

# NEWS RELEASE

FOR IMMEDIATE RELEASE

Thursday, April 28, 2022



## MOUNTAIN VALLEY MD HOLDINGS PROVIDES BUSINESS UPDATE

Toronto, Ontario – April 28, 2022 - Mountain Valley MD Holdings Inc. (the “Company” or “MVMD”) (CSE: MVMD) (OTCQX: MVMDF) (FRA: 20MP) is pleased to provide a business update on its technologies and key initiatives.

### KEY TECHNOLOGIES:

MVMD’s primary technologies are being developed with the objective to improve the administration, efficacy and safety of new and existing medicines, therapies, and nutraceuticals.

- The Company’s Quicksome™ desiccation technology utilizes advanced liposomal technology and other stabilizing molecules to encapsulate and formulate active ingredients into more efficient product formats that are delivered sublingually or that could be applied to novel applications to address cold chain distribution challenges. Where successfully applied, Quicksome™ supports a new generation of product formulations that could enable new supply chain methods and enhance efficacy and safety of vaccines, pharmaceuticals, and nutraceuticals.
- The Company’s patented Quicksol™ technology covers the macrocyclic lactone class of anti-parasitic drugs, where proprietary solubilization techniques that use no harmful organic solvents have been initially applied to the drugs ivermectin and selamectin, which, if successful in pre-clinical trials, could be effectively applied in oncology and multiple anti-viral and anti-parasitic applications that could positively impact human and animal health globally.
- The Company’s patent-pending Porous Aluminum Nanostructure Adjuvant (“PANA”) technology has high surface area for vaccine-antigen binding that the Company believes may provide vaccine dose sparing advantages with long-term stability in aqueous media, and greater stability in harsh environments.

### SIGNIFICANT PROJECTS:

MVMD’s primary technologies are being researched across various initiatives in the health and wellness industry, including the following:

#### **COLD CHAIN**

- Cold chain is a temperature-controlled supply chain that prescribes necessary conditions during the transport, storage, and handling of vaccines and drugs to minimize excessive heat or cold exposure that can render product ineffective. The World Health Organization’s (WHO) guideline for temperature requirements for

three defined vaccine management categories\* includes traditional cold chain between +2°C and +8°C, Extended Controlled Temperature Conditions (ECTC) above +8°C for a specified number of days to support vaccine distribution, and Controlled Temperature Chain (CTC) where the vaccine must be able to tolerate ambient temperatures of at least +40°C for a minimum of 3 days.

- On July 31, 2020, the Company announced its results from a U.S. Food and Drug Administration (FDA) Polio Vaccine Lab evaluation that confirmed the Company had successfully preserved Polio D Antigen in its proprietary Quicksome™ rapid dissolve sublingual technology. In addition to its sublingual cold chain work, the Company studied in the first half of 2021, whether it could apply a thin Quicksome™ desiccated liposome layer of Trivalent Inactivated Poliovirus Vaccine (tIPV) inside a vial for five days of exposure at 40 degrees Celsius and then reconstituted for injection at the point of administration.
- Based on the cold chain technology achievements announced in July of 2021, the Company has advanced additional characterization studies with its proprietary Quicksome™ technology to optimize application across different human and animal vaccines. The Company believes the technology would allow for long term stability and ease of global distribution, appropriate for pandemic preparedness, as well as other administration and distribution advantages, including elimination of cold chain storage requirements and the related expenses, while reducing instances of vaccine spoilage.
- MVMD is finalizing agreements with third-party organizations who specialize in vaccine research and is initiating studies of the Company's technologies across an expanded vaccine target list, including those that have broad commercialization potential.
- Additionally, MVMD is in discussions with a potential partner in South America to apply the Company's cold chain technology to targeted husbandry animal vaccines.

## ***INSULIN***

- Diabetes is a disease in which the human or animal body either can't produce insulin or can't properly use the insulin it produces. Insulin is a hormone produced by the pancreas and its role is to regulate the amount of glucose circulating in the blood.
- In MVMD's view, despite significant innovation in recent years in relation to diabetes, insulin remains a cornerstone of treatment, and there continues to be an unmet need in the insulin space, resulting from challenges such as costs, the use of needles, hypoglycemia, and fear of injection.
- The Company is advancing its exploration of the application of its technology to the needleless administration of insulin and is currently planning the execution of formulation experiments with the goal of optimizing the potential delivery of rapid-acting human insulin in a sublingual format. Additionally, the Company has initiated the selection process for a third party CRO and is engaging experts in insulin science to support planning of necessary trials to validate the potential delivery of rapid-acting human insulin in a sublingual format.

- The Company expects to have further information on formulation developments and to complete testing of formulations in a Type 1 diabetes model in the second half of 2022.

### **TUBERCULOSIS**

- Tuberculosis (TB) is a disease that is caused by bacteria that spread from person to person through microscopic droplets released into the air. TB affects roughly 25% of the world's population and is the leading infectious disease killer in the world, claiming approximately 1.5 million lives each year.\*\*
- In March of 2021, the Company announced that it had confirmed its ability to create a solubilized selamectin product using its patented Quicksol™ technology applied to the macrocyclic lactone drug class. Selamectin drug is characterized as a highly insoluble molecule and MVMD believes that there is significant potential in treating mycobacterium-based infections in humans and animals with its solubilized format of the drug, Selactosol™ 1.5%.
- MVMD has completed its initial assessment and established the plan to optimize the formulation, the necessary testing assays, and related preclinical protocols required to advance studies for its novel Selactosol™ 1.5% targeting mycobacterium-based infections. MVMD intends to commence pre-clinical studies with its Selactosol™ 1.5% solution in the latter half of 2022.

### **ONCOLOGY**

- As announced on May 3, 2021, pre-clinical trials for Triple-negative Breast Cancer, Metastatic Melanoma and Lewis Lung Carcinoma were conducted to support MVMD's exploration of application of its technology to potential cancer treatments. Preliminary murine cell model studies were completed, and the research conducted presented some noteworthy exploratory findings that have resulted in MVMD expanding its oncology work to explore human cell line tumors with further investigational cell viability and proliferation research studies being executed over the past two quarters.
- MVMD is also reviewing additional pre-clinical models to explore combinations of its patented Soluvec™ with existing chemotherapeutic and immunomodulatory treatments across solid tumor and hematological malignancies.
- On April 5, 2022, the Company was granted a Patent for 'Novel Injectable, Infusable, Instillable Ivermectin Adjuvant for Cancer Therapies' for its solubilized ivermectin (Soluvec™). The issuance of this patent verifies the novel approach of MVMD's technology as applied to potential cancer types that the Company is exploring and assists in safeguarding the invention in support of potential commercial value in the future as the technology progresses through trials.

### **HUSBANDRY ANIMALS**

- Previously, the Company had disclosed the application of its Quicksol™ technology to the drug ivermectin and belief that a more solubilized format versus current in-market products would have novel applications across the broad husbandry animal marketplace.

- The Company completed initial husbandry animal trials in Bangladesh, previously announced on March 16, 2021, that were conducted with MVMD's injectable solubilized ivermectin technology, Soluvec™ 1%. The studies were conducted under the supervision of The People's Republic of Bangladesh's Ministry of Fisheries & Livestock and informed the requirements for final commercialization pathway inside of Bangladesh.
- Over the past six months, MVMD has been coordinating dosing and formulation testing and conducting extended stability tests on GMP manufactured Soluvec™ 1% in order to optimize the formulation for different conditions and environments. The results of some of the stability testing have now been received and have indicated that the base formula requires optimization and further stability testing in order to allow for the scaling of batch sizes for production and ensuring Soluvec™ 1% product applications have a predictable shelf life. This work is expected to proceed through to the first quarter of 2023.
- Concurrently, MVMD is working with its partner in Bangladesh to negotiate a commercial licensing agreement that would include management by the licensee of a local manufacturing partner and process for scaled Soluvec™ 1% commercial production requirements and completion of market specific stability testing for the husbandry animal applications inside Bangladesh, in support of pursuing government approval inside Bangladesh necessary to enable Soluvec™ 1% product to be commercialized.
- It is currently anticipated that Soluvec™ 1% will be ready for retail product introduction by the licensee in the first quarter of 2023, however this may be a longer or shorter period depending on various factors such as the results of the additional stability testing and the related timing of regulatory review and approval.

### **AQUACULTURE**

- The Company's partner in Bangladesh is working with the local Ministry of Fisheries, which engaged MVMD to evaluate whether a combined application of both its Quicksol™ and Quicksome™ technologies to a novel fish food application would be able to reduce the effect of parasitic infections across a variety of farmed fish species. The Company is working with the Ministry to finalize key protocols in these different species and is completing the trial planning protocol and aims to commence the trials in the third quarter of 2022.
- Additionally, MVMD is coordinating the research framework with an acclaimed international university to conduct a collaborative study of Soluvec™ 1% coated fish feed to study its health benefits in targeted aquatic species. It is anticipated the related studies will commence in the in the fourth quarter of 2022.

### **NUTRACEUTICALS**

- Following evaluation of North American GMP manufacturing options for MVMD's nutraceutical product strategy, the Company is in the final stages of securing its third-party lead production partner.
- The Company's strategy will be to secure the selected lead manufacturing partner as a licensee, who will in turn produce nutraceutical products based on or embodying MVMD's proprietary technologies for third parties approved by and who

have an agreement with MVMD. The Company believes this strategy will help ensure product quality, support the ability to scale production, streamline audit process for royalty agreements, and provide the necessary protection of its technology and trade secrets versus having numerous licensed partners each replicating the manufacturing process for their own products.

- MVMD's current licensing arrangements with Circadian Wellness and Red White & Bloom Brands, and future such agreements, are anticipated to be supported by this strategy.
- Securing the lead manufacturer and finalizing the scaled GMP production environment is intended to align with MVMD's anticipated increased business development efforts in the latter half of 2022 to secure additional nutraceutical licensing partnerships.

### ***DOSE SPARING ADJUVANT***

- The Company's patent-pending PANA technology has high surface area for vaccine-antigen binding that the Company believes may provide vaccine dose sparing advantages with long-term stability in aqueous media, and greater stability in harsh environments
- In partnership with the Tulane University School of Medicine in New Orleans, Louisiana, as previously disclosed, the Company executed a study comparing an existing Alhydrogel adjuvant to the Company's invented stable nano-particulate adjuvant by both intramuscular injection and intradermal injection immunization. The study evaluated the antibody responses following vaccination with fractional doses of IPV and compared delivery types with IPV alone or adjuvanted. The evaluation of MVMD's novel aluminum nanoparticle adjuvant from this study demonstrated no toxicity or adverse reactions when combined with tIPV in intramuscular or intradermal injection. However, the initial results were not satisfactory in terms of producing a robust response or desired elevation in the immune response over IPV alone.
- The Company continues its work with its key advisors at Tulane University to explore if changes in the adjuvant development and administration may support a positive research outcome across a broad spectrum of vaccines. MVMD anticipates exploratory progress over the third quarter of 2022, related to results from ongoing characterization work that will inform the plan forward and related timing for the technology evaluation.

### **R&D COVID-19**

- The Company had explored the application of a solubilized form of ivermectin in the potential treatment of COVID-19. In May 2021 the Company announced the results from its third-party Bio Safety Level 4 ("BSL-4") COVID-19 viral clearance study conducted with its solubilized ivermectin technology, Soluvec™. In management's view based on an internal review of publicly available literature, the positive indicators from the BSL-4 trials are consistent in general with various global trials and contribute to evidence for the effect of ivermectin on inhibition of viral replication and the potential application as a treatment for COVID-19.

- MVMD also acknowledges the positions of certain regulatory bodies, for example Health Canada and the Food and Drug Administration in the United States, that ivermectin has not be authorized or approved for use in the treatment of COVID-19. The Company’s primary focus, in line with its “cold chain” work, has been on those jurisdictions which may have less access to vaccines and other treatments, where ivermectin has been studied for use in the treatment of COVID-19, and which might benefit from access to a solubilized form of the drug.
- In addition to potential sublingual administration applications, MVMD believes that its solubilized form of ivermectin could be favourable for front line emergency use applications, including injection and intravenous uses, potentially for COVID-19 treatments where authorized or in research for future possible pandemics.
- Due to the complexity and cost of human ivermectin trials, as well as the global and regulatory landscape for approval of treatments for COVID-19, the Company is currently working to evaluate the business case for further studies in humans, including stability of human grade GMP product, with academic and non-academic partnerships.

The Company intends to provide further updates on its trials and developments as they become available.

#### REFERENCE SOURCES

\* WHO - The Extended Controlled Temperature Conditions  
<https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/vaccine-standardization/extended-controlled-temperature-conditions>

\*\* Tuberculosis – Global Impact  
<https://www.cdc.gov/globalhealth/newsroom/topics/tb/index.html>

#### **ABOUT MOUNTAIN VALLEY MD HOLDINGS INC.**

Mountain Valley MD is building a world-class organization centered around the implementation and licensing of its key technologies to global pharmaceutical, vaccine and nutraceutical third parties:

- patented Quicksome™ oral drug formulation and delivery technologies,
- patented Quicksol™ solubility formulation technology

Consistent with its vision towards “More Life”, MVMD applies its Quicksome™ and Quicksol™ technologies to its work for advanced delivery of vaccines and pharmaceutical drugs as well as the development of products for pain management, weight loss, energy, focus, sleep, anxiety, and more.

MVMD’s patented Quicksome™ desiccation technology utilizes advanced liposomes and other stabilizing molecules to encapsulate and formulate active ingredients into highly efficient product formats that are consumed orally. The result is a new generation of

product formulations that could be capable of delivering vaccines, drugs and nutraceuticals into the body faster, with greater impact, efficiency and accuracy.

MVMD's patented Quicksol™ technology covers all highly solubilized macrocyclic lactones that could be effectively applied in multiple viral applications that could positively impact human and animal health globally.

For more Company information and contact details, visit [www.mvmd.com](http://www.mvmd.com).

SOURCE: Mountain Valley MD Holdings Inc.

For further information:

Dennis Hancock  
President and Chief Executive Officer  
Mountain Valley MD Holdings Inc.  
Investor Relations @ 647-725-9755  
Email: [info@mvmd.com](mailto:info@mvmd.com)

[www.mvmd.com](http://www.mvmd.com)

#### **CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING INFORMATION**

*Certain statements contained in this news release may constitute forward-looking information. Forward-looking information is often, but not always, identified by the use of words such as "anticipate", "plan", "estimate", "expect", "may", "will", "intend", "should", and similar expressions. Forward-looking information involves known and unknown risks, uncertainties and other factors that may cause actual results or events to differ materially from those anticipated in such forward-looking information.*

*The Company's actual results could differ materially from those anticipated in this forward-looking information as a result of regulatory decisions, competitive factors in the industries in which the Company operates, prevailing economic conditions, and other factors, many of which are beyond the control of the Company.*

*The Company is making forward-looking statements, including but not limited to: its technologies and key initiatives, generally; the Company's objective being to improve the administration, efficacy and safety of new and existing medicines, therapies, and nutraceuticals; the ability to apply the Company's Quicksome™ technology to novel applications, in addition to sublingual uses; the ability to apply selamectin, if successful in pre-clinical trials, effectively in oncology and multiple anti-viral and anti-parasitic applications and whether that could impact human and animal health globally; the ability of the Company's PANA technology to provide vaccine dose sparing advantages with long-term stability in aqueous media, and greater stability in harsh environments; the ability or likelihood that the Quicksome™ technology would allow for long term stability and ease of global distribution, be appropriate for pandemic preparedness, or provide other administration and distribution advantages, including elimination of cold chain storage requirements and the related expenses, while reducing instances of vaccine spoilage; the ability of the Company to complete studies of the Company's technologies across an expanded heat-labile vaccine target list, including those that have broad commercialization potential; continued discussions with a potential partner in South America to apply the Company's cold chain technology to targeted husbandry animal vaccines; the Company's ability to advance exploration of the application of its technology to the needleless administration of insulin; the ability of the Company to execute formulation experiments with the goal of optimizing the potential delivery of rapid-acting human insulin in a sublingual format; the ability of MVMD to select a third party CRO and engage experts in insulin science to support planning of necessary trials to validate the potential delivery of rapid-acting human insulin in a sublingual format; the ability of the Company*

*to provide further information on formulation developments and to complete testing of formulations in a Type 1 diabetes model in the second half of 2022; the Company's ability to execute on its plan to optimize the formulation, the necessary testing assays, and related preclinical protocols required to advance studies for its novel Selactosol™ 1.5% targeting mycobacterium-based infections, and the commencement of the related pre-clinical studies with its Selactosol™ 1.5% solution in the latter half of 2022; the ability of MVMD to expand its oncology work to include additional pre-clinical models to explore combinations of its patented Soluvec™ with existing chemotherapeutic and immunomodulatory treatments across solid tumor and hematological malignancies; the ability of the Company (or its licensee(s)) to optimize the base formula and complete additional stability testing and the results thereof allowing for the scaling of batch sizes for production and ensuring Soluvec™ 1% product applications have a predictable shelf life, and the timing thereof (through to the first quarter of 2023); the ability for the Company to secure a commercial license agreement in Bangladesh to manage the a local manufacturing partner and process for scaled Soluvec™ 1% commercial production requirements and completion of market specific stability testing for the husbandry animal applications inside Bangladesh, and the completion of the work leading to the commercialization Soluvec™ 1% in the first quarter of 2023, or any longer or shorter period and that timing depending on various factors such as the results of the additional stability testing and the related timing of regulatory review and approval; the work being done with the Ministry and timing to commence aquaculture trials in the third quarter of 2022; the ability of MVMD to coordinate a research framework with an acclaimed international university to conduct a collaborative study of Soluvec™ 1% coated fish feed to study its health benefits in targeted aquatic species, and the timing of the commencement of the studies in the fourth quarter of 2022; the securing of an agreement with MVMD's selected third-party lead production partner, the benefit of such an engagement and arrangement with a single manufacturer, the nature of the arrangement, including between MVMD and the manufacturer, and MVMD and the licensees, and such licensees including Red White & Bloom and Circadian Wellness, and the ability of the Company to increase business development efforts in the latter half of 2022 and to secure additional nutraceutical licensing partnerships; the ability of the Company to continue its work with its key advisors and Tulane University with respect to the dose sparing adjuvant; the Company's intentions and plans with respect to the application of a solubilized form of ivermectin in the potential treatment of COVID-19 and whether it could be favourable for front line emergency use applications, including injection and intravenous uses, potentially for COVID-19 treatments where authorized or in research for future possible pandemics; the Company's future plans for further studies in humans, including stability of human grade GMP product, with academic and non-academic partnerships, with regarding to the foregoing; and the ability of the Company to provide further updates on its trials and developments as they become available.*

*The Company believes that the expectations reflected in the forward-looking information are reasonable, but no assurance can be given that these expectations will prove to be correct and such forward-looking information should not be unduly relied upon. Any forward-looking information contained in this news release represents the Company's expectations as of the date hereof and is subject to change after such date. The Company disclaims any intention or obligation to update or revise any forward-looking information whether as a result of new information, future events or otherwise, except as required by applicable securities legislation.*

*Neither the CSE nor OTCQX has reviewed or approved the contents of this press release.*