

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of December 2016
Commission File Number 0-30314

PORTAGE BIOTECH INC.

(Translation of registrant's name into English)

47 Avenue Rd., Suite 200, Toronto, Ontario, Canada M5R 2G3

(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b):

82- _____.

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.

Dated: December 9, 2016

PORTAGE BIOTECH INC.

By: /s/ Kam Shah
Kam Shah
Chief Financial Officer

NEWS RELEASE

BIOHAVEN' BHV-0223 IS GRANTED ORPHAN DRUG DESIGNATION IN THE TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS

Toronto, Ontario, December 9, 2016 – Portage Biotech Inc. ("Portage" or "the Company") (OTC: PTGEF, Canadian Securities Exchange: PBT.U), is pleased to announce that Biohaven has issued today the following press release:

New Haven, Connecticut (PRWEB) Dec 9, 2016 -Biohaven Pharmaceutical Holding Company Ltd. (the "Company" or "Biohaven") announced today that the U.S. Food and Drug Administration ("FDA") has granted the Company's orphan drug designation request covering its drug candidate BHV-0223, an orally dissolving tablet being developed for the treatment of Amyotrophic Lateral Sclerosis ("ALS"), also referred to as Lou Gehrig's disease. This is the Company's third orphan drug designation request granted by the FDA.

ALS is a progressive neurodegenerative motor neuron disease that affects nerve cells in the brain and the spinal cord. The disease belongs to a group of disorders known as motor neuron diseases, which are characterized by the gradual degeneration and death of motor neurons. ALS affects up to 20,000 individuals in the United States and typically presents in patients with painless muscle weakness, trouble swallowing and muscle atrophy that ultimately progresses to paralysis and death. Since the FDA's approval of riluzole in 1995, there have not been further clinical improvements or advances in ALS drug therapeutics over the last two decades. Several therapies are currently in clinical trials.

BHV-0223 is a sublingually absorbed and oral dissolving tablet (ODT) formulation of riluzole. BHV-0223's novel formulation is designed to address some of the shortcomings associated with the solid oral dosage form of riluzole that ALS patients have difficulty swallowing. Because BHV-0223 is designed to be systemically absorbed through the oral mucosa, rather than through the gastrointestinal system, the Company believes that it can eliminate the negative food effect associated with riluzole, bypass first-pass metabolism and deliver effective doses of the drug at lower concentrations, while also allowing sublingual absorption in patients who experience difficulty swallowing and eliminating the need for three hour fasting twice daily.

Robert Berman, M.D., CMO of Biohaven commented, "Patients with ALS develop a wide range of disabilities with the vast majority developing significant difficulty swallowing. Eventually, most muscles under voluntary control are affected, and individuals lose their strength and the ability to move their arms, legs, and body. As a sublingually administered and orally dissolving tablet form of riluzole, we believe that BHV-0233 may offer important advantages to ALS patients."

Vlad Coric, M.D., CEO of Biohaven, added, "Receiving the orphan drug designation request approval for BHV-0223 in the treatment of ALS advances our global development strategy and one of our primary goals of providing therapies for patients suffering from neurologic disorders with high unmet need. If approved, this unique formulation will provide another therapeutic option to patients living with this devastating disease."

"As shareholders in Biohaven we have been very impressed with Biohaven's interaction with the FDA" said Gregory Bailey, M.D. Chairman of Portage "and the rapid progress they are making in the development of their products."

About BHV-0223

BHV-0223 is a novel formulation of a glutamate-modulating agent that utilizes the Zydis® ODT fast-dissolve technology under an exclusive worldwide agreement with Catalent. Agents that modulate glutamate neurotransmission may have therapeutic potential in multiple disease states involving glutamate dysfunction, including ALS, ataxia, Alzheimer's disease, Rett syndrome, dementia, dystonia, tinnitus, anxiety disorders, and affective disorders like major depressive disorder. Biohaven is pursuing the use of glutamate-modulating agents across several therapeutic indications. The Company intends to pursue regulatory approval of BHV-0223 for ALS in the United States under Section 505(b)(2) of the U.S. Federal Food, Drug and Cosmetic Act. The FDA cleared the Company's investigational new drug application (IND) for BHV-0223 in August 2015, and Biohaven has completed a pharmacokinetic study with this drug candidate in humans and is planning to launch a pivotal bioequivalence study in 2017.

About Orphan Drug Designation

The FDA, through its Office of Orphan Products Development (OOPD), grants orphan status to drugs and biologic products that are intended for the safe and effective treatment, diagnosis, or prevention of rare diseases or disorders that affect fewer than 200,000 people in the United States. Orphan drug designation provides a drug developer with several benefits and incentives, including a period of orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances. Further information regarding Orphan Drug Designation can be found at:

<http://www.fda.gov/forindustry/developingproductsforrareconditions/howtoapplyfororphanproductdesignation/default.htm>

About Biohaven

Biohaven is a privately-held biopharmaceutical company with particular expertise in late-stage clinical development, with a portfolio of multiple late-stage drug candidates. Biohaven has licensed intellectual property from Yale University, Catalent, ALS Biopharma LLC, Massachusetts General Hospital and two global pharmaceutical companies. The Company has advanced multiple drug candidates into the clinic and plans to commence pivotal trials of its lead drug candidate in early 2017.

About Portage:

Portage is engaged in the discovery and development of pharmaceutical and biotech products through clinical "proof of concept" with a focus on areas of unmet clinical need. Following proof of concept, Portage will seek to sell or license these products to large pharmaceutical or biotechnology companies for further development and commercialization.

Portage is seeking discovery and co-development partners with expertise in areas such as cancer, infectious disease, neurology and psychiatry to develop and commercialize its therapies. Portage has an interest in novel targeted therapies, stem cell therapies, and new indications for older marketed products that have been found to have novel patentable characteristics that bring new value to patients.

Portage looks to work with a wide range of partners in all phases of development. Collaboration with Portage may include direct funding of other companies or investing human capital from our extensive pool of talented scientists and physicians. Specifically, Portage invests sweat equity as well as, or instead of, capital. Portage's network of associated drug developers, financiers, scientists and physicians can provide substantial value for our partners by mitigating risks, designing clinical trials, providing regulatory expertise, and maximizing the rewards of clinical development.

Portage's other portfolio companies comprise:

Portage Pharmaceuticals Limited ("PPL"), which is wholly owned by Portage - PPL management developed an improved, fully human cell penetrating peptide platform called CellPorter[®] and nominated its first lead candidate from the CellPorter[®] platform, a potent anti-inflammatory peptide that it plans to develop for ophthalmological diseases, including Dry Eye Disease.

EyGen Limited ("EyGen") a new ophthalmic company, wholly owned by PPL, focused on developing preclinical ophthalmology assets through proof of concept. EyGen's lead asset is PPL-003, a potent anti-inflammatory created by PPL and being developed for topical ophthalmic delivery in patients with ocular surface and anterior segment diseases.

Sentien Biotechnologies Ltd, wherein Portage holds under 20% equity on a fully diluted basis, is a Boston-based firm developing an extracorporeal stem cell therapy for acute kidney injury. Sentien is preparing to file its IND and has just raised more capital to support its first-in-man trial.

For further information, contact Kam Shah, Chief Financial Officer, at (416) 929-1806 or ks@portagebiotech.com or our web site www.portagebiotech.com

Forward-Looking Statements

This news release includes forward-looking statements within the meaning of the U.S. federal and Canadian securities laws. Any such statements reflect Portage's current views and assumptions about future events and financial performance. Portage cannot assure that future events or performance will occur. Important risks and factors that could cause actual results or events to differ materially from those indicated in our forward-looking statements.

Portage assumes no obligation and expressly disclaims any duty to update the information in this News Release.