

REFINITIV

DELTA REPORT

10-Q

BIVI - BIOVIE INC.

10-Q - DECEMBER 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2024

The following comparison report has been automatically generated

TOTAL DELTAS	712
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 CHANGES	152
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 DELETIONS	235
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 ADDITIONS	325
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended: September 30, December 31, 2024

☐ 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: 001-39015

BIOVIE INC.

(Exact name of registrant as specified in its charter)

Nevada

(State or other jurisdiction of incorporation or organization)

46-2510769

(I.R.S. Employer Identification Number)

680 W Nye Lane Suite 204

Carson City, NV 89703

(Address of principal executive offices, Zip Code)

(775) 775-888-3162

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A Common Stock, \$0.0001 par value per share	BIVI	The NASDAQ Stock Market, LLC

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐

No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act

Yes ☐

No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the past 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒

No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒No ☐

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

Large Accelerated Filer ☐Accelerated Filer ☐Non-Accelerated Filer ☒Smaller reporting company ☒Emerging growth company ☐

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

Indicate by check mark if the registrant has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7362(b)) by the registered public accounting firm that prepared or issued its audit report.

Yes ☐No ☒

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

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐No ☒

There were 17,768,174 18,451,981 shares of the Registrant’s Class A Common Stock, \$0.0001 par value per share, outstanding as of November 7, 2024 February 7, 2025.

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BIOVIE INC.

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, and Section 27A of the Securities Act of 1933, as amended (the “Securities Act”). Any statements contained in this report that are not statements of historical fact may be forward-looking statements. When we use the words “intends,” “estimates,” “predicts,” “potential,” “continues,” “anticipates,” “plans,” “expects,” “believes,” “should,” “could,” “may,” “will” or the negative of these terms or other comparable terminology, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties, which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. These factors include our research and development activities, distributor channel; compliance with regulatory impositions; and our capital needs. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission (the “Commission”) that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The Company assumes no obligation and does not intend to update these forward-looking statements, except as required by law. When used in this report, the terms “BioVie”, “Company”, “we”, “our”, and “us” refer to BioVie Inc.

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PART I – FINANCIAL INFORMATION
Item 1. Financial Statements

BioVie Inc.
Condensed Balance Sheets
(Unaudited)

	September 30, 2024	June 30, 2024	December 31, 2024	June 30, 2024
ASSETS				
CURRENT ASSETS:				
Cash and cash equivalents	\$ 20,023,405	\$ 23,843,798	\$ 24,405,517	\$ 23,843,798
Prepaid and other current assets	127,680	204,392	275,835	204,392
Total current assets	<u>20,151,085</u>	<u>24,048,190</u>	<u>24,681,352</u>	<u>24,048,190</u>
Operating lease right-of-use assets, net	390,777	406,726		
Operating lease right-of-use asset, net			374,303	406,726
Intangible assets, net	350,374	407,718	293,030	407,718
Goodwill	<u>345,711</u>	<u>345,711</u>	<u>345,711</u>	<u>345,711</u>
TOTAL ASSETS	<u><u>\$ 21,237,947</u></u>	<u><u>\$ 25,208,345</u></u>	<u><u>\$ 25,694,396</u></u>	<u><u>\$ 25,208,345</u></u>
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES:				
Accounts payable and accrued expenses	\$ 3,452,972	\$ 3,586,912	\$ 1,382,501	\$ 3,586,912
Current portion of operating lease liabilities	63,664	60,343		
Current portion of note payable, net of financing cost, unearned premium and discount of \$820,242 at September 30, 2024 and \$701,210 at June 30, 2024	3,320,242	5,701,210		
Current portion of operating lease liability			67,111	60,343
Current portion of notes payable, net of financing cost, unearned premium and discount of \$701,210 at June 30, 2024			-	5,701,210
Warrant liability	<u>1,254</u>	<u>3,771</u>	<u>7,290</u>	<u>3,771</u>
Total current liabilities	<u>6,838,132</u>	<u>9,352,236</u>	<u>1,456,902</u>	<u>9,352,236</u>
Operating lease liabilities, net of current portion	332,730	349,894		
Operating lease liability, net of current portion			<u>314,915</u>	<u>349,894</u>

TOTAL LIABILITIES	<u>7,170,862</u>	<u>9,702,130</u>	<u>1,771,817</u>	<u>9,702,130</u>
Commitments and contingencies (Note 10)				
STOCKHOLDERS' EQUITY :				
Preferred stock; \$0.001 par value; 10,000,000 shares authorized; 0 shares issued and outstanding	-	-	-	-
Common stock, \$0.0001 par value; 800,000,000 shares authorized at September 30, 2024 and June 30, 2024, respectively; 7,982,986 shares issued of which 7,956,660 shares are outstanding at September 30, 2024; and 6,216,398 shares issued of which 6,190,072 shares outstanding at June 30, 2024	6,406	6,229		
Common stock, \$0.0001 par value; 800,000,000 shares authorized at December 31, 2024 and June 30, 2024; 18,478,307 shares issued of which 18,451,981 shares are outstanding at December 31, 2024; and 6,216,398 shares issued of which 6,190,072 shares outstanding at June 30, 2024			7,456	6,229
Additional paid in capital	352,770,440	349,732,674	369,781,837	349,732,674
Accumulated deficit	(338,709,734)	(334,232,661)	(345,866,687)	(334,232,661)
Treasury stock	(27)	(27)	(27)	(27)
Total stockholders' equity	<u>14,067,085</u>	<u>15,506,215</u>	<u>23,922,579</u>	<u>15,506,215</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 21,237,947</u>	<u>\$ 25,208,345</u>	<u>\$ 25,694,396</u>	<u>\$ 25,208,345</u>

See accompanying notes to unaudited condensed financial statements

BioVie Inc.
Condensed Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Three Months Ended December 31, 2024	Three Months Ended December 31, 2023	Six Months Ended December 31, 2024	Six Months Ended December 31, 2023
OPERATING EXPENSES:						
Amortization of intangible assets	\$ 57,344	\$ 57,344	\$ 57,344	\$ 57,344	\$ 114,688	\$ 114,688
Research and development expenses	1,990,198	8,875,659	4,704,806	6,470,262	6,695,003	15,345,922
Selling, general and administrative expenses	2,074,540	1,942,818	2,530,679	2,253,802	4,605,219	4,196,619
TOTAL OPERATING EXPENSES	4,122,082	10,875,821	7,292,829	8,781,408	11,414,910	19,657,229
LOSS FROM OPERATIONS	(4,122,082)	(10,875,821)	(7,292,829)	(8,781,408)	(11,414,910)	(19,657,229)
OTHER EXPENSE (INCOME):						
Change in fair value of derivative liabilities	(2,517)	(707,802)	6,036	(982,534)	3,519	(1,690,336)
Interest expense	256,024	1,004,668	66,700	820,600	322,725	1,825,268
Interest income	(223,557)	(462,223)	(253,036)	(218,029)	(476,593)	(680,252)
TOTAL OTHER EXPENSE (INCOME), NET	29,950	(165,357)				
TOTAL OTHER INCOME, NET			(180,300)	(379,963)	(150,349)	(545,320)
NET LOSS	\$ (4,152,032)	\$ (10,710,464)	\$ (7,112,529)	\$ (8,401,445)	\$ (11,264,561)	\$ (19,111,909)
Deemed dividend related to ratchet adjustment to warrants	325,041	-	44,424	-	369,465	-

NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (4,477,073)</u>	<u>\$ (10,710,464)</u>	<u>\$ (7,156,953)</u>	<u>\$ (8,401,445)</u>	<u>\$ (11,634,026)</u>	<u>\$ (19,111,909)</u>
NET LOSS PER COMMON SHARE						
- Basic	<u>\$ (0.70)</u>	<u>\$ (2.92)</u>	<u>\$ (0.46)</u>	<u>\$ (2.20)</u>	<u>\$ (1.05)</u>	<u>\$ (5.10)</u>
- Diluted	<u>\$ (0.70)</u>	<u>\$ (2.92)</u>	<u>\$ (0.46)</u>	<u>\$ (2.20)</u>	<u>\$ (1.05)</u>	<u>\$ (5.10)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING						
- Basic	6,398,360	3,672,490	15,717,247	3,817,077	11,042,832	3,744,476
- Diluted	6,398,360	3,672,490	15,717,247	3,817,077	11,042,832	3,744,476
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	<u>\$ (4,477,073)</u>	<u>\$ (10,710,464)</u>	<u>\$ (7,156,953)</u>	<u>\$ (8,401,445)</u>	<u>\$ (11,634,026)</u>	<u>\$ (19,111,909)</u>
Other comprehensive loss						
Unrealized gain on available-for-sale investments	-	-				
Reclassification of unrealized gains on available-for-sale investments upon settlement	-	(176,591)	-	-	-	(176,591)
Total other comprehensive loss	-	(176,591)	-	-	-	(176,591)
Comprehensive loss	<u>\$ (4,477,073)</u>	<u>\$ (10,887,055)</u>	<u>\$ (7,156,953)</u>	<u>\$ (8,401,445)</u>	<u>\$ (11,634,026)</u>	<u>\$ (19,288,500)</u>

See accompanying notes to unaudited condensed financial statements

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BioVie Inc.
Condensed Statements of Changes in Stockholders' Equity
(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Treasury Stock Shares	Treasury Stock Amount	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance, June 30, 2023	3,645,183	\$ 3,643	\$ 316,385,759	(2,288)	\$ (2)	\$ 176,591	\$ (301,225,705)	\$ 15,340,286
Stock-based compensation - stock options	-	-	808,027	-	-	-	-	808,027
Stock-based compensation - restricted stock units	-	-	380,834	-	-	-	-	380,834
Proceeds from issuance of common stock, net of costs of \$118,891	43,220	4	1,905,832	-	-	-	-	1,905,836
Issuance of common stock from vesting of - restricted stock units	3,873	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	(10,710,464)	(10,710,464)
Reclassification of unrealized gains on available for sale investments upon settlement	-	-	-	-	-	(176,591)	-	(176,591)
Balance, September 30, 2023	<u>3,692,276</u>	<u>\$ 3,647</u>	<u>\$ 319,480,452</u>	<u>(2,288)</u>	<u>\$ (2)</u>	<u>\$ -</u>	<u>\$ (311,936,169)</u>	<u>\$ 7,547,928</u>
Balance, June 30, 2024	6,216,398	\$ 6,229	\$ 349,732,674	(26,326)	\$ (27)	\$ -	\$ (334,232,661)	\$ 15,506,215
Stock-based compensation - stock options	-	-	118,898	-	-	-	-	118,898
Stock-based compensation - restricted stock units	-	-	301,491	-	-	-	-	301,491
Issuance of common stock from vesting of - restricted stock units	3,408	-	-	-	-	-	-	-
Stock-based compensation - issuance of common stock for services rendered	15,000	2	33,448	-	-	-	-	33,450

Proceeds from issuance of common stock, net of costs of \$747,408	1,627,943	163	2,258,900	-	-	-	-	2,259,063
Issuance of additional shares for fractional shares effected by the reverse split	120,237	12	(12)	-	-	-	-	-
Deemed dividend for ratchet adjustment to warrants	-	-	325,041	-	-	-	(325,041)	-
Net Loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>(4,152,032)</u>	<u>(4,152,032)</u>
Balance, September 30, 2024	<u>7,982,986</u>	<u>\$ 6,406</u>	<u>\$ 352,770,440</u>	<u>(26,326)</u>	<u>\$ (27)</u>	<u>\$ -</u>	<u>\$ (338,709,734)</u>	<u>\$ 14,067,085</u>
See accompanying notes to unaudited condensed financial statements								

BioVie Inc.
Condensed Statements of Changes in Stockholders' Equity
(Unaudited)

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Treasury Stock Shares	Treasury Stock Amount	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
Balance, June 30, 2023	3,645,183	\$ 3,643 #	\$ 316,385,759	(2,288)	\$ (2)	\$ 176,591	\$ (301,225,705)	\$ 15,340,286
Stock-based compensation - stock options	-	-	808,027	-	-	-	-	808,027
Stock-based compensation - restricted stock units	-	-	380,834	-	-	-	-	380,834
Proceeds from issuance of common stock, net of costs of \$118,891	43,220	4	1,905,832	-	-	-	-	1,905,836
Issuance of common stock from vesting of - restricted stock units	3,873	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	(10,710,464)	(10,710,464)
Reclassification of unrealized gains on available for sale investments upon settlement	-	-	-	-	-	(176,591)	-	(176,591)
Balance, September 30, 2023	3,692,276	3,647	319,480,452	(2,288)	(2)	-	(311,936,169)	7,547,928
Stock-based compensation - stock options	-	-	619,701	-	-	-	-	619,701
Stock-based compensation - restricted stock units	-	-	303,173	-	-	-	-	303,173
Proceeds from issuance of common stock, net of costs of \$258,254	290,090	290	7,421,588	-	-	-	-	7,421,878
Issuance of common stock from vesting of - restricted stock units	4,305	4	(4)	-	-	-	-	-
Net loss	-	-	-	-	-	-	(8,401,445)	(8,401,445)

Balance, December 31, 2023	<u>3,986,671</u>	<u>\$ 3,941</u>	<u>\$ 327,824,910</u>	<u>(2,288)</u>	<u>\$ (2)</u>	<u>\$ -</u>	<u>\$ (320,337,614)</u>	<u>\$ 7,491,235</u>
Balance, June 30, 2024	6,216,398	\$ 6,229	349,732,674	(26,326)	\$ (27)	\$ -	\$ (334,232,661)	\$ 15,506,215
Stock-based compensation - stock options	-	-	118,898	-	-	-	-	118,898
Stock-based compensation - restricted stock units	-	-	301,491	-	-	-	-	301,491
Issuance of common stock from vesting of - restricted stock units	3,408	-	-	-	-	-	-	-
Stock-based compensation - issuance of common stock for services rendered	15,000	2	33,448	-	-	-	-	33,450
Proceeds from issuance of common stock, net of costs of \$747,408	1,627,943	163	2,258,900	-	-	-	-	2,259,063
Issuance of additional shares for fractional shares effected by the reverse split	120,237	12	(12)	-	-	-	-	-
Deemed dividend for ratchet adjustment to warrants	-	-	325,041	-	-	-	(325,041)	-
Net Loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>(4,152,032)</u>	<u>(4,152,032)</u>
Balance, September 30, 2024	7,982,986	6,406	352,770,440	(26,326)	(27)	-	(338,709,734)	14,067,085
Stock-based compensation - stock options	-	-	385,328	-	-	-	-	385,328
Stock-based compensation - restricted stock units	-	-	265,804	-	-	-	-	265,804
Issuance of common stock from vesting of - restricted stock units	3,807	-	-	-	-	-	-	-
Exercise of warrants	2,231,300	224	2,901,117	-	-	-	-	2,901,341
Cashless exercise of warrants	4,214	-	-	-	-	-	-	-

Proceeds from issuance of common stock, net of costs of \$2,492,880	8,256,000	826	13,414,724	-	-	-	-	13,415,550
Deemed dividend for ratchet adjustment to warrants	-	-	44,424	-	-	-	(44,424)	-
Net Loss	-	-	-	-	-	-	(7,112,529)	(7,112,529)
Balance, December 31, 2024	18,478,307	\$ 7,456	\$ 369,781,837	(26,326)	\$ (27)	\$ -	\$ (345,866,687)	\$ 23,922,579
See accompanying notes to unaudited condensed financial statements								

BioVie Inc.

Condensed Statements of Cash Flows
(Unaudited)

	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Six Months Ended December 31, 2024	Six Months Ended December 31, 2023
CASH FLOWS FROM OPERATING ACTIVITIES:				
Net loss	\$ (4,152,032)	\$ (10,710,464)	\$ (11,264,561)	\$ (19,111,909)
Adjustments to reconcile net loss to net cash used in operating activities:				
Amortization of intangible assets	57,344	57,344	114,688	114,688
Stock based compensation - restricted stock units	301,491	380,834	567,295	684,007
Stock based compensation expense - stock options	118,898	808,027	504,226	1,427,728
Stock based compensation expense - issuance of common stock for services rendered	33,450	-	33,450	-
Amortization of financing costs	9,456	37,825	11,820	68,560
Accretion of unearned loan discount	88,970	355,877	111,212	645,027
Accretion of loan premium	20,606	82,424	25,758	149,394
Realized gain on maturity of available-for sale	-	(223,865)	-	(223,865)
Non-cash lease expense from right-of-use assets	15,949	10,041	32,423	20,371
Change in fair value of derivative liabilities	(2,517)	(707,802)	3,519	(1,690,336)
Changes in operating assets and liabilities:				
Prepaid and other current assets	76,712	(1,446,761)	(71,443)	(232,437)
Accounts payable and accrued expenses	(133,940)	(761,499)	(2,204,411)	131,837
Operating lease liabilities	(13,843)	(10,645)	(28,211)	(21,579)
Other current liabilities	-	(48,385)	-	(48,385)
Net cash used in operating activities	(3,579,456)	(12,177,049)	(12,164,235)	(18,086,899)
CASH FLOWS FROM INVESTING ACTIVITIES:				
Proceeds from (purchases of) U.S. Treasury Bills (available-for-sale)	-	14,525,000		
Net cash provided by (used in) investing activities	-	14,525,000		
Proceeds from U.S. Treasury Bills (available-for-sale)			-	14,525,000
Net cash provided by investing activities			-	14,525,000
CASH FLOWS FROM FINANCING ACTIVITIES:				
Net proceeds from issuance of common stock	2,259,063	1,905,836	15,674,613	9,327,714
Proceeds from exercise of warrants			2,901,341	-

Payment of loan premium			(850,000)	-
Payments of note payable	(2,500,000)	(2,500,000)	(5,000,000)	(5,000,000)
Net cash used in financing activities	(240,937)	(594,164)		
Net cash provided by financing activities			12,725,954	4,327,714
Net change in cash and cash equivalents	(3,820,393)	1,753,787	561,719	765,815
Cash and cash equivalents, beginning of period	23,843,798	19,460,883	23,843,798	19,460,883
Cash and cash equivalents, end of period	<u>\$ 20,023,405</u>	<u>\$ 21,214,670</u>	<u>\$ 24,405,517</u>	<u>\$ 20,226,698</u>
SUPPLEMENTAL CASH FLOW INFORMATION:				
Cash paid for interest	<u>\$ 136,992</u>	<u>\$ 528,541</u>	<u>\$ 173,935</u>	<u>\$ 962,288</u>
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING ACTIVITIES:				
Reclassification of unrealized gains on U.S. Treasury Bills (available-for-sale investments) upon settlement	<u>\$ -</u>	<u>\$ 176,591</u>	<u>\$ -</u>	<u>\$ 176,591</u>
Deemed dividend for ratchet adjustment to warrants	<u>\$ 325,041</u>	<u>\$ -</u>	<u>\$ 369,465</u>	<u>\$ -</u>

See accompanying notes to unaudited condensed financial statements

BioVie Inc.

Notes to Condensed Financial Statements

For the Three and Six Months Ended September 30, 2024 December 31, 2024 and 2023
(unaudited)

1. Background Information

BioVie Inc. (the “Company” or “we” or “our”) is a clinical-stage company developing innovative drug therapies to treat chronic debilitating conditions including neurological and neuro-degenerative disorders and liver disease.

The Company acquired the biopharmaceutical assets of NeurMedix, Inc. (“NeurMedix”) a privately held clinical-stage pharmaceutical company and a related party in June 2021. The acquired assets included NE3107, NE3107 or (“Bezisterim”). Bezisterim, the approved generic name for NE3107 is an investigational, novel, orally administered small molecule that is thought to inhibit inflammation-driven insulin resistance and major pathological inflammatory cascades with a novel mechanism of action. There is emerging scientific consensus that both inflammation and insulin resistance may play fundamental roles in the development of Alzheimer’s disease (“AD”) and Parkinson’s disease (“PD”), and NE3107 Bezisterim could, if approved by the U.S. Food and Drug Administration (“FDA”), represent an entirely new medical approach to treating these devastating conditions affecting an estimated 6 million Americans suffering from AD and 1 million Americans suffering from PD.

Neurodegenerative Disease Program

In neurodegenerative disease, the Company’s drug candidate Bezisterim (NE3107) inhibits activation of inflammatory actions extracellular single-regulated kinase (“ERK”) and nuclear factor kappa-light-chain-enhancer of activated B cells (“NFκB”) (including interactions with tumor necrosis factor (“TNF”) signaling and other relevant inflammatory pathways) that lead to neuroinflammation and insulin resistance. NE3107 does not interfere with their homeostatic functions (e.g., insulin signaling and neuron growth and survival). Both inflammation and insulin resistance are drivers of AD and PD.

Alzheimer’s Disease

On November 29, 2023, the Company announced the analysis of its unblinded, topline efficacy data from its Phase 3 clinical trial (NCT04669028) of NE3107 in the treatment of mild to moderate AD. The study has co-primary endpoints looking at cognition using the Alzheimer’s Disease Assessment Scale-Cognitive Scale (ADAS-Cog 12) and function using the Clinical Dementia Rating-Sum of Boxes (CDR-SB). Patients were randomly assigned, 1:1 versus placebo, to receive sequentially 5 mg of NE3107 orally twice a day for 14 days, then 10 mg orally twice a day for 14 days, followed by 26 weeks of 20 mg orally twice daily.

Upon trial completion, as the Company began the process of unblinding the trial data, the Company found significant deviation from protocol and current good clinical practices (“cGCPs”) violations at 15 study sites (virtually all of which were from one geographic area). This highly unusual level of suspected improprieties led the Company to exclude all patients from these sites and to refer the sites to the FDA Office of Scientific Investigations (“OSI”) for potential further action. After the patient exclusions, 81 patients remained in the Modified Intent to Treat population, 57 of whom were in the Per-Protocol population which included those who completed the trial and were verified to take study drug from pharmacokinetic data.

The trial was originally designed to be 80% powered with 125 patients in each of the treatment and placebo arms. The unplanned exclusion of so many patients left the trial underpowered for the primary endpoints. In the Per-Protocol population, which included those patients who completed the trial and who were further verified to have taken the study drug (based on pharmacokinetic data), an observed descriptive change from baseline appeared to suggest a slowing of cognitive loss; these same patients experienced an advantage in age deceleration vs. placebo as measured by DNA epigenetic change. Age deceleration is used by longevity researchers to measure the difference between the patient’s biological age, in this case as measured by the Horvath DNA methylation Skin Blood Clock, relative to the patient’s actual chronological age. This test was a non-primary/secondary endpoint, other-outcome measure, done via blood test collected at week 30 (end of study). Additional DNA methylation data continues to be collected and analyzed.

Parkinson’s Disease

The Phase 2 study of bezisterim (NE3107) for the treatment of PD (NCT05083260), completed in December 2022, was a double-blind, placebo-controlled, safety, tolerability, and pharmacokinetics study in PD participants treated with carbidopa/levodopa and bezisterim (NE3107). Forty-five patients with a defined L-dopa “off state” were randomized 1:1 to placebo: bezisterim (NE3107) 20 mg twice daily for 28 days. This trial was launched with two design objectives: 1) the primary objective was safety and a drug-drug interaction study as requested by the FDA to measure the potential for adverse interactions of bezisterim (NE3107) with carbidopa/ levodopa; and 2) the secondary objective was to determine if preclinical indications of promotoric activity and apparent enhancement of levodopa activity could be seen in humans. Both objectives were met.

To extend this Phase 2 data in progressed patients, the Company has designed a new Phase 2 study of bezisterim (NE3107) as a potential first line therapy to treat patients with new onset PD. In July 2024, the Company submitted the new protocol and received a response from the FDA which permitted the Company to proceed with the study. The trial is anticipated to commence during the first calendar quarter of 2025.

Long COVID Program

In April 2024, the Company announced the grant of a clinical trial award of up to \$13.1 million from the U.S. Department of Defense (“DOD”), awarded through the Peer Reviewed Medical Research Program of the Congressionally Directed Medical Research Programs. In August 2024, U.S. Army Medical Research and Development Command, Office of Human Research Oversight (“OHRO”) approved the Company’s plan to evaluate bezisterim (NE3107) for the treatment of neurological symptoms that are associated with long COVID. and the FDA authorized our Investigational New Drug (“IND”) application for bezisterim (NE3107) allowing us the Company to study a novel, anti-inflammatory approach or the treatment of the debilitating neurocognitive symptoms associated with long covid. The Company anticipates the trial to commence by early first calendar quarter of 2025. The Company has been was reimbursed approximately \$325,000 for the trial costs during the three six months ended September 30, 2024 December 31, 2024. Subsequent to December 31, 2024, additional reimbursements of approximately \$2.6 million were received for trial costs incurred through December 31, 2024.

Liver Disease Program

In liver disease, our investigational drug candidate BIV201 (continuous infusion terlipressin), which has been granted both FDA Fast Track designation status and FDA Orphan Drug status, is being evaluated and discussed after receiving guidance from the FDA regarding the design of Phase 3 clinical testing of BIV201 for the treatment of ascites due to chronic liver cirrhosis. BIV201 is administered as a patent-pending liquid formulation.

In June 2021, the Company initiated a Phase 2 study (NCT04112199) designed to evaluate the efficacy of BIV201 (terlipressin, administered by continuous infusion for two 28-day treatment cycles) combined with standard-of-care (“SOC”), compared to SOC alone, for the treatment of refractory ascites. The primary endpoints of the study are the incidence of ascites-related complications and change in ascites fluid accumulation during treatment compared to a pre-treatment period.

In March 2023, the Company announced enrollment was paused and that data from the first 15 patients treated with BIV201 plus SOC appeared to show at least a 30% reduction in ascites fluid during the 28 days after treatment initiation compared to the 28 days prior to treatment. The change in ascites volume was significantly different from those patients receiving SOC treatment. Patients who completed the treatment with BIV201 experienced a 53% reduction in ascites fluid, which was sustained (43% reduction) during the three months after treatment initiation as compared to the three-month pre-treatment period.

In June 2023, the Company requested and subsequently received guidance from the FDA regarding the design and endpoints for definitive clinical testing of BIV201 for the treatment of ascites due to chronic liver cirrhosis. The Company is currently finalizing protocol designs for the Phase 3 study of BIV201 for the treatment of ascites due to chronic liver cirrhosis.

The BIV201 development program was initiated by LAT Pharma LLC. On April 11, 2016, the Company acquired LAT Pharma LLC and the rights to its BIV201 development program. The Company currently owns all development and marketing rights to this drug candidate. Pursuant to the Agreement and Plan of Merger entered into on April 11, 2016, between our predecessor entities, LAT Pharma LLC and NanoAntibiotics, Inc., BioVie is obligated to pay a low single digit royalty on net sales of BIV201 (continuous infusion terlipressin) to be shared among LAT Pharma Members, PharmaIn Corporation, and The Barrett Edge, Inc.

2. Liquidity and Going Concern

The Company’s operations are subject to a number of factors that can affect its operating results and financial conditions. Such factors include, but are not limited to: the results of clinical testing and trial activities of the Company’s products, products; the Company’s ability to obtain regulatory approval to market its products; competition from products manufactured and sold or being developed by other companies; the price of, and demand for, Company products; the Company’s ability to negotiate favorable licensing or other manufacturing and marketing agreements for its products; and the Company’s ability to raise capital. The Company’s financial statements have been prepared assuming the Company will continue as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. As of September 30, 2024 December 31, 2024, the Company had working capital of approximately \$13.3 23.2 million, cash and cash equivalents of totaling approximately \$20.0 24.4 million, stockholders’ equity of approximately \$14.1 23.9 million, and an accumulated deficit of approximately \$338.7 345.9 million. The Company is in the pre-revenue stage and no revenues are expected in the foreseeable future. The Company’s future operations are dependent on the success of the Company’s ongoing development and commercialization efforts, as well as its ability to secure additional financing as needed. Projected cash flows could be extended if further measures are taken to delay planned expenditures on our research protocols and slow the progress in the Company’s development and launch of next phase clinical programs.

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The future viability of the Company is largely dependent upon its ability to raise additional capital to finance its operations. Management expects that future sources of funding may include sales of equity, obtaining loans, or other strategic transactions.

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Although management continues to pursue the Company's strategic plans, there is no assurance that the Company will be successful in obtaining sufficient financing on terms acceptable to the Company, if at all, to fund continuing operations. These circumstances raise substantial doubt on the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

3. Significant Accounting Policies

Basis of Presentation – Interim Financial Information

These unaudited interim condensed financial statements and related notes have been prepared in accordance with accounting principles generally accepted in the United State of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X of the Securities and Exchange Commission (the "SEC") for Interim Reporting. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements. The unaudited interim condensed financial statements furnished reflect all adjustments (consisting of normal recurring accruals) that are, in the opinion of management, considered necessary for a fair presentation of the results for the interim periods presented. Interim results are not necessarily indicative of the results for the full year. The condensed balance sheet at June 30, 2024, was derived from audited annual financial statements but does not contain all the footnote disclosures from the annual financial statements. These unaudited interim condensed financial statements should be read in conjunction with the Company's audited financial statements for the fiscal years ended June 30, 2024 and 2023 in our Annual Report on Form 10-K filed with the SEC on September 30, 2024 (the "2024 Form 10-K"). A summary of significant accounting policies can also be found in those audited financial statements in the 2024 Form 10-K.

Cash and cash equivalents

Cash and cash equivalents consisted of cash deposits and money market funds held at a bank and funds held in a brokerage account which included a U.S. treasury money market fund and U.S. Treasury Bills with original maturities of three months or less.

Investments in U.S. Treasury Bills

Investments in U.S. Treasury Bills with maturities greater than three months, are accounted for as available-for-sale and are recorded at fair value. Realized gains were included in the accompanying condensed statements of operations and comprehensive loss from the settlement of available-for-sale investments during the **three six** months ended **September 30, 2023** **December 31, 2023**. The Company had no outstanding investment securities with original maturities of greater than three months at the time of purchase as of and during the three **and six** months ended **September 30, 2024** **December 31, 2024**.

Concentration of Credit Risk in the Financial Service Industry

As of **September 30, 2024** **December 31, 2024**, the Company had cash deposited in certain financial institutions in excess of federally insured levels. The Company regularly monitors the financial stability of these financial institutions and believes that it is not exposed to any significant credit risk in cash and cash equivalents. However, if liquidity and financial stability concerns arise with respect to banks and financial institutions, either nationally or in specific regions, the Company's ability to access cash or enter into new financing arrangements may be threatened, which could have a material adverse effect on its business, financial condition and results of operations.

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Fair value measurement of assets and liabilities

We determine the fair values of our financial instruments based on the fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value assumes that the transaction to sell the asset or transfer the liability occurs in the principal or most advantageous market for the asset or liability and establishes that the fair value of an asset or liability shall be determined based on the assumptions that market participants would use in pricing the asset or liability. The classification of a financial asset or liability within the hierarchy is based upon the lowest level input that is significant to the fair value measurement. The fair value hierarchy prioritizes the inputs into three levels that may be used to measure fair value:

Level 1 - Inputs are unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 - Inputs are quoted prices for similar assets and liabilities in active markets or inputs that are observable for the asset or liability, either directly or indirectly through market corroboration, for substantially the full term of the financial instrument.

Level 3 - Inputs are unobservable inputs based on our assumptions.

The Company's financial instruments include cash and cash equivalents, accounts payable and the carrying value of the operating lease liabilities and notes payable. The carrying amounts of cash and accounts payable approximate their fair value, due to the short-term nature of these items. The carrying amounts of notes payable and operating lease liabilities approximate their fair values since they bear interest at rates which approximate market rates for similar debt instruments.

Net Loss per Common Share

Basic net loss per common share is computed by dividing the net loss attributable to Common Stockholders by the weighted average number of shares of Common Stock outstanding during the period. Diluted net loss per common share is computed by dividing the net loss attributable to Common Stockholders by the weighted average number of shares of Common Stock outstanding and potentially outstanding shares of Common Stock during the period to reflect the potential dilution that could occur from common shares issuable through stock options, warrants, and convertible debentures. For the three and six months ending September 30, 2024, December 31, 2024 and 2023, such amounts were excluded from the diluted loss since their effect was considered anti-dilutive due to the net loss for the periods presented.

The weighted average number of common shares outstanding at September 30, 2024 of 6,398,360 includes the weighted average effect of the pre-funded warrants issued in connection with the September 2024 Offering, the exercise of which requires nominal consideration for the delivery of the shares of common stock (see Note 8).

The table below shows the potential shares of common stock, presented based on amounts outstanding at each year period end, which were excluded from the computation of diluted net loss per share attributable to common stockholders because including them would have had an anti-dilutive effect:

	September 30, 2024 Number of Shares	September 30, 2023 Number of Shares	December 31, 2024 Number of Shares	December 31, 2023 Number of Shares
Stock Options	517,996	395,286	967,811	471,333
Warrants	4,316,002	777,029	9,600,835	777,029
Restricted Stock Units	34,564	55,773	97,067	68,743
Notes payable conversion option	35,817	71,633	-	71,633
Total	4,904,379	1,299,721	10,665,713	1,388,738

Reverse stock split

The company effected a 1:10 reverse split of the issued and outstanding shares of its Class A common stock which was approved by the board of directors after the approval obtained from shareholders at a special meeting on July 29, 2024 which became effective on Nasdaq on August 6, 2024, 5 trading days after the shareholders' approval was obtained. All historical share and earnings per share amounts have been retroactively adjusted to reflect the split.

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Grant program

The Company records expenses related to the DOD long Long Covid Program as such expenses are incurred. The reimbursement of such expenses is recognized upon receipt of the reimbursement as a credit against the respective expense account.

Recent Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses (“DISE”), which will require additional disclosure of the nature of expenses included in the income statement in response to longstanding requests from investors for more information about an entity’s expenses. The new standard requires disclosures about specific types of expenses included in the expense captions presented on the face of the income statement as well as disclosures about selling expenses. The new standard will be effective for public companies for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. The requirements will be applied prospectively with the option for retrospective application. Early adoption is permitted. The Company is currently evaluating the impact of this accounting standard update on its financial statements.

4. Intangible Assets

The Company's intangible assets consist of intellectual property acquired from LAT Pharma, Inc. and are amortized over their estimated useful lives.

The following is a summary of the Company's intangible assets:

	September 30, 2024	June 30, 2024	December 31, 2024	June 30, 2024
Intellectual Property	\$ 2,293,770	\$ 2,293,770	\$ 2,293,770	\$ 2,293,770
Less: Accumulated Amortization	(1,943,396)	(1,886,052)	(2,000,740)	(1,886,052)
Intellectual Property, Net	<u>\$ 350,374</u>	<u>\$ 407,718</u>	<u>\$ 293,030</u>	<u>\$ 407,718</u>

Amortization expense was \$57,344 in each of the three-month periods ended September 30, 2024, December 31, 2024 and 2023. Amortization expense was \$114,688 in each of the six-month periods ended December 31, 2024 and 2023. The Company amortizes intellectual property over the expected original useful lives of 10 years.

Estimated future amortization expense is as follows:

Year ending June 30, 2025 (Remaining 9 months)	\$ 172,033	
Year ending June 30, 2025 (Remaining 6 months)		\$ 114,689
2026	178,341	178,341
	<u>\$ 350,374</u>	<u>\$ 293,030</u>

5. Related Party Transactions

Equity Transactions with Acuitas

On July 15, 2022, the Company entered into a securities purchase agreement with Acuitas Group Holdings, LLC ("Acuitas"), the Company's largest stockholder, pursuant to which Acuitas agreed to purchase from the Company, in a private placement, (i) an aggregate of 363,636 shares of the Company's Common Stock, at a price of \$16.50 per share (the "PIPE Shares"), and (ii) a warrant to purchase 727,273 shares of Common Stock ("PIPE Warrant Shares"), at an exercise price of \$18.20, with a term of exercise of five years. The down round feature reduced the exercise price of the PIPE Warrant Shares to \$10.00 per share on March 6, 2024 and again to \$1.53 per share on September 25, 2024 and again to \$1.37 on October 22, 2024 in connection with the offering offerings further described in Note 8, as the Company sold stock at a price lower than its initial exercise price. The

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For the three months ended September 30, 2024, the Company calculated the difference in fair value of the PIPE Warrant Shares between the stated exercise price and the reduced exercise price and recorded \$325,041 as a deemed dividend in the accompanying ~~condesnsed~~ condensed statement of changes in stockholders' equity. The fair value of the PIPE Warrant Shares were estimated using the Black Scholes Method with the following inputs, the stock price of \$1.20, exercise price of \$1.53 and \$10.00, remaining term of 2.9 years, risk free rate of 3.5% and volatility of 93.0%.

Table For the three months ended December 31, 2024, the Company calculated the difference in fair value of Contents the PIPE Warrant Shares between the stated exercise price and the reduced exercise price and recorded \$44,424 as a deemed dividend in the accompanying condensed statement of changes in stockholders' equity. The fair value of the PIPE Warrant Shares were estimated using the Black Scholes Method with the following inputs, the stock price of \$3.36, exercise price of \$1.53 and \$1.37, remaining term of 2.8 years, risk free rate of 3.99% and volatility of 94.0%.

For the six months ended December 31, 2024, the Company recorded \$369,465 as a deemed dividend in the accompanying condensed statement in stockholders' equity.

Consulting expenses

During the three months ended December 31, 2024, the Company paid a Director of the Company \$50,000 for consulting services which are reflected as a component of selling, general and administrative expenses on the accompanying condensed statement of operations and comprehensive loss.

6. Notes Payable

On November 30, 2021 (the "Closing Date"), the Company entered into a Loan and Security Agreement and the Supplement to the Loan and Security Agreement and Promissory Notes (together, the "Loan Agreement") with Avenue Venture Opportunities Fund, L.P. ("AVOPI") and Avenue Venture Opportunities Fund II, L.P. ("AVOPII," and together with AVOPI, "Avenue") for growth capital loans in an aggregate commitment amount of up to \$20 million (the "Loan"). On the Closing Date, \$15 million of the Loan was funded ("Tranche 1"). The Loan provided for an additional \$5 million to be available to the Company on or prior to September 15, 2022, subject to the Company's achievement of certain milestones with respect to certain of its ongoing clinical trials, which were not achieved. The Loan bears bore interest at an annual rate equal to the greater of (a) the sum of 7.00% plus the prime rate as reported in The Wall Street Journal and (b) 10.75%. The prime rate on September 30, 2024, Loan was 8.50%. The Loan is secured by a lien upon and security interest in all of the Company's assets, including intellectual property, subject to agreed exceptions. The Loan was paid in full on its maturity date of the Loan is December 1, 2024.

The Loan Agreement required monthly interest-only payments during the first eighteen months of the term of the Loan. Following the interest-only period, on July 1, 2023, the Company pays equal monthly payments of principal, plus accrued interest, until the Loan's maturity date when all remaining principal and accrued interest is due. If the Company prepays the Loan, it will be required to pay (a) a prepayment fee in an amount equal to 3.0% of the principal amount of the Loan that is prepaid during the interest-only period; and (b) a prepayment fee in an amount equal to 1.0% of the principal amount of the Loan that is prepaid after the interest-only period. At the Loan's maturity date, or on the date of the prepayment of the Loan, the Company will be obligated to pay along with a final payment equal to 4.25% of the Loan commitment amount, or \$850,000, the sum of Tranche 1 and Tranche 2, which amounts to \$850,000 (the "Loan Premium").

The Loan Agreement includes included a conversion option to convert up to \$5.0 million of the principal amount of the Loan outstanding at the option of Avenue, into shares of the Company's Common Stock at a conversion price of \$69.80 per share (the "Conversion Option").

On the Closing Date, the Company also issued to Avenue warrants to purchase 36,101 shares of Common Stock of the Company (the "Avenue Warrants") at an exercise price per share equal to \$58.20. The Avenue Warrants are exercisable until November 30, 2026.

The amount of the carrying value of the notes payable was determined by allocating portions of the outstanding principal of the notes, resulting in approximately \$1.4 million allocated to the fair value of the Avenue Warrants, and approximately \$2.2 million allocated to the fair value of the embedded Conversion Option. Accordingly, the total amount of unearned discount of approximately \$3.6 million, the total direct financing cost of approximately \$390,000 and the Loan Premium of \$850,000 are being were amortized using the effective interest method over the term of the Loan. The adjusted effective interest rate is 24%.

Total interest expense associated with this loan the Loan was approximately \$252,000 62,000, which is reflected as a component of interest expense on the accompanying condensed statements of operations and comprehensive loss for the three months ended September 30, 2024 December 31, 2024. Interest expense associated with this loan was comprised of interest incurred on the outstanding principal of the loan of approximately \$132,000 33,000, amortization of financing costs of approximately \$9,500 2,000, amortization of the unearned discount of \$89,000 22,000, and the accretion of the Loan Premium of approximately \$21,000 5,000. Total interest expense associated with the Loan was approximately \$312,000, which is reflected as a component of interest expense on the accompanying condensed statements of operations and comprehensive loss for the six months ended December 31, 2024. Interest expense associated with this loan was comprised of interest incurred on the outstanding principal of the loan of approximately \$163,000, amortization of financing costs of approximately \$12,000, amortization of the unearned discount of approximately \$111,000, and the accretion of the Loan Premium of approximately \$26,000.

Total interest expense associated with the Loan for the three months ended September 30, 2023 December 31, 2023 was approximately \$1 682,000 on the accompanying condensed statements of operations and comprehensive loss. Interest expense was comprised of interest incurred on the outstanding principal of the loan of approximately \$429,000, amortization of financing costs of approximately \$31,000, amortization of the unearned discount of approximately \$289,000 and the accretion of Loan Premium of approximately \$67,000. Total interest expense associated with the Loan for the six months ended December 31, 2023 was approximately \$1.5 million on the accompanying condensed statements of operations and comprehensive loss. Interest expense was comprised of interest incurred on the outstanding principal of the loan of approximately \$525,000 955,000, amortization of financing costs of approximately \$38,000 69,000, amortization of the unearned discount of approximately \$356,000 645,000 and the accretion of Loan Premium of approximately \$82,000 149,000.

As of September 30, 2024, the remaining principal balance of \$2.5 million under the Loan is payable in 3 monthly equal installments. For the three months ended September 30, 2024, the Company paid back \$2.5 million of the original loan of \$15 million.

The following is a summary of the Notes Payable as of September 30, 2024 December 31, 2024 and June 30, 2024:

Current portion of Notes Payable			
	September 30, 2024		June 30, 2024
Current portion of Notes Payable	\$ 2,500,000	\$	5,000,000
Less: debt financing costs	(2,364)		(11,820)
Less: unearned discount	(22,242)		(111,212)
Plus: accretion of Loan Premium	844,848		824,242
Current portion of Notes Payable, net of financing costs, unearned premium and discount	\$ 3,320,242	\$	5,701,210
Estimated future amortization expense and accretion of Loan Premium are as follows:			
	Unearned Discount	Debt Financing Costs	Loan Premium
Year ending June 30, 2025 (Remaining 9 months)	\$ 22,242	\$ 2,364	\$ 5,152
Total	\$ 22,242	\$ 2,364	\$ 5,152

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	December 31, 2024	June 30, 2024
Current portion of Notes Payable	\$ -	\$ 5,000,000
Less: debt financing costs	-	(11,820)
Less: unearned discount	-	(111,212)
Plus: accretion of Loan Premium	-	824,242
Current portion of Notes Payable, net of financing costs, unearned premium and discount	<u>\$ -</u>	<u>\$ 5,701,210</u>

7. Fair Value Measurements

At **September 30, 2024** December 31, 2024 and June 30, 2024, the estimated fair value of derivative liabilities measured on a recurring basis are as follows:

	Fair Value Measurements at September 30, 2024				Fair Value Measurements at December 31, 2024			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Derivative liability - Warrants	\$ -	\$ -	\$ 1,254	\$ 1,254	\$ -	\$ -	\$ 7,290	\$ 7,290
Derivative liability - Conversion Option	-	-	-	-	-	-	-	-
Total derivative liabilities	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 1,254</u>	<u>\$ 1,254</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 7,290</u>	<u>\$ 7,290</u>

	Fair Value Measurements at June 30, 2024			
	Level 1	Level 2	Level 3	Total
Derivative liability - Warrants	\$ -	\$ -	\$ 3,771	\$ 3,771
Derivative liability - Conversion option	-	-	-	-
Total derivative liabilities	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 3,771</u>	<u>\$ 3,771</u>

The following table presents the activity for level 3 liabilities measured at fair value using unobservable inputs for the three months ended September 30, 2024:

	Derivative liabilities - Warrants	Derivative liability - Conversion Option on Convertible Debenture
Balance at June 30, 2024	\$ 3,771	\$ -
Additions to level 3 liabilities	-	-
Change in fair value of level 3 liabilities	(2,517)	-
Transfer in and/or out of Level 3	-	-
Balance at September 30, 2024	<u>\$ 1,254</u>	<u>\$ -</u>

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The following table presents the activity for level 3 liabilities measured at fair value using unobservable inputs for the **three** **six** months ended **September 30, 2023** **December 31, 2024**:

	Derivative liability - Warrants	Derivative liability - Conversion Option
Balance at June 30, 2023	\$ 894,280	\$ 925,762
Additions to level 3 liabilities	-	-
Change in fair value of level 3 liabilities	(271,883)	(435,919)
Transfer in and/or out of level 3	-	-
Balance at September 30, 2023	\$ 622,397	\$ 489,843

	Derivative liabilities - Warrants	Derivative liability - Conversion Option
Balance at June 30, 2024	\$ 3,771	\$ -
Additions to level 3 liabilities	-	-
Change in fair value of level 3 liabilities	3,519	-
Transfer in and/or out of Level 3	-	-
Balance at December 31, 2024	\$ 7,290	\$ -

The following table presents the activity for level 3 liabilities measured at fair value using unobservable inputs for the six months ended December 31, 2023;

	Derivative liability - Warrants	Derivative liability - Conversion Option
Balance at June 30, 2023	\$ 894,280	\$ 925,762
Additions to level 3 liabilities	-	-
Change in fair value of level 3 liabilities	(771,122)	(919,214)
Transfer in and/or out of level 3	-	-
Balance at December 31, 2023	\$ 123,158	\$ 6,548

The fair **values** **value** of derivative liabilities for the Avenue Warrants and Conversion Option at **September 30, 2024** **December 31, 2024**, in the accompanying condensed balance sheets, **were approximately \$1,300 and approximately zero, respectively.** **was \$7,290.** The total change in the fair value of the derivative liabilities totaled approximately **\$2,500** **\$3,519** and **\$708,000** **\$1.7 million** for the **three** **six** months ended **September 30, 2024** **December 31, 2024** and 2023, respectively; and accordingly, was recorded in the accompanying condensed statements of operations and comprehensive loss. The assumptions used in the Black Scholes model to value the derivative liabilities at **September 30, 2024** **December 31, 2024** included the closing stock price of **\$1.20** **2.00** per share; for the Avenue Warrants, the exercise price of \$58.20, remaining term **2.2** **1.9** year, years, risk free rate of **3.7%** **4.2%** and volatility of **91.0%** **95.0%**; and for the **.** The Conversion Option the conversion price was nil as of **\$69.80**; remaining term of 2 months, risk free rate of **4.8%** **December 31, 2024** and volatility of **75.0%** **June 30, 2024**.

Derivative liability – Avenue Warrants

The Avenue Warrants were not considered to be indexed to the Company's own stock, and accordingly, were recorded as a derivative liability at fair value in the accompanying condensed balance sheets at **September 30, 2024** **December 31, 2024** and June 30, 2024, respectively.

The Black Scholes model was used to calculate the fair value of the derivative warrant to bifurcate the amount from the Avenue Loan amount funded. The Avenue Warrants are recorded at **their** fair **values** **value** at the date of issuance and remeasured at each subsequent reporting period end date.

Embedded derivative liability – Conversion Option

The Conversion Option ~~is~~ **was** accounted for as an embedded derivative liability and required bifurcation from the Loan amount. The Black Scholes model was used to calculate the fair value of the Conversion Option to bifurcate it from the Loan.

Financial assets

As of **September 30, 2024** **December 31, 2024**, investments in U.S. Treasury Bills were valued through use of quoted prices and are classified as Level 1. The following table presents information about our assets that are measured at fair value on a recurring basis using the above input categories.

	Fair Value Measurements at September 30, 2024			
	Level 1	Level 2	Level 3	Total
Cash	\$ 6,326,252	\$ -	\$ -	\$ 6,326,252
U.S. Treasury Bills due in 3 months or less at purchase	13,697,153	-	-	13,697,153
Total	<u>\$ 20,023,405</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 20,023,405</u>

Fair Value Measurements at December 31, 2024				
	Level 1	Level 2	Level 3	Total
Cash	\$ 4,326,075	\$ -	\$ -	\$ 4,326,075
U.S. Treasury Bills due in 3 months or less at purchase	20,079,442	-	-	20,079,442
Total	<u>\$ 24,405,517</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 24,405,517</u>

Fair Value Measurements at June 30, 2024				
	Level 1	Level 2	Level 3	Total
Cash	\$ 12,763,941	\$ -	\$ -	\$ 12,763,941
U.S. Treasury Bills due in 3 months or less at purchase	11,079,857	-	-	11,079,857
Total	<u>\$ 23,843,798</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 23,843,798</u>

8. Equity Transactions

Issuance of common stock for cash

On August 31, 2022, the Company entered into a Controlled Equity Offering Sales Agreement (the “Sales Agreement”) with Cantor Fitzgerald & Co. and B. Riley Securities, Inc. (collectively, the “Agents”), pursuant to which the Company may issue and sell from time-to-time shares of the Company’s common stock through the Agents, subject to the terms and conditions of the Sales Agreement. On April 6, 2023, the Company and B. Riley Securities, Inc. mutually agreed to terminate B. Riley Securities, Inc.’s role as a sales agent under the Sales Agreement. During the three months ended **September 30, 2024** **December 31, 2023**, the Company sold **2,143** 290,090 shares of common stock under the Sales Agreement for total net proceeds of approximately **\$6,400** 7.4 million after 3% commissions and expenses of approximately **\$200** 258,000. During the **three** six months ended **September 30, 2023** **December 31, 2023**, the Company sold **43,220** 333,310 shares of common stock under the Sales Agreement for total net proceeds of approximately **\$1.9** 9.3 million after 3% commissions and expenses of approximately **\$119,000** 377,000. During the six months ended December 31, 2024, the Company sold approximately 2,143 shares of its Common Stock under its Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co for total net proceeds of approximately \$6,400 after 3% commissions and offering costs totaling approximately \$200. On September 25, 2024, the Company filed a prospectus supplement to suspend sales under the Controlled Equity Offering Sales Agreement.

On September 25, 2024, the Company closed a best efforts public offering (the “September 2024 Offering”) of 1,360,800 shares of its common stock, par value \$0.0001 per share, pre-funded warrants (the “September Pre-funded Warrants”) to purchase 600,000 shares of Common Stock, and warrants to purchase up to 1,960,800 shares of Common Stock (the “September Common Warrants”) at a combined public offering price of \$1.53 per **Share, share**, or September Pre-funded Warrant, and the associated September Common Warrant. 265,000 September Pre-funded Warrants were exercised in the three months ended September 30, 2024 and reflected on the condensed statement of changes in stockholders’ equity as a component of proceeds from issuance of common stock. The September Common Warrants have an exercise price of \$1.53 per share and **are were** immediately exercisable upon issuance and will expire on the fifth anniversary date of the original issuance date. The gross proceeds to the Company from the September 2024 Offering were approximately \$3.0 million, before deducting placement agent fees and offering expenses of approximately \$747,000. Additionally, upon closing, the Company issued the placement agent warrants (“September Placement Agent’s Warrants”) to purchase 98,040 shares of Common Stock exercisable at a per share price of \$1.91, which was equal to 125% of the public offering price per share. The September Placement Agent’s Warrants are exercisable during a five-year period commencing 180 days from September 25, 2024.

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In October 2024, the Company closed three registered direct offerings totaling 8,256,000 shares of its common stock, par value \$0.0001 per share, and two concurrent private placements of warrants to purchase up to 7,110,000 shares of Common Stock (the “October Common Warrants”) priced at-the-market under Nasdaq rules at prices ranging from \$1.50 to \$2.83 per share (the “October Offerings”). The October Common Warrants have exercise prices ranging from \$1.37 to \$2.12 per share and are exercisable beginning six months following issuance and will expire on the fifth anniversary date of the original issuance dates. The gross proceeds to the Company from the October Offerings totaled approximately \$15.9 million, before deducting placement agent fees and offering expenses of approximately \$2.5 million. Additionally, upon closing of the October Offerings, the Company issued placement agent warrants (the “October Placement Agent’s Warrants”) to purchase 412,800 shares of Common Stock in the aggregate exercisable at a per share price ranging from \$1.88 to \$3.54, which was equal to 125% of the offering price per share in the applicable October Offering. The October Placement Agent’s Warrants are exercisable during a five-year period commencing 180 days from each of the respective closing dates of the October Offerings. During the three months ended December 31, 2024, 1,896,300 of common warrants from the September 2024 Offering were exercised at \$1.53 per share for proceeds totaling approximately \$2.9 million, and 335,000 September Pre-funded Warrants were also exercised. In addition, 6,667 September Placement Agent’s Warrants were exercised on a cashless exercise basis and 4,214 common shares were issued.

Issuance of common stock for services

On August 12, 2024, the Company awarded 15,000 shares of Common Stock to a vendor as part of their fees in exchange for services. The fair value of the Common Stock at the date of issuance was \$2.23 per share. The stock-based compensation expense related to this Common Stock issuance was \$33,450.

Stock Options

The following table summarizes the activity relating to the Company’s stock options for the **three** six months ended **September 30, 2024** December 31, 2024:

	Options	Weighted-Average Exercise Price	Weighted Remaining Average Contractual Term	Aggregate Intrinsic Value	Options	Weighted-Average Exercise Price	Weighted Remaining Average Contractual Term	Aggregate Intrinsic Value
Outstanding at June 30, 2024	518,076	\$ 54.11	6.1	\$ -	518,076	\$ 54.11	6.1	\$ -
Options Granted					490,261	2.40	7.1	-
Options Expired	(80)	87.50	-	-	(31,736)	71.34	-	-
Outstanding at September 30, 2024	517,996	\$ 54.10	5.9	\$ -				
Exercisable at September 30, 2024	321,382	\$ 66.77	4.7	\$ -				
Options Canceled					(8,790)	17.01	-	-
Outstanding at December 31, 2024					967,811	\$ 27.69	6.4	\$ 32,196

Exercisable
at
December
31, 2024

409,987 \$ 48.46 5.6 \$ 10,732

The fair value of each option on the date of grant is estimated using the Black-Scholes option pricing model. The pricing model reflects the following weighted-average assumptions for the six months ended December 31, 2024 and 2023:

	December 31, 2024	December 31, 2023
Expected life of options (in years)	4	5
Expected volatility	93.44%	87.11%
Risk free interest rate	4.34%	4.80%
Dividend Yield	0%	0%

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On December 20, 2024, the Company issued to employees and directors stock options to purchase 208,902 and 113,055 shares of common stock, respectively; at an exercise price of \$1.90, the Company's stock price at the close on December 20, 2024. The fair value of the stock options issued to Directors were \$1.20 per share. The fair value of the stock options issued to Management was \$1.43 per share.

The Company recorded stock based stock-based compensation expense relating to the vesting of stock options of approximately \$119,000 385,000 and \$808,000 620,000 for the three months ended September 30, 2024 December 31, 2024 and 2023, respectively. The total stock-based compensation expense from stocks options for the six months ended December 31, 2024 and 2023 was \$504,000 and \$1.4 million, respectively.

Restricted stock units:

On November 9, 2023 November 20, 2024, the Company issued equity awards for as part of the board of directors' annual compensation. Four Two directors received 18,270 66,900 RSUs restricted stock units ("RSUs") with a grant date fair value of \$30.10 3.36 per share. In addition, two share and three directors received stock options to purchase 18,325 168,300 shares of common stock at an exercise price of \$30.10 3.36 per share with a grant date fair value of \$18.30 \$2.11 per share. The equity awards RSUs vest quarterly on February 9, 2024 February 8, 2025, May 9, 2024 May 8, 2025, August 9, 2024 August 8, 2025 and the earlier of November 9, 2024 November 8, 2025 or the next annual shareholders' meeting. During the three months ended September 30, 2024 December 31, 2024, 3,409 3,410 shares were issued related to the final tranche of these RSUs vested. On July 25, 2024, Mr. Gorlin resigned that vested, from the Board directors' annual equity awards granted November 9, 2023.

Additionally, during the three months ended December 31, 2024, 397 shares were issued related to the vesting of Directors, and as RSUs previously awarded to a result, 1,159 of his RSUs were cancelled. consultant.

The following table summarizes vesting of the unvested restricted stock units: units outstanding at June 30, 2024 and December 31, 2024:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested at June 30, 2024	40,291	\$ 44.59	40,291	\$ 44.59
Issued			66,900	3.36
Vested	(3,409)	30.10	(15,291)	47.33
Canceled	(1,159)	-	(2,913)	36.45
Unvested at September 30, 2024	35,723	\$ 46.99		
Unvested at December 31, 2024			88,987	\$ 13.41

The total stock-based compensation expense from restricted stock units for the three months ended September 30, 2024 December 31, 2024 and 2023 was approximately \$301,000 266,000 and \$381,000 303,000, respectively. The total stock-based compensation expense from restricted stock units for the six months ended December 31, 2024 and 2023 was approximately \$567,000 and \$684,000, respectively.

There were 8,080 RSUs that vested on November 23, 2024 and the related shares of common stock will be issued and delivered by March 15, 2025.

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Stock Warrants

The following table summarizes the warrants activity during the **three** **six** months ended **September 30, 2024** **December 31, 2024**:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
Outstanding and exercisable at June 30, 2024	1,932,029	14.03	4.0	-	1,932,029	\$ 14.03	4.0	\$ -
Granted	2,658,840	1.54	5.0	-	10,181,640	1.65	4.8	-
Exercised	(265,000)	1.53	-	-	(2,502,967)	1.53	-	-
Expired	(9,867)	22.50	-	-	(9,867)	22.50	-	-
Outstanding and exercisable at September 30, 2024	4,316,002	\$ 5.66	4.5	\$ -				
Outstanding and exercisable at December 31, 2024					9,600,835	\$ 3.50	4.6	\$ 3,322,376

Of The table below shows the above expiration of the warrants outstanding at September 30, 2024, 271 expire in the fiscal year ending June 30, 2025, 3,518 expire in the fiscal year ending June 30, 2026, 763,373 expire in the fiscal year ending June 30, 2027, 1,155,000 expire in the fiscal year ending June 30, 2029 and 2,393,840 expire in the fiscal year ending June 30, 2030. as of December 31, 2024:

As of September 30, 2024, the Company had 335,000 prefunded warrants, 3,882,962 warrants and 98,040 placement agent warrants outstanding.

	Number of Warrants
Expiring June 30, 2025	271
2026	3,518
2027	36,100
2028	727,273
2029	1,155,000
2030	7,678,673
Total outstanding warrants	9,600,835

9. Leases

Office Leases

The Company pays an annual rent of \$2,200 for its headquarters at 680 W Nye Lane, Suite 201, Carson City Nevada 89703. The rental agreement was for a one-year term, commenced on October 1, 2023, and has been subsequently renewed for another year at the same rate.

The Company's San Diego office lease at 5090 Shoreham Place Suite 212, San Diego, CA 92122 commenced in February 2024. The current monthly base rate for the office space is \$9,685, with an annual increase of four percent. The term for the office lease is 60 months.

Total operating lease expense for the three months ended September 30, 2024 December 31, 2024 and 2023 of was approximately \$32,000 and \$13,000, respectively, were and for the six months ended December 31, 2024 and 2023 was approximately \$63,000 and \$26,000, respectively, which is included in the accompanying condensed statements of operations and comprehensive loss as a component of selling, general and administrative expenses.

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The right-of-use asset, net and current and non-current portion of the operating lease liabilities included in the accompanying condensed balance sheets are as follows:

	September 30, 2024	June 30, 2024	December 31, 2024	June 30, 2024
Assets				
Operating lease right-of-use asset, net	\$ 390,777	\$ 406,726	\$ 374,303	\$ 406,726
Liabilities				
Current portion of operating lease liability	\$ 63,664	\$ 60,343	\$ 67,111	\$ 60,343
Operating lease liability, net of current portion	332,730	349,894	314,915	349,894
Total operating lease liability	\$ 396,394	\$ 410,237	\$ 382,026	\$ 410,237

At September 30, 2024 December 31, 2024, the future estimated minimum lease payments under non-cancelable operating leases are as follows:

Year ending June 30, 2025 (Remaining 9 months)	\$ 89,199	
Year ending June 30, 2025 (Remaining 6 months)		\$ 59,805
2026	122,042	122,042
2027	126,313	126,313
2028	130,734	130,734
2029	77,796	77,796
Total minimum lease payments	546,084	516,690
Less amount representing interest	(149,690)	(134,664)
Present value of future minimum lease payments	396,394	382,026
Less current portion of operating lease liability	(63,664)	(67,111)
Operating lease liability, net of current portion	\$ 332,730	\$ 314,915

Total cash paid for amounts included in the measurement of lease liabilities were \$29,055 58,110 and \$12,900 25,800 for the three six months ended September 30, 2024 December 31, 2024 and 2023, respectively.

The weighted average remaining lease term and discount rate as of September 30, 2024 December 31, 2024 and June 30, 2024 were as follows:

	September 30, 2024	June 30, 2024	December 31, 2024	June 30, 2024
Weighted average remaining lease term (Years)				
Operating lease	4.3	4.6	4.1	4.6
Weighted average discount rate				
Operating lease	15.00 %	15.00 %	15.00 %	15.00 %

10. Commitments and Contingencies

Royalty Agreements

Pursuant to the Agreement and Plan of Merger entered into on April 11, 2016, by and between our predecessor entities, LAT Pharma and NanoAntibiotics, Inc., the Company is obligated to pay a low single digit royalty on net sales of BIV201 (continuous infusion terlipressin) to be shared by the members of LAT Pharma Members, PharmaIn Corporation, and The Barrett Edge, Inc.

Pursuant to the Technology Transfer Agreement entered into on July 25, 2016, by and between the Company and the University of Padova (Italy), the Company is obligated to pay a low single digit royalty on net sales of all terlipressin products covered by US patent no. 9,655,645 and any future foreign issuances, capped at a maximum of \$200,000 per year.

Shareholder class action complaint

On January 19, 2024, a purported shareholder class action complaint, captioned *Eric Olmstead v. BioVie Inc. et al.*, No. 3:24-cv-00035, was filed in the U.S. District Court for the District of Nevada, naming the Company and certain of its officers as defendants. On February 22, 2024, a second, related putative securities class action was filed in the same court asserting similar claims against the same defendants, captioned *Way v. BioVie Inc. et al.*, No. 2:24-cv-00361. On April 15, 2024, the court consolidated these two actions under the caption *In re BioVie Inc. Securities Litigation*, No. 3:24-cv-00035, appointed the lead plaintiff, and approved selection of the lead counsel. On June 21, 2024, the lead plaintiff filed an amended complaint, alleging that the defendants made material misrepresentations and/or omissions of material fact relating to the Company's business, operations, compliance, and prospects, including information related to the NM101 Phase 3 study and trial of bezisterim (NE3107) in mild to moderate probable AD, in violation of Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5 promulgated thereunder. The class action is on behalf of purchasers of the Company's securities during the period from December 7, 2022 through November 28, 2023, and seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorney's fees. The defendants filed a motion to dismiss the amended complaint on August 21, 2024, and plaintiffs filed their opposition on October 21, 2024. The defendant's and the defendants' reply brief is due was filed on December 5, 2024.

On December 30, 2024, a shareholder derivative lawsuit was filed in the United States District Court for the District of Nevada by putative stockholder Andrew Hulm, allegedly on behalf of the Company, that piggy-backs on the securities class action also pending in that court. The derivative complaint names certain current and former officers and directors as defendants, and generally alleges that they breached their fiduciary duties by causing or failing to prevent the securities violations alleged in the securities class action.

The Company believes that the lawsuit is claims are without merit and intends intend to defend vigorously against them, but there can be no assurances as to the case vigorously. At this early stage of the proceedings, the Company is unable to make any prediction regarding the outcome of the litigation. No adjustment or accruals have been reflected in the accompanying condensed financial statements. outcome.

11. Employee Benefit Plan

On August 1, 2021, the Company began sponsoring an employee benefit plan subject to Section 401(K) of the Internal Revenue Service Code (the "401K Plan") pursuant to which, all employees meeting eligibility requirements are able to participate.

Subject to certain limitations in the Internal Revenue Code, eligible employees are permitted to make contributions to the 401K Plan on a pre-tax salary reduction basis and the Company will match 5% of the first 5% of an employee's contributions to the 401K Plan. The Company made contributions into the plan of approximately \$34,500 27,500 and \$30,900 20,500, for the three months ended September 30, 2024 December 31, 2024 and 2023, respectively. The Company made contributions into the plan of approximately \$62,000 and \$51,400, for the six months ended December 31, 2024 and 2023, respectively.

12. Subsequent Events

In October 2024, the Company closed three registered direct offerings totaling 8,256,000 shares of its common stock, par value \$0.0001 per share, and two concurrent private placements of warrants to purchase up to 8,256,000 shares of Common Stock (the “October Common Warrants”) priced at-the-market under Nasdaq rules at prices ranging from \$1.50 to \$2.83 per share (the “October Offerings”). The October Common Warrants have exercise prices ranging from \$1.37 to \$2.83 per share and are exercisable beginning six months following issuance and will expire on the fifth anniversary date of the original issuance dates. The gross proceeds to the Company from the October Offerings totaled approximately \$15.9 million, before deducting placement agent fees and offering expenses of approximately \$2.8 million. Additionally, upon closing of the October Offerings the Company issued placement agent warrants (the “October Placement Agent’s Warrants”) to purchase 412,800 shares of Common Stock in the aggregate exercisable at a per share price ranging from \$1.88 to \$3.54, which was equal to 125% of the offering price per share in the applicable October Offering. The October Placement Agent’s Warrants are exercisable during a five-year period commencing 180 days from each of the respective closing dates of the October Offerings. Additionally in October, 1,216,300 of the common warrants from the September 2024 Offering were exercised at \$1.53 per share for proceeds totaling approximately \$1.9 million.

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

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, and Section 27A of the Securities Act of 1933, as amended. Any statements contained in this report that are not statements of historical fact may be forward-looking statements. When we use the words "intends," "estimates," "predicts," "potential," "continues," "anticipates," "plans," "expects," "believes," "should," "could," "may," "will" or the negative of these terms or other comparable terminology, we are identifying forward-looking statements. Forward-looking statements involve risks and uncertainties, which may cause our actual results, performance or achievements to be materially different from those expressed or implied by forward-looking statements. These factors include, among others: our research and development activities and distributor channel; compliance with regulatory requirements; and our ability to satisfy our capital needs. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements.

You are cautioned not to place undue reliance on the forward-looking statements in this report, which speak only as of the date of this report. Except as may be required by applicable law, we do not undertake or intend to update or revise our forward-looking statements, and we assume no obligation to update any forward-looking statements contained in this report as a result of new information or future events or developments, except as required by law. Thus, you should not assume that our silence over time means that actual events are bearing out as expressed or implied in such forward-looking statements. You should carefully review and consider the various disclosures we make in this report and our other reports filed with the Securities and Exchange Commission (the "SEC") that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

The following discussion of the Company's financial condition and the results of operations should be read in conjunction with the Financial Statements and Notes thereto appearing elsewhere in this report.

Management's Discussion

BioVie Inc. (the "Company" or "we" or "our") is a clinical-stage company developing innovative drug therapies to treat chronic debilitating conditions including neurological and neuro-degenerative disorders and liver disease.

Neurodegenerative Disease Program

The Company acquired the biopharmaceutical assets of NeurMedix, Inc. ("NeurMedix") a privately held clinical-stage pharmaceutical company and a related party in June 2021. The acquired assets included NE3107. In April 2024, the Company announced that the United States Adopted Names Council, and the World Health Organization International Nonproprietary Names expert committee had approved "bezisterim" as the non-proprietary (generic) name for NE3107. Bezisterim (NE3107) is an investigational, novel, orally administered small molecule that is thought to inhibit inflammation-driven insulin resistance and major pathological inflammatory cascades with a novel mechanism of action. There is emerging scientific consensus that both inflammation and insulin resistance may play fundamental roles in the development of AD and PD, and bezisterim (NE3107) could, if approved by FDA, represent an entirely new medical approach to treating these devastating conditions affecting an estimated 6 million Americans suffering from AD and 1 million Americans suffering from PD.

In neurodegenerative disease, bezisterim (NE3107) inhibits activation of inflammatory ERK and nuclear factor kappa-light-chain-enhancer of activated B cells ("NFκB") (including interactions with TNF signaling and other relevant inflammatory pathways) that lead to neuroinflammation and insulin resistance. Bezisterim (NE3107) does not interfere with their homeostatic functions (e.g., insulin signaling and neuron growth and survival). Both inflammation and insulin resistance are drivers of AD and PD.

Chronic neuroinflammation, insulin resistance, and oxidative stress are common features in the major neurodegenerative diseases, including AD, PD, frontotemporal lobar dementia, and Amyotrophic lateral sclerosis. Bezisterim (NE3107) is an investigational oral small molecule, blood-brain permeable, compound with potential anti-inflammatory, insulin sensitizing, and ERK-binding properties that may allow it to selectively inhibit ERK-, NFκB- and TNF-stimulated inflammation. Bezisterim's (NE3107) potential to inhibit neuroinflammation and insulin resistance forms the basis for the Company's work testing the molecule in AD, PD, and long COVID patients. Bezisterim (NE3107) is patented in the United States, Australia, Canada, Europe and South Korea.

Parkinson's Disease

Parkinson's disease ("PD") is driven in large part by neuroinflammation and activation of brain microglia, leading to increased proinflammatory cytokines (particularly TNF). Multiple daily administrations of levodopa (converted to dopamine in the brain) is the current standard of care treatment for this movement disorder. However, levodopa effectiveness diminishes over time necessitating increased dosage and prolonged daily administration leads to side effects of uncontrolled movements called levodopa-induced dyskinesia, commonly referred to as LID, which is exacerbated by high dose levodopa. Although levodopa provides symptomatic benefit, it does not slow PD progression.

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The Phase 2 study of bezisterim (NE3107) for the treatment of PD (NCT05083260), completed in December 2022, was a double-blind, placebo-controlled, safety, tolerability, and pharmacokinetics study in PD participants treated with carbidopa/levodopa and bezisterim (NE3107). Forty-five patients with a defined L-dopa “off state” were randomized 1:1 to placebo: bezisterim (NE3107) 20 mg twice daily for 28 days. This trial was launched with two design objectives: 1) the primary objective was safety and a drug-drug interaction study as requested by the FDA to measure the potential for adverse interactions of bezisterim (NE3107) with carbidopa/ levodopa; and 2) the secondary objective was to determine if preclinical indications of promotoric activity and apparent enhancement of levodopa activity could be seen in humans. Both objectives were met.

To extend this Phase 2 data in progressed patients, the Company has designed a new Phase 2 study of bezisterim (NE3107) as a potential first line therapy to treat patients with new onset PD. In August/July 2024, the Company submitted the new protocol and received a response from the FDA authorized which permitted the protocol for this new Company to proceed with the study. The trial is anticipated to commence during the first calendar quarter of 2025.

Long COVID Program

In April 2024, the Company announced the grant of a clinical trial award of up to \$13.1 million from the U.S. Department of Defense (“DOD”), awarded through the Peer Reviewed Medical Research Program of the Congressionally Directed Medical Research Programs. In August 2024, U.S. Army Medical Research and Development Command, Office of Human Research Oversight (“OHRO”) approved the Company’s plan to evaluate bezisterim (NE3107) for the treatment of neurological symptoms that are associated with long COVID. and the FDA authorized our Investigational New Drug (“IND”) application for bezisterim (NE3107) allowing us the Company to study a novel, anti-inflammatory approach or the treatment of the debilitating neurocognitive symptoms associated with long covid. The Company anticipates the trial to commence by early 2025.

Liver Disease Program

In liver disease, our investigational drug candidate BIV201 (continuous infusion terlipressin), which has been granted both FDA Fast Track designation status and FDA Orphan Drug status, is being evaluated and discussed after receiving guidance from the FDA regarding the design of Phase 3 clinical testing of BIV201 for the treatment of ascites due to chronic liver cirrhosis. BIV201 is administered as a patent-pending liquid formulation.

In June 2021, the Company initiated a Phase 2 study (NCT04112199) designed to evaluate the efficacy of BIV201 (terlipressin, administered by continuous infusion for two 28-day treatment cycles) combined with standard-of-care (“SOC”), compared to SOC alone, for the treatment of refractory ascites. The primary endpoints of the study are the incidence of ascites-related complications and change in ascites fluid accumulation during treatment compared to a pre-treatment period.

In March 2023, the Company announced enrollment was paused and that data from the first 15 patients treated with BIV201 plus SOC appeared to show at least a 30% reduction in ascites fluid during the 28 days after treatment initiation compared to the 28 days prior to treatment. The change in ascites volume was significantly different from those patients receiving SOC treatment. Patients who completed the treatment with BIV201 experienced a 53% reduction in ascites fluid, which was sustained (43% reduction) during the three months after treatment initiation as compared to the three-month pre-treatment period.

In June 2023, the Company requested and subsequently received guidance from the FDA regarding the design and endpoints for definitive clinical testing of BIV201 for the treatment of ascites due to chronic liver cirrhosis. The Company is currently finalizing protocol designs for the Phase 3 study of BIV201 for the treatment of ascites due to chronic liver cirrhosis.

While the active agent, terlipressin, is approved in the U.S. and in about 40 countries for related complications of advanced liver cirrhosis, treatment of ascites is not included in these authorizations. Patients with refractory ascites suffer from frequent life-threatening complications, generate more than \$5 billion in annual treatment costs, and have an estimated 50% mortality rate within 6 to 12 months. The FDA has not approved any drug to treat refractory ascites.

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Comparison of the three months ended **September 30, 2024** **December 31, 2024** to the three months ended **September 30, 2023** **December 31, 2023**

Net loss

The net loss for the three months ended **September 30, 2024** **December 31, 2024** was approximately **\$4.2 million** and **\$7.1 million** as compared to the net loss of **\$10.7 million** **\$8.4 million** for the three months ended **September 30, 2023** **December 31, 2023**. The net decrease of **\$6.5 million** **\$1.3 million** for the three months ended **September 30, 2024** **December 31, 2024** was comprised of a decrease in research and development expenses of **\$6.9 million** **\$1.8 million**, offset by increased selling, general and administrative expenses of approximately **\$132,000** **\$277,000** and a decrease in other (expense) income, net of approximately **\$195,000** **\$200,000**.

Total operating expenses for the three months ended **September 30, 2024** **December 31, 2024** were approximately **\$4.1 million** **\$7.3 million** as compared to **\$10.9 million** **\$8.8 million** for the three months ended **September 30, 2023** **December 31, 2023**. The net decrease of approximately **\$6.8 million** **\$1.5 million** for the three months ended **September 30, 2024** **December 31, 2024** was comprised of decreased research and development expenses of approximately **\$6.9 million** **\$1.8 million** primarily due to the completion of clinical trials in the prior fiscal year, offset by a net increase in selling general and administrative expenses of approximately **\$132,000**, primarily attributed to increased legal expenses related to regulatory, patent filings and litigation related to the class action suit, **\$277,000**.

Research and Development Expenses

Research and development (“R&D”) expenses were approximately **\$2.0 million** **\$4.7 million** and **\$6.5 million** for the three months ended **September 30, 2024**, **December 31, 2024** and **2023**, respectively. The **\$1.8 million** net decline of approximately **\$6.9 million** from **\$8.9 million** for three months ended **September 30, 2023**. The net decrease in R&D expenses of approximately **\$6.9 million** was primarily attributed to the completion increase in direct cost related to the development and preparation of the new clinical trials studies to be launched in the first calendar quarter of 2025 of **\$3.4 million**; offset by the decline in cost of approximately **\$3.1 million** from completed studies; and other decreases in related expenses such as the clinical teams’ payroll of approximately **\$461,000**, reflecting the reduction in force in December 2023, and a decrease in consultancy expense of approximately **\$1.0 million**, resulting from declining use of consultants as the clinical studies were completed in the prior fiscal year, ended **June 30, 2024**, causing decreased clinical trials expenses of **\$5.2 million**, a decline decrease in the clinical team expense consisting of reductions in clinical team payroll of **Chemistry, Manufacturing and Controls (“CMC”)** and new drug discovery totaling approximately **\$915,000**, reduction in the use of consultants of approximately **\$547,000**, **\$344,000**, a reduction in the use of regulatory and other consultants totaling approximately **\$274,000**, **\$186,000**, and a decrease in other related expenses of approximately **\$126,000** **\$59,000** in travel, conferences and publications. This was offset by increased expenses in **Chemistry, Manufacturing and Controls (“CMC”)** totaling approximately **\$155,000** related to drug production and drug discovery development.

The decline in clinical studies of **\$5.2 million** represented the net decrease in clinical trial studies expense due the completion of the clinical trials in fiscal year 2024 offset by the planning and development of the two new clinical studies **PD** and **LC**. The table below summarizes the expense amounts expenses incurred for the three months ended **September 30, 2024** **December 31, 2024** and 2023 by study:

	Three Months Ended September 2024	Three Months Ended September 2023	Increase (Decrease)	Three Months Ended December 31, 2024	Three Months Ended December 31, 2023	Increase (Decrease)
New Development						
Current Studies						
Sunrise PD Phase 2	\$ 241,000	\$ -	\$ 241,000	\$ 1,161,342	\$ -	\$ 1,161,342
Long Covid Program, net of \$325,000 reimbursement	145,000	-	145,000			
Long Covid Program				2,255,898	-	2,255,898
Investigator-Initiated studies				2,159	-	2,159
	<u>\$ 386,000</u>	<u>\$ -</u>	<u>\$ 386,000</u>	<u>\$ 3,419,399</u>	<u>\$ -</u>	<u>\$ 3,419,399</u>
Completed Studies						

Ascites BIV201 Phase 2b	\$	(60,000)	\$	384,000	\$	(444,000)	\$	48,562	\$	132,633	\$	(84,071)
AD mild to moderate pivotal Phase 3		27,000		3,636,000		(3,609,000)		26,091		2,685,413		(2,659,322)
PD Phase 2		-		440,000		(440,000)		-		308,705		(308,705)
Investigator-Initiated studies		-		1,081,000		(1,081,000)		-		14,913		(14,913)
Other studies in development/canceled								-		2,625		(2,625)
	\$	(33,000)	\$	5,541,000	\$	(5,574,000)	\$	74,653	\$	3,144,289	\$	(3,069,636)

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$2.1 million, \$2.5 million and \$1.9 million, \$2.3 million for the three months ended September 30, 2024, December 31, 2024 and 2023, respectively. The net decrease/increase of approximately \$132,000, \$200,000 was primarily attributed to the an increase in other consultancy fees of approximately \$593,000, increased audit and accounting fees of approximately \$42,000, and increases in legal fee expenses for shareholders' meeting and regulatory filing fees of approximately \$400,000 and insurance premiums of approximately \$29,000; \$25,000. This was offset by declines in the executive teams team's compensation totaling approximately \$78,000 reflecting the reduction in force in December 2023, director compensation expense of approximately \$188,000, \$141,000, investor relations and other filing of approximately \$90,000, legal fees of approximately \$49,000, \$24,000 and other professional conference & meetings and consulting fees of website development totaling approximately \$52,000, \$22,000 and \$29,000, respectively.

Other Income and Expense

Other expense, income, net was approximately \$30,000, \$180,000 compared to other income, net of \$165,000, \$380,000, for the three months ended September 30, 2024, December 31, 2024 and 2023, respectively. The net increase/decrease in other expense/income, net of approximately \$195,000, \$200,000 is comprised of a reduction in the change in fair value of the related derivative liabilities of approximately \$705,000 and \$989,000, which was offset by a reduction in interest expense of approximately \$749,000, offset by a reduction \$754,000 due to the notes payable being paid off on December 1, 2024, and an increase in interest income of approximately \$239,000, \$35,000.

Comparison of the six months ended December 31, 2024 to the six months ended December 21, 2023

Net loss

The net loss for the six months ended December 31, 2024 was approximately \$11.3 million as compared to the net loss of \$19.1 million for the six months ended December 31, 2023. The net decrease of \$7.8 million was comprised of decreases in research and development expenses of \$8.7 million, offset by increased selling, general and administrative expenses of approximately \$409,000 and a decrease in other income, net of approximately \$395,000.

Total operating expenses for the six months ended December 31, 2024 were approximately \$11.4 million as compared to \$19.7 million for the six months ended December 31, 2023. The net decrease of approximately \$8.3 million was comprised of decreased research and development expenses of approximately \$8.7 million primarily due to the completion of clinical trials in the prior fiscal year, offset by increased selling, general and administrative expenses of approximately \$409,000.

Research and Development Expenses

Research and development expenses were approximately \$6.7 million and \$15.3 million for the six months ended December 31, 2024 and 2023, respectively. The \$8.7 million net decline was primarily attributed to the completion of the clinical studies in the prior fiscal year and comprised of a net decrease in direct study costs of approximately \$4.6 million, and decreases in related expenses such as the clinical team payroll of \$1.4 million, reflecting the reduction in force in December 2023, and consultants expenses of \$1.9 million, reflecting a declining use of consultants and a reduction in the use of regulatory and other consultants totaling approximately \$440,000 as the clinical studies completed in the prior fiscal year, a decrease in Chemistry, Manufacturing and Controls ("CMC") and new drug discovery totaling approximately \$179,000, and a decrease in travel & conferences of approximately \$93,000 and publications of approximately \$93,000.

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The decrease in clinical studies of approximately \$4.6 million represented the net decrease in clinical trial studies expense due the completion of the clinical trials in the prior fiscal year offset by the planning and development of the two new clinical studies PD and LC. The table below summarizes the expense amounts for the six months ended December 31, 2024 and 2023 by study:

	Six Months Ended December 31, 2024	Six Months Ended December 31, 2023	Increase (Decrease)
Current Studies			
Sunrise PD Phase 2	\$ 1,677,534	\$ 20,000	\$ 1,657,534
Long Covid Program, net of \$325,000 reimbursement	2,401,028	-	2,401,028
Investigator-Initiated studies	12,738	-	12,738
	<u>\$ 4,091,300</u>	<u>\$ 20,000</u>	<u>\$ 4,071,300</u>
Completed Studies			
Ascites BIV201 Phase 2b	\$ (11,117)	\$ 517,006	\$ (528,123)
AD mild to moderate pivotal Phase 3	44,124	6,139,494	(6,095,370)
PD Phase 2	-	485,033	(485,033)
Investigator-Initiated studies	-	87,058	(87,058)
Other studies in development/canceled	18,253	1,472,168	(1,453,915)
	<u>\$ 51,260</u>	<u>\$ 8,700,759</u>	<u>\$ (8,649,499)</u>

Selling, General and Administrative Expenses

Selling, general and administrative expenses were approximately \$4.6 million and \$4.2 million for the six months ended December 31, 2024 and 2023, respectively. The net increase of approximately \$409,000 was primarily attributed to the net increase in other consultancy fees of approximately \$540,000, and other increases in audit and accounting fees of approximately \$61,000, legal fees of \$376,000, insurance and office expense of approximately \$30,000 and \$21,000, respectively; offset by declines in the executive team’s compensation totaling approximately \$266,000, director compensation expense of approximately \$138,000, investor relations of approximately \$139,000, conference & meetings and website development totaling approximately \$36,000 and \$29,000, respectively, and shareholders’ meetings and filing fees totaling approximately \$12,000.

Other Income and Expense

Other income, net was approximately \$150,000 compared to approximately \$545,000 for the six months ended December 31, 2024 and 2023, respectively. The net decrease in other income, net of approximately \$395,000 is comprised of a change in fair value of the related derivative liabilities of approximately \$1.7 million, and a reduction in interest income of approximately \$204,000. This was offset by a reduction in interest expense of approximately \$1.5 million due to the notes payable being paid in full on December 1, 2024.

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Capital Resources and Liquidity

As of September 30, 2024 December 31, 2024, the Company had working capital of approximately \$13.3 million \$23.2 million, cash and cash equivalents totaling approximately \$20.0 million \$24.4 million, stockholders' equity of approximately \$14.1 million \$23.9 million, and an accumulated deficit of approximately \$338.7 million \$345.9 million.

The Company used net cash in operations totaling approximately \$3.6 million \$12.2 million and net cash provided by financing activities was approximately \$241,000 \$12.7 million comprised of net proceeds from the capital raise activities of \$2.3 million \$15.7 million and proceeds from exercise of warrants of \$2.9 million offset by the payment of \$2.5 million \$5.0 million of the Company's notes payable. payable and payment of \$850,000 loan premium.

The Company has not generated any revenue and no revenues are expected in the foreseeable future. The Company's future operations are dependent on the success of the Company's ongoing development and commercialization efforts, as well as its ability to secure additional financing. Management expects that future sources of funding may include sales of equity, obtaining loans, or other strategic transactions.

Although management continues to pursue the Company's strategic plans, there is no assurance that the Company will be successful in obtaining sufficient financing on terms acceptable to the Company, if at all, to fund continuing operations. These circumstances raise substantial doubt on the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Controlled Equity Offering

During the three six months ended September 30, 2024 December 31, 2024, the Company sold approximately 2,143 shares of its Common Stock under its Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co for total net proceeds of approximately \$6,400 after 3% commissions and offering costs totaling approximately \$200. On September 25, 2024, the Company filed a prospectus supplement to suspend sales under the Controlled Equity Offering Sales Agreement.

Registered Direct Offerings

On September 25, 2024, the Company closed a best efforts public offering (the "September 2024 Offering") of 1,360,800 shares of its common stock, par value \$0.0001 per share, pre-funded warrants (the "September Pre-funded Warrants") to purchase 600,000 shares of Common Stock, and warrants to purchase up to 1,960,800 shares of Common Stock (the "September Common Warrants") at a combined public offering price of \$1.53 per Share, share, or September Pre-funded Warrant, and the associated September Common Warrant. 265,000 September Pre-funded Warrants were exercised in the three months ended September 30, 2024 and reflected on the condensed statement of changes in stockholders' equity as a component of proceeds from issuance of common stock. The September Common Warrants have an exercise price of \$1.53 per share and are were immediately exercisable upon issuance and will expire on the fifth anniversary date of the original issuance date. The gross proceeds to the Company from the September 2024 Offering were approximately \$3.0 million, before deducting placement agent fees and offering expenses of approximately \$747,000. Additionally, upon closing, the Company issued the placement agent warrants ("September Placement Agent's Warrants") to purchase 98,040 shares of Common Stock exercisable at a per share price of \$1.91, which was equal to 125% of the public offering price per share. The September Placement Agent's Warrants are exercisable during a five-year period commencing 180 days from September 25, 2024.

In October 2024, the Company closed three registered direct offerings totaling 8,256,000 shares of its common stock, par value \$0.0001 per share, and two concurrent private placements of warrants to purchase up to 8,256,000 7,110,000 shares of Common Stock (the "October Common Warrants") priced at-the-market under Nasdaq rules at prices ranging from \$1.50 to \$2.83 per share (the "October Offerings"). The October Common Warrants have exercise prices ranging from \$1.37 to \$2.83 \$2.12 per share and are exercisable beginning six months following issuance and will expire on the fifth anniversary date of the original issuance dates. The gross proceeds to the Company from the October Offerings totaled approximately \$15.9 million, before deducting placement agent fees and offering expenses of approximately \$2.8 million \$2.5 million. Additionally, upon closing of the October Offerings the Company issued placement agent warrants (the "October Placement Agent's Warrants") to purchase 412,800 shares of Common Stock in the aggregate exercisable at a per share price ranging from \$1.88 to \$3.54, which was equal to 125% of the offering price per share in the applicable October Offering. The October Placement Agent's Warrants are exercisable during a five-year period commencing 180 days from each of the respective closing dates of the October Offerings.

Critical Accounting Policies and Estimates

For the three-month six-month period ended September 30, 2024 December 31, 2024, the Company added a Grant Program accounting policy that is disclosed in the Significant Accounting Policies section of the this Form 10-Q. There were no other significant changes to the Company's critical accounting policies as identified in the Annual Report Form 10-K for the fiscal year ended June 30, 2024.

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New Accounting Pronouncements

The Company considered the applicability and impact of recent accounting pronouncements and determined those to be either not applicable or expected to have minimal impact on our balance sheets or statement of operations and comprehensive loss.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable to smaller reporting companies.

Item 4. Controls and Procedures

We maintain “disclosure controls and procedures.” Such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in Securities and Exchange Commission rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Office and Chief Financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Our disclosure controls and procedures have been designed to meet reasonable assurance standards. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgement in evaluating the cost-benefit relationship of possible disclosure and procedures. The design of and disclosure controls and procedures also are based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Based on their evaluation as of the end of the period covered by this Quarterly Report on Form 10-Q, our Chief Executive Officer and Chief Financial Officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level, as appropriate, to allow timely decisions regarding required disclosure.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15f and 15d-15(f) under the Exchange Act) that occurred during the quarter three months ended September 30, 2024 December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

To our knowledge, other than described below, neither the Company nor any of its officers or directors is a party to any material legal proceeding or litigation and such persons know of no material legal proceeding or contemplated or threatened litigation, other than as described below. There are no judgments against **us the Company** or our officers or directors. None of our officers or directors has been convicted of a felony or misdemeanor relating to securities or performance in corporate office.

On January 19, 2024, a purported shareholder class action complaint, captioned Eric Olmstead v. BioVie Inc. et al., No. 3:24-cv-00035, was filed in the U.S. District Court for the District of Nevada, naming the Company and certain of its officers as defendants. On February 22, 2024, a second, related putative securities class action was filed in the same court asserting similar claims against the same defendants, captioned Way v. BioVie Inc. et al., No. 2:24-cv-00361. On April 15, 2024, the court consolidated these two actions under the caption In re BioVie Inc. Securities Litigation, No. 3:24-cv-00035, appointed the lead plaintiff, and approved selection of the lead counsel. On June 21, 2024, the lead plaintiff filed an amended complaint, alleging that the defendants made material misrepresentations and/or omissions of material fact relating to the Company's business, operations, compliance, and prospects, including information related to the NM101 Phase 3 study and trial of bezisterim (NE3107) in mild to moderate probable AD, in violation of Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5 promulgated thereunder. The class action is on behalf of purchasers of the Company's securities during the period from December 7, 2022 through November 28, 2023 and seeks unspecified monetary damages on behalf of the putative class and an award of costs and expenses, including attorney's fees. The defendants filed a motion to dismiss the amended complaint on August 21, 2024, and plaintiffs filed their opposition on October 21, 2024. The defendants' reply brief is **due** **was filed** December 5, 2024. The defendants believe that the claims are without merit and intend to defend vigorously against them, but there can be no assurances as to the outcome.

On December 30, 2024, a shareholder derivative lawsuit was filed in the United States District Court for the District of Nevada by putative stockholder Andrew Hulm, allegedly on behalf of the Company, that piggy-backs on the securities class action also pending in that court. The derivative complaint names certain current and former officers and directors as defendants, and generally alleges that they breached their fiduciary duties by causing or failing to prevent the securities violations alleged in the securities class action. The derivative complaint also alleges claims for unjust enrichment, waste of corporate assets, gross mismanagement, and abuse of control as against all defendants. The defendants believe that the claims are without merit and intend to defend vigorously against them, but there can be no assurances as to the outcome.

Item 1A. Risk Factors

Except as described below, there There have been no material changes to the Risk Factors previously disclosed in our 2024 Form **10-K**, **10-K** and our quarterly report for the period ended September 30, 2024 (the "Q1 2025 10-Q"). The risks described in our 2024 Form 10-K, our Q1 2025 10-Q and below are not the only risks facing our company. Additional risks and uncertainties not currently known to **us the Company** or that we currently deem to be immaterial also may materially adversely affect our business, financial condition, and/or operating results.

Risks Relating to Our Business and Industry

We rely and will continue to rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or do not successfully perform and comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We depend, and will continue to depend, on third parties, including, but not limited to, contract research organizations ("CROs"), clinical trial sites and clinical trial principal investigators, contract laboratories, IRBs, manufacturers, suppliers, and other third parties to conduct our clinical trials, including those for our drug candidates bezisterim (NE3107) and BIV201. We rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we retain ultimate responsibility for ensuring that each of our studies is conducted in accordance with the protocol and applicable legal, regulatory, and scientific standards and regulations, and our reliance on third parties does not relieve **us the Company** of our regulatory responsibilities. We and these third parties are required to comply with cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for the conduct of clinical trials on product candidates in clinical development. Regulatory authorities enforce cGCPs through periodic inspections and for-cause inspections of clinical trial principal investigators and trial sites. If, due to the failure of either the Company or a third party, a clinical trial fails to comply with applicable cGCPs, FDA's IND requirements, other applicable regulatory requirements, or requirements set forth in the applicable IRB-approved protocol, the Company may be required to conduct additional clinical trials to support our marketing applications, which would delay the regulatory approval process. **For example, our drug product candidate bezisterim (NE3107) was cleared by FDA for use in a Phase 3, randomized, double blind, placebo controlled, parallel group, multicenter study in subjects who have mild to moderate AD. Enrollment in that trial began in August 2021, with a planned primary completion in late 2022/early 2023. On November 29, 2023, the Company announced topline efficacy data from its Phase 3 clinical trial (NCT04669028) of bezisterim (NE3107) in the treatment of mild to moderate AD. Upon trial completion, as the Company began the process of analyzing the trial data, the Company found significant deviations from the protocol and cGCP violations at 15 study sites (virtually all of which were from one geographic area). This highly unusual level of suspected improprieties led the Company to exclude all patients from these sites. We subsequently notified FDA's OSI of such significant deviations from study protocol, the**

suspected improprieties, and the study sites involved. The identification of significant deviations from study protocol and numerous GCP violations at multiple study sites raised questions regarding the validity and robustness of data from these study sites. The unplanned exclusion of so many patients left the trial underpowered for its primary endpoints. However, based on the remaining dataset from those other sites determined to be in compliance with the protocol and GCP's, a preliminary signal of efficacy was detected. The Company is considering: (1) employing the adaptive trial feature of the protocol to continue enrolling patients to achieve statistical significance; and/or (2) designing a new Phase 3 study of bezisterim (NE3107) that leverages the most recent scientific literature relating to AD along with the company's understanding regarding the effects of bezisterim (NE3107) in persons with mild-moderate AD.

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Although we design the clinical trials for our product candidates, our CROs are tasked with facilitating and monitoring these trials. As a result, many aspects of our clinical development programs, including site and investigator selection, and the conduct, timing, and monitoring of the study, is outside our direct control, either partially or in whole. Our reliance on third parties to conduct clinical trials also results in less direct control over the collection, management, and quality of data developed through clinical trials than would be the case if we were relying entirely upon our own employees. Communicating with third parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Our business may be impacted if any of these third parties violates applicable federal, state, or foreign laws and/or regulations, including but not limited to FDA's IND regulations, cGCPs, fraud and abuse or false claims laws, healthcare privacy and data security laws, or provide us the Company or government agencies with inaccurate, misleading, or incomplete data.

Adverse Developments Affecting the Financial Services Industry and Concentration of Risk

As of September 30, 2024, the Company had cash deposited in a certain financial institution in excess of federally insured levels. The Company regularly monitors the financial stability of the financial institution and believes that it is not exposed to any significant credit risk in cash and cash equivalents. Bank failures, events involving limited liquidity, defaults, non-performance, or other adverse developments that affect financial institutions, or concerns or rumors about such events, may lead to liquidity constraints. In 2023, certain U.S. government banking regulators took steps to intervene in the operations of certain financial institutions due to liquidity concerns, which caused general heightened uncertainties in financial markets. While previous bank failures have not had a material direct impact on the Company's operations, if further liquidity and financial stability concerns arise with respect to banks and financial institutions, either nationally or in specific regions, the Company's ability to access cash or enter into new financing arrangements may be threatened, which could have a material adverse effect on its business, financial condition and results of operations.

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Risks Relating To Our Common Stock

You may experience future dilution as a result of future equity offerings or if we issue shares subject to options, warrants, stock awards or other arrangements.

As of September 30, 2024 December 31, 2024, our Articles of Incorporation, as amended, authorize the issuance of 800,000,000 shares of Common Stock, and we had 7,982,986 18,478,307 shares of Common Stock issued and 7,956,660 18,451,981 issued and outstanding. Accordingly, we may issue up to an additional 792,043,340 781,548,019 shares of Common Stock. The future issuance of Common Stock may result in substantial dilution in the percentage of our Common Stock held by our then existing stockholders. We may value any Common Stock in the future on an arbitrary basis. The issuance of Common Stock for future services or acquisitions or other corporate actions may have the effect of diluting the value of the shares held by our investors, might have an adverse effect on any trading market for our Common Stock and could impair our ability to raise capital in the future through the sale of equity securities.

In order to raise additional capital, we may in the future offer additional shares of our Common Stock or other securities convertible into or exchangeable for our Common Stock. We may sell shares or other securities in offerings at a price per share that is less than the current market price of our securities, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The sale of additional shares of our Common Stock or other securities convertible into or exchangeable for our Common Stock would dilute all of our stockholders, and if such sales of convertible securities into or exchangeable into our Common Stock occur at a deemed issuance price that is lower than the current exercise price of our outstanding warrants sold to Acuitas Group Holdings, LLC (“Acuitas”) in August 2022, the exercise price for those warrants would adjust downward to the deemed issuance price pursuant to price adjustment protection contained within those warrants.

As of September 30, 2024 December 31, 2024, there were warrants outstanding to purchase an aggregate of 4,316,002 9,600,835 shares of our Common Stock at exercise prices ranging from \$1.53 \$1.37 to \$125.00 per share and 517,996 967,811 shares issuable upon exercise of outstanding options at exercise prices ranging from \$4.70 \$1.90 to \$420.90 per share and restricted stock units totaling 34,566. In addition, pursuant to the Loan and Security Agreement and the Supplement to the Loan and Security Agreement, each entered into on November 30, 2021, with Avenue Venture Opportunities Fund II, L.P. and Avenue Venture Opportunities Fund, L.P., the lenders have the option to convert up to \$5 million of the outstanding loan amount into shares of our Common Stock at a conversion price of \$69.80 per share. 97,067. We may also grant additional options, warrants or equity awards. To the extent such shares are issued, the interest of holders of our Common Stock will be diluted.

Moreover, we are obligated to issue shares of our Common Stock upon achievement of certain clinical, regulatory and commercial milestones with respect to certain of our drug candidates (i.e., bezisterim (NE3107), NE3291, NE3413, and NE3789) pursuant to the asset purchase agreement, dated April 27, 2021, by and among the Company, NeurMedix and Acuitas, as amended on May 9, 2021. The achievement of these milestones could result in the issuance of up to 1.8 million shares of our Common Stock, further diluting the interest of holders of our Common Stock.

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Item 2. Unregistered sales of equity securities

On August 12, 2024, the Company issued 15,000 shares of Common Stock to a vendor as part of their fees in exchange for services. The fair value of the Common Stock at the date of issuance was \$2.23 per share. The stock-based compensation expense related to this Common Stock issuance was \$33,450.

The offers, sales, and issuances of the securities described above were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act and/or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering, as applicable. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited or sophisticated person and had adequate access, through employment, business or other relationships, to information about **us, the Company.**

Other than equity securities issued in transactions disclosed above and on our Current Reports on Form 8-K filed with the SEC on October 22, 2024, October 24, 2024 and October 29, 2024, there were no unregistered sales of equity securities during the period.

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

None

Item 5. Other Information

None

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Item 6. Exhibits

(a) Exhibit index

Exhibit

4.1 31.1*	Form of Placement Agent's Warrant Agreement (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on October 22, 2024).
4.2	Form of Placement Agent's Warrant Agreement (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on October 24, 2024).
4.3	Form of Placement Agent's Warrant Agreement (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed on October 29, 2024).
10.1***	Placement Agent Agreement, dated October 21, 2024, by and between the Company and the Placement Agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 22, 2024).
10.2***	Placement Agent Agreement, dated October 23, 2024, by and between the Company and the Placement Agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 24, 2024).
10.3***	Placement Agent Agreement, dated October 28, 2024, by and between the Company and the Placement Agent (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed on October 29, 2024).
31.1*	Certification of Chief Executive Officer (Principal Executive Officer) required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
31.2*	Certification of Chief Financial Officer (Principal Financial Officer) required by Rule 13a-14(a) or Rule 15d-14(a) under the Securities Exchange Act of 1934, as amended.
32.1**	Certifications of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer (Principal Financial Officer) pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document

* Filed herewith.

** Furnished herewith. This certification is being furnished solely to accompany this report pursuant to 18 U.S.C. Section 1350, and is not being filed for purposes of Section 18 of the Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filings of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

*** Certain portions of this Exhibit have been omitted pursuant to Regulation S-K Item 601(a)(6) promulgated under the Exchange Act. The Registrant agrees to furnish supplementally a copy of any omitted schedule to the SEC upon request.

SIGNATURES

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

BioVie Inc.,

Signature	Titles	Date
/s/ Cuong V Do Cuong V Do	Chairman and Chief Executive Officer (Principal Executive Officer)	November 13, 2024 February 11, 2025
/s/ Joanne Wendy Kim Joanne Wendy Kim	Chief Financial Officer (Principal Financial and Accounting Officer)	November 13, 2024 February 11, 2025

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002
AND RULE 13-A14 OF THE EXCHANGE ACT OF 1934

CERTIFICATION

I, Cuong V Do, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioVie Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a - 15(f) and 15d - 15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: **November 13, 2024** **February 11, 2025**

/s/ Cuong V Do

Cuong V Do
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

**CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES OXLEY ACT OF 2002
AND RULE 13-A14 OF THE EXCHANGE ACT OF 1934**

CERTIFICATION

I, Joanne Wendy Kim, certify that:

1. I have reviewed this quarterly report on Form 10-Q of BioVie Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a - 15(f) and 15d - 15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

- d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of the annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
- a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
- b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: **November 13, 2024** **February 11, 2025**

/s/ Joanne Wendy Kim
Joanne Wendy Kim
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of BioVie Inc. (the "Company") on Form 10-Q for the period ended **September 30, 2024** **December 31, 2024**, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Cuong V Do, Chief Executive Officer of the Company certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002, that, to my 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.

Date: **November 13, 2024** **February 11, 2025**

/s/ Cuong V Do
Cuong V Do
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of BioVie Inc. (the "Company") on Form 10-Q for the period ended **September 30, 2024** **December 31, 2024**, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Joanne Wendy Kim, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes Oxley Act of 2002, that, to my 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.

Date: **November 13, 2024** February 11, 2025

/s/ Joanne Wendy Kim

Joanne Wendy Kim
Chief Financial Officer
(Principal Financial and Accounting Officer)

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