Sona Announces U.S. Partnership and Preliminary Evaluation Results for Its COVID-19 Saliva Test

written by Raj Shah | November 9, 2021

This news release constitutes a "designated news release" for the purposes of the Company's prospectus supplement dated April 9, 2021, to its short form base prospectus dated March 31, 2021.

November 8, 2021 (Source) – Sona Nanotech Inc. (CSE: SONA), (OTCQB: SNANF) (the "**Company**" or "**Sona**"), a developer of rapid, point-of-care diagnostic tests, is pleased to announce that it has entered into a binding licensing agreement with U.S. Food and Drug Administration ("FDA") registered Arlington Scientific Inc. ("**ASI**" or "**Arlington**") of Springville, Utah, an in-vitro diagnostics developer, manufacturer and distributor, to bring Sona's rapid saliva COVID-19 test to market. Under the terms of the agreement, Sona licenses the intellectual property for its rapid saliva COVID-19 test and ASI undertakes to secure an FDA Emergency Use Authorization ("**EUA**") for point-of-care and at-home use for the test and any necessary associated activities, including medical ethics review board approval, the coordination and underwriting of US-based clinical and any other studies, and FDA EUA application submissions and follow-up. If an FDA EUA is granted, Arlington will coordinate manufacturing and distribution of the test in the U.S. exclusively on a profit-sharing basis by which it would also earn a share of any of Sona's profits from international sales.

Over the past few months, the Company undertook a thorough analysis and optimization work for its rapid saliva COVID-19

test which resulted in modifications being made to its design. A preliminary evaluation of the resulting test, run by Arlington, compared thirty-seven live viral samples from patients that had generated a positive result with a BinaxNow COVID-19 rapid antigen test. Of the thirty-seven samples tested, thirty-four generated a positive result on both tests. Further testing in an independent lab using PCR confirmed frozen positive samples with CT cut-off of 30 cycles and frozen, pre-COVID-19 negative samples, generated 93% sensitivity (14/15) and 100% specificity (30/30). Further evaluation against PCR test-confirmed COVID-19 positive samples will be required for any regulatory submission or declaration.

Under the terms of the licensing agreement which was signed today, Sona provides ASI with a license to the test technology, its documentation and ancillary support, as well as providing key biological materials for the test at its cost. ASI is responsible for securing an FDA EUA and all associated data required as outlined in the FDA EUA templates or requested by the FDA during the review and approval process. If ASI secures an FDA EUA for the test within six months, ASI will be permitted to manufacture and distribute the test in the US exclusively, subject to certain conditions, and will pay Sona a set percentage of profits from its test sales under a formula that accounts for certain costs of goods sold from each party. Further, ASI will receive from Sona a set percentage of its profits of other sales not facilitated by ASI. The agreement has a term of five years, after which it is annually renewable by mutual agreement of the Parties, and provides both parties with customary audit rights.

Sona’s CEO, David Regan, commented: “We are pleased that we took the time necessary to undertake the highly uncertain process of reconfiguring our rapid saliva COVID-19 test to the point that it has achieved these encouraging, preliminary results. Our

collaboration with Arlington has been instrumental in evaluating the test with live samples and we now look forward to working together with this leading U.S. test developer to advance our easy-to-use rapid saliva COVID-19 test to market. While there are many further hurdles to clear before we have a marketable product, no rapid saliva test has yet received an FDA EUA so Sona would look forward to making this contribution to the ongoing efforts to mitigate the continuing pandemic."

Arlington Scientific CEO, Ben Card added, "As a leading FDA-registered developer with over 35 years of in-vitro diagnostic device regulatory and manufacturing expertise and longstanding agreements with the major U.S. medical device distributors, Arlington is pleased to partner with Sona on a test that can offer such ease of use, particularly for children and the infirm. We believe that rapid testing will continue to play an important role in reducing infection transmissions and this saliva test, if approved, would be the first of its kind in the U.S. market, adding to the series of innovative products introduced by Arlington."

The Company is not making any express or implied claims that its product has the ability to eliminate, cure or contain the COVID-19 virus (or SARS-2 Coronavirus) at this time. Regulatory approvals for the product will be required before sales may be permitted.

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About Arlington Scientific Inc.

Arlington Scientific Inc. is an FDA registered establishment with over 35 years of medical device manufacturing expertise in

diagnostic reagents and serological test kits. ASI is at the forefront of innovation and was the first to develop an automated nontreponemal algorithm for the detection of syphilis; the first to develop the only automated nontreponemal (RPR) syphilis analyzer FDA cleared for diagnostic, blood donor screening and cadaveric (non-heart beating) donor screening; the first to include mercury free RPR reagents, implementation of liquid controls, screw cap lids, warp resistant test cards, extended shelf life for reagents and developing in-vitro diagnostic RPR tests for use with CPD and CPDA-1 anticoagulants.

About Sona Nanotech Inc.

Sona Nanotech is a nanotechnology life sciences firm that has developed multiple proprietary methods for the manufacture of various types of gold nanoparticles and is experienced in the development of rapid, lateral flow assay, in-vitro diagnostic tests. The principal business carried out and intended to be continued by Sona is the development of rapid, in-vitro diagnostic tests as well as research and development into potential applications for its proprietary technologies. Sona Nanotech’s gold nanorod particles are CTAB (cetrimonium bromide) free, eliminating the toxicity risks associated with the use of other gold nanorod technologies in medical applications. As such, it is expected that Sona’s gold nanotechnologies may be adapted for use in applications, as a safe and effective delivery system for multiple medical treatments, subject to application-specific validation and the approval of various regulatory boards, including Health Canada and the FDA.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION: This press release includes certain “forward-looking statements” under applicable Canadian securities legislation, including statements regarding Sona and ASI’s plans to develop and pursue regulatory approval for rapid tests for COVID-19. Forward-looking statements are necessarily based upon a number of estimates and assumptions that, while considered reasonable, are subject to known and unknown risks, uncertainties, and other factors which may cause the actual results and future events to differ materially from those expressed or implied by such forward-looking statements, including the risk that the test does not perform sufficiently well in a clinical trial or other studies to warrant regulatory submission or declaration, or if submitted to regulators, that the test would be granted required regulatory approvals. There can be no assurance that such statements will prove to be accurate, as actual results and future events could differ materially from those anticipated in such statements. Accordingly, readers should not place undue reliance on forward-looking statements. Sona 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 required by law.

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