# CLARIFICATION - Asep Medical Holdings Inc. Provides Update on its Prior Disclosure Regarding Proprietary Diagnostic & Therapeutic Technologies

VANCOUVER, BC, Dec. 28, 2022 /CNW/ - **Asep Medical Holdings Inc. ("Asep Inc." or the "Company")** (CSE: ASEP) (OTCQB: SEPSF) (FSE: JJ8) at the request of IIROC the Company would like to provide clarification on the disclosure regarding the diagnostic and therapeutic technologies of the Company and its subsidiaries Sepset Biosciences Inc. ("Sepset") and ABT Innovations Inc. ("ABT") that was included in a news release dated December 23, 2022.

The Company is addressing antibiotic failure on two fronts — a novel diagnostic assay that detects severe sepsis in the emergency room (ER) and a peptide technology that combats hard-to-treat infections known as biofilms. Antibiotic failure is generally referred to as any situation where bacteria survive antibiotic treatment, and the clinical symptoms of the infection persist[1]. With around 49 million sepsis cases per year worldwide and over 11 million deaths[2], faster and more accurate sepsis detection will save lives. In addition, there are currently no approved treatments for biofilm infections, which is alarming since 65%[3] of all infections are biofilms.

Asep Inc.'s diagnostic technology, Sepset$^{ER\ (™)}$, is a blood-based gene expression assay that can provide an early and accurate diagnosis of severe incidences of the deadly disease sepsis. Sepset$^{ER}$ can deliver a sepsis diagnosis within 60-90 minutes (based on internal laboratory testing at UBC), whereas conventional blood culture testing often takes, on average, ~15 hours but can be as long as five days[4]. Early detection of sepsis, along with timely, appropriate treatments, increases the probability of survival for patients[5] significantly. The diagnostic test, developed under the direction of leading UBC microbiologist and the Company's Founder, Chairman and CEO, Dr. Robert E.W. Hancock, enables early and accurate diagnosis of the deadly disease sepsis, which caused 11 million deaths globally in 2017[2]. The diagnostic test builds off of a 2014 eBioMedicine paper[6] that identified a sepsis gene expression signature among severely ill sepsis patients. It should be noted that the Company's sepsis diagnostic technology is patented in China, Australia, and 13 European countries. A patent is pending in North America.

In addition to speeding up the process of sepsis detection, Asep Inc. also offers a patented peptide technology that targets and suppresses biofilm regrowth and reduces inflammation, addressing the ineffectiveness of current treatments for a wide range of hard-to-treat infections. The technology covers a broad range of therapeutic applications, including bacterial biofilm infections (medical device infections, chronic infections, lung, bladder, wound, dental, skin, ear-nose and throat, sinusitis, orthopaedic, etc.), anti-inflammatories, anti-infective immune-modulators and vaccine adjuvants. The peptide technology is in advanced development through collaboration with its pre-clinical partner, iFyber, LLC. iFyber is a preclinical contract research organization based in Ithaca, NY, with expertise in antimicrobial wound dressings, biomaterials and wound care management. The Company believes that once the necessary regulatory approvals have been achieved and the requisite product testing has been completed, there will be various paths for the Company to consider with respect to monetizing this product and generating revenue.

The diagnostic assay is proceeding towards a definitive trial in the USA for 510(k) (FDA) approval, with trials currently anticipated to start mid-2023 and completed to allow application for regulatory 510(k) approval by year's end. Successful approval will enable the company to start selling diagnostic assays for sepsis in early 2024. The Company is currently developing the final diagnostic assay format.

The peptide therapeutic technology is in advanced pre-clinical testing, having been proven in relevant animal models. Its use in dental practice mouthwashes has been demonstrated in a small number of human volunteers, and a larger trial will be performed with Bohai in 2023. If successful this anti-biofilm hygiene treatment will be marketed, estimated in late 2023. Advanced anti-biofilm bandages have demonstrated efficacy in animal models and are estimated to start the 510(k) clinical process in late 2023. Other therapeutic indications for biofilm infections, e.g., for chronic rhinosinusitis, a condition causing 242,000 Hospital visits annually in the USA, have demonstrated efficacy in animal models and will enter formal preclinical studies in 2023/24 (with an FDA application soon after based on the results of the preclinical trials). The SafeCoat technology has worked in animal models but is at an earlier stage of development. For therapeutic indications, the Company is finalizing formulations and performing tests of dosage, dosing interval, safety, toxicity, and pharmacokinetics.

Peer review of papers covering technologies is considered an independent evaluation of the quality and trustworthiness of data. The diagnostic technology has been published in two peer-reviewed eBiomedicine studies and independently verified by a lab at the University of Toronto. The mouthwash application is the subject of a paper in the final stages of preparation, while anti-biofilm activity against human dental pathogens forming biofilms on hydroxyapatite (the material from which teeth and bones are made) has been demonstrated in several peer-reviewed publications. Activity against wound pathogens in animal and human organoid models has been published in peer-reviewed publications, and the enhanced wound dressings are the subject of a paper in the final stages of preparation for publication. The activity against the human sinusitis pathogens in an animal model of sinusitis is published in a peer-reviewed publication. The efficacy of the SafeCoat technology has been published in a peer-reviewed publication.

To date, both the sepsis and peptide technologies have received substantial non-dilutive R & D grant funding from organizations such as the Bill & Melinda Gates Foundation and Genome Canada. These grants were accepted before and after the Company's formation.

"Our vision is to address major unmet needs in human medicine. Having developed two new technologies to diagnose sepsis and treat biofilm infections, when approved, we believe hospitals and clinics globally should be interested in treating their patients using these novel technologies to improve patient outcomes," stated Dr. Robert E. W. Hancock, the Founder, Chairman and CEO of Asep Inc.

The Company has achieved significant milestones since its IPO on November 18, 2021, including —

### ABOUT ASEP MEDICAL HOLDINGS INC.

- Finalized an exclusive licensing agreement with UBC for the sepsis diagnostic technology
- Continued collaboration with iFyber, LLC for anti-biofilm wound dressings that use the Company's peptide technology
- Delivered compelling results from a commissioned independent sepsis study by RTI Health Solutions, which determined that earlier and faster diagnosis of sepsis could save U.S. hospitals $22 billion per year
- Reached an agreement with Chinese firm, Bohai Biomedical for a feasibility study of a peptide-based oral rinse for the Chinese market
- Recently acquired Vancouver-based SafeCoat Medical Inc. for development and commercialization of a peptide-based medical device coating

Asep Medical Holdings Inc. is dedicated to addressing antibiotic failure by developing novel solutions for significant unmet medical needs. The Company is a consolidation of two existing private companies (Sepset Biosciences Inc. and ABT Innovations Inc.) that are both in the advanced development of both proprietary diagnostic tools, enabling the early and timely identification of severe sepsis as well as broad-spectrum therapeutic agents to address multidrug-resistant biofilm infections.

Sepset Biosciences Inc. is developing a diagnostic technology that involves a patient gene expression signature that predicts severe sepsis, one of the significant diseases leading to antibiotic failure, since antibiotics are the primary treatment for sepsis. Despite this, sepsis is responsible for nearly 20% of all deaths on the planet. The Sepset$^{ER}$ test is a blood-based gene expression assay that is straightforward to implement, and results are obtained in about an hour in the

emergency room or intensive care unit. This proprietary diagnostic technology differs from current diagnostic tests in enabling diagnosis of severe sepsis within 60-90 minutes of initiating the test, while other diagnostics provide a diagnosis after ~15 hours but can be as long as five days[4]. Asep Inc. believes this will enable critical early decisions to be made by physicians regarding appropriate therapies and reduce overall morbidity and mortality due to sepsis.

ABT Innovations Inc.'s peptide technology covers a broad range of therapeutic applications, including bacterial biofilm infections (medical device infections, chronic infections, lung, bladder, wound, dental, skin, ear-nose and throat, sinusitis, orthopaedic, etc.), anti-inflammatories, anti-infective immune-modulators and vaccine adjuvants.

Neither the CSE nor any Market Regulator (as that term is defined in the policies of the CSE) accepts responsibility for the adequacy or accuracy of this release.

**FORWARD-LOOKING STATEMENTS**

This news release contains certain "forward-looking statements" within the meaning of such statements under applicable securities law. Forward-looking statements are frequently characterized by words such as "anticipates," "plan," "continue," "expect," "project," "intend," "believe," "anticipate," "estimate," "may," "will," "potential," "proposed," "positioned" and other similar words, or statements that certain events or conditions "may" or "will" occur. These statements include but are not limited to the successful clinical testing of our Sepsis diagnostic test and its intended filing for regulatory approval; the Company not receiving regulatory approval as planned or at all; the undertaking of pre-clinical studies on our lead therapeutic, with the expectation that this will lead to fast-track clinical trials; the timeframe for diagnosis of sepsis with the company's products; the potential opportunities for generation of revenue; the therapeutic benefits of the company's products; and other statement regarding the company's proposed business plans. Various assumptions were used in drawing conclusions or making the predictions contained in the forward-looking statements throughout this news release. Forward-looking statements are based on the opinions and estimates of management at the date the statements are made and are subject to a variety of risks including the risk that the company's products may not perform as expected; that the company may not receive the requisite regulatory approvals or results of testing; the Company's testing of the products may not be successful and approvals may not be obtained in the estimated timelines or at all; the company may not be able to generate revenue from its products as expected or at all; the market for the company's products may not be as described in this news release; and various other risk factors identified in the Asep Medical Inc.'s prospectus dated November 9, 2021, and in the company's management discussion and analysis, available for review under the Company's profile at www.sedar.com and uncertainties and other factors that could cause actual events or results to differ materially from those projected in the forward-looking statements. Asep Medical Inc. is under no obligation, and expressly disclaims any intention or obligation, to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as expressly required by applicable law.

**ENDNOTES**


1. https://doi.org/10.3389/fddsv.2022.892975
2. https://doi.org/10.1016/S0140-6736(19)32989-7
3. https://doi.org/10.1038/s41579-021-00585-w
4. https://ccforum.biomedcentral.com/articles/10.1186/cc11202
5. https://doi.org/10.4046/trd.2018.0041
6. https://doi.org/10.1016/j.ebiom.2014.10.003


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