bioVie

NASDAQ: **BIVI**

REDCHIP

Market Data

BioVie Inc
NASDAQ: **BIVI**

Fiscal Year	June
Industry	Biotechnology
Recent Price	$9.30
Market Cap	$129.3M
Shares Out.	13.9M
Float	2.3M
Insider Ownership	82%
Avg. Volume (30-day)	30,160
Current Assets[1]	$13.3M

[1] Balances as of June 30, 2020 and includes proceeds from September 2020 offering

As of Sep 24, 2020

Company Website

biovieinc.com

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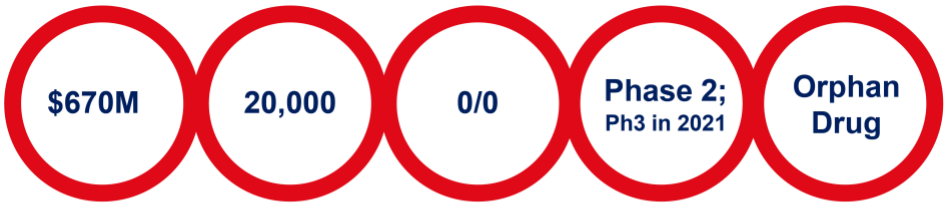
Company Overview

BioVie Inc. (NASDAQ: BIVI) is a clinical-stage company developing innovative drug therapies for liver disease. The Company's drug candidate, BIV201 (continuous infusion terlipressin), has an Orphan Drug designation for the treatment of refractory ascites, FDA Fast Track status, and US patent pending. BIV201 also has an Orphan Drug designation for the treatment of hepatorenal syndrome (HRS). 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. The FDA has never approved terlipressin. BioVie is targeting this landmark achievement.



$670M — Addressable US ascites market size*; Projected BIV201 US peak sales of $450 M with 67% penetration

20,000 — US patients targeted for BIV201 therapy

0/0 — Number of FDA-approved drugs to specifically treat ascites; Number of direct competitors

Phase 2; Ph3 in 2021 — Mid-stage Phase 2 Orphan drug candidate; *FDA Fast Track* and will seek *Breakthrough Therapy* status

Orphan Drug — *Orphan Drug* designations for ascites and HRS with potential 7 years market exclusivity**; Patent-pending liquid formulations

Sources/Notes:

* D'Amico 2014; BioVie poster presentation at AASLD 2019. Assumes three 28-day treatment regimens annually.
** If first to market.

U.S. Market Revenue Potential

	Estimated US Patients (000s)	Total Addressable Market (TAM)	Projected Peak US Sales
Refractory Ascites	20.0[1]	$670 M	**$450 M**
Bleeding Esophageal Varices (BEV)	6.6[3]	$166 M	$83 M
Catecholamine-Resistant Hypotension/Shock	125,000[2]	$150 M	$75 M
Hepatorenal Syndrome (HRS)	16.8[3]	$67 M	$34 M
		TOTAL:	**$642 M**

Sources/Notes:

1. D'Amico 2014; Gines 2004
2. Third party market assessment, published 2015
3. US Patient Hospital Discharge Data, 2016; BioVie poster presentation at AASLD 2019.

Value Proposition

BIV201 is a potential future treatment option for thousands of patients suffering from ascites and other life-threatening complications of advanced liver cirrhosis caused by hepatitis, NASH, and alcoholism. The initial target for BIV201 therapy is refractory ascites, a very serious complication of liver cirrhosis with an estimated 50% mortality rate within 6 – 12 months. Ascites patients incur more than $5 billion in annual treatment costs. No drugs are currently approved for treating refractory ascites.

With positive top-line results from its Phase 2a clinical trial of BIV201 completed in April 2019, BioVie is now preparing for a larger, multi-center, randomized and controlled Phase 2 clinical trial to be followed by a pivotal Phase 3 trial. The trials are expected to take place at ~20 sites across the U.S., including Mayo Clinic, Mount Sinai, and Johns Hopkins. The trial protocol was submitted to the FDA in October 2019 and guidance received in May 2020. Additionally, the FDA's CMC Division cleared the Company's new patent-pending liquid formulation of terlipressin in a pre-filled syringe for use in the Phase 2 trial, subject minor additional testing.

BioVie is led by a highly experienced and effective management team, including majority shareholder and Chairman and CEO Terren Peizer who has founded and successfully commercialized several healthcare companies. This team is complemented by an accomplished board that includes Cuong Do, former Chief Strategy Officer at Merck; 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 refractory ascites (no drugs ever approved for treating refractory ascites)
  - High cost of patient care creates strong economic rationale for drug therapy
  - Planning to commence Phase 2 trial in late 2020, and pivotal Phase 3 in 2021
  - Planning to submit NDA for US marketing approval in 2022
  - Estimated $450 million US ascites sales opportunity
  - High profit margins anticipated
- **Robust intellectual property**
  - IP estate includes two Orphan drug designations
  - Creating global patent estate to cover proprietary liquid terlipressin formulations
  - Additional revenue opportunities for related conditions and global expansions
- **Experienced and effective management team**
  - Terren Peizer, Chairman & CEO; 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
  - Jonathan Adams, President & COO; 30 years of biopharma experience, including finance, technology commercialization, global product launches, drug marketing and sales force management
  - Penelope Markham, PhD, Chief Scientific Officer; 20+ years of experience in infectious disease and drug discovery research; 20+ publications in peer-reviewed journals and multiple patents