

Market Data

BioVie Inc
NASDAQ: BIVI

Fiscal Year: June

Industry: Biotechnology

Recent Price: \$14.34

Market Cap: \$205.1M

Shares Out.: 14.3M

Float: 2.3M

Insider Ownership: 82%

Avg. Volume (100-day): 97,548

Cash (mrq): \$11.9M

As of June 3, 2021

Company Website
biovieinc.com

Corporate Headquarters
2120 Colorado Avenue Suite 230
Santa Monica, CA 90404

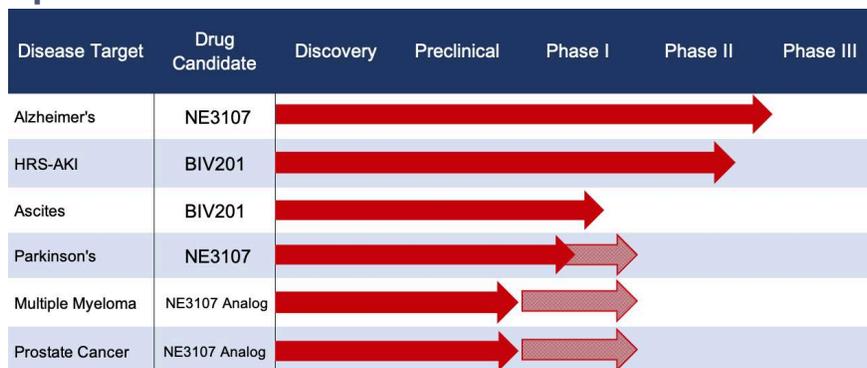
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Company Overview

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing transformative therapies to overcome unmet medical needs in chronic debilitating conditions. In liver disease, the Company's Orphan drug candidate BIV201 (continuous infusion terlipressin), with FDA Fast Track status, is being evaluated in a US Phase 2 study for the treatment of refractory ascites with top-line results expected in early 2022. It is administered as a patent-pending liquid formulation. The active agent is approved in about 40 countries for related complications of advanced liver cirrhosis but is not available in the US or Japan. In neuro-degenerative disease, BioVie recently acquired the assets of NeurMedix Inc., including NE3107, an ERK inhibitor that selectively reduces neuroinflammation and insulin resistance. Both are drivers of Alzheimer's and Parkinson's diseases. It was recently authorized by the FDA to commence a potentially pivotal US Phase 3 clinical trial. NE3107 and related compounds are globally patented first-in-class small molecules with additional potential to treat certain cancers.

Pipeline



* Drug-drug interaction study with levodopa required to proceed to Phase 2

Value Proposition

Liver Cirrhosis: BIV201 is being developed as a future treatment option for thousands of patients suffering from ascites and other life-threatening complications of advanced liver cirrhosis caused by NASH, hepatitis, and alcoholism. The initial target for BIV201 therapy is 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 – 12 months. The FDA has never approved any drugs to treat refractory ascites.

A Phase 2a clinical trial of BIV201 was successfully completed in 2019, and a multi-center, randomized and controlled Phase 2b trial is currently underway at prestigious medical centers including the Mayo Clinic, Vanderbilt University and University of Pennsylvania. Top-line results are expected early next year, to be followed by a single pivotal Phase 3 trial beginning in 2022.

Value Proposition (cont.)

Neurodegenerative Disease: The FDA has authorized a potentially pivotal Phase 3 randomized, double-blind, placebo-controlled, parallel group, multicenter study to evaluate NE3107 in subjects who have mild to moderate Alzheimer's disease (NCT04669028). An estimated six million Americans suffer from Alzheimer's. BioVie is planning to initiate this trial in mid-2021 and targeting primary completion in late 2022. In addition to Alzheimer's disease, the Company plans to advance NE3107 in Parkinson's based on promising results from preclinical studies. Inflammation-driven insulin resistance is implicated in a broad range of serious diseases, including multiple myeloma and prostate cancer, which will be explored in the coming months using NE3107 or related compounds acquired from NeurMedix.

BioVie is led by a highly experienced and effective management team, including majority shareholder and Chairman Terren Peizer who has founded and successfully commercialized several healthcare companies, and CEO Cuong Do, former Chief Strategy Officer at Merck. They are complemented by an accomplished board that includes Jim Lang, CEO of Eversana; Steve Gorlin, co-founder of several highly successful biotech companies; Robert Hariri MD, PhD, CEO of Celularity, Inc.; Sig Rogich, CEO of Rogich Communications Group, Michael Sherman, former managing director at Barclays and Lehman Brothers, and Richard Berman, former Chairman of National Investment Managers.

Investment Highlights

- **BIV201 is a novel therapeutic approach to a severe unmet medical need**
 - Only late-stage drug candidate in development for ascites (no drugs ever approved by the FDA)
 - High cost of care creates strong economic rationale for reimbursement
 - Phase 2 trial is underway, pivotal Phase 3 expected in 2022 with NDA submission in early 2024
 - Estimated \$450 million US ascites sales opportunity with high profit margins
- **NE3107: Phase 3 asset and first-in-class molecule targeting Alzheimer's Disease**
 - Growing body of evidence shows the promise of reducing neuroinflammation in Alzheimer's
 - Additional key benefit of NE3107 is the potential to reduce insulin resistance
 - Efficacy and mechanism of action demonstrated in Parkinson's and other models
 - Potential for excellent safety profile based on pre-clinical and clinical trials
 - Related compounds have potential to treat multiple myeloma and prostate cancer
 - Multi-billion dollar sales potential for Alzheimer's Disease
- **Robust intellectual property**
 - BIV201 IP estate includes two Orphan drug designations (ascites & HRS) and patent-pending global estate to cover proprietary liquid terlipressin formulations
 - NE3107 and related compounds covered by multiple issued patents both in US and worldwide
- **Experienced and effective management team**
 - Terren Peizer, Chairman; founded and successfully commercialized several healthcare companies. Chairman of Acuitas Group Holdings, a personal holding company that owns all his portfolio company interests, \$1.5B invested directly into portfolio companies; majority shareholder of BioVie.
 - Cuong Do, CEO; former Chief Strategy Officer at Merck; a veteran biotech and pharmaceutical entrepreneur, having previously founded Callidus Biopharma (sold to Amicus Therapeutics), Lysodel Therapeutics and M6P Therapeutics.
 - Jonathan Adams, COO – Liver Cirrhosis; 30+ years of biopharma experience, including technology commercialization, finance, global product launches, drug marketing and sales force management.
 - Clarence Ahlem, COO – Neurodegenerative Disease; 35+ years of experience in developing NE3107 and related assets with accomplished track record in the biopharma industry.
 - Chris Reading PhD, CSO – Neurodegenerative Disease; 40+ years in biopharma; former CSO of Hollis-Eden Pharmaceuticals; MD Anderson Cancer Center; 130+ peer-reviewed publications.
 - J. Wendy Kim, CFO; 35 years in finance/accounting with 22 years combined experience at KPMG and BDO; as CFO managed corporate finance and operations and closed M&A transactions and secured financings.