

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): July 25, 2022

INMED PHARMACEUTICALS INC.
(Exact Name of Company as Specified in Charter)

British Columbia
(State or Other Jurisdiction
of Incorporation)

001-39685
(Commission File Number)

98-1428279
(IRS Employer
Identification No.)

InMed Pharmaceuticals Inc.
Suite 310 - 815 W. Hastings Street,
Vancouver, B.C.
Canada

(Address of Principal Executive Offices)

V6C 1B4
(Zip Code)

Company's telephone number, including area code: (604) 669-7207

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|-----------------------------|-------------------|---|
| Common Shares, no par value | INM | The Nasdaq Stock Market LLC |

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On July 25, 2022, the Company provided an update on its Phase 2 clinical trial using investigational drug INM-755 cannabitol (“CBN”) cream for the treatment of patients with epidermolysis bullosa (“EB”).

The information set forth in this Item 7.01, including Exhibits 99.1, is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section. The information set forth in this Item 7.01, including Exhibit 99.1, shall not be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

The following exhibits shall be deemed to be furnished, and not filed:

| Exhibit No. | Description |
|--------------------|---|
| 99.1 | News release, dated July 25, 2022 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document and included as Exhibit 101) |

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

INMED PHARMACEUTICALS INC.

Date: July 26, 2022

By: /s/ Eric A Adams
Eric A Adam
President & CEO



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InMed Announces Update on Phase 2 Clinical Trial Investigating INM-755 Cannabinol Cream for Epidermolysis Bullosa

- **Phase 2 clinical trial recently expanded to include adolescents following independent review of early safety data**
- **First adolescent patient with EB enrolled into clinical trial and completed treatment**
- **International patent granted for the use of cannabinol for the treatment of epidermolysis bullosa**

Vancouver, BC – July 25, 2022 – **InMed Pharmaceuticals Inc.** (“InMed” or the “Company”) (Nasdaq: INM), a leader in the research, development, manufacturing and commercialization of rare cannabinoids, today provided an update on its Phase 2 clinical trial using investigational drug INM-755 cannabinol (“CBN”) cream for the treatment of patients with epidermolysis bullosa (“EB”).

Adolescent patients now eligible to participate in clinical trial

Based on the safety data of the first five adult patients who completed the Phase 2 study, an independent Data Monitoring Committee (“DMC”) agreed it is safe to allow the enrollment of adolescent patients with EB, defined as persons aged twelve to seventeen, into InMed’s Phase 2 clinical trial evaluating INM-755 CBN cream for the treatment of EB. The first adult patient was enrolled in December 2021 and, to date, nine patients have been enrolled in the study. The inclusion of adolescents will have a positive impact in the enrollment rate for the remainder of the clinical trial.

First adolescent patient enrolled into clinical trial

With the DMC approval to enroll adolescent patients into InMed’s INM-755 Phase 2 clinical trial, the first adolescent patient with EB has been enrolled into the clinical trial and has completed treatment at the clinical site in Greece.

Patent granted in Japan

InMed has recently been granted a patent for the use of CBN in the treatment of EB in Japan. This patent allows for the use of topically administered CBN in patients with epidermolysis bullosa simplex (EBS). The Company’s overall patent strategy is to continue to prosecute patent applications in other jurisdictions including Europe and the United States.

Eight clinical trial sites fully activated

InMed’s Phase 2 clinical trial now has eight clinical trial sites fully activated to screen and enroll patients. Two more sites are expected to be fully activated soon. The clinical trial is taking place in seven countries including Austria, Germany, Greece, France, Italy, Israel and Spain. The planned clinical site in Serbia will not be participating in the study due to staffing capacity issues related to the ongoing impact of the COVID-19 virus.

“We are pleased that the initial safety data from InMed’s Phase 2 EB clinical trial has allowed the inclusion of adolescent patients,” stated Alexandra Mancini, Senior Vice President of Clinical and Regulatory Affairs at InMed. “With the inclusion of adolescents and increased number of patients available for screening, the target remains to complete enrollment of 20 patients in 2022.”

The Phase 2 study, 755-201-EB, is designed to enroll up to 20 patients. All four subtypes of inherited EB, being EB Simplex, Dystrophic EB, Junctional EB, and Kindler Syndrome, are eligible for this study. InMed will evaluate the safety of INM-755 (cannabinol) cream and its preliminary efficacy in treating symptoms and healing wounds over a 28-day period. The study uses a within-patient, double-blind design whereby matched index areas will be randomized to INM-755 (cannabinol) cream or vehicle cream as a control. To learn more about this EB study, view the detailed study description on the National Institutes of Health (NIH) clinicaltrials.gov website.

Learn more about InMed's INM-755 EB study: <https://www.inmedpharma.com/pharmaceutical/inm-755-for-epidermolysis-bullosa/>

What is epidermolysis bullosa?

Epidermolysis bullosa, or EB, is a group of rare genetic skin diseases characterized by fragile skin that can lead to extensive blistering and wounding. It affects skin and mucous membranes, particularly of the gastrointestinal tract, genitourinary and respiratory systems. It is a debilitating disease affecting a small number of people, thus earning it an orphan-disease status. The disease has no definitive cure and all currently approved treatments are directed towards symptom relief. Learn more: <https://www.inmedpharma.com/learn/what-is-epidermolysis-bullosa/>.

About InMed: InMed Pharmaceuticals is a global leader in the research, development, manufacturing and commercialization of rare cannabinoids. Together with its subsidiary BayMedica LLC, the Company has unparalleled cannabinoid manufacturing capabilities to serve a spectrum of consumer markets, including pharmaceutical and health and wellness. InMed is also a clinical-stage company developing a pipeline of rare cannabinoid therapeutics and dedicated to delivering new treatment alternatives to patients that may benefit from cannabinoid-based pharmaceutical drugs. For more information, visit www.inmedpharma.com and www.baymedica.com.

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Cautionary Note Regarding Forward-Looking Information:

This news release contains “forward-looking information” and “forward-looking statements” (collectively, “forward-looking information”) within the meaning of applicable securities laws. Forward-looking information is based on management’s current expectations and beliefs and is subject to a number of risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. Forward-looking information in this news release includes statements about: an update on Phase 2 clinical trial investigating INM-755 cannabimol cream for EB; the Phase 2 clinical trial recently being expanded to include adolescents following independent review of early safety data; the inclusion of adolescents having a positive impact in the enrollment rate for the remainder of the clinical trial and the target remains to complete enrollment of 20 patients in 2022; being granted a patent for the use of CBN in the treatment of EB in Japan; continuing to prosecute patents in other jurisdictions; having eight clinical trial sites fully activated to screen and enroll patients with two more sites expected to be fully activated soon; being able to demonstrate that cannabimol cream is a safe and effective treatment for epidermolysis bullosa; continuing to prosecute patents in other jurisdictions, including being a global leader in the research, development, manufacturing and commercialization of rare cannabinoids; and delivering new treatment alternatives to patients that may benefit from cannabinoid-based pharmaceutical drugs.

With respect to the forward-looking information contained in this news release, InMed has made numerous assumptions regarding, among other things: the ability to obtain all necessary regulatory approvals on a timely basis, or at all; and continued economic and market stability. While InMed considers these assumptions to be reasonable, these assumptions are inherently subject to significant business, economic, competitive, market and social uncertainties and contingencies. Additionally, there are known and unknown risk factors which could cause InMed’s actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking information contained herein. A complete discussion of the risks and uncertainties facing InMed’s stand-alone business is disclosed in InMed’s Annual Report on Form 10-K and other filings with the Security and Exchange Commission on www.sec.gov.

All forward-looking information herein is qualified in its entirety by this cautionary statement, and InMed disclaims any obligation to revise or update any such forward-looking information or to publicly announce the result of any revisions to any of the forward-looking information contained herein to reflect future results, events or developments, except as required by law.