



NEWS RELEASE

Assertio Holdings, Inc. Announces FDA Orange Book Listing for New Sympazan® Oral Film Patent

1/9/2023

Extends Intellectual Property Protections to 2039

LAKE FOREST, Ill., Jan. 09, 2023 (GLOBE NEWSWIRE) -- Assertio Holdings, Inc. ("Assertio" or the "Company") (Nasdaq: ASRT), a specialty pharmaceutical company offering differentiated products to patients, today announced that U.S. Patent, No. 11541002 for Sympazan® oral film is now listed in the U.S. Food and Drug Administration ("FDA") publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book.

The patent, which is valid until 2039, is assigned to Aquestive Therapeutics, Inc. and exclusively licensed to Assertio. It covers an oral film for delivering clobazam and methods for using the film to treat epilepsy and/or seizures. Aquestive will continue to prosecute additional US patent application(s) to further strengthen the portfolio on this product.

"We are pleased to see this patent listed in the Orange Book, as originally anticipated in our Sympazan licensing agreement with Aquestive. This patent is complementary to two other Sympazan patents already listed in the Orange Book and extends patent coverage until 2039 for this innovative and attractive oral film delivery system for clobazam," Dan Peisert, President and Chief Executive Officer of Assertio.

"Sympazan exemplifies the type of longer duration assets we are seeking to add to the portfolio as we continue to diversify and expand our platform," said Vanessa Fox, Vice President, Business Development and Commercial Analytics. "We continue to work a robust pipeline of business development projects in support of our goal to add \$50 million of incremental gross profit by 2024, of which we have now secured \$18 million from the combination of our Otrexup and Sympazan transactions, both of which include notable growth opportunities."

About Sympazan

Trade Name	Sympazan® (clobazam) oral film formulation
Indication	For the adjunctive treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) in patients aged 2 years of age or older
Last to Expire Orange Book Listed Patent	September 2039
Trailing 12 Months Revenue Ended 6/30/22	Approximately \$9.5 Million

WARNING: RISKS FROM CONCOMITANT USE WITH OPIOIDS; ABUSE, MISUSE, AND ADDICTION; and DEPENDENCE AND WITHDRAWAL REACTIONS

- Concomitant use of benzodiazepines and opioids may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing of these drugs in patients for whom alternative treatment options are inadequate. Limit dosages and durations to the minimum required. Follow patients for signs and symptoms of respiratory depression and sedation.
- The use of benzodiazepines, including SYMPAZAN, exposes users to risks of abuse, misuse, and addiction, which can lead to overdose or death. Before prescribing SYMPAZAN and throughout treatment, assess each patient's risk for abuse, misuse, and addiction.
- Abrupt discontinuation or rapid dosage reduction of SYMPAZAN after continued use may precipitate acute withdrawal reactions, which can be life-threatening. To reduce the risk of withdrawal reactions, use a gradual taper to discontinue SYMPAZAN.

Important Safety Information

SYMPAZAN is a benzodiazepine medicine. Taking benzodiazepines with opioid medicines, alcohol, or other central nervous system (CNS) depressants (including street drugs) can cause severe drowsiness, breathing problems (respiratory depression), coma, and death.

Get emergency help right away if any of the following happens:

- shallow or slowed breathing
- breathing stops (which may lead to the heart stopping)
- excessive sleepiness (sedation)

Do not drive or operate heavy machinery until you know how taking SYMPAZAN with opioids affects you.

Please see full Prescribing Information including Boxed Warning on risks from concomitant use with opioids; abuse, misuse and addiction; and dependence and withdrawal reactions at www.sympazan.com/pdfs/pi.pdf

About Assertio

Assertio is a specialty pharmaceutical company offering differentiated products to patients utilizing a non-personal promotional model. We have built and continue to build our commercial portfolio by identifying new opportunities within our existing products as well as acquisitions or licensing of additional approved products. To learn more about Assertio, visit www.assertiotx.com.

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Forward Looking Statements

Statements in this communication that are not historical facts are forward-looking statements that reflect Assertio's current expectations, assumptions and estimates of future performance and economic conditions. These forward-looking statements are made in reliance on the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements relate to, among other things, future events or the future performance or operations of Assertio, including our ability to realize the benefits from our operating model, successfully acquire and integrate new assets including Sympazan and explore new business development initiatives, as well as Aquestive's ability to successfully prosecute the pending patent application and timing of allowance by the USPTO. All statements other than historical facts may be forward-looking statements and can be identified by words such as "anticipate," "believe," "could," "design," "estimate," "expect," "forecast," "goal," "guidance," "imply," "intend," "may", "objective," "opportunity," "outlook," "plan," "position," "potential," "predict," "project," "prospective," "pursue," "seek," "should," "strategy," "target," "would," "will," "aim" or other similar expressions that convey the uncertainty of future events or outcomes and are used to identify forward-looking statements. Such forward-looking statements are not guarantees of future performance and are subject to risks, uncertainties and other factors, some of which are beyond the control of Assertio, including the risks described in Assertio's Annual Report on Form 10-K and

Quarterly Reports on Form 10-Q filed with the U.S. Securities and Exchange Commission ("SEC") and in other filings Assertio makes with the SEC from time to time. Investors and potential investors are urged not to place undue reliance on forward-looking statements in this communication, which speak only as of this date. While Assertio may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to update or revise any forward-looking-statements contained in this press release whether as a result of new information or future events, except as may be required by applicable law. Nothing contained herein constitutes or will be deemed to constitute a forecast, projection or estimate of the future financial performance or expected results of Assertio.

Source: Assertio Holdings, Inc.