\$ (0.34)

In accordance with U.S. GAAP, only expenses specifically identifiable and related to a business to be disposed may be allocated to discontinued operations. As such, the general and administrative expenses recorded in discontinued operations include corporate costs incurred directly in support of the Clinics business.

## **NOTE 11 – RELATED PARTY TRANSACTIONS**

### *PsychoGenics, Inc.*

In April 2023 we entered into a contract with PsychoGenics, Inc. (“PsychoGenics”) for the conduct of one of our preclinical studies. PsychoGenics is a contract manufacturing organization with extensive preclinical experience in CNS and orphan disorders. Pursuant to the contract, we made aggregate payments to PsychoGenics totaling approximately \$0.3 million over the term of the contract. The contract was completed in September 2023.

Dr. Emer Leahy, a member of our Board, is the current Chief Executive Officer and a less than 5% owner of PsychoGenics.

### *Consulting Agreement with Prof. Lawrence Steinman*

The Steinman Consulting Agreement memorializes the compensation arrangements pursuant to which Prof. Steinman has been compensated for his services to our Company, as previously disclosed in our public filings. Pursuant to the Steinman Consulting Agreement, Prof. Steinman provides a variety of consulting and advisory services relating principally to the clinical and commercial development of our product candidates, including our research and development strategy through all phases of discovery and preclinical development, identifying potential partners for our pre-clinical assets, and business development efforts related to our pre-clinical assets, among other things. Pursuant to the Steinman Consulting Agreement, Prof. Steinman receives \$25,000 per quarter for his services.

## **NOTE 12 – SUBSEQUENT EVENTS**

The Company has evaluated events and transactions subsequent to September 30, 2024 through the date these condensed consolidated financial statements were included on Form 10-Q and filed with the SEC. During this period, the Company did not have any material reportable subsequent events, except as disclosed below.

On November 12, 2024, Dr. Graeme Currie resigned from his position as Chief Development Officer effective as of November 15, 2024. In the interim, the Company will proceed with clinical development of its product candidates without disruption, in consultation with its existing consultants.

## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*You should read the following discussion and analysis of financial condition and operating results together with our financial statements and the related notes and other financial information included elsewhere in this quarterly report on Form 10-Q, as well as our audited consolidated financial statements and related notes as disclosed in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed on March 29, 2024. This discussion contains forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth in the section of this report captioned "Risk Factors" and elsewhere in this Quarterly Report on Form 10-Q as well as the risk factors set forth in the section titled "Risk Factors" included in our Annual Report on Form 10-K, our actual results may differ materially from those anticipated in these forward-looking statements. For convenience of presentation some of the numbers have been rounded in the text below.*

Throughout this report, the terms "our," "we," "us," and the "Company" refer to Pasithea Therapeutics Corp. and its subsidiaries, Pasithea Therapeutics Limited (U.K.), Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda, Pasithea Clinics Inc., Alpha-5 Integrin, LLC ("Alpha-5"), and AlloMek Therapeutics, LLC ("AlloMek"). Pasithea Therapeutics Limited (U.K.), legally dissolved as of January 2, 2024, was a private limited Company, registered in the United Kingdom (U.K.). Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda, is a private limited Company registered in Portugal. Pasithea Clinics Inc. is incorporated in Delaware. Alpha-5 and AlloMek, are both Delaware limited liability companies. The operations of Pasithea Therapeutics Limited (U.K.), Pasithea Therapeutics Portugal, Sociedade Unipessoal Lda, and Pasithea Clinics Inc. have been discontinued.

### CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements are generally identified by the use of such words as "may," "could," "should," "would," "believe," "anticipate," "forecast," "estimate," "expect," "intend," "plan," "continue," "outlook," "will," "potential" and similar statements of a future or forward-looking nature. These forward-looking statements speak only as of the date of filing this Quarterly Report with the SEC, and include, without limitation, statements about the following:

- our lack of operating history;
- the expectation that we will incur significant operating losses for the foreseeable future and will need significant additional capital;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our plans to develop and commercialize our product candidates involves a lengthy and expensive process, with an uncertain outcome;
- the initiation, enrollment, timing, progress, results, and cost of our research and development programs and our current and future preclinical studies and clinical trials, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available;
- the timing of interim data and final results from our clinical trials for PAS-004;
- the potential safety and efficacy of our product candidates and the therapeutic implications of clinical and preclinical data;
- the timing and focus of our future preclinical studies and clinical trials, and the reporting of data from those studies and trials;
- the size of the market opportunity for our future product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;

- the success of competing therapies that are or may become available;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our future product candidates;
- our ability to obtain and maintain regulatory approval of our future product candidates;
- our plans relating to the further development of our future product candidates, including additional disease states or indications we may pursue;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our dependence on third parties;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- our plans and ability to obtain or protect intellectual property rights, including extensions of patent terms where available and our ability to avoid infringing the intellectual property rights of others;
- our financial performance and sustaining an active trading market for our Common Stock and Public Warrants;
- our ability to restructure our operations to comply with any potential future changes in government regulation;
- disruptions to the development of our product candidates due to public health crises, such as epidemics and pandemics, including the COVID-19 global pandemic;
- the impact of global economic and market conditions and political developments on our business, including, among others, rising inflation and capital market disruptions, economic sanctions, bank failures, regional conflicts around the world, and economic slowdowns or recessions that may result from such developments which could harm our research and development efforts as well as the value of our Common Stock and our ability to access capital markets;
- business interruptions resulting from geopolitical actions and global events, including political instability, natural disasters and events of terrorism and wars such as the war between Ukraine and Russia, and the corresponding tensions created from such conflict between Russia, the United States and countries in Europe as well as other countries such as China, and the conflict between Hamas and Israel; and
- our reliance on foreign contract research organizations (CROs) and contract manufacturing organizations (CMOs), including WuXi AppTec, that may be subject to U.S. legislation, including the proposed BIOSECURE bill, trade restrictions and other foreign regulatory requirements which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material or have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. You should refer to the “*Risk Factors*” section of this Quarterly Report for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. We operate in an evolving environment and new risk factors and uncertainties may emerge from time to time. It is not possible for management to predict all risk factors and uncertainties. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether because of any new information, future events, changed circumstances or otherwise. You should review the factors and risks and other information we describe in the reports we will file from time to time with the SEC.

## *Company Summary*

We are a clinical-stage biotechnology company primarily focused on the discovery, research and development of innovative treatments for CNS disorders and other diseases, including RASopathies.

Our primary operations, the Therapeutics segment, are focused on developing our lead therapeutic candidate, PAS-004, a next-generation macrocyclic mitogen-activated protein kinase, or MEK inhibitor that we believe may address the limitations and liabilities associated with existing drugs with a similar mechanism of action. PAS-004 is a small molecule allosteric inhibitor of MEK 1 and MEK 2 for potential use in the treatment of a range of RASopathies, including neurofibromatosis type 1 (“NF1”)- associated neurofibromas and a number of oncology indications, among others that we acquired from AlloMek Therapeutics, LLC in October 2022. In December 2023, the FDA cleared our IND for PAS-004 and we received a study may proceed letter from the FDA for our Phase 1 multicenter, open-label, dose escalation trial of PAS-004 in patients with MAPK pathway-driven advanced tumors with a documented RAS, NF1 or RAF mutation or patients who have failed BRAF/MEK inhibition.

We are currently conducting the Phase 1 clinical trial at four clinical sites in the United States and plan to open an additional three sites in Eastern Europe in the fourth quarter of 2024. Our clinical development plan for PAS-004 is to begin a Phase 1/2a clinical trial in adult patients with NF1-associated plexiform and/or cutaneous neurofibromas followed by pediatric patients and ultimately seek FDA marketing approval in these patient populations.

Additionally, we have two programs that are in the discovery stage, which we believe address limitations in the treatment paradigm of the indications we plan to address with these programs, which are currently ALS for PAS-003 and schizophrenia for PAS-001. During the year ended December 31, 2023, we determined to cease further development of our PAS-002 program for multiple sclerosis due to several factors including the significant capital, resources and time required to develop the program, and the current and projected availability of effective treatment options for MS patients, among others.

Our ability to generate product revenue will depend on the successful development, regulatory approval and eventual commercialization of one or more of our product candidates. Until such time we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings, or other capital sources, including potential collaborations with other companies or other strategic transactions. Adequate funding may not be available to us on acceptable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of our product candidates.

We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates through all stages of development and clinical trials and, ultimately, seek regulatory approval. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We expect our expenses and capital requirements will increase significantly in connection with our ongoing activities as we:

- continue our ongoing and planned research and development of our product candidates;
- initiate nonclinical studies and clinical trials for any additional product candidates that we may pursue;
- scale up external manufacturing capacity with the aim of securing sufficient quantities to meet our capacity requirements for clinical trials and potential commercialization;
- establish a sales, marketing and distribution infrastructure to commercialize any approved product candidates and related additional commercial manufacturing costs;
- develop, maintain, expand, protect and enforce our intellectual property portfolio;
- acquire or in-license product candidates and technologies; and
- add clinical, operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts.

## Recent Developments

### *Clinical Updates*

On September 9, 2024, we announced the successful completion of long-term chronic toxicity studies for our lead candidate PAS-004. On September 26, 2024, we announced safety, tolerability, pharmacokinetic (PK) and preliminary efficacy data from the first two cohorts of patients in our Phase I clinical trial of PAS-004.

### *September 2024 Offering*

On September 26, 2024, we entered into a securities purchase agreement (the “September 2024 Offering”) with an institutional investor, pursuant to which we agreed to sell pre-funded warrants (“Pre-Funded Warrants”) to purchase up to an aggregate of 1,219,513 shares of Common Stock at an exercise price of \$0.001 per share, Series A warrants to purchase up to an aggregate of 1,219,513 shares of Common Stock at an exercise price of \$3.85 per share, and Series B warrants (together with the Series A Warrants, the “September 2024 PIPE Warrants”) to purchase up to an aggregate of 1,219,513 shares of Common Stock with an exercise price of \$3.85 per share. The combined purchase price per Pre-Funded Warrant and accompanying September 2024 PIPE Warrants was \$4.099. Aggregate gross proceeds from the September 2024 Offering were approximately \$4.5 million and the September 2024 Offering closed on September 30, 2024.

### *Scientific Advisory Board*

On September 3, 2024, we announced that Rebecca Brown, M.D., Ph.D., was appointed as a member of our Scientific Advisory Board. Dr. Brown is currently Director of the Neurofibromatosis Clinic at The Mount Sinai Hospital and Assistant Professor in the Department of Neurology (Division of Neuro-Oncology), Internal Medicine, and Neurosurgery at the institution.

### *Reverse Stock Split*

On December 28, 2023, we filed a Certificate of Amendment to our Second Amended and Restated Certificate of Incorporation reflecting a one-for-20 reverse stock split (the “Reverse Stock Split”) of our issued and outstanding shares of Common Stock which became effective at 12:01 a.m. Eastern Time on January 2, 2024. As a result of the Reverse Stock Split, every 20 shares of Common Stock issued and outstanding were converted into one share of Common Stock, with a corresponding reduction in the number of authorized shares of Common Stock from 495,000,000 to 100,000,000. The Reverse Stock Split affected all stockholders uniformly and did not alter any stockholder’s percentage interest in our equity, except to the extent that the Reverse Stock Split resulted in some stockholders owning a fractional share. No fractional shares were issued in connection with the Reverse Stock Split. Stockholders who were otherwise entitled to receive a fractional share instead received a cash payment (without interest) equal to such a fraction multiplied by the average of the closing sales prices of Common Stock on The Nasdaq Capital Market for the five consecutive trading days immediately preceding the effective date of the Reverse Stock Split (with such average closing sales prices adjusted to give effect to the Reverse Stock Split). All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, convertible debt and warrants, were adjusted as a result of the Reverse Stock Split, as required by the terms of those securities.

The accompanying condensed consolidated financial statements reflect the Reverse Stock Split. All share and per share information data herein that relates to our Common Stock prior to the effective date has been retroactively restated to reflect the Reverse Stock Split.

## Impact of Inflation

We have recently experienced higher costs across our business as a result of inflation, including higher costs related to employee compensation and outside services. We expect inflation to continue to have a negative impact throughout 2024, and it is uncertain whether we will be able to offset the impact of inflationary pressures in the near term.

### Results of Operations

#### Comparison of the Three and Nine Months Ended September 30, 2024 and 2023

Our financial results for the three and nine months ended September 30, 2024 and 2023 are summarized as follows:

	For the Three Months Ended September 30,		Change	% Change
	2024	2023		
General and administrative	\$ 1,423,228	\$ 2,164,560	\$ (741,332)	(34.3)
Research and development	1,581,376	1,624,766	(43,390)	(2.7)
Loss from operations	(3,004,604)	(3,789,326)	784,722	(20.7)
Other income, net	4,770	176,736	(171,966)	(97.3)
Net loss from continuing operations	(2,999,834)	(3,612,590)	612,756	(17.0)
Net loss from discontinued operations, net of tax	-	-	-	-
Net loss	\$ (2,999,834)	\$ (3,612,590)	\$ 612,756	(17.0)

	For the Nine Months Ended September 30,		Change	% Change
	2024	2023		
General and administrative	\$ 5,301,934	\$ 6,081,362	\$ (779,428)	(12.8)
Research and development	5,688,478	4,749,217	939,261	19.8
Loss from operations	(10,990,412)	(10,830,579)	(159,833)	1.5
Other income, net	263,489	354,095	(90,606)	(25.6)
Net loss from continuing operations	(10,726,923)	(10,476,484)	(250,439)	2.4
Net loss from discontinued operations, net of tax	-	(437,015)	437,015	(100.0)
Net loss	\$ (10,726,923)	\$ (10,913,499)	\$ 186,576	(1.7)

### *General and administrative*

General and administrative expenses consist primarily of personnel expenses, including salaries, benefits, and stock-based compensation expense, for employees and consultants in executive, finance and accounting, legal, operations support, information technology and human resource functions. General and administrative expenses also include corporate facility costs not otherwise included in research and development expenses, including rent, utilities, depreciation, amortization, and maintenance, as well as legal fees related to intellectual property and corporate matters, fees for accounting and consulting services and other expenses, including insurance, public company and corporate communications, information technology, and board fees.

General and administrative expenses decreased by approximately \$741,000, or 34%, for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. The decrease was primarily driven by decreases in (i) legal expenses of approximately \$493,000, (ii) public company and corporate communications expenses of approximately \$217,000, (iii) accounting and business development of approximately \$115,000, and (iv) personnel, other income and gain on payable of approximately \$43,000 offset by an increase in (i) consulting costs of approximately \$78,000, (ii) non-cash stock based expense of approximately \$28,000, and (iii) other expense and gain on disposal of assets of \$21,000.

General and administrative expenses decreased by approximately \$779,000, or 13%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. The decrease was primarily driven by decreases in (i) personnel costs of approximately \$326,000, (ii) legal expenses of approximately \$322,000, (iii) accounting and business development of approximately \$210,000, (iv) public company and corporate communications expenses of approximately \$137,000, (v) other income of approximately \$117,000, and (vi) gain on payable of \$18,000, offset by an increases in (i) office expenses, including franchise taxes and insurance of approximately \$152,000, (ii) consulting costs of approximately \$114,000, (iii) non-cash amortization and depreciation, stock-based compensation of approximately \$80,000, and (iv) other expense of approximately \$5,000.

We expect general and administrative expenses to continue at lower levels in fiscal year 2024 as compared to fiscal year 2023 due to the non-recurring expenses that were incurred in 2023 related to the unsolicited, non-binding proposal to acquire all our outstanding shares from a third party and the tender offer we completed in September 2023.

### *Research and Development*

Research and development expenses relate to activities primarily focused on the development of PAS-004 for the three and nine months ended September 30, 2024, and PAS-004, PAS-003, and PAS-001 for the three and nine months ended September 30, 2023.

Research and development expenses decreased by approximately \$44,000, or 3%, for the three months ended September 30, 2024 compared to the three months ended September 30, 2023. The decrease was primarily driven by decreases in (i) preclinical research and development expenses related to our discovery programs of approximately \$403,000 and (ii) personnel expenses and stock compensation expense of approximately \$137,000 related to the closure of our research laboratory and reduction in related workforce, offset by increases in (i) consulting expenses of approximately \$35,000, (ii) general research and development expenses of approximately \$181,000, (iii) manufacturing and CMC expenses of approximately \$160,000 and (iv) clinical trial costs of approximately \$120,000 related to the initiation of the Phase 1 clinical trial of PAS-004.

Research and development expenses increased by approximately \$939,000, or 20%, for the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023. The increase was primarily driven by increases in (i) clinical trial costs of approximately \$1,647,000 related to the initiation of the Phase 1 clinical trial of PAS-004, (ii) general research and development expenses of approximately \$246,000, (iii) consulting costs of approximately \$137,000, (iv) stock compensation and personnel cost of approximately \$182,000 and (v) manufacturing and CMC expenses of approximately \$22,000 offset by (i) preclinical research and development related to our discovery programs of approximately \$1,295,000.

We expect research and development expenses to increase in fiscal year 2024 as compared to fiscal year 2023 primarily due to the clinical development of PAS-004 as well as PAS-004 CMC activities, offset by decreases in preclinical research and development related to the closure of our research laboratory.

### *Other income, net*

For the three months ended September 30, 2024, other income, net decreased by approximately \$172,000, or 97%, compared to the three months ended September 30, 2023. The decrease in other income, net is due primarily to a decrease in the fair value of the Public Warrants and the Representative Warrants (as such terms are defined in “Note 2 – Summary of Significant Accounting Policies” in the Notes to Unaudited Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q) that occurred during the three months ended September 30, 2024, compared to a larger increase in the fair value of the Public Warrants and the Representative Warrants that occurred during the three months ended September 30, 2023.

For the nine months ended September 30, 2024, other income, net decreased by approximately \$91,000, or 26%, compared to the nine months ended September 30, 2023. The increase in other income, net is due primarily to an increase in the fair value of warrant liabilities of approximately \$191,000, offset by dividend income of \$343,000 during the nine months ended September 30, 2024 compared to approximately \$254,000 of dividend income during the nine months ended September 30, 2023. See “Note 2 – Summary of Significant Accounting Policies” in the Notes to Unaudited Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for more information on the accounting treatment of the Public Warrants and the Representative Warrants.

### *Discontinued Operations*

During the year ended December 31, 2023, we discontinued our support services to anti-depression clinics in the U.K. and related at-home services in New York, NY. We also discontinued our clinical operations in Los Angeles, CA and disposed of the related property. Accordingly, we discontinued the operations of our Clinics segment provided by our subsidiaries, and currently have one reportable segment, the Therapeutics segment, related to the research and development of our therapeutic product candidates. As of June 30, 2023, all activity related to our discontinued subsidiaries is included in Net loss from discontinued operations, net of tax in the condensed consolidated statements of operations and comprehensive loss.

### **Working Capital**

	<b>As of September 30, 2024</b>	<b>As of December 31, 2023</b>
Current assets	\$ 9,778,772	\$ 16,692,154
Current liabilities	660,397	2,634,040
Working capital	<u>\$ 9,118,375</u>	<u>\$ 14,058,114</u>

Working capital decreased by approximately \$5.0 million between December 31, 2023 and September 30, 2024 primarily due to cash used to fund operations for the nine months ended September 30, 2024.

### *Liquidity and Financial Condition*

	<b>Nine Months Ended September 30,</b>	
	<b>2024</b>	<b>2023</b>
Net loss from continuing operations	<u>\$ (10,726,923)</u>	<u>\$ (10,476,484)</u>
Net cash used in operating activities	\$ (11,480,402)	\$ (9,519,789)
Net cash provided by investing activities	-	20,663
Net cash provided by (used in) financing activities	4,541,184	(3,726,416)
Effect of foreign currency translation	(30,665)	(7,056)
Net cash used in discontinued operations	-	(270,576)
Decrease in cash and cash equivalents	<u>\$ (6,969,883)</u>	<u>\$ (13,503,174)</u>

Cash and cash equivalents decreased by approximately \$7.0 million for the nine months ended September 30, 2024 compared to a decrease of approximately \$13.5 million for the nine months ended September 30, 2023, which was primarily attributable to cash used to fund operations and an increase in prepaid expenses.

## Liquidity & Capital Resources Outlook

As of September 30, 2024, we had approximately \$9.4 million in operating bank accounts and money market funds, with working capital of approximately \$9.1 million. We have incurred significant operating losses and negative cash flows from operations. On September 30, 2024, we had an accumulated deficit of approximately \$46.4 million. We have incurred recurring losses, have experienced recurring negative operating cash flows, and require significant cash resources to execute our business plans. Historically, our major sources of cash have been comprised of proceeds from various public and private offerings of our capital stock. We received aggregate gross proceeds of approximately \$4.5 million as a result of the September 2024 Offering. We are dependent on obtaining additional working capital funding from the sale of equity and/or debt securities to continue to execute our development plans and continue operations. Based on the foregoing, management believes that we will not have sufficient working capital to meet our needs through twelve months from the issuance date of the condensed consolidated financial statements, without raising additional capital.

### *Liquidity & Capital Resources Outlook*

Our primary use of cash is to fund operating expenses, primarily general and administrative and research and development expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our outstanding accounts payable, accrued expenses and prepaid expenses.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, timing, progress and results of discovery, preclinical development, laboratory testing and clinical trials for our product candidates;
- the costs of manufacturing our product candidates for clinical trials and in preparation for marketing approval and commercialization;
- the extent to which we enter into collaborations or other arrangements with third parties in order to further develop our product candidates;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the costs and fees associated with the discovery, acquisition or in-license of additional product candidates or technologies;
- expenses needed to attract and retain skilled personnel;
- the costs required to scale up our clinical, regulatory and manufacturing capabilities;
- the costs of future commercialization activities, if any, including establishing sales, marketing, manufacturing and distribution capabilities, for any of our product candidates for which we receive marketing approval; and
- revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval.

We will need significant additional funds to meet operational needs and capital requirements for clinical trials, other research and development expenditures, and business development activities. We currently have no credit facility or committed sources of capital. Because of the numerous risks and uncertainties associated with the development and commercialization of our product candidates, we are unable to estimate the amounts of increased capital outlays and operating expenditures associated with our current and anticipated clinical studies.

#### *Contractual Obligations*

See Note 9 – Commitments and Contingencies in the Notes to Unaudited Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for a summary of our contractual obligations.

#### *Off-Balance Sheet Arrangements*

During the periods presented, we did not have any off-balance sheet arrangements as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated under the Exchange Act.

#### *Critical Accounting Estimates*

Our critical accounting estimates, which include (1) revenue recognition, (2) stock-based compensation and (3) fair value measurements, are more fully described in the Notes to our Consolidated Financial Statements included in our Form 10-K for the fiscal year ended December 31, 2023, as filed on March 29, 2024. During the nine months ended September 30, 2024, there were no material changes to our critical accounting policies and estimates from those described in our Form 10-K.

#### *Recent Accounting Pronouncements*

See Note 2 – Summary of Significant Accounting Policies in the Notes to our Unaudited Condensed Consolidated Financial Statements in Part I, Item 1 of this Form 10-Q for a description of recent accounting pronouncements applicable to our financial statements.

### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

Not Applicable. As a smaller reporting company, we are not required to provide the information required by this Item.

### **Item 4. Controls and Procedures**

#### *Evaluation of Disclosure Controls and Procedures*

Our Chief Executive Officer and Chief Financial Officer have evaluated the Company's disclosure controls and procedures, and have concluded, based on their evaluation as of the end of the period covered by this report, that our disclosure controls and procedures, as defined in the Securities Exchange Act of 1934, as amended (the Exchange Act), Rule 13a-15(e), are not effective at a reasonable assurance level due to the material weakness described below.

Notwithstanding the material weakness, our management, including our Chief Executive Officer and Chief Financial Officer, has concluded that the condensed consolidated financial statements included in this Quarterly Report present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in accordance with U.S. Generally Accepted Accounting Principles.

*Remediation of Previously Identified Material Weakness*

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

As previously disclosed in our Form 10-K for the year ended December 31, 2023, as filed on March 29, 2024, management in connection with our independent auditors identified a material weakness in our controls related to the review of the annual income tax provision prepared by a third-party firm during the audit process related to our fiscal year ended December 31, 2023. Specifically, we did not maintain effective controls to sufficiently review the completeness and accuracy of the annual tax provision in Note 10 to our financial statements (the "Tax Provision Disclosure") included in our Form 10-K for the year ended December 31, 2023.

In response to the material weakness, management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, initiated a reassessment of our processes and controls related to the Tax Provision Disclosure and developed an action plan to remediate this matter, which included creating processes to ensure a thorough review of all materials and schedules prepared by third parties with respect to the Tax Provision Disclosure and engaging a tax professional to prepare and review any Tax Provision Disclosures. Management believes the involvement of the tax professional provides sufficient remediation, and the related controls will be subject to testing as applicable during the year.

*Evaluation of Changes in Internal Control over Financial Reporting*

Other than the remediation of the material weakness described above, there have been no changes in the Company's internal control over financial reporting during the three months ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

## PART II. OTHER INFORMATION

### Item 1. Legal Proceedings

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, we believe would individually or in the aggregate have a material adverse effect on our business, results of operations, financial condition or cash flows.

### Item 1A. Risk Factors

There have been no material changes to the risk factors set forth in the section titled “Risk Factors” included in our Annual Report on Form 10-K for the year ended December 31, 2023, as filed on March 29, 2024. Our business involves significant risks. You should carefully consider the risks and uncertainties described in our Form 10-K, together with all of the other information in this Quarterly Report on Form 10-Q, as well as our audited consolidated financial statements and related notes as disclosed in our Form 10-K. The risks and uncertainties described in our Form 10-K are not the only ones we face. Additional risk and uncertainties that we are unaware of or that we deem immaterial may also become important factors that adversely affect our business. The realization of any of these risks and uncertainties could have a material adverse effect on our reputation, business, financial condition, results of operations, growth and future prospects as well as our ability to accomplish our strategic objectives. In that event, the market price of our common stock and Public Warrants could decline, and you could lose part or all of your investment.

### 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.

#### *(a) Departure of Certain Officers*

On November 12, 2024, Dr. Graeme Currie resigned from his position as Chief Development Officer effective as of November 15, 2024. In the interim, the Company will proceed with clinical development of its product candidates without disruption, in consultation with its existing consultants.

#### *(c) Insider Trading Arrangements and Policies*

During the quarter ended September 30, 2024, none of the Company’s directors or officers adopted or terminated a “Rule 10b5-1 trading arrangement” or “non-Rule 10b5-1 trading arrangement,” as those terms are defined in Regulation S-K, Item 408, that was intended to satisfy the affirmative defense conditions of Rule 10b5-1(c).

## Item 6. Exhibits

<b>Exhibit No.</b>	<b>Description</b>
4.1	<a href="#">Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 of the Company's Form 8-K filed with the Commission on September 30, 2024).</a>
4.2	<a href="#">Form of Warrant (incorporated by reference to Exhibit 4.2 of the Company's Form 8-K filed with the Commission on September 30, 2024).</a>
4.3	<a href="#">Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.3 of the Company's Form 8-K filed with the Commission on September 30, 2024).</a>
10.1	<a href="#">Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K filed with the Commission on September 30, 2024).</a>
10.2	<a href="#">Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed with the Commission on September 30, 2024).</a>
31.1*	<a href="#">Certification of the Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
31.2*	<a href="#">Certification of the Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</a>
32.1**	<a href="#">Certification of the Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
32.2**	<a href="#">Certification of the Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

\* Filed herewith.

\*\* Furnished, not filed.

**SIGNATURES**

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

**PASITHEA THERAPEUTICS CORP.**

By: /s/ Tiago Reis Marques  
Tiago Reis Marques  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 13, 2024

By: /s/ Daniel Schneiderman  
Daniel Schneiderman  
Chief Financial Officer  
(Principal Financial Officer and  
Principal Accounting Officer)

Date: November 13, 2024

**PASITHEA THERAPEUTICS CORP.**  
**CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Tiago Reis Marques, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Pasithea Therapeutics Corp. (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.

By: /s/ Tiago Reis Marques  
Tiago Reis Marques  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 13, 2024

**PASITHEA THERAPEUTICS CORP.**  
**CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Daniel Schneiderman, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2024 of Pasithea Therapeutics Corp. (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.

By: /s/ Daniel Schneiderman  
Daniel Schneiderman  
Chief Financial Officer  
(Principal Financial Officer and  
Principal Accounting Officer)

Date: November 13, 2024

**PASITHEA THERAPEUTICS CORP.**  
**CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Pasithea Therapeutics Corp. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacity and on the date 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 to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Tiago Reis Marques  
Tiago Reis Marques  
Chief Executive Officer  
(Principal Executive Officer)

Date: November 13, 2024

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.

**PASITHEA THERAPEUTICS CORP.  
CERTIFICATION PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with this Quarterly Report on Form 10-Q for the period ended September 30, 2024 of Pasithea Therapeutics Corp. (the "Company") as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, in the capacity and on the date 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 to his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

By: /s/ Daniel Schneiderman  
Daniel Schneiderman  
Chief Financial Officer  
(Principal Financial Officer and  
Principal Accounting Officer)

Date: November 13, 2024

The foregoing certification is being furnished solely pursuant to 18 U.S.C. Section 1350 and is not being filed as part of the Report or as a separate disclosure document.