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Tonix Pharmaceuticals Holding Corp. (NASDAQ/TNXP/\$4.39/Not rated)

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2016 Year-End Results and Operation Highlights Announced

Tonix has announced 2016 year-end results and noted a number of operational achievements in the related press release. The company reported a net loss for the fourth quarter ended December 31, 2016 of \$7.5 million or \$2.08 per share (based upon post-split shares) compared to a net loss of \$13.4 million or \$7.96 per share for the 2015 period. For the full year of 2016, Tonix reported a net loss of \$38.8 million or \$15.41 per share compared to a net loss of \$48.1 million or \$28.62 per share in 2015. Excluding non-cash expenditures, the full year net loss for 2016 was \$35.2 million compared to \$43.5 million for the 2015 period. The reduction in net operating loss for 2016 compared to 2015 was largely due to the shift in clinical focus from fibromyalgia to PTSD and a reduction in non-cash charges.

Tonix reported cash and cash equivalents at December 31st of \$26.1 million compared to \$43 million in cash and equivalents at yearend 2015. Tonix's cash burn for 2016 was \$37.3 million, down from \$42.5 million in 2015. Subsequent to the yearend, Tonix completed two financings which added approximately \$17.4 to the Company's coffers. Considering the Company is now funding only the TNX-102 SL HONOR clinical program, having disbanded the fibromyalgia program in 2015, it would appear Tonix has sufficient cash to meet its current operational needs for 2017.

Clinical Status

As previously announced, Tonix enrolled the first patient for its Phase III HONOR trial as of the end of March. At that point in time, the trial had 11 US sites open and enrolling out of the 30+ sites expected to participate in the trial. As of this morning, 25 sites are now recruiting patients, which includes four sites in Texas, a new site in New York City, and additional sites in Florida and California. The Company has not made any further public announcements concerning patient enrollment beyond that of late March. Patient enrollment progress will determine the eventual timing of the scheduled interim analysis that has been placed at 50% enrollment. The interim analysis is still expected to occur during the first half of 2018. Tonix is hopeful that sufficient proof of efficacy as determined by statistical significance against the placebo arm will enable a potential determination by the FDA to accept a single trial for registration. For this to happen, it will be critical for the trial to be adequately powered to overcome trial "drop-outs", unexpected placebo effect and any other patient data that may might be invalidated for other reasons such as protocol violations.

Management is incentivized to make sure the trial progresses on schedule. As noted in the recently filed 2016 10K, the Company granted 10-year options to certain employees to purchase 28,250 shares, at an exercise price of \$5.50, of the Company's common stock. The options vest based on the number of patients that are enrolled in the HONOR Study at December 31, 2017, subject to a one year minimum service period prior to vesting. The number of enrolled patients that triggers vesting was not disclosed.



TNX-601-Follow-on Product for PTSD

As we mentioned in our last Note, now that the HONOR trial is underway, investors will also be assessing the prospects of the Company's preclinical pipeline, which at present, consists of TNX-801, the live smallpox vaccine candidate and TNX-601, a novel formulation of tianeptine, tianeptine oxalate, Tonix is developing as a follow-on PTSD candidate for use in daytime dosing. Recall that TNX-102 SL is administered as a night-time medication to improve sleep quality in PTSD-afflicted patients. Tianeptine (sodium form) is sold as the branded drug **Stablon** in France by Servier SA and under brand **Coaxil** and other brand names in Russia and some countries in the Mideast and Asia. It is prescribed largely for major depressive disorder. A small number of studies published over the last 20 years have suggested that tianeptine may be a useful treatment for PTSD. Tonix is hopeful its novel tianeptine oxalate salt formulation will yield improved shelf-life stability and manufacturability consistency relative to the currently marketed tianeptine.

Tianeptine, originally developed by the French Society of Medical Research in the 1960's, chemically is a tricyclic antidepressant that acts as a low-affinity agonist of the mu-opioid receptor and also as a serotonin reuptake stimulant. Tianeptine is thought to increase the spontaneous activity of hippocampal cells and accelerate their return to normal functionality following excessive neuroendocrine stress. The drug's mode of action also supports anxiolytic (anti-anxiety) activity and has a mildly positive effect on memory and cognition. It is tianeptine's anxiolytic and stress mediation attributes that Tonix hopes will prove complementary to TNX-102 SL. Tonix was issued US patent 9,314,469 B2 "Method for treating neurocognitive dysfunction," in April 2016 which covers certain use claims of tianeptine for cognitive dysfunction.

Comment

From our perspective today, we believe investors will remain focused on patient enrollment progress in the HONOR Phase III trial. As the Company's back pipeline potential product candidates are still in pre-IND preclinical development and management has not yet given guidance on the expected timing of one or both of these products moving closer to an IND filing, we suspect investors may not begin to focus on these programs until further news surrounding their progress becomes available. *SG*





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