# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## BIOVIE INC.

**Form: 8-K**

**Date Filed: 2018-11-29**

Corporate Issuer CIK: 1580149

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

# FORM 8-K

**CURRENT REPORT**
**Pursuant to Section 13 or 15(d)**
**of the Securities Exchange Act of 1934.**

**Date of Report: November 28, 2018**
**(Date of earliest event reported)**

# BioVie Inc.

(Exact name of registrant as specified in its charter)

| Nevada | 000-55292 | 46-2510769 |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification Number) |

| 11601 Wilshire Blvd., Suite 1100, Los Angeles, CA | 90025 |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

**(312) 283-5793**
**(Registrant's telephone number, including area code)**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

¨ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

¨ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

¨ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b–2 of this chapter).

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. ☐

**Item 8.01 Other Events**

On November 28, 2018, BioVie Inc. **("BioVie")** issued a press release announcing that the U.S. Food and Drug Administration had granted an Orphan Drug designation to Biovie for terlipressin for the treatment of hepatorenal syndrome. A copy of the press release is provided as Exhibit 99.1 to this Current Report.

**Item 9.01 Exhibits**

(d) Exhibits

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release of BioVie Inc. dated November 28, 2018 |

**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 hereunto duly authorized.

Dated: November 29, 2018

**BIOVIE INC.**

By: /s/ Jonathan Adams
Jonathan Adams
President & Chief Operating Officer

**EXHIBIT INDEX**

| Exhibit Number | Description |
| --- | --- |
| 99.1 | Press Release of BioVie Inc. dated November 28, 2018 |

**BioVie's New Drug Candidate BIV201 Receives FDA Orphan Drug Designation for the Treatment of Hepatorenal Syndrome (HRS)**

BioVie Inc. (OTCQB: BIVI) ("BioVie" or the "Company"), a clinical-stage company developing innovative drug therapies for liver disease, announced today that the US Food and Drug Administration (FDA) has granted an Orphan Drug designation to BioVie for terlipressin for the treatment of hepatorenal syndrome (HRS). BIV201 is a new drug candidate currently being tested in a mid-stage (Phase 2a) clinical study in patients with refractory ascites due to advanced liver cirrhosis. The Company previously secured an Orphan Drug designation for terlipressin for treating ascites, and is exploring additional Orphan designation opportunities.

"An estimated 12,000 to 33,000 Americans develop HRS each year," said BioVie CEO Terren Peizer. "Our novel drug candidate BIV201 could potentially become an effective treatment option for this condition." Two forms of hepatorenal syndrome are recognized, Type 1 (HRS-1) and Type 2 (HRS-2), which are categorized by deterioration in kidney function. While HRS-1 involves rapidly progressing kidney failure with a high probability of death (median survival time is only 2 to 4 weeks), HRS-2 is characterized by a progressive but slower deterioration in kidney function, with a longer survival time of approximately 6 months. The FDA has not approved any drug therapies specifically for treating HRS and it represents a critical unmet medical need.

An Orphan Drug designation typically provides 7 years of market exclusivity to the company that is first to obtain FDA marketing approval for the drug for the designated rare disease or condition. Additionally, the sponsor can benefit from certain financial incentives, including research and development tax credits. If the same drug has already been approved, the proposed drug needs to demonstrate clinical superiority to obtain Orphan exclusivity for the same indication.

**About BIV201**

BIV201 (continuous infusion terlipressin) represents a potential new treatment option for thousands of patients suffering from ascites, HRS, and other life-threatening complications of advanced liver cirrhosis caused by hepatitis, nonalcoholic steatohepatitis (NASH), and alcoholism. The initial disease target for BIV201 therapy is ascites, which is a serious complication of advanced liver cirrhosis. The FDA has never approved a drug specifically for treating ascites. The active agent in BIV201, terlipressin, is approved for use in about 40 countries for the treatment of related complications of advanced liver cirrhosis, but is not available in the US or Japan. In addition to Orphan Drug designations for ascites and HRS, BIV201 has FDA Fast Track status and US patent protection. For more information about BioVie, please visit our website: *www.biovieinc.com*.

**Forward-Looking Statements**

This press release contains forward-looking statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 that involve risks, uncertainties and assumptions that could cause BioVie's actual results and experience to differ materially from anticipated results and expectations expressed in these forward-looking statements. BioVie has in some cases identified forward-looking statements by using words such as "anticipates," "believes," "hopes," "estimates," "looks," "expects," "plans," "intends," "goal," "potential," "may," "suggest," and similar expressions. Among other factors that could cause actual results to differ materially from those expressed in forward-looking statements are BioVie's need for, and the availability of, substantial capital in the future to fund its operations and research and development; and the risks that BioVie's compounds may experience delays or difficulties in commencing or completing clinical studies, may not successfully complete pre-clinical or clinical testing, or may not be granted regulatory approval to be sold and marketed in the United States or elsewhere. A more complete description of these risk factors is included in BioVie's filings with the Securities and Exchange Commission under its former name. In addition to the risks described above and in BioVie's filings with the SEC, other unknown or unpredictable factors also could affect BioVie's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. Given these uncertainties, you should not place undue reliance on any forward-looking statements. BioVie undertakes no obligation to release publicly the results of any revisions to any such forward-looking statements that may be made to reflect events or circumstances after the date of this press release or to reflect the occurrence of unanticipated events, except as required by applicable law or regulation. BioVie cannot guarantee the approval of patents or Orphan-drug applications, nor the completion or success of its clinical trials.

CONTACT INFORMATION

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