Issuer Free Writing Prospectus
Filed Pursuant to Rule 433
Registration No. 333-235976

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We have filed a registration statement on Form S-1 (including a prospectus, which currently is in preliminary form) with the U.S. Securities and Exchange Commission ("SEC") for the offering to which the registration statement relates. The registration has not yet become effective. Before you invest, you should read the preliminary registration statement (including the risk factors described therein) and other documents we have filed with the SEC for more complete information about us and this offering. You may access these documents for free by visiting EDGAR on the SEC Web site at www.sec.gov. The preliminary prospectus, dated January 21, 2020, is available on the SEC Web site at www.sec.gov/Archives/edgar/data/.

Alternatively, we or any underwriter participating in the offering will arrange to send you the preliminary prospectus and, when available, the final prospectus and/or any supplements thereto if you contact A.G.P./Alliance Global Partners, 590 Madison Avenue, 36th Floor, New York, NY 10022 or via telephone at 212-624-2006 or email: presentation@allianceg.com.

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Tonix Pharmaceuticals establishes niche as PTSD expert

The group is in the throes of developing an array of pharmaceutical products which take aim at neuropsychiatric conditions

- Tonmya, its chief drug, is designed to treat post-traumatic stress disorder (PTSD).
- The pill has clinched a coveted Breakthrough mark from the US Food and Drug Administration and is already in Phase 3 trials.
- Another key product, TNX-801, is a potential smallpox vaccine that is a synthetic form of horsepox.

What Tonix Pharmaceuticals does:

Tonix Pharmaceuticals Holding Corp (NASDAQ:TNXP) is in the throes of developing an array of pharmaceutical products which take aim at neuropsychiatric conditions.

Its chief treatment is Tonmya (TNX-102SL), which contains 2.8 mg of cyclobenzaprine HCl and treats post-traumatic stress disorder (PTSD) as well as fibromyalgia and agitation in Alzheimer's disease, plus alcohol use disorders, and is in Phase 3 trials. Drilling into the details, Tonmya has proved successful in improving the quality of sleep for patients with PTSD as well as those with fibromyalgia, which triggers musculoskeletal pain and fatigue.

Tonmya has already been elevated to the rank of being a Breakthrough therapy by the US Food and Drug Administration (FDA).

Also in the New York City-based company's line-up are TNX-801, a possible smallpox vaccine that is a synthetic version of horsepox, and TNX-601 CR or tianeptine oxalate, another treatment for PTSD as well as depression.

Tianeptine oxalate is a polymorph and salt of tianeptine, which has been used for decades across European, Asian and Latin American countries, but has yet to be approved by the FDA in the US. Last year, Tonix won a European patent that protects TNX-601 for treating neurocognitive dysfunction linked to corticosteroid treatment.

The company has a few other products, which include TNX-701, a kind of small molecule used to prevent radiation effects that is popular on the biodefense front as well as TNX-1300 (double-mutant cocaine esterase), which is already in a Phase 2 stage to curb cocaine intoxication.

Taking a look a bit further ahead to its pre-clinical pipeline are Tonix's TNX-1500 (anti-CD154), a monoclonal antibody which can be used to prevent the rejection of organ transplants as well as some autoimmune conditions, and TNX-1700 (rTFF2), a biologic that treats gastric and pancreatic cancers.

How is it doing:

Tonix is making considerable advances on the clinical trial front. Its scientists have thus far enrolled 250 civilian and military patients with PTSD in its Phase 3 RECOVERY trial which kicked off in March of 2019 and is evaluating Tonmya's effectiveness in treating this disorder which stems from trauma such as military combat.

Put simply, PTSD is a memory processing disorder characterized by the reliving of trauma via nightmares and flashbacks. Results from an interim analysis using the drug are set to be unveiled in the first quarter of 2020 while the study's topline data should arrive in the second quarter. All of the patients taking part in the Phase 3 study suffered a trauma less than nine years ago.

On top of this, Tonix has also begun signing up patients with fibromyalgia in a Phase 3 RELIEF trial; interim data from this analysis is expected in the second half of 2020.

In the category of additional victories, the company's agitation in Alzheimer's disease program, which focuses on its drug TNX-102 SL - is phase 2 ready as well and is likely to generate considerable interest as there are currently no FDA-approved treatments for agitation in Alzheimer's disease – which also involves sleep deprivation.

The FDA has already tagged the drug's development as a Fast Track program and a patent has been filed to further TNX-102 SL's use to treat agitation and cognitive decline in dementia and neurodegenerative diseases like Alzheimer's. The company's development for alcohol use disorder, meanwhile, is in the pre-investigational new drug application stage.

On January 29, the firm unveiled pre-clinical results of TNX-801 - the possible smallpox vaccine that is a synthetic version of horsepox - in a poster at the 2020 ASM Biothreats Conference held from January 28 to the 30th in Arlington, Virginia. The poster, which was entitled "Synthetic Chimeric Horsepox Virus (scHPXV) Vaccination Protects Macaques from Monkeypox," showcased the analysis of TNX-801 and offered proof that it works.

At the company's helm as founder and CEO is Dr. Seth Lederman, who has a medical degree from Columbia University's medical school where he later worked as a professor and as an attending physician in the Edward Daniels Faulkner Arthritis Clinic at Columbia Presbyterian. While at Columbia, Dr. Lederman discovered the CD40-Ligand and also worked on clarifying the molecular basis of Tcell helper function. Making the switch to the pharma business, Lederman went on to set up Targent Pharmaceuticals, which sold levoleucovorin, a treatment for advanced colorectal cancer, now marketed as Fusilev by Spectrum Pharmaceuticals.

Tonix's chief medical officer, meanwhile, is Dr. Gregory Sullivan, a psychiatrist by trade, who was most recently an assistant professor of Psychiatry in the department of Psychiatry at Columbia University Medical Center as well as a research scientist at the New York State Psychiatric Institute. His expertise is in the treatment of anxiety and mood disorders, including PTSD.

Also sitting on Tonix's Scientific advisory board is Dr. Harvey Moldofsky, the medical director of the Sleep Disorders Clinic of the Center for Sleep and Chronobiology as well as the president of the Toronto Psychiatric Research Foundation. Having focused his career on studying sleep physiology and biologic rhythms, Dr. Moldofsky has become an expert in the effects of fibromyalgia and the connections between musculoskeletal pain and fatigue.

Inflection points:

Interim analysis from Tonix's Phase 3 trial, which has enrolled 250 civilian and military PTSD patients and is evaluating the effectiveness of Tonmya (TNX-102SL), will be unveiled in the first quarter of 2020, while topline data will be released in the second quarter.

Interim data for the trial measuring the benefits of Tonmya for patients with fibromyalgia are expected in the second half of this year.

Tonix's pre-clinical pipeline of drugs, which have yet to hit trials, include TNX-1500 (anti-CD154), a monoclonal antibody used to treat organ transplant rejection, and TNX-1700 (rTFF2), which treats gastric and pancreatic cancers.

What the boss says:

"PTSD is a relatively new indication and I like to think of Tonix as the world leader in PTSD drug research," Dr. Lederman told Proactive in an interview. "There are two approved drugs on the market, but they aren't viewed as very effective to the point that Veteran Administration guidelines don't even recommend pharmacotherapy as a first-line therapy."

"If you look at the national PTSD problem, about three-quarters of our PTSD patients are civilians, so our latest study will reflect that," Lederman added.
