

1 March 2021

ASX and MEDIA RELEASE

Dotz Nano business and trading update

Dotz Nano Limited (ASX:DTZ) ("**Dotz**" or the "**Company**") an advanced technology company developing, manufacturing and commercialising marking, tracing and verification solutions, provides the following update on its trading suspension, business operations and commercial discussions.

Proposed transaction relating to virus detection technology with Caerus Therapeutics Inc

Dotz requested a trading halt on 18 November 2020 in relation to a proposed transaction with US-based Caerus Therapeutics Inc. ("**Caerus**"), a diagnostic research company that identifies and develops new therapeutic biomarkers and antibodies to treat a broad spectrum of human diseases.

As first announced on 11 May 2020 and subsequently on 21 and 31 July 2020, Dotz has been researching the ability to apply its non-toxic, molecular carbon-based verification technology to assist in fighting the COVID-19 pandemic, including diagnostics and surface sanitisation. In particular, since March 2020, Dotz has been researching the ability of its fluorescent-based technology to detect viruses in the field, in real-time.

One challenge that emerged as part of Dotz's research was achieving high specificity – the ability for Dotz's technology to identify SARS-CoV-2 without being triggered by other viruses, which may create false positives. In this regard, Caerus had preliminary data demonstrating that specific detection of SARS-CoV-2 RNA is possible by utilising the "RT-LAMP" method (an existing one-step nucleic acid amplification method to multiply specific sequences of RNA to diagnose infectious diseases caused by specific RNA viruses). Accordingly, Dotz approached and began working with Caerus in mid-September 2020 (ultimately entering into a Services and Research Agreement on 19 November 2020 (the "**Caerus Service Agreement**")) to facilitate the development and commercialisation of the Company's Rapid SARS-CoV-2 Diagnostic kit, now incorporating RT-LAMP (the "**Dotz Test Kit**").

As a result of initial work undertaken by Caerus, Dotz had proposed to enter into an Asset Purchase Agreement (the "**Caerus Asset Purchase Agreement**"). Dotz notes that the Caerus Asset Purchase Agreement was simply a precautionary measure to ensure that the Company was protected in respect of any potential contamination of intellectual property rights relating to its Dotz Test Kit and Virus Detection Solution. As the Caerus Service Agreement already provided Dotz with sufficient protection regarding the intellectual property rights attaching to the Dotz Test Kit, and the main reason for entering into the Caerus Asset Purchase Agreement was to provide the Company with absolute certainty in this regard and to properly remunerate and incentivise Caerus (Caerus was going to be further engaged by the Company to assist with the development and commercialisation of its Dotz Test Kit and Virus Detection Solution).

However, due to concerns raised by the ASX in relation to ASX Listing Rules 11.1.2 and 11.1.3 (namely, ASX considering the execution of the Caerus Asset Purchase Agreement constituted a material change to the nature of Dotz, and would require, amongst other things, Dotz to recompile with Chapters 1 and 2 of the ASX Listing Rules as though it was a new listing), the Caerus Asset Purchase Agreement was terminated on 2 December 2020. As a result, Dotz agreed to amend the Caerus Service Agreement on 28 February 2021 (the "**Updated Caerus Service Agreement**") to ensure ongoing protection of its intellectual property rights in the Dotz Test Kit and to remunerate and incentivise Caerus as Dotz continues to pursue the development and commercialisation of the Dotz Test Kit with the assistance of Caerus (as summarised below).

ASX has confirmed that ASX Listing Rules 11.1.2 and 11.1.3 do not apply to the transactions contemplated by the Updated Caerus Service Agreement.

Updated Caerus Service Agreement

Under the Updated Caerus Service Agreement, Dotz will leverage Caerus' extensive diagnostic resources and expertise, including a state-of-the art laboratory, to continue to research and develop its own virus detection technology. Importantly, Dotz retains all intellectual property rights as well as any improvements in respect of the Dotz Test Kits.

The material terms of the Updated Caerus Service Agreement are:

Term	The agreement will continue until terminated by either party. Dotz may terminate upon 30 days' prior notice. Summary termination rights exist for both parties in the event of insolvency or material breach of the agreement occurring in respect of the other party.							
Services	<p>The services provided to date include:</p> <ul style="list-style-type: none">(a) optimising testing procedures;(b) screening of new primers (singular and in combination) to further increase test selectivity and specificity;(c) completing the requirements for CE submission;(d) submitting the test for CE mark authorisation; and(e) assisting with on-going requirements for FDA submission. <p>The services to be provided going forward will be set out in statements of work issued by Dotz from time to time. These are expected to include, developing and optimising testing procedures, screening of new primers, and completion of the requirements for FDA submission.</p>							
Fees	<p>To date, Dotz has paid approximately US\$54,000 in fees under the agreement.</p> <p>The fees payable for the services going forward will be comprised of:</p> <ul style="list-style-type: none">○ cash fees as outlined in a fee schedule set out in each statement of work. The first statement of work , the majority of which has been carried out as at the date of this announcement, will consist of fees in the amount of between US\$93,500 to US\$105,000 for services provided over an approximate six-week period; and○ a one-off grant of 2,000,000 options to Caerus (or its nominees) with an exercise price of A\$0.001 each and an expiry date of 4 December 2022. The options will vest and become exercisable as follows, subject to the agreement not having been terminated before the Vesting Date: <table><tr><th>Number of options</th><th>Vesting Date</th></tr><tr><td>1,000,000</td><td>Completion of the first statement of work (at the date of this announcement, the outstanding items in the first statement of work relate to the completion of requirements for FDA submissions and submitting the test kit for FDA Emergency Use Authorisation).</td></tr><tr><td>1,000,000</td><td>Completion of the second statement of work. The contents of the second statement of work are being negotiated and remain subject to agreement.</td></tr></table>		Number of options	Vesting Date	1,000,000	Completion of the first statement of work (at the date of this announcement, the outstanding items in the first statement of work relate to the completion of requirements for FDA submissions and submitting the test kit for FDA Emergency Use Authorisation).	1,000,000	Completion of the second statement of work. The contents of the second statement of work are being negotiated and remain subject to agreement.
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	<p>Dotz considers that the grant of options (expected to occur no later than 31 March 2021) with a nominal exercise price (akin to 'performance rights') is an appropriate means to incentive Caerus to deliver the statements of work required. The grant of such options is for the purposes of incentivising performance, rather than fundraising. Assuming that these options vest, the estimated value of these options is US\$368,060 (based on Dotz's last traded share price of A\$0.24, an exercise price of A\$0.001 and AUD/USD exchange rate of \$0.77)).</p> <p>No other consideration is payable by Dotz to Caerus other than as set out above.</p>
<i>Intellectual property</i>	All intellectual property developed pursuant to the engagement shall vest in Dotz for no additional consideration. In particular, Dotz retains all intellectual property rights as well as any improvements in respect of the Dotz Test Kits.
<i>Non-compete</i>	Caerus is subject to non-compete obligations for a period of 12 months following the expiry or termination of the agreement from, amongst other things, providing services or otherwise designing, developing or manufacturing a product in the field of virus diagnostics and related operations.

Update on development and commercialisation of the Dotz Test Kits

Whilst its securities have been suspended from trading, Dotz has continued to operate as usual. Dotz provides the following update on the development and commercialisation progress of its Dotz Test Kits.

CE mark authorisation. On 25 January 2021, Dotz obtained authorisation to use the CE mark for its Dotz Test Kits. The CE mark authorisation clears the Dotz Test Kits for sale in the European Union (although it is noted that some countries in the European Union have additional import regulatory requirements that Dotz will still need to comply with if it intends to sell the Dotz Test Kits in those countries).

The Dotz Test Kit has the following features:

- i. 100% True Positive Rates for viral loads of 2500 copies per mL;
- ii. the limit of detection for the Dotz Test Kit is 2500 copies per mL when using 1mL of input sample. The True Positive Rates at other limits at other copy numbers are as follows:

Virus	Material	Copy Number per mL	True Positive Rate
2019 Novel Coronavirus	Chemically- inactivated SARS-Cov-2 in VITM	2,500	100%
		1,250	86%
		625	81%
		313	64%
N/A	Nuclease-Free Water	0	0%

- iii. 100% specificity, following a negative cross-reactivity results for a range of other viruses;
- iv. test results within 15-17 minutes (when using two heating blocks);
- v. visual detection by colour change of the reagents; and
- vi. simultaneous testing of up to hundreds of samples using standard heating blocks (other materials including a viral RNA extraction kit are required for testing but not included in the Dotz Test Kit).

While the Dotz Test Kit has been created and tested for use with both nasopharyngeal swab and saliva samples, the CE mark authorisation is based only on nasopharyngeal swab samples to simplify the application process. The standard method of sample collection in the European Union and most other parts of the world is nasopharyngeal swab sampling. Dotz intends to make a secondary CE submission for the Dotz Test Kit in respect of saliva samples, which is expected to occur by 15 March 2021.



FDA Emergency Use Authorisation Application. The final step before Dotz can apply for an Emergency Use Authorisation (“EUA”) from the FDA of the Dotz Test Kit is the testing of 30 SARS-CoV-2 positive people with a broad range of viral loads (referenced by CDC approved PCR tests). To this end, Dotz has commenced a clinical trial of its virus detection technology with Excelya in Greece (and is no longer engaged in clinical trials with Sheba Medical Centre in Israel due to its inability to deliver confirmed SARS-CoV-2 patients following decreases in confirmed SARS-CoV-2 patients in Israel). Dotz has begun preparing for its FDA submission of the Dotz Test Kit, which is expected to be submitted by the end of March 2021.

For completeness, Dotz notes that due to changes in the development of the Dotz Test Kit, Brazilian genetics company, FullDNA Diagnósticos Médicos Ltda, will not be engaged by Dotz to assist with results analysis as contemplated by the previously announced letter of intent with Dotz dated 28 June 2020. In addition, Dotz notes that it is not a party to any agreement with the University of Washington or any other similar institutions / businesses in relation to the Dotz Test Kits. Dotz’s involvement with the University of Washington has been indirect, through its arrangements with FullDNA Diagnósticos Médicos Ltda (which have ceased).

Manufacturing. As part of its regulatory and commercialisation efforts, Dotz was required to list an ISO13485 manufacturer of its Dotz Test Kits. Dotz entered into a services agreement for manufacturing and regulatory consultancy with established US-based manufacturer Systaaq Diagnostic Products (“**Systaaq**”) on 13 December 2020 to satisfy a key CE requirement and to prepare for commercialisation and production of the Dotz Test Kits. Systaaq is a well-established manufacturer of SARS-CoV-2 PCR-based kits with significant production capabilities. Dotz is also currently negotiating a manufacturing agreement for the Dotz Test Kits with Systaaq and is engaged in confidential negotiations with additional manufacturers in Canada and Asia. Dotz has not entered into any binding manufacturing agreements with those manufacturers at this stage, or any other manufacturers, and there can be no certainty that any binding agreements will be reached.

Business Development. Assuming Dotz obtains all necessary regulatory approvals for its Dotz Test Kit (whether the approved Dotz Test Kit is based on nasopharyngeal swab or saliva samples), Dotz anticipates there will be significant demand for either Dotz Test Kit based on test results achieved to date and its engagement with prospective customers. While Dotz has previously engaged in confidential preliminary discussions and negotiations with counterparties for the supply of its Dotz Test Kits, those discussions remain at preliminary stages as Dotz focuses on obtaining the required regulatory approvals. In this regard, Dotz has not reached any binding agreements for the sale of the Dotz Test Kits and there is no certainty that any binding agreements will be reached. There is no certainty Dotz will obtain all necessary regulatory approvals, or even if it does, there is no certainty as to the likely success of the Dotz Test Kit on the market following the receipt of such required regulatory approvals.

Pricing and budgeted revenue. Dotz estimates the Dotz Test Kits will retail for approximately US\$5 to US\$6 dollars. This costing is based on its discussions with potential buyers in various regions, the price of similar and alternative products and the estimated production costs per unit, which is expected to be less than US\$2 (also based on Dotz’s discussions with Systaaq and other manufacturers), delivering an anticipated gross profit margin of between 60-70 percent (subject to mass production). However, given the inherent uncertainty and evolving dynamics of the COVID pandemic, the preliminary stages of Dotz’s test kit business activities and the fact that many factors remain outside its control, Dotz advises that it has not budgeted for any material revenue from the sale of its Dotz Test Kits (and is not able at this stage to accurately prepare such a budget). The revenues of Dotz (if any) from the sale of its Dotz Test Kits will depend on a range of factors outside its control, including the timing that Dotz receives (if at all) its regulatory approvals for its Dotz Test Kits for both swab and saliva samples, the success of its competitors, the demand from potential customers and the status of the COVID pandemic.



Material risks. Set out below is a summary of the material risks Dotz expects to face as part of the continued development and commercialisation of the Dotz Test Kit.

- **Innovative technological development** – The Dotz Test Kit is at a relatively early development stage and substantial testing is necessary to commercialise the Dotz Test Kit. No guarantee can be provided that the testing will be successful or result in an approved product that can be marketed and sold.
- **Manufacturing and production risks** - The manufacturing process for the Dotz Test Kit has not yet been scaled up to commercial scale. In order to satisfy the manufacturing requirements of the U.S. Food and Drug Administration (**FDA**) and European Union, the Dotz Test Kit must be manufactured in a facility which maintains the Quality Management Systems under ISO13485 for Design, Development, Manufacturing & Distribution of in-vitro diagnostic products. As disclosed above, the Company is currently under negotiations with such a facility for the manufacture of the Dotz Test Kit, however cautions that there can be no certainty that an agreement will be reached on favourable terms, or at all.
- **Clinical trials risks** - As disclosed above, the Company's product development plans for the Dotz Test Kit includes the conduct of human clinical trials. Such trials can be difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Even if the results of the Company's initial clinical trials for the Dotz Test Kit are favourable, regulatory authorities or the Company's partners may suspend, delay or terminate the trials at any time. Further, even if the Company views the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with the Company's interpretation of the data. Clinical development of the Dotz Test Kit may fail for a number of other reasons, including lack of efficacy. Failure can occur at any stage of the trials, requiring the Company to abandon or repeat clinical trials. The Company and/or the relevant regulatory authorities, and institutions where the clinical trials are conducted, may suspend the Company's clinical trials at any time if it appears that the trials are exposing the trial participants and or the staff involved in conducting the clinical trial to unacceptable health risks. Alternatively there is the risk that despite conducting the relevant clinical trial in compliance with regulatory requirements, the results of the trial do not support any further development or result in a rejection by the relevant regulator. As a result the Company may fail to commercialise or out-license the Dotz Test Kit.
- **Licensing and regulatory risks** - As with any company involved in developing diagnostic products in the medicinal industry, the Company and its partners will need to obtain regulatory approval in each country in which they intend to market the product in question. The Dotz Test Kit may not satisfy requirements for regulatory marketing approval and/or the approval process may take longer than expected.
- **Commercialisation risk** - There is no guarantee that the Company will be able to successfully develop or commercialise the Dotz Test Kits, and if it is unable to do so it will not be able to realise any material revenues in the future.
- **Reliance on third parties** - The Company will be required to outsource key components of the development and manufacture of the Dotz Test Kit (including, amongst other things, certain components of the clinical trials and the manufacturing processes). There is no guarantee that such suppliers, consultants or other experts will be readily available or available on reasonable terms, within the Company's budgets.
- **Intellectual property risk** – While intellectual property developed pursuant to the Caerus Service Agreement vests in the Company, the Company may still face intellectual property risks which are inherent as part of the continued development and commercialisation of the Dotz Test Kit, including (without limitation) third party claims and risks of intellectual property infringement.



- **Other risks** – The Company will face a number of other risks inherent as part of the continued development and commercialisation of the Dotz Test Kit, including (without limitation) product liability risk, competition risk, and reliance on key management personnel.

-ENDS-

This announcement has been authorised for release by the Board of Dotz Nano Limited.

For further information, please contact:

Investors:

Eric Kuret
Market Eye

E: eric.kuret@marketeye.com.au

P: +61 3 9591 8904

Media:

Tristan Everett
Market Eye

E: tristan.everett@marketeye.com.au

P: +61 403 789 096

About Dotz Nano Limited

Dotz Nano Limited (ASX: DTZ) is a technology leader in research, production and marketing of anti-counterfeiting, authentication and tracing solutions. Dotz has strong, established distributors in North America, Europe, Japan, China and Australia as well as scientific collaborations and partnerships with leading academic institutes.

Its unique products ValiDotz, BioDotz, Fluorensic and InSpec are exceptional solutions for numerous applications, such as: bio-imaging, liquids tagging, lubricants and DEF authentication, polymers tagging, anti-counterfeiting, brand & reputation protection and oil & gas industry.

To learn more about Dotz, please visit the website and corporate video via the following link www.dotz.tech

About Caerus Therapeutics Inc

Caerus Therapeutics Inc. is a related entity to Caerus Discovery. Founded in 2010, Caerus Discovery LLC. is a development stage company based in Prince William County's Innovation Park, Manassas, VA. Both Caerus Therapeutics Inc and Caerus Discovery LLC were founded by Drs. Cohava Gelber and Soren Mogelsvang, with support from two corporate partners, to identify and develop new therapeutic targets for treatment of human diseases. All research conducted by Caerus Discovery LLC belongs to Caerus Therapeutics Inc.

Caerus' technology platform has several proprietary and patented components, including the Immune Synapse and different subtractive immunization approaches. With a state-of-the-art laboratory, Caerus is uniquely positioned to discover novel biomarkers, targets and therapeutic antibodies, in a broad spectrum of human diseases.

To learn more about Caerus, please visit the website and corporate video via the following link <http://www.caerusdiscovery.com/>

About SYSTAAQ Diagnostic Products

SYSTAAQ Diagnostic Products engages in molecular diagnostics, offering a wide range of products and services in the field of molecular testing. SYSTAAQ provides innovative, cost-effective, timely and reliable solutions in biomedical research and laboratory diagnostics.

SYSTAAQ operates a state-of-the-art molecular facility at Manassas, Virginia (USA) with a team of scientists dedicated to the best practices in quality and design control. Molecular products are manufactured under good manufacturing



practices (GMP) and ISO 13485:2016 Certification. A variety of product labeling standards, including RUO, ASR, CE and IVD, are developed and released under the appropriate design control process and launched as per any country's specific regulatory requirements.

SYSTAAQ Diagnostic Products has constructed facilities to meet the unique requirements for amplified nucleic acid testing. A high-quality standard is maintained through a continuous investment in process improvements and a team of technical specialists who help to ensure optimal performance during development and product release stages.

To learn more about Systaaq, please visit the website and corporate video via the following link
<https://www.systaaq.com/>

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on the Company's beliefs, assumptions, and expectations and on information currently available to the Company. Forward-looking statements involve known and unknown risks, uncertainties, contingencies and other factors, many of which are beyond the Company's control (including but not limited to the COVID-19 pandemic), subject to change without notice and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialise our products including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialise new products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory submissions and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position.

You should not place undue reliance on forward-looking statements because they speak only as of the date when made. Given the current uncertainties regarding the impact of the COVID-19 on the trading conditions impacting the Company, the financial markets and anti-counterfeiting, authentication and tracing solutions services world-wide, investors are cautioned not to place undue reliance on the current trading outlook.

The Company may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.