Hemab Therapeutics Reports Third Quarter 2026 Financial Results and Provides Corporate Update

November 10, 2026

Dosed first participant in Phase 1 clinical trial of HMB-003 for management of heavy menstrual bleeding, a condition affecting more than 23 million women in the U.S. alone

Announced data showing HMB-003 reduced severe menstrual bleeding in a cynomolgus monkey model; data to be presented at the 68th ASH Annual Meeting and Exposition in December 2026

Announced first clinical data for sutacimig in Factor VII deficiency (FVIID), showing shortening of prothrombin time by more than 50% in both participants and ~5x accumulation of endogenous FVII(a) in the participant with PK/PD data, after a single dose; updated Phase 2b data to be presented at ASH in December 2026

Initiated SOLARA, a pivotal Phase 3 trial of once-weekly subcutaneous sutacimig in Glanzmann thrombasthenia (GT), the first pivotal trial of a subcutaneous prophylactic treatment in GT

Expects to present data from the ongoing VELORA Pioneer Phase 1/2 trial of HMB-002 in Von Willebrand Disease at the 20th EAHAD (European Association for Haemophilia and Allied Disorders) Congress in February 2027

Strengthened Board of Directors with the appointment of Keli Walbert bringing two decades of commercial leadership and proven track record of successful launches to Hemab

CAMBRIDGE, Mass. and COPENHAGEN, Denmark , Nov. 10, 2026 (GLOBE NEWSWIRE) -- Hemab Therapeutics (Nasdaq: COAG), a clinical-stage biotechnology company developing therapies that reimagine the treatment of blood coagulation disorders to sustain life and human resilience, today announced financial results for the third quarter ended September 30, 2026, and recent business highlights.

“We are excited to have started our Phase 3 study in Glanzmann thrombasthenia, transitioning Hemab to a biotech company with clinical stage programs ranging from Phase 1 to Phase 3 across our portfolio,” said Benny Sørensen, MD, PhD, CEO of Hemab. “As our programs advance, we continue to expand our development efforts for larger, underserved markets across coagulation disorders, from the high-severity populations we started with to conditions like heavy menstrual bleeding that affect millions of women each year. We are also excited to have dosed our first participant in the Phase 1 trial of HMB-003 in heavy menstrual bleeding, and look forward to sharing additional preclinical and clinical data from all three programs in the coming months.”

Corporate Highlights

- In September, the Company appointed Keli Walbert to its Board of Directors, who brings more than 20 years of commercial leadership experience in biopharmaceuticals, including as Executive Vice President, U.S. Commercial at Horizon Therapeutics and prior leadership roles at AbbVie, Abbott and United Healthcare. Ms. Walbert has led commercial launches from very common to rare diseases, including HUMIRA®, TEPEZZA® and DUOPA®, and serves on the Company's audit committee.

Recent Business Highlights and Anticipated Milestones
Sutacimig: Sutacimig is a bispecific antibody in clinical development for two indications: GT and Factor VII deficiency (FVIID). Sutacimig has received Fast Track, Orphan Drug, and Breakthrough Therapy Designations from the U.S. Food and Drug Administration (FDA) for the treatment of GT. In Europe, the European Medicines Agency (EMA) has granted sutacimig Orphan Medicinal Product designation for the treatment of GT and access to the Priority Medicines (PRIME) scheme. Sutacimig has also received the Innovative Licensing and Access Pathway (ILAP) designation from the UK Medicines and Healthcare products Regulatory Agency (MHRA).

Glanzmann Thrombasthenia: GT is a congenital, severe, lifelong bleeding disorder caused by defects in platelet aggregation, with substantial geographic variation in prevalence, from approximately 1 in 100,000 individuals in high-prevalence regions such as the Gulf Cooperation Council (GCC) countries to between 1 in 350,000 and 1 in 600,000 in the United States. There are currently no approved prophylactic treatment options for GT; management is limited to platelet transfusions, antifibrinolytics, recombinant Factor VIIa, and bone marrow transplantation.

- In November, the Company initiated SOLARA, an open-label, single-arm, multicenter Phase 3 trial enrolling approximately 75 participants aged 12 to 70 years with GT who have had at least four treated bleeding events in the 12 months before screening. Adolescent enrollment will be gated by the data safety monitoring committee. The trial is being conducted at sites in the United States and other countries.

- The trial has two consecutive periods, so that each participant serves as their own control: a 24-week run-in period, in which participants continue their current on-demand standard of care, without sutacimig while treated bleeding events are prospectively recorded, followed by a 48-week treatment period, in which participants receive sutacimig 0.2 mg/kg by subcutaneous injection once weekly. The primary endpoint is the annualized treated bleed rate (ATBR) during sutacimig prophylaxis compared with the run-in period. Secondary endpoints include high-intensity ATBR, annualized treated bleed days, ATBR by bleed type and cause, the proportion of participants with reductions in ATBR, and safety, tolerability, immunogenicity and pharmacokinetics. Participants who complete the treatment period will have the opportunity to continue sutacimig treatment in a separate open-label extension study.
- SOLARA is being conducted under the Company's active Investigational New Drug (IND) application. SOLARA is designed as a single-arm trial using intra-participant comparisons. The FDA recommended that the Company consider a randomized controlled design. However, the FDA acknowledged the Company's concerns about the feasibility of randomization in GT. In light of substantial variability in treated bleeding rates, the heterogeneity of the patient population, and the practical challenges of randomized trials in a rare disease, the Company has determined to proceed with a single-arm trial.
- SOLARA is the first pivotal trial of a subcutaneous prophylactic treatment in GT. The first participants have been consented and are scheduled to enter the trial's run-in period in the fourth quarter of 2026.

Factor VII Deficiency: FVIID is a congenital severe bleeding disorder, with prevalence of moderate and severe forms estimated at approximately 1 in 500,000 globally and characterized by impaired blood clotting and increased bleeding risk.

- In November, the Company announced first clinical data from the single ascending dose cohort of the ongoing Phase 2b trial of sutacimig in FVIID (NCT07347249). As of July 24, 2026, two participants with severe congenital FVIID had received a single subcutaneous dose. Adverse events were low grade and assessed as not related to treatment. Baseline prothrombin time of ≥180 seconds shortened by more than 50% in both participants. In the participant with PK/PD data available to date, sutacimig produced sustained accumulation (~5x) of endogenous total FVII(a), with exposure maintained through Day 22. Updated data for all dosed participants will be presented as a poster at the 68th ASH Annual Meeting and Exposition on December 14, 2026.

HMB-002 - Von Willebrand Disease: HMB-002 is a novel monovalent antibody designed for subcutaneous prophylactic treatment of VWD, the most common inherited bleeding disorder, with approximately 140,000 patients diagnosed across all severity levels in the United States, of whom more than an estimated 50,000 require treatment for bleeding events.

- Presented data at ISTH 2026 from the ongoing VELORA Pioneer Phase 1/2 trial demonstrating proof of mechanism, a ≥2.4-fold peak increase in VWF and FVIII, normalization of peak thrombin generation and APTT, and a durability profile supporting potential monthly subcutaneous dosing. The single ascending dose portion of the study was not designed to measure efficacy, and the following preliminary clinical observations are descriptive in nature. Across the single ascending dose cohorts, 8 of 9 evaluable patients had zero treated bleeds in the 28 days following HMB-002 dosing, with a mean ATBR of 1.6, compared with a baseline mean ATBR of 20.1 prior to treatment.
- The Company expects to report additional data from the trial at the 20th EAHAD (European Association for Haemophilia and Allied Disorders) Congress in February 2027.

HMB-003 - Novel Antifibrinolytic Program: HMB-003 is a novel fatty-acid-conjugated peptide antifibrinolytic, designed to stabilize clots and reduce bleeding across multiple settings, beginning in heavy menstrual bleeding, an indication affecting one in three reproductive-age women, over 23 million women, in the U.S.

- In September, the Company dosed the first participant in its Phase 1 clinical trial of HMB-003 in healthy volunteers for management of heavy menstrual bleeding (NCT07798505). The trial is a randomized, placebo-controlled, single-ascending-dose escalation trial designed to evaluate the safety, tolerability, pharmacokinetics, and pharmacodynamics of HMB-003 in healthy adult volunteers. Results from this study are expected to inform dose selection and clinical development plans for HMB-003 across additional high-unmet-need bleeding conditions.
- Preclinical data presented at ISTH 2026 demonstrated potent and selective plasmin inhibition, with HMB-003 directly inhibiting plasmin at its active site and blocking fibrinolysis across both tPA- and uPA-driven pathways, while showing no effect on thrombin generation, platelet function, or coagulation in nonclinical studies, and antifibrinolytic activity for approximately one week following a single subcutaneous dose in minipigs. In November, the Company announced additional preclinical data showing that, in human plasma and whole blood, HMB-003 inhibited fibrinolysis in a concentration-dependent manner, with no observed effect on thrombin generation or platelet aggregation in human plasma. In minipigs, a single subcutaneous dose reached peak plasma levels within hours and had a terminal half-life of 6 to 7 days, with complete ex vivo inhibition of fibrinolysis for up to 7 days followed by a full return to baseline. In a cynomolgus monkey model of menstrual bleeding, HMB-003 reduced the proportion of severe bleeding days and shifted bleeding toward lower intensity compared with the baseline observation phase. The Company will present these data as a poster at the 68th ASH Annual Meeting and Exposition on December 13, 2026, and expects initial clinical data from the ongoing Phase 1 trial in mid-2027.

Third Quarter 2026 Financial Results

- **Cash Position and Cash Runway:** Cash, cash equivalents, and marketable securities totaled $430.2 million as of September 30, 2026, compared to $457.5 million as of June 30, 2026. The decrease primarily reflects cash used in operating activities. The Company believes its current cash, cash equivalents, and marketable securities will enable it to fund its operating expenses and capital expenditure requirements into 2029.

- **Research and Development Expenses:** Research and development expenses were $24.6 million for the three months ended September 30, 2026, compared to $14.6 million for the three months ended September 30, 2025. The increase was due to costs related to the advancement of clinical programs**,** increases in personnel-related expenses and equity-based compensation, in addition to discovery and consulting fees related to company growth to support the advancement of our programs.
- **General and Administrative Expenses:** General and administrative expenses were $5.1 million for the three months ended September 30, 2026, compared to $2.5 million for the three months ended September 30, 2025, due to professional services, equity-based compensation and other costs associated with operating as a public company.
- **Net Loss:** Net loss was $27.3 million, or $0.58 per share, for the three months ended September 30, 2026, compared to a net loss of $17.1 million, or $18.04 per share, for the three months ended September 30, 2025. The decrease in net loss per share primarily reflects the increase in weighted-average shares outstanding during the three months ended September 30, 2026 following the Company's initial public offering and the subsequent conversion of preferred stock into common stock in May 2026 in connection with the closing of the Company's initial public offering.

Conference Call Information: The Company will host a conference call and webcast today at 8:00 a.m. ET. Listeners can register for the webcast on the investors page of the company's website (https://ir.hemab.com/) or directly through this link. Analysts wishing to participate in the question and answer session should use this link. A replay of the webcast will be available on the company's website approximately two hours after the call's conclusion and will be available for approximately 90 days following the call. Those who plan on participating are advised to join 15 minutes prior to the start time.

About Glanzmann Thrombasthenia
Glanzmann thrombasthenia (GT) is a severe bleeding disorder marked by debilitating, sometimes life-threatening bleeding episodes. Results from an international natural history study (Glanzmann's 360) revealed the substantial burden of this disease: 88% of the 117 participants reported at least one bleed in the previous week with 65% requiring a bleed-related hospital visit in the prior six months. These bleeding episodes significantly impacted patients' mental health and quality of life, with over 80% having missed work or school, over 50% facing limitations in attending social events, and over 50% experiencing restrictions in travel. To date, there are no approved prophylactic treatment options for GT.

About Factor VII Deficiency
Factor VII deficiency (FVIID) is a congenital severe bleeding disorder characterized by reduced levels of Factor VII, a naturally circulating blood coagulation protein. Patients with clinically severe FVIID suffer from recurrent, unpredictable, life-threatening or potentially disabling bleeding at critical sites, such as in the central nervous system, gastrointestinal tract and intra-articular locations, as well as recurrent mucocutaneous bleeds of the nose and gums with additional risks for female patients, consisting of heavy menstrual bleeding and potentially life-threatening post-partum hemorrhage.

About Sutacimig (formerly HMB-001)
Sutacimig is a subcutaneously administered bispecific antibody that is designed to bind and stabilize endogenous Factor VIIa with one antibody arm and bind to TLT-1 on activated platelets with the other arm. This mechanism is designed to allow for the accumulation of endogenous Factor VIIa in the body and recruitment of Factor VIIa directly to the surface of the activated platelets, where it amplifies thrombin generation at the platelet surface. Sutacimig is designed to be a first-in-class prophylactic treatment for Glanzmann thrombasthenia (GT) with the potential to treat other debilitating bleeding disorders. The U.S. Food and Drug Administration has granted Fast Track Designation, Orphan Drug Designation, and Breakthrough Therapy Designation to sutacimig for the treatment of GT, and the UK Medicines and Healthcare products Regulatory Agency has awarded sutacimig designation under the Innovative Licensing and Access Pathway (ILAP); it has been designated as an orphan medicinal product in the European Union for the treatment of GT, and the European Medicines Agency (EMA) has granted sutacimig access to the Priority Medicines (PRIME) scheme. For more information, please visit clinicaltrials.gov (NCT06211634).

About Von Willebrand Disease
Von Willebrand Disease (VWD) is the most common inherited bleeding disorder, characterized by quantitative or qualitative defects in Von Willebrand Factor (VWF), often resulting in frequent mucocutaneous bleeding events and heavy menstrual bleeding in women. The severity of bleeding ranges from low-volume events to potentially life-threatening hemorrhages. Chronic blood loss frequently leads to iron deficiency anemia, exacerbating the disease burden and reducing quality of life, particularly for those with clinically understated subtypes. Despite its prevalence, current treatment options for VWD primarily focus on managing symptoms rather than addressing the underlying biology of the disease.

About Heavy Menstrual Bleeding
Heavy menstrual bleeding is a common condition characterized by excessive menstrual blood loss that disrupts a person's physical, emotional, social, and daily life, affecting an estimated one in three reproductive-age women, or more than 23 million women in the U.S. alone. The condition is frequently associated with pain, iron-deficiency anemia, and fatigue, and carries a significant social burden, including stigma and substantial lost days from work and school. Current treatment options are limited. Tranexamic acid (TXA), the primary non-hormonal therapy, has a short half-life that requires frequent dosing throughout menstruation, limiting adherence. Hormonal therapies are not suitable, or not preferred, for many women. To date, there remains no approved non-hormonal, customized hemostatic treatment option for heavy menstrual bleeding.

About HMB-002
HMB-002 is a monovalent human antibody being developed as the first-in-class subcutaneous prophylactic treatment for Von Willebrand Disease targeting the underlying cause of the disease, a condition driven by a deficiency or defect in Von Willebrand

Factor (VWF), a key regulator of hemostasis. By specifically targeting the C-terminal CK domain of VWF, which is distinct from regions critical to its essential interactions, HMB-002 shields the protein from degradation, boosting endogenous levels without compromising its function. Clinical and nonclinical data suggest strong potential for meaningful therapeutic benefit. For more information, please visit clinicaltrials.gov (NCT06610201 and NCT06754852).

About HMB-003
HMB-003 is a subcutaneously administered peptide-based plasmin inhibitor with a durable half-life — a proven therapeutic target in coagulation medicine — being developed as a novel antifibrinolytic designed to reduce bleeding across multiple settings. Engineered to directly inhibit plasmin at its active site, HMB-003 blocks fibrinolysis independently of the plasminogen activation pathway. HMB-003 is optimized to provide sustained bleed protection across multiple high-unmet-need conditions, ranging from heavy menstrual bleeding and hereditary hemorrhagic telangiectasia to peri-operative bleeding management. For more information, please visit clinicaltrials.gov (NCT07798505).

About Hemab Therapeutics
Hemab Therapeutics Holdings, Inc. is a clinical-stage biotechnology company developing therapies that reimagine the treatment of blood coagulation disorders to sustain life and human resilience. Hemab's mission is to discover, develop, and commercialize innovative therapies for the millions of patients worldwide suffering from serious bleeding and thrombotic diseases. Hemab is building a franchise of innovative therapeutics designed to address critical gaps in the treatment of coagulation disorders, including sutacimig (HMB-001), a bispecific antibody in clinical development for the prophylactic treatment of Glanzmann thrombasthenia and Factor VII deficiency, HMB-002, a monovalent antibody in clinical development for the prophylactic treatment of Von Willebrand Disease, and HMB-003, an antifibrinolytic targeting plasmin inhibition in clinical development for heavy menstrual bleeding.

Learn more at hemab.com. Follow us on LinkedIn, Facebook, Instagram, and X.

Cautionary Note Regarding Forward-Looking Statements
This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this press release, including statements regarding Hemab's strategy, future operations, prospects and plans, objectives of management, the anticipated timing of reporting and presenting preclinical and clinical data, including from the Phase 1 trial of HMB-003, the anticipated enrollment, timing of entry into the run-in period, conduct and progression of the SOLARA Phase 3 clinical trial of sutacimig, the suitability of SOLARA's single-arm, intra-participant trial design for evaluating sutacimig in GT, the potential for the design and results of SOLARA to support regulatory approval of sutacimig, the clinical potential of sutacimig, HMB-002 and HMB-003, including their potential therapeutic benefits and use across additional indications, Hemab's plans to expand its pipeline, and the sufficiency of Hemab's cash resources for the period anticipated, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "objective," "ongoing," "plan," "predict," "project," "potential," "should," or "would," or the negative of these terms, or other comparable terminology are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Hemab may not actually achieve the plans, intentions or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including: uncertainties inherent in the identification and development of product candidates, including the initiation and completion of preclinical studies and clinical trials; uncertainties as to the availability and timing of results from preclinical studies and clinical trials; the timing of and Hemab's ability to initiate and enroll patients in clinical trials; whether results from preclinical studies and earlier clinical trials will be predictive of the results of later clinical trials; the risk that the FDA or other regulatory authorities may not agree that SOLARA's single-arm, intra-participant design is adequate to establish the safety or effectiveness of sutacimig for GT, may not accept the results of SOLARA as substantial evidence supporting approval, or may require Hemab to conduct one or more additional clinical trials, including a randomized controlled trial, before submitting or obtaining approval of a marketing application for sutacimig; the risk that Hemab's decision to proceed with the current SOLARA design notwithstanding the FDA's recommendation that Hemab consider a randomized controlled design could result in delays in, additional costs associated with, or the inability to obtain regulatory approval for sutacimig on the timeline anticipated or at all; whether Hemab's cash resources will be sufficient to fund Hemab's foreseeable and unforeseeable operating expenses and capital expenditure requirements; as well as the risks and uncertainties identified in Hemab's filings with the Securities and Exchange Commission (SEC), including Hemab's most recent Form 10-Q and in subsequent filings Hemab may make with the SEC. In addition, the forward-looking statements included in this press release represent Hemab's views as of the date of this press release. Hemab anticipates that subsequent events and developments will cause its views to change. However, while Hemab may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Hemab's views as of any date subsequent to the date of this press release.

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Hemab Therapeutics Holdings, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses				
Research and development	$ 24,639	$ 14,555	$ 64,436	$ 41,530
General and administrative	5,119	2,500	15,013	8,142
Total operating expenses	29,758	17,055	79,449	49,672
Loss from operations	(29,758)	(17,055)	(79,449)	(49,672)
Other income (expense), net				
Interest income	3,384	215	7,461	1,023
Other income (expense), net	(237)	(127)	(1,351)	3,981
Total other income, net	3,147	88	6,110	5,004
Loss before income tax expense	(26,611)	(16,967)	(73,339)	(44,668)
Income tax (expense) benefit	(693)	(98)	(802)	88
Net loss	$ (27,304)	$ (17,065)	$ (74,141)	$ (44,580)
Net loss per share, basic and diluted	$ (0.58)	$ (18.04)	$ (2.84)	$ (47.12)
Weighted average shares outstanding, basic and diluted	46,712,044	946,000	26,090,769	946,000
Other comprehensive income (loss)				
Net loss	$ (27,304)	$ (17,065)	$ (74,141)	$ (44,580)
Net unrealized (loss) gain on available-for-sale debt securities	96	—	(2,827)	365
Reclassification of realized loss on available-for- sale debt securities	1	—	1	—
Total other comprehensive income (loss)	97	—	(2,826)	365
Total comprehensive loss	$ (27,207)	$ (17,065)	$ (76,967)	$ (44,215)

Hemab Therapeutics Holdings, Inc.
Selected Condensed Consolidated Balance Sheet Data
(In thousands)
(Unaudited)

	September 30, 2026	**December 31, 2025**
Assets		
Cash and cash equivalents	$ 239,149	$ 87,974
Marketable securities	191,089	97,511
Prepaid expenses and other current assets	7,920	7,066
Property and equipment, net	555	609
Operating right-of-use assets	850	1,092
Other non-current assets	3,149	531
Total assets	442,712	194,783
Liabilities and stockholders' equity (deficit)		
Accounts payable	5,952	5,734
Operating lease liabilities	462	647
Operating lease liabilities, net of current portion	503	573
Accrued expenses and other current liabilities	6,526	4,296
Total liabilities	13,443	11,250
Total convertible preferred stock and convertible preference shares	-	360,168
Total stockholders' equity (deficit)	$ 429,269	$ (176,635)

Hemab Therapeutics Holdings, Inc.
Selected Condensed Consolidated Statements of Cash Flows Data
(In thousands)
(Unaudited)

	Nine Months Ended September 30,		
	2026	**2025**	**Change**
Net cash used in operating activities	$ (72,512)	$ (44,761)	$ (27,751)
Net cash (used in) provided by investing activities	(93,180)	15,508	(108,688)
Net cash provided by (used in) financing activities	317,166	(89)	317,255
Effect of foreign exchange rate changes on cash and cash equivalents	(299)	-	(299)
Net increase (decrease) in cash and cash equivalents	$ 151,175	$ (29,342)	$ 180,517