



S&P 500

4,454.98
+5.93 (+0.13%)

Dow 30

34,805.58
+40.76 (+0.12%)

Nasdaq

15,046.49
-5.76 (-0.04%)

Russell 2000

2,251.19
-7.85 (-0.35%)

CISION

Wake Network, Inc. Receives Certificate of Drug Registration for Microdose Formulation in Jamaica

Thu, September 23, 2021, 6:00 AM · 2 min read

TORONTO, Sept. 23, 2021 /CNW/ - Wake Network, Inc. ("Wake" or the "Company"), a global leader in naturally-derived psilocybin production and the developer of genomics-based integration therapies, is pleased to announce the Company has received a Certificate of Drug Registration from the Jamaican Ministry of Health & Wellness for its naturally derived psilocybin microdose formulation, PSIL428.

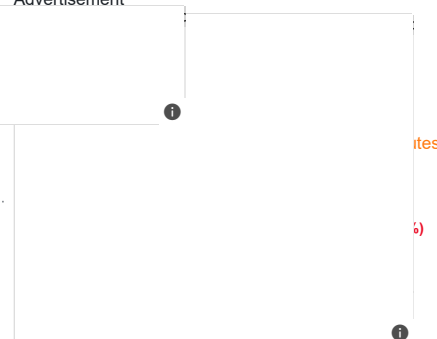


Wake Network, Inc. Logo (CNW Group/Wake Network, Inc.)

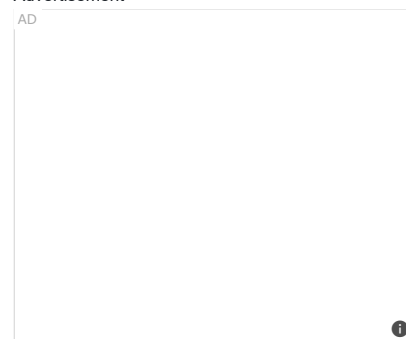
This is a critical milestone for Wake to run its own clinical trials by creating safety and efficacy data for its legal, proprietary psilocybin drug product, PSIL428. PSIL428 is one of the first psilocybin microdose formulations produced worldwide, which is derived from natural fungi material. This will allow the Company to address the growing demand for mushroom-based psilocybin microdosing used for therapeutic purposes. It also adds a layer of control that is committed to quality, consistency, and reliability from dose to dose.

PSIL428 and the data on its safety and efficacy created through Wake's clinical trials will be available to clinics, treatment centres, and academic centres worldwide. As one of the only legal natural psilocybin drug forms in the world, it can be

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Symbol	Last Price	Change	% Change
MMED.NE	3.1700	-0.0800	-2.4615%
Mind Medicine (MindMed) Inc.			

TRENDING

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4. Wolfgang Puck on restaurant industry staffing hurdle: 'Wages are not the issue'
5. 'I don't think we've done enough to get vaccines overseas': Doctor



formulation being registered as a research drug by the Jamaican Ministry of Health & Wellness", said Olga Chernoloz, Chief Scientific Officer of Wake, "It means that Wake and the clinical communities that are interested in investigating the clinical potential of psilocybin will now have access to this product. PSIL428's natural origin is an added bonus for those considering the potential benefits of full-spectrum formulations."

PSIL 428 will be used in Wake's double-blind, randomized, placebo-controlled clinical trial assessing the effects of microdosing on anxiety and depression. The study is fully approved and registered with the National Institutes of Health, [ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04989972) Identifier: NCT04989972

ABOUT WAKE NETWORK, INC.

Wake Network, Inc. is a fungi bioscience company focused on advancing, through research, the field of psychedelic and fungi-based therapeutics. To address the growing need for psychedelic-assisted mental health support in medicine and society at large, Wake has partnered with academics, governments and best-in-class mycologists around the world. Wake is currently developing fungus-derived psilocybin and is making advancements in the engineering of novel psychedelic biologics, while working on proving out their safety through proprietary genetics-based integration therapies.

Caution Regarding Forward-Looking Information

This news release contains forward-looking statements within the meaning of applicable securities laws. All statements that are not historical facts, including without limitation, statements regarding future estimates, plans, programs, forecasts, projections, objectives, assumptions, expectations, or beliefs of future performance, are "forward-looking statements." Forward-looking statements can be identified by the use of words such as "plans", "expects" or "does not expect", "is expected", "estimates", "intends", "anticipates" or "does not anticipate", or "believes", or variations of such words and phrases or statements that certain actions, events or results "may", "could", "would", "might" or "will" be taken, occur or be achieved. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, events or developments to be materially different from any

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regarding the Company, including but not limited to expected growth, results of operations, performance, industry trends and growth opportunities. While the Company considers these assumptions to be reasonable based on currently available information, they may prove to be incorrect. By their nature, forward-looking statements involve known and unknown risks, uncertainties and other factors which may cause the actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including but not limited to: dependence on obtaining and maintaining regulatory approvals, including federal, provincial, municipal, local or other licences, to operate and expand the Company's facilities; the Company's limited operating history and lack of historical profits; reliance on management; the Company's requirements for additional financing and the effect of capital market conditions and other factors on the availability of capital; competition, including from more established or better financed competitors; the need to secure and maintain corporate alliances and partnerships, including with research and development institutions, customers and suppliers; the Company's ability to develop technology and make scientific discoveries related to the biosynthesis of psilocybin and psilocin; the anticipated potential of biosynthesis to produce psychedelic compounds with the desired attributes; the Company's ability to develop an additional revenue stream from its work in biosynthesis of psilocybin and psilocin; the Company's ability to conduct the clinical trials that it intends to; the ability of the Company to discover new and/or more effective options for patients to treat their conditions; the development and implementation of medical protocols and treatment standard operating procedures for the use of psychedelic therapies; the Company's ability to successfully withstand the economic and geopolitical impact of the COVID-19 pandemic; the medical benefits, safety, efficacy, dosing and social acceptance of psychedelics; and the cultivation and harvest of psilocybe mushrooms; and any other factors or developments that may hinder the market or the Company's growth.

These factors should be considered carefully, and readers are cautioned not to place undue reliance on such forward-looking statements. Although the Company has attempted to identify

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actions, events or results to differ from those anticipated, estimated or intended. There can be no assurance that forward-looking statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in forward-looking statements. The Company has no obligation to update any forward-looking statement, even if new information becomes available as a result of future events, new information or for any other reason except as required by law. Readers should not place undue reliance on the Company's forward-looking statements.

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MindMed and Liechti Lab Provide Results from their Psilocybin R&D Collaboration

Mind Medicine (MindMed) Inc. (NASDAQ: MNMD), (NEO: MMED), (DE: MMQ) (the "Company"), a leading biotech company developing psychedelic-inspired therapies, is pleased to announce that Dr. Matthias Liechti...
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Motley Fool

Why Shares of Cassava Sciences Rose 15% Today

Shares of Cassava Sciences (NASDAQ: SAVA) -- the biotech company responsible for Alzheimer's drug candidate simufilam -- are up 15% as of Thursday's market close after the company released interim data from a...
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The New York Times

Moderna vs. Pfizer: Both Knockouts, but One Seems to Have the Edge

It was a constant refrain from federal health officials after the coronavirus vaccines were authorized: These shots are all equally effective. That has turned out not to be true. Roughly 221 million doses of the Pfizer-BioNTec...
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Biogen's Aduhelm Struggles Don't Hurt Lilly's Outlook, Says Analyst

Lilly's experimental Alzheimer's therapy, donanemab, still has a "transformational growth opportunity," despite Biogen's embattled rollout of Aduhelm, says J.P. Morgan Christ Schott.

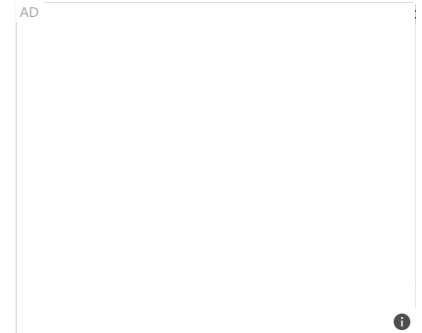
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WHO recommends Regeneron's monoclonal antibody treatment for COVID-19

Shares of Regeneron Pharmaceuticals Inc. were down 0.1% in premarket trading on Friday after the World Health Organization recommended its monoclonal antibody as a treatment for COVID-19. The global body says t...

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Yahoo Finance

CDC recommends Pfizer/BioNTech boosters for certain segments of population

A CDC advisory panel voted Thursday to recommend COVID-19 boosters of the Pfizer/BioNTech vaccine for a broad population of U.S. residents. The CDC released guidance that overruled the panel.

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Reuters

AstraZeneca invests in Imperial's self-amplifying RNA technology with eye on future drugs

AstraZeneca Plc on Thursday struck a deal with the firm behind Imperial College London's experimental COVID-19 vaccine to develop and sell drugs based on its self-amplifying RNA technology platform in other disease area...

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Reuters

UPDATE 3-Novavax applies to WHO for emergency listing of COVID-19 vaccine

Novavax Inc and its partner Serum Institute of India have applied to the World Health Organization for an emergency use listing of Novavax's COVID-19 vaccine, potentially clearing the way for the shot to ship to man...

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Yahoo Sports

WSU president: Nick Rolovich still not vaccinated, says there will be 'no free pass for anybody' regarding mandate

Washington state employees must be fully vaccinated by Oct. 18 and Rolovich is out of time to get a two-dose vaccine before the deadline.



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The supermodel said she's "permanently deformed" from the fat freezing procedure, and has filed a lawsuit against CoolSculpting's parent company

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Investor's Business Daily

Pfizer Nabs Booster OK In U.S. — But How Long Will It Hold The Covid Lead?

Vaccine stocks popped Thursday after the FDA authorized Pfizer and BioNTech's Covid booster shot for at-risk groups.

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MarketWatch

CDC: We are not changing the definition of 'fully vaccinated' now that COVID-19 boosters are available

The Centers for Disease Control and Prevention does not plan to change the definition of what it means to be "fully vaccinated" right now that BioNTech SE and Pfizer Inc.'s COVID-19 booster shots are available for a large grou...

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Benzinga

Why Novavax Shares Are Surging Higher Today

Novavax Inc (NASDAQ: NVAX) is trading significantly higher Thursday after the company, along with Serum Institute, announced a submission to the World Health Organization for emergency use listing for Novavax's COVID...

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MarketWatch

Whether COVID-19 boosters get approved or not, Pfizer and Moderna have already made their money

It's likely that millions of COVID-19 booster shots will be administered in the U.S. in the coming months, but that doesn't mean companies like Moderna and Pfizer will report an unexpected revenue windfall this year.

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The Conversation

Half of unvaccinated workers say they'd rather quit than get a shot — but real-world data suggest few are following through

Forceful words don't always result in strong action. AP Photo/Damian DovarganesAre workplace vaccine mandates prompting some employees to quit rather than get a shot? A hospital in Lowville, New York, for example,...

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