



azitra

Azitra, Inc. Strengthens Global Intellectual Property Portfolio with Newly Granted and Allowed Patents

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- Newly issued U.S. patent protects a flaggrin-secreting strain of *Staphylococcus epidermidis* for the treatment of atopic dermatitis. Issuance date was July 16, 2024
- Newly allowed patents in the U.S. and China protect the composition of a flaggrin-secreting strain of *Staphylococcus epidermidis*
- Newly allowed Canada patent protects a flaggrin-secreting strain of *Staphylococcus epidermidis* for a number of skin diseases, including atopic dermatitis
- Atopic dermatitis is a high unmet need with no FDA-approved treatment option and affects approximately 16.5 million people in the United States
- Broadens Azitra's global intellectual property (IP) position for its platform using metagenomics and engineered skin bacteria for precision dermatology

BRANFORD, Conn.--(BUSINESS WIRE)--Jul. 23, 2024-- Azitra, Inc. (NYSE American: AZTR), a clinical-stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today announced that the U.S. Patent and Trademark Office (USPTO) has granted U.S. patent No. 12,036,248, covering future potential pipeline candidates for indications including atopic dermatitis, titled "Therapeutic treatment of skin disease with recombinant skin microorganisms."

The Company also announced three additional newly allowed patents in three countries, including the U.S., Canada, and China:

- Methods and Compositions for Treating Inflammatory Skin Disease with Recombinant Microorganisms
 - U.S. Patent Application No. 16/121,903
 - Covers the composition of flaggrin-secreting strains of *Staphylococcus epidermidis*
- Methods and Compositions for Treating Atopic Dermatitis with Recombinant Microorganisms
 - Canadian Patent Application No. 3067364
 - Covers the use of flaggrin-secreting strains of *Staphylococcus epidermidis* for atopic dermatitis and other skin diseases
- Methods and Compositions for Treating Inflammatory Skin Disease with Recombinant Microorganisms
 - Chinese Patent Application No. 201880071303.9
 - Covers the composition of flaggrin-secreting strains of *Staphylococcus epidermidis*

Travis Whittill, Azitra's COO, co-founder, and inventor of the patents stated, "We are delighted to announce our second US patent issuance this year and three additional patent allowances in key markets in the U.S., Canada, and China. The indication addressed by the newly issued U.S. patent, atopic dermatitis, affects approximately 16.5 million people in the United States. There are numerous diseases associated with flaggrin deficiency, and the newly issued U.S. patent extends our protection to include a major market in the U.S., atopic dermatitis, particularly those with mild to moderate disease. Additionally, the new patent allowances in China and Canada extend our IP strength globally."

Azitra is developing live biotherapeutic product candidates intended to treat various skin diseases with precision dermatology. In many patients with atopic dermatitis, there is missing or abnormal flaggrin levels. Azitra is developing a novel topical treatment modality for flaggrin-deficient diseases that directly addresses the disease pathophysiology by delivering flaggrin to the skin. The strain consists of a functional unit of the human flaggrin protein with an attached cell penetrating peptide. The goal is to supplement the skin with stable delivery of flaggrin via topical application and deeper skin penetration with a cell penetrating peptide.

This modality of a topical live biotherapeutic consisting of a protein-secreting of *S. epidermidis* to deliver missing proteins is similar to Azitra's ATR-12 product candidate, which delivers Lympho-epithelial Kazal-type-related inhibitor (LEKTI) for Netherton syndrome, caused by missing LEKTI. Azitra has initiated a first-in-human study of ATR-12 for adult Netherton syndrome patients ([NCT06137457](#)), which is now open for enrollment.

After issuance of the Canadian, Chinese and two US patents mentioned above, Azitra will hold 4 granted U.S. patents, 14 granted international patents, 9 pending U.S. patent applications, and 44 pending international patent applications.

About Azitra, Inc.

Azitra, Inc. is an early-stage clinical biopharmaceutical company focused on developing innovative therapies for precision dermatology using engineered proteins and topical live biotherapeutic products. The Company has built a proprietary platform that includes a microbial library comprised of approximately 1,500 unique bacterial strains that can be screened for unique therapeutic characteristics. The platform is augmented by artificial intelligence and machine learning technology that analyzes, predicts and helps screen the Company's library of strains for drug like molecules. The Company's initial focus is on the development of genetically engineered strains of *Staphylococcus epidermidis*, or *S. epidermidis*, which the Company considers to be an optimal therapeutic candidate species for engineering of dermatologic therapies. For more information, please visit <https://azitrainc.com/>.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, statements regarding the expected issuance of patents relating to the three patent allowances and the expected benefits of the recently issued patent covering atopic dermatitis and Azitra's development of live biotherapeutic product candidates intended to treat atopic dermatitis.

Any forward-looking statements in this press release are based on current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, (i) the risk that we may not realize the expected benefits of the newly issued patent or the patents to be issued based upon the three patent allowances, (ii) if we do realize the expected benefits for such patents, we may not be able to protect our rights under such patents, (iii) we are in the early preclinical stages of developing our live biotherapeutic product candidates intended to treat atopic dermatitis and there can be no assurance that we will be able to advance any such product candidate to clinical trials or, if we do, that such clinical trials will be successful, (iv) we may fail to timely raise additional required funding as and when needed, and those other risks described or incorporated by reference in our prospectus dated July 15, 2024 filed with the SEC on July 15, 2024. Azitra explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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