

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: December 31, 2025

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)-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
Warrants to purchase Class A Common Stock, \$0.0001 par value per share	BIVIW	The NASDAQ Stock Market, LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the 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 whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes

No

There were 7,543,571 shares of the Registrant's Class A Common Stock, \$0.0001 par value per share, outstanding as of February 5, 2026.



TABLE OF CONTENTS

PART I – FINANCIAL INFORMATION

<u>Item 1.</u>	<u>Unaudited Financial Statements</u>	
	<u>Condensed Balance Sheets at December 31, 2025 and June 30, 2025</u>	<u>4</u>
	<u>Condensed Statements of Operations - for the three and six months ended December 31, 2025 and 2024</u>	<u>5</u>
	<u>Condensed Statements of Changes in Stockholders' Equity - for the three and six months ended December 31, 2025 and 2024</u>	<u>6</u>
	<u>Condensed Statements of Cash Flows - for the six months ended December 31, 2025 and 2024</u>	<u>7</u>
	<u>Notes to Unaudited Condensed Financial Statements</u>	<u>8</u>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>20</u>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>26</u>
<u>Item 4.</u>	<u>Controls and Procedures</u>	<u>26</u>

PART II – OTHER INFORMATION

<u>Item 1.</u>	<u>Legal Proceedings</u>	<u>27</u>
<u>Item 1A.</u>	<u>Risk Factors</u>	<u>27</u>
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	<u>30</u>
<u>Item 3.</u>	<u>Defaults Upon Senior Securities</u>	<u>30</u>
<u>Item 4.</u>	<u>Mine Safety Disclosures</u>	<u>30</u>
<u>Item 5.</u>	<u>Other Information</u>	<u>30</u>
<u>Item 6.</u>	<u>Exhibits</u>	<u>31</u>

<u>SIGNATURES</u>		<u>32</u>
-------------------	--	-----------

BIOVIE INC.

FORWARD-LOOKING STATEMENTS

This report contains forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), 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 that attempt to advise interested parties of the risks, uncertainties and other factors that may affect our business.

When used in this report, the terms “BioVie”, “Company”, “we”, “our”, and “us” refer to BioVie Inc.

PART I – FINANCIAL INFORMATION
Item 1. Financial Statements

BioVie Inc.
Condensed Balance Sheets
(Unaudited)

	<u>December 31,</u> <u>2025</u>	<u>June 30,</u> <u>2025</u>
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	\$ 20,540,585	\$ 17,544,547
Grant receivable	195,481	2,104,050
Prepaid and other current assets	1,055,368	1,049,897
Total current assets	<u>21,791,434</u>	<u>20,698,494</u>
Operating lease right-of-use asset, net	302,495	339,653
Intangible assets, net	63,653	178,341
Goodwill	345,711	345,711
TOTAL ASSETS	<u>\$ 22,503,293</u>	<u>\$ 21,562,199</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accrued expenses	\$ 2,923,344	\$ 2,200,320
Current portion of operating lease liability	82,398	74,464
Total current liabilities	<u>3,005,742</u>	<u>2,274,784</u>
Operating lease liability, net of current portion	232,517	275,430
TOTAL LIABILITIES	<u>3,238,259</u>	<u>2,550,214</u>
Commitments and contingencies (Note 8)		
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 December 31, 2025 and June 30, 2025; 7,543,571 shares issued of which 7,540,734 shares outstanding at December 31, 2025; and 1,917,061 shares issued of which 1,914,224 shares are outstanding at June 30, 2025	754	192
Additional paid in capital	382,609,131	371,156,068
Accumulated deficit	(363,344,822)	(352,144,246)
Treasury stock	(29)	(29)
Total stockholders' equity	<u>19,265,034</u>	<u>19,011,985</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 22,503,293</u>	<u>\$ 21,562,199</u>

See accompanying notes to unaudited condensed financial statements

BioVie Inc.
Condensed Statements of Operations
(Unaudited)

	Three Months Ended December 31, 2025	Three Months Ended December 31, 2024	Six Months Ended December 31, 2025	Six Months Ended December 31, 2024
OPERATING EXPENSES:				
Amortization of intangible assets	\$ 57,344	\$ 57,344	\$ 114,688	\$ 114,688
Research and development expenses	4,269,479	4,704,806	7,205,849	6,695,003
General and administrative expenses	1,935,482	2,530,679	4,226,362	4,605,219
TOTAL OPERATING EXPENSES	6,262,305	7,292,829	11,546,899	11,414,910
LOSS FROM OPERATIONS	(6,262,305)	(7,292,829)	(11,546,899)	(11,414,910)
OTHER (INCOME) EXPENSE:				
Change in fair value of derivative liabilities	-	6,036	-	3,519
Interest expense	5,967	66,700	7,956	322,725
Interest income	(198,797)	(253,036)	(397,823)	(476,593)
TOTAL OTHER INCOME, NET	(192,830)	(180,300)	(389,867)	(150,349)
NET LOSS	\$ (6,069,475)	\$ (7,112,529)	\$ (11,157,032)	\$ (11,264,561)
Deemed dividend related to ratchet adjustment to warrants	-	44,424	43,544	369,465
NET LOSS ATTRIBUTABLE TO COMMON STOCKHOLDERS	\$ (6,069,475)	\$ (7,156,953)	\$ (11,200,576)	\$ (11,634,026)
NET LOSS PER COMMON SHARE				
- Basic	\$ (0.77)	\$ (4.55)	\$ (1.70)	\$ (10.54)
- Diluted	\$ (0.77)	\$ (4.55)	\$ (1.70)	\$ (10.54)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
- Basic	7,920,795	1,571,725	6,574,967	1,104,284
- Diluted	7,920,795	1,571,725	6,574,967	1,104,284

See accompanying notes to unaudited condensed financial statements

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

	<u>Common Stock Shares</u>	<u>Common Stock Amount</u>	<u>Additional Paid in Capital</u>	<u>Treasury Stock Shares</u>	<u>Treasury Stock Amount</u>	<u>Accumulated Other Comprehensive Income</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
Balance, June 30, 2024	621,640	\$ 62	349,738,841	(2,633)	\$ (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	341	-	-	-	-	-	-	-
Stock-based compensation - issuance of common stock for services rendered	1,500	-	33,450	-	-	-	-	33,450
Proceeds from issuance of common stock, net of costs of \$747,408	162,794	16	2,259,047	-	-	-	-	2,259,063
Issuance of additional shares for fractional shares effected by the reverse split	12,024	1	(1)	-	-	-	-	-
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	798,299	79	352,776,767	(2,633)	(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	381	-	-	-	-	-	-	-
Exercise of warrants	223,130	22	2,901,319	-	-	-	-	2,901,341
Cashless exercise of warrants	422	-	-	-	-	-	-	-
Proceeds from issuance of common stock, net of costs of \$2,492,880	825,600	83	13,415,467	-	-	-	-	13,415,550
Deemed dividend for ratchet adjustment to warrants	-	-	44,424	-	-	-	(44,424)	-
Net Loss	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>-</u>	<u>(7,112,529)</u>	<u>(7,112,529)</u>
Balance, December 31, 2024	<u>1,847,832</u>	<u>\$ 184</u>	<u>\$369,789,109</u>	<u>(2,633)</u>	<u>\$ (27)</u>	<u>\$ -</u>	<u>\$(345,866,687)</u>	<u>\$ 23,922,579</u>
Balance, June 30, 2025	1,917,061	\$ 192	\$371,156,068	(2,837)	\$ (29)	\$ -	\$(352,144,246)	\$ 19,011,985

Stock - based compensation - stock options	-	-	268,388	-	-	-	-	268,388
Stock-based compensation - restricted stock units and restricted shares	-	-	270,559	-	-	-	-	270,559
Proceeds from issuance of common stock, net of costs of \$1,543,038	5,620,000	562	10,457,067	-	-	-	-	10,457,629
Issuance of common stock from vesting of restricted stock units	3,255	-	-	-	-	-	-	-
Deemed dividend for ratchet adjustment to warrants	-	-	43,544	-	-	-	(43,544)	-
Net Loss	-	-	-	-	-	-	(5,087,557)	(5,087,557)
Balance, September 30, 2025	7,540,316	754	382,195,626	(2,837)	(29)	-	(357,275,347)	24,921,004
Stock - based compensation - stock options	-	-	197,336	-	-	-	-	197,336
Stock-based compensation - restricted stock units and restricted shares	-	-	216,169	-	-	-	-	216,169
Issuance of common stock from vesting of restricted stock units	3,255	-	-	-	-	-	-	-
Net Loss	-	-	-	-	-	-	(6,069,475)	(6,069,475)
Balance, December 31, 2025	<u>7,543,571</u>	<u>\$ 754</u>	<u>\$382,609,131</u>	<u>(2,837)</u>	<u>\$ (29)</u>	<u>\$ -</u>	<u>\$(363,344,822)</u>	<u>\$ 19,265,034</u>

See accompanying notes to unaudited condensed financial statements

BioVie Inc.
Condensed Statements of Cash Flows
(Unaudited)

	<u>Six Months Ended</u> <u>December 31, 2025</u>	<u>Six Months Ended</u> <u>December 31, 2024</u>
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	\$ (11,157,032)	\$ (11,264,561)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of intangible assets	114,688	114,688
Stock based compensation - restricted stock units and restricted shares	486,728	567,295
Stock based compensation expense - stock options	465,724	504,226
Stock based compensation expense - issuance of common stock for services rendered	-	33,450
Amortization of financing costs	-	11,820
Accretion of unearned loan discount	-	111,212
Accretion of loan premium	-	25,758
Non-cash lease expense from right-of-use assets	37,158	32,423
Change in fair value of derivative liabilities	-	3,519
Changes in operating assets and liabilities:		
Grant receivable	1,908,569	-
Prepaid and other current assets	(5,471)	(71,443)
Accounts payable and accrued expenses	723,024	(2,204,411)
Operating lease liabilities	(34,979)	(28,211)
Net cash used in operating activities	<u>(7,461,591)</u>	<u>(12,164,235)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from issuance of common stock	10,457,629	15,674,613
Proceeds from exercise of warrants	-	2,901,341
Payment of loan premium	-	(850,000)
Payment of loan premium	-	(5,000,000)
Net cash provided by financing activities	<u>10,457,629</u>	<u>12,725,954</u>
Net change in cash and cash equivalents	2,996,038	561,719
Cash and cash equivalents, beginning of period	<u>17,544,547</u>	<u>23,843,798</u>
Cash and cash equivalents, end of period	<u>\$ 20,540,585</u>	<u>\$ 24,405,517</u>
SUPPLEMENTAL CASH FLOW INFORMATION:		
Cash paid for interest	<u>\$ 7,956</u>	<u>\$ 173,935</u>
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING AND FINANCING ACTIVITIES:		
Deemed dividend for ratchet adjustment to warrants	\$ 43,544	\$ 369,465

See accompanying notes to unaudited condensed financial statements

BioVie Inc.
Notes to Condensed Financial Statements
For the Three and Six Months Ended December 31, 2025 and 2024
(unaudited)

1. Background Information

BioVie Inc. (the “Company” or “we” or “our”) is a clinical-stage company developing innovative drug therapies for the treatment of neurological and neurodegenerative disorders and advanced liver disease.

Neurodegenerative Disease Programs

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 (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 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 Alzheimer's Disease, 1 million Americans suffering from Parkinson's Disease, and approximately 20 million adults in the US suffering from Long COVID, with millions more affected worldwide.

In neurodegenerative disease, the Company’s drug candidate bezisterim is an orally bioavailable, Blood Brain Barrier (“BBB”)-permeable, insulin-sensitizer that is also anti-inflammatory. In addition, it is not immunosuppressive and has a low risk of drug-drug interaction. Bezisterim inhibits activation of inflammatory action 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. By binding to ERK and selectively modulating NFκB activation and TNF- α production without interfering with their homeostatic functions, BioVie believes that bezisterim may offer clinical improvements in several disease indications, including PD, AD and long COVID.

Parkinson’s Disease

The Company designed a Phase 2b study of bezisterim as a potential first line therapy to treat patients with new onset PD. This trial evaluates the safety and efficacy of bezisterim on motor and non-motor symptoms in patients with PD who haven't been treated with carbidopa/levodopa. The PD Phase 2b study, multicenter, randomized, double-blind, placebo-controlled trial with a hybrid decentralized design will last 20 weeks from the initial screening phase to the safety follow up. The trial commenced in April 2025 and completed enrollment of 60 patients in December 2025. Topline results from the trial are expected in the first half of 2026.

The Phase 2 study of bezisterim for the treatment of PD (NCT05083260) that completed in December 2022, was a double-blind, placebo-controlled, safety, tolerability, and pharmacokinetics study in PD participants treated with carbidopa/levodopa and bezisterim. Forty-five patients with a defined L-dopa “off state” were randomized 1:1 to placebo: bezisterim 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 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.

Long COVID Program

Long COVID is a condition in which symptoms of COVID-19, the acute respiratory disease caused by the SARS-CoV-2 virus, persist for an extended period, generally three months or more. Common symptoms include lingering loss of smell and taste, extreme fatigue, and “brain fog,” though persistent cardiovascular and respiratory problems, muscle weakness, and neurologic issues have also been documented.

In April 2024, the Company was awarded a clinical trial grant of \$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 for the treatment of neurological symptoms that are associated with long COVID and the FDA authorized our Investigational New Drug (“IND”) application for bezisterim allowing the Company to study a novel, anti-inflammatory approach or the treatment of the debilitating neurocognitive symptoms associated with long COVID.

The Phase 2 ADDRESS-LC study is a randomized (1:1), placebo-controlled, multicenter trial evaluating the efficacy, safety and tolerability of bezisterim in adult participants with long COVID who have cognitive impairment sequelae and fatigue. Individuals who have been diagnosed with long COVID and have neurocognitive dysfunction and self-reported fatigue may meet qualification criteria.

As of December 31, 2025, the total cost incurred was approximately \$6.7 million and \$6.4 million was reimbursed as of January 20, 2026. Grant reimbursements recognized for the corresponding research and development expenses in the accompanying condensed statements of operations totaled approximately \$706,000 and zero for the three months ended December 31, 2025 and 2024, respectively. Grant reimbursements recognized for the corresponding research and development expenses in the accompanying condensed statements of operations totaled approximately \$1.0 million and \$325,000 for the six months ended December 31, 2025 and 2024, respectively.

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 bezisterim in the treatment of mild to moderate AD. The study had 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 bezisterim 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.

Liver Cirrhosis Program

In liver disease, our investigational drug candidate BIV201 (continuous infusion terlipressin), which was granted both FDA Fast Track designation status and FDA Orphan Drug Status, is being evaluated as a treatment option for patients suffering from ascites and other life-threatening complications of advanced liver cirrhosis caused by non-alcoholic steatohepatitis (NASH), hepatitis, and alcoholism. The initial target for BIV201 therapy was refractory ascites. These patients 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.

After receiving guidance from the FDA regarding the design of Phase 3 clinical testing of BIV201 for the treatment of patients with cirrhosis and ascites, the Company is now targeting a broader ascites patient population. The Company is currently finalizing the protocol design for the Phase 3 study of BIV201 with a focus on demonstrating clinical benefit through a composite primary endpoint of complications and disease progression in patients with cirrhosis and ascites who have recently recovered from acute kidney injury (“AKI”). This patient population is not limited to those having refractory ascites. Ascites is a common complication of advanced liver cirrhosis involving the accumulation of large volumes of fluid in the abdomen, often exceeding five liters, due to liver and kidney dysfunction. BIV201 is administered in a continuous infusion of terlipressin as a patent-pending liquid formulation with patents issued in the U.S., China, Japan, Chile and India to date. Terlipressin, the drug is used in over 40 countries to treat related complications of liver cirrhosis (Type 1 hepatorenal syndrome and bleeding esophageal varices) that was approved in the U.S. in 2022 (to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function) but is not approved in Japan.

The BIV201 development program was initiated by LAT Pharma LLC. On April 11, 2016, BioVie acquired LAT Pharma LLC and the rights to its BIV201 development program and 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 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, 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 December 31, 2025, the Company had working capital of approximately \$18.8 million, cash and cash equivalents of approximately \$20.5 million, stockholders’ equity of approximately \$19.3 million, and an accumulated deficit of approximately \$363.3 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 in our research protocols and slow the progress in the Company’s development and launch of next phase clinical programs.

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.

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 States 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, 2025, 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, 2025 and 2024 in our Annual Report on Form 10-K filed with the SEC on August 15, 2025 (the “2025 Form 10-K”). A summary of significant accounting policies can also be found in those audited financial statements in the 2025 Form 10-K.

Reverse stock split

The Company effected a 1:10 reverse stock split of the issued and outstanding shares of its Common Stock on July 7, 2025 which was approved by the board of directors prior to shareholders' approval at the special meeting on June 23, 2025. All historical share and earnings per share amounts presented have been retroactively adjusted to reflect the reverse stock split.

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.

Concentration of Credit Risk in the Financial Service Industry

As of December 31, 2025, the Company had cash deposited in a certain financial institution 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.

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, accounts payable, and the carrying value of the operating lease liabilities. 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 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, restricted stock units, and convertible debentures. For the three and six months ending December 31, 2025 and 2024, 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 for the three and six months ended December 31, 2025 of 7,920,795 and 6,574,967, respectively, includes the weighted average effect of the pre-funded warrants issued in connection with the August 2025 Offering, the exercise of which requires nominal consideration for the delivery of the shares of common stock (see Note 6).

[Table of Contents](#)

The table below shows the potential shares of common stock, presented based on amounts outstanding at each 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:

	December 31, 2025	December 31, 2024
	Number of Shares	Number of Shares
Stock Options	80,593	96,782
Warrants	7,902,037	960,084
Restricted Stock Units	2,202	9,707
	<u>7,984,832</u>	<u>1,066,573</u>

Grant program

The Company records expenses related to the DOD Long Covid Program as incurred. The reimbursements of such expenses are recognized as a credit against the respective expense account upon receipt, or when it is probable the reimbursement will be received.

Segment Reporting

The Company operates as one operating segment with a focus on its efforts to develop drug therapies for the treatment of neurological and neurodegenerative disorders and advanced liver disease. The Company's Chief Executive Officer ("CEO"), as the chief operating decision maker, manages and allocates resources to the operations of the Company based on the line items included within these financial statements. This enables the CEO to assess the overall level of available resources and determine how best to deploy these resources across functions, clinical trials, and development projects in line with the long-term company-wide strategic goals.

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:

	<u>December 31, 2025</u>	<u>June 30, 2025</u>
Intellectual Property	\$ 2,293,770	\$ 2,293,770
Less: Accumulated Amortization	(2,230,117)	(2,115,429)
Intellectual Property, net	<u>\$ 63,653</u>	<u>\$ 178,341</u>

Amortization expense was \$57,344 in each of the three-month periods ended December 31, 2025 and 2024. Amortization expense was \$114,688 in each of the six-month periods ended December 31, 2025 and 2024. The Company amortizes intellectual property over the expected original useful lives of 10 years and the remaining amortization expense for the year ending June 30, 2026 is \$63,653.

5. Fair Value Measurements

Financial assets

As of December 31, 2025, 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 December 31, 2025			
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Cash	\$ 4,307,717	\$ -	\$ -	\$ 4,307,717
U.S. Treasury Bills due in 3 months or less at purchase	16,232,868	-	-	16,232,868
Total	<u>\$ 20,540,585</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 20,540,585</u>

	Fair Value Measurements at June 30, 2025			
	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
Cash	\$ 3,978,271	\$ -	\$ -	\$ 3,978,271
U.S. Treasury Bills due in 3 months or less at purchase	13,566,276	-	-	13,566,276
Total	<u>\$ 17,544,547</u>	<u>\$ -</u>	<u>\$ -</u>	<u>\$ 17,544,547</u>

6. Equity Transactions

Equity Transactions with Acuitas (former related party)

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 36,364 shares of the Company’s Common Stock, at a price of \$165.00 per share (the “PIPE Shares”), and (ii) a warrant to purchase 72,728 shares of Common Stock (“PIPE Warrant Shares”), at an original exercise price of \$182.00, with a term of exercise of five years.

As a result of the Company’s subsequent capital raises, the warrants’ down round features (the “ratchet adjustment”) resulted in deemed dividends recognized in the accompanying condensed statements of changes in stockholders’ equity for the three months ended September 30, 2025 and 2024 and the three months ended December 31, 2024.

For the three months ended September 30, 2024, the deemed dividend of \$325,041 was recognized based on ratchet adjustments from the September 25, 2024 capital raises, that reduced the exercise prices from \$100.00 to \$15.30 per share. The fair value of the PIPE Warrant Shares were estimated using the Black Scholes Method with the following inputs at September 2024, the stock price of \$12.00, exercise price of \$15.30 and \$100.00, remaining term of 2.9 years, risk free rate of 3.5% and volatility of 93.0%, resulting in a \$325,041 deemed dividend.

The October 22, 2024 capital raise further reduced the exercise prices from \$15.30 per share to \$13.70 per share which drove an additional ratchet adjustment in the second quarter of fiscal year 2025. For the three months ended December 31, 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 \$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 \$33.60, exercise price of \$15.30 and \$13.70, remaining term of 2.8 years, risk free rate of 3.99% and volatility of 94.0%.

For the three months ended September 30, 2025, the deemed dividend of \$43,544 recognized from the ratchet adjustment resulting from the August 2025 capital raise, that reduced the exercise price from \$13.70 to \$2.50 per share. The fair value of the PIPE Warrant Shares was estimated using the Black Scholes Method with the following inputs, the stock price of \$1.79, exercise price of \$13.70 and reduced exercise price of \$2.50, remaining term of 2.0 years, risk free rate of 3.8% and volatility of 94.0%.

Issuance of common stock for cash

On August 11, 2025, the Company closed an underwritten public offering of (i) 5,620,000 units (the “Units”), with each Unit consisting of one share of common stock and one warrant (the “Warrants”) and (ii) 380,000 pre-funded units (the “Pre-Funded Units”), with each Pre-Funded Unit consisting of one pre-funded warrant and one Warrant. The underwriter also exercised its over-allotment option in part and purchased an additional 667,300 Warrants. The offering resulted in net proceeds of approximately \$10.5 million, after deducting underwriting discounts and commissions and other estimated offering expenses. Each Unit was sold to the public at a price of \$2.00 per Unit and each Pre-Funded Unit was sold to the public at a price of \$1.999 per Pre-Funded Unit (which represents the public offering price of each Unit less the \$0.0001 per share nominal exercise price for each Pre-Funded Warrant). On August 8, 2025, the Warrants commenced trading on The Nasdaq Capital Market under the symbol “BIVIW.” Each Warrant is immediately exercisable, entitles the holder to purchase one share of common stock at an exercise price of \$2.50 per share and expires five years from the date of issuance. Each Pre-Funded Warrant is immediately exercisable, entitles the holder to purchase one share of common stock, and may be exercised at any time until exercised in full. Additionally, upon closing, the Company issued the underwriter warrants to purchase 300,000 shares of Common Stock exercisable at a per share price of \$2.50, which was equal to 125% of the public offering price per share. The underwriter’s Warrants are exercisable during a five-year period commencing 180 days from August 11, 2025.

Stock Options

The following table summarizes the activity relating to the Company's stock options for the six months ended December 31, 2025:

	<u>Options</u>	<u>Weighted-Average Exercise Price</u>	<u>Weighted Remaining Average Contractual Term</u>	<u>Aggregate Intrinsic Value</u>
Outstanding at June 30, 2025	84,872	\$ 286.20	6.2	\$ -
Options Expired	(4,279)	\$ 1,389.43	0.0	\$ -
Outstanding at December 31, 2025	<u>80,593</u>	\$ 227.62	6.0	\$ -
Exercisable at December 31, 2025	<u>63,087</u>	\$ 244.44	5.6	\$ -

The Company recorded stock-based compensation expense relating to the vesting of stock options of approximately \$197,000 and \$385,000 for the three months ended December 31, 2025 and 2024, respectively. The Company recorded stock-based compensation expense relating to the vesting of stock options of approximately \$466,000 and \$504,000 for the six months ended December 31, 2025 and 2024, respectively.

On January 5, 2026 (the "Grant Date"), directors' annual compensation was approved and the directors were granted stock options to purchase a total of 355,000 shares of common stock, at an exercise price of \$1.31 per share, the closing stock price on the grant date. The stock options vest from the beginning of service on November 11, 2025 in four equal installments on February 11, 2026, May 11, 2026, August 11, 2026 and the earlier of November 11, 2026 or the 2026 annual shareholders' meeting.

On January 5, 2026, (the "Grant Date"), the Company awarded bonus and retention incentive stock options to certain directors and employees to purchase a total of 812,700 and 1,538,850, respectively; shares of common stock, at an exercise price of \$1.31 per share, the closing stock price on the Grant Date. The directors' stock options vested 75% on the Grant Date with the remaining balance vesting in equal installments on the first, second and third Grant Date anniversary. The employees' stock options vested 55% on grant date with the remaining balance will vest in equal installments on the first, second and third Grant Date anniversary.

Restricted stock units:

On September 2, 2025 (the "Grant Date"), the Company awarded a total of 1,500 RSUs to a consultant at the grant date fair value of \$1.58. The RSUs vest in five equal installments at the Grant Date and over the next four calendar quarters beginning December 31, 2025.

[Table of Contents](#)

The following table summarizes vesting of restricted stock units:

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Unvested at June 30, 2025	7,212	\$ 116.41
Granted	1,500	1.58
Vested	(7,313)	86.96
Unvested at December 31, 2025	<u>1,399</u>	<u>\$ 147.26</u>

The total stock-based compensation expense from restricted stock units for the three months ended December 31, 2025 and 2024 was approximately \$216,000 and \$266,000, respectively. The total stock-based compensation expense from restricted stock units for the six months ended December 31, 2025 and 2024 was approximately \$487,000 and \$567,000, respectively.

There were 803 RSUs that vested on November 23, 2025 and the related shares of common stock will be issued and delivered by March 15, 2026.

Stock Warrants

The following table summarizes the warrants activity during the six months ended December 31, 2025:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (Years)	Aggregate Intrinsic Value
Outstanding and exercisable at June 30, 2025	960,098	\$ 35.02	4.1	\$ -
Granted	6,967,300	2.50	5.0	-
Canceled	(25,001)	150.00	-	-
Expired	(360)	1,250.00	-	-
Outstanding and exercisable at December 31, 2025	<u>7,902,037</u>	<u>\$ 5.82</u>	<u>4.5</u>	<u>\$ -</u>

The table below shows the expiration of the warrants outstanding as of December 31, 2025:

	Number of Warrants
Expiring June 30,	
2027	3,610
2028	72,728
2029	90,508
2030	767,891
2031	6,967,300
Total outstanding warrants	<u>7,902,037</u>

The warrants table excludes 380,000 prefunded warrants with an exercise price of \$0.0001 and no expiration. None of the prefunded warrants were exercised during the six months ended December 31, 2025.

7. 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, 2022 and has been subsequently renewed at each annual maturity date at the same rate.

The Company's San Diego office lease at 5090 Shoreham Place Suite 206, San Diego, CA 92122 resulted from an amendment that commenced on February 12, 2024 for a larger space. The current monthly base rate for the office space is \$10,024, with an annual increase of four percent. The term of the lease is 60 months.

Total operating lease expense for the three months ended December 31, 2025 and 2024 of approximately \$32,000 and \$32,000, respectively, and for the six months ended December 31, 2025 and 2024 of approximately \$64,000 and \$63,000, respectively, were included in the accompanying condensed statements of operations as a component of general and administrative expenses.

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:

	<u>December 31, 2025</u>	<u>June 30, 2025</u>
Assets		
Operating lease right-of-use asset, net	\$ 302,495	\$ 339,653
Liabilities		
Current portion of operating lease liability	\$ 82,398	\$ 74,464
Operating lease liability, net of current portion	232,517	275,430
Total operating lease liability	<u>\$ 314,915</u>	<u>\$ 349,894</u>

At December 31, 2025, the future estimated minimum lease payments under non-cancelable operating leases are as follows:

Year ending June 30, 2026 (Remaining 6 months)	\$ 61,898
2027	126,313
2028	130,734
2029	77,796
Total minimum lease payments	<u>396,741</u>
Less amount representing interest	<u>(81,826)</u>
Present value of future minimum lease payments	<u>\$ 314,915</u>

Total cash paid for amounts included in the measurement of lease liabilities were \$60,144 and \$58,110 for the six months ended December 31, 2025 and 2024, respectively.

The weighted average remaining lease term and discount rate as of December 31, 2025 and June 30, 2025 were as follows:

	<u>December 31, 2025</u>	<u>June 30, 2025</u>
Weighted average remaining lease term (Years)		
Operating lease	3.1	3.6
Weighted average discount rate		
Operating lease	15.00%	15.00%

8. 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 was obligated to pay a 5% on net sales (capped at a maximum of \$200,000 per year) of all terlipressin products covered by US Patent No. 11364277, expiring in 2036 and the European Patent No. EP3347032, expiring in 2036 and pending patent applications in the U.S., Europe, China and Japan, related to the administration of terlipressin as a continuous infusion for the treatment of ascites.

Pursuant to the Intellectual Property Rights Agreement entered into on April 18, 2019, by and between the Company and DOCUCHEM SLU, the Company is obligated to pay DOCUCHEM SLU \$25,000 on the issuance of the U.S. patent for terlipressin and \$50,000 each calendar year in which the gross sales in the U.S. of a product covered by a claim of an issued U.S. patent as directed to terlipressin exceeds \$10,000,000.

Shareholder class action complaint and shareholder derivative complaints

On January 19, 2024, a purported securities 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 (the “Securities Class Action”), 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 on March 27, 2025, the court denied that motion. The parties are now engaged in fact discovery.

Three shareholder derivative lawsuits piggy-backing on the Securities Class Action were filed in the United States District Court for the District of Nevada, allegedly on behalf of the Company, by three putative stockholders: Andrew Hulm on December 30, 2024; William Settel on April 28, 2025 and Cline Wilkerson on September 11, 2025, (collectively the “Related Derivative Lawsuits”). Each Related Derivative Lawsuit names the same current and former officers and directors as defendants and alleges essentially the same claims: that the defendants breached their fiduciary duties by causing or failing to prevent the securities violations alleged in the Securities Class Action, and related claims for unjust enrichment, waste of corporate assets, gross mismanagement, and abuse of control. On September 29, 2025, at the request of the parties, the court consolidated all three Related Derivative Lawsuits under the caption *In re BioVie Inc. Derivative Litigation*, Case No. 3:24-cv-0602-CSD (the “Consolidated Derivative Action”). On January 27, 2026, at the request of the parties, the court stayed the Consolidated Derivative Action pending resolution of a summary judgment motion by defendants in the Securities Class Action.

The Company believes that the claims are without merit and intends to defend vigorously against them, but there can be no assurances as to the outcome.

9. 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 \$19,300 and \$27,500, for the three months ended December 31, 2025 and 2024, respectively. The Company made contributions into the plan of approximately \$75,200 and 62,000, for the six months ended December 31, 2025 and 2024, respectively.

10. Segment Reporting

The Company operates as one operating segment with a focus on its efforts to develop drug therapies for the treatment of neurological and neurodegenerative disorders and advanced liver disease. The Company's CEO, as the chief operating decision maker, manages and allocates resources to the operations of the Company based on the line items included within these condensed financial statements and segment performance is evaluated based on net loss. This enables the CEO to assess the overall level of available resources and determine how best to deploy these resources across functions, clinical trials, and development projects in line with the long-term company-wide strategic goals. The measurement of segment assets is reported on the condensed balance sheet as total assets. All of the Company’s tangible assets are held in the United States.

The following table presents selected financial information with respect to the Company’s single operating segment and its significant segment approximated expenses for the six months ended December 31, 2025 and 2024:

	<u>Six months ended</u> <u>December 31, 2025</u>	<u>Six months ended</u> <u>December 31, 2024</u>
Clinical studies	\$ 4,941,000	\$ 4,130,000
Clinical teams	1,902,000	1,813,000
Chemistry, manufacturing and controls	76,000	619,000
Other research and development expenses	287,000	133,000
General and administrative expenses	4,226,000	4,605,000
Amortization of intangible assets	115,000	115,000
Other income, net	(390,000)	(150,000)
Net loss	<u>\$ (11,157,000)</u>	<u>\$ (11,265,000)</u>

11. Subsequent Events

Option Therapeutics Inc. (“Option”) was incorporated under the law of the state of Delaware on May 1, 2025 and was established by the Company for the potential spin-off of the Company’s Liver Disease Program. On January 23, 2026, Option filed a registration statement on Form S-1 for the potential initial public offering (“IPO”) of shares of Option's common stock, par value \$0.001 per share (“Option Common Stock”). Option will commence operations upon the effective date of the IPO. As of December 31, 2025, Option is authorized to issue 100 shares of Option Common Stock, and 100 shares were issued and outstanding, all owned by the Company.

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 for the treatment of neurological and neurodegenerative disorders and advanced 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 (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 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, 1 million Americans suffering from PD and Long COVID (“LC”) affects approximately 20 million adults in the US, and millions more worldwide.

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

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.

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 commenced in April 2025.

Long COVID Program

In April 2024, the Company was awarded a clinical trial grant of \$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, the FDA and the U.S. Army Medical Research and Development Command, Office of Human Research Oversight ("OHRO") approved the Company's plan, including the FDA approving the associated Investigation New Drug Application ("IND"), to evaluate bezisterim for the treatment of neurological symptoms that are associated with long COVID. The trial commenced in May 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 as a treatment option for patients suffering from ascites and other life-threatening complications of advanced liver cirrhosis caused by non-alcoholic steatohepatitis (NASH), hepatitis, and alcoholism. The initial target for BIV201 therapy was refractory ascites. These patients 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.

After receiving guidance from the FDA regarding the design of Phase 3 clinical testing of BIV201 for the treatment of patients with cirrhosis and ascites, the Company is now targeting a broader ascites patient population. The Company is currently finalizing the protocol design for the Phase 3 study of BIV201 with a focus on demonstrating clinical benefit through a composite primary endpoint of complications and disease progression in patients with cirrhosis and ascites who have recently recovered from acute kidney injury ("AKI"). This patient population is not limited to those having refractory ascites. BIV201 is administered as a patent-pending liquid formulation with patents issued in US, China, Japan, Chile and India to date.

C. 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 bezisterim in the treatment of mild to moderate AD. The study had 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 bezisterim 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.

Comparison of the three months ended December 31, 2025 to the three months ended December 31, 2024

Net loss

The net loss for the three months ended December 31, 2025 was approximately \$6.1 million as compared to the net loss of approximately \$7.1 million for the three months ended December 31, 2024. The net decrease of \$1.0 million for the three months ended December 31, 2025 was comprised of a net decrease in research and development ("R&D") expenses of approximately \$435,000, and a net decrease in general and administrative expenses of approximately \$595,000.

Total operating expenses for the three months ended December 31, 2025 were approximately \$6.3 million as compared to \$7.3 million for the three months ended December 31, 2024. The net decrease of approximately \$1.0 million for the three months ended December 31, 2025, was comprised of a net decrease in R&D expenses of approximately \$435,000 and a net decrease in general and administrative expenses of approximately \$595,000.

Research and Development Expenses

R&D expenses were approximately \$4.3 million and \$4.7 million for the three months ended December 31, 2025 and 2024, respectively. The net decrease of approximately \$435,000 was primarily attributed to the Long COVID ("LC") studies' decline in net expenses due to the large start-up contractual payments made to the Contract Research Organizations ("CRO") and no reimbursements received during the three months ended December 31, 2024; offset by increased cost from the Sunrise PD Phase 2 study, from the increased activities in the Sunrise PD Phase 2 study became fully enrolled. The table below indicates the cost incurred by study program.

	Three months ended December 31, 2025	Three months ended December 31, 2024	Increase (Decrease)
Sunrise PD Phase 2	\$ 2,627,000	\$ 1,158,000	\$ 1,469,000
Liver Program Phase 3	3,000	45,000	(42,000)
Long COVID Phase 2	1,195,000	2,256,000	(1,061,000)
Long COVID Phase 2 - reimbursements	(706,000)	-	(706,000)
	<u>\$ 3,119,000</u>	<u>\$ 3,459,000</u>	<u>\$ (340,000)</u>

General and Administrative Expenses

General and administrative expenses were approximately \$1.9 million and \$2.5 million for the three months ended December 31, 2025 and 2024, respectively. The net decrease of approximately \$595,000 was primarily attributed to decreases in stock-based compensation for the executive team and directors of approximately \$154,000 and \$58,000, respectively, consultancy fees of approximately \$593,000, investor and public relation fees of approximately \$30,000, filing fees of approximately \$41,000, offset by increased legal fees related to the class action litigation of approximately \$331,000, and insurance premiums of approximately \$20,000.

Other Income and Expense

Other income, net was approximately \$193,000 compared to other income, net of approximately \$180,000, for the three months ended December 31, 2025 and 2024, respectively. The net increase in other income of approximately \$13,000 was primarily comprised of a reduction in interest expense of approximately \$61,000 due to the payoff of the notes payable on December 1, 2024, offset by a reduction in interest income of approximately \$54,000.

Comparison of the six months ended December 31, 2025 to the six months ended December 31, 2024*Net loss*

The net loss for the six months ended December 31, 2025 was approximately \$11.2 million comparable to the net loss of approximately \$11.3 million for the six months ended December 31, 2024. The net decrease of approximately \$108,000 for the six months ended December 31, 2025 was comprised of the net increase in operating expenses of approximately \$132,000 offset by the increase in other income, net of approximately \$240,000.

Total operating expenses for the six months ended December 31, 2025 were approximately \$11.5 million as compared to \$11.4 million for the six months ended December 31, 2024. The net R&D increase of approximately \$132,000 for the six months ended December 31, 2025, was comprised of net increased research and development expenses of approximately \$511,000 primarily attributed to the development and launch of both the Long COVID program in April 2025 and Sunrise PD Phase 2 studies in May 2025 offset by the decline in general and administrative expenses of approximately \$379,000.

Research and Development Expenses

R&D expenses were approximately \$7.2 million for the six months ended December 31, 2025, an increase of approximately \$511,000 from \$6.7 million for six months ended December 31, 2024. The net increase in R&D expenses of approximately \$511,000 is comprised of increased direct study costs of approximately \$818,000, clinical team compensation of approximately \$88,000, travel and conferences of approximately \$153,000, offset by approximately \$541,000 of Chemistry, Manufacturing and Controls (“CMC”) expenses that have been temporarily curtailed.

As the table indicates below, the increase in clinical studies of approximately \$818,000 were comprised of the increased Sunrise PD Phase 2 study cost of approximately \$2.3 million and the decline in Long Covid Phase 2 study cost of net of reimbursements totaling approximately \$1.5 million that consisted of the large contractual start-up fee paid the CRO and the lag in receiving the reimbursements during the six months ended December 31, 2024.

	<u>Six months ended December 31, 2025</u>	<u>Six months ended December 31, 2024</u>	<u>Increase (Decrease)</u>
Sunrise PD Phase 2	\$ 3,984,000	\$ 1,675,000	\$ 2,309,000
Liver Program Phase 3	15,000	43,000	(28,000)
Long COVID Phase 2	1,980,000	2,726,000	(746,000)
Long COVID Phase 2 - reimbursements	(1,042,000)	(325,000)	(717,000)
	<u>\$ 4,937,000</u>	<u>\$ 4,119,000</u>	<u>\$ 818,000</u>

General and Administrative Expenses

General and administrative expenses were approximately \$4.2 million and \$4.6 million for the six months ended December 31, 2025 and 2024, respectively. The net decrease of approximately \$379,000 was primarily attributed to decreases in stock-based compensation for the executive team and directors of approximately \$238,000 and \$151,000, respectively and consultancy fees of approximately \$565,000; offset by a net increase in legal fee expenses of approximately \$546,000 that primarily represented legal fees related to the class action litigation.

Other Income and Expense

Other income, net was approximately \$390,000 compared to other income, net of \$150,000, for the six months ended December 31, 2025 and 2024, respectively. The net increase in other income of approximately \$240,000 was comprised of a reduction in interest expense of approximately \$315,000 due to the payoff of the notes payable on December 1, 2024, offset by a reduction in interest income of approximately \$79,000.

Capital Resources and Liquidity

As of December 31, 2025, the Company had working capital of approximately \$18.8 million, cash and cash equivalents totaling approximately \$20.5 million, stockholders' equity of approximately \$19.3 million, and an accumulated deficit of approximately \$363.3 million.

The Company used net cash in operations totaling approximately \$7.5 million and net cash provided by financing activities was comprised of net proceeds from capital raise activities of \$10.5 million.

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.

Registered Offering

On August 11, 2025, the Company closed an underwritten public offering (the "Offering") of (i) 5,620,000 units (the "Units"), with each Unit consisting of one share of common stock and one warrant (the "Warrants") and (ii) 380,000 pre-funded units (the "Pre-Funded Units"), with each Pre-Funded Unit consisting of one pre-funded warrant and one Warrant. The underwriter also exercised its over-allotment option in part and purchased an additional 667,300 Warrants. The Offering resulted in net proceeds of approximately \$10.5 million, after deducting underwriting discounts and commissions and other estimated offering expenses. Each Unit was sold to the public at a price of \$2.00 per Unit and each Pre-Funded Unit was sold to the public at a price of \$1.999 per Pre-Funded Unit (which represents the public offering price of each Unit less the \$0.0001 per share nominal exercise price for each Pre-Funded Warrant). On August 8, 2025, the Warrants commenced trading on The Nasdaq Capital Market under the symbol "BIVIW." Each Warrant is immediately exercisable, entitles the holder to purchase one share of common stock at an exercise price of \$2.50 per share and expires five years from the date of issuance. Each Pre-Funded Warrant is immediately exercisable, entitles the holder to purchase one share of common stock and may be exercised at any time until exercised in full. Additionally, upon closing, the Company issued the underwriter warrants to purchase 300,000 shares of Common Stock exercisable at a per share price of \$2.50, which was equal to 125% of the public offering price per share. The underwriter's Warrants are exercisable during a five-year period commencing 180 days from August 11, 2025.

Critical Accounting Policies and Estimates

There were no 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, 2025 (the "2025 Form 10-K").

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 three months ended December 31, 2025, 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 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 securities 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 (the “Securities Class Action”), 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 denied on March 27, 2025, the court denied that motion. The parties are now engaged in fact discovery.

Three shareholder derivative lawsuits piggy-backing on the Securities Class Action were filed in the United States District Court for the District of Nevada, allegedly on behalf of the Company, by three putative stockholders: Andrew Hulm on December 30, 2024; William Settel on April 28, 2025 and Cline Wilkerson on September 11, 2025, (collectively the “Related Derivative Lawsuits”). Each Related Derivative Lawsuit names the same current and former officers and directors as defendants and alleges essentially the same claims: that the defendants breached their fiduciary duties by causing or failing to prevent the securities violations alleged in the Securities Class Action, and related claims for unjust enrichment, waste of corporate assets, gross mismanagement, and abuse of control. On September 29, 2025, at the request of the parties, the court consolidated all three Related Derivative Lawsuits under the caption *In re BioVie Inc. Derivative Litigation*, Case No. 3:24-cv-0602-CSD (the “Consolidated Derivative Action”). On January 27, 2026, at the request of the parties, the court stayed the Consolidated Derivative Action pending resolution of a summary judgment motion by defendants in the Securities Class Action.

The Company believes that the claims are without merit and intends to defend vigorously against them, but there can be no assurances as to the outcome.

Item 1A. Risk Factors

Except as described below, there have been no material changes to the Risk Factors previously disclosed in our 2025 Form 10-K. The risks described in our 2025 Form 10-K and below are not the only risks facing our company. Additional risks and uncertainties not currently known to us 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 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.

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 or government agencies with inaccurate, misleading, or incomplete data.

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.

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 in any other offering 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 “Acuitas Warrants”), 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 December 31, 2025, there were warrants outstanding to purchase an aggregate of 8,282,037 shares of our Common Stock at exercise prices ranging from \$0.0001 to \$582.00 per share, 80,593 shares issuable upon exercise of outstanding options at exercise prices ranging from \$19.00 to \$4,209.00 per share and restricted stock units totaling 2,202. 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 180,000 shares of our Common Stock, further diluting the interest of holders of our Common Stock.

Item 2. Unregistered sales of equity securities

There were no unregistered sales of equity securities during the three months period ended December 31, 2025.

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

None

Item 5. Other Information

None

Item 6. Exhibits

(a) Exhibit index

Exhibit

- 10.1 BioVie Inc. 2019 Omnibus Equity Incentive Plan (Amended and Restated through November 10, 2025) (incorporated by reference to Appendix A to the Definitive Proxy Statement on Schedule 14A, filed on September 25, 2025).
- [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.SCHXBRL Taxonomy Extension Schema Document
- 101.CALXBRL Taxonomy Extension Calculation Linkbase Document
- 101.LABXBRL 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.

SIGNATURES

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

BioVie Inc.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Cuong V Do</u> Cuong V Do	Chairman and Chief Executive Officer (Principal Executive Officer)	February 6, 2026
<u>/s/ Joanne Wendy Kim</u> Joanne Wendy Kim	Chief Financial Officer (Principal Financial and Accounting Officer)	February 6, 2026

**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: February 6, 2026

/s/ Cuong V Do

Cuong V Do
Chief Executive Officer
(Principal Executive Officer)

**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: February 6, 2026

/s/ Joanne Wendy Kim

Joanne Wendy Kim
Chief Financial Officer

(Principal Financial and Accounting Officer)

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 December 31, 2025, 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: February 6, 2026

/s/ Cuong V Do

Cuong V Do
Chief Executive Officer
(Principal Executive Officer)

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 December 31, 2025, 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: February 6, 2026

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