Gossamer Bio Enters into Option Agreement to Acquire Respira Therapeutics and Its Lead Candidate, RT234, an Inhaled, On-Demand Vardenafil for Pulmonary Hypertension

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- RT234 is an investigational inhaled, as needed (PRN) vardenafil formulation for PAH and PH-ILD, where no on demand treatments exist -

- Capital-efficient structure with no upfront cash, no cash upon exercise, and limited dilution -

- Opportunity to expand pulmonary hypertension franchise through complementary program without diverting resources from near-term execution -

SAN DIEGO--(BUSINESS WIRE)--Sep. 25, 2025-- Gossamer Bio, Inc. (Nasdaq: GOSS), a late-stage, clinical biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of pulmonary arterial hypertension (PAH) and pulmonary hypertension associated with interstitial lung disease (PH-ILD), today announced it has entered into an option agreement to acquire Respira Therapeutics (Respira) and its lead product candidate, RT234, an investigational inhaled vardenafil dry-powder therapy designed for as needed (PRN) use in pulmonary hypertension (PH), including PAH and PH-ILD. Despite existing treatment options, the majority of PH patients continue to struggle with debilitating symptoms that disrupt daily life and limit their independence, because there are no approved PRN therapies in PAH or PH-ILD.

“There is a clear unmet need for an ‘as needed’ therapy in PAH and PH-ILD, where patients lack an option for rapid symptom management. Supported by positive clinical data, RT234, an investigational inhaled, as needed therapy, is intended to address this gap and supplement chronic treatments,” said Faheem Hasnain, Co-Founder, Chairman, and CEO of Gossamer Bio.

“RT234 would be an excellent complement to seralutinib as we look to expand our pulmonary hypertension franchise and deepen our engagement with PH clinicians and patients and to reinforce our long-term commitment to those living with pulmonary hypertension. The option transaction structure gives us flexibility in decision making as we approach key corporate milestones, keeping our attention squarely on near-term seralutinib priorities in PAH and PH-ILD.”

Pursuant to the option agreement, Gossamer will issue 2.5 million shares in connection with signing, equating to about 1% of Gossamer’s common shares outstanding, with an additional 1.5 million shares due upon exercise of the option. Additionally, current and former shareholders of Respira will be eligible for certain success-based clinical, regulatory, and commercial milestone payments and a high single-digit royalty on potential net sales of RT234. During the option period, Gossamer will fund certain pre-agreed development expenses for up to approximately 2 years, focused on CMC and device readiness. This structure is designed to minimize near-term cash burn and preserve Gossamer’s financial position, while allowing for the continued preparation of RT234 for subsequent clinical development by advancing foundational CMC and device work during the option period.

RT234 is an inhaled, PRN formulation of vardenafil delivered via a dry-powder inhaler. Vardenafil is an FDA-approved phosphodiesterase type 5 (PDE5) inhibitor for a non-PH indication. While PDE5 inhibitors sildenafil and tadalafil are FDA-approved for the chronic treatment of PAH, on demand use in PAH and PH-ILD represents a novel treatment approach, with no currently approved PRN therapies. Unlike existing treatments, RT234 is designed to provide rapid, on-demand relief of exertional symptoms such as breathlessness on top of background therapy.

In two completed open-label Phase 2 studies in PAH patients, RT234 demonstrated rapid and clinically meaningful improvements in both hemodynamic and functional measures. Hemodynamic benefits included reductions in pulmonary vascular resistance and favorable changes in mean pulmonary arterial pressure and cardiac output. Acute functional gains were also observed, such as improvements in six-minute walk distance and encouraging signals during cardiopulmonary exercise testing. No major safety issues have been observed to date.

RT234’s on demand profile is potentially synergistic to Gossamer’s existing PH programs, is consistent with our plan to build a PH-focused commercial enterprise, and is intended to be part of a complete PH toolkit for physicians and patients. Additionally, positive FDA interactions support a clear clinical development path. If the option is exercised, Gossamer intends to pursue a 505(b)(2) regulatory pathway for inhaled RT234 in the United States, which could simplify the approval process by referencing existing data. If the option is exercised, Gossamer does not expect to commence clinical trials of RT234 until at least 2027.

Respira Therapeutics is backed by Samsara BioCapital, a leading life sciences investment firm focused on advancing innovative therapies for patients with high unmet needs.

About Gossamer Bio

Gossamer Bio is a late-stage, clinical biopharmaceutical company focused on the development and commercialization of seralutinib for the treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease. Its goal is to be an industry leader in, and to enhance the lives of patients living with pulmonary hypertension.

Forward-Looking Statements

Gossamer cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. These statements are based on the Company's current beliefs and expectations. Such forward-looking statements include, but are not limited to, statements regarding: the potential exercise of the option to acquire Respira, the related issuances of shares of Gossamer's common stock and other contemplated consideration upon the option exercise and the achievement of milestones, and the timing thereof; the anticipated timing of completing certain CMC and device work; the development potential of RT234; the potential synergies between Gossamer's existing PH programs and RT234; the clinical development path for RT234 and the timing thereof, including the timing to commence clinical trials of RT234; and the ability to pursue a 505(b)2 regulatory pathway. The inclusion of forward-looking statements should not be regarded as a representation by Gossamer that any of its plans will be achieved.

Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in Gossamer's business, including, without limitation: unanticipated developments may impact Gossamer's ability to exercise the option to acquire Respira or to realize the anticipated benefits or synergies from the acquisition of Respira; unforeseen challenges or delays in development activities for RT234; the possibility that various closing conditions for the transaction may not be satisfied or waived; the effects of disruption caused by the transaction making it more difficult to maintain relationships with employees, collaborators, vendors and other business partners; risks related to diverting management's attention from the Company's ongoing business operations; unexpected liabilities or expenses resulting from the option agreement and any completion of the acquisition; potential delays in the commencement, enrollment and completion of clinical trials; disruption to our operations from unexpected events, including clinical trial delays; the Company's dependence on third parties in connection with product manufacturing, research and preclinical and clinical testing; the results of preclinical studies and early clinical trials are not necessarily predictive of future results; the success of Gossamer's clinical trials and preclinical studies for seralutinib; regulatory developments in the United States and foreign countries; unexpected adverse side effects or inadequate efficacy of seralutinib that may limit its development, regulatory approval and/or commercialization, or may result in clinical holds, recalls or product liability claims; Gossamer's ability to obtain and maintain intellectual property protection for seralutinib; Gossamer may use its capital resources sooner than it expects; and other risks described in the Company's prior press releases and the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's annual report on Form 10-K and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and Gossamer undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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