Helus Pharma Reports Second Quarter Fiscal 2027 Financial Results and Recent Business Highlights

November 16, 2026

Appointed Michael Halstead as Chief Executive Officer to lead Helus Pharma through late-stage development and commercialization

Completed enrollment in the Phase 3 APPROACH pivotal study of HLP003 in major depressive disorder ("MDD"); topline data remains on track for Q4 2026[1,2]

Announced design of upcoming HLP004 Phase 2 monotherapy study in generalized anxiety disorder ("GAD"); expected to initiate in Q1 2027[1,2]

Appointed Dr. Suresh Durgam, former Executive Vice President and Chief Medical Officer of Intra-Cellular Therapies, Inc. to the Company's Board of Directors

Appointed Helus Pharma board member, Mark Lawson, independent Chair of the Board of Directors

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, Nov. 16, 2026 (GLOBE NEWSWIRE) -- Helus Pharma Inc. (Nasdaq: HELP) (Cboe CA: HELP) (the "Company" or "Helus Pharma"), a clinical-stage pharmaceutical company committed to improving the treatment landscape in mental health through the development and commercialization of novel serotonergic agonists ("NSAs"), today reported recent business highlights and financial results for its fiscal quarter ended September 30, 2026.

"Since joining Helus Pharma as Chief Executive Officer, I have had the opportunity to work closely with our teams and gain a deep appreciation for the potential our development programs have to positively impact the treatment of mental health related conditions and the dedication of our employees," said Michael Halstead, Chief Executive Officer of Helus Pharma. "We continue to expect topline results from the APPROACH study in the fourth quarter of 2026, and we remain focused on disciplined execution across our portfolio. With enrollment ongoing in the EMBRACE and EXTEND studies in our Phase 3 adjunctive MDD program and the anticipated initiation of our Phase 2 HLP004 monotherapy study in generalized anxiety disorder in the first quarter of 2027, we believe we are well positioned to continue to advance our pipeline to deliver important treatments to patients."

During the quarter, Helus Pharma completed enrollment in APPROACH, its Phase 3 pivotal study evaluating HLP003 as an adjunctive treatment in MDD. APPROACH enrolled 223 adults with moderate to severe MDD, who experience inadequate response despite a stable antidepressant regimen. Previously reported HLP003 Phase 2 data demonstrated a durable and clinically meaningful treatment effect. The topline Phase 3 APPROACH data readout remains on track for Q4 2026.[1,2]

The Company also recently announced the design of its upcoming HLP004 Phase 2 monotherapy study for the potential treatment of GAD. The Phase 2 HLP004 study is expected to initiate in Q1 2027.[1,2]

Recent Business and Pipeline Highlights:

HLP003: Continued advancement of the Phase 3 PARADIGM program

- APPROACH has completed enrollment, and the study is on track for topline data readout in Q4 2026.[1,2]
- Enrollment is ongoing in EMBRACE, the second pivotal study in the Phase 3 PARADIGM program.
- Participant rollover is ongoing into the EXTEND long-term extension study to evaluate long-term safety, durability of clinical effect and the potential role of redosing.

HLP004: Phase 2 monotherapy study for the potential treatment of GAD

- The study will be a multi-center, randomized, double-blind, placebo-controlled study, evaluating the efficacy and safety of two 30 mg doses of HLP004 monotherapy administered three weeks apart versus inactive placebo in adult patients with GAD.
- The trial will enroll approximately 144 adult participants with the Diagnostic and Statistical Manual of Mental Disorders fifth edition primary diagnosis of GAD, who have a minimum Hamilton Anxiety Rating Scale ("HAM-A") total score of ≥ 20 at

screening and baseline with randomization in a 1:1 ratio to either 30mg of HLP004 or inactive placebo.
- The primary endpoint and key secondary endpoint are change from baseline in HAM-A total score at Week 6 and Week 12, respectively.
- The Phase 2 dose-ranging study demonstrated evidence that supported the selection of 30 mg as the appropriate dose for further development in a monotherapy GAD study.
- The Company intends to initiate the Phase 2 HLP004 monotherapy study in Q1 2027.[1,2]

HLP005: Advancement toward development candidate selection

Helus Pharma's HLP005 program builds upon the current understanding of the mechanism of action of NSAs and aims to identify key polypharmacological combinations capable of mediating therapeutic effects for target indications. The Company continues to advance the HLP005 program with a drug development candidate anticipated in the second half of 2027. [1,2]

Second Quarter Financial Highlights

Unless otherwise noted, all dollar amounts are expressed in United States dollars.

- Cash totaled $171.1 million as of September 30, 2026.
- Net loss was $103.1 million for the quarter ended September 30, 2026, compared to a net loss of $33.7 million in the same period last year.
- Operating expenses excluding share-based compensation consisting of research, general, and administrative costs totaled approximately $39.6 million for the quarter ended September 30, 2026, compared to $28.5 million, in the same period last year.
- Cash flows used in operating activities were $35.3 million for the quarter ended September 30, 2026, compared to $34.5 million in the same period last year.
- Operating cash flow and expenses were higher than the same period last year, driven by the continued advancement of the APPROACH, EMBRACE, and EXTEND HLP003 Phase 3 trials.

About Helus Pharma

Helus Pharma is a clinical stage pharmaceutical company committed to improving the treatment landscape in mental health through the development of NSAs, 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.

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".

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, uncertainties, and other important factors 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 development and commercialization plans; the design, size, enrollment, initiation, endpoints, and readouts of and from any trials or studies, including Phase 3 topline data readout, the initiation of HLP004 Phase 2 monotherapy study, the ability to enroll eligible participants in the HLP004 Phase 2 monotherapy study, and the progression of the HLP005 program towards drug development candidate selection; the potential of the Company’s development programs to positively impact the treatment of mental health related conditions; the Company’s belief that it is well-positioned to continue advancing its pipeline and creating long-term value for shareholders; and plans to engineer proprietary drug discovery platforms, innovative drug delivery systems, novel formulation approaches and treatment regimens for mental health conditions; and the timing of any of the foregoing.

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; the results of the Company’s clinical trials; the Company’s ability to pursue and obtain regulatory approval for its product candidates; the Company’s ability to enroll and retain participants in its clinical trials; the Company’s need for additional financing; the Company’s dependence on key personnel, including in connection with recent changes in management; the regulation of controlled substances; 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 three and six months ended September 30, 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 U.S. Food and Drug Administration, 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.

Non-IFRS Financial Measures

In this press release, the Company refers to certain non-IFRS financial measures, including operating expenses excluding share-based compensation. The Company considers certain non-IFRS measures to be meaningful indicators of the performance of its business. These measures do not have a standardized meaning under IFRS Accounting Standards and may not be comparable to (and may be calculated differently by) other companies that present similar measures. Accordingly, these measures should not be considered in isolation from nor as a substitute for the Company’s financial information reported under IFRS Accounting Standards. Operating expenses excluding share-based compensation is calculated as operating expenses less share-based compensation. The Company believes this measure provides investors with useful supplemental information regarding the operating performance of the Company’s business. For the three months ended September 30, 2026, operating expenses of $104.5 million, compared to $28.9 million in the same period last year, less share-based compensation of $65.0 million, compared to $0.4 million in the same period last year, result in operating expenses excluding share-based compensation of approximately $39.6 million, compared to $28.5 million, in the same period last year.

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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