



Helus Pharma Completes Enrollment in Phase 3 APPROACH Study of HLP003 in Adjunctive Treatment of Major Depressive Disorder Ahead of Schedule

July 21, 2026

Enrollment continues in EMBRACE, the second pivotal study of the Phase 3 PARADIGM Program

Participant rollover is ongoing into the EXTEND long-term study generating long-term safety and durability data

APPROACH topline data readout on track for Q4 2026^{1,2}

HLP003 previously granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration ("FDA")

HLP003 Phase 2 data demonstrated durable efficacy, with a mean ~23-point reduction in Montgomery-Asberg Depression Rating Scale ("MADRS") score from baseline 12 months after two 16 mg doses administered three weeks apart, and 100% response and 71% remission rates based on a MADRS benchmark of ≤ 10 , with remission rising to 100% using more recent peer-study benchmarks of ≤ 12 ^{3,4}

This news release constitutes a "designated news release" for the purpose of the Company's prospectus supplement dated December 30, 2025, to its short form base shelf prospectus dated September 17, 2025, as amended on December 19, 2025.

NEW YORK and TORONTO, July 21, 2026 (GLOBE NEWSWIRE) -- Helus Pharma (Nasdaq: HELP) (Cboe CA: HELP) (the "Company" or "Helus Pharma") a clinical stage pharmaceutical company committed to helping minds heal by developing novel serotonergic agonists ("NSAs"), today announced that it has completed enrollment in its APPROACH Phase 3 pivotal study of HLP003 in patients living with Major Depressive Disorder ("MDD").

APPROACH enrolled adults with moderate to severe MDD, who experience inadequate response despite a stable antidepressant regimen. Completion of enrollment represents an important milestone for Helus Pharma and advances the Company toward the expected release of topline data in the fourth quarter of 2026.^{1,2}

Current first line antidepressant treatments are only effective in a small proportion of MDD patients.⁵ For those that do not achieve remission, FDA-approved adjunctive atypical antipsychotics can provide modest benefit.⁶ However, their use is often limited by side effects such as weight gain, cardiometabolic dysfunction, movement disorders (such as tardive dyskinesia) and sedation, often resulting in treatment discontinuation.⁷ A novel adjunctive intermittent treatment such as HLP003 could potentially provide a more practical real-world solution.

"Completion of enrollment in APPROACH ahead of schedule demonstrates the focus and execution of our clinical team, investigators and study partners. We thank them and the trial participants for achieving this important milestone. We believe the pace of enrollment of participants reflects not only the efficiency of our clinical team, but also the strength of our screening and site selection processes. Despite rigorous eligibility requirements, we successfully enrolled participants with baseline disease severity aligned with that of our Phase 2 study, reinforcing the quality and integrity of the Phase 3 study population," said Eric So, Interim Chief Executive Officer of Helus Pharma. "With participant enrollment now complete, our focus turns to completing the study and preparing for topline data in Q4 2026.^{1,2} We believe the durability, remission rates, and overall profile demonstrated in our Phase 2 study support the potential of HLP003 to meaningfully improve outcomes for patients living with MDD, and we look forward to advancing the program through the next stage of development and toward a potential FDA New Drug Application in 2028."^{1,2}

The milestone comes amid growing adoption of innovative, clinic-administered treatments for difficult-to-treat depression. Johnson & Johnson reported worldwide SPRAVATO® sales of US\$584 million in the second quarter of 2026, an increase of approximately 25% from the first quarter of 2026 and 40.8% from the second quarter of 2025, including US\$514 million in U.S. sales.⁸ While HLP003 and SPRAVATO are distinct treatments with different mechanisms, clinical profiles and development pathways, Helus Pharma believes this continued growth provides further evidence of significant patient and provider demand for new approaches to treating depression and the increasing adoption of novel treatments in interventional psychiatry.

The APPROACH study, and broader PARADIGM Program, incorporate key considerations outlined in the FDAs recently finalized guidance. These include rigorous placebo-controlled evaluation, measures intended to support the interpretability of study results, assessment of clinical outcomes beyond the primary endpoint, defined safety monitoring and the collection of longer-term safety,

durability and redosing data through the EXTEND study.

"We have developed an industry leading development engine, which we believe will not only continue to drive the APPROACH study to completion, but will serve to accelerate EMBRACE and EXTEND studies, respectively,"^{1,2} said Amir Inamdar, Chief Medical Officer. "The APPROACH study, and the PARADIGM Program in its entirety, are designed to generate robust evidence across efficacy, durability, safety and tolerability. The early completion of enrollment in APPROACH brings us closer to determining whether HLP003 can provide a durable clinical benefit within a practical adjunctive treatment model for people with MDD."

Enrollment is continuing in EMBRACE, the second pivotal study in the Phase 3 PARADIGM Program. Eligible participants from APPROACH and EMBRACE may also roll over into EXTEND, Helus Pharma's long-term extension study, which is designed to further evaluate safety, durability of clinical effect and the potential role of redosing.

Beyond its clinical development program, Helus Pharma has developed a broad intellectual property portfolio supporting its differentiated and proprietary NSA pipeline, with more than 350 patent applications filed and more than 100 patents granted worldwide.

About the APPROACH Pivotal Study

- HLP003 is an investigational deuterated psilocin analogue that has received FDA Breakthrough Therapy Designation and APPROACH is the first pivotal trial to assess HLP003 as a potential adjunctive treatment for MDD.
- APPROACH has completed enrollment of 223 participants with moderate to severe MDD (MADRS $\geq$ 24) who are on a stable dose of antidepressant medication but are responding inadequately.
- Participants were randomized 1:1 to receive HLP003 (16 mg) or placebo. Each study arm evaluates a two-dose regimen, with doses administered three weeks apart.
- The primary endpoint is change from baseline in MADRS at six weeks after the first dose compared to placebo.
- The key secondary endpoint is change from baseline in MADRS at 12 weeks, compared to placebo.
- Participants are eligible to roll over into EXTEND, the blinded long-term extension study with opportunity for redosing.
- Topline data release to include both the primary and key secondary endpoints and is on track for Q4 2026.^{1,2}

About Helus Pharma

Helus Pharma™, the commercial operating name of Cybin Inc. is a clinical stage pharmaceutical company committed to helping minds heal by developing proprietary NSAs - novel serotonergic agonists: synthetic molecules designed to activate serotonin pathways that are believed to promote neuroplasticity. The Company's proprietary NSAs are intended to address the large unmet need for people who suffer from depression, anxiety, and other mental health conditions.

With class leading data, Helus Pharma aims to improve the treatment landscape through the introduction of NSAs that aim to provide durable improvements in mental health. Helus Pharma is currently developing HLP003, a proprietary NSA, in Phase 3 clinical development for the adjunctive treatment of MDD that has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration and HLP004, also a proprietary NSA in Phase 2 for GAD. Additionally, Helus Pharma has an extensive research portfolio of investigational NSAs.

The Company operates in Canada, the United States, the United Kingdom, and Ireland. For Company updates and to learn more about Helus Pharma, visit www.helus.com or follow the team on X, LinkedIn, YouTube and Instagram. Helus Pharma™ is a trademark of Helus Pharma Corp.

Notes

1. There is no assurance that this timeline will be met or that the program will advance clinical trials, at all. Drug development involves long lead times, is very expensive and involves many variables of uncertainty. Anticipated timelines regarding drug development and recruitment of patients for participation in clinical trials are dependent on various factors and are based on reasonable assumptions informed by current knowledge and information available to the Company. Such statements are informed by, among other things, eligibility and exclusion criteria for the trial, design of the clinical trial, competition with other companies for clinical sites or patients, perceived risks and benefits of the prescription drug product candidate, the number, availability, location and accessibility of clinical trial sites, regulatory guidelines for developing a drug with safety studies, proof of concept studies, and pivotal studies for new drug application submission and approval, and assumes the success of implementation and results of such studies on timelines indicated as possible by such guidelines, other industry examples, and the Company's development efforts to date.
2. There is no assurance that timelines will be met. Anticipated timelines regarding the initiation, advancement and results of clinical trials are based on reasonable assumptions informed by current knowledge and information available to the Company. See "Cautionary Notes and Forward-Looking Statements".
3. Popova V, Daly EJ, Trivedi M, et al. Efficacy and Safety of Flexibly Dosed Esketamine Nasal Spray Combined With a Newly Initiated Oral Antidepressant in Treatment-Resistant Depression: A Randomized Double-Blind Active-Controlled Study TRANSFORM-2. *Am J Psychiatry* 2019; 176: 428-438.

4. Definium Therapeutics, "Definium Therapeutics Announces Positive Topline Results from Phase 3 Emerge Study of DT120 Orally Disintegrating Tablet (ODT) in Major Depressive Disorder," press release, June 22, 2026.
5. Rush AJ, Trivedi MH, Wisniewski SR, et al. (2006). Acute and long-term outcomes in depressed outpatients requiring one or several treatment steps: A STAR*D Report. *AM J Psychiatry*, 163, 1905-1917.
6. McIntyre RS, Stahl SM, Shim SR, Pompili M, Goldberg JF, Correll CU, et al. Adjunctive Antipsychotics in Major Depressive Disorder: A Systematic Review and Network Meta-Analysis. *JAMA Psychiatry*. Published online May 6, 2026. doi:10.1001/jamapsychiatry.2026.0658.
7. Spielmans GI, Berman MI, Linardatos E, Rosenlicht NZ, Perry A, et al. (2013) Adjunctive Atypical Antipsychotic Treatment for Major Depressive Disorder: A Meta-analysis of Depression, Quality of Life, and Safety Outcomes. *PLoS Med*10(3):e1001403.doi:10.1371/journal.pmed.1001403
8. Johnson & Johnson, "Johnson & Johnson Reports Q2 2026 Results, Raises 2026 Outlook," press release, July 15, 2026.

Cautionary Notes and Forward-Looking Statements

Certain statements in this news release relating to the Company are forward-looking statements or forward-looking information within the meaning of applicable securities laws (collectively, "forward-looking statements") and are prospective in nature. Forward-looking statements are not based on historical facts, but rather on current expectations and projections about future events and are therefore subject to risks and uncertainties which could cause actual results to differ materially from the future results expressed or implied by the forward-looking statements. These statements generally can be identified by the use of forward-looking words such as "may", "should", "could", "potential", "possible", "intend", "estimate", "plan", "anticipate", "expect", "believe" or "continue", or the negative thereof or similar variations. Forward-looking statements in this news release include statements regarding the Company's plan to readout topline data in the fourth quarter of 2026; the Company's expectation that a novel adjunctive intermittent treatment such as HLP003 could provide a more practical real-world solution; the Company's expectation that HLP003 is a transformative treatment option for patients living with MDD; the Company's progress on and expectations with respect to the APPROACH trial; submission of FDA New Drug Application for HLP003 in 2028; the potential of HLP003 to meaningfully improve outcomes for patients living with MDD; the Company's belief that the continued growth of the adoption of innovative, clinic-administered treatments for difficult-to-treat depression provides further evidence of significant patient and provider demand for new approaches to treating depression and the increasing adoption of novel treatments in interventional psychiatry; the Company's belief that its drug development engine can continue to drive the APPROACH study to completion and serve to accelerate EMBRACE and EXTEND studies, respectively; the Company's continued enrollment in EMBRACE; the possibility of eligible participants from APPROACH and EMBRACE to also roll over into EXTEND; and plans to engineer proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens for mental health conditions.

These forward-looking statements are based on reasonable assumptions and estimates of management of the Company at the time such statements were made. Actual future results may differ materially as forward-looking statements involve known and unknown risks, uncertainties, and other factors which may cause the actual results, performance, or achievements of the Company to materially differ from any future results, performance, or achievements expressed or implied by such forward-looking statements. Such factors, among other things, include: fluctuations in general macroeconomic conditions; fluctuations in securities markets; expectations regarding the size of the NSA market; the ability of the Company to successfully achieve its business objectives; plans for growth; political, social and environmental uncertainties; employee relations; the presence of laws and regulations that may impose restrictions in the markets where the Company operates; implications of disease outbreaks on the Company's operations; and the risk factors set out in each of the Company's management's discussion and analysis for the year ended March 31, 2026, and the Company's annual information form for the year ended March 31, 2026, which are available under the Company's profile on SEDAR+ at www.sedarplus.ca/ and with the U.S. Securities and Exchange Commission on EDGAR at www.sec.gov/edgar. Although the forward-looking statements contained in this news release are based upon what management of the Company believes, or believed at the time, to be reasonable assumptions, the Company cannot assure shareholders that actual results will be consistent with such forward-looking statements, as there may be other factors that cause results not to be as anticipated, estimated or intended. Readers should not place undue reliance on the forward-looking statements contained in this news release. The Company assumes no obligation to update the forward-looking statements of beliefs, opinions, projections, or other factors, should they change, except as required by law.

The Company makes no medical, treatment or health benefit claims about the Company's proposed products. The FDA, Health Canada or other similar regulatory authorities have not evaluated claims regarding NSAs or HLP003, HLP004 and other programs of the Company. The efficacy of such products has not been confirmed by approved research. There is no assurance that the use of NSAs, HLP003, HLP004 or other programs of the Company can diagnose, treat, cure or prevent any disease or condition. Rigorous scientific research and clinical trials are needed. If Helus Pharma cannot obtain the approvals or research necessary to commercialize its business, it may have a material adverse effect on the Company's performance and operations.

Neither Cboe Canada, nor the Nasdaq Global Market stock exchange, have approved or disapproved the contents of this news release and are not responsible for the adequacy and accuracy of the contents herein.

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