

# FDA Filing expected in Q3 for NASDAQ Company's JW-100 treatment for Eczema; Jupiter Wellness, Inc. (NASDAQ: JUPW)

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JUPITER, FLORIDA, UNITED STATES, June 22, 2021 /EINPresswire.com/ -- FDA Filing expected this Q3 for NASDAQ Company's JW-100 treatment for Eczema; Jupiter Wellness, Inc. (NASDAQ: JUPW)



Jupiter Wellness is a leading developer of cannabidiol (CBD) based medical therapeutics and wellness products. The Company's clinical pipeline of prescription CBD-enhanced skin care therapeutics address indications including eczema, burns, herpes cold sores, and skin cancer. Jupiter generates revenues from a growing line of proprietary over-the-counter skincare products including its flagship CaniSun™ sunscreen and other wellness brands sold through its robust distribution platform.

#### \$JUPW NASDAQ Overview

JUPW maybe the next JAZZ / JUPW Acquisition Reported \$28 Million Revenue for 2020

Developer of CBD Treatments for the Multi-Billion Dollar Skin Care Market.



We are excited by these initial results and the potential for JW-100. The early clinical data shows JW-100's potential to disrupt the billion-dollar market for the treatment of eczema"

Brian John, CEO of JUPW

☐Multiple Clinical Studies Underway on Company's Proprietary Products.

□□OI Signed to Acquire Company and its Affiliates with Over 300 SKUs.

☐ Highly Qualified Management with Extensive Accomplishments in Place.

☐ Threstment in Theme Park Business Sees Surge in Recent Business as the Pandemic Declines.

Jupiter Wellness, Inc. (NASDAQ: JUPW) is a leading

developer of Herbal based medical therapeutics and wellness products. The JUPW clinical pipeline of prescription enhanced skin care therapeutics address indications including eczema, burns, herpes cold sores, and skin cancer. JUPW generates revenues from a growing line of proprietary over-the-counter skincare products including its flagship CaniSun™ sunscreen and other wellness brands sold through its robust distribution platform.

JUPW is NASDAQ listed and has an attractive share structure with only

11,410,188 shares currently outstanding.

□ LUPW Advances Clinical Pipeline of **Topical Treatments** 

On April 29thJUPW announced an update on its clinical pipeline of Herbal based therapeutic topical formulations including JW-100 for the treatment of eczema, JW-200 for skin cancer, JW-300 for burns, and JW-400 for herpes cold sores.

Commenced Patient Enrollment for Skin Cancer: Study Completion Expected Q4 2021

The JUPW JW-200 is designed to provide action and relief in the treatment of Actinic Keratosis (AK), the most common precancer that forms on skin as a result of exposure to ultraviolet (UV) rays. The objective of this double blinded, placebo-controlled study is to evaluate the efficacy of JW-200 in both the treatment and prevention of disease, with a primary efficacy endpoint of the percentage of patients with complete clearance of AK lesions. An estimated 120 adults diagnosed with AK will be recruited, with an expected study completion date of Q4 2021.

The Skin Cancer Foundation estimates 58 million Americans have one or more AK lesions which appear as raised, scaly discolored patches on sunexposed skin. Left untreated, approximately 20% of AK lesions progress to squamous cell carcinoma. The skin cancer treatment market was \$8.19 billion 2019 and is estimated to



## \$JUPW Listed on the NASDAQ

# CANISUN.

#### **Endorsement Deal With Ernie Els**

- Multi-Year Agreement to utilize player's name, endorse and likeness to advertise, promote and sell CaniSun, CaniSkin
- World Golf Hall of Famer
- One of golf's most prolific winners with a global reach of
- Former World No. 1 with 72 professional career victories
- 4 Major Championships 2 World Golf Championships
- Record for the most consecutive weeks inside the Top-10 of the Official World Golf Ranking
- Els name also has a global reach beyond golfing, in bus endeavors and charitable work Named one of the Top Five Most Positive Athletes in the World
- by the United Nations NGO Voting Academy



"I've been using CaniSun sunscreen and I love the product. This is an easy endorsement for someone who is in the sun as

## \$JUPW signs PGA Golfer Ernie Els

## CANISUÑ.

#### Distribution to Global Theme Parks

- Acquired SRM Entertainment in December 2020
- Award-winning innovation company with over 30 years of success designing, manufacturing and selling creative products and services globally to customers including Fortune 500 companies
- Long-standing preferred vendor for theme parks including: Orlando, Beijing, Hong Kong, Shanghai &
- Developed products for major movie and theme park brands and characters
- Jupiter's strategy is to substantially increase sales of sun care products through venues frequented by
- Build brand awareness with global customer base







\$JUPW Massive Distribution Pipeline

reach \$14.55 billion by 2027.

Patient Recruitment Started for First Degree Burns: Topline Data Expected Q4 2021

The JUPW JW-300 is being evaluated in a clinical study for the treatment of first-degree burns resulting from sun exposure. The double blinded, placebo-controlled trial is recruiting an estimated 44 patients who have first degree burns induced by UVB irradiation. The primary endpoint is the



reduction in erythema within 24 hours of treatment. The trial is expected to be completed in Q3 2021, with topline data expected Q4 2021.

Preparing for Upcoming IND Meeting with U.S. FDA for Eczema Phase I/II Study

JUPW is preparing for a meeting in Q3 2021 with the U.S. Food and Drug Administration (FDA) regarding the Company's Investigational New Drug (IND) application that it expects to file. JUPW will propose its clinical protocol for a Phase I/II study based on the efficacy and safety shown in the recently completed exploratory study of JW-100 for the treatment of atopic dermatitis (eczema). The study showed that JW-100 cleared or reduced eczema following two weeks of use in more than half of the subjects, achieving ISGA clear or almost clear (1 or 2) with at least a 2-grade improvement from baseline after treatment, versus 20% and 15% in the CBD-only and placebo arms.

The global eczema market is valued at \$10 billion and is expected to grow at a CAGR of 13% through 2025. Ten percent of the U.S. population, or 31.6 million people, have eczema, and according to NationalEczema.org, 86% of people are not satisfied with their current treatment.

JW-400 for Treatment of Herpes Cold Sores Expected to Commence Recruitment Q4 2021

The double blind, placebo controlled JUPW study is now preparing for recruitment of 40 patients with recurrent herpes labialis infection (HSV) who had their initial infection more than one year prior. The primary endpoint is the duration of the herpes labialis episode. The herpes simplex virus treatment market was \$4.8 billion in 2017. Nearly half of Americans age14-29 have HSV-1, known as the cold sore virus.

IJUPW Enters into Letter of Intent to Acquire JustCBD and its Affiliates

On April 20thJUPW announced it has signed a non-binding Letter of Intent with JustCBD and its

affiliates to purchase 51% of JustCBD for \$30 million in cash. Per the Letter of Intent, JustCBD would also receive a put option to sell, at its sole discretion, the remaining 49% of JustCBD to JUPW for an additional \$30 million in a combination of JUPW common stock (not to exceed 25% of the outstanding shares of JUPW) and preferred shares, both valued at \$5.00 per share.

The closing of the transaction is subject to the completion of due diligence, the negotiation and execution of definitive transaction agreements, availability of financing and any necessary regulatory approvals. There can be no assurance that the transaction will be consummated. A condition of the closing of the transaction is that JUPW will enter into a 3-year management operating agreement whereby key members of the JustCBD management team will be retained by JUPW. In addition, it is anticipated that JustCBD will receive representation on the JUPW board of directors.

JustCBD is a leading global manufacturer, retailer and wholesaler of consumer CBD products with over 300 SKUs across a wide variety of categories. Preliminary unaudited 2020 consolidated financial statements of JustCBD and its affiliates show approximately \$28 million of revenue. JustCBD has engaged a leading SEC audit firm to complete its audit, which audit is in process.

JUPW management believes this acquisition will be highly accretive to JUPW and its shareholders and puts the Company at the forefront of CBD consumer related products on the market today.

### IJUPW to Support Growth in CBD-Based Pharma & Consumer Products

On April 16thJUPW announced it has appointed Dr. Glynn Wilson as Chief Science Officer, Rich Miller as Chief Compliance Officer, and Ryan Allison as Chief Operating Officer. Over the past quarters, JUPW has grown its CBD-based consumer wellness business to include 40 products across seven brands in six categories, while also advancing its clinical pipeline with three indications in Phase 1 equivalent studies and one indication ready for an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) based on a successful Phase 1 equivalent which met its primary endpoint.

Dr. Glynn Wilson, who continues to serve as Chairman of the Board and was formerly Head of R&D at JUPW, will now serve as Chief Science Officer overseeing the JUPW pipeline of clinical indications including eczema. Should JW-100 continue to show similar efficacy in advanced stage trials, the JUPW lead product candidate would address a \$10 billion global market, in which a competing product is projected to reach \$2 billion in annual sales. Dr. Wilson will guide the development strategy and clinical design for the JUPW CBD-based topical product candidates for indications including skin cancer, burns, and herpes cold sores, all of which are currently in Phase 1 equivalent human trials. Dr. Wilson was formerly Head of Drug Delivery at SmithKline Beecham and was Founder, CEO and Chairman of TapImmune, a developer of cancer vaccines.

Rich Miller continues to serve as a Director for JUPW and now moves into the newly created

position of Chief Compliance Officer overseeing regulatory affairs for securities, CBD-based products, JUPW subsidiaries, manufacturing, and international trade. As JUPW expands through both organic growth and acquisition, Mr. Miller serves a critical role in assuring the Company defines best practices in innovation as a leader in its industry segments.

Ryan Allison, formerly Vice President of Business Development, moves into the position of Chief Operating Officer overseeing growth as JUPW capitalizes on unprecedented opportunities in the CBD pharma and wellness space. Mr. Allison is a strong leader who has been at the forefront of building high-performance, data-driven organizations and business infrastructure throughout his career across many industries including healthcare and the federal government. Earlier in his career Mr. Allison served at VMware where he was an early member of the cloud computing team and an instrumental player in securing a foothold in the infant cloud landscape, a market segment VMware continues to lead in today.

□SRM Division Sees Significant Monthly Sales Growth as Global Theme Parks Set to Reopen

On March 11th JUPW announced that SRM Entertainment was on track for the month of March to produce its highest monthly sales since the wholly owned subsidiary was acquired in December of 2020.

SRM designs, manufactures, and sells creative products and services globally to customers including Fortune 500 companies with a focus in the hospitality industry and the world's most iconic theme parks in locations including Orlando, Florida, Southern California, and other high profile cities worldwide.

JUPW made a strategic decision to make an investment in the hard-hit theme park and hospitality industry and acquire SRM to keep a quality operation active through the pandemic. With hospitality venues and theme parks starting to move towards fully re-opening, JUPW is seeing a significant increase in purchase orders and shipments.

For additional information on Jupiter Wellness, Inc. (JUPW) visit <u>www.jupiterwellnessinc.com</u>.

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