



NEWS RELEASE

BioVie Acquires Biopharma Assets from Privately Held NeurMedix

2021-04-27

Includes Pivotal Phase 3 Alzheimer's Asset NE3107

Cuong V. Do Named CEO of The New BioVie

Conference Call Scheduled for April 27, 2021 at 5:00PM EDT

SANTA MONICA, Calif., April 27, 2021 (GLOBE NEWSWIRE) -- BioVie Inc. (NASDAQ: BIVI) ("BioVie" or "Company"), a clinical-stage company developing innovative drug therapies for chronic debilitating liver diseases, today announced the acquisition of the biopharmaceutical assets of NeurMedix, Inc., (NeurMedix), a San Diego based privately held clinical-stage pharmaceutical company focused on novel therapeutic assets for the treatment of neurodegenerative and neurological disorders, as well as certain cancers. Under the terms of the agreement, BioVie will pay to NeurMedix consideration consisting of 8,361,308 newly issued BioVie shares and approximately \$3.0 million cash at closing, an additional \$7.3 million cash payment after all contemplated clinical programs have been funded and a pivotal Phase 3 clinical trial for NeurMedix' lead drug candidate, NE3107, has met its primary endpoints, and additional shares over time as various significant clinical, regulatory, and commercial milestones are met, as detailed below. The transaction is expected to close in June 2021.

The transaction transforms BioVie's pipeline by expanding its focus into several compelling therapeutic areas with high unmet medical needs. NeurMedix's lead clinical drug candidate, NE3107, 17 α -ethynyl-androst-5-ene-3 β ,7 β ,17 β -triol, is a first-in-class small molecule, orally administered, highly effective inhibitor of insulin resistance and the pathological inflammatory cascade and with a novel mechanism of action. There is emerging scientific consensus that both inflammation and insulin resistance play fundamental roles in the development of Alzheimer's and Parkinson's Disease. NE3107 uniquely inhibits neuroinflammation and insulin resistance in the brain, which is different from insulin resistance in the periphery. Consequently, NE3107 could represent an entirely new medical approach to treating these devastating conditions affecting an estimated 6 million Americans suffering from

Alzheimer's and 1 million from Parkinson's. This unique molecule has demonstrated a wide safety margin, absence of immunosuppression and the ability to cross the blood-brain barrier in pre-clinical and Phase 2 clinical trials. In February, NeurMedix announced authorization by the U.S. Food & Drug Administration to initiate its pivotal Phase 3, randomized, double-blind, placebo-controlled, parallel group, multicenter study of NE3107 in subjects who have mild to moderate Alzheimer's Disease (**NCT04669028**). This trial will include 316 adult patients with expected initiation mid-2021 and expected primary completion in 2H 2022. In addition to Alzheimer's Disease, BioVie will endeavor to advance NE3107 in a range of other diseases where insulin resistance and inflammation is implicated, including Parkinson's, multiple myeloma and prostate cancer in the coming year.

Concurrent with the assets acquisition, BioVie announced the appointment of Cuong V. Do as President and CEO, effective immediately.

Commenting on the announcement, Terren Peizer, Chairman of BioVie said, "We believe this is a transformative transaction for BioVie. With it, BioVie has acquired an attractive portfolio of agents with broad therapeutic potential in Alzheimer's Disease, Parkinson's Disease, several oncology indications and potentially many other areas. Combined with BioVie's lead candidate BIV201 in development for the treatment of advanced liver diseases, we expect to have two molecules entering pivotal Phase 3 studies in the coming year. The company's pipeline is now focused on several attractive areas of unmet medical need with significant market potential. With the appointment of a proven leader and strategic thinker like Cuong Do as President & CEO, who brings over 30 years of industry experience, we are confident in our ability to fully realize this significant commercial opportunity."

Mr. Do is a veteran biotech and pharmaceutical entrepreneur, having previously founded Callidus Biopharma (sold to Amicus Therapeutics), Lysodel Therapeutics and M6P Therapeutics. Previously, Mr. Do was President, Global Strategy Group at Samsung, where he helped create the strategy for Samsung's biologics business. Prior to Samsung, he was the Chief Strategy Officer for Merck where he helped focused the company's portfolio and its future on oncology. He was also a former senior partner at McKinsey & Company, where he spent 17 years and helped build the healthcare, high-tech and corporate finance practices.

"NeurMedix's lead asset NE3107 is one of the most exciting inhibitors of the pathological inflammatory cascade I have seen," said Mr. Do. "Research done to date indicates that this is a highly-targeted small molecule that crosses the blood-brain barrier with an excellent safety-profile. NE3107 blocks insulin resistance and neuroinflammation at the right time and place, without inhibiting homeostatic activity. This asset has extremely broad potential, and I look forward to working with the highly talented NeurMedix clinical team to advance these assets."

Under the terms of the agreement, BioVie has agreed to pay the following consideration to the shareholders of NeurMedix:

- Payments at closing
 - 8,361,308 million newly issued BioVie shares
 - Approximately \$3.0 million in cash
- An additional \$7.3 million cash payment payable after all contemplated clinical programs have been funded and a pivotal Phase clinical trial for NeurMedix's Alzheimer's drug candidate has met its primary endpoint
- Contingent payments in additional BioVie shares (capped at 90% ownership) upon achievement of significant milestones
 - \$350 million upon hitting endpoints in pivotal trials
 - \$700 million upon FDA acceptance of NDA filing
 - \$1,200 million upon FDA approval of NDA
 - \$750 million upon achieving \$1.0 billion trailing 12-month net sales

Conference Call

BioVie will host a conference call today April 27, 2021 at 5:00PM ET to discuss the transaction and the company's forward-looking plans. The webcast link below can be used to access the event both live and via replay.

Conference Call & Webcast Details

Domestic: 877-451-6152

International: 201-389-0879

Conference ID: 13719347

Webcast: <http://public.viavid.com/index.php?id=144714>

Advisors

Moelis & Co. is acting as exclusive financial advisor to BioVie. Hogan Lovells is serving as legal counsel to BioVie, and Greenberg Traurig is serving as legal counsel to NeurMedix. The Weinstein Group advised BioVie in the scientific diligence of the NeurMedix assets and clinical trial plans.

About NeurMedix, Inc.

NeurMedix, Inc. is a clinical-stage biopharmaceutical company that engages in developing products for the treatment of neurological and neuro-degenerative disorders and certain cancers. The company's new drug candidate has successfully completed 11 pre-clinical, and 6 Phase 1, Phase 1/2, and Phase 2 clinical studies in various inflammatory diseases indicating its broad effect in inhibiting inflammatory cascade without evidence of immunosuppression. In addition to Alzheimer's Disease, NeurMedix plans to enter clinical trials for the treatment of

Parkinson's Disease and several oncological indications. The company's focus is on diseases with significant unmet medical needs and commercial potential in order to expedite FDA review, minimize capital requirements and optimize shareholder value.

About BioVie's Liver Cirrhosis Program

BioVie Inc. is developing BIV201 (continuous infusion terlipressin) an Orphan drug candidate for the treatment of ascites due to advanced liver cirrhosis. First-to-market Orphan therapies typically receive 7 years of market exclusivity in the US for the designated use. The initial disease target for BIV201 therapy is ascites, which is a serious complication of advanced liver cirrhosis, and future development opportunities include hepatorenal syndrome (HRS) and other life-threatening complications. The Company recently initiated patient screening in its second US Phase 2 clinical trial, and upon completion will commence a pivotal Phase 3 trial shortly thereafter. The trial design is summarized on www.clinicaltrials.gov, trial identifier NCT04112199. The FDA has never approved any drug specifically for treating ascites, and the Company is not aware of any competing drugs in late-stage development for 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. For more information, visit <http://www.biovieinc.com/>.

Forward-Looking Statements

This press release contains forward-looking statements, which may be identified by words such as "expect," "look forward to," "anticipate" "intend," "plan," "believe," "seek," "estimate," "will," "project" or words of similar meaning. Although BioVie Inc. believes such forward-looking statements are based on reasonable assumptions, it can give no assurance that its expectations will be attained. Actual results may vary materially from those expressed or implied by the statements herein due to the Company's ability to successfully raise sufficient capital on reasonable terms or at all, available cash on hand and contractual and statutory limitations that could impair our ability to pay future dividends, our ability to complete our clinical trials and to obtain approval for our product candidates, to successfully defend potential future litigation, changes in local or national economic conditions as well as various additional risks, many of which are now unknown and generally out of the Company's control, and which are detailed from time to time in reports filed by the Company with the SEC, including quarterly reports on Form 10-Q, reports on Form 8-K and annual reports on Form 10-K. BioVie Inc. does not undertake any duty to update any statements contained herein (including any forward-looking statements), except as required by law.

Contact:

INVESTOR RELATIONS:

Bruce Mackle

Managing Director
LifeSci Advisors, LLC
bmackle@lifesciadvisors.com