#### FORM 51-102F3

#### **Material Change Report**

## 1. Name and Address of Company

Sona Nanotech Inc. ("**Sona**" or the "**Company**") 2001 - 1969 Upper Water Street Halifax, Nova Scotia B3J 3R7

## 2. Date of Material Change

November 25, 2020

#### 3. News Release

Press releases reporting the material change described in this report was issued through Newsfile Corp. on November 25 and November 30, 2020 and filed on SEDAR.

# 4. Summary of Material Change

Sona announced the withdrawal of its application for an Interim Order authorization ("IO") from Health Canada for the marketing of its rapid, COVID-19 antigen test in order to obtain more clinical data to augment its submission.

#### 5. Full Description of Material Change

On November 25, 2020, Sona announced the withdrawal of its application for an Interim Order authorization ("IO") from Health Canada for the marketing of its rapid, COVID-19 antigen test in order to obtain more clinical data to augment its submission. The Company stated its commitment to working with regulators to provide additional information and analysis on its test and to re-submitting its application as quickly as possible

In addition to continuing to pursue approval of the Company's rapid COVID-19 antigen test, which uses a nasal pharyngeal swab, the Company continues to validate its saliva sample-based version of the test. The Company intends to seek a large-scale trial specifically for its saliva-based test.

Company President and Chief Scientific Officer, Darren Rowles, commented "We have confidence in our rapid COVID-19 antigen test and its ability to detect the virus, especially within the first week of symptom onset. The regulatory approval path for antigen tests is new with evolving guidelines and Sona's test is unique, creating a challenging environment for test developers and regulators alike. We are, however, committed to obtaining the data needed to successfully achieve authorizations."

On November 30, 2020, Sona announce receipt of further feedback from Health Canada, subsequent to its withdrawal of its application for an IO for the marketing of its rapid, COVID-19 antigen test. As part of its review, Health Canada commissioned an evaluation from the National

Microbiology Laboratory (NML) whose evaluation produced discordant results to the Company's prior analytical and clinical studies conducted by MRIGlobal and SaudiVax

The Company intends to obtain additional data and use it to augment its submission with the FDA and potentially for a resubmission to Health Canada. The Company will also use its existing data to support a CE Mark application in Europe and to augment its submission for regulatory approval from the SaudiFDA. The Company is also accelerating the validation of its COVID-19 saliva-based test through analytical experiments and is seeking a near-term clinical validation study, as discussed below.

Prior to the Company's regulatory submission in August, no guidelines existed on performance criteria or clinical data requirements for rapid antigen tests in Canada. In evaluating Sona's test, the NML followed a uniform evaluation process for both rapid antigen tests that detect the nucleocapsid and those, like Sona's, that detect spike proteins. The Company had several fundamental concerns with respect to the generic evaluation process followed that did not take into account the unique characteristics of the Sona test. Based on Health Canada's responses to the Company's concerns about the evaluation process, the Company considered a withdrawal from the process to be in the best interest of the business in order to focus on collecting further clinical data.

With a view to reconciling the discordancy, the Company intends to obtain more data on the performance of its test, including more samples from patients within 0-6 days since symptom onset, as requested by Health Canada. While the test showed 100% sensitivity with such samples in its SaudiVax Clinical Evaluation Study, only seven such positive samples were obtained in that study of 39 positive samples, as previously disclosed on the Company's website (https://sonanano.com/wp-content/uploads/2020/11/Sona-SaudiVax\_Clinical\_Evaluation\_Whitepaper.pdf).

While the Company looks to close the gap on the discordancy in evaluation results in Canada for its nasal pharyngeal test, and continue efforts with the EU and Saudi regulatory processes, it will accelerate the development of its saliva-based rapid COVID-19 antigen test, as well as its suite of other non-COVID-19 test prototypes, which are all based on its proprietary gold nanorod technology, including its concussion prototype assay. As previously announced, the Company intends to seek a large-scale clinical trial specifically to validate its saliva-based self test for COVID-19.

Company Chief Executive Officer, David Regan, commented "The development and understanding of rapid antigen tests has been a fluid and dynamic process over the nine months since this pandemic began. Sona Nanotech, leveraging its proprietary gold nanorod technology, has done the extraordinary in developing one of only a handful of such tests. While our regulatory road has not been straight forward, every entity that has evaluated our test has confirmed its ability to detect the COVID-19 virus and it achieved strong results from our in-field trials. We will now seek further study data to provide sufficient substantiation of clinical performance to warrant regulatory approval."

Sona Nanotech's rapid COVID-19 antigen test offers results within 15 minutes, using a pregnancy-type lateral flow test that is easy to administer and interpret by non-experts without the need for either laboratory equipment or a device to read its results. Underpinned by Sona Nanotech's proprietary, patent-pending, gold nanorod technology, its test showed 85% agreement to RT-PCR results in patients in an in-field Clinical Evaluation Study of 99 patients and 96% sensitivity in laboratory studies.

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.

#### 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. The principal business carried out and intended to be continued by Sona is the development and application of its proprietary technologies for use in multiplex diagnostic testing platforms that will improve performance over existing tests in the market. Sona Nanotech's gold nanorod particles are CTAB (cetyltrimethylammonium) free, eliminating the toxicity risks associated with the use of other gold nanorod technologies in medical applications. It is expected that Sona Nanotech's gold nanotechnologies may be adapted for use in applications, as a safe and effective delivery system for multiple medical treatments, pending the approval of various regulatory boards including Health Canada and the FDA.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION: This report includes certain "forward-looking statements" under applicable Canadian securities legislation, including statements regarding Sona's plan to re-submit to the FDA and Health Canada, and to augment its application to Saudi FDA, the anticipated use of rapid COVID-19 antigen tests to reduce spread of the virus and anticipated demand for Sona's test, and the development and trials for Sona's saliva test technology. 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 Sona may not be successful in obtaining additional data necessary for regulatory approvals, or in obtaining required approvals once additional data is that potential customers may not adopt its products, that Sona's saliva test technology may not prove to deliver the same level of testing accuracy and sensitivity as its nasal pharyngeal swab-based test, that Sona may not be successful in identifying or reaching agreements with additional manufacturing partners, that Sona's manufacturing partners are not able to scale up manufacturing of Sona's products to the anticipated level, that raw materials may not be available in the amounts or on the schedules required to achieve Sona's manufacturing targets, that Sona may not be able to obtain further clinical data, that Sona may not resubmit to Health Canada and that regulatory requirements may change. 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.

#### 6. Reliance on subsection 7.1(2) or (3) of National Instrument 51-102

Not applicable.

## 7. Omitted Information

No significant facts remain confidential in, and no information has been omitted from, this report on the basis that it is confidential information.

## 8. Executive Officer

David Regan Chief Executive Officer Sona Nanotech Inc. Telephone: +1.902.536.1932

# 9. Date of Report

December 2, 2020