

November 28, 2023



Ensysce Biosciences and OncoZenge Announce Letter of Intent for the Co-development of BupiZenge(TM) in the United States

Collaboration Aims to Accelerate Development of BupiZenge™, a Novel Pain Treatment for Oral Mucositis Associated with Cancer Treatment

SAN DIEGO, CA and STOCKHOLM, SWEDEN / ACCESSWIRE / November 28, 2023 / Ensysce Biosciences, Inc. ("Ensysce" or the "Company") (NASDAQ:ENSC), a clinical-stage company applying transformative chemistry to improve prescription drug safety, and OncoZenge AB ("OncoZenge") (STO:ONCOZ), a clinical-stage company developing a transformative treatment for oral pain, are pleased to announce today that they have signed a letter of intent (LOI) to explore a strategic collaboration to accelerate the commercialization of BupiZenge™ in the United States.

BupiZenge™ is OncoZenge's novel approach to treating pain caused by oral mucositis, an often severely debilitating condition of painful swelling and ulcerations of the mouth that commonly results from head and neck radiation and/or chemotherapy used to treat cancer. Left untreated, oral intake of food or fluids may be severely impeded and may adversely impact a patient's prognosis and quality of life.

BupiZenge™ is a non-opioid oral formulation of the well-established local anesthetic bupivacaine. OncoZenge has successfully progressed BupiZenge™ through Phase 2 in the European Union (EU) and is currently in planning for the registrational Phase 3 program. Results from the Phase 2 study conducted in head and neck cancer patients with oral mucositis demonstrated strong efficacy in relieving pain with good safety and tolerability.

The proposed collaboration aims to leverage the expertise and resources of both companies to accelerate the path to market in the United States for this innovative therapy that addresses critical unmet needs in the fields of analgesia and oncology.

Stian Kildal, CEO of OncoZenge, commented, "This collaboration aligns with our mission to enhance patient quality of life and provides a firm foundation for access to the important US market. In Ensysce we have found an experienced team that shares our passion and commitment to progress BupiZenge towards market approval. Together we have the potential to accelerate the introduction of our pain medication to those millions of patients who lack safe and effective treatment options under today's Standard of Care."

"We are thrilled to embark on this co-development with OncoZenge to further diversify our current portfolio of highly novel opioid pain products with BupiZenge," said Dr. Lynn Kirkpatrick, CEO of Ensysce. "Joining forces strengthens the opportunity to accelerate the

development and delivery of this transformative therapy while working to gain regulatory approval and launch in the United States. Together, we aim to make a meaningful impact in the field of pain management and oncology to improve patients' quality of life."

About Ensysce Biosciences

Ensysce Biosciences is a clinical-stage company using its proprietary technology platforms to develop safer prescription drugs. Leveraging its Trypsin-Activated Abuse Protection (TAAP™) and Multi-Pill Abuse Resistance (MPAR®) platforms, the Company is developing unique, tamper-proof treatment options for pain that minimize the risk of both drug abuse and overdose. Ensysce's products are anticipated to provide safer options to treat patients suffering from severe pain and assist in preventing deaths caused by medication abuse. The platforms are covered by an extensive worldwide intellectual property portfolio for a wide array of prescription drug compositions. For more information, please visit www.ensysce.com.

About OncoZenge AB

OncoZenge develops a novel, effective, safe and well-tolerated treatment for oral pain in conditions where currently available treatment options either do not achieve sufficient pain relief or are associated with significant side effects. BupiZenge™ is a new oral lozenge formulation of bupivacaine, an anaesthetic with decades of clinical experience. OncoZenge's lead indication is oral pain due to an inflammatory condition called oral mucositis that affects millions of patients receiving cancer treatment. Oral mucositis causes profound physical and psychological suffering and is a large unmet medical need for an effective, opioid-sparing treatment option. BupiZenge™ has shown significantly better pain relief compared to standard of care in this indication in a Phase 2 trial. OncoZenge has its headquarters in Stockholm, Sweden, and its share is publicly traded on Nasdaq First North Growth Market under the ticker ONCOZ.

Forward-Looking Statements

Statements contained in this press release that are not purely historical may be deemed to be forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. Without limiting the foregoing, the use of words such as "may," "intends," "can," "might," "will," "expect," "plan," "possible," "believe" and other similar expressions are intended to identify forward-looking statements. The product candidates discussed are in clinic and not approved and there can be no assurance that the clinical programs will be successful in demonstrating safety and/or efficacy, that Ensysce will not encounter problems or delays in clinical development, or that any product candidate will ever receive regulatory approval or be successfully commercialized. All forward-looking statements are based on estimates and assumptions by Ensysce's management that, although Ensysce believes to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that Ensysce expected. In addition, Ensysce's business is subject to additional risks and uncertainties, including among others, the initiation and conduct of preclinical studies and clinical trials; the timing and availability of data from preclinical studies and clinical trials; expectations for regulatory submissions and approvals; potential safety concerns related to, or efficacy of, Ensysce's product candidates; the availability or commercial potential of product candidates; the ability

of Ensysce to fund its continued operations, including its planned clinical trials; the dilutive effect of stock issuances from our fundraising; and Ensysce's and its partners' ability to perform under their license, collaboration and manufacturing arrangements. These statements are also subject to a number of material risks and uncertainties that are described in Ensysce's most recent quarterly report on Form 10-Q and current reports on Form 8-K, which are available, free of charge, at the SEC's website at www.sec.gov. Any forward-looking statement speaks only as of the date on which it was made. Ensysce undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required under applicable law.

Ensysce Biosciences Company Contact:

Lynn Kirkpatrick, Ph.D.
Chief Executive Officer
(858) 263-4196

Ensysce Biosciences Investor Relations Contact:

Shannon Devine
MZ North America
Main: 203-741-8811
ENSC@mzgroup.us

OncoZenge AB Contact:

Stian Kildal
Chief Executive Officer
+46 76 115 3797
stian.kildal@oncozenge.se

SOURCE: Ensysce Biosciences Inc. and OncoZenge AB

View source version on accesswire.com:

<https://www.accesswire.com/810266/ensysce-biosciences-and-oncozenge-announce--letter-of-intent-for-the-co-development-of-bupizengetm-in-the-united-states>