

# ANNUAL INFORMATION FORM FOR THE PERIOD ENDED DECEMBER 31, 2022

Dated: March 31, 2023

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### **GLOSSARY OF CERTAIN TERMS**

- "1961 Convention" has the meaning ascribed thereto under "Regulatory Framework United Kingdom".
- "2018 Ministerial Order" has the meaning ascribed thereto under "Regulatory Overview Canada Cannabis Tracking System".
- **"2020 Agency Agreement"** means the agency agreement dated November 27, 2020 among the Corporation and the 2020 Agents.
- "2020 Agents" means Echelon Wealth Partners Inc., Beacon Securities Limited and Canaccord Genuity Corp.
- "2021 Warrant Repricing" has the meaning ascribed thereto under "General Development of the Business Three Year History Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".
- "ACMPR" has the meaning ascribed thereto under "Regulatory Overview Canada Background".
- "Additional December 2020 Units" has the meaning ascribed thereto under "General Development of the Business Three Year History Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".
- "Additional Units" has the meaning ascribed thereto under "Recent Developments (January 1, 2022 to Present).
- "AGCO" has the meaning ascribed thereto under "Regulatory Overview Canada Provincial and Territorial Regulatory Regimes".
- "Agents" means Sprott Capital Partners LP and Paradigm Capital Inc.
- "Agency Agreement" means the agency agreement dated December 13, 2018, and amended March 13, 2019 and April 15, 2019, among the Corporation and the Agents in connection with the Offering.
- "AIF" means this annual information form.
- "Altea" means Altea Farmaceutica S.A., a Colombian company specialized in the manufacturing and development of pharmaceutical products and derma-cosmetics.
- "Altea Manufacturing Agreement" means the manufacturing agreement dated December 11, 2028 between the Corporation and Altea pursuant to which Altea agreed to act, and the Corporation appointed Altea as, the excusive manufacturer of Avicanna's products in Columbia.
- "Amending Regulations" has the meaning ascribed thereto under "Regulatory Overview Canada Cannabis Tracking System".
- "ANMAT" has the meaning ascribed thereto under "Regulatory Framework Argentina".
- "Annual Required Filings" has the meaning ascribed thereto under "General Development of the Business Three Year History Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".

- "APIs" has the meaning ascribed to it under "Description of the Business Products Raw Materials and Bulk Formulations".
- "ARTG" has the meaning ascribed thereto under "Regulatory Framework Australia".
- "Astral" means Astral Health Ltd. a company incorporated in the United Kingdom specialized on the distribution of CBPMs.
- "April 2020 Offering" has the meaning ascribed thereto under "General Development of the Business Three Year History Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".
- "August 2020 Offering" has the meaning ascribed thereto under "General Development of the Business Three Year History Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".
- "August 2020 Units" has the meaning ascribed thereto under "General Development of the Business Three Year History Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".
- "August 2020 Warrant" has the meaning ascribed thereto under "General Development of the Business Three Year History Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".
- "ARCSA" has the meaning ascribed thereto under "Regulatory Framework Ecuador".
- "Avicanna" means Avicanna Inc.
- "Avicanna LATAM" means Avicanna LATAM S.A.S., a wholly-owned subsidiary of Avicanna.
- "Bio-Gate" has the meaning ascribed thereto under "General Development of the Business Three Year History General Development of the Business Three Year History Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".
- "Board of Directors" or "Board" means the board of directors of the Corporation.
- "Bondue" means Inmobiliaria Bondue S.A.S.
- "Broker Warrant" has the meaning ascribed thereto under "General Development of the Business Three Year History Fiscal Year 2020 (January 1, 2020 to December 31, 2020)"
- "Business Day" means any day except Saturday, Sunday, any statutory holiday in the Province of Ontario or any other day on which the principal chartered banks in the City of Toronto are closed for business.
- "CAIMED" means the Centro de Atencion e Investigacion Medica CAIMED S.A.S.
- "Cannabis Act" means the Cannabis Act, S.C. 2018, c. 16
- "Cannabis Regulations" means the Cannabis Regulations, SOR/2018-144
- "Cannabis Research Licence" has the meaning ascribed thereto under "Regulatory Overview Canada Licenses, Permits and Authorizations".

"Cannabis Tracking and Licensing System" has the meaning ascribed thereto under "Regulatory Overview – Canada – Cannabis Tracking System".

"Cannvalate" means Cannavalate Pty Ltd.

"CBD" means cannabidiol.

"CBG" means cannabigerol.

"CBN" means cannabinol.

"CBPMs" means cannabis based cannabis based products for medicinal use.

"CDSA" has the meaning ascribed thereto under "Regulatory Overview - Canada - Background".

"Charles River" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"Colombian Licenses" has the meaning ascribed thereto under "Regulatory Framework - Colombia".

"Common Shares" means the voting common shares in the capital of the Corporation.

"CONICET" has the meaning ascribed thereto under "Regulatory Overview - Argentina".

"Corporation" means has the definition ascribed thereto on the face page of this AIF.

"COVID-19" means the novel strain of coronavirus that emerged in Wuhan, China in December, 2019.

"CPNP" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"Criminal Code" has the meaning ascribed thereto under "Regulatory Framework - Colombia".

"CSA" has the meaning ascribed thereto under "Regulatory Framework - United States of America".

"CTO" means the cease trade order issued by the OSC on June 11, 2021 in connection with the Corporation's failure to file the Required Documents within the prescribed time.

"DEA" has the meaning ascribed thereto under "Regulatory Framework – United States of America".

"December 2020 Warrant" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"December 2020 Units" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"December Prospectus Offering" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"Debenture Certificates" means the certificates issued to the holders of Debentures representing and governing the terms and conditions of the Debentures.

"Debenture Warrants" means the Common Share purchase warrants issued by the Corporation on March 1, 2019 in connection with the issuance of the Debentures.

"Drug Policy Commission" has the meaning ascribed thereto under "Regulatory Framework - Colombia".

"DS 404" has the meaning ascribed thereto under "Regulatory Framework - Chile".

"DS 405" has the meaning ascribed thereto under "Regulatory Framework - Chile".

"DSHEA" has the meaning ascribed thereto under "Regulatory Framework - United States of America".

"DTC" means the Depository Trust Company.

"Extracts" means plant-derived cannabinoid extracts, purified cannabinoids including distillates and isolates.

"Face Principal Amount" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"FDA" means the Food and Drug Administration of the United States of America.

"FNE" has the meaning ascribed thereto under "Regulatory Overview – Colombia".

"forward-looking statements" has the meaning ascribed thereto under "Forward-Looking Statements".

"FSE" means the Frankfurt Stock Exchange.

"Funded Amount" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".

"GACP" means Good Agricultural and Collection Practices

"GMP" means Good Manufacturing Practice.

"Good Preparation Practices" or "GPP" has the meaning ascribed thereto under "Regulatory Overview - Colombia".

"GRAS" has the meaning ascribed thereto under "Regulatory Framework – United States of America".

"Heritage" has the meaning ascribed thereto under "General Development of the Business – Three Year History - General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".

"HCPs" has the meaning ascribed thereto under "Regulatory Framework – United Kingdom".

- "ICA" means Colombian Agriculture Institute.
- "IFRS" means International Financial Reporting Standards.
- "IHR" means the Industrial Hemp Regulations, SOR/2018-145.
- "INASE" has the meaning ascribed thereto under "General Framework Argentina".
- "INTA" has the meaning ascribed thereto under "Regulatory Overview Argentina"
- "Interim Required Filings" has the meaning ascribed thereto under "General Development of the Business Three Year History Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".
- "INVIMA" means the Instituto Nacional de Vigilancia de Medicamentos y Alimentos, a regulatory authority created under the Colombian Ministry of Health.
- "ISP" has the meaning ascribed thereto under "Regulatory Framework Chile".
- "IT" has the meaning ascribed thereto under "Risk Factors Risks Related to the Corporation's Business and Industry Information Systems Security Threats".
- "January 2020 Offering" has the meaning ascribed thereto under "General Development of the Business Three Year History Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".
- "January 2022 Debentures" has the meaning ascribed thereto under "Recent Developments (January 1, 2022 to Present).
- "January 2022 Offering" has the meaning ascribed thereto under "Recent Developments (January 1, 2022 to Present).
- "January 2022 Warrant" has the meaning ascribed thereto under "Recent Developments (January 1, 2022 to Present).
- "January 2022 Units" has the meaning ascribed thereto under "Recent Developments (January 1, 2022 to Present).
- "LC2019" has the meaning ascribed thereto under "General Development of the Business Three Year History Fiscal Year 2019 (January 1, 2019 to December 31, 2019)".
- "Legacy Plan" means the Corporation's stock option plan adopted April 1, 2017 and replaced by the LTIP.
- "Listing Date" means July 18, 2019.
- "LTIP" means the Corporation's omnibus long term incentive plan adopted June 3, 2019.
- "LYPHE Group" or "LYPHE" means LYPHE Group Ltd.
- "MA" has the meaning ascribed thereto under "Regulatory Framework United Kingdom".

"MAGP" has the meaning ascribed thereto under "Regulatory Framework - Uruguay".

"MAGP Import Authorization" als the meaning ascribed thereto under "Regulatory Framework – Uruguay".

"March 2021 Offering" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".

"March 2021 Units" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".

"March 2022 Offering" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2022 (January 1, 2022 to December 31, 2022)".

"March 2022 Units" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2022 to December 31, 2022)".

"Maturity Date" has the meaning ascribed thereto under "Recent Developments (January 1, 2022 to Present)".

"MC-RWE Study" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"MCTO" means the management cease trade order issued by the OSC on April 9, 2021.

"MDA" has the meaning ascribed thereto under "Regulatory Framework - United Kingdom".

"MDR" has the meaning ascribed thereto under "Regulatory Framework - United Kingdom".

"MediPharm Labs" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"MHSC" has the meaning ascribed thereto under "Business Description.

"Minister" has the meaning ascribed thereto under "Regulatory Framework - Canada - Security Clearances".

"MJL" means the Colombian Ministry of Justice and Law.

"Mountain Valley" means Mountain Valley MD Inc.

"My Cannabis" means 2516167 Ontario Inc., an Ontario corporation doing business as My Cannabis, a wholly-owned subsidiary of Avicanna.

"NBLC" has the meaning ascribed thereto under "Regulatory Overview – Canada – Provincial and Territorial Regulatory Regimes".

"ND Act" has the meaning ascribed thereto under "Regulatory Framework - Australia".

"New Classes of Cannabis" has the meaning ascribed thereto under "Regulatory Overview – Canada – Cannabis Tracking System".

"NI 52-110" means National Instrument 52-110 - Audit Committees.

"NLC" has the meaning ascribed thereto under "Regulatory Overview – Canada – Provincial and Territorial Regulatory Regimes".

"NOP" means National Organic Program.

"November 2020 Debentures" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"November 2020 Debenture Financing" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"NSERC" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"**NSLC**" has the meaning ascribed thereto under "*Regulatory Overview – Canada – Provincial and Territorial Regulatory Regimes*".

"OBCA" means the Business Corporations Act (Ontario).

"October 2021 Offering" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"October 2021 Units" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"ODC" has the meaning ascribed thereto under "Regulatory Framework - Australia".

"Offering" means the offering of Special Warrants which took place on December 13, 2018, at which time 540,484 Special Warrants were issued, and [♠], 2019, at which time, 228,328 Special Warrants were issued, all in accordance with the terms of the Agency Agreement.

"Order" has the meaning ascribed thereto under "Cease Trade Orders, Bankruptcies, Penalties, or Sanctions – Cease Trade Orders".

"OSC" means the Ontario Securities Commission, the Corporation's principal regulator.

"OTC" means over-the-counter medicines sold directly to consumers without a prescription.

"Outstanding Warrants" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"Partial Revocation Order" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".

"PCT" has the meaning ascribed thereto under "Business Description - Intellectual Property".

"PDL" has the meaning ascribed thereto under "Regulatory Overview - Canada - Health Products Containing Cannabis".

"**Percos**" means Percos S.A. a Colombian based company that specializes in the distribution of cosmetic products in Colombia.

"person" includes an individual, partnership, association, body corporate, trustee, executor, administrator or legal representative.

"Proposed Warrant" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".

"Proposed Warrant Exercise Price" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".

"**Prospectus**" means the Corporation's final long-form non-offering prospectus filed on SEDAR on July 9, 2019 in connection with the Offering that qualified the distribution of the securities under the Offering;

"Pure Global" means Pure Global Cannabis Inc.

"R&D" means research and development.

"Regulations" means both the Cannabis Regulations and the IHR.

"Required Filings" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".

"Restricted Share Units" means the restricted share units of the Corporation granted pursuant to the LTIP.

"RWB" or "Red White & Bloom" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"RWET" has the meaning ascribed thereto under "Business Description – Products – Medical Cannabis Products – Real Word Evidence Trials".

"SAHPRA" has the meaning ascribed thereto under "Regulatory Framework - South Africa".

"SAS" has the meaning ascribed thereto under "Regulatory Framework - Australia".

"Sativa Nativa" means Sativa Nativa S.A.S.

"Secretary" has the meaning ascribed thereto under "Regulatory Framework - Australia".

"SEDAR" means the System for Electronic Document Analysis and Retrieval, accessible at www.sedar.com.

"SENASA" has the meaning ascribed thereto under "Regulatory Framework - Argentina".

"SDM Agreement" has the meaning ascribed thereto under "General Development of the Business – Three Year history – Recent Developments (January 1, 2020 to December 31, 2020)".

"Shoppers" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"SickKids" means Toronto's Hospital for Sick Children.

"SLGA" has the meaning ascribed thereto under "Regulatory Overview - Canada - Provincial and Territorial Regulatory Regimes".

"SMGH" means Santa Marta Golden Hemp S.A.S.

"SN" means Sativa Nativa S.A.S.

"SN Share" means the voting common shares in the capital of SN.

"South Africa Medicines Act" shall have the meaning ascribed thereto under "Regulatory Overview – South Africa".

"Stock Options" means the option to purchase Common Shares in the capital of the Corporation granted pursuant to the Legacy Plan and/or the LTIP.

"Sunnybrook Hospital" has the meaning ascribed thereto under "General Development of the Business – Three Year History – General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".

"**Term Loan** has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".

"Term Loan Warrants" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"TGA" has the meaning ascribed thereto under "Regulatory Framework – Australia".

"TG Act" has the meaning ascribed thereto under "Regulatory Framework - Australia".

"THC" means tetrahydrocannabinol.

"Thompson Rivers University" means Thompson Rivers University.

"Triggering Event" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2019 (January 1, 2019 to December 31, 2019)".

"TSX" means the Toronto Stock Exchange.

"U of Guelph" means the University of Guelph.

"U of T Faculty of Pharmacy" means the Leslie Dan Faculty of Pharmacy at the University of Toronto located at 144 College Street, Toronto Ontario.

"UHN" means University Health Network.

"UHN Services Agreement" has the meaning ascribed thereto under General Developments of the Business – Three Year History – General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021).

"UNSI" has the meaning ascribed thereto under "Regulatory Overview - Uruguay".

"U.S." means the United States of America.

"USD" means U.S. dollars.

"USDA" means the United States Department of Agriculture.

"UWI" means the University of West Indies.

"**UWI Services Agreement**" means the services agreement dated December 12, 2018 entered into between the Corporation and UWI.

"Valens" means Valens Agritech Ltd.

"Valens Agreement" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Recent Developments (January 1, 2020 to December 31, 2020)".

"Viola" has the meaning ascribed thereto under "General Development of the Business – Three Year History - General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021)".

"Warrant" means a common share purchase warrant in the capital of the Corporation.

"Warrant Amendment" has the meaning ascribed thereto under "General Development of the Business – Three Year History – Fiscal Year 2020 (January 1, 2020 to December 31, 2020)".

"We Bay" means We Bay S.A.S.

### **MEANINGS OF CERTAIN REFERENCES**

In this annual information form ("Annual Information Form" or "AIF"), references to the "Company", "Corporation", "Avicanna", "we", "us", or "its" are references to Avicanna Inc. References to "management" in this AIF mean the persons acting in the capacity of Avicanna's Chief Executive Officer, Chief Financial Officer. Any statement in this AIF made by or on behalf of management are made in such person's capacities as officers of Avicanna and not in their personal capacities.

All references in this AIF to the Corporation also include references to all subsidiaries of the Corporation as applicable, unless the context requires otherwise.

#### FORWARD-LOOKING INFORMATION

This AIF contains forward-looking information and forward-looking statements, within the meaning of applicable Canadian securities legislation, (collectively, "forward-looking statements"), which reflect management's expectations regarding the Corporation's future growth, results from operations (including, without limitation, future production and capital expenditures), performance (both operational and financial) and business prospects, future business plans and opportunities. Wherever possible, words such as "predicts", "projects", "targets", "plans", "expects", "does not expect", "budget", "scheduled", "estimates", "forecasts", "anticipate" or "does not anticipate", "believe", "intend" and similar expressions or statements that certain actions, events or results "may", "could", "would", "might" or "will" be taken, occur or be achieved, or the negative or grammatical variation thereof or other variations thereof, or comparable terminology have been used to identify forward-looking statements. These forward-looking statements include, among other things, statements relating to:

- expectations regarding our revenue, expenses and operations;
- expectations with respect to regulatory approvals including, Health Canada, ANVISA and INVIMA approvals with respect to our products and the genetic registration process and quota applications in Colombia;
- plans for future products and enhancements of existing products, including, without limitation, our expectations and intentions regarding pharmaceuticals, phyto-therapeutics, lifestyle, dermacosmetics and Extracts;
- plans to sell our Extracts;
- the ailments for which our intended pharmaceutical products will be used to treat;
- business plans, growth strategy and growth rate, including, without limitation, our intentions with respect to market positioning, our projected synergies expected from vertical integration of our business and our business segments;
- the timing of our business objectives including our clinical trials, product testing, product manufacturing and production of Extracts;
- plans to research, develop, implement, adopt, market and sell new technology or products, including continued research, development and commercialization regarding our products and proposed products;
- expansion and acceptance of our products in different markets;

- the timing and possible outcome of obtaining necessary regulatory approvals for any new markets in which the Corporation anticipates selling;
- the intended outcome of collaborations with third parties, including, without limitation, the expected
  results of clinical trials, the expected results of prevalence studies and the expected timing of Health
  Canada applications;
- expectations with respect to changes to the Canadian and Colombian cannabis regulatory regimes;
- the timing and possible outcome of regulatory and legislative matters, including, without limitation, Health Canada, the FDA, EU and other regulatory approval processes;
- Listings and approvals by provincial regulatory boards for products in the Canadian adult use channels;
- future plans, objectives or economic performance, or the assumption underlying any of the foregoing;
- our treatment under regulatory regimes and applicable laws;
- expected production, yield and capacity;
- the jurisdictions in which we will pursue distribution and manufacturing licences;
- manufacturing and distribution partnerships and agreements;
- plans to expand distribution to new locations in North America, Europe and Latin America;
- plans related to marketing, distribution, and production capacity;
- our anticipated agreements with third parties, including, without limitation, the terms thereof, the timing of such agreements, the expected outcomes of such agreements and the geographic locations of such parties;
- our planned business objectives and future dividend policy;
- requirements for additional capital and future financing options;
- currency fluctuations;
- availability and expectations regarding of cash flow to fund capital requirements
- the time and attention each executive officer and director will devote to our business;
- the compensation structure for executive officers and directors;
- future intellectual property, R&D, product formulations, and business lines;
- the intentions of the Board with respect to the executive compensation plans and corporate governance plans described herein;
- on-going implications of COVID-19;

- statements relating to the business and future activities of, and developments related to, the Corporation, including such things as future business strategy, competitive strengths, goals, expansion and growth of the Corporation's business, operations and plans; and
- other events or conditions that may occur in the future.

Forward-looking statements are not a guarantee of future performance and are based upon a number of management's estimates and assumptions, in light of management's experience and perception of trends, current conditions and expected developments, as well as other factors that management believes to be relevant and reasonable in the circumstances, as of the date of this AIF including, without limitation, the following:

- the impacts of COVID-19 to our business;
- the future customer concentration;
- the ability to anticipate future needs of customers;
- no unusual delays to receive regulatory approvals for our clinical trials or cultivation quotas;
- our expectations with respect to the competitive landscape of the industry in which we operate and our present intentions to differentiate our business within that industry;
- the regulatory framework governing cannabis for recreational and medicinal use in Canada, Colombia, and any other jurisdiction in which we may conduct our business in the future;
- our ability to successfully execute growth strategies and business plans;
- there being no significant delays in the completion of our cultivation facilities;
- there being no significant delays in the development and commercialization of our products;
- maintaining sufficient and effective production and R&D capabilities;
- our ability to analyze customer data;
- our ability to secure partnerships with manufacturers and distributors in international markets;
- the ability of our strategic partnerships to effectively operate;
- our ability to develop a brand to market our products successfully to consumers;
- future production and supply levels, and future consumer demand levels;
- the price of cannabis and cannabis related products;
- continuing to attract and retain key personnel;
- the demand for our products will grow for the foreseeable future;
- there being no significant barriers to acceptance of our products in the market;
- the general economic, financial market, regulatory and political conditions in which the Corporation operates and the absence of material adverse changes in the Corporation's industry, regulatory environmental or the global economy; and
- other considerations that management believes to be appropriate in the circumstances.

While we consider these assumptions to be reasonable, the assumptions are inherently subject to significant business, social, economic, political, regulatory, and competitive risks, as well as other uncertainties, contingencies and factors that could cause actual actions, events, conditions, results, performance or achievements to be materially different from those projected in the forward-looking statements. Many assumptions are based on factors and events that are not within our control and there is no assurance they will prove to be correct.

Furthermore, such forward-looking statements involve a variety of known and unknown risks, uncertainties and other factors which may cause the actual plans, intentions, activities, results, performance or achievements of the Corporation to be materially different from any future plans, intentions, activities, results, performance or achievements expressed or implied by such forward-looking statements. Such risks include, without limitation:

- our business segments are heavily regulated in Canada, the United States, Europe and Colombia;
- the regulatory regime is evolving and uncertainty exists regarding the impact of the regime on the Corporation;
- the political environment surrounding the cannabis industry is in flux and subject to change;
- the inability to successfully complete clinical trials or obtain regulatory approval of products;
- risks of foreign operations generally, including but not limited to agriculture and drug policies, nationalization, expropriation, contractual rights, foreign exchange restrictions, currency fluctuations, export quotas, royalty and tax increases, and risks of loss due to civil strife, acts of war, guerilla activities and insurrections;
- the potential inability to enforce judgments obtained in Canada against any person or company incorporated, continued or otherwise organized under the laws of a foreign jurisdiction or that resides outside of Canada, even if the party has appointed an agent for service of process;
- the potential inability to obtain or retain licences required to grow, store and sell cannabis in Colombia,
- the potential inability to establish and maintain bank accounts:
- potential involvement in regulatory or agency proceedings, investigations and audits;
- compliance with evolving environmental, health and safety laws;
- the potential risk of exposure resulting from the control of foreign subsidiaries in Colombia;
- potential government policy changes or shifts in public opinion;
- exposure to foreign exchange risks;
- inflationary risks based on Colombia's historic experience of double digit rates of inflation;
- the potential that Colombia will impose repatriation of earnings restrictions in the future;
- Colombian political and economic conditions are subject to intervention and change;
- constraints on marketing of products;

- the cannabis industry and market is subject to general business risks, and those associated with agricultural and regulated consumer products;
- competitive conditions, consumer tastes, patient requirements and spending patterns remain relatively unknown;
- there are no assurances that the cannabis industry and market will continue to exist or grow as anticipated;
- the industry is changing at rapid speeds, and we may be unable to keep pace;
- the consumer perception of cannabis can be significantly influenced by scientific research or findings, regulatory investigations, litigation, media, and other publicity;
- future clinical research into effective medical cannabis therapies could raise concerns regarding, and perceptions relating to, cannabis;
- the Corporation may need to continue to raise capital to meet its operating demands;
- limited history of operations;
- the inability to retain and attract employees and key personnel;
- potential for delays in obtaining, or restructuring conditions imposed by, regulatory approvals;
- potential increases in material and labour costs;
- we have incurred losses since inception and may continue to incur losses in the future;
- the ownership of the Common Shares is heavily concentrated among our directors and officers;
- the potential to experience difficulty developing new products and remaining competitive;
- the completion and commercial viability of new products in the prototype stage;
- construction risk in connection with the facilities in Colombia;
- potential for adverse environmental conditions, accidents, labour disputes and changes in the regulatory environment;
- reliance on third-party manufacturers and distributors;
- there can be no assurances of profit generation or immediate results;
- risks against which we are unable or unwilling to insure against;
- shareholder dilution pursuant to additional financings;
- transportation disruptions to our courier services;
- the cost of our key inputs is unpredictable;
- compliance with laws relating to privacy, data protection, and consumer protection;
- potential for information systems security threats;
- we are reliant on key suppliers and skilled labour;
- inability to effectively implement quality control systems;

- there is a potential for conflicts of interest to arise among our key stakeholders;
- we may be unable to sustain our pricing models;
- we may not be able to successfully identify or complete future acquisitions;
- we may be unable to effectively protect personal information;
- exposure to product recalls, liability claims, regulatory action and litigation based on products;
- we may be unable to protect intellectual property in relevant markets;
- the market price for the Common Shares may be volatile and subject to wide fluctuations;
- we may not be able to effectively prevent fraudulent or illegal activities by our employees, contractors or consultants;
- we may not be able to effectively prevent security breaches at our facilities;
- management may not be able to effectively manage our growth;
- outside factors may harm our reputation;
- we may become subject to legal proceedings from time to time;
- management has limited experience managing public companies;
- we may be unable to effectively protect our trade secrets;
- securities analysts may publish negative coverage;
- our financial statements have been prepared on a going concern basis;
- risks related to our internal control measures;
- we may be dependent on the performance of our subsidiaries;
- · certain of our operating subsidiaries are not wholly-owned;
- there may be future sales of the Common Shares by directors, officers and principal shareholders;
- interruptions or changes in the availability or economics of our supply chain; and
- other factors discussed under "Risk Factors".

Although we have attempted to identify important factors that could cause actual actions, events, conditions, results, performance or achievements to differ materially from those described in forward-looking statements, there may be other factors that cause actions, events, conditions, results, performance or achievements to differ from those anticipated, estimated or intended. See "*Risk Factors*" for a discussion of certain factors investors should carefully consider before deciding to invest.

Readers are cautioned that the foregoing lists of important assumptions and risks, uncertainties and other factors are not exhaustive. Other events or circumstances could cause actual results to differ materially from those estimated or projected and expressed in, or implied by, the forward-looking information contained herein. There can be no assurance that forward-looking statements will prove to be accurate, as

actual results and future events could differ materially from those anticipated in such information. Accordingly, readers should not place undue reliance on forward-looking statements.

Forward-looking statements contained herein are made as of the date of this AIF and we disclaim any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or results or otherwise, except as and to the extent required by applicable securities laws. The purpose of forward-looking statements is to provide the reader with a description of management's expectations, and such forward-looking statements may not be appropriate for any other purpose. You should not place undue reliance on forward-looking statements contained in this AIF. Although the Corporation believes that the expectations reflected in such forward-looking statements are reasonable, it can give no assurance that such expectations will prove to have been correct. The Corporation undertakes no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law. The forward-looking statements contained in this AIF and therein are expressly qualified in their entirety by this cautionary statement. Potential purchasers of the Securities should read this entire AIF, and consult their own professional advisors to ascertain and assess the income tax and legal risks and other aspects associated with holding Securities.

### **DATE OF INFORMATION**

The information in this AIF is presented as of the date of the AIF, unless otherwise indicated.

### PRESENTATION OF FINANCIAL INFORMATION

Unless otherwise indicated, all references to "\$" or "dollars" are to Canadian dollars, which is Avicanna's functional currency. The fiscal year end of all entities within the corporate structure of Avicanna is December 31. Avicanna's consolidated financial statements (the "financial statements") are prepared in accordance with IFRS.

### **EXCHANGE RATE INFORMATION**

This Annual Information Form contains reference to Canadian dollars, referred to herein as "\$", United States dollars, referred to herein as "US\$".

The following table sets forth, for each period indicated, the high and low exchange rates, the average exchange rate, and the exchange rate at the end of the period, based on the rate of exchange of one U.S. dollar in exchange for Canadian dollars published by the Bank of Canada.

	2022	2021	2020
High	0.8011	0.8306	0.7863
Low	0.7218	0.7727	0.6898
Average	0.7370	0.7980	0.7454
Closing	0.7652	0.7810	0.7854

On March 31, 2023, the average daily exchange rate as reported by the Bank of Canada was US\$1.00 = \$1.2509 or \$1.00 = US\$0.7994

### THIRD-PARTY INFORMATION

Unless otherwise indicated, information contained in this AIF concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunities and market share, is based on information from independent industry organizations, other third-party sources (including industry publications surveys, and forecasts), and management studies and estimates.

Unless otherwise indicated, our estimates are derived from publicly available information released by independent industry analysts and third-party sources, as well as data from our internal research, and include assumptions made by us which we believe to be reasonable based on our knowledge of our industry and markets. Although Avicanna believes these sources to be generally reliable, market and industry data are subject to interpretation and cannot be verified with complete certainty due to limits on the availability and reliability of raw data, the voluntary nature of the data gathering process, and other limitations and uncertainties inherent in any statistical survey. Our internal research and assumptions have not been verified by any independent source, and we have not independently verified any third-party information. While we believe the market position, market opportunity, and market share information included in this AIF are generally reliable, such information is inherently imprecise. In addition, projections, assumptions, and estimates of our future performance and the future performance of the industry and markets in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described under the heading "Forward-Looking Statements" and "Risk Factors".

### **CORPORATE STRUCTURE**

We incorporated under our current name, Avicanna Inc., on November 25, 2016, under the OBCA. Our registered office is located at 480 University Avenue, Suite 1502, Toronto Ontario M5G 1V2.

On July 8, 2019, the Articles of the Corporation were amended to remove the private company restrictions.

### **Intercorporate Relationships**

The following chart illustrates, as at the date of this AIF, the Corporation's material subsidiaries, the percentage of voting securities of each that are held by Avicanna, and their respective jurisdiction of incorporation, continuance, formation, or organization.

Subsidiary Name	Ownership Interest by Avicanna	<u>Jurisdiction</u>
2516167 Ontario Inc. d.b.a. My	100%	Ontario, Canada
Cannabis		
Avicanna LATAM S.A.S.	100%	Republic of Colombia
Santa Marta Golden Hemp S.A.S.	60.5%(2)	Republic of Colombia
Sigma Magdalena Canada Inc.	45% <sup>(3)</sup>	Ontario, Canada
Avicanna (UK) Limited	100%	United Kingdom
Avicanna USA Inc.	100%	Delaware, USA

### Notes:

- (1) The remaining 39.5% of SMGH is owned by Bondue (38.4%) and Lucas Echeverri Robledo (1.1%). Bondue is owned and controlled by Mr. Giancarlo Davila Char, one of our directors.
- (2) The remaining 55% is owned by Sigma Expansion One Inc.

# **GENERAL DEVELOPMENT OF THE BUSINESS**

### **Three Year History**

## Fiscal Year 2020 (January 1, 2020 to December 31, 2020)

On January 7, 2020, the Corporation entered into an exclusive distribution agreement with Medical Cannabis by Shoppers™ ("Shoppers"), a subsidiary of Shoppers Drug Mart Inc., to distribute the Corporation's Rho Phyto™ medical cannabis and Pura Earth™ derma-cosmetic (consumer retail) product lines in Canada, which include sublingual sprays, oil drops, gels, creams, tablets and capsules (the "SDM Agreement").

On January 13, 2020, the Corporation announced the results from its first of three cosmetic clinical studies conducted by CAIMED, an open-label, randomized, passive-control study examining the impact of its Pura Earth™ topical cream containing 0.5% cannabidiol and 1% hemp oil on skin hydration. This study achieved its primary endpoint of enhanced hydration.

On January 24, 2020, the Corporation closed a private placement under which we issued 822,721 units at a price of \$2.50 per unit for aggregate gross proceeds of \$2,056,802.50 (the "January 2020 Offering"). Each unit issued under the offering was comprised of one Common Share and one-half of one Warrant. Each whole Warrant is exercisable into one Common Share at an exercise price of \$3.00 per Common Share for a period expiring on January 24, 2023 subject to acceleration.

On February 6, 2020, the Corporation announced that it had been rated the highest amongst the global cannabis companies participating in the SAM Corporate Sustainability Assessment, a sustainability index that has become the basis for numerous S&P Global ESG indices.

On February 7, 2020, the Corporation entered into an agreement with Valens Agritech Ltd. ("Valens") whereby Valens agreed to license the Corporation's intellectual property for the manufacture of Avicanna's medical cannabis products for distribution in Canada (the "Valens Agreement").

On February 21, 2020, the Corporation received results from the remaining two of three cosmetic clinical studies conducted by CAIMED in Colombia. The second study evaluated Avicanna's Pura Earth™ facial cream containing 0.5% cannabidiol and 0.1% hemp oil on skin hydration and characteristics associated with acne-prone skin. The primary endpoint of enhanced hydration was met. Furthermore, a significant decrease in oily skin was evident in a subset of individuals with higher sebum production. The third study evaluated the effect of Avicanna's Pura Earth™ topical serum containing 1% cannabidiol and apple stem cells on skin characteristics associated with aging. The results indicate an enhanced skin hydration effect following application of the cream and after 2 months of use. There were no reports of adverse events requiring discontinuation or medical intervention in any of the three studies conducted.

On February 24, 2020, the Corporation announced that it entered into an importation and distribution agreement with Cannvalate Pty Ltd. ("Cannvalate") to supply its Rho Phyto™ medical cannabis products to provide to patients under the Australian Therapeutic Goods Administration Special Access Scheme, as well as to supply cannabis active APIs. The Corporation also agreed to supply Cannvalate with a line of advanced cannabinoid phyto-therapeutic products on a white-labelled basis. Under the agreement, the Corporation appointed Cannvalate as an exclusive distributor for the Rho Products in Australia, subject to

Cannvalate meeting minimum purchase requirements. The agreement with Cannvalate was amended on July 31, 2020 to update Cannvalate's status as the Corporation's non-exclusive distributor in Australia.

On March 17, 2020, the Corporation exported 10 mg of CBD isolate to the University of Buenos Aires in Argentina for research purposes.

On March 22, 2020, the Corporation's sublingual, oil drops, and capsules products were approved for commercial sale in Canada by Health Canada.

On March 28, 2020, the Corporation's gel and cream products were approved for commercial sale in Canada by Health Canada.

On April 2, 2020, the Corporation received an amendment to the Cannabis Research Licence, received on August 19, 2019, to include the ability to conduct research under the Cannabis Research Licence in another lab controlled by Avicanna within JLABS @ Toronto.

On April 21, 2020, the Corporation closed a private placement under which we issued 3,200,000 units at a price of \$0.80 per unit for aggregate gross proceeds of \$2.56 million (the "April 2020 Offering"). Each unit issued under the offering was comprised of one Common Share and one-quarter of one Warrant. Each whole Warrant is exercisable into one Common Share at an exercise price of \$1.20 per Common Share for a period expiring on April 20, 2022 subject to acceleration. The Corporation further announces that it is proposing to amend the exercise price of 411,360 Warrants (the "Outstanding Warrants") effective as at the close of business on May 5, 2020. The Outstanding Warrants were originally issued by the Corporation pursuant to a CAD\$2.06 million non-brokered private placement financing of units on January 24, 2020. Each Outstanding Warrant entitles the holder thereof to purchase one (1) Common Share in the capital of the Corporation on or before January 24, 2023 at an exercise price of CAD\$3.00 per Common Share. None of the Outstanding Warrants are held by insiders of the Corporation. The exercise price of the Outstanding Warrants is proposed to be amended to CAD\$1.40 per Common Share, which was at a premium to the five (5) day volume weighted average price of the Common Shares as of April 21, 2020 (the "Warrant Amendment").

On May 7, 2020, the Corporation announced that, through its cultivation subsidiary SMGH, it had received the approval from the Colombian government for the industrial export of hemp seeds to the US.

On May 14, 2020, the Corporation announced that it entered into a multi-faceted strategic manufacturing agreement with MediPharm Labs Corp., (TSX: LABS) (OTCQX: MEDIF) (FSE: MLZ) ("MediPharm Labs") involving intellectual property licensing for the purposes of production, and domestic and international distribution of Avicanna's proprietary formulations. MediPharm Labs is a global leader in specialized, research-driven pharmaceutical-quality cannabis extraction, distillation and derivative products. Pursuant to the strategic manufacturing agreement, MediPharm Labs manufactures and produces Avicanna's advanced Rho Phyto™ medical cannabis products and Pura Earth™ topicals for commercial sales through Medical Cannabis by Shoppers™.

On June 9, 2020, the Corporation announced that it satisfied all regulatory requirements to successfully register the first three products of its premium CBD-based derma-cosmetic product line, Pura Earth™, on the European Commission's Cosmetic Product Notification Portal (the "CPNP"). The first group of products registered with the CPNP are Pura Earth's Anti-Aging Cream, Intensive Moisturizing Cream and Clear Skin Gel products.

On June 18, 2020, the Corporation announced that, pursuant to its announcement on May 7, 2020, through its cultivation subsidiary SMGH, it has pioneered the first ever export of feminized hemp seeds to the US and completed the first sale of seeds for net revenue of CAD\$380,000.

June 23, 2020, the Corporation announced that it expanded its research collaboration with Dr. Christine Allen's Research Group in the Leslie Dan Faculty of Pharmacy at the University of Toronto, to include the expedited development of a cannabinoid-based treatment for lung inflammation associated with COVID-19.

On July 15, 2020, the Corporation announced that its Rho Phyto<sup>™</sup> product line of advanced medical cannabis products will be the subject of a Medical Cannabis Real-World Evidence study ("**MC-RWE Study**") led by Dr. Hance Clarke of UHN in Toronto, Canada. The Rho Phyto products were developed in accordance with the recent Health Canada Cannabis 2.0 regulations that allow for more advanced, higher quality, medical cannabis product offerings.

On July 24, 2020, the Corporation announced that research collaborators, Dr. Christine Allen at the University of Toronto and Dr. Jibran Khokhar at the University of Guelph, have received two independent peer-reviewed grants from the Natural Sciences and Engineering Research Council of Canada ("**NSERC**"). The NSERC Alliance grants will be used to expand the investigators' collaborative research with Avicanna.

On August 11, 2020, the Corporation announced that it entered into a distribution agreement with Red White & Bloom Brands Inc. (CSE: RWB) (OTC: RWBYF) ("**RWB**" or "**Red White & Bloom**") for the exclusive distribution of Avicanna's advanced and clinically backed CBD-based cosmetic and topical products Pura H&W <sup>TM</sup> by RWB in the US and certain other markets.

On August 12, 2020, the Corporation announced the launch of RHO Phyto™ Micro Drop oils in Canada on the Shoppers platform as well as through the MC-RWE study at UHN as announced by the Corporation on July 15, 2020.

Offering"). Under the August 2020 Offering, the Corporation issued an aggregate of 1,952,410 units (the "August 2020 Units") at a price of \$1.40 per August 2020 Unit for aggregate gross proceeds of approximately CAD\$2.7 million. Each August 2020 Unit was comprised of one (1) Common Share and one-half of one (1/2) Warrant (each whole Warrant, an "August 2020 Warrant"). Each August 2020 Warrant is exercisable into one Common Share in the capital of the Corporation at a price of CAD\$2.00 per Common Share until August 18, 2022, subject to the Corporation's right to accelerate the expiry date of the August 2020 Warrants on not less than thirty (30) days' notice in the event that the volume weighted average trading price of the Common Shares exceeds CAD\$3.00 for any ten (10) consecutive trading days on the TSX.

On August 24, 2020, the Corporation announced that it completed exports of CBG and CBD isolates into the United States, CBD isolate into Germany and the commencement of a pilot tracking system for the export of its API products in partnership with TruTrace Technologies Inc. (CSE: TTT) (OTCQB: TTTSF). The Corporation further announced that the Colombian Ministry of Justice and Law has granted SMGH a commercial and industrial cultivation quota for 12,264 THC plants.

On September 4, 2020, the Corporation announced that, through its majority owned subsidiary, SMGH, it completed exports of CBD water soluble formula into the United States and CBD-based cosmetics into the United Kingdom. The Corporation further announced that the Colombian Ministry of Health granted SMGH a commercial and industrial fabrication quota to produce psychoactive THC derivatives.

On September 14, 2020, the Corporation announced that, through its wholly owned subsidiary Avicanna LATAM, the Corporation's pharmacy in Bogota has been certified with GPP and authorized by INVIMA for the sale of compounded pharmaceutical products to service medical prescriptions of individual patients in Colombia.

On September 21, 2020, the Corporation announced the launch of its RHO Phyto Rapid Act Sprays on the Shoppers portal, as well as through the Medical Cannabis Real-World Evidence Study at UHN.

On September 29, 2020, the Corporation announced that it entered into an agreement whereby Avicanna will develop certain hemp-derived cannabinoid-based products including sublingual and sustained released tablets intended for the sleep market for a US distributor.

On October 20, 2020, the Corporation announced the results of its annual general and special meeting.

On November 2, 2020, the Corporation closed a non-brokered convertible debenture financing, pursuant to which it issued convertible debentures (the "November 2020 Debentures") with an aggregate Face Principal Amount (as defined below) of \$1,100,000 (the "November 2020 Debenture Financing"). The November 2020 Debentures bear interest at 8.0% per annum and will mature on the date that is 12 months from the date of issuance, with the first year of interest payable in advance on the date of issuance and capitalized and added into the principal amount (such aggregate amount being, the "Face Principal Amount"). In connection with the November 2020 Debenture Financing, the Corporation also issued an aggregate of 550,000 Warrants, each exercisable at a price of \$1.50 per Common Share until November 2, 2022, subject to acceleration rights.

On November 26, 2020, the Corporation entered into an agreement with Charles River Laboratories Montreal ULC ("Charles River") for the evaluation of certain of Avicanna's products for attenuating pain and inflammation in an animal model of osteoarthritis.

On December 8, 2020, the Corporation closed a marketed public offering of 5,966,900 units (the "December 2020 Units") of the Corporation at a price of \$0.85 per December 2020 Unit, for gross proceeds of \$5,071,865 (the "December Prospectus Offering"). Each December 2020 Unit was comprised of one Common Share and one Warrant of the Corporation (each full Warrant, a "December 2020 Warrant" and collectively the "December 2020 Warrants"). Each December 2020 Warrant is exercisable for one Common Share at a price of \$1.20 per share at any time for a period of 36 months following closing of the December Prospectus Offering. Pursuant to the terms of the 2020 Agency Agreement, Avicanna (i) paid the 2020 Agents a cash commission equal to 7% of the gross proceeds from the sale of December 2020 Units with the exception of gross proceeds raised from subscribers included in the Corporation's President's List (as the term is defined in the 2020 Agency Agreement) which was subject to a reduced cash fee of 3.5% of the aggregate gross proceeds of sales from the President's List; and (ii) issued the 2020 Agents broker warrants ("Broker Warrants") equal to 7% of the number of December 2020 Units which was subject to a reduced number of Broker Warrants equal to 3,5% of the December 2020 Units sold to purchasers on the President's List. On December 31, 2020, the Corporation announced the closing of an over-allotment option issued to a syndicate of agents led by Echelon Wealth Partners Inc., as lead agent and solebookrunner, and including Beacon Securities Limited and Canaccord Genuity Corp., pursuant to which an additional 895,034 December 2020 Units ("Additional December 2020 Units") were issued at a price of \$0.85 per unit, for gross proceeds of approximately \$760,780. Pursuant to the terms of the 2020 Agency Agreement, Avicanna (i) paid the 2020 Agents a cash commission equal to 7% of the gross proceeds from the sale of Additional December 2020 Units with the exception of gross proceeds raised from subscribers included in the Corporation's President's List which was subject to a reduced cash fee of 3.5% of the aggregate gross proceeds of sales from the President's List; and (ii) issued the 2020 Agents Broker Warrants equal to 7% of the number of Additional December 2020 Units which was subject to a reduced number of Broker Warrants equal to 3,5% of the Additional December 2020 Units sold to purchasers on the President's List. Each Broker Warrant is exercisable for one Common Share and one Warrant at an exercise price of \$0.85 per Broker Warrant. Including the December 2020 Units sold pursuant to the over-allotment option, a total of 6,861,934 December 2020 Units were issued under the December Prospectus Offering for aggregate gross proceeds of approximately \$5,832,645.

On December 10, 2020, the Corporation announced the launch of its medical cannabis program in Colombia, under compound pharmacy legislation "Formulaciones Magistrales", in which Avicanna will provide its standardized, industry-leading cannabinoid formulary to patients and the medical community. Additionally, this program includes the education and training of the medical community and a comprehensive patient support program.

On December 17, 2020, the Corporation announced that it entered into an importation and distribution agreement with Alliancepharma Technologies S.A. for the distribution of the Corporation's advanced and clinically supported medical and pharmaceutical formulations in Ecuador. The Corporation also entered into an agreement with Spenta S.A., an Ecuadorian cosmetic distributor, for the distribution of its Pura Earth branded derma-cosmetic product line in Ecuador. As part of its commercial expansion plans, the Corporation also completed an export of feminized seeds to Uruguay from its majority-owned cultivation subsidiary, SMGH in Santa Marta, Colombia.

On December 23, 2020, the Corporation announced that its formulary of RHO Phyto products, previously exclusively available through Medical Cannabis by Shoppers, are to be made available through the adultuse provincial retail channels in addition to Medical Cannabis by Shoppers.

# General Development of the Business – Three Year History – Fiscal Year 2021 (January 1, 2021 to December 31, 2021)

Effective January 1, 2021, the Corporation entered into a research agreement with Thompson Rivers University for the evaluation of cannabinoids and terpenoids for their anti-inflammatory and anti-bacterial effects and the evaluation of cannabinoid-based products in tissue models of inflammation.

On January 6, 2021, the Corporation announced that it entered into a master services agreement with UHN for projects to be performed by Dr. Peter Carlen as the principal investigator related to epilepsy (the "UHN Services Agreement"). Additionally, the Corporation announced it completed the technical transfer and first pharmaceutical pilot production of its epilepsy drug candidate at Altea in Bogota, Colombia, a major step required for the final preparation for its registration and commercialization in South America.

On January 21, 2021, the Corporation announced an update and amendment to its collaboration with Dr. Jibran Khokhar, Assistant Professor at the University of Guelph, and initiated prioritized pre-clinical studies on the RHO Phyto formulations that are commercialized in Canada and Colombia. Additionally, the Corporation provided an update on research projects with the University of Toronto and Thompson Rivers University as well as a change to its management team.

On January 28, 2021, the Corporation announced the launch of its RHO Phyto™ Deep Tissue Gels through Shoppers as well as through additional adult use channels. The Corporation also announced the initiation of pre-clinical osteoarthritis evaluations after successful in vitro studies and the enrollment of the Deep Tissue Gels in the MC-RWE study. The MC-RWE study is led by UHN with the goal to evaluate the effectiveness of medical cannabis on pain, sleep and other related comorbidities.

On February 3, 2021, the Corporation entered into a joint development agreement with Bio-Gate AG ("**Bio-Gate**"), a German bio-medical company with a focus on health technologies such as cosmetics and dermatology products for the joint development of cosmetic and dermatology products that combine Bio-Gate AG's proprietary MicroSilver BG<sup>™</sup> technology and hemp-derived CBD.

On February 9, 2021, the Corporation announced that it entered into an intellectual property licensing and royalty agreement with Harrington Wellness Inc. for the commercialization of a CBD topical product line targeting athletes and active consumers in Canada and the U.S.

On March 4, 2021, the Corporation closed a non-brokered private placement (the "March 2021 Offering"). Under the March 2021 Offering, the Corporation has issued an aggregate of 4,480,000 units (the "March 2021 Units") at a price of CAD\$1.25 per March 2021 Unit for aggregate gross proceeds of approximately CAD\$5.6 million. Each March 2021 Unit is comprised of one (1) Common Share and one (1) Common Share purchase warrant, each of which is exercisable into one Common Share at a price of CAD\$1.75 per share until March 4, 2024.

On March 23, 2021, the Corporation announced that it entered into an intellectual property licensing and royalty agreement with VB Brands California LLC ("**Viola**") to use Viola's brand in connection with the sale of specific cannabinoid-based product formulations developed by Avicanna in Canada through medical and consumer retail sales channels.

On March 29, 2021 the Corporation announced that through its majority owned subsidiary SMGH, the Corporation was granted a quota by the Colombian government to cultivate and process up to 10,267 kilograms of dry cannabis flower to manufacture psychoactive (THC) crude and standardized extracts and final phyto-therapeutic products for export purposes and to produce seed from registered psychoactive varieties for commercial purposes. The Corporation also announced that through SMGH it has completed its first commercial export to Chile of 20.75 kilograms of high THC and high CBD full spectrum psychoactive cannabis resin to a leading Chilean homeopathic and naturopathic pharmaceutical company.

On March 29, 2021, the Corporation announced that it will miss the deadline of March 31, 2021, to file its audited financial statements for the years ended December 31, 2020, and accompanying management's discussion and analysis, this AIF and related certifications (collectively, the "Annual Required Filings"). This inability to file the Annual Required Filings was due, in part, to the Corporation's auditors requiring additional time to complete their audit and assess the accounting and disclosure contained in the Required Filings related to certain revenue transactions.

On March 29, 2021, the Corporation informed the OSC about its anticipated delay in filing the Annual Required Filings and applied pursuant to Part 4 of National Policy 12-203 – *Management Cease Trade Orders* for a MCTO pending the filing of the Annual Required Filings and all subsequent continuous disclosure documents within the timelines prescribed by applicable securities laws. The MCTO, which prohibits the Corporation's management from trading in the securities of the Corporation until two full business days following the filing of all Annual Required Filings and all subsequent continuous disclosure documents within the timelines prescribed by applicable securities laws, was issued by the OSC on April 9, 2021. The MCTO did not affect the ability of shareholders who are not insiders of the Corporation to trade their securities. Subsequently, on May 10, the Corporation announced that it anticipated that it would not be able to complete and file its interim financial statements for the three month period ended March 31, 2021, and accompanying management's discussion and analysis and related certifications (collectively, the "Interim Required Filings") by the filing deadline of May 15, 2021.

On April 20, 2021, the Corporation announced the initial listings for sale of its RHO Phyto line of products with the Ontario, Manitoba, Saskatchewan, and New Brunswick provincial retailers.

On May 6, 2021, the Corporation announced that it entered into a relationship agreement whereby Sunnybrook Health Sciences Centre ("Sunnybrook Hospital") will distribute RHO Phyto products to patients with appropriate medical authorization at Odette Cancer Centre pharmacy.

On May 7, 2021, the Corporation announced the resignation of Ms. Janet Giesselman from the board of directors.

On May 26, 2021, the Corporation announced that three (3) Pura Earth product were launched in Canada in Q2 2021 through the Medical Cannabis by Shoppers online portal and in adult-use channels including the provincial retailers and storefronts in Ontario and Saskatchewan.

On June 3, 2021, the Corporation announced, among other things, that each of David Allan White and Benjamin Leavenworth had advised the Corporation that they will not be standing for re-election to the Corporation's board of directors at the Corporation's annual general meeting of shareholders scheduled to be held on June 24, 2021.

On June 11, 2021, the OSC issued a CTO in respect of the Corporation as a result of the Corporation's defaulting in filing the Required Filings within the prescribed filing time and the MCTO was accordingly revoked at such time.

On June 15, 2021 the Corporation announced the expansion of its RHO Phyto product portfolio with the availability for sale of its oil drop and sublingual spray formulations in the medical and adult use sales channels in Canada.

On June 24, 2021, the Corporation held its annual general meeting of shareholders, at which the members of the Board Of Directors were elected, including the re-election of each of Aras Azadian, Dr. Chandrakant Panchal, Setu Purohit and Giancarlo Davila Char, and the introduction of newly elected members, being each of Flavio Jose Zaclis, Dr. Assad J. Kazeminy and John McVicar. In addition, the Corporation's shareholders also approved the re-appointment of MNP LLP as the Corporation's auditors for the ensuing year at the meeting and authorized the board of directors to fix the auditors' remuneration.

On June 29, 2021, the Corporation announced the completion of the initial development phase prospective products pursuant to its joint development agreement with Bio-Gate.

On July 7, 2021, the Corporation announced the execution of a multi-year supply agreement by SMGH with a Brazilian pharmaceutical company to supply industrial volumes of high THC and high CBD full spectrum psychoactive cannabis resin, which are expected to be used by the Brazilian pharmaceutical company in the production of medicinal cannabis products to be commercialized pursuant to Brazil's medicinal cannabis regulations.

On July 15, 2021, the Corporation appointed Kingston Ross Pasnak LLP as its independent registered public accounting firm following the resignation of MNP LLP as its independent registered public accounting firm on such date. There were no reservations or modified opinions in MNP LLPs audit report for the fiscal year ended December 31, 2019, however, there was a reportable event with respect to an unresolved issue, as such terms are defined in National Instrument 51-102 — *Continuous Disclosure*, related to MNP LLP's conclusion that it would not be in a position to issue an opinion on the Corporation's financial statements for the year ended December 31, 2020 due to an internal control issue it believed it had identified in conducting its audit.

On July 28, 2021, the Corporation announced the completion of its first export of Aureus<sup>™</sup> branded psychoactive full spectrum cannabis extract by SMGH in Colombia to a customer in Austria.

On July 30, 2021, the OSC issued an order (the "Partial Revocation Order") partially revoking the CTO in order to permit the Corporation to conduct a financing on a private placement basis, as further described below.

On August 3, 2021, the Corporation announced the completion of its first export of Aureus<sup>™</sup> branded high concentration THC psychoactive full spectrum cannabis crude oil by SMGH in Colombia to a customer in Peru.

On August 11, 2021, the Corporation announced the execution of an exclusive licensing agreement with Heritage Cannabis Holdings Corp. ("Heritage") for the commercialization of a number of Avicanna's advanced CBD-based topical products under Heritage's medical cannabis brands targeting patients registered to purchase medical cannabis in Canada. Under the terms of the agreement with Heritage, which has an initial three-year term, Avicanna has exclusively licensed, subject to certain conditions and exceptions, the use of certain proprietary product formulations to Heritage to be marketed and sold under Heritage's medical Opticann branded products in non-competing medical sales channels in Canada. For the exclusive license, Heritage is required to meet certain minimum sales requirements every year for each product licensed under the agreement and will pay Avicanna a fee for each product manufactured and a royalty for each product sold to its medical cannabis consumers.

On August 19, 2021, the Corporation announced that, in accordance with the Partial Revocation Order, the Corporation completed a secured term loan financing (the "Term Loan") in the principal amount of \$2,118,000, which Term Loan was subject to an original issue discount of approximately 15%, such that \$1,800,000 (the "Funded Amount") was advanced by the lender thereof to the Corporation. The Term Loan is due October 19, 2022 and will accrue interest at a rate of 5% per annum, subject to an increase to 18% per annum upon the occurrence of certain events of default. The Corporation is required to repay the face value of the Term Loan in 12 equal monthly installments beginning on October 18, 2021, with a right of prepayment in full, subject to the payment of interest that would have accrued had the Term Loan remained outstanding for the full 14 month term. The obligations of the Corporation in respect of the Term Loan were secured by way of a general security agreement made in favour of the lender, granting a security interest in the assets of the Corporation of sufficient value. In connection with the Term Loan and following the full revocation of the CTO by the OSC, the Corporation has agreed to issue to the lender of the Term Loan such number of common share purchase warrants (each, a "Proposed Warrant") of the Corporation representing 100% warrant coverage for the Funded Amount, each of which will be transferable and entitle the holder to acquire one Common Share for a period of 36 months. The exercise price of the Proposed Warrants (the "Proposed Warrant Exercise Price") is proposed to be 125% of the five-day volumeweighted average trading price of the Common Shares on the TSX for a period of five trading days following (i) the full revocation of the CTO, (ii) satisfaction of all additional conditions set by the TSX, and (iii) resumption of trading of the Common Shares on the TSX, subject to an upward adjustment in the event that such exercise price would otherwise result in the holder holding Proposed Warrants exercisable for such number of Common Shares representing more than 25% of the number of Common Shares outstanding, on a non-diluted basis, as at such date. The number of Proposed Warrants to be issued by the Corporation shall be the Funded Amount divided by the Proposed Warrant Exercise Price.

On August 24, 2021, the Corporation announced the expansion of sales of its Pura Earth and RHO Phyto topical products into the consumer retail adult-use sales channels in Alberta, Canada.

On August 27, 2021, the Corporation announced the completion of its first Aureus<sup>™</sup> branded psychoactive product by SMGH in Colombia to a Brazilian pharmaceutical company in Brazil, pursuant to the agreement the Corporation announced on July 7, 2021.

On September 10, the OSC revoked the CTO, following the Corporation's filing of the Required Filings and interim financial statements, management's discussion and analysis, and certification of the foregoing for the period ended June 30, 2021.

On September 16, 2021, the Corporation announced that it had completed product registration and its first commercial export of its Pura Earth branded derma-cosmetics products in Ecuador.

On October 1, 2021, the Corporation announced that through SMGH, it had completed its first commercial exports of its proprietary genetics in the form of feminized cannabis seeds to Peru and Argentina.

On October 18, 2021, the Corporation closed a non-brokered private placement (the "October 2021 Offering"). Under the October 2021 Offering, the Corporation has issued an aggregate of 4,587,022 units (the "October 2021 Units") at a price of \$0.85 per October 2021 Unit for aggregate gross proceeds of approximately \$3.9 million. Each October 2021 Unit is comprised of one (1) Common Share and one-half of one (0.5) Common Share purchase warrant, each of which is exercisable into one Common Share at a price of \$1.10 per share until October 18, 2024.

On October 19, 2021, the Corporation announced the proposed repricing ("the "**2021 Warrant Repricing**") of 1,589,098 Common Share purchase warrants (the "**Term Loan Warrants**") expiring September 20, 2024, issued to the lender that advanced the Term Loan. The exercise price of the Term Loan Warrants was reduced from \$1.13 to \$1.10.

On November 4, 2021, the Corporation announced that SMGH had met global conformity standards of Good Agricultural and Collection Practices ("GACP") GACP, an international guide set forth by the European Medicines Agency, for starting materials of herbal origin for its 360,000 square foot cultivation project in Santa Marta, Colombia. The certification allows for the expansion of the Corporation's raw materials supply business to include organic and now GACP certified dried flower and biomass at a global level.

On November 5, 2021, the Corporation announced that with immediate effect, Setu Purohit would no longer serve as President and Chief Legal Officer of the Corporation.

On November 8, 2021, the Corporation announced the finalization of the 2021 Warrant Repricing, effective the date thereof.

On November 9, 2021, the Corporation announced the launch of Viola brands nationwide in Canada through the Medical Cannabis by Shoppers<sup>TM.</sup>

On November 11, 2021, the Corporation announced the resignation of one of its Directors, Flavio Jose Zaclis, effective the date thereof.

On November 25, 2021, the Corporation announced it successfully exported its RHO Phyto line of products to its distribution partner, Bryden Stokes Limited, in Barbados.

On November 30, 2021, the Corporation announced that it has entered into a partnership with an established Argentine pharmaceutical company to register and commercialize Avicanna's proprietary cannabinoid-based pharmaceutical preparations through the licensing of its intellectual property and supply of its active pharmaceutical ingredients.

On December 6, 2021, the Corporation announced that it had filed a provisional patent application in the United States Patent and Trademark Office for a novel oral cannabinoid technology, which is intended to be commercialized globally for medical and pharmaceutical applications including treatment of various neurological diseases and disorders.

On December 20, 2021, the Corporation announced the launch of re+PLAY sports recovery-based CBD brand through partnership with Harrington Wellness, founded by National Basketball Association veteran Al Harrington.

On December 22, 2021, the Corporation announced the brand launch and commercialization of its proprietary and clinically backed derma-cosmetics brand, Pura H&W, through its exclusive partnership with Red White and Bloom.

On December 24, 2021, the Corporation announced that, through its majority owned Colombian subsidiary, SMGH, it has expanded reach for its Aureus raw materials in the European Union with a commercial export of purified CBG into the Czech Republic. The completed export into the Czech Republic marks the Corporation's first commercial export of CBG into the European Union and the twelfth (12th) market that the Aureus branded products has entered.

# General Development of the Business – Three Year History – Fiscal Year 2022 (January 1, 2022 to December 31, 2022)

On January 4, 2022, Eileen McCormack was appointed to the Board concurrently with the resignation of Setu Purohit.

On January 10, 2022, Stephen Kim was appointed as the Chief Legal Officer & General Counsel of Avicanna USA Inc.

On January 14, 2022, SMGH, the Corporation's majority owned subsidiary, SMGH entered into a Master Supply Agreement with established Chilean pharmaceutical company Knop Laboratorios S.A. to supply a range of cannabinoid-based active pharmaceutical ingredients for the manufacturing, and commercialization of proprietary cannabinoid-based pharmaceutical products in Latin America.

On January 28, 2022, the Corporation closed a non-brokered private placement (the "January 2022 Offering") of 1,626 convertible debenture units of the Company (the "January 2022 Units") at a price of \$800 per January 2022 Unit (representing an original issue discount equal to 20%), for aggregate gross proceeds of approximately \$1,550,400. Each January 2022 Unit consists of an aggregate of \$1,000 principal amount of secured subordinated convertible debentures (the "January 2022 Debentures") and 545 Common Share purchase warrants (each, a "January 2022 Warrant"). The January 2022 Debentures will mature one year following the closing of the Offering (the "Maturity Date").

Each January 2022 Debenture shall be convertible at any time following the date that is six months from the closing of the Offering, at the option of the holder, into Common Shares at a price of: (A) \$1.20 per share, if converted between the period commencing six months from the closing of the Offering and ending on the second business day prior to the Maturity Date; or (B) \$0.85 per share, if converted anytime after the second business day prior to the Maturity Date. The January 2022 Debentures will not bear interest prior to the Maturity Date, after which they will bear interest at a rate of 15% per annum (based on a year of 360 days composed of twelve 30-day months). Upon a change of control of the Corporation, holders of January 2022 Debentures will have the right to require the Corporation to repurchase their January 2022 Debentures, in whole or in part, at a price equal to 105% of the principal amount of the January 2022 Debentures then outstanding. The Corporation shall have the right at any time and from time to time during the period commencing on the date that is six months from the closing of the January 2022 Offering and the Maturity Date, to repay up to 50% of the principal amount of the then outstanding January 2022 Debentures. The January 2022 Debentures will rank pari passu in right of payment of principal with all other Debentures issued under the Offering and will be subordinate to the Term Loan. Each January 2022 Warrant is exercisable into one Common Share at a price of \$1.10 per share for a period of three years from the closing of the January 2022 Offering.

In connection with the January 2022 Offering, the Corporation granted to the subscribers of January 2022 Units a right to subscribe for and purchase additional units (the "Additional Units") on substantially the

same terms as the January 2022 Units issued pursuant to the January 2022 Offering if: (A) at any time it wishes to prepay the then outstanding Term Loan, and desires to fund, in its sole discretion, such prepayment through the issuance of such Additional Units; or (B) an event of default occurs in respect of the Term Loan, in each case for the purpose of raising sufficient funds to prepay or repay, as applicable, the Term Loan. The issuance of Additional Units shall be subject in all respects to the approval of the TSX and the terms thereof shall be substantially the same terms as the January 2022 Units issued pursuant to the January 2022 Offering, including the same maturity date as the Maturity Date notwithstanding the issue date thereof, subject to any increase in the exercise price of the warrants and the conversion price of the convertible debentures, in each case which will form part of any Additional Units to be offered, to be not less than the then minimum pricing permitted by the TSX, and any proration and corresponding reduction of the original issue discount applied to such Additional Units, having regard to the maturity date of the Additional Units.

On March 31, 2022 the Corporation announced that it has closed a non-brokered private placement (the "March 2022 Offering") offering of 7,210,194 units of the Corporation (the "March 2022 Units") at a price of \$0.35 per Unit for aggregate gross proceeds of approximately \$2.5 million. Each March 2022 Unit is comprised of one common share in the capital of the Corporation and one-half of one (0.5) common share purchase warrant of the Corporation (each whole warrant, a "March 2022 Warrant"); and, each March 2022 Warrant shall entitle the holder thereof to acquire one (1) common share in the capital of the Corporation at an exercise price of \$0.40 per share, subject to adjustment in certain events, until March 31, 2025. The Corporation paid an aggregate total of approximately \$32,500 in cash finders' fees and issued an aggregate total of 92,857 finder's warrants (each a "March 2022 Finder Warrant") in connection with the March 2022 Offering to certain finders in connection with subscriptions for March 2022 Units made by purchasers introduced to the Corporation by such finders. Each March 2022 Finder Warrant entitles the holder thereof to acquire one common share in the capital of the Corporation at an exercise price of \$0.40 per share, subject to adjustment in certain events, until March 31, 2025

On May 6, 2022, the Corporation announced that it has closed a strategic non-brokered private placement offering of 4,210,931 units of the Corporation (the "May 2022 Units") at a price of \$0.35 per May 2022 Unit for aggregate gross proceeds of approximately \$1.475 million (the "May 2022 Offering"). Each May 2022 Unit is comprised of one common share in the capital of the Corporation and one-half of one (0.5) common share purchase warrant of the Corporation (each whole warrant, a "May 2022 Warrant"). Each May 2022 Warrant shall entitle the holder thereof to acquire one (1) common share at an exercise price of \$0.40 per share, subject to adjustment in certain events, for a period of 36 months.

On May 12, 2022, the Corporation announced that it had accepted the resignation of its Chief Financial Officer, Dave Sohi effective May 18, 2022 and announce that Phillip Cardella would assume the position of Interim Chief Financial Officer effective May 18, 2022.

On June 24, 2022 the Corporation announced the sale of 100% of its stake in SN for the sum of \$675,000.

On August 17, 2022, the Corporation announced that it had closed a strategic non-brokered private placement offering of 7,949,433 units of the Corporation (the "August 2022 Units") at a price of \$0.35 per August 2022 Unit for aggregate gross proceeds of approximately \$2.782 million (the "August 2022 Offering"). Each August 2022 Unit is comprised of one common share in the capital of the Corporation and one-half of one (0.5) common share purchase warrant of the Corporation (each whole warrant, a "August 2022 Warrant"). Each August 2022 Warrant shall entitle the holder thereof to acquire one (1) common

share at an exercise price of \$0.40 per share, subject to adjustment in certain events, for a period of 36 months.

On August 29, 2022, the Corporation terminated the Distribution Agreement dated August 11, 2020 with Red White & Bloom Brands Inc.

On August 31, 2022, the Corporation held its annual general and special meetings of shareholders, at which the members of the Board Of Directors were elected, including the re-election of each of Aras Azadian, Dr. Chandrakant Panchal, Giancarlo Davila Char, John McVicar and Eileen McCormack. In addition, the Corporation's shareholders also approved: (i) fixing the number of directors for the ensuing year at five and empowering the board of directors of the Company to adjust such number between shareholder meetings by way of resolution in accordance with the Company's constating documents; (ii) the reappointment of Kingston Ross Pasnak LLP as the Company's auditors for the ensuing year and authorized the board of directors to fix the auditors' remuneration; and (iii) the unallocated awards under the omnibus long-term incentive plan of the Company.

On October 31, 2022, the Corporation announced that it had entered into an extension agreement (the "Extension Agreement") in connection with the Term Loan. In accordance with the Extension Agreement, the maturity date of the Term Loan was extended by five months, from October 19, 2022, to March 19, 2023 (the "New Maturity Date"). Pursuant to the Extension Agreement, the Corporation will continue to make interest payments as required by the original loan agreement in respect of the Term Loan, and will also make monthly repayments of principal beginning in November 2022 and ending in February 2023, following which the outstanding principal on the Term Loan will come due on the New Maturity Date. The Term Loan continues to bear interest at 5% per annum, calculated monthly.

On November 11, 2022, the Corporation announced that it has closed a non-brokered private placement offering of 1,790,750 units of the Company (the "November 2022 Units") at a price of \$0.35 per November 2022 Unit for aggregate gross proceeds of approximately \$626,762.50 (the "November 2022 Offering"). Each November 2022 Unit is comprised of one common share in the capital of the Corporation and one-half of one (0.5) common share purchase warrant of the Corporation (each whole warrant, a "November 2022 Warrant"); and, each November 2022 Warrant shall entitle the holder thereof to acquire one (1) common share in the capital of the Corporation at an exercise price of \$0.40 per share, subject to adjustment in certain events, until November 10, 2025. The Corporation has paid an aggregate total of approximately \$13,649.83 in cash finders' fees and issued an aggregate total of 38,999 finder's warrants (each a "November 2022 Finder Warrants") in connection with the November 2022 Offering to certain finders in connection with subscriptions for November 2022 Units made by purchasers introduced to the Corporation by such finders. Each November 2022 Finder Warrant entitles the holder thereof to acquire one common share in the capital of the Corporation at an exercise price of \$0.40 per share, subject to adjustment in certain events, until November 10, 2025

On December 21, 2022, Phillip Cardella was appointed as the Corporation's Chief Financial Officer.

On December 21, 2022, the Corporation announced that it had closed a non-brokered private placement offering of 5,054,562 units of the Company (the "**December 2022 Units**") at a price of \$0.35 per Unit for aggregate gross proceeds of approximately \$1.769 million (the "**December 2022 Offering**"). Each December 2022 Unit is comprised of one common share in the capital of the Corporation and one-half of

one (0.5) common share purchase warrant of the Company (each whole warrant, a "**December 2022 Warrant**"); and, each December 2022 Warrant shall entitle the holder thereof to acquire one (1) common share in the capital of the Corporation at an exercise price of \$0.40 per share, subject to adjustment in certain events, until December 21, 2025. The Corporation has paid an aggregate total of approximately \$5,499.90 in cash finders' fees in connection with the December 2022 Offering to certain finders in connection with subscriptions for December 2022 Units made by purchasers introduced to the Corporation by such finders.

### Recent Developments (January 1, 2023 to Present)

On January 30, 2023, the Corporation announced that the Corporation had entered agreements with the holders of the January 2022 Debentures, bearing an aggregate principal amount of \$1,938,000 and a maturity date of January 28, 2023 (the "Original Maturity Date") and 1,056,210 January 2022 Warrants, to amend the terms of the January 2022 Debentures and the January 2022 Warrants (the "January 2023 Amending Agreements"). An aggregate of \$250,000 of January 2022 Debentures and 136,250 January 2022 Warrants (the "January 2022 Insider Warrants") were originally issued to insiders of the Corporation pursuant to the January 2022 Offering. Pursuant and subject to the terms of the January 2023 Amending Agreements, the exercise price of the January 2022 Warrants will be amended from \$1.10 to \$0.55 per common share of the Corporation and will have their expiry date amended from January 28, 2025, to January 28, 2026 (the "January 2023 Warrant Amendments"). January 2022 Debentures bearing an aggregate principal amount of \$876,000 will have their conversion price amended from \$0.85 to \$0.40 per common share (the "Repriced January 2023 Debentures"), while the remaining January 2022 Debentures (the "Extended January 2023 Debentures", and together with the Repriced January 2023 Debentures, the "Amended January 2023 Debentures") bearing an aggregate principal amount of \$1,062,000 will have their maturity date extended to July 28, 2023 (the "January 2023 Debenture Amendments"). A total of 3,439,409 common shares are issuable upon conversion of the Amended January 2023 Debentures. The Repriced January 2023 Debentures will be converted into an aggregate of 2,190,000 common shares on or before the Original Maturity Date. Pursuant to the policy of the TSX the January 2023 Warrant Amendments with respect to the January 2022 Insider Warrants are subject to approval of the disinterested shareholders of the Corporation, which the Corporation intends to seek at its next annual and special meetings of shareholders. If disinterested shareholder approval is not obtained, the January 2022 Insider Warrants will not be subject to the January 2023 Warrant Amendments. The January 2023 Warrant Amendments with respect to the holders of the January 2022 Debentures who are not insiders will take effect ten (10) business days following the date of this release. The January 2023 Warrant Amendments and the January 2023 Debenture Amendments remain subject to the approval of TSX.

On March 21, 2023, the Corporation announced that it had closed a non-brokered private placement offering of 3,096,230 units of the Company (the "March 2023 Units") at a price of \$0.40 per March 2023 Unit for aggregate gross proceeds of approximately \$1.24 million (the "March 2023 Offering"). Each March 2023 Unit is comprised of one common share in the capital of the Corporation and one-half of one (0.5) common share purchase warrant of the Corporation (each whole warrant, a "March 2023 Warrant"); and, each March 2023 Warrant shall entitle the holder thereof to acquire one (1) common share in the capital of the Corporation at an exercise price of \$0.50 per share, subject to adjustment in certain events, until March 20, 2026. The Corporation has paid an aggregate total of approximately \$7,500 in cash finders' fees and issued an aggregate total of 18,750 finder's warrants (each a "March 2023 Finder Warrants") in connection with the March 2023 Offering to certain finders in connection with subscriptions for March 2023 Units made

by purchasers introduced to the Corporation by such finders. Each March 2023 Finder Warrant entitles the holder thereof to acquire one common share in the Corporation at an exercise price of \$0.41 per share, subject to adjustment in certain events, until March 20, 2026.

### **DESCRIPTION OF THE BUSINESS**

# **Summary**

Avicanna is a commercial stage Canadian biopharmaceutical company established in cannabinoid research, development, and evidenced-based products for the global consumer, medical cannabis, and pharmaceutical market segments. Avicanna conducts its research in Canada, in collaboration with leading Canadian academic and medical institutions and has established an industry leading scientific platform including advanced R&D and clinical development which has led to the commercialization of over twenty (20) products across four main market segments:

### **Medical Cannabis & Wellness Products**

Marketed under the RHO Phyto™ brand, or Magisterial Preparations (compound pharmacy) preparations, or private-label brands, these medical and wellness products are a line of pharmaceutical-grade cannabis products containing varying ratios of cannabidiol ("CBD") and tetrahydrocannabinol ("THC"). The product portfolio contains a full formulary of products including oral, sublingual, topical, and transdermal deliveries designed to have controlled dosing, enhanced absorption and stability studies supported by pre-clinical data. These products are developed using pharmaceutical drug development processes and are supported with pre-clinical data. The formulary is marketed with consumer, patient and medical community education and training. Avicanna's medical and wellness product portfolio also forms the foundation of the Corporation's pharmaceutical pipeline with the contribution of the formulations that form the basis of the products as well as the data generated from sales and participation of the products in real world evidence studies.



# Market opportunity

RHO Phyto has been established as a leading medical brand in Canada and is currently available nationwide to patients in medical channels including a strategic partnership with Medical Cannabis by Shoppers™, a subsidiary of Shoppers Drug Mart Inc.™ ("Shoppers Drug Mart"), other national medical portals as well as clinical institutions such The University Health Network ("UHN") and the Odette Cancer Centre pharmacy of Sunnybrook Health Science Centre.

# **CBD Derma-Cosmetic Products**



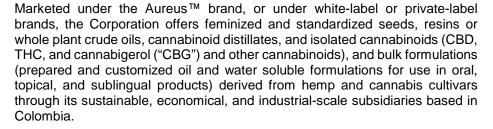


Marketed under the Pura  $H\&W^\intercal M$  or Pura Earth  $^\intercal M$  brands, these registered, clinically tested, cosmetic products include a portfolio of functional CBD consumer derma-cosmetic and topical products.

### Market opportunity

Currently available nationwide in Canada across medical and cannabis adultuse channels through retailers in four provinces. These products are also in early stages of commercialization internationally where CBD is permitted under cosmetics designations including USA, Colombia, Ecuador, and in the European Union, initially in Germany, Switzerland, and Austria.

### Cannabis Raw Materials, Seeds, and Bulk Formulations





### Market opportunity

The cannabis raw materials supplied by Avicanna's Colombian subsidiary form part of the Company's supply chain and source of reliable input products for its consumer retail, medical cannabis, and pharmaceutical products for Global markets. The business unit is also dedicated to providing consistent, high-quality source of input materials for the Company's global partners for use in the development and production of food, cosmetic, medical, and pharmaceutical products. The Company has formed several strategic supply relationships and has exported Aureus branded Colombia into 16 countries for research and manufacturing purposes.

### **Pharmaceutical Pipeline**



Leveraging Avicanna's scientific platform, vertical integration, and real-world evidence, Avicanna has established a pipeline of indication specific cannabinoid-based drug candidates that are in various stages of clinical development and commercialization. Avicanna's drug candidates are in preclinical stage and designed to address unmet medical needs in the areas of dermatology, chronic pain and various neurological disorders.

# Market opportunity

The proprietary cannabinoid-based drug candidates are designed to address unmet medical needs in the areas of neurology, depression, sleep, dermatology, and pain. The pipeline of products is intended to be marketed once drug applications have been submitted and approved from national drug

agencies and specific drug candidates from including Trunerox™ are in registration stage across several Latin American countries.

Avicanna is established as a cannabinoid biopharmaceutical company and it conducts its R&D in Canada through its own laboratories and, in collaboration with leading Canadian academic and medical institutions. With ongoing observational clinical trials on its, medical cannabis and a pipeline of pharmaceutical products, Avicanna's dedication to researching the role that cannabinoids play in an increasingly wider scope of products has been at the core of the Corporation's vision since its inception. Avicanna's scientific team have established one of the most comprehensive scientific platforms in the cannabinoid industry which over the past 5 years has yielded more than thirty proprietary formulations that are now commercial under the brands of Pura Earth, Pura H&W, and RHO Phyto and continue to make advancements in its pharmaceutical pipeline.

### **Products**

Our products are grouped into four main categories:

- (i) Medical cannabis and wellness products;
- (ii) CBD Derma-Cosmetic products;
- (iii) Pharmaceutical products; and,
- (iv) Cannabis raw materials and bulk formulations, including
  - Feminized seeds
  - Resins or whole plant crude oils
  - Cannabinoid distillates
  - Isolated and purified cannabinoids;

The products that have been commercialized are medical cannabis and derma-cosmetic products as well as cannabis raw materials and bulk formulations. Our pharmaceutical products are still in various stages of pre-clinical and clinical development and drug registration.

Location (company)	Commercial/ Distribution Partner	Analytical Transfer	Export Permit Submission Date	Dossier Submission Date	Dossier Expected	Deficiency letter
Colombia (TBD)	Avicanna	Completed	N/A	The second week of November 2021	Q3 2023	Expected by Mid-April 2023
Brazil	Hypera	Q1 2023	Obtained Dec 2022	End of Q2 2022	End of Q2 2023	Expected by the fourth week of April 2023
	Greencare	Q1 2023	Obtained Dec 2022	End of Q2 2022	End of Q2 2023	Expected by the first week of April 2023

Ecuador	Alliance	N/A	Obtained Sept	The second	End of Q1	Received
	Pharma		2022	week of July	2023	Feb 13,
				2022		2023

The commercial ready products are offered under our own brands and are also available for private label or white label, along with any supporting quality, analytical, pre-clinical or other scientific data relating to those products.

Our current commercial brands include:



## RHO Phyto™

Used for medical cannabis & wellness products



#### Pura H&W™ and Pura Earth™

Used for CBD derma-cosmetic and topical products



#### Aureus™

Used for cannabis raw materials, seeds and bulk formulations

For the medical cannabis and derma-cosmetic products, Avicanna uses third party manufacturers and, in jurisdictions that permit it, cannabis raw materials sourced from our cultivation operations. All commercial ready products are sold through distributors or direct to consumers, depending on the jurisdiction.

The following table shows the sales figures in dollars for each category of products that accounted for 15% or more of the total consolidated revenue of the Corporation for the financial years ended December 31, 2020, 2021 and 2022, derived from (a) sales to entities in which the Corporation maintains an investment accounted for by the equity method; (b) sales to customers, other than those referred to in (a); and (c) sales or transfers to controlling shareholders.

Years ended December 31,

	2022	2021	2020
Statement of Financial Position			
Service revenues	\$ 120,631	\$ 87,945	\$ 13,471
License revenue	1,106,120	403,000	530,264
Product sales	2,806,737	2,777,961	1,026,325
	\$ 4,033,488	\$ 3,268,906	\$ 1,570,060

#### Medical Cannabis & Wellness Products

Avicanna's medical cannabis and wellness (or as we sometimes refer to them as "phyto-therapeutic") products are designed for medical or homeopathic use, but are not pharmaceuticals or drugs. Our medical cannabis products include oral and topical product categories that are developed and designed to be accurate in dosing and offer a range of ratios of cannabinoids. The R&D work by Avicanna and through its research partnerships have resulted in oral formulations with both rapid and delayed onset release profiles and topical preparations with deep tissue and localized applications. Where jurisdictions permit, Avicanna's education and commercial plans demonstrate the medical cannabis product line's potential in treating a wide range of clinical indications and, more specifically, specific comorbidities including pain, sleep, appetite, anxiety, and depression that are prevalent in various medical conditions.

# **RHO Phyto product offerings**

- **Micro Drops:** The Micro Drops are blood-orange flavoured and utilize Avicanna's inverted emulsion technology to provide absorption and shelf-life stability. The product is administered with metered dosing using an oral syringe that allows for accurate titration.
- Rapid Act Sprays: The oral sprays are lemon-mint flavoured and utilize Avicanna's sublingual
  delivery technology to provide a rapid acting effect. The product is administered discreetly, is easy
  to use, and delivers accurate, consistent dosing in every spray.
- **Deep Tissue Gel:** The water-based gels utilize Avicanna's deep tissue technology and combines cannabinoids with synergistic terpenes and natural excipients including menthol and beta-caryophyllene in a pharmaceutical-grade, airless pump.
- **Ultra CBD local cream:** The high CBD topical cream is designed for application on sensitive skin and free from THC and allergens including terpenes, perfumes and vitamins. Ultra CBD Topical Cream is, unscented, and oil based.
- **Pipeline:** The Company continues to advance its pipeline of medical products through its scientific platform and R&D infrastructure which includes novel drug delivery mechanisms including capsules, tablets, and water-soluble formulations, in addition to the incorporation of rare cannabinoids into specific formulations.

We market the medical cannabis products using our RHO Phyto<sup>™</sup> brand. Specific medical cannabis products are also available under a private label or white-label arrangement and may be marketed under different product categories depending on the jurisdiction.

Avicanna uses third party contract manufacturers to produce the medical cannabis products. In jurisdictions that permit it, we produce the medical cannabis products using cannabis raw materials supplied by our cultivation operations; otherwise, cannabis raw materials are sourced locally, such as in Canada.

#### Canada

In Canada, our medical cannabis products are sold by Shoppers under the RHO Phyto brand to patients who consume cannabis for medical purposes. The medical cannabis products are also available for sale in certain provinces through the consumer retail (adult-use) sales channels to take advantage of the opportunity to provide consumers who buy cannabis products from the retail/adult-use sales channel and use the products for medical, wellness, or therapeutic purposes.

Avicanna continues its intellectual property and licensing agreements with Harrington Wellness and VB Brands LLC, to sell Avicanna's medical cannabis products under their brands – re+PLAY and Viola, respectively. The re+PLAY and Viola products are intended to be sold in the medical sales channel by Shoppers and in the retail/adult-use sales channel.

#### Colombia

Avicanna has its RHO Phyto line of products in the Colombian marketplace through a compound pharmacy model known as Formulaciones Magistrales. Selling under this model requires that medical professionals prescribe our medical cannabis products to their patients.

The medical cannabis products consumed by patients in Colombia are manufactured using cannabis raw materials sourced from the Corporation's cultivation operations and are produced at our Good Production Practices (GPP) certified compound pharmacy laboratory. The medical cannabis products in Colombia include drug delivery systems including oil drops, sublingual sprays, and topicals.

#### U.S.A.

Avicanna continues its intellectual property and licensing agreement with Harrington Wellness for the commercialization of a CBD topical product line targeting athletes and active consumers in Canada and the U.S., the product line will be marketed as a topical and not as a product with any therapeutic or medical benefits.

# Barbados

Avicanna continues its distribution agreement with Bryden Stokes, an established health and pharmaceutical product distributor in the Caribbean region to distribute its RHO Phyto line of products and is planning to expand its offering to other Caribbean islands in the curse of HY1 2023.

# Other potential markets

Avicanna will look to launch its medical cannabis product offering in other potential markets in 2023. Several countries have defined or are expected to define regulations that will permit medical use of cannabinoids through various models and this trend seems to continue at a global level where governments are prioritizing medical cannabis over adult use. Avicanna expects to pursue commercial efforts in Europe and certain Latin American countries in 2023. Where possible, we intend to use our Colombian operations as a hub for export to countries that regulate the use of cannabis for medical purposes. In cases where we cannot export from Colombia, we explore ways to find and use a strategic local partner to manufacture and distribute our products in the relevant market. See "Description of the Business – Cultivation Operations".

#### **CBD Derma-Cosmetic Products**

Our CBD derma-cosmetic products are hemp-derived CBD-based topical products, most of which have a cosmetic purpose and designed to achieve a specific aesthetic objective and which we refer to as our derma-cosmetic products. Our derma-cosmetic products are formulated with a view towards the health and beauty of the skin. We are focused on high-end cosmetic formulations supported by research data as a way to differentiate our product line from those of our competitors.

We have developed a line of derma-cosmetics that include beauty treatments, moisture and protection products, and specialized care. They are intended to be marketed under various product names, depending on the particular jurisdiction that may permit their sale. These derma-cosmetic products have finalized formulations and the ingredients and the way that they are made are trade secrets to Avicanna. See "Description of the Business - Intellectual Property" for additional details.

#### Colombia

Pura H&W/Pura Earth products have been manufactured and sold in Colombia since November 2019 using cannabis raw materials sourced from our Colombia operations and using a Colombian contract manufacturer, which manufactures our product to the highest standards.

#### Canada

In Canada, sales continue of our derma-cosmetic products under our Pura Earth brand in the provincial adult use sales channels.

We have also entered into an agreement with Shoppers<sup>™</sup> for the distribution of Pura Earth branded topical products through medical sales channels, which were launched through the Shoppers online portal in the third quarter of fiscal 2021.

## Ecuador

In Ecuador, Pura branded products were launched in 2021 under an agreement with Spenta S.A. where the products were made available as a registered cosmetic through retailers and e-commerce channels, continue to be made available.

## Germany

In Germany Pura branded products are planned to be launched in HY1 2023 under an agreement with Bio-Gate AG where the products will be made available as a registered cosmetic through e-commerce channels initially with the plan to expand to retail channels over time.

#### Other potential markets

Avicanna continues to explore opportunities for the distribution of the derma-cosmetic products under our brands and under private label or white label brands in other countries. We believe the market potential for CBD-based derma-cosmetic products is promising, especially as the regulations relating to CBD in various countries become clearer. Where possible, we intend to use our Colombian operations as a hub for export to countries that regulate cosmetics containing cannabinoids. In cases where we cannot export from Colombia, we explore ways to find and use a strategic local partner to manufacture and distribute our products in the relevant market. See "Description of the Business – Cultivation Operations".

## Pharmaceutical Pipeline

The Company continues clinical development of its pharmaceutical pipeline and is exploring several potential pathways to submit drug applications for marketing authorizations with national drug agencies such as the FDA, Health Canada, and Latin American health authorities including ANVISA in Brazil and INVIMA in Colombia.

- Marketing authorization and commercial pathways:
  - Generic pharmaceutical (LATAM market expected commercialization in 2023)
  - Special Cannabis regimen or Phyto-therapeutic designations (LATAM market expected commercialization in 2023)
  - Rare disease pharmaceutical pipeline (Canada, USA, EU, LATAM markets expected commercialization 2024)
  - Over the counter (Canada, USA, EU markets expected commercialization 2024)
- Trunerox <sup>™</sup> 10% CBD (100 mg/ml Cannabidiol)
  - Pharmaceutical preparation under GMP standards with completed technical dossier in a Colombian CMO.
  - Expected marketing authorization during 2023 in Colombia, Ecuador, and Brazil

# Raw Materials, Seeds and Bulk Formulations

Under the Aureus brand, Avicanna offers feminized seeds, resins or whole plant crude oils, cannabinoid distillates, and isolated cannabinoids, and bulk formulations. Avicanna generally refers to resins, distillates, and isolates as "APIs". While API is an acronym for active pharmaceutical ingredients, Avicanna's customers use the APIs for a number of manufacturing applications other than pharmaceuticals.

- Feminized seeds seeds for growing cannabis or hemp. "Hemp" is a legal definition of cannabis relating to the amount of THC the particular genetic expresses as a percentage of dry weight. This THC threshold varies from country to country.
- API offered as THC, CBD, and CBG dominant products (as the target compounds, note below).
   The CBD and CBG APIs are sourced from USDA National Organic Program organic certified hemp cultivar of cannabis.
  - o Resins or plant crude oils typically, 30-60% purity of the target compounds.
  - o Cannabinoid distillates typically, 60-90% purity of the target compounds.
  - o *Isolated cannabinoids* typically, above 95% purity of the target compounds.

• Bulk formulations – these are rudimentary formulations offered to manufacturers or distributors for use in oral, sublingual, and topical formulations. Customized bulk formulations, including combining APIs, are also available part of the product portfolio.

To date, through SMGH, we have distributed seeds, raw materials (Isolates and resins) and bulk formulations in 16 countries including Canada (to the Corporation for research purposes), Colombia, the UK, South Africa, Argentina, the U.S., Germany, Chile, Peru, Brazil, Czech Republic, Portugal, Lesotho, Spain, Austria and Uruguay. We are preparing for distribution of these products to other countries in Europe and Latin America. These products are distributed to importers in other countries for scientific purposes, to be used in the manufacture of other products, or for medical purposes.

We intend to manufacture our derma-cosmetics, medical cannabis, and pharmaceutical products using our raw materials whenever possible. We are currently producing a higher quantity of raw materials than our anticipated needs for our finished products for additional sources of revenue.

#### **Research & Development**

With 5+ years of R&D, preclinical and clinical development on cannabinoids, Avicanna has an established cannabinoid-based scientific platform and intellectual property portfolio. Avicanna's dedication to product development and evaluating the potential role of cannabinoids for therapeutic benefit has been at the core of the Company's vision since its inception. The Company has successfully developed and delivered 31+ commercial products from its scientific platform where it owns all related intellectual property. Key attributes of Avicanna's platform include:

- Over thirty-one (31) proprietary commercial products
- Seven Canadian Government research grants awarded since 2020
- Seven pending patent applications
- Drug development pipeline capsules fast dissolution, controlled release tablets, and other formulations providing as absorption and on sets.
- Four Health Canada cannabis research licenses issued to institutional collaborators over the past 4 years
- Academic and clinical collaborations over the past 4 years including: Hospital for Sick Children, University of Toronto, University of Guelph, University Health Network, Charles River, Thompson Rivers University and Sunnybrook Health Sciences Centre (Hospital)

Avicanna's preclinical and clinical development is conducted in collaboration with leading university and hospital partners. In collaboration with our research partners, we have successfully obtained seven peer-reviewed government grants supporting our research projects over the past two years. All formulations developed and data generated in collaboration with our partners are considered Avicanna Intellectual Property. Highlighted below are some of the Company's ongoing research projects.

• Through the **University of Guelph** in collaboration with Dr. Jibran Khokhar, Avicanna's RHO Phyto products are undergoing pharmacokinetic, electrophysiological, and behavioral evaluation with

- comparison to basic MCT oil products. Additionally, various cannabinoid ratios and terpenes are being evaluated with Avicanna formulations in animal models of addiction and withdrawal from alcohol and nicotine, and neuropathic pain for pharmaceutical development.
- The collaboration with the University Health Network and Dr. Peter Carlen is focused on
  evaluating Avicanna's formulations with various cannabinoid and terpenes ratios for reduction of
  seizure frequency and severity in various preclinical models related to epilepsy as a part of the
  company's pharmaceutical pipeline.
- The collaboration with Thompson River University led by Dr. Kingsley Donkar and team is focused
  on evaluating optimal cannabinoid and terpenes ratios for their effect on various bacteria and fungi
  in addition to the assessment of those ratios anti-inflammatory effects on tissue models including
  lung, nasal and airways caused by the COVID-19 virus.

# Summary of R&D Projects

Partner Institution & Researcher	Project Highlights	Project Status
University of Guelph – Dr. Jibran Khokhar	Preclinical pharmacokinetic and behavioral analysis of RHO Phyto products in comparison to MCT based products. Drug discovery for cannabinoid-based products in animal model of alcohol and nicotine addiction for attenuating withdrawal side effects.	Pharmacokinetic study: analysis of results expected in Q2-2022.  Animal model of toxicosis completed – Commencing treatment study Q2 2022.  Animal model of addiction completed – commencing treatment study Q3 2022.  Currently, evaluating neuropathic pain model and expecting study to commence Q4 2022.
University Health Network – Dr. Peter Carlen	Filed US patent application for a novel Cannabinoid formulation in reducing incidence of seizures and sudden unexpected death in Epilepsy in Q4 2021.	Completed set up of epilepsy in organoid model to be used for high throughput testing of Avicanna's formulations.  Avicanna's formulation to be tested in Q2 in an <i>in vivo</i> Epilepsy model to substantiate provisional patent filed.  All on-going studies continue to evaluate other cannabinoids in various ratios for their effects on seizures.
Hospital for Sick Kids – Dr. Elena Pope	Evaluation of Avicanna's 3% CBD cream in a real-world observational trial for individuals with various dermatological conditions including epidermolysis bullosa patients.	Study commenced Q1 2022. Results from the study are expected to supported application to Health Canada for Clinical Trial.
Thompson Rivers University – Dr. Kingsley Donkar	Evaluation of various ratios for cannabinoids in Avicanna formulation in tissue model of inflammation.  Evaluation of cannabinoids for antibacterial effects.	Testing of tissue models of inflammation began in Q4 . Results from study are anticipated to be completed by Q2 2023.  Testing of various combinations of cannabinoids for antibacterial effects including bactericide, biofilm and minimum inhibitory concentrations expected to be completed end of Q2 2023.

#### Clinical development

The following table provides a summary of the current stage of clinical development for each indication and/or product that Avicanna is targeting across its product platform:

Indication	Drug Discovery and Optimization	Pre-clinical Stage	Clinical Protocol Development	Clinical Studies	Observational (non- interventional)
Epilepsy	Ongoing	Ongoing	-	-	Under
					Development
Epidermolysis	Complete	Under	Complete	Pre-CTA	Initiated
Bullosa		development		for Phase	
		-		2/3	
Pain	Complete	•	-	ı	Ongoing
Sleep	Complete	-	-	-	Ongoing
Anxiety	Complete	-	-	ı	Ongoing
Depressed	Complete	-	-		Ongoing
mood					
Osteoarthritis	Complete	Ongoing	=	ı	Ongoing
Eczema	Complete	-	Complete	Complete <sup>1</sup>	-
Acne Prone	Complete	-	Complete	Complete <sup>1</sup>	-
Anti-Aging	Complete	-	Complete	Complete <sup>1</sup>	-

<sup>1</sup>Cosmetic Trial

#### The Real-World Evidence Opportunity

The commercial availability of RHO Phyto in Canada has led to the inclusion of RHO Phyto products in a number of real-world evidence ("RWE") trials on specific therapeutic indications and patient populations. RHO Phyto products are participating in the University Health Network's Medical Cannabis Real-World Evidence (MC-RWE) clinical study led by Dr. Hance Clarke. The prospective, non-interventional, observational study will examine the efficacy of a select group of medical cannabis products on patient reported outcomes of pain, sleep, depression, and anxiety. The study will track patients' use and symptoms over a 6-month period.

Recently, Avicanna launched its pharmaceutical candidate for epidermolysis bullosa under medical cannabis legislation in Canada. This product has been included in RWE studies focused on specific endpoints related to the dermatological conditions and assessed by Dr. Elena Pope as a part of a long-term collaboration with the Hospital for Sick Children. Additionally, this product will be participating in the MC-RWE focused on patient reported outcomes on pain, sleep, anxiety, and depression.

Avicanna entered into an agreement with Santé Cannabis, a clinical research site and contract research organization ("CRO"), to evaluate our proprietary CBG transdermal gel in an observational real-world evidence study in patients with musculoskeletal pain and inflammation. The study will enroll 100 patients with arthritis including osteoarthritis, rheumatoid arthritis, fibromyalgia, muscle an/or joint pain, localised pain, post-surgical pain, muscular and/or structural injuries. The study will gather patient demographics,

medical history, medication use, overall symptom questionnaires and complete a Musculoskeletal Health Questionnaire, a validated measure of symptoms and quality of life related to musculoskeletal pain and inflammation over a three-month period.

Data derived from RWE trials in Canada is expected to be a component of an overarching imperative of minimizing risk and maximizing efficacy from industry-leading research and development. The data is also expected to be utilized in the optimization of formulations, enhancement of clinical protocols, prioritization of pharmaceutical trials, and educational materials for the medical community.

# **Cultivation Operations**

SMGH is focused on commercial cannabis and is located in Santa Marta, Colombia in the foothills of the Sierra Nevada Mountains. The location offers 12 hours of daily sunlight year-round, while the tropical weather of Santa Marta and micro-climate of the Sierra Nevada Mountains provide optimal conditions to maximize the number and amount of harvests. Access to cost efficient energy sources and construction labour allow for affordable expansion and production. Both companies also have easy access to the local Santa Marta shipping port which is expected to provide low cost shipping for export.

SMGH focus on cultivating high yielding THC, CBD, and CBG plants, as well as those expressing rarer cannabinoids, and the production of cannabis raw materials to be made available for manufacturing of our products as well as for wholesale distribution.

# Cultivation, Processing and Extraction Facilities

The Corporation's subsidiary, SMGH, continued its shadehouse, outdoor and greenhouse cultivation efforts. SMGH currently operates cultivation facilities that include 150,000 square feet of shadehouse space, 156,000 square feet of outdoor space and 14,000 square feet of customized greenhouse space. Currently, the production capacity is 1,500 kilograms of dried flower each month.

SMGH was granted its USDA organic certifications for the cultivation of hemp and the Good Agricultural Collection Practices certification (GACP), which the Corporation considers a key competitive advantage moving forward.

The size of the analytical laboratory in SMGH is 1,883 square feet and the extraction capacity to process biomass is 186 kg of biomass per day in 2 production shifts and continue to provide analytical services to SMGH. Extraction and refinement (distillation and isolation) are done using processes developed by Avicanna R&D activities and are thus commercially sensitive proprietary information to Avicanna.

The following is a summary of the licences and quotas granted or applied for by SMGH:

Cultivation of Psychoactive Cannabis Licence and Cultivation Quotas

SMGH was granted a licence for the cultivation of psychoactive cannabis from the MJL on November 24, 2017 pursuant to resolution number 973. The licence has been amended four times. The first amendment was on June 1, 2018 to permit the cultivation of psychoactive cannabis for scientific purposes pursuant to resolution number 472. The second amendment was on October 2, 2020 to amend the named legal representatives of SMGH pursuant to resolution number 1557. The third amendment was on October 16, 2020 to include Avicanna LATAM as a third-party authorized to be involved in the activities executed under the license pursuant to resolution number

1715. The fourth amendment was on July 7, 2021 to amend the named legal representatives of SMGH pursuant to resolution number 877.

The cultivation of psychoactive cannabis licenses grant SN and SMGH the right to cultivate psychoactive cannabis plants for: (i) production of seeds for sowing; (ii) grain production; (iii) manufacturing cannabis derivatives; and (iv) scientific purposes.

The MJL has granted SMGH the following psychoactive cultivation quotas:

- (a) for the 2020 calendar year,
  - to cultivate -under the modality of production of seeds for sowing- 441 plants for genetic maintenance and -under the modality of derivative manufacturing- 2.841 for the characterization of psychoactive cannabis derivatives pursuant to resolution number 415 which was issued on April 8, 2020;
  - (ii) to cultivate -under the modality of derivative manufacturing- 11.587 plants to produce cannabis derivatives for commercial export purposes and 677 plants to produce cannabis derivatives that will be used for product development pursuant to resolution number 1249 which was issued on August 14, 2020;
  - (iii) to cultivate -under the modality of production of seeds for sowing- 8.152 plants for the production of seeds for sowing pursuant to resolution number 1713 which was issued on October 16, 2020;
- (b) for the 2021 calendar year,
  - (i) to cultivate -under the modality of production of seeds for sowing- 720 plants for genetic maintenance, 1.720 plants for export purposes and 580 plants to produce the 25.850 plants of AV030 that will produce flower for the cannabis derivatives manufacturing quota granted with resolution number 348 of March 21, 2021, pursuant to resolution 279 of March 26, 2021,
  - (ii) to cultivate -under the modality of derivative manufacturing- 25.850 AV030 plants for flower production that will be used in the cannabis derivatives manufacturing quota granted with resolution 348 of March 21, 2021, pursuant to resolution 279 of March 26, 2021;
  - (iii) to cultivate -under the modality of scientific purposes- 800 plants for R&D purposes, pursuant to resolution 279 of March 26, 2021;
  - (iv) to cultivate -under the modality of production of seeds for sowing- 1.340 AV030 plants to produce clones, pursuant to resolution 1547 of October 8, 2021;
  - (v) to cultivate -under the modality of derivative manufacturing- 43.781 AV030 plants for flower production that will be used in the cannabis derivatives manufacturing quota

granted with resolution 348 of March 21, 2021, pursuant to resolution 1547 of October 8, 2021;

- (vi) to cultivate -under the modality of scientific purposes- 801 plants for R&D purposes, pursuant to resolution 1547 of October 8, 2021;
- (c) for the 2022 calendar year,
  - (i) to cultivate -under the modality of production of seeds for sowing- 4,092 plants for genetic maintenance, 548 plants for export purposes and 2,328 plants to produce the 78.850 plants of AV030 that will produce flower for the cannabis derivatives manufacturing quota granted with resolution number 652 of April 27, 2022, pursuant to resolution 886 of May 17, 2022,
  - (ii) to cultivate -under the modality of derivative manufacturing- 78.850 AV030 plants for flower production that will be used in the cannabis derivatives manufacturing quota granted with resolution 652 of April 27, 2022, pursuant to resolution 886 of May 17, 2022;
- Cultivation of Non-Psychoactive Cannabis Licence

SMGH was granted a license for the cultivation of non-psychoactive cannabis from the MJL on May 29, 2018 pursuant to resolution 463. This license has been amended twice. The first amendment was on October 2, 2020 to amend the named legal representatives of SMGH pursuant to resolution number 1556. The second amendment was on October 17, 2020 to include Avicanna LATAM as a third party authorized to be involved in the activities executed under the license pursuant to resolution number 1714. The third amendment was on July 7, 2021, to amend the named legal representatives of SMGH pursuant to resolution number 876. This license grants SMGH the right to cultivate non-psychoactive cannabis plants for: (i) production of seeds; (ii) manufacturing of cannabis derivatives; (iii) production of grain (iv) scientific purposes; and (v) and industrial purposes.

The cultivation of non-psychoactive cannabis plants does not require a quota.

#### Manufacturing of Cannabis Derivatives License

SMGH was granted a license for the manufacturing of cannabis derivatives from the MHSC on October 27, 2017 pursuant to resolution number 4282. This license has been amended twice. The first amendment was on August 17, 2018 to include the modality of scientific purposes. The second amendment was on October 21, 2021, to amend the name of the Legal Representative of SMGH pursuant to resolution 2021047003. This license grants SMGH the right to manufacture cannabis derivatives for: (i) national use; (ii) scientific purposes; and (iii) exportation purposes. In connection with this license, on December 26, 2017 SMGH was registered in the FNE as a manufacturer of cannabis derivatives for national use and exportation purposes pursuant to resolution number 777. This registration was amended on September 14, 2018 to include scientific purposes, pursuant to resolution number 639.

The manufacture of non-psychoactive cannabis derivatives does not require a quota.

The MHSC has granted SMGH the following psychoactive cannabis derivatives manufacturing quotas:

- (a) for the 2020 calendar year,
  - (iii) for the SMGH lab to receive 9 kilograms (dry weight) of cannabis flower from the psychoactive genetic "COMA KUSH AV030" under the modality of scientific purposes to manufacture psychoactive cannabis derivatives and characterize them, pursuant to resolution number 217 granted on February 19, 2020,
  - (iv) for the SMGH lab to receive 9 kilograms (dry weight) of cannabis flower from each of the following 5 non-psychoactive genetics: "GERMAN BLUE CHEESE-AV071", "PURPLE SEA-AV079", "SUGAR BIT-AV074", "TOMMY HAZE-AV040" and "BITTERSWEET CHEESE-AV073", for a total of 45 kilograms (dry weight) of cannabis flower -under the modality of scientific purposes- to manufacture psychoactive cannabis derivatives and characterize them, pursuant to resolution number 332 granted on March 5, 2020 and,
  - (v) for the SMGH lab to receive 9 kilograms (dry weight) of cannabis flower from each of SMGH's 20 registered psychoactive genetics (not including "COMA KUSH – AV030"), for a total of 180 kilograms (dry weigh) of cannabis flower -under the modality of scientific purposes- to manufacture psychoactive cannabis derivatives and characterize them, pursuant to resolution number 331 granted on March 5, 2020.
  - (vi) for the SMGH lab to receive 165 kilograms (dry weight) of cannabis flower from the non-psychoactive genetic "NN-AV011" -under the modality of scientific purposes- to manufacture psychoactive cannabis derivatives, pursuant to resolution number 757 granted on May 14, 2020.
  - (vii) for the SMGH lab to receive 272 kilograms (dry weight) of cannabis flower from the non-psychoactive genetic "NN-AV011" and 42 kilograms (dry weight) of cannabis flower from the psychoactive genetic "COMA KUSH AV030" -under the modality of scientific purposes- to manufacture psychoactive cannabis derivatives, pursuant to resolution number 1177 granted on July 21, 2020.
  - (viii) for the SMGH lab to receive 670 kilograms (dry weight) of cannabis flower from the non-psychoactive genetic "NN-AV011" and 721 kilograms (dry weight) of cannabis flower from the psychoactive genetic "COMA KUSH AV030" -under the modality of export purposes- to manufacture psychoactive cannabis derivatives which will be exported, pursuant to resolution number 1422 granted on August 21, 2020.
  - (ix) For the SMGH lab to receive 282 kilograms (dry weight) of cannabis flower from the non psychoactive genetic "NN-AV011" -under the modality of national use- to manufacture psychoactive cannabis derivatives which will be sold to Avicanna LATAM to be used in the manufacturing of magistral preparations, pursuant to resolution number 2495 granted on December 28, 2020.
- (d) For the 2021 calendar year,

- (i) for the SMGH lab to receive 7,497 kilograms (dry weight) of cannabis flower from the non-psychoactive genetic "NN-AV011" and 2,770 kilograms (dry weight) of cannabis flower from the psychoactive genetic "COMA KUSH – AV030" -under the modality of export purposes- to manufacture psychoactive cannabis derivatives which will be exported or used in the manufacturing of finished products that will be exported, pursuant to resolution number 348 granted on March 17, 2021.
- (ii) for the SMGH lab to receive 21.13 kilograms (dry weight) of cannabis flower from the non-psychoactive genetic "NN-AV011" and 4.1 kilograms (dry weight) of cannabis flower from the psychoactive genetic "COMA KUSH – AV030" -under the modality of national use- to manufacture psychoactive cannabis derivatives which will be used in the manufacturing of finished products under the compound pharmacy model, pursuant to resolution number 794 granted on June 10, 2021.
- (e) For the 2022 calendar year,
  - (i) for the SMGH lab to receive 7,497 kilograms (dry weight) of cannabis flower from the non-psychoactive genetic "NN-AV011" and 2,770 kilograms (dry weight) of cannabis flower from the psychoactive genetic "COMA KUSH – AV030" -under the modality of export purposes- to manufacture psychoactive cannabis derivatives which will be exported or used in the manufacturing of finished products that will be exported, pursuant to resolution number 348 granted on March 17, 2021.
- Registration of Psychoactive and Non-Psychoactive Cannabis Strains

During 2019, SMGH successfully characterized and received registration for twenty-one psychoactive cannabis strains and eight non-psychoactive cannabis strains.

#### Cultivation Operations – Summary

The following table provides a summary of our current and anticipated cultivation activities.

SMGH Site	Status and Activities						
Laboratory	Extraction lab 1 is operational and has a capacity of processing 186 kg of flower/day, resulting in production capacity of 28kg of resin per day.						
Equipment	High performance liquid chromatography equipment is in place on site to allow for cannabinoid profiling.						
Shadehouse and Greenhouse Capacity	We currently have 340,000 square feet of shadehouse and outdoor space plus 20,000 customized greenhouse.						
Genetic Registration / Quota Status	Achieved genetic registration of 8 non-psychoactive strain and 21 psychoactive strains.						

SMGH Site	Status and Activities				
	The latest cultivation quota obtained was a supplementary psychoactive cultivation quota under the modalities of production of seeds for sowing, derivative manufacturing and scientific purposes.				
	The latest manufacturing quota obtained was the ordinary quota under the modalities of export purposes and national use.				
Cultivation Activities	Continued cultivation of both psychoactive and non-psychoactive genetic strains.				

#### Notes:

(1) See "Regulatory Framework – Colombia – Genetic Registration Process in Colombia".

# **Intellectual Property**

Our future commercial success depends, in part, on our ability to: obtain, maintain, defend, and enforce our patents and trademarks; preserve the confidentiality of our trade secrets; and operate without infringing, misappropriating, or violating the valid and enforceable patents and proprietary rights of third parties. Our ability to stop third parties from making, using, or selling our products may depend on the extent to which we have rights under valid and enforceable patents, trademarks or trade secrets that cover these activities.

Our intellectual property portfolio covers patents on cannabinoid compositions and methods of treatments for dermatological and neurological indications. We do not currently own or in-licence any patent related to our products. Our patent portfolio includes seven (7) pending applications.

Our lead product candidate AVCN319301, an oral cannabinoid composition specifically formulated using advanced drug delivery systems to achieve better therapeutic efficacy and bioavailability of lipophilic cannabinoid compounds is under development for neuropathic pain. In pre-clinical studies, AVCN319301 upon administration to a mammal showed strong bioavailability profile as compared to controlled compositions. On September 5, 2019, we filed a U.S. provisional patent application on its formulation, delivery system and bioavailability profile. The provisional application was formalized on September 4, 2020 andunder examination by the USPTO. The application was published in the official journal of the USPTO.

Our second lead product candidate AVCN583601 for dermatological indications has successfully completed formulation development and *in vivo* toxicology studies in animal models. We filed a U.S. provisional patent application for AVCN583601 on March 8, 2021 on its composition of matter and *in vitro* and *in vivo* test results. We originally filed a U.S. provisional patent application for AVCN583601 on March 5, 2019 which we abandoned to refile on March 6, 2020 and March 8, 2021. This application is not yet published.

We were also studying a product candidate AVCN771201 in pre-clinical studies for the treatment of lung inflammation induced by respiratory infections including severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, commonly known as COVID-19 infection. On July 29, 2020, we filed a U.S.

provisional patent application on the formulation and its delivery mechanism for the treatment of lung inflammation. The due date to formalize the U.S. provisional application was July 29, 2021. There were delays in getting the desired supporting data on the patent claims, therefore, we abandoned the U.S. provisional patent application. The development of this product is now terminated.

For our derma-cosmetic product line, we filed a U.S. non-provisional patent application on December 10, 2019 and formalized a U.S. provisional patent application on October 21, 2020, which was originally filed on October 21, 2019. Both of these applications were published in the official journal of the USPTO during the first half of 2021. These patent applications have been filed for two topical compositions containing 0.5% cannabidiol and 1% hemp seed oil with altogether different excipients. Both these products are intended to be used for promoting hydration and improving appearance of the skin. In November 2020, we extended both these applications and filed two international Patent Co-operation Treaty ("PCT") applications with the World Intellectual Property Organization.

The PCT is an international treaty with more than 150 contracting states. By filing a single "international" patent application, we can simultaneously seek protection on our inventions in multiple jurisdictions instead of filing several separate national or regional patent applications. The granting of patents remains under the control of the national or regional patent offices in what is called the "national phase".

On August 15, 2019, we filed a U.S. provisional patent application with respect to improved technical and agricultural methods to make cannabis cultivation more suitable for tropical and inter-tropical climatic regions. We abandoned this U.S. provisional patent application.

Our research team has also formulated a deep penetrating topical cannabinoid composition AVCN467504 intended to be used for musculoskeletal inflammation and pain. The product candidate showed good skin penetration profile in *in-vitro* studies and is currently in pre-clinical testing. On July 16, 2021, we filed a U.S. provisional application on the composition of matter and its use for the treatment of musculoskeletal inflammation and pain. We formalized this application in the US in July 2022. This published application is now under examination by the USPTO.

In December 2022, we completed *in-vivo* animal model studies on a product candidate AVCN319302 being developed for patients with epilepsy. In 2021, preliminary electrophysiological studies on seizure-induced cortical slices taken from wildtype mouse determined that treatment with AVCN319302 produced significant anti-convulsant effects compared to treatment with cannabidiol ("CBD") or tetrahydrocannabinol ("THC") alone. These results, obtained in a well-established *in vitro* model, suggest that, in addition to anti-convulsant properties, AVCN319302 demonstrates strong potential to treat patients diagnosed with intractable forms of epilepsies and those at risk of seizure-induced Sudden Unexpected Death in Epilepsy ("SUDEP"). The product candidate was tested further in the maximal electroshock (MES) *in vivo* animal models to confirm the anti-seizure effects in comparison to CBD alone. AVCN319302 further demonstrated strong anti-convulsant properties and therapeutic index value as compared to CBD alone. A PCT patent application was filed in the WIPO on December 01, 2022, for the use of AVCN319302 in epilepsy by claiming the priority date of a provisional patent filed in the US in 2021.

Our provisional patent applications are not eligible to become issued patents until we file non-provisional patent applications after generating more data to support our patent claims within 12 months of filing thereof. If we do not timely file any non-provisional patent applications, we may lose our priority dates with

respect to our provisional patent applications and any patent protection on the invention disclosed in our provisional patent applications.

In parallel to the development of novel products and processes, we also take the necessary steps to protect our trademarks. We actively submit trademark applications in applicable jurisdictions as we continue to expand.

We have a total of 74 active trademark filings covering our company logos, word marks and design marks. After successful registration of trademarks, we actively watch new trademark filings by third parties to maintain market exclusivity and to ensure continued value of our registered marks.

The following table show our pending and registered trademarks in various jurisdictions:

Trademark	Туре	Pending	Registered	Abandoned applications	Lapsed registrations
AVICANNA	Word Mark		Canada, Colombia, European Union, Argentina		Mexico
	Design Mark	Argentina	Canada, Colombia, European Union		Mexico
PURA EARTH	Word Mark		Colombia, European Union, Argentina, UK, Canada	USA	Mexico
	Design Mark		Canada, Colombia, European Union, Argentina, UK, Ecuador, South Africa, USA		Mexico

RHO PHYTO	Word Mark	Canada, Barbados, St. Vincent	Australia, European Union, UK, Colombia, Japan, Argentina, Mexico, South Africa	Brazil	
	Design Mark	Barbados, St. Vincent	Canada, Australia <sup>1</sup> , European Union, Japan, Colombia, Argentina, UK, South Africa	USA	Mexico
AUREUS	Word Mark		European Union, UK, Colombia		
	Design Mark		European Union, UK, Colombia, South Africa		
PURA ELEMENTS	Word Mark		Canada, Colombia, European Union, UK	Mexico, USA	
ELEVATING NATURE THROUGH SCIENCE	Tagline/Slog an	Canada			
AUREUS SANTA MARTA	Design Mark		South Africa		
PURA H&W	Word Mark	Canada, India, South Africa	European Union, Peru, Australia, United States, UK, Chile, New Zealand,	China, Brazil, Thailand	

		Colombia, Switzerland, Ecuador, Mexico, Japan, South Korea	
RHO	Composite mark	Australia <sup>2</sup>	
TRUNEROX	Drug name (word mark)	Peru, Colombia	

<sup>&</sup>lt;sup>1</sup>for non-topical medical cannabis goods

# Employees, Specialized Skill and Knowledge

As at the date of this AIF, Avicanna has 15 employees located in Canada and 5 independent contractors. Of this total, all independent contractors are located in Canada.

In addition, as at the date of this AIF: (i) Avicanna LATAM has 16 employees and 2 independent contractors, all of which are located in Colombia; (ii) SMGH has 48 employees and 3 independent contractors, all of which are located in Colombia; and (iii) Avicanna USA Inc has 1 employee which is located in USA.

Our business requires specialized knowledge and technical skill around cannabis cultivation and processing in Colombia, clinical sciences, product formulations, product testing, clinical testing, quality assurance, GMP standards and ingredient sourcing. The required skills and knowledge are available to us through our current employees and management.

# **Competitive Conditions**

See description below under "Risk Factors – Risks Related to the Corporation's Business and Industry – Competition".

We operate in a fast-growing market that has created a competitive environment for companies who operate in the cannabis industry. However there remains a significant lack of traditional sources of bank lending and equity capital available to fund the operations of companies in the cannabis sector. Because of the rapid growth of this sector, we face competition from other companies in the sector who are accessing

<sup>&</sup>lt;sup>2</sup>for topical medical cannabis goods

the equity capital markets and/or who have a greater amount of unallocated funds to take advantage of opportunities in the cannabis industry.

The industry is also entering a period of significant consolidation, creating larger companies that may have increased geographic scope and other economies of scale. Increased competition by larger, better-financed competitors with geographic or other structural advantages could materially and adversely affect the business, financial condition and results of operations of the Corporation. To remain competitive, we will require a continued level of investment in R&D and protection and capitalization of our proprietary information. Readers are cautioned that we may not have sufficient resources at all times to maintain a level of R&D and cultivation to remain competitive, which could materially and adversely affect our business, financial condition and results of operations.

There are an increasing number of market entrants in Colombia and, as a result, we anticipate facing increased competition for the production of Extracts. However, we hope to differentiate ourselves from our competitors with the products of our R&D activities and industrial scale extraction, distillation, and isolation equipment to lower the cost of production and, therefore, increase our margins relative to other market participants. As the process for cannabinoid isolation requires specific expertise, and resources and associated costs, we anticipate there to be few companies with the capacity to provide the quality of isolates demanded by companies as they move toward manufacturing practices that require batch-to-batch consistency.

We further intend to differentiate ourselves from other market entrants by using organic agricultural practices and we plan to do so at scale.

We believe that the climates in jurisdictions that permit industrial hemp (including Canada and Europe), which is a source of CBD for local manufacturers of downstream products, remain less favourable when compared to Colombia for cost advantages and year-round growth.

Our Extracts, when ultimately produced, are expected to be used in the manufacturing of our own products, so that the cost of R&D as well as production can be lowered and controlled as much as possible. Our Extracts, when produced, are also expected to be sold to third parties since our projected capacity will outweigh what is required to formulate our products.

## Components

See description above under "Description of our Business – Research and Development", "Description of our Business – Products", "Description of our Business – Cultivate Operations", "Description of our Business – Intellectual Property".

Avicanna cultivates and uses its own raw materials and proprietary formulations for the manufacture of its finished products. The raw materials are produced at Avicanna's subsidiary SMGH's facilities for distribution in Colombia and internationally.

In preparation for the launch of the CBD-based derma-cosmetic and medical cannabis products in Canada, Avicanna intends on using Canadian-sourced raw materials.

## **Intangible Properties**

We recognize the importance of our intangible assets such as brand names, copyrights, licences, patents and trademarks. See "Description of Business - *Intellectual Property*". The Corporation relies on non-disclosure and confidentiality agreements to protect its intellectual property rights. We have a portfolio of seven active patent applications and intend to seek patent protection for other products in accordance with our intellectual property strategy.

# **Cycles**

We do not expect our business to be cyclical or seasonal. Our R&D activities are year-round and the climate in Colombia is ideal for year-round growing and processing of all possible varieties of cannabis.

## **Economic Dependence**

Avicanna currently has the relationships in place to manufacture its finished products using contract manufacturers located in Colombia and Canada. Disruption of the Corporation's manufacturing and distribution contracts may have a material adverse effect on the Corporation's revenue.

## **Foreign Operations**

Avicanna is dependent on its foreign operations in Colombia and the success thereof, as well as the legislative developments in each of those countries. See "Description of our Business – Cultivation Operations" and "Regulatory Framework" for additional details.

At present, approximately half of our operations are focused in Colombia. For a description of the regulatory environment to which we are subject, please see "*Regulatory Framework – Colombia*" for additional details.

#### Management Experience in Colombia

We have taken steps to ensure that our management and Board are familiar with all applicable aspects of doing business in Colombia. We have hired three independent law firms in Colombia to assist us with compliance with Colombian law and advising us as to the various regulations and customs applicable to our business. In addition, our Colombian team includes one in-house lawyer who is based in Bogota and who is fluent in Spanish and English.

Additionally, we work with internationally recognized accounting firms who support our internal finance and accounting team in Colombia, who are Colombian and have extensive experience in Colombia. Our Colombian office also includes a regulatory team, one of whom are former INVIMA staff members and one of whom is a former ICA staff member.

Giancarlo Davila Char, one of our directors has experience doing business in Colombia and is familiar with the laws and requirements of Colombia.

For more information and biographies of these individuals, see "Directors and Executive Officers – Management".

Our management ensures key business documents are translated into English in order to properly read and assess the documents. Additionally, with their advisors, they have a thorough understanding of the laws and requirements of Colombia. Our management team visits the Colombia operations at least every

three to six weeks, with our Chief Financial Officer visiting quarterly. The majority of our operations in Colombia are staffed by full time residents of Colombia.

#### **REGULATORY OVERVIEW**

#### Canada

The following summary addresses the primary Canadian federal and provincial laws and regulations associated with the production and distribution of legal cannabis and related products. It does not address the laws and regulations of any other jurisdiction. The Corporation believes that, as of the date of this AIF, it is in material compliance with all laws and regulations summarized below. In this section, the terms "cannabis", "CBD", "client", "industrial hemp", "licence" and "THC" have the meanings given to such terms in the Cannabis Act and the Cannabis Regulations, including, without limitation, the IHR.

## Background

On October 17, 2018, the Cannabis Act and the Cannabis Regulations came into force, legalizing the sale of cannabis for adult recreational use. Prior to the enactment of the Cannabis Act and the Cannabis Regulations, only the sale of cannabis for medical purposes was legal, which was regulated by the Access to Cannabis for Medical Purposes Regulations ("ACMPR") under the Controlled Drugs and Substances Act (Canada) ("CDSA"). The Cannabis Act and the Cannabis Regulations replaced the CDSA and the ACMPR as the governing laws and regulations in respect of the production, processing, sale and distribution of cannabis for medical and adult recreational use.

The Cannabis Act and Cannabis Regulations that came into force in 2018 were limited to the regulation of dried cannabis, cannabis oil, fresh cannabis, cannabis plants and cannabis plant seeds. On October 17, 2019, three new classes of cannabis, being edible cannabis, cannabis extracts and cannabis topicals (collectively, the "**New Classes of Cannabis**") were authorized by the Regulations Amending the Cannabis Regulations (New Classes of Cannabis) (the "**Amending Regulations**").

The Cannabis Act provides a licensing and permitting scheme for the cultivation, processing, importation, exportation, testing, packaging, labelling, sending, delivery, transportation, sale, possession and disposal of cannabis for adult recreational use, implemented by the Cannabis Regulations. The Cannabis Act and the Cannabis Regulations maintain separate access to cannabis for medical purposes. Under the Cannabis Act and the Cannabis Regulations, import and export permits will only be issued in respect of cannabis for medical or scientific purposes or in respect of industrial hemp and in accordance with the IHR. Import and export permits will not be issued in respect of cannabis for adult recreational use.

The Cannabis Regulations, among other things, set out regulations relating to the following matters: (1) licences, permits and authorizations; (2) security clearances and physical security measures; (3) good production practices; (4) cannabis products; (5) packaging and labelling; (6) cannabis for medical purposes; (7) drugs containing cannabis; (8) combination products and devices; (9) importation and exportation for medical or scientific purposes; (10) document retention; and (11) reporting and disclosure.

#### Licences. Permits and Authorizations

Part 2 of the Cannabis Regulations establish six classes of licences: cultivation licences; processing licences; analytical testing licences; sales for medical purposes licences; research licences ("Cannabis Research Licence"); and cannabis drug licences. The Cannabis Regulations also create subclasses for cultivation licences (standard cultivation, micro-cultivation and nursery) and processing licences (standard

processing and micro-processing). Different licences and each subclass therein carry different rules and requirements that are intended to be proportional to the public health and safety risks posed by each licence category and subclass. Pursuant to Section 9 of the Cannabis Regulations all licences issued under the Cannabis Act must include certain requirements including the effective date and expiry date of the licence and may be renewed on or before the expiry date.

The Corporation was granted a Cannabis Research Licence at its research laboratory in JLABS @ Toronto pursuant to the Cannabis Act and Cannabis Regulations effective August 16, 2019 with an expiry date of August 16, 2022. The Corporation's Cannabis Research Licence was amended on April 2, 2020 to include additional research space within JLABS @ Toronto.

The IHR under the Cannabis Act came into force on October 17, 2018. The IHR remained largely the same as they were under the CDSA but now they permit the sale of hemp plants to licensed cannabis producers, the use of additional parts of the hemp plant and licensing requirements were introduced in accordance with the low risk posed by industrial hemp. The Industrial Hemp Regulations define "industrial hemp" as cannabis plants – or any part of the plant – in which the concentration of THC is 0.3% or less in the flowering heads and leaves.

#### Security Clearances

Part 3 of the Cannabis Regulations sets out that certain people associated with cannabis licence holders, including individuals occupying a "key position" such as directors, officers, significant shareholders and individuals identified by the Minister of Health (the "Minister"), must hold a valid security clearance issued by the Minister. Under the Cannabis Regulations, the Minister may refuse to grant security clearances to individuals with associations to organized crime or with past convictions for, or an association with, drug trafficking, corruption or violent offences. The scope of bases upon which the Minister may decline a security clearance has expanded under the Cannabis Regulations compared with the ACMPR, but the overall approach is largely the same as under the ACMPR, except that the security clearance requirements apply to parent companies as well as corporate licensees. Individuals who have histories of non-violent, lower-risk criminal activity (for example, simple possession of cannabis, or small-scale cultivation of cannabis plants) are not precluded from participating in the legal cannabis industry, and the grant of security clearance to such individuals is at the discretion of the Minister and such applications will be reviewed on a case-by-case basis.

Security clearances issued under the ACMPR are considered to be security clearances for the purposes of the Cannabis Act and Cannabis Regulations.

# Cannabis Tracking and Licensing System

Under Part 6 of the Cannabis Act, the Minister is authorized to establish and maintain a national cannabis tracking system. The Cannabis Regulations provide the Minister with the authority to make a ministerial order that would require specified persons to report specific information about their authorized activities with cannabis, in the form and manner specified by the Minister.

The ministerial order regarding the Cannabis Tracking System (together with the licensing portal, collectively known as the "Cannabis Tracking and Licensing System" or "CTLS") was published in the Canada Gazette, Part II, on September 5, 2018 and came into effect on October 17, 2018 (the "2018 Ministerial Order"). The 2018 Ministerial Order was repealed and replaced by the new ministerial order, the Cannabis Tracking System Order, published in the Canada Gazette, Part II on June 26, 2019 and in force on October 17, 2019 in order to address the unique public health and public safety risks associated with the New Classes of Cannabis authorized by the Amending Regulations.

The purpose of the Cannabis Tracking and Licensing System is to enable the submission of licence applications, amendments and renewals through an online portal and track the flow of cannabis throughout the supply chain as a means of preventing the illegal inversion and diversion of cannabis into and out of the regulated system. Under the Cannabis Tracking and Licensing System, a holder of a licence for cultivation, licence for processing, or a licence for sale for medical purposes is required to submit monthly reports to Health Canada, among other things. The tracking function of the CTLS mitigates diversion of cannabis into, and out of, the regulated medical and recreational markets. The Cannabis Act provides the Minister with authority to order that any particular persons report specific information about their authorized activities with cannabis, in a form and manner specified by the Minister.

#### Cannabis Products

Part 6 of the Cannabis Regulations sets out the requirements for cannabis products and permits the sale of dried cannabis, cannabis oil, fresh cannabis, cannabis plants, cannabis plant seeds, edible cannabis, cannabis extracts and cannabis topicals. THC content is limited by the Cannabis Regulations.

As mentioned above, prior to the passage of the Amending Regulations, the Cannabis Act only permitted the sale of dried cannabis, cannabis oil, fresh cannabis, cannabis plants and cannabis plant seeds. The Amending Regulations permit the product and sale of the New Classes of Cannabis. As is the case for dried or fresh cannabis and cannabis oil, a processing licence is required in order to produce edible cannabis, cannabis extracts and cannabis topicals, and to package and label these types of cannabis products for sale to consumers. Holders of processing licences issued prior to October 17, 2019 were required to amend their processing licence before they could begin manufacturing products belonging to New Classes of Cannabis.

Section 244(1) of the Cannabis Regulations requires the filing of a notice with Health Canada at least 60 days before releasing a new product to the market, with the exception of cannabis plants or cannabis plant seeds. As a result, December 16, 2019 was the earliest date that products in the New Classes of Cannabis could be made available for sale.

In addition, if a holder of a processing licence chooses to process edible cannabis and food products on the same site, then the production, packaging, labelling, and storage of cannabis and the production, packaging, and labelling of food products will need to be conducted in separate buildings. All cannabis production is required to occur in a separate building from any food production.

# Physical Security Measures

Part 4 of the Cannabis Regulations set out requirements pertaining to physical security measures, in order to ensure that a licence holder's site is adequately secured and safeguarded at all times to protect public safety and to minimize the risks of diversion. Each licence holder is responsible for understanding and complying with required physical security measures that apply to their licence, which includes requirements such as ensuring the entire perimeter of a licensed site is continuously monitored and the monitoring system is connected to a back-up generator. Licence holders must be able to demonstrate that their site is secured in accordance with the Cannabis Regulations.

# Packaging & Labeling

Part 7 of the Cannabis Regulations sets out strict requirements pertaining to the packaging and labelling of cannabis products. These requirements are intended to promote informed consumer choice and allow for the safe handling and transportation of cannabis, while also reducing the appeal of cannabis to youth.

All cannabis products are required to be packaged in a manner that is tamper-proof and child-resistant in accordance with the Cannabis Regulations and in plain packaging. The Cannabis Regulations impose strict limits on the use of colours, graphics, and other special characteristics of packaging. Cannabis package labels must include specific information, such as: (i) product source information, including the class of cannabis and the name, phone number and email of the licence holder; (ii) a mandatory health warning, rotating between Health Canada's list of standard health warnings; (iii) the Health Canada standardized cannabis symbol; and (iv) information specifying THC and CBD content.

#### Promotion

Subdivision A of Division 2 of the Cannabis Act and Part 6.1 of the Cannabis Regulations set out restrictions regarding the promotion of cannabis products. Subject to a few exceptions, all promotions of cannabis products are prohibited unless authorized by the Cannabis Act. While these restrictions also apply to the New Classes of Cannabis, the Amending Regulations also prohibit certain representations and associations on products, their packages and labels and associated promotional activity, including: certain flavours in cannabis extracts (e.g. confectionary, dessert, soft drink, and energy drink) that are appealing to youth; health or cosmetic benefits unless registered as a health product; energy value and nutrient content representations that go beyond those permitted in the list of ingredients and in the cannabis-specific nutrition facts table; statements reasonably likely to create the impression the edible cannabis or accessory is intended to meet particular dietary requirements; and promotion that could reasonably associate the cannabis, the cannabis accessory or the service related to cannabis with an alcoholic beverage, a tobacco product or a vaping product.

#### **Product Composition**

The Amending Regulations introduced restrictions on product composition specific to each New Class of Cannabis including specific THC limits. Examples of other product-specific restrictions are listed in Part 6 of the Cannabis Regulations, and include:

- Edible cannabis: must be shelf stable; only food and food additives will be allowed to be used as ingredients in edible cannabis and the use of food additives will need to be in accordance with the limits and purposes that are prescribed for foods in the Food and Drug Regulations; must not have caffeine added, however the use of ingredients containing naturally occurring caffeine will be permitted in edible cannabis products provided that the total amount of caffeine in each immediate container does not exceed 30 milligrams; must not contain alcohol in excess of 0.5% w/w; must not contain anything that would cause the sale of the edible cannabis, if it was a food regulated under the Food and Drugs Act (Canada), to be prohibited and must not be fortified with vitamins or mineral nutrients.
- Cannabis extracts: must not contain ingredients that are sugars, sweeteners or sweetening agents, nor any ingredient listed on Column 1 of Schedule 2 to the Tobacco and Vaping Products Act (Canada) (which is a list of ingredients that are prohibited in vaping products) except if those ingredients and their levels are naturally occurring in an ingredient used to produce the extract.
- Cannabis topicals: must not contain anything that may cause injury to the health of the consumer when the product is used as intended or in a reasonably foreseeable way.

#### Health Products Containing Cannabis

Under the current regulatory framework, cannabis is not permitted for use in a natural health product or a non-prescription drug product, as phytocannabinoids are included as prescription drugs on the Human and Veterinary Prescription Drug List ("**PDL**"). Although, Health Canada has previously authorized prescription drug products containing cannabis, the agency maintains that there remains significant scientific uncertainty regarding the pharmacological actions, therapeutic effectiveness and safety of the majority of

phytocannabinoids. The cannabis- based prescription drug products that have been authorized by Health Canada have been studied, authorized and used in specific conditions. While these authorized products have contributed to the global body of knowledge concerning the safety and efficacy of cannabis-based therapies, Health Canada has stated that the presence of scientific uncertainty and limited market experience gives rise to the need for a precautionary approach. Listing all phytocannabinoids on the PDL addresses this uncertainty by allowing healthcare practitioners to monitor and manage any unanticipated effects. All phytocannabinoids will remain listed on the PDL until there is sufficient scientific evidence (e.g., as demonstrated through a submission to Health Canada) to change the prescription status of a particular phytocannabinoid when used in specific conditions.

Cannabis is also expressly prohibited for use in cosmetic products as it is included on Health Canada's Cosmetic Ingredient Hotlist, List of Ingredients Prohibited for Use in Cosmetic Products.

## Cannabis for Medical Purposes

With the Cannabis Act and the Cannabis Regulations coming into force on October 17, 2017, the medical cannabis regime migrated from the CDSA and the ACMPR to the Cannabis Act and the Cannabis Regulations. The medical cannabis regulatory framework under the Cannabis Act and the Cannabis Regulations remains substantively the same as it existed under the CDSA and the ACMPR, with adjustments to create consistency with rules for recreational use, improve patient access, and reduce the risk of abuse within the medical access system. Under Part 14 of the Cannabis Regulations, three options are available for obtaining cannabis for medical purposes: (i) register with a holder of a licence to sell for medical purposes; (ii) register with Health Canada to produce a limited amount of cannabis for their own medical purposes; or (iii) designate someone else to produce cannabis for them. With respect to (ii) and (iii), starting materials, such as cannabis plants or seeds, must be obtained from medical sales licence holders.

#### Provincial and Territorial Regulatory Regimes

While the Cannabis Act provides for the regulation of the commercial production of cannabis for adult recreational purposes and related matters by the federal government, the Cannabis Act includes provisions stipulating that the provinces and territories of Canada have authority to regulate other aspects of adult recreational use cannabis (similar to what is currently the case for liquor and tobacco products), such as retail sale and distribution, minimum age requirements above that in place under the Cannabis Act, places where cannabis can be consumed, and a range of other matters. The governments of every Canadian province and territory have, to varying degrees, regulatory regimes for the distribution and sale of cannabis for adult recreational purposes within those jurisdictions. Each of these Canadian jurisdictions has established a minimum age of 19 years for cannabis use, except for Québec and Alberta, where the minimum age is 21 and 18, respectively.

**Québec**: In Québec, all recreational cannabis is managed and sold through outlets of the Société québécoise du cannabis, a subsidiary of the Société des alcools du Québec, and its online site.

Ontario: In Ontario, the distribution and online retail sale of recreational cannabis is conducted through the Ontario Cannabis Retail Corporation, under the oversight of the Alcohol and Gaming Commission of Ontario (the "AGCO"). Ontario also permits the sale of recreational cannabis through private brick-and-mortar retailers. Initially, Ontario employed a "phased" approach to retail licensing, setting a maximum cap of 25 licences available to be issued to allow operators to open for business beginning April 1, 2019. The Ontario government has now moved to open the market for private cannabis retail stores in Ontario. Until December 13, 2019, a temporary cap of 25 retail store authorizations was imposed while cannabis supply stabilizes. On July 3, 2019, the Government of Ontario announced its plans for a second allocation of 50 additional cannabis retail store authorizations. The AGCO held a lottery draw for the allocation of 42 retail store

authorizations. A separate process governed the allocation of eight retail store authorizations for those who wish to operate a store on a First Nations reserve. On March 2, 2020, the restrictions on the total number of store authorizations permitted in Ontario, and their regional distribution, was revoked. The AGCO has begun accepting applications for retail store authorizations from all interested applicants. Federally licensed producers may now own or control, directly or indirectly, up to 25% of a corporation holding a cannabis Retail Operator Licence (required to hold a Retail Store Authorization) in Ontario, an increase from the previous threshold of 9.9%.

**British Columbia**: In British Columbia, recreational cannabis is sold through both public and licensed privately-operated stores, with the provincial Liquor Distribution Branch handling wholesale distribution.

**Alberta**: In Alberta, cannabis products are sold by private retailers that receive their products from a government- regulated distributor, the Alberta Gaming, Liquor and Cannabis Commission (the "**AGLC**"), similar to the distribution system currently in place for alcohol in the province. Only licensed retail outlets are to be permitted to sell cannabis with online sales run by the AGLC.

Saskatchewan: In Saskatchewan, the Government of Saskatchewan implemented a framework in which both wholesale and retail recreational cannabis are conducted by the private sector and regulated by the Saskatchewan Liquor and Gaming Authority (the "SLGA") with municipalities having the option of opting out of having a cannabis store if they choose. A number of retail permits have been issued to private stores. SLGA is currently accepting applications for retail permits, wholesale cannabis permits and federally licensed producer registrations. Permitted wholesalers can sell to permitted retailers and other permitted wholesalers but not to the general public. Wholesale operations must be physically located within Saskatchewan and product can only be sold and distributed within Saskatchewan. Further, only federally licensed producers registered with SLGA will be allowed to sell into the Saskatchewan market.

**Manitoba**: In Manitoba, operated "hybrid mode" for cannabis distribution applies whereby the supply of cannabis is secured and tracked by the Manitoba Liquor and Lotteries Corp.; however, licensed private retail stores will be permitted to sell adult-use cannabis.

**New Brunswick**: In New Brunswick, recreational cannabis is sold and online sales run by Cannabis NB, a subsidiary of a network of tightly-controlled, stand-alone stores through the New Brunswick Liquor Corporation (the "**NBLC**"). The NBLC also controls the distribution and wholesale of cannabis in the province. The New Brunswick government had issued a request for proposals in order to find a single private operator to take over the Cannabis NB operations which would privatize the government-operated corporation created to handle retail sale of adult use cannabis. This would result in the retail model changing from government-operated to privately-operated in New Brunswick. New Brunswick has discontinued the request for proposal process in late March 2021. Cannabis NB remains the only legal retailer of recreational cannabis in the province of New Brunswick.

**Nova Scotia**: In Nova Scotia, the Nova Scotia Liquor Corporation (the "**NSLC**") is responsible for the regulation of cannabis in the province, and recreational cannabis is only to be sold publicly through government-operated storefronts and online sales. There is no private licensing of retail. The NSLC also controls the distribution and wholesale of cannabis in the province.

**Prince Edward Island**: In Prince Edward Island, similar to Nova Scotia, sale of cannabis is government-run through government retail sales and online, overseen by the Prince Edward Island Cannabis Management Corporation, who is also responsible for the distribution and wholesale of cannabis in the province. There is no private licensing of retail.

**Newfoundland and Labrador**: In Newfoundland and Labrador, recreational cannabis is sold through licensed private retail stores, with its crown-owned liquor corporation, the Newfoundland and Labrador

Liquor Corp. (the "**NLC**"), issuing private retailer licences and overseeing the wholesale and distribution to the private sellers. The NLC controls the possession, sale and delivery of cannabis, and sets prices. It is also the initial online retailer, although licences may later be issued to private interests.

**Yukon**: The Yukon had initially limited the distribution and sale of recreational cannabis to government outlets and government-run online stores, but has since opened up its retail market to permit licensed private retailers in the territory. Cannabis retail licenses are issued by the Cannabis Licensing Board. Authorized retailers must purchase cannabis from the Yukon Liquor Corporation, acting as the wholesaler and distributor in the territory.

**Northwest Territories**: The Northwest Territories Liquor Commission controls the importation and distribution of cannabis, whether through retail outlets or by mail order service run by the commission. Communities in the Northwest Territories are able to hold a plebiscite to prohibit cannabis sales in their communities, similar to options currently available to restrict alcohol in the Northwest Territories.

**Nunavut**: Nunavut permits the sale of cannabis through both public and private retailers, including online. The Nunavut Liquor and Cannabis Commission is responsible for distribution and wholesale in the territory.

#### Colombia

The Corporation's core operations in Colombia are carried out through its Colombian subsidiaries, Avicanna LATAM, SMGH, and Sativa Nativa. As cultivators of cannabis (both psychoactive and non-psychoactive) and manufacturer of cannabis products, the Corporation's Colombian subsidiaries are substantially dependent on the licenses for cultivation, manufacturing, quotas (for psychoactive cannabis) and a Good Preparation Practices ("GPP") certification.

The following summary addresses the primary Colombian laws and regulations associated with the regulation of cannabis for medical and scientific purposes. It does not address the laws and regulations of any other jurisdiction. The Corporation believes that, as of the date of this Prospectus, it is in material compliance with all laws and regulations summarized below.

# Background

Over the past 50 years, Colombia developed comprehensive regulation that took a hardline approach to narcotics and trafficking in response to the growing influence of international treaties and the efforts of governments to coordinate their drug policies. In the mid-1990s, Colombia decriminalized personal possession and consumption of cannabis under Judgment C-221 of 1994 of the Constitutional Court. While this represented a shift in approach by Colombian lawmakers, a constitutional amendment in 2009 reversed the effects of Judgment C-221 of 1994 and reinstated the prohibition on personal possession and consumption of narcotic or psychotropic substances, even on a personal dose basis, unless supported by a medical prescription.

Despite the constitutional amendment in 2009, Colombian cannabis legislation trended towards a preventative and rehabilitative approach. The Colombian Constitutional Court, through rulings SU-642 of 1998 and C-336 of 2008, among others, established that the right to the free development of personality, also known as the right to autonomy and personal identity, grants individuals the right to self-determination, the freedom and independence to govern his/her own existence and determine a lifestyle according to his/her own interests; provided, that the rights of others and the constitutional order are respected.

In January 2013, the Advisory Commission on Drug Policy (the "**Drug Policy Commission**") was established to provide recommendations on how legislation should treat criminal networks and citizen drug users, as well as the quantities to be considered as suitable personal amounts. In July 2014, the Drug Policy Commission issued an initial report submitted to the Ministry of Justice analyzing the conditions of

drug use in Colombia and proposing guidelines to update the policy.

In May 2015, the Drug Policy Commission published its final report, which proposed a review of the drug policy in the country and made important recommendations, such as: (i) the creation of an agency for drug policy; (ii) measures to help reduce the risk to consumers; (iii) to rethink the fumigation involved with cultivation; (iv) regulation of medicinal cannabis; (v) alternative means to measure the success of policies against drugs; (vi) modernize the National Statute on Drugs and Psychoactive Substances; and (vii) to lead the global drug policy debate.

As a result of the final report of the Drug Policy Commission, the Colombian President approved and sanctioned Law 1787 of 2016 to regulate the use of cannabis for therapeutic purposes. The law marked a new direction in the legislative approach to drugs. Law 1787 amended articles 375, 376 and 377 of the Colombian Criminal Code (the "Criminal Code") to remove sanctions against the medical and scientific use of cannabis used under a license granted by the relevant authorities. This amendment was required given that the Criminal Code expressly provided a general prohibition to the cultivation, conservation or financing of marijuana plantations among other related activities.

The following table summarizes regulations applicable to the cultivation, fabrication, import, export and use of cannabis in Colombia.

Regulation:	Regulates:
Law 1787 of 2016	Legalizes the use of Cannabis for medical and scientific purposes
11 of Part 8 of Book 2 of Decree 780	Regulates law 1787 establishing a licensing system and process, defines psychoactive and non-psychoactive cannabis and the quota system for psychoactive cannabis in accordance with Single Convention of Narcotics of 1961 and amendments
Ministry of Justice, Ministry of Health	Regulates Decree 811 of 2021 in matters related to licenses, quotas and authorizations for the safe and informed access to the use of cannabis, cannabis plants, cannabis by-products and cannabis products.
Ministry of Justice, Ministry of Health and Ministry of Commerce, Industry	Regulates Decree 811 of 2021 in matters related to international commerce transactions with cannabis seeds, cannabis grain, cannabis vegetable component, cannabis plants, cannabis, cannabis by-products and cannabis related products.
Resolution 578 of 2017 from the Ministry of Justice	Regulates the cost of the following licences: Seed Use Cultivation of psychoactive plants (High-THC cultivation licence) Cultivation of non-psychoactive plants (Low-THC cultivation licence)
Resolution 2891 of 2017 from the Ministry of Health	Regulates the cost of the High-THC production licence.

Regulation:	Regulates:
Resolution 1478 of 2006 from the Ministry of Health	Regulation of the control, monitoring and surveillance of the import, export, processing, synthesis, manufacture, distribution, dispensing, purchase, sale, destruction and use of controlled substances, medicines or products containing them and on those which are State Monopoly
Resolution 315 of 2020 from the Ministry of Health	Updates the list of controlled substances, medicines or products containing them and of those which are State Monopoly, among other dispositions relating to the import, export, manufacture, distribution, dispensing, purchase, sale of these substances and products.
Decree 2200 of 2005 from the Ministry of Health	Regulates pharmaceutical services including the Magistral Preparations
Guidelines for the GPP certification for Magistral Preparations with Cannabis issued the 25 of October 2019 by INVIMA	Establishes the requirements for labs to obtain the GPP certification for the fabrication of Magistral Preparations with Cannabis derivatives
Resolution 3168 of 2015 from the Colombian Agricultural Institute	Regulates the production, import, export, sale and registration of seeds.

#### Licenses

The Ministries of Health, Justice, Defense, Commerce, and Agriculture issued Decree 811 of 2021 to define the licenses that may be granted in respect of permissible activities related to medicinal and industrial cannabis including but not limited to:

- (i) production of cannabis derivatives;
- (ii) planting of psychoactive cannabis plants; and
- (iii) planting of non-psychoactive cannabis plants.

SMGH has obtained licenses (collectively, the "Colombian Licenses") in each of the above categories, required to conduct its operations. The Colombian Licenses are not transferable, exchangeable or assignable and are valid for five years and may be renewed for an additional five-year term upon request and then for additional ten-year terms upon request. Each of the Colombian Licenses is in good standing and has not expired. None of the Colombian Licenses are subject to any current, pending, or threatened regulatory actions. Below is a table showing a general overview of the Colombian Licenses along with the government authority that grants them.

License Type	Status	Issued by	Key Requirements for Compliance, Maintenance, Renewal for all license types
License to cultivate plants of Non- Psychoactive Cannabis	Obtained	Ministry of Justice	Attending inspections;
License to cultivate plants of Psychoactive Cannabis	Obtained	Ministry of Justice	Reporting suspicious activity;  Keeping up-to-date records;

License to manufacture Cannabis Derivatives for a) national use, b) Scientific Research and c) export	Obtained	Ministry of Health	Amending license within 30 days of occurrence of certain fundamental changes;
Registration as a non-psychoactive and psychoactive cannabis plant breeding unit	Obtained	ICA	Filling import and export
Registration to Export non-psychoactive and psychoactive cannabis seeds	Obtained	ICA	declarations with the Ministry of Justice and FNE;
Registration to produce non-psychoactive and psychoactive cannabis seeds	Obtained	ICA	Compliance with security protocol;
Registration as a non-psychoactive and psychoactive cannabis plant agronomic evaluation unit	Obtained	ICA	Observing quotas; payment of applicable fees.

A detailed list of the Colombian Licenses held by SMGH which are required to conduct their respective operations in compliance with applicable laws, is included in the following tables.

# SMGH:

License Type	Status	Issued by
License to cultivate plants of Non- Psychoactive Cannabis for a) grain and seed production for sowing, b) cannabis derivatives manufacturing, c) industrial purposes and d) scientific purposes	Obtained	Res. 463 of 2018
License to cultivate plants of Psychoactive Cannabis for a) grain production, b) seed production for sowing, c) cannabis derivatives manufacturing, and d) scientific purposes	Obtained	Res. 973 of 2017, as amended by Res.472 of 2018
License to manufacture Cannabis Derivatives for a) national use, b) Scientific Research and c) export	Obtained	Res. 4282 of 2017, as amended by Res. 3466 of 2018
Registration as a non-psychoactive and psychoactive cannabis plant breeding unit	Obtained	Res. 30924 of 2018
Registration to Export non- psychoactive and psychoactive cannabis seeds	Obtained	Res. 63766 of 2020

License Type	Status	Issued by
Registration to produce non- psychoactive and psychoactive cannabis seeds	Obtained	Res. 31425 of 2018 as amended by Res. 7016 of 2019

#### Magistral Preparations with Cannabis

Avicanna LATAM produces a category of products known as magistral preparations with cannabis, regulated under Decree 811 of 2021 and Decree 2200 of 2005. Magistral preparations are customized prescription products that do not require a marketing authorization, as they are not mass-market products with standardized characteristics but must be prepared in a laboratory that is GPP Certified.

In order to sell and distribute such medicines in Colombia, it is necessary to comply with the Guidelines for the GPP certification for Magistral Preparations with Cannabis issued the 25 of October of 2019 by INVIMA. The Corporation is required to operate, or have an agreement with, a laboratory that is certified as complying with for GPP for Magistral Preparations with Cannabis. Avicanna LATAM has a laboratory that is GPP certified for magistral preparations with cannabis.

#### Quotas

Decree 811 of 2021, along with Resolution 227 of 2022 from the Ministry of Justice, Ministry of Health and Ministry of Agriculture and Rural Development, sets out the requirements and criteria for the assignment of quotas for psychoactive cannabis plant cultivation, and psychoactive cannabis by-product production. Psychoactive cannabis cultivation is subject to quotas that limit the number of plants that may be cultivated and psychoactive cannabis by-product production is subject to quotas that limit the amount of dry flower that the license holder's lab may receive and use to manufacture psychoactive cannabis by-products. Non-psychoactive cannabis is not subject to the quota system.

SMGH received commercial cultivation and by-product production quotas in 2020, 2021 and 2022.

#### Strain Registration

SMGH has 29 cannabis strains registered, and Sativa Nativa has 31 cannabis strains at various stages of the registration process. In order to secure quotas, a licensee's cannabis strains must undergo a defined registration process. Each strain, whether High- or Low-THC, must undergo agronomical evaluation by the Colombian Agricultural Institute (ICA). In order for strains be included in the National Registry of Cultivars, the following steps must be completed:

- (i) Agronomical Evaluation; and
- (ii) Strain Registration (legal document that includes the strain in the Colombian National Registry of Cultivars);

The following table shows SMGH's strains that have been registered with the ICA, each of which is formalized by a resolution signed by the ICA and such resolution is a public access document.

#### SMGH:

	Strain ID	Status
1	AV019	Registered
2	AV008	Registered
3	AV030	Registered
4	AV011	Registered
5	AV071	Registered
6	AV046	Registered
7	AV026	Registered
8	AV018	Registered
9	AV067	Registered
10	AV025	Registered
11	AV032	Registered
12	AV028	Registered
13	AV001	Registered
14	AV060	Registered
15	AV057	Registered
16	AV038	Registered
17	AV047	Registered
18	AV079	Registered
19	AV074	Registered
20	AV040	Registered
21	AV029	Registered
22	AV070	Registered
23	AV024	Registered
24	AV005	Registered
25	AV017	Registered
26	AV073	Registered
27	AV034	Registered
28	AV033	Registered

	Strain ID	Status
29	AV076	Registered

## Cosmetic Regulation

The Corporation's business also includes the manufacturing and commercialization of CBD-based cosmetics in Colombia. Cosmetic products in Colombia are regulated by decisions issued by the Andean Community of Nations. The relevant regulations in health regulatory matters for Cosmetic Products are the following:

- Decision 516 of 2002 and Decision 833 of 2018 of the Andean Community of Nations, which
  entered into effect in March 2021 and partially repealed Decision 516 of 2002, establish a common
  substantive regulation regarding Health Law for Cosmetic Products in the Andean Community
  countries (Bolivia, Colombia, Ecuador and Peru) and national norms that complement it (provided
  they do not contradict it or establish additional or contrary requirements)
- Decree 219 of 1998, which regulated the quality and monitoring of Cosmetic Products
- Law 9 of 1979, which establishes the general framework for health surveillance and control

In Colombia, cosmetics must undergo a registration process called Compulsory Sanitary Notification (NSO), which is overseen by INVIMA, prior to the commercialization. Applicable regulations establish requirements related to labeling, manufacturing facilities and composition of the products.

Ingredients in the list of accepted ingredients of the U.S. Food & Drug Administration ("FDA"), the Cosmetics Toiletry & Fragrance Association (CTFA), the European Cosmetic Toiletry and Perfumery Association (COLIPA) and the Directives of the European Union, are permitted in cosmetic products, including the following cannabis ingredients: Cannabis sativa Flower Extract, Cannabis sativa Flower / Leaf / Stem Extract, Cannabis Sativa Seed Extract, Cannabis Sativa Seed Oil Glycereth-8 Esters, Cannabis Sativa Seed Oil PEG-8 Esters, Cannabis Sativa Seedcake, Cannabis Sativa Seedcake Powder, Cannabis Sativa Stem Powder, Hydrolyzed Cannabis Sativa Seed Extract, Hydrolyzed Hemp Seed Extract, Apocynum Cannabinum Root Extract, and Cannabidiol.

Avicanna LATAM has obtained NSOs in respect of each of the ten products in its Pura H&W (formerly Pura Earth) cosmetic line. The NSOs are listed in the following table:

Product Name	NSO
CREMA ACLARANTE	NSOC86610-18CO
CREMA FACIAL ANTIEDAD	NSOC86608-18CO
CREMA CONTORNO DE OJOS	NSOC86599-18CO
CREMA EMOLIENTE INTENSIVA	NSOC866609-18CO
CREMA HUMECTANTE PARA PIEL CON IMPERFECCIONES	NSOC866600-18CO
LOCIÓN CORPORAL HUMECTANTE	NSOC86594-18CO
LOCIÓN FACIAL HUMECTANTE NOCHE	NSOC89512-18CO
LOCIÓN FACIAL HUMECTANTE	NSOC86606-18CO
SERUM REGENERADOR	NSOC89511-18CO
GEL CORPORAL REFRESCANTE	NSOC09287-21CO

## South Africa

The legislative framework which regulates cannabis and cannabis related products in South Africa primarily comprises the *Drugs and Drug Trafficking Act 140 of 1992* and the *Medicines and Related Substances Act 101 of 1965* ("**South Africa Medicines Act**").

The South Africa Medicines Act regulates medicines and scheduled substances. The South Africa Medicines Act defines a "medicine" as follows:

- "(a) any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in -
  - (i) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or
  - (ii) restoring, correcting or modifying any somatic or psychic or organic function in humans, and
- (b) includes any veterinary medicine".

A "scheduled substance" is defined by the South Africa Medicines Act as "any medicine or other substance prescribed by the Minister (of Health) under section 22A" and therefore includes both medicines and non-medicines listed in the schedules to the South Africa Medicines Act.

CBD is listed as a Schedule 4 substance to the South Africa Medicines Act (subject to certain exceptions). Any scheduled substance may only be manufactured, imported or exported and a person may only act as a wholesaler of or distribute a scheduled substance if that person has obtained a licence from the South African Health Products Regulatory Authority ("SAHPRA") in terms of section 22C of the South Africa Medicines Act. This section provides that the manufacturers, wholesalers and distributors may apply for such a licence.

Schedule 4 substances may only be sold by certain persons, including (i) pharmacists, who may only sell Schedule 4 substances on prescription; (ii) manufacturers of or wholesale dealers in pharmaceutical products, which may only sell Schedule 4 substances to a person who may lawfully possess such substances; (iii) medical practitioners and dentists and certain other practitioners, nurses and persons who are registered under the Health Professions Act, 1974; and (iv) veterinarians. A Schedule 4 substance may be possessed by a person who is in possession of a prescription issued by an authorised prescriber and by medical practitioners, dentists, veterinarians, practitioners, nurses or other persons registered under the Health Professions Act, 1974 and pharmacists.

If a Schedule 4 substance is sold for analytical purposes, manufacture of foods, cosmetics, educational or scientific purposes, it may only be sold by a pharmacist if a permit has been obtained from the Director-General for such purpose. See section 22A(7)(a) of the South Africa Medicines Act.

The classification of CBD and preparations and mixtures of CBD as Schedule 4 substances is subject to two exceptions.

The first exception is in terms of a notice published by the Minister of Health of South Africa on the recommendation of SAHPRA, in terms of section 36(1) of the South Africa Medicines Act, which excludes from Schedule 4 all preparations containing CBD that:

contain a maximum daily dose of 20 mg CBD and make only an accepted low risk claim or health claim which only refers to:

general health enhancement without any reference to specific diseases;

health maintenance; or

relief of minor symptoms (not related to a disease or disorder); or

consist of processed products made from cannabis raw plant material and processed products, where only the naturally occurring cannabinoids found in the source material are contained in the product, and which contain no more than 0,001% THC and not more than 0,0075% total CBD. [Government Notice No. R756, Government Gazette No. 42477.]

The second exception is in terms of the following provision in Schedule 4:

"All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for: industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and analytical laboratory purposes."

"Medicinal purpose" is defined for purposes of section 22A of the South Africa Medicines Act as:

"for the purposes of the <u>treatment or prevention of a disease</u> or some other <u>definite curative or therapeutic purpose</u>, but does not include the satisfaction or relief of a habit or craving for the substance used or for any other such substance, except where the substance is administered or used in a hospital or similar institution maintained wholly or partly by the Government or a provincial government or approved for such purpose by the Minister".

A product containing CBD, which would otherwise be a Schedule 4 substance, is therefore excluded from the requirements in the Medicines Act if it:

- contains less than a maximum daily dose of 20 mg of CBD and only makes the permitted low risk claims or health claims as set out above;
- consists of processed products that contain only the naturally occurring quantity of cannabinoids found in the source material and contain THC and/or CBD that does not exceed the prescribed thresholds as set out above; or
- is specifically packed, labelled, sold and used for (i) industrial purposes, including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose; and (ii) analytical laboratory purposes.

# **United Kingdom**

Pure CBD is not considered a controlled drug in the UK.

The Misuse of Drugs Act 1971 (the "MDA") defines the following as controlled drugs in relation to cannabis:

- (i) CBN;
- (ii) "Cannabinol derivatives" (defined as meaning the following substances, except where contained in cannabis or cannabis resin, namely tetrahydro derivatives of cannabinol (such as THC) and 3-alkyl homologues of cannabinol or of its tetrahydro derivatives);
- (iii) "Cannabis" (defined as meaning any plant of the genus Cannabis but excluding the mature stalk of any such plant, fibre produced from mature stalk of any such plant, or the seed of any such plant after separation from the rest of the plant);
- (iv) "Cannabis resin";
- (v) any "esther or ether or cannabinol or of a cannabinol derivative";
- (vi) any salt of any of these substances; and
- (vii) any "preparation or product" containing these substances (unless it falls within a narrow exception).

The UK Home Office has determined that CBD as an isolated substance, in its pure form, is not a controlled drug for the purposes of the MDA. Pure CBD is not a controlled drug under the MDA. Consequently, the sale, possession and import of products containing CBD are not restricted as a result of their CBD content. However, since it is very difficult to isolate pure CBD, the Home Office has issued caution against CBD products which may unintentionally include other cannabinoids such as CBN or THC, being substances which remain controlled drugs under the MDA. Products containing CBD or other non-controlled cannabinoids may however be regulated from a food or cosmetics regulations perspective (see further below).

There is an exception for products that contain less than 1 milligram of a controlled drug, where the controlled drug element is not readily recoverable and where the product is not designed for the administration of the controlled drug to a person. The Corporation is aware of CBD products containing trace amounts of controlled drugs being sold by reputable retailers in the UK, presumably pursuant to this exception (although it is not clear).

An exempt product is not subject to the restrictions on the import, production, sale or possession imposed on controlled drugs by the MDA. An exempt product is defined in accordance with a three-step test under the Misuse of Drugs Regulations 2001 (the "MDR") where:

- (i) the product is not designed for administration of the controlled drug to a human being or animal (it is understood that the primary object or purpose of the product is not intended to be the administration of a controlled drug, such that the controlled drug is incidental to the product);
- (ii) the controlled drug in any component part is packaged in such a form, or in combination with other active or inert substances in such a manner, that it cannot be recovered by readily applicable means or in a yield which constitutes a risk to health; and
- (iii) no one component part of the product or preparation contains more than one milligram of the controlled drug or one microgram in the case of lysergide or any other N-alkyl derivative of lysergamide.

The EU cosmetic products regulation prohibits the use of narcotics, both in natural and synthetic forms: all substances listed in Tables I and II of the Single Convention on Narcotic Drugs signed in New York on 30 March 1961 (the "1961 Convention") are prohibited from use in cosmetics. However, the 1961 Convention does not specifically list CBD as a separately prohibited controlled substance and it uses a narrow definition of cannabis which is limited to mean "the flowering or fruiting tops of the cannabis plant (excluding the seeds and leaves when not accompanied by the tops) from which the resin has not been extracted, by whatever name they may be designated". Therefore, CBD extracted from cannabis, cannabis resin, cannabis extracts and cannabis tinctures originating from the seeds and leaves that are not accompanied with the fruiting tops of the cannabis plant CBD may be used in cosmetics.

For the import and distribution in the UK of any product that contains THC, requires the importer to obtain a controlled drug import licence from the UK Home Office (as well as the corresponding export licence from the country of export) and a domestic licence to supply and possess any product that contains THC.

To supply CBPMs, these products will need to be prescribed as an unlicensed medicine under the "specials" medicines route. There are two other routes through which CBPMs can be used in the UK: (i) investigational medicinal product route (authorisation required from the MHRA, whereby MHRA expects that documentary evidence that the requested supply is for clinical need that cannot be met by an unlicensed medicine be obtained by manufacturers, importers or distributors and that this evidence should be made available on request of the Licensing Authority); or (ii) the Marketing Authorisation route ("MA") (where the MA is issued based on quality, efficacy and safety criteria to a product), which do not apply to the Corporation.

Any prescriptions for unlicensed CBPMs to patients in England would need to be made by doctors who are on the GMC Specialist Register. The unlicensed CBPMs will only be supplied if:

- (i) there is an unsolicited order from a Specialist doctor;
- (ii) the Importer must have a Home Office Import and Domestic Licence. The wholesaler / manufacturer must have a Home Office Domestic Licence and MHRA Wholesaler Dealer's Licence or Manufacturer's (Specials) Licence for possession and supply of unlicensed CBPMs;
- (iii) the product is manufactured and assembled in accordance with the specification of a person who is a doctor on the GMC Specialist Register, responsible for the patient's care;
- (iv) the product is for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient that cannot be met by existing licensed medicines; and
- (v) the product is manufactured and supplied under specific conditions.

The sale of unlicensed medicines is subject to a general prohibition which provides that a person may not sell or supply, or offer to sell or supply, an unauthorised medicinal product in the UK unless that person has a marketing authorisation, under Regulation 46 of the Human Medicines Regulations. One of the exemptions to this prohibition is where the clinical needs of a patient cannot be met by products with a marketing authorisation available in the UK, and where an unlicensed medicine is prescribed on a "individual patient" basis.

Pursuant to Regulation 167 of the Human Medicines Regulations, the requirement for a marketing authorisation under Regulation 46 above does not apply if:

(i) the medicinal product is supplied in response to an unsolicited order;

- (ii) the medicinal product is manufactured and assembled in accordance with the specification of a person who is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber;
- (iii) the medicinal product is for use by a patient for whose treatment that person is directly responsible in order to fulfil the special needs of that patient; and
- (iv) a number of conditions (set out as conditions A to G in Regulation 167 are met).

The conditions under Regulation 167 set out as A to G cover a number of requirements such as ensuring that the unlicensed medicines are supplied to suitable health care professionals ("**HCPs**") or that the manufacture of the medicines is carried to the specification of the HCPs amongst others.

Condition B of Regulation 167 of the Human Medicines Regulations 2012 states that no advertisement relating to the medicinal product can published by any person. This means that the advertising of unlicensed CBPMs, to the members of the public, is prohibited. A specials manufacturer, importer or wholesaler may advertise the services they provide, but the particulars of specials medicines must not be advertised. However, they may provide factual responses upon requests for specific specials or the range of products they are able to supply.

### Australia

Importation of medicinal cannabis products

Pursuant to regulation 5 of the Customs (Prohibited Imports) Regulations 1956 (Cth), cannabis (including extracts and tinctures of cannabis), cannabis resin, and cannabinoids, and products containing such ingredients, that are not Approved Products (as defined therein), cannot be imported into Australia unless they are for medicinal or scientific research (i.e. clinical trial) purposes.

In light of this, apart from the Approved Products, generally the only cannabis-based products that are currently permitted to be imported into Australia, subject to the licensing requirements discussed below, are medicinal cannabis products (which include cannabis ingredients used to manufacture medicinal cannabis products).

Pursuant to section 4 of the *Narcotic Drugs Act 1967* (Cth) ("**ND Act**"), a medicinal cannabis product means a product, including but not limited to a substance, composition, preparation or mixture, that:

- (a) includes, or is from, any part of the cannabis plant; and
- (b) is for use for the purposes of curing, or alleviating the symptoms of, a disease, ailment or injury.

Medicinal cannabis products are subject to additional regulation by:

- (a) the Office of Drug Control ("**ODC**") of the Australian Department of Health, in relation to the importation and manufacture of medicinal cannabis products, discussed further below; and
- (b) the Therapeutic Goods Administration ("**TGA**") in relation to the supply of medicinal cannabis products, which is also discussed further below.

In order to import medicinal cannabis products into Australia, the importer must hold:

- (a) a licence to import to import narcotic, psychotropic and precursor substances (for the purposes of this section, a "**Licence**"); and
- (b) a permission to import each consignment of each specific product (for the purposes of this section, a "**Permit**:),

and must comply with any conditions of the Licence and Permit.

In relation to the Licence, an application for the Licence must be made in writing to the Secretary of the Australian Department of Health ("**Secretary**") by the proposed importer, in the approved form. Licences are issued for a 12 month period.

The Secretary will not grant a Licence unless the applicant has provided all requested information to the Secretary, the applicant, and any agents or employees thereof are fit and proper persons to be granted the Licence, and the premises on which the applicant proposes to keep the drugs meet the security requirements for that purpose.

Once a Licence is granted, certain requirements must be complied with including:

- (a) keeping in safe custody at all times any drug that is in the possession of the Licence holder and if the drug is moved from one place to another, taking adequate precautions to ensure that the removal is safely carried out:
- (b) taking reasonable precautions for the purpose of ensuring that there is no danger of loss or theft of any drug in the possession of the Licence holder:
- (c) not supplying any medicinal cannabis products unless satisfied that the product will be used solely for medical or scientific purposes; and
- (d) keeping records including about the name and quantity of each drug in the Licence holder's possession, and the quantity of each drug supplied by the Licence holder, and information about the person to whom the drug was supplied.

An application for each Permit must be made in writing to the Secretary by the proposed importer, in the approved form.

The Secretary will not grant a Permit unless the applicant has provided all requested information to the Secretary and has made proper arrangements for the safe transportation and custody of the products; and

- (a) if the product is required for the manufacture of a drug at certain premises
  - (i) the applicant is a holder of a manufacturer's licence in relation to the manufacture of the drug at those premises pursuant to requirements of the ND Act, which is administered by the ODC (ND Manufacturer's Licence); and
  - (ii) if, under a law of the State or Territory in which those premises are situated, the manufacture of the drug is prohibited unless a licence to manufacture the drug has been granted under that law, the applicant is, for the purposes of that law, the holder of a licence authorising the applicant to manufacture the drug at those premises (State/Territory-based Manufacturer's Licence); or
- (b) if the product is required for the purposes of the applicant's business as a seller or supplier
  - (i) the applicant is, under a law of the State or Territory in which the premises at or from which the applicant conducts that business are situated, the holder of a licence authorising the applicant to sell or supply the product at or from those premises (<u>State/Territory-based Supplier's Licence</u>); or
- (c) otherwise, the product is required by the applicant for medical or scientific purposes.

A Permit will specify the quantity of the product the holder may import as well as any other conditions or requirements, including with respect to possession, safe custody, transportation, use or disposal of the product to be complied with by the holder of the Permission.

Any medicinal cannabis products that are imported into Australia may only be supplied in Australia in accordance with one of the ways discussed in the section below.

Distribution of medicinal cannabis products

As noted above, the supply of medicinal cannabis products (being therapeutic goods) in Australia is regulated by the TGA.

Pursuant to the *Therapeutic Goods Act 1989* (Cth) ("**TG Act**"), it is an offence to supply therapeutic goods in Australia unless the goods are included in the Australian Register of Therapeutic Goods ("**ARTG**"), are exempt from being included in the ARTG, or are otherwise authorised by the TGA.

Therefore, medicinal cannabis products can only be supplied to patients in Australia in one of the following ways:

- (a) following inclusion of the particular medicinal cannabis product in the ARTG this requires a sponsor to submit an application to the TGA which includes data as to the quality, safety, efficacy and performance of the product and its intended use; or
- (b) under the TGA's Special Access Scheme ("SAS") a medical practitioner may use one of the following two SAS Categories to access an unapproved medicinal cannabis product for an individual patient:
  - (i) SAS Category A: a prescribing medical practitioner (a medical doctor) or a health practitioner on behalf of a prescribing medical practitioner (e.g. a nurse practitioner or pharmacist) may, with notification to the TGA, supply unapproved medicinal cannabis products to a "Category A patient", being a person who is seriously ill with a condition from which death is reasonably likely to occur within a matter of months, or from which premature death is reasonably likely to occur in the absence of early treatment; or
  - (ii) SAS Category B: if a patient is not a "Category A patient", a health practitioner may nevertheless make an application to the TGA for approval to supply unapproved medicinal cannabis products to the patient (which requires a thorough clinical justification for the use of the product, including the seriousness of the condition, details of previous treatment and reasons why a currently approved therapeutic good cannot be used for the treatment of the individual patient in the particular circumstance); or
- (c) under the TGA's Authorised Prescriber Scheme a medical practitioner may apply to the TGA to become an "Authorised Prescriber" of unapproved medicinal cannabis products so that the medical practitioner may prescribe the products to a class (or classes) of recipients with a particular medical condition; or
- (d) through a clinical trial involving the medicinal cannabis product.

Depending on the Australian state(s) and/or Territory(ies) in which the importer of medicinal cannabis products (that are prescribed in any of the ways discussed above) operates, relevant State or Territory-based Supplier's Licence(s) (to the extent applicable) will also need to be obtained.

In addition, if the laws of the State or Territory where a medical practitioner who prescribes medicinal cannabis products is located, require the practitioner to obtain approval or authorisation from that State's or Territory's Department of Health to prescribe and supply medicinal cannabis products, such approval or authorisation is required to be obtained. In this regard, since April 2018, a 'single-in' application process has been developed through which practitioners can notify or apply to both the TGA and the relevant State's or Territory's Department of Health (where applicable) to prescribe and supply medicinal cannabis products.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> See https://www.tga.gov.au/special-access-scheme-and-authorised-prescriber-online-system.

### **United States of America**

### General Overview

The following overview is subject to and qualified by the more detailed descriptions in the following sections entitled "United States Federal Regulation of Hemp", "State Regulation of Hemp", "FDA Regulation", "Future Uncertainty of Legal Status" and "The Corporation's Regulatory Compliance Activities".

While both Hemp and marijuana come from the same plant genus and species, Cannabis sativa L., Hemp and marijuana are legally distinct and are generally regulated in the United States, respectively, by separate overarching bodies of law, namely the 2018 Farm Bill and the U.S. Controlled Substances Act (21 U.S.C. § 802(16), et. seq.) (the "CSA") . Pursuant to the 2018 Farm Bill, Hemp is defined as the plant Cannabis sativa L. and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis. Thus Hemp, by legal definition, contains insufficient levels of THC to create an intoxicating effect as compared to marijuana.

The 2018 Farm Bill removed Hemp, and the THC in Hemp, from the purview of the CSA. Hemp is now deemed a legal agricultural commodity in the United States, and is no longer classified as a controlled substance. Accordingly, the U.S. Drug Enforcement Administration ("**DEA**") no longer has any claim to interfere with the interstate commerce of Hemp products, so long as the delta-9 THC level is no more than 0.3% on a dry weight basis.

The 2018 Farm Bill also provides that state and Native American tribal governments may impose separate restrictions or requirements on Hemp growth. However, individual states cannot interfere with the interstate transportation or shipment of lawfully produced Hemp or Hemp products.

However, states take varying and inconsistent approaches to regulating the production and sale of Hemp and Hemp- derived CBD products. In some cases, states may remain silent on the issue. While some states explicitly authorize and regulate the production of Hemp and the sale of Hemp-derived CBD products, or otherwise provide legal protection for authorized individuals to engage in commercial Hemp activities, other states may have implemented state-specific laws, regulations, or policies prohibiting Hemp production and/or the sale of Hemp-derived CBD products, or otherwise maintain outdated laws that do not distinguish between marijuana and Hemp. In some states, the sale of CBD, notwithstanding its origin from Hemp or marijuana, is either restricted to state medical or adult-use marijuana program licencees or remains otherwise unlawful under state laws. Additionally, a number of states prohibit the sale of ingestible CBD products based on the FDA's position that, pursuant to the FDCA, it is unlawful to introduce food containing added CBD or THC into interstate commerce, or to market CBD or THC products as, or in, dietary supplements, regardless of whether the substances are Hemp-derived.

The FDA regulates consumable products and the 2018 Farm Bill explicitly preserved FDA's authority over Hemp products. Based on FDA commentary and actions to date, the industry assumption is that consumable Hemp CBD products will similarly be regulated by FDA to ensure that the products are not adulterated or misbranded. While FDA has yet to implement a formal regulatory scheme for Hemp products, the FDA is actively working to implement a regulatory pathway for these products. Through its efforts, and as reiterated by FDA Commissioner Dr. Stephen M. Hahn as recently as March 5, 2020, the FDA is in the process of reviewing safety considerations, engaging with industry stakeholders, assessing appropriate enforcement discretion options and seeking public feedback in re-opening the public docket to obtain additional scientific data on CBD. These actions reinforce that the FDA is actively working to find a solution and place on the market for Hemp products, and likely considering Hemp CBD products in the category of dietary supplements for purposes of labeling and marketing. The solution may include notice and-comment rulemaking and an interim risk-based enforcement policy while the FDA potentially engages in this process.

In the interim, as this process develops, certain U.S. government agencies (such as the FDA) and certain U.S. federal officials have challenged the scope of permissible commercial activity. FDA representatives, for example, have stated they believe that producers of CBD-based products produce and sell their products in violation of the FDCA at this time.

The FDA also continues to enforce against violations of the FDCA by issuing warning letters to companies marketing and selling Hemp-derived CBD products as unapproved drugs. Notably, on November 25, 2019, the FDA issued warning letters to companies marketing and selling Hemp derived CBD products deemed unapproved drugs. The letters reiterate the FDA's position that CBD cannot be added to food and dietary supplements. As indicated by the FDA's March 5, 2020 statement and Congressional report, the FDA continues to actively evaluate a risk-based enforcement policy and rulemaking to permit the use of CBD in dietary supplements. Important to note is that these warning letters have been issued, for the most part, to companies making aggressive disease and/or health claims about their CBD products and the ability for those products to prevent, treat, or cure diseases and conditions such as Alzheimer's, seizures, and depression.

Legal barriers applicable to, and risks associated with, selling Hemp and Hemp-derived CBD products result from a number of evolving factors to include the activities and interpretations of the FDA and the patchwork of state laws. Stakeholders take different positions regarding the scope of legal activity in light of the interplay of U.S. federal and state law, and in light of recent developments, such as the removal of Hemp and its extracts, including CBD, from the CSA pursuant to the 2018 Farm Bill, the FDA's pending draft guidance<sup>2</sup> on CBD products that may establish a new regulatory framework allowing for certain Hemp-derived ingredients in foods and supplements, and H.R. 8179 (which, if passed, would legalize the use of hemp, CBD, and other hemp derivatives as a dietary ingredient in dietary supplements), the September 30, 2017 decision of the World Anti-Doping Agency to drop CBD from its list of prohibited substances, and the World Health Organization Expert Committee on Drug Dependence preliminary report finding that CBD is safe, well-tolerated, and not associated with abuse potential.<sup>3</sup>

United States Federal Regulation of Hemp

# **Development of Current Regulatory Framework Summary**

In addition to customary regulations applicable to any commercial business, the Corporation's operations are subject to state and federal regulation in the United States with respect to the production, distribution and sale of Hemp products intended for human ingestion or topical application and, with respect to certain products, by animals.

Hemp is an agricultural commodity cultivated for use in the production of a wide range of products globally. Among others, hemp is used in the agriculture, textile, recycling, automotive, furniture, food and beverage, paper, construction materials and personal care industries.

Numerous unique, chemical compounds are extractable from Hemp, including THC and CBD. Hemp, as defined in the 2018 Farm Bill, is distinguishable from marijuana, due to the absence of more than trace amounts (i.e. no more than 0.3%) of the intoxicating compound THC.

Hemp was widely grown in the U.S. as an agricultural commodity from the colonial period into the early 1900s and was commonly used in the manufacture of paper, fabrics, and other products. By 1970, however, the CSA explicitly prohibited the cultivation of any variety of Cannabis without a DEA permit.

 $^2$  On July 22, 2020, FDA submitted a draft guidance titled "Cannabidiol Enforcement Policy; Draft Guidance for Industry," to the White House Office of Management and Budget for review.

<sup>&</sup>lt;sup>3</sup> World Health Organization Expert Committee on Drug Dependence, Cannabidiol (CBD) Pre-Review Report, November 10, 2017, https://www.who.int/medicines/access/controlled-substances/5.2\_CBD.pdf.

Per the plain language of the CSA, only certain parts of the Cannabis plant (generally, what was historically considered to be the intoxicating portions of the plant) are controlled and defined as marijuana, while other parts of the Cannabis plant (now inclusive of Hemp) are exempted from CSA control. Consumer goods containing hemp seeds or "hemp hearts," for example, have long been lawfully imported into the U.S. and legally sold in commerce due to the fact that the sterilized seeds are clearly exempt from the definition of marijuana under the CSA and are not otherwise controlled substances. Nonetheless, from the enactment of the CSA until the passage of the 2014 Farm Bill, cultivating hemp for any purpose in the U.S. without a DEA registration was federally illegal. The 2014 Farm Bill loosened the federal prohibition on the domestic production of hemp, by allowing hemp to be cultivated within the context of an agricultural pilot program and where permitted by state law. On December 20, 2018, the 2018 Farm Bill became law. The 2018 Farm Bill also allows farmers to access crop insurance and fully participate in United States Department of Agriculture ("USDA") programs for certification and competitive grants. State and tribal governments may impose separate restrictions or requirements on Hemp production, but they cannot interfere with the interstate transport of lawfully produced Hemp or Hemp products.

#### The 2014 Farm Bill

On February 7, 2014, the 2014 Farm Bill was signed into law. The 2014 Farm Bill authorizes institutions of higher education and state departments of agriculture to cultivate hemp, notwithstanding the CSA or any other federal law, provided that certain conditions are met. The scope of the 2014 Farm Bill is limited to cultivation that is: (a) for research purposes (inclusive of market research); (b) part of an "agricultural pilot program" or other agricultural or academic research; and (c) permitted by state law.

The various state Hemp programs have different requirements regarding the registration of cultivators and processors, the involvement of institutions of higher education, and permissible commercialization. The 2014 Farm Bill does not provide a federal regulatory framework or require states to adopt and implement hemp cultivation programs. As a result, participating states take differing approaches with respect to the activities permitted under their respective pilot programs.

Activities determined to be compliant with the 2014 Farm Bill are protected from federal interference by the Appropriations Rider. The Appropriations Rider generally prohibits the DOJ or DEA's use of funds in contravention of the 2014 Farm Bill. Activities determined to be outside the scope of the 2014 Farm Bill are not protected by the Appropriations Rider and may be subject to federal enforcement action. The Appropriations Rider has been renewed on several occasions.

Rather than distinguishing between "hemp" and "marijuana" based on the part of the plant from which a product is derived, the 2014 Farm Bill definition includes all parts of the cannabis plant, and distinguishes Hemp from marijuana on the basis of the concentration of THC. Any plants that exceed the 0.3% THC threshold are considered marijuana (a Schedule I controlled substance), and thus are not compliant with the 2014 Farm Bill. Notwithstanding the passage of the 2018 Farm Bill and the publication of the IFR, the Hemp cultivation and research provisions contained in the 2014 Farm Bill remain in effect for the immediate future. It is anticipated that many states will rely on their existing pilot program regimes in submitting a 2018 Farm Bill plan to assume primary regulatory authority over Hemp production. Because the 2018 Farm Bill permits states and Native American tribes to regulate the production of Hemp more restrictively than the 2014 Farm Bill, variances in these jurisdictions' laws and regulations on Hemp are likely to persist. Compliance with state law remains imperative under both the 2014 and 2018 Farm Bills.

# FDA Approval of Epidiolex

On June 25, 2018, the FDA issued to GW Pharmaceuticals plc its approval for Epidiolex, the first Cannabisderived prescription medicine to be available in the U.S. The active ingredient in Epidiolex is CBD isolate derived from Marijuana-based plants.

### The 2018 Farm Bill

The 2018 Farm Bill became law on December 20, 2018. Prior to this law, all non-exempt Cannabis parts grown in the United States were scheduled as a controlled substance under the CSA, and as a result, the cultivation of Hemp for any purpose in the United States without a Schedule I registration with the DEA was, unless exempted by the 2014 Farm Bill, illegal. The passage of the 2018 Farm Bill materially changed U.S. federal laws governing Hemp by removing Hemp from the CSA and establishing a federal regulatory framework for Hemp production. Specifically, the 2018 Farm Bill: (a) explicitly amended the CSA to exclude all parts of the cannabis plant (including its cannabinoids, derivatives, and extracts) containing a THC concentration of not more than 0.3% on a dry weight basis from the definition of marijuana; (b) allows the commercial production and sale of Hemp in interstate commerce; (c) establishes the USDA as the primary federal agency regulating the cultivation of Hemp in the United States, while allowing states to adopt their own plans to regulate Hemp cultivation; and (d) affords farmers the opportunity to obtain crop insurance and research grants.

The 2018 Farm Bill also creates a specific exemption from the CSA for THC found in Hemp. By defining Hemp to include its "cannabinoids, derivatives, and extracts," popular Hemp products, such as Hemp-derived CBD, are no longer subject to DEA control. Accordingly, the DEA no longer has regulatory authority to interfere with the interstate commerce of Hemp products, so long as the THC level of such products is no more than 0.3%. Although the DEA no longer regulates Hemp, marijuana continues to be classified as a Schedule I controlled substance under the CSA. As a result, CBD and other cannabinoids, including, without limitation, CBG, if derived from marijuana as defined by the CSA, also remain Schedule I controlled substances under U.S. federal law. Though chemically and genetically distinct, Hemp and marijuana appear similar to the naked eye. The active enforcement against illegal marijuana and marijuana-based products under current federal law may inadvertently result in enforcement actions taken against Hemp or Hemp-derived products.

The 2018 Farm Bill amends the Agricultural Marketing Act of 1946 to categorize Hemp as an agricultural commodity under the regulatory purview of the USDA in coordination with state departments of agriculture. Although the USDA will be the primary federal regulatory agency overseeing Hemp production in the United States, states, U.S. territories, and Indian tribes desiring to obtain (or retain) primary regulatory authority over Hemp production activities within their borders are allowed to do so after submitting a plan for regulation to the USDA, and receiving approval from the USDA for the same. Pursuant to the 2018 Farm Bill, states, U.S. territories, and Tribal governments can adopt their own regulatory plans for hemp production, even if more restrictive than federal regulations, so long as the plans meet minimum federal standards and are approved by the USDA. Hemp production in states and tribal territories that choose not to submit their own plans (and that do not prohibit hemp production) will be governed by USDA regulation.

On October 31, 2019, the USDA released the IFR, which governs the domestic production of Hemp under the 2018 Farm Bill. The IFR also specifies the provisions that a state or tribal Hemp plan must contain to be in compliance with the 2018 Farm Bill. Since the IFR became effective, the USDA has been reviewing Hemp production plans submitted by state and tribal governments. Once USDA formally receives a plan, the agency will have 60 days to review and approve or disapprove the plan.<sup>4</sup>

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<sup>&</sup>lt;sup>4</sup> The status of the USDA's review of plans, including which states have USDA-approved hemp plans, is available at https://www.ams.usda.gov/rules-regulations/hemp/state-and-tribal-plan-review.

As noted above, U.S. state and tribal governments may impose separate restrictions or requirements on Hemp cultivation and the sale of Hemp products; however, states may not interfere with the interstate transportation or shipment of lawfully produced Hemp or Hemp products. This was confirmed in a May 2019 memorandum released by the USDA's Office of General Counsel. That memorandum reiterates that, due to enactment of the 2018 Farm Bill, states and Native American tribes may not prohibit the interstate transportation or shipment of hemp lawfully produced under the 2014 or 2018 Farm Bills. Notwithstanding the passage of the 2018 Farm Bill and the publication of the IFR, the hemp cultivation and research provisions contained in the 2014 Farm Bill remain in effect for the immediate future and will be repealed on or about November 1, 2021. The IFR will be effective from October 31, 2019 through November 1, 2021, at which time the USDA will adopt permanent regulations.

Important to note is that the 2018 Farm Bill preserves the authority and jurisdiction of the FDA, under the FDCA, to regulate the manufacture, marketing, and sale of food, drugs, dietary supplements, and cosmetics, including products that contain Hemp extracts and derivatives, such as CBD. As a result, the FDCA will apply to Hemp-derived food, drugs, dietary supplements, and cosmetics introduced, or prepared for introduction, into interstate commerce.

On March 5, 2020, FDA Commissioner Dr. Stephen M. Hahn issued a statement on the FDA's ongoing work related to CBD products. The statement makes clear that the FDA will continue its work to educate the public on CBD's perceived safety risks and that the FDA is taking steps to solicit additional public feedback, data, and research on the science, safety, and quality of CBD products. These new steps include re-opening the public docket so that FDA can obtain additional scientific data on CBD, which will include a process by which confidential and proprietary information can be shared with the FDA and kept protected. Additionally, Commissioner Hahn's statement reiterates that the FDA will continue to monitor and police the CBD products marketplace and is evaluating the issuance of a risk-based enforcement policy that provides greater transparency and clarity regarding factors the FDA intends to consider in prioritizing enforcement decisions.

Much of Commissioner Hahn's statement was also included in the FDA's congressionally mandated report on CBD, which was also submitted on March 5, 2020. Importantly, the report confirms that the FDA is actively considering pathways to allow the marketing of CBD as a dietary supplement, which may include a notice and-comment rulemaking and an interim risk-based enforcement policy while the FDA potentially engages in this process. The

report signals the FDA's continued interest in certain questions about CBD, including effects from sustained use, effects from different methods of exposure, and effects on the developing brain and on the unborn child and breastfed newborn. The report acknowledges that the FDA is receiving inquiries about whether "full spectrum" and "broad spectrum" Hemp products can currently be marketed and sold, but the FDA has not yet answered the question conclusively. Largely, the report does little to address the current regulatory ambiguity for CBD and does not set a timeline for agency action, but it does signal the FDA's clear interest in a pathway for the use of CBD in dietary supplements. Further to this point, Commissioner Hahn has publicly stated that it would be a "fool's game" for the FDA to pull CBD products from the market entirely, as their use is already widespread.<sup>6</sup>

In addition, under the 2018 Farm Bill, CBG, which has a THC level of less than 0.3%, can also be lawfully produced and extracted from hemp. Unlike CBD however, CBG has not been approved as a drug, and the FDA itself has acknowledged that "parts of the cannabis plant that do not contain THC or CBD might fall

<sup>5</sup> Congress recently approved an appropriations measure that includes language extending state hemp pilot programs authorized under the 2014 Farm Bill. See https://www.hempgrower.com/article/congress-passes-hemp-pilot-program-extension/.

<sup>&</sup>lt;sup>6</sup> See Hank Schultz, FDA Chief Hahn says it would be 'fool's game' to try to shut down CBD markets, NUTRA (Feb. 28, 2020), https://www.nutraingredients-usa.com/Article/2020/02/28/FDA-chief-Hahn-says-it-would-be-fool-s-game-to-try-to-shut-down-CBD-markets.

outside the scope of the [drug exclusion rule]." If CBG is approved as a drug at some point in the future, it also seems likely that the drug exclusion rule would not apply given that the rule contains an exception for substances marketed as foods or dietary supplements prior to any FDA clinical investigation. At present, CBG products are being widely marketed as foods and dietary supplements. Further, CBG is not listed on the schedules set out in the U.N. Single Convention on Narcotic Drugs of 1961 and does not appear to be controlled by any other international treaty. This means that countries are not required to control CBG.

## State Regulation of Hemp

Under both the 2014 and the 2018 Farm Bills, states retain significant discretion and authority to adopt their own regulatory regimes governing hemp production. As a result, the 50 U.S. states have taken varied approaches to the regulation of hemp-derived CBD. A few states, including Idaho, have taken a restrictive approach to Hemp-derived CBD products generally, and states including California, Maryland, Massachusetts, North Carolina and Washington State have laws, regulations, or guidance that prohibits the sale of CBD food products. However, enforcement has been inconsistent, and legislation to overcome these restrictions is actively being considered in some of these states. A growing number of states including Alaska, Colorado, Florida, Indiana, Ohio, Oregon, Texas, Utah, Virginia and West Virginia, have passed laws that: 1) explicitly exempt Hemp extracts such as CBD from legal prohibitions normally incurred by controlled substances such as marijuana, and 2) establish frameworks to expressly permit the sale of Hemp-derived CBD products, including ingestible products. It is the Corporation's position that where state law is silent on the subject of hemp-derived CBD's legality, U.S. federal law provides protection, particularly in those states that have adopted legislation that explicitly exempt from control of those products and substances that are exempted by federal law.

The varying regulations with respect to the treatment of Hemp from state to state continue to evolve. The FDCA governs, among other things, food and drugs in the United States. One purpose of the FDCA is to forbid the movement in interstate commerce of adulterated and misbranded food, drugs, medical devices and cosmetics. The FDA is charged with protecting the integrity of the U.S. food supply and its cosmetic products, as well as monitoring the safety and efficacy of drugs, biological products, and almost any compound intended for human or animal consumption, among other areas. To date, the FDA has approved one drug (Epidiolex) containing CBD as an active ingredient, and has taken the position that CBD cannot be marketed as a dietary supplement or added to food because a product containing CBD was approved as a drug and substantial clinical trials studying CBD as a new drug were made public prior to the marketing of any food or dietary supplements containing CBD, and therefore dietary supplements or food are precluded from containing this ingredient (such restrictions referred to as "**Prior Drug Exclusion**"). This creates additional barriers to lawfully selling certain CBD and CBD-based products in the U.S.

Notably, the FDA does not impose the same restrictions on the use of CBD in cosmetic products. The FDA states on its website that "[c]ertain cosmetic ingredients are prohibited or restricted by regulation, but currently that is not the case for any cannabis or cannabis-derived ingredients.<sup>9</sup> However the FDA further notes that such cosmetic products must comply with all applicable legal requirements, including the adulteration and misbranding provisions of the FDCA specific to cosmetic products.

The Dietary Supplement Health and Education Act of 1994 ("**DSHEA**"), an amendment to the federal FDCA, established a framework governing the composition, safety, labeling, manufacturing and marketing of dietary supplements in the United States. Generally, under DSHEA, dietary ingredients marketed in the United States prior to October 15, 1994 may be used in dietary supplements without notifying the FDA.

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<sup>&</sup>lt;sup>7</sup> Ky. Rev. Stat. §§ 260.850-.858.

<sup>&</sup>lt;sup>8</sup> U.S. Food and Drug Administration, Mission Statement: https://www.fda.gov/ about-fda/what-we-do#mission.

<sup>&</sup>lt;sup>9</sup> U.S. Food and Drug Administration, "FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidol (CBD), Questions and Answers," https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including- cannabidol-cbd#qandas.

"New" dietary ingredients (i.e. dietary ingredients "not marketed in the United States before October 15, 1994") must be the subject of a new dietary ingredient notification submitted to the FDA unless the ingredient has been "present in the food supply as an article used for food" and is not "chemically altered". Any new dietary ingredient notification must provide the FDA with evidence of a "history of use or other evidence of safety" establishing that use of the dietary ingredient "will reasonably be expected to be safe". To date, the FDA has taken the position that CBD was not marketed in the United States before October 15, 1994 and as such would be considered a new dietary ingredient subject to the notification requirement.

The FDA has also taken the position that CBD cannot be marketed as a dietary supplement because it has been the subject of investigation as a new drug prior to being marketed as a conventional food or dietary supplement (the Prior Drug Exclusion). According to the FDA, the submission of the IND application for Epidiolex by Greenwich Biosciences, the U.S. subsidiary of London-based GW Pharmaceuticals, preceded the sales and marketing of CBD as a dietary supplement. Excluded from the DSHEA definition of a dietary supplement is: "an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public, which was not before such approval, certification, licensing, or authorization marketed as a dietary supplement or as a food unless the Secretary, in the Secretary's discretion, has issued a regulation, after notice and comment, finding that the article would be lawful under this Act". The FDA interprets the Prior Drug Exclusion applying as of the date in which FDA authorized the new drug for investigation. As discussed below, the FDA takes the position that CBD was not marketed in a food or dietary supplement prior to the conditions under the Prior Drug Exclusion.

The FDCA provides that a substance added to food is unsafe unless the substance is Generally Recognized as Safe ("**GRAS**"). The FDA has not recognized CBD as GRAS for human consumption, although certain Hemp seed derivatives may be considered GRAS. Further research is needed to determine if other cannabinoids would be considered GRAS or what steps would be necessary for them to be recognized as GRAS. Enforcement of this GRAS limitation as it relates to the use of CBD in food has been generally limited to products making unlawful drug or disease claims, with the FDA also asserting its position that CBD is not a permissible food or dietary supplement ingredient.

The FDA continues to evaluate the Hemp CBD landscape and to update the public with its ongoing work. On December 20, 2018, the FDA released a statement from former Commissioner Scott Gottlieb, which restated FDA's current position, opining that products containing CBD ingredients may not be sold as food or dietary supplements. The statement also contained, for the first time, a clear path toward FDA's permanent and formal acceptance of hemp- derived CBD as a food or dietary supplement ingredient. Thus, the FDA has indicated that it is considering using its authority to issue a regulation that will specifically allow hemp-derived CBD in foods and supplements.

Statements from the FDA since continue to reiterate FDA's position and its intent to find a regulatory pathway for Hemp CBD products. Further statements issued in July 2019 made clear that the FDA is "[p]aving the way for regulatory clarity[.]" FDA "is committed to evaluating the regulatory frameworks for non-drug uses, including products marketed as foods and dietary supplements[.]" Importantly, FDA "recognize[s] that there is substantial public interest in marketing and accessing CBD in food, including dietary supplements . . . [and that] [t]he statutory provisions that currently prohibit marketing CBD in these forms also allow the FDA to issue a regulation creating an exception, and some stakeholders have asked

<sup>&</sup>lt;sup>10</sup> 21 CFR § 1308.35 (a)(2). The DEA's final rule on legal hemp materials and products specifically excludes materials used for human consumption.

<sup>&</sup>lt;sup>11</sup> Amy Abernathy, M.D., Ph.D., et al., "FDA is Committed to Sound, Science-based Policy on CBD," fda.gov, https://www.fda.gov/news- events/fda-voices /fda-committed-sound-science-based-policy-cbd.

that the FDA consider issuing such a regulation to allow for the marketing of CBD in conventional foods or as a dietary supplement, or both."13

As it continues down this path, the FDA is "[I]istening to and learning from stakeholders[.]" The FDA held a public hearing on May 31, 2019 to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing Cannabis or Cannabis-derived compounds. The FDA CBD working group was expected to release a report on its progress in Fall 2019, which was delayed until March 2020.

On July 16, 2019, the FDA issued a consumer update on its efforts to address "unanswered questions about the science, safety, and quality of products containing CBD" through the feedback from the May 31, 2019 hearing and information and data gathered through a public docket. Specifically, the FDA noted concerns regarding potential liver toxicity, questions about cumulative exposure to CBD over time, the effects of CBD on special populations (e.g., the elderly, children, adolescents, pregnant and lactating women), and the safety of CBD use in animals including pets. On October 16, 2019, the FDA issued another consumer update cautioning against the use of CBD, THC, and marijuana during pregnancy or while breastfeeding due to the current lack of comprehensive research studying the effects of CBD on the developing fetus, pregnant mother, or breastfed baby. On November 25, 2019, the FDA provided another consumer update stating there is limited available information about CBD, including about its effects on the body. Also in November 2019, the FDA also sent another round of warning letters to companies marketing CBD products with disease claims. In addition, the FDA reiterated its position that CBD cannot be added to food and dietary supplements and stated that it is "not aware of any basis to conclude that CBD is GRAS among qualified experts for its use in human or animal food."

On March 5, 2020, FDA Commissioner Dr. Stephen M. Hahn issued a statement on the FDA's work related to CBD products. The statement makes clear that the FDA will continue its work to educate the public on CBD's perceived safety risks and that the FDA is taking steps to solicit additional public feedback, data, and research on the science, safety, and quality of CBD products. These new steps include re-opening the public docket so that FDA can obtain additional scientific data on CBD, which will include a process by which confidential and proprietary information can be shared with the FDA and kept protected. Additionally, Commissioner Hahn's statement reiterates that the FDA will continue to monitor and police the CBD products marketplace and is evaluating the issuance of a risk-based enforcement policy that provides greater transparency and clarity regarding factors the FDA intends to consider in prioritizing enforcement decisions.

Much of Commissioner Hahn's statement was also included in the FDA's congressionally mandated report on CBD, which was also submitted on March 5, 2020. Importantly, the report confirms that the FDA is actively considering pathways to allow the marketing of CBD as a dietary supplement, which may include a notice-and-comment rulemaking and an interim risk-based enforcement policy while the FDA potentially engages in this process. The report signals the FDA's continued interest in certain questions about CBD, including effects from sustained use, effects from different methods of exposure, and effects on the

<sup>&</sup>lt;sup>13</sup> Id.

<sup>&</sup>lt;sup>14</sup> Id.

<sup>&</sup>lt;sup>15</sup> Id

<sup>&</sup>lt;sup>16</sup> U.S. Food and Drug Administration, "What You Should Know About Using Cannabis, Including CBD, When Pregnant or Breastfeeding," https://www.fda.gov/consumers/consumer-updates/what-you-should-know-about-using-cannabis-including-cbd-when-pregnant-or-breastfeeding.

<sup>&</sup>lt;sup>17</sup> U.S. Food and Drug Administration, "FDA warns 15 companies for illegally selling various products containing cannabidiol as agency details safety concerns," https://www.fda.gov/news-events/press-announcements/fda-warns-15-companies-illegally-selling-various-products-containing- cannabidiol-agency-details.

<sup>18</sup> Id.

developing brain and on the unborn child and breastfed newborn. The report acknowledges that the FDA is receiving inquiries about whether "full spectrum" and "broad spectrum" Hemp products can currently be marketed and sold, but the FDA has not yet answered the question conclusively. Largely, the report does little to address the current regulatory ambiguity for CBD and does not set a timeline for agency action, but it does signal the FDA's clear interest in a pathway for the use of CBD in dietary supplements. Further to this point, Commissioner Hahn has publicly stated that it would be a "fool's game" for the FDA to pull CBD products from the market entirely, as their use is already widespread.<sup>19</sup>

Despite the position taken by the FDA that there is no evidence of CBD being marketed as a food or dietary supplement prior to drug trials being commenced and made public, there is substantial uncertainty and different interpretations among U.S. state and federal regulatory agencies, legislators, academics and businesses as to whether cannabinoids including CBD were present in the food supply and marketed prior to October 15, 1994 or whether such inclusion of cannabinoids is otherwise permitted by the FDA as dietary ingredients, notwithstanding that cannabis and the cannabinoids contained therein have been therapeutically used and consumed as food by human beings for centuries even if not specifically marketed as CBD or other cannabinoids. As a result, the uncertainties regarding the distribution and sale of Hemp-derived CBD products cannot be resolved without further federal legislation, regulation, or a definitive judicial interpretation of existing legislation and rules.

Hemp derived products may be legally sold and marketed in the United States where they contain Hemp lawfully imported from another country or cultivated domestically pursuant to a state agricultural program, provided the product complies with the FDCA and applicable state and federal law. Textiles, fibers, and certain food and cosmetic products containing Hemp seed and Hemp seed oils can be lawfully sold in compliance with federal law. Consumable Hemp-derived CBD products, however, may only be legal to the extent they are lawfully sourced, sold in a state where state law does not prohibit such sale and where they are compliant with the FDCA. Compliance with the FDCA may prove difficult for many consumable Hemp-derived CBD products, while other Hemp-based products such as Hemp or CBD topicals, Hemp seed, Hemp seed oils and certain non-consumable products may be able to achieve compliance with FDCA more easily.

# Future Uncertainty of Legal Status

There remain a number of considerations and uncertainties regarding the cultivation, sourcing, production and distribution of Hemp and products containing Hemp derivatives. Applicable laws and regulations remain subject to change as there are different interpretations among federal, state and local regulatory agencies, legislators, academics and businesses with respect to the treatment of the importation of derivatives from exempted portions of the cannabis plant and the scope of operation of 2018 Farm Bill-compliant Hemp programs. These different U.S. federal, state and local agency interpretations, as discussed above, touch on the regulation of cannabinoids by the FDA and the extent to which imported derivatives, and/or 2018 Farm Bill-compliant cultivators and processors may engage in interstate commerce, whether under federal and/or state law. Additionally, the current regulatory landscape in the United States may be drastically impacted by federal legislation. On September 4, 2020, H.R. 8179, the Hemp and Hemp-Derived CBD Consumer Protection and Market Stabilization Act of 2020, was introduced and proposes to make hemp, CBD derived from hemp, and any other ingredient derived from Hemp lawful for use as a dietary ingredient in dietary supplements.<sup>20</sup> The uncertainties likely cannot be resolved without further U.S. federal and state legislation, regulation or a definitive judicial interpretation of existing legislation and rules.

### Argentina

<sup>&</sup>lt;sup>19</sup> See https://www.nutraingredients-usa.com/Article/2020/02/28/FDA-chief-Hahn-says-it-would-be-fool-s-game-to-try-to-shut-down-CBD- markets#.

<sup>&</sup>lt;sup>20</sup> H.R. 8179, 116th Cong. (2020).

The import of isolated CBD and cannabis resin for medical and scientific research studies, is legal in Argentina.

The Argentine legislation allows three mechanisms for the importation, distribution and sale of Cannabis (as defined in the 1961 UN Single Convention), its seeds, its resin, other cannabis extracts and products derived from the Cannabis plant (whether or not they contain traces of THC) of such cannabis plant derived products in Argentina. Such mechanisms are as follows:

- (i) For the medical treatment of those patients with refractory epilepsy enrolled in the Program created by Law 27,350 (National Program for the Study and Research of the Medicinal Use of the Cannabis Plant, its Derivatives and Non-Conventional Treatments). In these cases, the import must be done by Argentina's National Administration of Drugs, Foods and Medical Devices ("ANMAT"). It is important to notice that this mechanism has not yet been properly implemented in Argentina, where most of the cannabis derived products are being import by the "Exception Access Regime" (see next point).
- (ii) For the medical treatment of those patients with refractory epilepsy not enrolled in the Program created by Law No. 27,350 (National Program for the Study and Research of the Medicinal Use of the Cannabis Plant, its Derivatives and Non-Conventional Treatments). In these cases, the import is done by the "Exception Access Regime", stated by Resolution No. 133/2019, for products containing cannabinoids or cannabis plant derivatives intended exclusively for medicinal use, for the treatment of an individual patient with a diagnosis of refractory epilepsy. In order for these products to be imported through this compassionate use mechanism, they must be prescribed for the treatment of individual patients by medical professionals with specialization in Child Neurology or Neurology. The prescription and affidavit signed by the attending physician and the patient (or his legal representatives) will work as an import authorization, that will only contemplate the quantity of product necessary to cover a treatment of up to 180 calendar days of import. No additional permits or authorizations are required to complete such import in accordance with the laws of Argentina.
- (iii) For medical and scientific research (according to Resolution No. 133/2019), for which the importer must have an authorization from ANMAT, issued under the Program created by Law No. 27,350 (when the scientific research does not have registration purposes) or not (when the scientific research has registration purposes). No additional permits or authorizations are required to complete such import in accordance with the laws of Argentina.

Complementing Law 27.350 article 6 of regulatory decree 883 of 2020 establishes that the National Institute of Agropecuary Technology ("INTA") and the National Council of Scientific and Technical Research ("CONICET") are authorized to cultivate Cannabis. It also establishes that the National Institute of Seeds ("INASE") will regulate the conditions of production, dissemination, handling and conditioning of the propagation organs of this species that allow the traceability of plant products.

Article 5 of Law 27.350 establishes that the Ministry of Health, in coordination with provincial public agencies, must promote the application of Law 27.350 in the provinces. Accordingly, the Ministry of Health has authorized several provincial plans to produce Cannabis and its derivatives through state-owned companies

INASE's Resolution 56 of 2018 establishes the requirements for the import of seeds as well as the use of the Seed Import Application Form generated by the management system, which is a sworn statement, among other documents for its implementation. INASE's Resolution 59 of 2019 establish the conditions for production, dissemination, management and conditioning activities carried out in greenhouses and premises with Cannabis SP.

In accordance with National Decree 1585 of 1996 the National Service for Agro-Food Health and Quality ("SENASA") has competence over the control of federal traffic, imports and exports of products, by-products and derivatives of animal and vegetable origin, agri-food products, pharmaco-veterinary and agrochemicals, fertilizers and amendments.

In article 13 of Resolution 816 of 2002 SENASA approved the administrative procedure for the import procedure of plants, their parts, means of support and/or organic growth (issuance of the Phytosanitary Import Authorization - AFIDI), products, by-products, derivatives of vegetable origin or goods and/or inputs containing as components or among their components, ingredients of vegetable origin.

Once a company has received the corresponding authorization from the Ministry of Health under Law 27.350, they can initiate the import procedure of cannabis seeds with INASE in accordance with Resolution 56 of 2018 and Resolution 59 of 2019 and with SENASA in accordance with National Decree 1585 of 1996 and Resolution 816 of 2002.

Finally, according to article 5 of Law 17.818 (construed together with ANMAT Disposition 4861/96 according to which Cannabis seeds are included in schedule IV as a narcotic) Cannabis, its derivatives and seeds, must be imported through ports of entry under the jurisdiction of the federal capital-city customs authority.

## **European Union**

The Corporation has plans to expand distribution to new locations in Europe. Legislative approaches to the regulation of CBD-related products vary country by country, including local regulations with respect to THC content, and continue to evolve. For example, to comply with more restrictive THC content specifications in Europe, products distributed therein must contain no more than 0.3% THC. In addition, all allowable product formulations under European Union guidelines must have the legal and appropriate labels and packaging based on the target country requirements. The Corporation intends that all products distributed to locations within the European Union will be tailored with specific attributes to ensure compliance with local regulations, as applicable.

## Chile

Pursuant to Supreme Decree 404 of the Chilean Ministry of Health ("**DS 404**") cannabis, cannabis raw resins, purified resins, extracts and tinctures are classified as narcotic drugs. The only reference or distinction that Chilean regulation makes regarding cannabinoids is in Supreme Decree 405 of the Chilean Ministry of Health ("**DS 405**") which establishes that THC is considered a psychotropic drug.

In accordance with DS 404 and DS 405, cannabis, cannabis resins, extracts, tinctures and THC can only be imported in the following cases and with the authorization of the Chilean Public Health Institute ("ISP"):

- (i) For scientific research, where these substances may be authorized for that purpose in accordance with the conditions established by a special resolution that the ISP must issue on the matter.
- (ii) For the manufacture of controlled pharmaceutical products for human use.

Article 8 of DS 404 and article 8 of DS 405 establish that the only entities with the power to carry out the importation process of cannabis, in any of its forms and THC are: Pharmaceutical Chemical Production Laboratories, Drugstores, Pharmacies, Hospitals and Medical or Scientific Research Institutions, all of which require prior authorization from the ISP.

Pursuant to article 8 subsection II of DS 404 and DS 405, every year on the month of October, any establishment or entity that is interested in importing cannabis to Chile has to present an application to the

ISP in addition to forecasts of products it expects to import for the following calendar year. The ISP will then determine the quantity of cannabis (or cannabis products) that may be imported during that period. The import request must indicate the following information:

- (i) Legal name and address of the establishment or its legal representative, plus the identification of the technical director of the establishment or the professional in the health area that will be responsible for the project -in the event that the importer is a scientific or medical research institution.
- (ii) Name and address of the exporter and country of origin of the product;
- (iii) Generic name and chemical identification nomenclature of the drug or product;
- (iii) Quantity to be imported;
- (iv) Pharmaceutical form, name and nature of the container, in the event of being a pharmaceutical preparation or specialty. This point is very important, since the determination of the types or quantities of cannabinoids allowed, whether considered in the plant itself, as extracts or finished products, will be defined in attention to this point. In other words, there is no predetermined list of raw materials or finished products based on cannabis or its derivatives nor is there an authorized predefined quantity of the components in them to be imported in Chile. The ISP analyzes their provenances on a case-by-case basis in response to the proposal that has been made; and
- (v) Identification of the customs through which the product will be admitted.

If approved, the result is the issuance of an official import certificate, which will be valid for 4 months from the date of issue. The effective import must be made within a maximum period of 6 months from the same date.

## **Ecuador**

In the 1st Supplement of the Official Gazette No. 107 of December 24, 2019, the Reform of the Criminal Law was published and entered into force on June 21, 2020.

Included among the reforms, was the decriminalization of possession of drugs that contain cannabis or derivatives as their active ingredient for therapeutic, palliative, or medicinal use, or for the practice of alternative medicine. In addition, the Law of Control and Prevention of the use of Drugs was amended, excluding non-psychoactive cannabis or hemp cannabis from control, extended to the cannabis plant or any part of the plant, wherein the THC content less than 1%.

The Reform of the Criminal Law came into force on June 21, 2020, the date from which the Ministry of Agriculture had 120 days to issue the regulations to control the import, cultivation, harvest, sale, industrialization and exportation of non-psychoactive cannabis and hemp.

On October 19<sup>th,</sup> 2020, the Ministry of Agriculture issued the Ministerial Agreement No. 109, which regulates the import, planting, growing, harvest, post harvest, storage, transportation, processing, marketing and export of non psychoactive cannabis or hemp and hemp for industrial use.

On February 11<sup>th</sup>, 2021, the Ministry of Health and the National Agency for Sanitary Regulation, Control and Surveillance ("ARCSA"), issued Resolution ARCSA-DE-002-2021-MAFG which stipulates the

technical regulation for the control of products of human use and consumption that contain cannabis or its derivatives.

This resolution establishes the following provisions regarding cosmetic products:

- (i) The ingredients that can be incorporated into cosmetic products and their corresponding functions and restrictions or conditions of use, are those allowed in the lists and provisions issued by the Food & Drug Administration of the United States; The Personal Care Products Council (PCPC) cosmetic ingredient listings; Directives or Regulations of the European Union that rule on cosmetic ingredients; and Cosmetics Europe –The Personal Care Association cosmetic ingredient listings.
- (ii) Cosmetic products that contain cannabis or cannabis derivatives, must contain 1% or less THC in the finished product.
- (iii)In order to obtain a Sanitary Notification, in addition to the requirements established in Decision 516/833 of the Andean Community, the following requirements must be submitted:
  - (a) Quantitative composition formula of the ingredient derived from cannabis in the formulation of the finished product; and
  - (b) Certificate of analysis showing that the concentration of THC in the finished product is equal to 1% or less.
- (iv) The certificate of analysis must by issued by one of the following establishments:
  - (a) Manufacturer of the finished product, if it complies with Good Manufacturing Practices certification;
  - (b) Laboratory with Good Manufacturing Practices certification for cosmetic products, which is different from the manufacturer;
  - (c) Laboratory with accreditation recognized by the Ecuadorian Accreditation Service (SAE), with scope for analysis of cosmetic products; or
- (d) Laboratory with ISO 17025 accreditation with scope for analysis of cosmetic products. Cosmetics finished products containing CBD isolates can be imported to Ecuador for commercialization. For this purpose, a Sanitary Notification must be obtained following the procedures established by the ARCSA.

## Uruguay

Pursuant to article 5 of the Uruguay Cannabis Regulation and Control Act 19.172 ("Act 19.172"), non-psychoactive cannabis (cannabis which contains up to 0,5% of THC) fall within the exceptions to the prohibition to cultivate, harvest and commercialize any plant from which narcotic substances can be extracted.

According to Act 19.172 and Presidential Decree 372/014 it is permissible to import into Uruguay cannabis sativa seeds from cannabis strains that contain less than 0,5% THC for commercial purposes.

In order to import cannabis seeds from cannabis strains that contain less than 0,5% THC into Uruguay, the Uruguayan Ministry of Agriculture, Livestock and Fishing ("MAGP") must provide prior authorization of the importation ("MAGP Import Authorization"). In order to request and obtain a MAGP Import Authorization, the importer must submit the following information along with the import request:

- (i) Name of the non-psychoactive cannabis strain
- (ii) Amount to be imported
- (iii) THC concentration level of the strain
- (iv) Name and address of the exporter (in accordance with the pro forma invoice)
- (v) Country of origin of the seeds
- (vi) Pro forma invoice

Additional documentation may be required to obtain a MAGP Import Authorization depending on the strain of the subject seeds. Additionally, the seed strain must be registered at its country of origin.

The MAGP Import Authorization will have a validity of 120 days and can only be utilized once. Strains or amounts that differ from the ones stated in the MAGP Import Authorization cannot be imported into Uruguay.

Besides the MAGP Import Authorization the importer must be registered as an importer in the Uruguayan National Seeds Institute ("**UNSI**") and have obtained an import authorization certificate from UNSI and a phytosanitary import authorization from the Uruguayan General Directorate of Agricultural Services.

In order to commercialize cannabis seeds within Uruguay, the seed strain must be registered in UNSI's commercial seed registry.

## **Austria**

The Austrian Narcotics Act and the Austrian Narcotics Ordinance regulate the import, handling and wholesale of pharmaceuticals and poisons, which include cannabis and cannabis-derived products, with certain exceptions.

Seeds and leaves that are not mixed with inflorescences or fruiting bodies are generally not covered by the Austrian Narcotics Act. Furthermore, inflorescences and fruiting bodies of those hemp varieties that are included in the Common Catalogue of Varieties of Agricultural Plant Species ("Gemeinsamer Sortenkatalog für landwirtschaftliche Pflanzenarten") are excluded. Inflorescences and fruiting bodies that are included in the Austrian Variety List ("Österreichische Sortenliste") are also exempt, as long as the THC content does not exceed 0.3%. Products from commercial hemp varieties that are either in the Common Catalogue of Varieties or the List of Varieties are exempt if the THC content does not exceed 0.3% before, during and after the production process. In addition, narcotic drugs must not be easily or economically profitable be obtained from the mentioned products.

Private entities and companies that have an active business licence for the production of pharmaceuticals and poisons and wholesale of pharmaceuticals and poisons pursuant to Article 94 Item 32 and Article 116 of the Austrian Trade Act, may apply for a federal licence pursuant to Article 6 Para 1 Item 1 of the Austrian

Narcotics Act for the authorization to import, production, and wholesale of products containing THC in any concentration.

## CBD and CBG

Purified CBD and CBG are not psychoactive substances and thus not considered to be narcotics according to the Austrian Narcotics Act. It is therefore permitted to import CBD and CBG isolates which do not contain any THC into Austria without obtaining any specific licence. Regarding the actual placement onto the European Union market (e.g. selling products in a store), several different regulations may apply related to the nature of the product containing the CBD or CBG isolate (foodstuff, animal feed, flavouring, cosmetic product, pharmakon etc.).

Depending on the nature or the intended use of the product(s) which contain CBD or CBG isolate different regulations may apply. For example, if the isolate is either used for or contained in foodstuff, food law regulations apply, namely European Regulation (EC) No 178/2002 and related regarding food safety as well as the European Novel Foods Regulation. The same principle applies if the isolate is considered to be a flavouring (Regulation (EC) 1334/2008), a cosmetic product (Regulation (EC) No 1223/2009), a pharmacon (Directive 2001/83/EC as well as Austrian Pharmaceuticals Act – "Arzneimittelgesetz") or animal feed (Austrian Animal Feed Act - "Futtermittelgesetz").

### Peru

In Peru, the use of cannabis is allowed only for medicinal and therapeutic purposes. The main regulation for its medicinal use is: (i) Law N° 30681, which regulates the medicinal and therapeutic usage of cannabis and cannabis derivatives, and (ii) Supreme Decree No. 005-2019/SA, which regulates Law N°30681. However, the following regulatory framework also applies to the use of cannabis for medicinal and therapeutic purposes:

- General Health Law N° 26842
- Law on Pharmaceutical Products, Medical Devices and Health Products Law N° 29459
- Regulations for Pharmaceutical Establishments Supreme Decree N° 014-2011-SA, as amended.
- Law 27262 Seed's Law.
- Regulation of Law No. 30681 Supreme Decree No. 006-2012-AG
- Legislative Decree No. 1053
- Supreme Decree No. 032-2003-AG
- Regulation of narcotic drugs, psychotropic substances and other substances subject to sanitary control - Supreme Decree No. 023-2001-SA.

Pursuant to Supreme Decree No. 005-2019/SA, any herbaceous plant of the Cannabis genus is divided into two (2) varieties according to the following classification for purposes of the Peruvian regulation and Cannabis Derivatives are defined as:

- a) Psychoactive Cannabis: Flowering tops of the Cannabis plant (with the exception of seeds and the leaves not attached to the tops) from which the resin, whatever the name designated for it, has not been extracted and the delta-9-tetrahydrocannabinol (THC) content of which is equal to or greater than 1% by dry weight, and which are used for medicinal and therapeutic purposes, as palliative therapy for some diseases. Use by burning or smoking of psychoactive Cannabis is excluded.
- b) Non-psychoactive Cannabis: The Cannabis plant, and any part of said plant, the delta-9-tetrahydrocannabinol (THC) content of which is less than 1% by dry weight. Non-psychoactive

- Cannabis, its parts and its derivatives, are non-controlled substances, and therefore excluded from the Regulation concerning Narcotics, Psychotropics, and other Substances subject to Sanitary Oversight, approved by Supreme Decree No. 023-2001-SA.
- c) Cannabis Derivatives: Any compound, mixture or preparation, or product derived from Cannabis for medicinal use, and understood, solely for purposes of this regulation, as herbal medication, pharmaceutical preparation, pharmaceutical product, and natural product for use in health, defined herein.

For the import of cannabis or its derivatives, the importer will need licenses depending on the activity to be carried out. For research and development purposes the required license is a License for scientific research issued by the Peruvian National Institute of Health (INS) and the Peruvian National Institute of Agronomic Innovation (INIA), for import and commercialization purposes the required license is a License for importation and/or marketing issued by the Peruvian General Directorate for Pharmaceuticals, Supplies and Drugs (DIGEMID), and for production the required license is a License for Production issued by DIGEMID.

For the importation of psychoactive cannabis or its derivatives, besides having one of the previously mentioned licenses, the importer must obtain an Official Import Certificate issued by DIGEMID.

For the importation of non-psychoactive cannabis or its derivatives, besides having one of the previously mentioned licenses, the importer must obtain a letter of non-objection issued by DIGEMD for the product to not be considered as a controlled substance and therefore not require and Official Import Certificate.

Decree No. 005-2019/SA establishes no differences in the treatment of cannabis seed regarding its conditions of psychoactive and non-psychoactive. Thus, both type of seed will receive the same treatment. Pursuant to the current Peruvian regulations, for the import of cannabis seeds the importer must have a License for scientific research issued by INS and INIA or a License for Production issued by DIGEMID, depending on the use the importer will give to the seeds. Additionally, for the importation of cannabis seeds a Phytosanitary Permit of Import issued by the Peruvian National Service of Agrarian and Environmental Health (SENASA) and a Phytosanitary Certificate issued by the corresponding authority of the exporting country are required regardless of the volume, use or method of importation.

## **Brazil**

The Brazilian Health Regulatory Agency (ANVISA) issued resolution RDC No. 327/2019, allowing for the opening of the Brazilian market to the cannabis sector. RDC No. 327/2019 came into force on March 2020. ANVISA also issued ANVISA's RDC No. 335/2020, dated as of January 24, 2020, which came into force on January 27, 2020.

## (i) RDC No. 327/2019

ANVISA's RDC No. 327/2019 of 9 December 2019 regulated cannabis sativa-derived products. As a result, cannabis sativa-derived products are no longer prohibited in Brazil vis-à-vis the manufacturing, importation and dispensing. Instead, commercialization of cannabis sativa-derived products is now subject to specific regulation and oversight as a health-regulated commodity by ANVISA.

Changes enacted in the 2019 ANVISA bill related to cannabis sativa-derived products were expected by many to generate additional market opportunities for cannabis sativa-derived products such as CBD and THC.

Cannabis sativa-derived products that do not meet the statutory requirements of ANVISA's RDC No. 327/2019 continue to be prohibited (aside from lawful use for R&D purposes or if subject to drugs specifics, as each of these opportunities is governed by different statutory and regulatory requirements, primarily administered by ANVISA). Cultivation is also not yet allowed and as such manufacturing in Brazil still depends on the importation of API.

# A. Regarding CBD-based products (finished products):

CBD-based products cannot not be introduced into domestic commerce without ANVISA's prior approval.

CBD-based products under ANVISA's RDC No. 327/2019 encompasses cannabidiol(CBD)-dominant and tetrahydrocannabinol (THC) & cannabidiol(CBD)-balanced portfolio.

The statutory definition of the term CBD-based products also includes "cannabis sativa-derived products containing APIs of plant derivatives (e.g., phytocannabinoids) or phytopharmaceuticals from cannabis sativa and intended to medicinal purposes only.

No concentration levels of CBD are statutorily determined (either minimum or maximum) by ANVISA.

When it comes to THC, CBD-based products may have THC concentration higher than 0.2%, provided that intended to use of those whose treatment is palliative. Otherwise, the maximum concentration allowed is 0.2%. The method of delivery (*i.e.*, dosage forms) of CBD-based products is limited to oral and/or nasal means.

The addition of excipients to CBD-based products is allowed provided they have specific functions, for example, in sustained release preparations or in enhancing product delivery (e.g., enhance absorption or control release of the product). Any excipient added to CBD-based products must be fully qualified by existing safety data with respect to the pharmaceutical use and listed with ANVISA. Synthetic substances other than excipients cannot be added to CBD-based products. Non-synthetic cannabinoid products, including CBD-dominant and THC & CBD-balanced portfolio are subject to ANVISA's RDC No. 327/2019.

Commercialization of cannabis sativa plant is prohibited.

The commercialization of CBD-based products into Brazilian market is subject to the licensing requirements under ANVISA's RDC No. 327/2019. Aside from the licensing required at the legal entity level (i.e., licensing of the establishment), ANVISA's RDC No. 327/2019 establishes a simple pathway for the listing of CBD-based products with the agency: "Autorização Sanitária". Good Distribution and Storage Practices (GDSP) of the importer is required, as well.

The manufacturer is also required to adhere to Good Manufacturing Practices (GMP) in relation to the CBD-based product. Do note that this statutory requirement is waived when the manufacturer does not have GMP but has an equivalent supporting documentation issued by a health regulator recognized by ANVISA. In this case, this equivalent supporting documentation will suffice provided the manufacturer requires the actual GMP within 3 years commencing from 9 December 2019 (which is the date of publication of ANVISA's RDC No. 327/2019).

Determining a Cota Anual for the importation of CBD-based products into Brazil (either APIs or end products) is required. Cota Anual is ruled by ANVISA's RDC No. 11/2013 and it basically set limits in relation to the number of CBD-based products that are allowed to be imported per year by the holder of the Autorização Sanitária.

Supporting documentation must be sent by the holder of the Autorização Sanitária to ANVISA for the settlement of such limit.

# B. Regarding API

Pursuant to Article 18 of ANVISA's RDC No. 327/2019, plant derivatives (e.g., phytocannabinoids) or phytopharmaceuticals from cannabis sativa can be imported into Brazil for local manufacturing of CBD-based products to be commercialized under ANVISA's RDC No. 327/2019. It is still prohibited only the importation of the cannabis sativa plant and flowers per se. There is no specific requirement related to the GMP of APIs.

ANVISA's is that APIs imported into Brazil for purposes of manufacturing of pilot batches falls into scope of ANVISA's RDC No. 11/2013. This importation does not require an Autorização Sanitária previously granted to. If the pilot batches end up for commercialization under ANVISA's RDC No. 327/2019, then an Autorização Sanitária will be required before putting the product in the domestic market and the volume of the APIs imported for purposes of manufacturing the pilot batches will be discounted from the total of the Cota Anual eventually granted in connection with the ANVISA's RDC No. 327/2019, i.e., the commercialization per se.

## (ii) RDC No. 335/2020

According to RDC No. 335/2020, CBD-based products may be imported into Brazil by patients or their legal representatives, for the patient's personal use only, relying on a medical prescription issued by a licensed doctor stating that patient medical condition would benefit from a CBD-based treatment.

A medical prescription issued by a licensed doctor attesting a medical condition that would benefit from a CBD-based treatment is the first step to be taken by the individual or his/her legal representatives in order to directly import CBD-based products into Brazil. Once the patient has such medical prescription, he/she or his/her legal representatives must complete the enrollment application with ANVISA.

Such enrollment application is entirely online at ANVISA's website and requires only the insertion of the personal data of the patient and the upload of the medical prescription stating that the patient's medical condition would benefit from a CBD-based treatment and that the prescribed CBD-based product is for personal use only.

When the enrollment application is submitted, ANVISA will process the request and provide via email an authorization for the importation of the CBD-based product indicated in the medical prescription. Such authorization is valid for 2 years from the date of its issuance.

Upon receipt of authorization from ANVISA, the patient or his/her legal representatives are allowed to purchase the CBD-Based Product and initiate the importation procedure for the 2-year period of the authorization/enrollment.

The importation procedure must go through "Remessa Expressa" or "Bagagem Acompanhada", via "SISCOMEX", which are all methods for importation of health-regulated products into Brazil (i.e., importation through regular mail is not allowed).

### **Barbados**

In Barbados, cannabis is listed in the Drug Abuse (Prevention and Control) Act Chapter 131 (The "Drug Abuse Act) in the First Schedule of Part 1 and is therefore a controlled drug as defined in the Drug Abuse Act. However, the Medical Cannabis Industry Act 2019-44 (the "Medicinal Act") was passed to provide for inter alia regulation for handling of medicinal cannabis in Barbados, to establish a Barbados Medical Cannabis Licensing Authority (the "BMCLA"), and the issuing of licenses for the handling of the medicinal cannabis.

The Medicinal Act defines the following terms under Section 2 of the Medicinal Act:

- a. CBD as an active ingredient found in the cannabis plant which reacts with specific receptors in the human body to give a therapeutic effect;
- b. "License" means a license issued to a person by the BMCLA to facilitate the handling of medicinal cannabis pursuant this act;
- c. "cannabis" has the meaning assigned to it in the Drug Abuse Act (as mentioned above);
- d. "medicinal cannabis" means cannabis, seeds, immature plants as well as all parts of the plant, along with resin extracted from any part of the plant, every compound, manufacture, salt, derivative, mixture or preparation from cannabis or cannabis concentrate that is cultivated, processed, manufactured, distributed, sold, tested, or analyzed under a license; and
- e. THC means the main active ingredients in cannabis and one of the many naturally occurring chemical compounds found in cannabis. The Medicinal Act refers to cannabis and medicinal cannabis which may appear as the same but there is a distinction as medicinal cannabis is cultivated, processed, manufactured, distributed, sold, tested, or analyzed under a license whereas cannabis is the Controlled Drug which is illegal as per the Drug Abuse Act.8

The Medicinal Act in Section 2 (2) states the following:

- a. The provisions of the Drug Abuse Act shall not prohibit, or otherwise be applied to the use of medicinal cannabis or cannabis pursuant to the Medicinal Act; or
- b. be used to restrict or render unlawful, the handling of medicinal cannabis by any person in accordance with the provisions of the Medicinal Act.

Hence, section 2 of the Medicinal Act makes the handling of medicinal cannabis lawful if the provisions of the act are followed. BMCLA is Responsible to Regulate the Barbadian Medicinal Cannabis Industry. The Medicinal Act establishes the BMCLA, who are responsible for inter alia the regulation of medicinal cannabis and the issuance of licenses for the handling of medicinal cannabis, developing policies, procedures and guidelines to establish the medicinal cannabis industry, and to ensure that medicinal cannabis is available to patients in a safe and efficient manner.

The use of medical cannabis is governed by Section 25 of the Medicinal Act which states that a person shall only use or consume medicinal cannabis where the medicinal cannabis is prescribed by a medical practitioner. A medical practitioner if someone who is qualified in the practice of medicine and is registered in the medical register as outlined in the Medical Profession Act, 2011.

### **RISK FACTORS**

You should carefully consider the risks described below, which are qualified in their entirety by reference to, and must be read in conjunction with, the detailed information appearing elsewhere in this AIF, and all other information contained in this AIF, including the consolidated financial statements and accompanying notes. The risks and uncertainties described or incorporated by reference herein are not the only ones the we face and should not be considered exhaustive. Additional risks and uncertainties, including those that we are unaware of or that are currently deemed immaterial, may also materially and adversely affect our business, operations and condition, financial or otherwise. We cannot provide assurance that we will

successfully address any or all of these risks. There is no assurance that any risk management steps taken will avoid future loss due to the occurrence of the adverse effects set out in the risk factors herein, or in the other documents incorporated or deemed incorporated by reference herein or other unforeseen risks.

These below risk factors, together with all other information included or incorporated by reference in this AIF, including, without limitation, the risks set out under the section "Forward-Looking Information" should be carefully reviewed and considered.

# **Risks Related to Our Securities**

# Forward-Looking Information

The forward-looking information included in this AIF relating to, among other things, the Corporation's future results, performance, achievements, prospects, targets, intentions or opportunities or the markets in which we operate is based on opinions, assumptions and estimates made by the Corporation's management in light of its experience and perception of historical trends, current conditions and expected future developments, as well as other factors that the Corporation believes are appropriate and reasonable in the circumstances. However, there can be no assurance that such estimates and assumptions will prove to be correct. The Corporation's actual results in the future may vary significantly from the historical and estimated results and those variations may be material. We make no representation that the Corporation's actual results in the future will be the same, in whole or in part, as those included in this AIF. See "Forward-Looking Statements".

# Volatile Market Price for the Common Shares

The Common Shares are currently listed and posted for trading on the TSX, the FSE and quoted on the OTCQX. The market price for the Common Shares may be volatile and subject to wide fluctuations in response to numerous factors, many of which are beyond the Corporation's control, including the following:

- actual or anticipated fluctuations in our quarterly results of operations;
- changes in our estimates of our future results of operations;
- changes in forecasts, estimates or recommendations of securities research analysts regarding our future results of operations or financial performance;
- changes in the economic performance or market valuations of other companies that investors deem comparable to us;
- additions or departures of our senior management team or other key employees;
- sales or perceived sales of additional Common Shares;
- significant acquisitions or business combinations, strategic partnerships, joint ventures or capital commitments by or involving us or our competitors; and
  - news reports relating to trends, concerns or competitive developments, regulatory changes and other related issues in our industry or target markets in which the Corporation operates; macroeconomic developments in North America and globally; and market perceptions of the attractiveness of particular industries.

Financial markets have in the past experienced significant price and volume fluctuations that have particularly affected the market prices of equity securities of companies and that have, in many cases, been unrelated to the operating performance, underlying asset values or prospects of such companies. Accordingly, the market price of the Common Shares may decline even if our operating results, financial condition or prospects have not changed. As well, certain institutional investors may base their investment decisions on consideration of our environmental, governance and social practices and performance against such institutions' respective investment guidelines and criteria, and failure to meet such criteria may result in a limited or no investment in the Common Shares by those institutions, which could materially adversely affect the trading price of the Common Shares. There can be no assurance that continuing fluctuations in price and volume will not occur. If such increased levels of volatility and market turmoil continue, our business, financial condition and results of operations could be materially adversely impacted and the trading price of the Common Shares could be materially adversely affected.

### No Immediate Plan to Declare Dividends

We currently intend to retain future earnings, if any, for future operation and expansion and have no current plans to pay any dividends for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of the Board and will depend on, among other things, our financial results, cash requirements, contractual restrictions and other factors that the Board may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any existing and future outstanding indebtedness we incur. As a result, investors may not receive any return on an investment in their Common Shares unless they sell them for a price greater than that which they paid for it.

# Difficulty to Forecast

The Corporation must rely largely on its own market research to forecast revenues as detailed forecasts are not generally obtainable from other sources at this early stage of the industry. Market research and projections by the Corporation are based on assumptions from limited and unreliable market data. A failure in demand could materialize as a result of competition, technological change or other factors and could have a material adverse effect on the business, results of operations and financial condition of the Corporation.

## The Market Price of the Common Shares May be Subject to Wide Price Fluctuations

The market price of the Common Shares may be subject to wide fluctuations in response to many factors, including variations in the operating results of the Corporation and its subsidiaries, divergence in financial results from analysts' expectations, changes in earnings estimates by stock market analysts, changes in the business prospects for the Corporation and its subsidiaries, general economic conditions, legislative changes, and other events and factors outside of the Corporation's control. In addition, stock markets have from time to time experienced extreme price and volume fluctuations, which, as well as general economic and political conditions, could adversely affect the market price for the Common Shares.

### Sales of Substantial Amounts of the Common Shares

Sales of substantial amounts of the Common Shares, or the availability of such securities for sale, could adversely affect the prevailing market prices for the Common Shares. A decline in the market prices of the

Common Shares could impair the Corporation's ability to raise additional capital through the sale of securities should it desire to do so.

# Securities or Industry Analysts

The trading market for the Common Shares will depend in part on the research and reports that securities or industry analysts publish about the Corporation or our business. Avicanna does not currently have and may never obtain research coverage by securities and industry analysts. If no securities or industry analysts commence covering us, the trading price for the Common Shares may be negatively impacted. If the Corporation obtains securities or industry analyst coverage and if one or more of the analysts who cover us downgrade the Common Shares or publish inaccurate or unfavorable research about our business, the trading price of the Common Shares may decline. If one or more of these analysts cease coverage of the Corporation or fail to publish reports on us regularly, demand for the Common Shares could decrease, which could cause the trading price and volume of the Common Shares to decline.

## **Public Corporation Expenses**

Prior to the date hereof, we have not been subject to the continuous and timely disclosure requirements of Canadian securities laws or other rules, regulations and policies of any securities exchange. We are working with our legal, accounting and financial advisors to identify those areas in which changes should be made to our financial management control systems to manage our obligations as a public issuer. These areas include corporate governance, corporate controls, internal audit, disclosure controls and procedures and financial reporting and accounting systems. We have made, and will continue to make, changes in these and other areas, including our internal controls over financial reporting. However, we cannot provide any assurance that these measures we may take will be sufficient to allow us to satisfy our obligations as a public issuer on a timely basis. In addition, compliance with reporting and other requirements applicable to public companies will require the time and attention of management, and will create additional costs for us, which may negatively impact our financial performance or results of operations. We cannot predict the amount of the additional costs we may incur, the timing of such costs or the impact that management's attention to these matters will have on our operations.

# Future Sales of Common Shares by Principal Shareholders, Officers and Directors

Subject to compliance with applicable securities laws and the terms of any lock-up arrangements described under "Escrowed Securities and Securities Subject to Contractual Restrictions on Transfer", our officers, directors, principal shareholders and their affiliates may sell some or all of the Common Shares held by such party in the future. No prediction can be made as to the effect, if any, such future sales of Common Shares will have on the market price of the Common Shares prevailing from time to time. However, the future sale of a substantial number of Common Shares by our officers, directors, and any principal shareholders and their affiliates, or the perception that such sales could occur, could materially adversely affect prevailing market prices for the Common Shares.

Accordingly, if the Corporation's principal shareholders sell substantial amounts of our securities in the public market, the market price of our securities could fall. Additional Common Shares issuable upon the exercise of stock options or the conversion of Common Shares may also be available for sale in the public market, which may also cause the market price of our Common Shares to fall.

## Risks Related to the Corporation's Business and Industry

### New Industry and Market

The cannabis industry and market are relatively new in the jurisdictions in which the Corporation operates, and this industry and market may not continue to exist or grow as anticipated or Avicanna may ultimately be unable to succeed in this new industry and market. These licensed producers are operating in a relatively new cannabis industry and market. The licensed producers are subject to general business risks, as well as risks associated with a business involving an agricultural product and a regulated consumer product. The Corporation holds a controlling interest in two licensed producers in Colombia that are licensed to harvest, extract, produce and sell both psychoactive (THC) and non-psychoactive (CBD) medical cannabis extract. Within Colombia, the Corporation intends to sell and market its proprietary medical and cosmetic cannabinoid-based products. To this extent the Corporation needs to build brand awareness in this industry, and in the markets it operates in through significant investments in its strategy, its licensed producers production capacity, quality assurance, and compliance with regulations. These activities may not promote the Corporation's brand and products as effectively as intended, or at all. Competitive conditions, consumer tastes, patient requirements and spending patterns in this new industry and market are relatively unknown and may have unique circumstances that differ from existing industries and markets. There are no assurances that this industry and market will continue to exist or grow as currently estimated or anticipated, or function and evolve in a manner consistent with management's expectations and assumptions. Any event or circumstance that affects the medical cannabis industry and market could have a material adverse effect on Avicanna's business, financial condition and results of operations.

# Rapidly Changing Industry

Similar to the risk of the infancy of the cannabis industry, the market for the Corporation's products and services is characterized by rapid intellectual property advances, changes in customer requirements, changes in protocols and evolving industry standards. If the Corporation is unable to develop enhancements to its existing products and services or acceptable new products and services that keep pace with rapidly changing developments, its products and services may become obsolete, less marketable and less competitive and the Corporation's business will be harmed.

# **Publicity or Consumer Perception**

The Corporation believes that the economic viability of the legal cannabis industry is highly dependent upon consumer perception regarding the safety, efficacy and quality of the cannabis produced. Consumer perception of cannabis products can be significantly influenced by scientific research or findings, regulatory investigations, litigation, media attention and other publicity regarding the consumption of cannabis products. There can be no assurance that future scientific research, findings, regulatory proceedings, litigation, media attention or other research findings or publicity will be favourable to the legal cannabis market or any particular product, or consistent with earlier publicity. Future research reports, findings, regulatory proceedings, litigation, media attention or other publicity that are perceived as less favourable than, or that question, earlier research reports, findings or publicity could have a material adverse effect on the demand for the Corporation's products and services, and, correspondingly, on the Corporation's business, results of operations, financial condition and cash flows. The effect of consumer perceptions on the legal cannabis market means that adverse scientific research reports, findings, regulatory proceedings,

litigation, media attention or other publicity, whether or not accurate or with merit, could have a material adverse effect on the demand for the Corporation's products and services, and, correspondingly, on the Corporation's business, results of operations, financial condition and cash flows. Further, adverse publicity reports or other media attention regarding the safety, efficacy and quality of cannabis in general, or associating the consumption of cannabis with illness or other negative effects or events, could have such a material adverse effect. Such adverse publicity reports or other media attention could arise even if the adverse effects associated with such products resulted from consumers' failure to consume such products appropriately or as directed.

### Future Clinical Research into Effective Medical Cannabis Therapies

Research in Canada and internationally regarding the medical benefits, viability, safety, efficacy, use and social acceptance of cannabis or isolated cannabinoids (such as CBD and THC) remains in early stages. There have been relatively few clinical trials on the benefits of cannabis or isolated cannabinoids (such as CBD and THC). Although the Corporation believes that the articles, reports and studies support its beliefs regarding the medical benefits, viability, safety, efficacy, dosing and social acceptance of cannabis, future research and clinical trials may prove such statements to be incorrect, or could raise concerns regarding, and perceptions relating to, cannabis. Given these risks, uncertainties and assumptions, investors should not place undue reliance on such articles and reports. Future research studies and clinical trials may draw opposing conclusions to those stated in this AIF or reach negative conclusions regarding the medical benefits, viability, safety, efficacy, dosing, social acceptance or other facts and perceptions related to medical cannabis, which could have a material adverse effect on the demand for the Corporation's products with the potential to lead to a material adverse effect on the Corporation's business, financial condition and results of operations or prospects.

# **Limited Operating History**

Avicanna has a very limited history of operations and is considered a start-up company. As such, Avicanna is subject to many risks common to such enterprises, including under-capitalization, cash shortages, limitations with respect to personnel, financial and other resources and lack of revenues. There is no assurance that we will be successful in achieving a return on shareholders' investment and the likelihood of our success must be considered in light of our early stage of operations.

## Key Personnel

The Corporation's success has depended and continues to depend upon its ability to attract and retain key management, including the Corporation's Chief Executive Officer, technical experts, and scientists. The Corporation will attempt to enhance its management and technical expertise by continuing to recruit qualified individuals who possess desired skills and experience in certain targeted areas. The Corporation's inability to retain employees and attract and retain sufficient additional employees or scientific and technical support resources could have a material adverse effect on the Corporation's business, results of operations, sales, cash flow or financial condition. Shortages in qualified personnel or the loss of key personnel could adversely affect the financial condition of the Corporation and results of operations of the business and could limit the Corporation's ability to develop and market its cannabis-related products. The loss of any of the Corporation's senior management or key employees could materially adversely affect the Corporation's ability to execute its business plan and strategy, and the Corporation may not be able to find adequate

replacements on a timely basis, or at all. The Corporation does not maintain key person life insurance policies on any employees.

## Factors which may Prevent Realization of Growth Targets

The Corporation is currently in the early development stage. The Corporation's growth strategy contemplates expanding the cultivation facilities of SN and SMGH with additional production resources. There is a risk that these additional resources will not be achieved on time, on budget, or at all, as they can be adversely affected by a variety of factors, including some that are discussed elsewhere in these risk factors and the following:

- delays in obtaining, or conditions imposed by, regulatory approvals;
- plant design errors;
- environmental pollution;
- non-performance by third party contractors;
- increases in materials or labour costs;
- construction performance falling below expected levels of output or efficiency;
- breakdown, aging or failure of equipment or processes;
- contractor or operator errors;
- labour disputes, disruptions or declines in productivity;
- inability to attract sufficient numbers of qualified workers;
- disruption in the supply of energy and utilities; or
- major incidents and/or catastrophic events such as fires, explosions, earthquakes or storms.

As a result, there is a risk that the Corporation may not have products, or a sufficient amount of products, available to meet the anticipated demand or to meet future demand when it arises.

### **Negative Cash Flow**

The Corporation has incurred losses since its inception. The Corporation may not be able to achieve or maintain profitability and may continue to incur significant losses in the future. In addition, the Corporation expects to continue to increase operating expenses as it implements initiatives to continue to grow its business. If the Corporation's revenues do not increase to offset these expected increases in costs and operating expenses, the Corporation will not be profitable.

# Concentration of Ownership of Common Shares

The officers and directors of the Corporation currently own, directly and indirectly, or exercise control or direction over, approximately 8% of the issued and outstanding Common Shares, on an undiluted basis. The Corporation's shareholders nominate and elect the Board, which generally has the ability to control the acquisition or disposition of the Corporation's assets, and the future issuance of its Common Shares or other securities. Accordingly, for any matters with respect to which a majority vote of the Common Shares may be required by law, the Corporation's directors and officers may have the ability to control such matters. Because the directors and officers control a substantial portion of such Common Shares, investors may

find it difficult or impossible to replace the Corporation's directors if they disagree with the way the Corporation's business is being operated.

# Inability to Develop New Products and Remain Competitive in the Market

The cannabis industry is in its early stages and it is likely that the Corporation and its competitors will seek to introduce new products in the future. In attempting to keep pace with any new market developments, the Corporation will need to expend significant amounts of capital in order to successfully develop and generate revenues from, new products. The Corporation may also be required to obtain additional regulatory approvals from applicable authorities based on the jurisdiction(s) in which it plans to distribute its products in, which may take significant time. The Corporation may not be successful in developing effective and safe new products, bringing such products to market in time to be effectively commercialized, or obtaining any required regulatory approvals, which together with capital expenditures made in the course of such product development and regulatory approval processes, may have a material adverse effect on the Corporation's business, financial condition and results of operations.

#### **Introduction of New Products**

Avicanna has a number of new products in the prototype stage which it anticipates will be introduced by the Corporation. Detailed costing of these products has not been completed. There can be no assurance that these new products can be brought to market, that they can be produced at a competitive price, or that they are commercially viable.

## **Construction Risk Factors**

The Corporation is subject to a number of construction risk factors, including the availability and performance of engineering and contractors, suppliers and consultants, the receipt of required governmental approvals and permits in connection with the construction of the facilities at SN and SMGH in Santa Marta, Colombia. Any delay in the performance of any one or more of the contractors, suppliers, consultants or other persons on which the Corporation is dependent in connection with its construction activities, a delay in or failure to receive the required governmental approvals and permits in a timely manner or on reasonable terms, or a delay in or failure in connection with the completion and successful operation of the operational elements in connection with construction could delay or prevent the construction of any expansion of the facilities. There can be no assurance that current or future construction plans implemented by the Corporation will be successfully completed on time, within budget and without design defect, that available personnel and equipment will be available in a timely manner or on reasonable terms to successfully complete construction projects, that the Corporation will be able to obtain all necessary governmental approvals and permits, or that the completion of the construction, the start-up costs and the ongoing operating costs will not be significantly higher than anticipated by the Corporation. Any of the foregoing factors could adversely impact the operations and financial condition of the Corporation.

### Co-Investment Risk

The Corporation has co-invested and may continue to co-invest in one or more investments with certain strategic investors and/or other third parties through joint ventures or other entities, which parties in certain cases may have different interests or superior rights to those of the Corporation. Although it is the Corporation's intent to retain control and other superior rights over the Corporation's investments, under

certain circumstances it may be possible that the Corporation relinquishes such rights over certain of its investments and, therefore, may have a limited ability to protect its position therein. In addition, even when the Corporation does maintain a control position with respect to its investments, the Corporation's investments may be subject to typical risks associated with third-party involvement, including the possibility that a third-party may have financial difficulties resulting in a negative impact on such investment, may have economic or business interests or goals that are inconsistent with those of the Corporation, or may be in a position to take (or block) action in a manner contrary to the Corporation's objectives. The Corporation may also, in certain circumstances, be liable for the actions of its third-party partners or co-investors. Co-investments by third parties may or may not be on substantially the same terms and conditions as the Corporation, and such different terms and conditions may be disadvantageous to the Corporation.

# Risk of Unspecified Investments

There can be no assurance that the Corporation will acquire favourable investment opportunities or that any such investments will generate revenues or profits. Failure to successfully manage the acquisition of investments could harm the Corporation's business, strategy and operating results in a material way. The Corporation's inability to implement its financing strategy successfully could adversely affect its profitability and its ability to satisfy its financial obligations. The transactions and their success may be exposed to a number of risks, including the risks that the Corporation may not be able to identify viable opportunities or, if it does identify viable opportunities, effect the transaction and that the investment may fail to perform.

### Insurance and Uninsured Risk

The Corporation's business is subject to a number of risks and hazards generally, including adverse environmental conditions, accidents, labour disputes and changes in the regulatory environment. Such occurrences could result in damage to assets, personal injury or death, environmental damage, delays in operations, monetary losses and possible legal liability.

Although the Corporation intends to continue to maintain insurance to protect against certain risks in such amounts as it considers to be reasonable, its insurance will not cover all of the potential risks associated with its operations. The Corporation may also be unable to maintain insurance to cover these risks at economically feasible premiums. Insurance coverage may not continue to be available or may not be adequate to cover any resulting liability.

# Reliance on Third-Party Suppliers, Manufacturers and Contractors

The Corporation intends to maintain a full supply chain for the provision of products and services to the regulated cannabis industry. Due to the uncertain regulatory landscape for regulating cannabis in Canada, Colombia, and the U.S., the Corporation's third-party suppliers, manufacturers and contractors may elect, at any time, to decline or withdraw services necessary for the Corporation's operations. Loss of its suppliers, service providers or distributors would have a material adverse effect on the Corporation's business and operational results. Disruption of the Corporation's manufacturing and distribution operations could adversely affect inventory supplies and the Corporation's ability to meet product delivery deadlines.

## No Assurances of Profit Generation or Immediate Results

There is no assurance as to whether the Corporation will be profitable, earn revenues, or pay dividends. The Corporation has incurred and anticipates that it will continue to incur substantial expenses relating to

the development and initial operations of its business. The payment and amount of any future dividends will depend upon, among other things, the Corporation's results of operations, cash flow, financial condition, and operating and capital requirements. There is no assurance that future dividends will be paid, and, if dividends are paid, there is no assurance with respect to the amount of any such dividends.

# **Ongoing Costs and Obligations**

The Corporation expects to incur significant ongoing costs and obligations related to its investment in infrastructure and growth and for regulatory compliance, which could have a material adverse impact on the Corporation's results of operations, financial condition and cash flows. In addition, future changes in regulations, more vigorous enforcement thereof or other unanticipated events could require extensive changes to the Corporation's operations, increase compliance costs or give rise to material liabilities, which could have a material adverse effect on the business, results of operations and financial condition of the Corporation. The Corporation's efforts to grow the business may be costlier than expected, and Avicanna may not be able to increase revenue enough to offset any higher operating expenses. Avicanna may incur significant losses in the future for a number of reasons, including the other risks described in this AIF, and unforeseen expenses, difficulties, complications and delays, and other unknown events. If Avicanna is unable to achieve and sustain profitability, the market price of the Common Shares may significantly decrease.

### Additional Financing

The building and operation of the Corporation's facilities and business are capital intensive. In order to execute the anticipated growth strategy, the Corporation will require some additional equity and/or debt financing to support on-going operations, to undertake capital expenditures or to undertake acquisitions or other business combination transactions.

There can be no assurance that additional financing will be available to the Corporation when needed or on terms which are acceptable. The Corporation's inability to raise financing to support on-going operations or to fund capital expenditures or acquisitions could limit the Corporation's growth and may have a material adverse effect upon future profitability. The Corporation may require additional financing to fund its operations to the point where it is generating positive cash flows.

If additional funds are raised through further issuances of equity or convertible debt securities existing shareholders could suffer significant dilution, and any new equity securities issued could have rights, preferences and privileges superior to those of holders of Common Shares. Any debt financing secured in the future could involve restrictive covenants relating to capital raising activities and other financial and operational matters, which may make it more difficult for the Corporation to obtain additional capital and to pursue business opportunities, including potential acquisitions.

## Competition

There is potential that the Corporation will face intense competition from other companies, some of which can be expected to have longer operating histories and more financial resources as well as manufacturing and marketing experience than the Corporation. Increased competition by larger and better financed competitors could materially and adversely affect the business, financial condition and results of operations of the Corporation.

Because of the early stage of the industry in which the Corporation operates, the Corporation expects to face additional competition from new entrants. If the number of users of medical cannabis products increases, the demand for products will increase and the Corporation expects that competition will become more intense, as current and future competitors begin to offer an increasing number of diversified products. To remain competitive, the Corporation will require a continued high level of investment in R&D, marketing, sales and client support. The Corporation may not have sufficient resources to maintain R&D, marketing, sales and client support efforts on a competitive basis which could materially and adversely affect the business, financial condition and results of operations of the Corporation.

# **Transportation Disruptions**

Due to the perishable and premium nature of the Corporation's products, the Corporation will depend on fast and efficient courier services to distribute its products. Any prolonged disruption of this courier service could have an adverse effect on the financial condition and results of operations of the Corporation. Rising costs associated with the courier services used by the Corporation to ship its products may also adversely impact the business of the Corporation and its ability to operate profitably.

# Reliance on Key Inputs

The Corporation's business is dependent on a number of key inputs and their related costs including raw materials and supplies related to its growing operations, as well as electricity, water and other local utilities. Any significant interruption or negative change in the availability or economics of the supply chain for key inputs could materially impact the business, financial condition and operating results of the Corporation. Any inability to secure required supplies and services or to do so on appropriate terms could have a materially adverse impact on the business, financial condition and operating results of the Corporation. Specifically, the Corporation plans to use its Extracts for use in its products. If the Corporation is unable to obtain, maintain and/or renew its quota for commercial cultivation of psychoactive genetic strains to permit it to produce sufficient or any THC Extracts, then the Corporation may have to purchase THC Extracts from other companies. In this case, the Corporation may not be able to purchase sufficient quantities of THC Extracts or may have to purchase the THC Extracts at prices that may reduce its margins.

## Risks Inherent in an Agricultural Business

A large portion of Avicanna's business involves the growing of medical cannabis, an agricultural product. Such business will be subject to the risks inherent in the agricultural business, such as insects, plant diseases, natural disasters and similar agricultural risks. While such growing will be completed in controlled outdoor and indoor environments, there can be no assurance that natural elements will not have a material adverse effect on any such future production, which may have an adverse effect on the financial results of the Corporation.

# Success of Quality Control Systems

The quality and safety of the Corporation's products are critical to the success of its business and operations. As such, it is imperative that the Corporation's (and its service providers') quality control systems operate effectively and successfully. Quality control systems can be negatively impacted by the design of the quality control systems, the quality training program, and adherence by employees to quality control guidelines. Although the Corporation strives to ensure that all of its service providers have

implemented and adhere to high caliber quality control systems, any significant failure or deterioration of such quality control systems could have a material adverse effect on the Corporation's business and operating results.

#### Potential for Conflicts of Interest

Certain of the employees and directors of the Corporation may also be directors, officers, consultants or stakeholders of other companies or enterprises, operating within the cannabis industry. As a result, there is the potential that conflicts of interest may arise between their duties to the Corporation and their duties to, or interests in, such other companies or enterprises. Certain of such conflicts may be required to be disclosed in accordance with, and subject to, such procedures and remedies as applicable under the OBCA, and applicable securities laws, however, such procedures and remedies may not fully protect the Corporation.

# Inability to Sustain Pricing Models

Significant price fluctuations for the fair market value of CBD and THC may have an adverse effect on the Corporation's future revenue, which would adversely affect the Corporation's results of operations and financial condition. In addition, increasing costs of labour, freight, energy, and other production inputs may increase the Corporation's costs and it may not be able to offset them through increases in pricing which could adversely affect its results from operations and financial condition.

### **Acquisition Risks**

The Corporation may acquire other companies in the future and there are risks inherent in any such acquisition. Specifically, there could be unknown or undisclosed risks or liabilities of such companies for which the Corporation is not sufficiently indemnified. Any such unknown or undisclosed risks or liabilities could materially and adversely affect the Corporation's financial performance and results of operations. The Corporation could encounter additional transaction and integration related costs or other factors such as the failure to realize all of the benefits from such acquisitions. All of these factors could cause dilution to the Corporation's earnings per share or decrease or delay the anticipated accretive effect of the acquisition and cause a decrease in the market price of the Corporation's securities. The Corporation may not be able to successfully integrate and combine the operations, personnel and technology infrastructure of any such acquired entity with its existing operations. If integration is not managed successfully by the Corporation's management, the Corporation may experience interruptions in its business activities, deterioration in its employee and customer relationships, increased costs of integration and harm to its reputation, all of which could have a material adverse effect on the Corporation's business, financial condition and results of operations. The Corporation may experience difficulties in combining corporate cultures, maintaining employee morale and retaining key employees. The integration of any such acquired companies may also impose substantial demands on management. There is no assurance that any such acquisitions will be successfully integrated in a timely manner.

# Use of Individual Information

The Corporation collects, processes, maintains and uses data, including sensitive information on individuals, available to the Corporation through its subsidiary, 2516167 Ontario Inc. (d.b.a. My Cannabis). The Corporation's current and future marketing and R&D programs and initiatives may depend on its ability

to collect, maintain and use this information, and its ability to do so is subject to evolving international, U.S., and Canadian laws and enforcement trends. The Corporation strives to comply with all applicable laws and other legal obligations relating to privacy, data protection and customer protection, including those relating to the use of data for marketing purposes. It is possible, however, that these requirements may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another, conflict with other rules, conflict with the Corporation's practices or fail to be observed by its employees or business partners. If so, the Corporation may suffer damage to its reputation and be subject to proceedings or actions against it by governmental entities or others. Any such proceeding or action could hurt the Corporation's reputation, force it to spend significant amounts to defend its practices, distract its management or otherwise have an adverse effect on its business.

# Information Systems Security Threats

The Corporation has entered into agreements with third parties for hardware, software, telecommunications and other information technology ("IT") services in connection with its operations. The Corporation's operations depend, in part, on how well it and its suppliers protect networks, equipment, IT systems and software against damage from a number of threats, including, but not limited to, cable cuts, damage to physical plants, natural disasters, terrorism, fire, power loss, hacking, computer viruses, vandalism and theft. The Corporation's operations also depend on the timely maintenance, upgrade and replacement of networks, equipment, IT systems and software, as well as pre-emptive expenses to mitigate the risks of failures. Any of these and other events could result in information system failures, delays and/or increases in capital expenses. The failure of information systems or a component of information systems could, depending on the nature of any such failure, adversely impact the Corporation's reputation and results of operations.

Cyber incidents can result from deliberate attacks or unintentional events. Cyber-attacks could result in any person gaining unauthorized access to digital systems for purposes of misappropriating assets or sensitive information, including personally identifiable information, corrupting data, or causing operational disruption. Cyber-attacks could also result in important remediation costs, increased cyber security costs, lost revenues due to a disruption of activities, litigation and reputational harm affecting customer and investor confidence, which could materially adversely affect our business and financial results.

The Corporation has not experienced any material losses to date relating to cyber-attacks or other information security breaches, but there can be no assurance that the Corporation will not incur such losses in the future which could be in excess of any available insurance, and could materially adversely affect our business and financial results. The Corporation's risk and exposure to these matters cannot be fully mitigated because of, among other things, the evolving nature of these threats. As a result, cyber security and the continued development and enhancement of controls, processes and practices designed to protect systems, computers, software, data and networks from attack, damage or unauthorized access is a priority. As cyber threats continue to evolve, the Corporation may be required to expend additional resources to continue to modify or enhance protective measures or to investigate and remediate any security vulnerabilities.

## Dependence on Suppliers and Skilled Labour

The ability of the Corporation to compete and grow will be dependent on it having access, at a reasonable cost and in a timely manner, to skilled labour, equipment, parts and components. No assurances can be given that the Corporation will be successful in maintaining its required supply of skilled labour, equipment, parts and components. It is also possible that the final costs of the major equipment contemplated by the

Corporation's capital expenditure program may be significantly greater than anticipated by the Corporation's management, and may be greater than funds available to the Corporation, in which circumstance the Corporation may curtail, or extend the timeframes for completing, its capital expenditure plans. This could have an adverse effect on the financial results of the Corporation.

# Operating Risk and Insurance Coverage

The Corporation has insurance to protect its assets, operations and employees. While the Corporation believes its insurance coverage addresses all material risks to which it is exposed and is adequate and customary in its current state of operations, such insurance is subject to coverage limits and exclusions and may not be available for the risks and hazards to which the Corporation is exposed. In addition, no assurance can be given that such insurance will be adequate to cover the Corporation's liabilities or will be generally available in the future or, if available, that premiums will be commercially justifiable. If the Corporation were to incur substantial liability and such damages were not covered by insurance or were in excess of policy limits, or if the Corporation were to incur such liability at a time when it is not able to obtain liability insurance, its business, results of operations and financial condition could be materially adversely affected.

# **Product Liability**

As a manufacturer and distributor of products designed to be consumed by humans, the Corporation faces an inherent risk of exposure to product liability claims, regulatory action and litigation if its products are alleged to have caused significant loss or injury. In addition, the manufacture and sale of the Corporation's products involve the risk of injury to consumers due to tampering by unauthorized third parties or product contamination. Previously unknown adverse reactions resulting from human consumption of the Corporation's products alone or in combination with other medications or substances could occur. The Corporation may be subject to various product liability claims, including, among others, that the Corporation's products caused injury or illness, include inadequate instructions for use or include inadequate warnings concerning possible side effects or interactions with other substances. A product liability claim or regulatory action against the Corporation could result in increased costs, could adversely affect the Corporation's reputation with its clients and consumers generally, and could have a material adverse effect on our results of operations and the financial condition of the Corporation. There can be no assurances that the Corporation will be able to obtain or maintain product liability insurance on acceptable terms or with adequate coverage against potential liabilities. Such insurance is expensive and may not be available in the future on acceptable terms, or at all. The inability to obtain sufficient insurance coverage on reasonable terms or to otherwise protect against potential product liability claims could prevent or inhibit the commercialization of the Corporation's potential products.

### **Product Recalls**

Manufacturers and distributors of products are sometimes subject to the recall or return of their products for a variety of reasons, including product defects, such as contamination, unintended harmful side effects or interactions with other substances, packaging safety and inadequate or inaccurate labeling disclosure. If any of the Corporation's products are recalled due to an alleged product defect or for any other reason, the Corporation could be required to incur the unexpected expense of the recall and any legal proceedings that might arise in connection with the recall. The Corporation may lose a significant amount of sales and may not be able to replace those sales at an acceptable margin or at all. In addition, a product recall may

require significant management attention. Although the Corporation has detailed procedures in place for testing finished products, there can be no assurance that any quality, potency or contamination problems will be detected in time to avoid unforeseen product recalls, regulatory action or lawsuits. Additionally, if one of the Corporation's significant brands were subject to recall, the image of that brand and the Corporation could be harmed. A recall for any of the foregoing reasons could lead to decreased demand for the Corporation's products and could have a material adverse effect on the results of operations and financial condition of the Corporation. Additionally, product recalls may lead to increased scrutiny of the Corporation's operations by Health Canada or other regulatory agencies, requiring further management attention and potential legal fees and other expenses.

### Fraudulent or Illegal Activity by the Corporation's Employees, Contractors and Consultants

The Corporation is exposed to the risk that its employees, independent contractors and consultants may engage in fraudulent or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or fail to disclose unauthorized activities to the Corporation that violates: (a) government regulations; (b) manufacturing standards; (c) federal and provincial healthcare fraud and abuse laws and regulations; or (d) laws that require the true, complete and accurate reporting of financial information or data. It is not always possible for the Corporation to identify and deter misconduct by its employees and other third parties, and the precautions taken by the Corporation to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting the Corporation from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against the Corporation, and it is not successful in defending itself or asserting its rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of the Corporation's operations, any of which could have a material adverse effect on the Corporation's business, financial condition and results of operations.

#### Security Breaches at Corporation's Facilities

Given the nature of the Corporation's product and its lack of legal availability outside of government approved channels, as well as the concentration of inventory in its Colombian facilities, and despite meeting or exceeding Colombian security requirements, there remains a risk of security breach as well as theft. A security breach at one of the Corporation's facilities could expose the Corporation to additional liability and to potentially costly litigation, increased expenses relating to the resolution and future prevention of these breaches and may deter potential patients from choosing the Corporation's products.

#### Management of Growth

The Corporation may be subject to growth-related risks including capacity constraints and pressure on its internal systems and controls. The ability of the Corporation to manage growth effectively will require it to continue to implement and improve its operational and financial systems and to expand, train and manage its employee base. The inability of the Corporation to deal with this growth may have a material adverse effect on the Corporation's business, financial condition, results of operations and prospects.

#### Reputational Harm

Damage to the Corporation's reputation can be the result of the actual or perceived occurrence of any number of events, and could include any negative publicity, whether true or not. The increased usage of social media and other web-based tools used to generate, publish and discuss user-generated content and to connect with other users has made it increasingly easier for individuals and groups to communicate and share opinions and views regarding the Corporation and its activities, whether true or not. Although the Corporation believes that it operates in a manner that is respectful to all stakeholders and that it takes pride in protecting its image and reputation, the Corporation does not ultimately have direct control over how it is perceived by others. Reputation loss may result in decreased investor confidence, increased challenges in developing and maintaining community relations and an impediment to the Corporation's overall ability to advance its projects, thereby having a material adverse impact on financial performance, financial condition, cash flows and growth prospects.

# Legal Proceedings

In the course of the Corporation's business, the Corporation may from time to time have access to confidential or proprietary information of third parties, and these parties could bring a claim against the Corporation asserting that it has misappropriated their technologies and improperly incorporated such technologies into its products. Due to these factors, there remains a constant risk of intellectual property litigation affecting the Corporation's business. In the future, the Corporation may be made a party to litigation involving intellectual property matters and such actions, if determined adversely, could have a material adverse effect on the Corporation.

#### Inability to Protect Intellectual Property

The Corporation's success depends a significant degree upon its ability to develop, maintain and protect proprietary products and technologies. The Corporation may file patent applications in the U.S., Canada, Colombia, Europe, and selectively in other foreign countries as part of its strategy to protect its proprietary products and technologies. However, patents provide only limited protection of the Corporation's intellectual property. The assertion of patent protection involves complex legal and factual determinations and is therefore uncertain and expensive. The Corporation cannot provide assurances that patents will be granted with respect to any of its pending patent applications, that the scope of any of its patents will be sufficiently broad to offer meaningful protection, or that it will develop additional proprietary technologies that are patentable. This could result in the Corporation's patent rights failing to create an effective competitive barrier. Losing a significant patent or failing to get a patent to issue from a pending patent application that the Corporation considers significant could have a material adverse effect on its business. The laws governing the scope of patent coverage in various countries continue to evolve. The laws of some foreign countries may not protect the Corporation's intellectual property rights to the same extent as the laws of Canada and the U.S. The Corporation holds patents only in selected countries. Therefore, third parties may be able to replicate technologies covered by the Corporation's patents in countries in which it does not have patent protection.

There can be no assurances that the steps taken by the Corporation to protect its intangible property, technology and information will be adequate to prevent misappropriation or independent third-party development of the Corporation's intangible property, technology or processes. It is likely that other

companies can duplicate a production process similar to the Corporation's. Other companies may also be able to materially duplicate the Corporation's proprietary plant strains. To the extent that any of the above would occur, revenue could be negatively affected, and in the future, the Corporation may have to litigate to enforce its intangible property rights, which could result in substantial costs and divert management's attention and other resources.

The Corporation's ability to successfully implement its business plan depends in part on its ability to obtain, maintain and build brand recognition using its trademarks, service marks, trade dress, domain names and other intellectual property rights, including the Corporation's names and logos. If the Corporation's efforts to protect its intellectual property are unsuccessful or inadequate, or if any third party misappropriates or infringes on its intellectual property, the value of its brands may be harmed, which could have a material adverse effect on the Corporation's business and might prevent its brands from achieving or maintaining market acceptance.

The Corporation may be unable to obtain registrations for its intellectual property rights for various reasons, including refusal by regulatory authorities to register trademarks or other intellectual property protections, prior registrations of which it is not aware, or it may encounter claims from prior users of similar intellectual property in areas where it operates or intends to conduct operations. This could harm its image, brand or competitive position and cause the Corporation to incur significant penalties and costs.

#### Intellectual Property Claims

The Corporation's future success and competitive position depends in part upon its ability to maintain its intellectual property portfolio. There can be no assurance that any patents will be issued on any existing or future patent applications. Even if such patents are issued, there can be no assurance that any patents issued or licensed to the Corporation will not be challenged. The Corporation's ability to establish and maintain a competitive position may be achieved in part by prosecuting claims against others who it believes to be infringing its rights. In addition, enforcement of the Corporation's patents in foreign jurisdictions will depend on the legal procedures in those jurisdictions. Even if such claims are found to be invalid, the Corporation's involvement in intellectual property litigation could have a material adverse effect on its ability to distribute any products that are the subject of such litigation. In addition, the Corporation's involvement in intellectual property litigation could result in significant expense, which could materially adversely affect the use responsibilities, whether or not such litigation is resolved in the Corporation's favour.

Companies in the retail and wholesale industries frequently own trademarks and trade secrets and often enter into litigation based on allegations of infringement or other violations of intangible property rights. The Corporation may be subject to intangible property rights claims in the future and its products may not be able to withstand any third-party claims or rights against their use. Any intangible property claims, with or without merit, could be time consuming, expensive to litigate or settle and could divert management resources and attention. An adverse determination also could prevent the Corporation from offering its products to others and may require that the Corporation procure substitute products or services.

With respect to any intangible property rights claim, the Corporation may have to pay damages or stop using intangible property found to be in violation of a third party's rights. The Corporation may have to seek a licence for the intangible property, which may not be available on reasonable terms and may significantly increase operating expenses. The technology also may not be available for licence at all. As a result, the

Corporation may also be required to pursue alternative options, which could require significant effort and expense. If the Corporation cannot licence or obtain an alternative for the infringing aspects of its business, it may be forced to limit product offerings and may be unable to compete effectively. Any of these results could harm the Corporation's brand and prevent it from generating sufficient revenue or achieving profitability.

Additionally, the Corporation will not be able to register any U.S. federal trademarks for its cannabis-related products. Because producing, manufacturing, processing, possessing, distributing, selling, and using cannabis is illegal under the *Controlled Substances Act*, and the Corporation's marks are being used (or intended to be used) in connection with goods that are illegal under the *Controlled Substances Act*, the actual lawful use of the marks in association with our products is not permitted. As a result, the Corporation likely will be unable to protect its cannabis-related product trademarks beyond the geographic areas in which it conducts business.

#### Constraints on Cross-border Travel for Employees

On October 22, 2018, the U.S. Customs and Border Protection released a policy statement indicating that Canadian citizens working in or facilitating the proliferation of the legal marijuana industry in Canada, travelling to the U.S. for reasons unrelated to the marijuana will generally be admissible. However, if the traveler is found to be entering into the U.S. for reasons related to the marijuana industry, they may be deemed inadmissible. Travel restrictions imposed on the Corporation's employees impair the Corporation's ability to take advantage of cost-efficient travel routes that may stop within the U.S. when employees are travelling for business.

#### Website Accessibility

Internet websites are visible by people everywhere, not just in jurisdictions where the activities described therein are considered legal. As a result, to the extent the Corporation sells services or products via webbased links targeting only jurisdictions in which such sales or services are compliant with state law, the Corporation may face legal action in other jurisdictions which are not the intended object of any of the Corporation's marketing efforts for engaging in any web-based activity that results in sales into such jurisdictions deemed illegal under applicable laws.

#### Limited Experience Managing a Public Company

Our Chief Executive Officer has limited experience managing a public company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies. While certain other executives and advisors we have engaged have such experience, our management team, as a whole, may not successfully or efficiently manage the ongoing transition to being a public issuer subject to significant regulatory oversight and reporting obligations under the securities laws and the continuous scrutiny of securities analysts and investors. These new obligations and constituents will require significant attention from our senior management, particularly from our Chief Executive Officer, and could divert their attention away from the day-to-day management of the Corporation's business, which could adversely affect the business, financial condition and results of operations.

#### Trade Secrets may be Difficult to Protect

The Corporation's success depends upon the skills, knowledge and experience of its scientific and technical personnel, consultants and advisors, as well as contractors. Because the Corporation operates in a highly competitive industry, it relies in part on trade secrets to protect its proprietary products and processes; however, trade secrets are difficult to protect. The Corporation enters into confidentiality or non-disclosure agreements with its corporate partners, employees, consultants, outside scientific collaborators, developers and other advisors. These agreements generally require that the receiving party keep confidential, and not disclose to third parties, confidential information developed by the receiving party or made known to the receiving party by the Corporation during the course of the receiving party's relationship with the Corporation. These agreements also generally provide that inventions conceived by the receiving party in the course of rendering services to the Corporation will be its exclusive property, and the Corporation enters into assignment agreements to perfect its rights.

These confidentiality, inventions and assignment agreements, where in place, may be breached and may not effectively assign intellectual property rights to the Corporation. The Corporation's trade secrets also could be independently discovered by competitors, in which case the Corporation would not be able to prevent the use of such trade secrets by its competitors. The enforcement of a claim alleging that a party illegally obtained and was using the Corporation's trade secrets could be difficult, expensive and time consuming and the outcome could be unpredictable. The failure to obtain or maintain meaningful trade secret protection could adversely affect the Corporation's competitive position.

#### Internal Controls

Effective internal controls are necessary for the Corporation to provide reliable financial reports and to help prevent fraud. Although the Corporation will undertake a number of procedures and will implement a number of safeguards, in each case, in order to help ensure the reliability of its financial reports, the Corporation cannot be certain that such measures will ensure that the Corporation will maintain adequate control over financial processes and reporting. During the course completing the audit of the Corporation's financial statements for the year ended December 31, 2020, the Corporation's auditors identified two material control weaknesses, namely: i) controls around the record keeping and source documentation for the Corporation's property, plant and equipment; and ii) weaknesses around the recording and approval of manual journal entries. Management determined that these material weaknesses did not have any impact on the Corporation's financial reporting or its ICFR. While management intends to undertake a detailed review of its internal control environment to address the material weaknesses identified, failure to implement required new or improved controls, or difficulties encountered in their implementation, could harm the Corporation's results of operations or cause it to fail to meet its reporting obligations. The identification of the material weaknesses and/or the inability to adequately address such weaknesses could adversely impact the market's confidence in the Corporation's consolidated financial statements and materially adversely affect the trading price of the Common Shares.

#### Risks Related to the Regulatory Environment

#### The Corporation's Business is Heavily Regulated

The activities of Avicanna and its subsidiaries are, and will continue to be, regulated as applicable laws continue to change and develop. Achievement of the Corporation's business objectives are contingent, in part, upon compliance with necessary and applicable regulatory requirements enacted by governmental authorities and obtaining all regulatory approvals necessary. Regulatory compliance and the process of obtaining regulatory approval can be costly and time consuming. No assurance can be given that Avicanna or its subsidiaries will be able to maintain the requisite licenses, permits, or authorizations to operate its business. Any delays in obtaining, or failure to obtain regulatory approvals would significantly delay the development of the Corporation's plans and could have a material adverse effect on the business, results of operations and financial condition of the Corporation. Further, the Corporation cannot predict what kind of regulatory requirements the business will be subject to in the future.

#### There is a Substantial Risk of Regulatory or Political Change

Achievement of the Corporation's business objectives is also contingent, in part, upon compliance with other regulatory requirements enacted by governmental authorities and obtaining other required regulatory approvals. The regulatory regimes applicable to the cannabis business in each of Canada, Colombia and the U.S. are currently undergoing significant proposed changes and the Corporation cannot predict the impact of the regime on its business once the structure of the regime is finalized. Similarly, the Corporation cannot predict the timeline required to secure all appropriate regulatory approvals for its products, or the extent of testing and documentation that may be required by governmental authorities. Any delays in obtaining, or failing to obtain, required regulatory approvals may significantly delay or impact the development of markets, products and sales initiatives and could have a material adverse effect on the business, results of operations and financial condition of the Corporation. The Corporation will incur ongoing costs and obligations related to regulatory compliance. Failure to comply with regulations may result in additional costs for corrective measures, penalties or in restrictions on the Corporation's operations. In addition, changes in regulations, more vigorous enforcement thereof or other unanticipated events could require extensive changes to the Corporation's operations, increased compliance costs or give rise to material liabilities, which could have a material adverse effect on the business, results of operations and financial condition of the Corporation.

Furthermore, there may be unknown additional regulatory fees and taxes that may be assessed in the future. The Corporation is aware that multiple jurisdictions have imposed or are considering special taxes or fees on businesses in the cannabis industry. It is a potential yet unknown risk at this time that other states are in the process of reviewing such additional fees and taxation. This could change the net income and return on the Corporation's investments and/or participation in the selected business opportunities.

# Global Financial Conditions can Reduce Share Prices and Limit Access To Financing

The economic viability of the Corporation's business plan is impacted by the Corporation's ability to obtain financing. Global economic conditions impact the general availability of financing through public and private debt and equity markets, as well as through other avenues.

Significant political, market and economic events may have wide-reaching effects and, to the extent they are not accurately anticipated or priced into markets, may result in sudden periods of market volatility and correction. Periods of market volatility and correction may have an adverse impact on economic growth and outlook, as well as lending and capital markets activity, all of which may impact the Corporation's ability to secure adequate financing on favourable terms, or at all.

Furthermore, general market, political and economic conditions, including, for example, inflation, interest and currency exchange rates, political developments, legislative or regulatory changes, social or labour unrest and stock market trends will affect the Corporation's operating environment and its operating costs, profit margins and share price. Uncertainty or adverse changes relating to government regulation, economic and foreign policy matters, and other world events have the potential to adversely affect the performance of and outlook for the Canadian and global economies, which in turn may affect the ability of the Corporation to access financing on favourable terms or at all. For example, recent uncertainty regarding Canada's ability to access North American markets via the North American Free Trade Agreement and increased levels of turmoil in certain geopolitical hotspots have the potential to increase uncertainty and volatility in Canadian and global markets, respectively. The occurrence of negative sentiment or events in the Canadian and broader global economy could have a material adverse effect on the Company's business, financial condition, results of operations, cash flows or prospects.

#### Clinical Testing and Regulatory Approval

The Corporation's success is dependent on the successful completion of clinical trials, regulatory approval and introduction of its products and technology into the market, and the Corporation does not know if it will be able to complete them. The actual timing of these events can vary dramatically due to factors such as delays or failures in the Corporation's clinical trials and the uncertainties inherent in the regulatory approval process. The Corporation might not be able to obtain the necessary results from its clinical trials or to gain regulatory approval necessary for licensing its products and technology. The Corporation's failure to achieve these objectives will mean that an investor will not be able to recoup their investment or to receive a profit on their investment.

#### Risks of Foreign Operations Generally

Certain of the Corporation's cannabis cultivation interests, operations and suppliers are located in foreign jurisdictions. As a result, the Corporation is subject to political, economic and other uncertainties, including, but not limited to, changes, sometimes frequent, in agriculture and drug policies or the personnel administering them, nationalization, expropriation of property without fair compensation, cancellation or modification of contract rights, foreign exchange restrictions, currency fluctuations, export quotas, royalty and tax increases and other risks arising out of foreign governmental sovereignty over the areas in which the Corporation's operations and their suppliers' operations are conducted, as well as risks of loss due to civil strife, acts of war, guerrilla activities and insurrections. The Corporation's operations may also be adversely affected by laws and policies of Canada affecting foreign trade, taxation and investment. In the event of a dispute arising in connection with its operations, the Corporation may be subject to the exclusive jurisdiction of foreign courts or may not be successful in subjecting foreign persons to the jurisdiction of courts in Canada or enforcing Canadian judgments in foreign jurisdictions. In addition, the Corporation's existing subsidiaries are formed pursuant to, and its operations are governed by, a number of complex legal and contractual relationships. The effectiveness of and enforcement of such contracts and relationships

with parties in these jurisdictions cannot be assured. Consequently, the Corporation's foreign cultivation, development and production activities could be substantially affected by factors beyond the Corporation's control, any of which could have a material adverse effect on the Corporation.

#### **Enforcement of Judgements**

Certain of the Corporation's operations and assets are located outside of Canada and certain of its directors and officers reside outside of Canada. Although the directors and officers who reside outside of Canada have appointed an agent for service of process in Canada, it may not be possible for investors to enforce against such person's judgements obtained in Canadian courts. Investors are advised that it may not be possible for them to enforce judgments obtained in Canada against any person or company that is incorporated, continued or otherwise organized under the laws of a foreign jurisdiction or that resides outside of Canada, even if the party has appointed an agent for service of process.

# Inability to Obtain or Retain Licences Required for the Business and Future Plans

The Corporation's ability to grow, store and sell cannabis in Colombia is dependent on the ability of the both SN and SMGH to retain the issued cannabis cultivation, manufacturing and distribution licences from the Colombian Ministry of Health and MJL. Licences, once issued, are subject to ongoing compliance and reporting requirements. Failure to comply with the requirements would have a material adverse impact on the business, financial condition and operating results of the Corporation. There is also no assurance of new licences or approvals from the Colombian Ministry of Health and MJL.

The Corporation may be required to obtain and maintain certain permits, licences and approvals in the jurisdictions where its products are manufactured and licensed. There can be no assurances that the Corporation will be able to obtain or maintain any necessary licences, permits, or approvals, including, without limitation, quotas to cultivate psychoactive cannabis for commercial purposes. Moreover, the Corporation and/or third party suppliers of CBD and THC extracts could be required to obtain permits and licences. Any material delay or inability to receive these items is likely to result in a delay and/or inhibit the Corporation's ability to conduct its business and would have an adverse effect on its business, financial condition and results from operations.

#### Ability to Establish and Maintain Bank Accounts

While Avicanna does not anticipate dealing with banking restrictions, there is a risk that banking institutions in countries and jurisdictions where the Corporation operates, such as Colombia, will not accept payments related to the cannabis industry. Such risks could increase costs and make it difficult to transfer funds. In the event financial service providers do not accept accounts or transactions related to the cannabis industry, it is possible that Avicanna may be required to seek alternative payment solutions. There are inherent risks associated with alternative payment methods including but not limited to reliability and security of such methods. Our inability to manage such risks may adversely affect Avicanna's operations and financial performance.

# Involvement in Regulatory or Agency Proceedings, Investigations and Audits

Our business and the business of the third parties with which we do business, requires compliance with many laws and regulations. Failure to comply with these laws and regulations could subject us or such third

parties to regulatory or agency proceedings or investigations and could also lead to damages awards, fines and penalties. We, or such third parties, may become involved in a number of government or agency proceedings, investigations and audits. The outcome of any regulatory or agency proceedings, investigations, audits, and other contingencies could harm our reputation or the reputations of the brands that we sell, require us to take, or refrain from taking, actions that could harm our operations or require us to pay substantial amounts of money, harming our financial condition. There can be no assurance that any pending or future regulatory or agency proceedings, investigations and audits will not result in substantial costs or a diversion of management's attention and resources or have a material adverse impact on our business, financial condition and results of operations.

# Environmental, Health and Safety Laws

The Corporation is subject to environmental, health and safety laws and regulations in each jurisdiction in which it operates. Such regulations govern, among other things, the maintenance of air and water quality standards and land reclamation, and the health and safety of the Corporation's employees. They also set forth limitations on the generation, transportation, storage and disposal of solid and hazardous waste. Environmental, health and safety legislations are evolving in a manner which will require stricter standards and enforcement, increased fines and penalties for non-compliance, more stringent assessments of proposed projects and a heightened degree of responsibility for companies and their officers, directors and employees. There is no assurance that future changes in environmental, health and safety regulations, if any, will not adversely affect the Corporation's operations.

Government environmental approvals and permits are currently and may in the future be required in connection with the Corporation's operations. To the extent such approvals are required and not obtained, the Corporation may be curtailed or prohibited from its proposed business activities or from proceeding with the development of its operations as currently proposed.

Failure to comply with applicable environmental laws, regulations and permitting requirements may result in enforcement actions thereunder, including orders issued by regulatory or judicial authorities causing operations to cease or be curtailed, and may include corrective measures requiring capital expenditures, installation of additional equipment, or remedial actions. The Corporation may be required to compensate those suffering loss or damage due to its operations and may have civil or criminal fines or penalties imposed on it for violations of applicable laws or regulations.

As with other companies engaged in similar activities or that own or operate real property, the Corporation faces inherent risks of environmental liability at its current and historical production sites. Certain environmental laws impose strict and, in certain circumstances, joint and several liability on current or previous owners or operators of real property for the cost of the investigation, removal or remediation of hazardous substances as well as liability for related damages to natural resources. In addition, the Corporation may discover new facts or conditions that may change its expectations or be faced with changes in environmental laws or their enforcement that would increase its liabilities. Furthermore, its costs of complying with current and future environmental and health and safety laws, or the Corporation's liabilities arising from past or future releases of, or exposure to, regulated materials, may have a material adverse effect on its business, financial condition and results of operations.

#### U.S. Cannabis Industry

As previously stated, violations of any federal laws and regulations could result in significant fines, penalties, administrative sanctions, convictions or settlements arising from civil proceedings conducted by either the federal government or private citizens, or criminal charges, including, but not limited to, disgorgement of profits, cessation of business activities or divestiture. A violation by the Corporation of U.S. federal law could have a material adverse effect on its reputation and ability to conduct business, the listing of its securities on any stock exchange, its financial position, operating results and profitability. In addition, it is difficult for the Corporation to estimate the time or resources that would be needed for the investigation of any such matters or its final resolution because, in part, the time and resources that may be needed are dependent on the nature and extent of any information requested by the applicable authorities involved, and such time or resources could be substantial. The approach to the enforcement of cannabis laws may be subject to change or may not proceed as previously outlined.

To date, the Corporation's involvement in the U.S. has only been in respect of the development and distribution of hemp-derived cannabinoid-based products for third parties and the export of hemp seeds to the United States. The Corporation may, in future periods, expand its operations in the United States. The Corporation intends to continue to monitor, evaluate and re-assess the regulatory framework in the United States on an ongoing basis.

#### Anti-Money Laundering Laws and Regulations

Entities operating in the United States are subject to a variety of laws and regulations in the U.S. that involve anti-money laundering, financial recordkeeping and proceeds of crime, including the U.S. Currency and Foreign Transactions Reporting Act of 1970 (commonly known as the Bank Secrecy Act), as amended by Title III of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (USA PATRIOT Act) and the rules and regulations thereunder, and any related or similar rules, regulations or guidelines, issued, administered or enforced by governmental authorities in the U.S. Further, under U.S. federal law, banks or other financial institutions that provide a cannabis business with a checking account, debit or credit card, small business loan, or any other service could be found guilty of money laundering, aiding and abetting, or conspiracy.

While the Corporation does not anticipate it to be the case given that its operations in the United States are only related to hemp-based products, which are regulated under the 2018 Farm Bill, any proceeds it receives from third parties that engage in businesses related to cannabis may be considered proceeds of crime, and the Corporation could be deemed to be aiding and abetting, due to the fact that cannabis remains illegal federally in the U.S.

#### **Risks Specifically Related to Colombian Operations**

# Control of Foreign Subsidiaries

Two of our subsidiaries, Avicanna LATAM (100% equity interest) and SMGH (60% equity interest), operate in, and are governed by the laws of, Colombia. Our Colombian subsidiaries are separate and distinct legal entities but Avicanna is nevertheless exposed to significant political risk resulting from operations in Colombia. In particular, operations in Colombia may be severely impacted by the changing political and

legal landscape (described in greater below). These risks may have a significant impact on the ability of Avicanna to carry on business operations. As well, any structure that separates the Board from operating subsidiaries may present challenges for the Board in effectively directing the decision making of the applicable subsidiary. Key operating decisions may be made at lower levels of the corporate hierarchy without being communicated to the Board for its consideration. Our corporate structure involving Colombian subsidiaries may also make it more difficult for the Board to fully understand the risks associated with each subsidiary.

#### Colombian Political and Economic Conditions

The Colombian government has exercised, and continues to exercise, significant influence over the Colombian economy and frequently intervenes in the Colombian economy to control inflation and affect other policies in such areas as wage and price controls, currency devaluations, capital controls and limits on imports, among other things. The Corporation's cannabis cultivation business, financial condition and results of operations may be adversely affected by changes in policy involving tariffs, exchange controls and other matters, as well as factors such as inflation, currency devaluation, exchange rates and controls, interest rates, changes in government leadership, policy, taxation and other political, economic or other developments in or affecting Colombia, including civil disturbances, regional terrorism, armed conflict and/or war. There is a risk of rebel, terrorist attacks and kidnappings against facilities and personnel involved in the cannabis cultivation operations at the Colombian properties in which the Corporation has an interest.

#### **Currency Risks**

The Corporation is exposed to foreign exchange risks since much of its revenue, cultivation and manufacturing costs are expected to be received/paid in or by reference to Colombian peso denominated prices while the majority of its general and administrative costs are in Canadian dollars. The exchange rates between Canadian dollars, Colombian pesos, Swiss francs and U.S. dollars have varied substantially recently. The Corporation does not engage in active hedging to minimize exchange rate risk.

# Inflationary Risks

Historically, Colombia has experienced double digit rates of inflation. If this continues, costs may increase substantially given respective changes in the exchange rates. In addition, this may affect the Corporation's ability to raise additional capital. The government's response to such inflationary pressures might include monetary and fiscal policy that may have an adverse effect on the Corporation.

# Repatriation of Earnings from Colombia

There are currently no restrictions on the repatriation from Colombia of earnings to foreign entities. However, there can be no assurance that restrictions on repatriations of earnings from Colombia will not be imposed in the future. Exchange control regulations require that any proceeds in foreign currency originated on exports of goods from Colombia (including minerals) be repatriated to Colombia. However, purchase of foreign currency is allowed through any Colombian authorized financial entities for the purpose of payments to foreign suppliers, repayment of foreign debt, payments of dividends to foreign stockholders and other foreign expenses.

#### Colombian Legal System

The Colombian legal system may expose Avicanna to risks such as: (a) effective legal redress in the courts, whether in respect of a breach of law or regulation or in an ownership dispute, being more difficult to obtain; (b) a higher degree of discretion on the part of governmental authorities; (c) the lack of judicial or administrative guidance on interpreting applicable rules and regulations; (d) inconsistencies or conflicts between and within various laws, regulations, decrees, orders and resolutions; or (e) relative inexperience of the judiciary and courts in such matters. The commitment of local business people, government officials and agencies and the judicial system to abide by legal requirements and negotiated agreements may be more uncertain in Colombia, creating particular concerns with respect to licenses and agreements for business. These may be susceptible to revision or cancellation and legal redress may be uncertain or delayed. There can be no assurance that joint ventures, licenses, license applications or other legal arrangements will not be adversely affected by the actions of government authorities or others and the effectiveness of and enforcement of such arrangements in Colombia cannot be assured.

#### **DIVIDEND POLICY**

The Corporation has not declared any cash dividends or distributions for any of our securities in the past and no such dividends or distributions are contemplated for the current financial year. As of the date hereof, there are no restrictions that prevent the Corporation from paying dividends on the Common Shares. The Corporation has neither declared nor paid any dividends on its shares and it is not contemplated that the Corporation will pay dividends in the immediate or foreseeable future. The Corporation currently intends to retain future earnings and other cash resources to fund the development and growth of our business and does not anticipate paying dividends in the foreseeable future. Any determination to pay dividends in the future will be at the discretion of the Board and will depend on many factors, including, among others, our financial condition, current and anticipated cash requirements, contractual restrictions, financing agreement covenants, solvency tests imposed by applicable corporate law and other factors that the Board may deem relevant.

#### **CAPITAL STRUCTURE**

The authorized capital of the Corporation consists of an unlimited number of Common Shares. As of the date of this AIF, there are 83,198,475 Common Shares issued and outstanding. In addition, as of the date of this AIF, there were 2,157,797 Common Shares issuable on the exercise of Stock Options, 28,096,314 Common Shares issuable on the exercise of Warrants, 2,046,379 Common Shares issuable on the vesting of Restricted Stock Units and up to 1,249,411 Common Shares issuable upon the conversion of the January 2022 Debentures.

Holders of Common Shares are entitled to receive notice of, attend and vote at, all meetings of the shareholders of the Corporation (except with respect to matters requiring the vote of a specified class or series voting separately as a class or series) and are entitled to one vote for each Common Share held on all matters to be voted on by shareholders at meetings of the shareholders of the Corporation. Holders of Common Shares are entitled to receive such dividends, if, as and when declared by the Board, in their sole discretion. All dividends which the Board may declare shall be declared and paid in equal amounts per Common Share on all Common Shares at the time outstanding. On liquidation, dissolution or winding up of the Corporation, the holders of Common Shares will be entitled to receive the property of the Corporation remaining after payment of all outstanding debts on a *pro rata* basis, but subject to the rights, privileges,

restrictions and conditions of any other class of shares issued by the Corporation. There are no pre-emptive, redemption or conversion rights attached to the Common Shares. All Common Shares, when issued, are and will be issued as fully paid and non-assessable Common Shares without liability for further calls or assessment.

#### MARKET FOR SECURITIES

# **Trading Price and Volume**

The Common Shares are listed and posted for trading on the TSX under the symbol "AVCN".

The following table sets forth the reported trading prices and monthly trading volumes of the Common Shares for the Corporation's financial year ended December 31, 2022 as well as the periods up to March 31, 2023:

Period	High Trading Price	Low Trading Price	Volume
January 2022	\$0.76	\$0.41	613,900
February 2022	\$0.60	\$0.41	957,700
March 2022	\$0.42	\$0.33	1,158,700
April 2022	\$0.39	\$0.26	1,220,400
May 2022	\$0.42	\$0.26	984,900
June 2022	\$0.35	\$0.18	1,048,500
July 2022	\$0.35	\$0.20	485,000
August 2022	\$0.41	\$0.30	787,000
September 2022	\$0.43	\$0.30	863,800
October 2022	\$0.33	\$0.28	538,300
November 2022	\$0.34	\$0.28	2,651,400
December 2022	\$0.43	\$0.30	2,258,400
January 2023	\$0.50	\$0.39	1,095,500
February 2023	\$0.43	\$0.38	527,800
March 2023	\$0.45	\$0.36	1,169,700

Notes:

(1) Source: Yahoo Finance.

#### **PRIOR SALES**

The following table summarizes the securities of the Corporation that are not listed or quoted for trading on a market place that have been issued during the financial year ended December 31, 2022 as well as the periods up to March 31, 2023.

Date	Type of Security	Issue/Exercise Price	Number of Securities
		(\$)	
Mar-21	Warrants <sup>(1)</sup>	1.75	4,480,000
Aug-21	Warrants <sup>(2)</sup>	1.10	1,636,364
Oct-21	Warrants <sup>(3)</sup>	1.10	2,293,511
Oct-21	Restricted Stock Units <sup>(4)</sup>	1.25	653,748
Oct-21	Options <sup>(4)</sup>	1.00	306,667
Jan-22	Warrants <sup>(5)</sup>	0.40	1,056,210
Jan-22	Convertible debenture <sup>(6)</sup>	0.85 – 1.20	2,280,000
Jan-22	Restricted Stock Units <sup>(4)</sup>	0.32	100,000
Mar-22	Warrants <sup>(7)</sup>	0.40	3,697,950
Apr-22	Restricted Stock Units <sup>(4)</sup>	0.32	1,158,916

May-22	Warrants <sup>(8)</sup>	0.40	2,105,466
Jun-22	Restricted Stock Units <sup>(4)</sup>	0.35	922,500
Aug-22	Warrants <sup>(9)</sup>	0.40	3,974,716
Oct-22	Restricted Stock Units <sup>(4)</sup>	0.32	382,274
Nov-22	Warrants <sup>(10)</sup>	0.40	934,375
Nov-22	Restricted Stock Units <sup>(4)</sup>	0.30	397,208
Nov-22	Options <sup>(4)</sup>	0.37	90,000
Dec-22	Warrants <sup>(11)</sup>	0.40	2,527,280
Jan-23	Restricted Stock Units <sup>(4)</sup>	0.48	1,297,797
Jan-23	Options <sup>(4)</sup>	0.60	625,000
Mar-23	Warrants <sup>(12)</sup>	0.50	1,548,115
Mar-23	Restricted Stock Units <sup>(4)</sup>	0.37	1,556,771

#### Notes:

- (1) Issued pursuant to the March 2021 Equity Financing.
- (2) Issued pursuant to August 2021 Secured Debt Financing
- (3) Issued pursuant to the October 2021 Equity Financing.
- (4) Granted pursuant to the Company's long-term incentive plan
- (5) Issued pursuant to the January 2022 convertible debt financing.
- (6) Issued pursuant to the January 2022 convertible debt financing. These debentures convert at \$1.20 per common share if exercised prior to January 20, 2023 and \$0.85 if exercised between January 21, 2023 and the maturity date.
- (7) Issued pursuant to the March 2022 Equity Financing; 92,857 of these warrants were issued as a finder's fee.
- (8) Issued pursuant to the May 2022 Equity Financing.
- (9) Issued pursuant to the August 2022 Equity Financing.
- (10) Issued pursuant to the November 2022 Equity Financing.
- (11) Issued pursuant to the December 2022 Equity Financing; 39,000 of these warrants were issued as a finder's fee.
- (12)Issued pursuant to the March 2023 Equity Financing; 18,750 of these warrants were issued as a finder's fee. See "Recent Developments (January 1, 2023 to Present)"

# ESCROWED SECURITIES AND SECURITIES SUBJECT TO CONTRACTUAL RESTRICTION ON TRANSFER

# **Voluntary Lock-Ups**

Prior to filing the Prospectus on July 8, 2019, we agreed with the Agents to cause each director, officer and holder of greater than 10% of the issued and outstanding Common Shares to enter into an agreement pursuant to which each such individual shall agree not to sell, transfer or pledge, or otherwise dispose of or transfer the economic consequences of any securities of the Corporation held by such individual for a period of 39 months following the Listing Date where 10% of such securities will be released from the agreement on the date that is three months following the Listing Date with the remaining securities released in six equal tranches of 15% every six months following the first release until all such securities are released. As of the effective date of these lock-up agreements 10,523,077 Common Shares (on a non-diluted basis)

were affected and 373,211 Common Shares remain affected after the directors and officers entered into another voluntary lock-up agreement as discussed in more detail below.

On October 29, 2019 the board of directors of the Corporation entered into another voluntary lock-up agreement to extend the term of their lock-up periods, affecting 7,176,850 Common Shares pursuant to which they will not sell, transfer or pledge, or otherwise dispose of or transfer the economic consequences of any securities of the Corporation held by such individual prior to July 1, 2020. On July 1, 2020, the Corporation released 10% of such securities to the respective directors, with the remaining securities released in six equal tranches of 15% every six months following the first release, subject to customary exceptions. On the same date, the executive officers of the Corporation entered into voluntary lock-up agreements pursuant to which they will not sell, transfer or pledge, or otherwise dispose of or transfer the economic consequences of any securities prior to January 1, 2020. On January 1, 2020 the Corporation released 10% of such securities to the respective executive officers, with the remaining securities released in six equal tranches of 15% every six months following the first release, subject to customary exceptions. These executive officer lock-up agreements affect 540,743 Common Shares of the Corporation. In addition, each of the directors and officers entering into one of these voluntary lock-up agreements described herein will not sell more than 5,000 Common Shares of the Corporation in any one week period during the first year following the initial release date under such agreement, without the consent of the Corporation.

Additionally, on October 29, 2019, Kyle Langstaff, a non-management founder of the Corporation, resigned as Vice President (Operations). As a demonstration of Mr. Langstaff's confidence in the Corporation, he entered into a voluntary lock-up agreement pursuant to which he agreed not to sell more than 10,000 Common Shares of the Corporation in any one week period prior to April 18, 2020, without the consent of the Corporation. Under Mr. Langstaff's lock-up agreement, 10% of his securities were released on October 18, 2019, and the remaining securities are to be released in six equal tranches of 15% every six months following the first release, subject to customary exceptions. 2,418,333 Common Shares were affected by this voluntary lock-up agreement.

Pursuant to the terms of the 2020 Agency Agreement all senior officer and directors entered into an agreement with Echelon Wealth Partners, a 2020 Agent, pursuant to which they agreed not to sell, transfer or pledge, or otherwise dispose of, any securities of the Corporation for a period of ninety (90) days following closing of the December Prospectus Offering, without the prior written consent of Echelon Wealth Partners, As at the date of this AIF, these lock-up agreements have expired and are no longer have any force or effect.

The following table summarizes the securities that are subject to contractual restriction on transfer:

Contractual Restriction	Number of Common Shares	Percentage of Common Shares
39 months	216,296	0.47%
Directors & Officers	6,459,165	14.08%
Mr. Langstaff	1,653,243	3.60%

# **DIRECTORS AND OFFICERS**

The following table sets forth the name, province and country of residence, position held with the Corporation, principal occupation during the preceding five (5) years, and the date on which they were first appointed as a director or officer of the Corporation (if applicable). As of the date of this AIF, the Corporation's Board consists of Aras Azadian, John McVicar, Dr. Chandrakant Panchal, Chairman of the Board, Giancarlo Davila Char, and Eileen McCormack. Directors will be elected annually, and they are expected to hold office until the Corporation's next annual meeting of shareholders, at which time they may be re-elected or replaced.

Name and Province of Residence	Position(s) with the Corporation	First Appointed as Director or Officer and Expiry of Term	Principal Occupations During Previous five Years
Aras Azadian Ontario, Canada	Chief Executive Officer and Director	November 25, 2016	Chief Executive Officer of the Corporation (2016-Present); and Chief Operating Officer of Panacea Global Incorporated (2013-2017).
John McVicar Ontario, Canada	Director <sup>(1)(2)(3)</sup>	June 24, 2021	Part-time executive and director (2020- Present); and Partner, Ernst & Young LLP (2002-2020).
Dr. Chandrakant Panchal Quebec, Canada	Chairman <sup>(1)(2)(3)</sup>	November 26, 2016	Chief Executive Officer of Axcelon Biopolymers Corp. (2008-Present).
Giancarlo Davila Char Miami, U.S.A.	Director	October 22, 2018	Commercial Manager of Caribbean Eco Soaps U.I.B.S. (2017 - Present); and Student (2013 - 2017).
Phillip Cardella Ontario, Canada	Chief Financial Officer	December 21, 2022	Officer of Corporation (2021 – Present) Assurance Manager, MNP LLP (2015 – 2021)
Eileen McCormack Ontario, Canada	Director (1)(2)(3)	January 4, 2022	Part time consultant; Head of New Product Planning and Business Development at AstraZeneca USA (2014-2017)

# Notes:

- (1) Member of the Audit Committee. Mr. McVicar is Chair of the Audit Committee.
- (2) Member of the Compensation Committee. Ms. McCormack is the Chair of the Compensation Committee.
- (3) Member of the Nominating & Corporate Governance Committee. Ms. McCormack is the Chair of the Nominating & Corporate Governance Committee.

As at the date of this AIF, the directors or executive officers of the Corporation, as a group, beneficially own, directly or indirectly, or exercise control or direction over, 6,641,873 Common Shares, representing

approximately 8% of the total number of Common Shares outstanding before giving effect to the exercise of Stock Options, and Warrants, and the settlement of Restricted Share Units held by such directors and executive officers. The statements as to the number of Common Shares beneficially owned, directly or indirectly, or over which control or direction is exercised by the directors and executive officers of the Corporation as a group are based upon information furnished by the directors and executive officers.

In addition, Giancarlo Davila Char is the sole shareholder of Bondue, which owns 38.4% of SMGH.

# CEASE TRADE ORDERS, BANKRUPTCIES, PENALTIES, OR SANCTIONS

# Cease Trade Orders

Other than as disclosed below, to the knowledge of the Corporation, no director or executive officer of the Corporation (nor any personal holding corporation of any of such persons) is, as of the date of this AIF, or was within 10 years before the date of this AIF, a director, chief executive officer or chief financial officer of any corporation (including the Corporation), that: (a) was subject to a cease trade order, an order similar to a cease trade order or an order that denied the relevant corporation access to any exemption under securities legislation, in each case that was in effect for a period of more than thirty (30) consecutive days (collectively, an "**Order**"), that was issued while the director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer; or (b) was subject to an Order that was issued after the director or executive officer ceased to be a director, chief executive officer or chief financial officer and which resulted from an event that occurred while that person was acting in the capacity as director, chief executive officer or chief financial officer.

On March 29, 2021, the Corporation applied for an MCTO with the OSC in connection with the anticipated delayed filing of the Required Filings. An MCTO was issued by the OSC on April 9, 2021. The MCTO issued on April 9, 2021 was revoked and the CTO was issued effective June 11, 2021. The CTO was revoked on September 10, 2021.

#### **Bankruptcies**

Except as described below, to the knowledge of the Corporation, no director or executive officer of the Corporation (nor any personal holding corporation of any of such persons), or shareholder holding a sufficient number of securities of the Corporation to affect materially the control of the Corporation: (a) is as of the date of this AIF or has been within 10 years before the date of this AIF, a director or executive officer of a corporation (including the Corporation) that while that person was acting in such capacity or within a year of that person ceasing to act in that capacity, became bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency or was subject to or instituted any proceedings, arrangement or compromise with creditors or had a receiver, receiver manager or trustee appointed to hold its assets; or (b) has within the ten (10) years before the date of this AIF become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or has been subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold the assets of such director, executive officer or shareholder.

Dr. Chandrakant Panchal was a director of Pure Global Cannabis Inc. ("Pure Global") when it commenced proceedings for creditor protection under the *Companies' Creditors Arrangement Act (Canada)* ("CCAA")

on March 19, 2019. Ernst & Young Inc. was appointed as monitor of Pure Global. On May 1, 2019, Dr. Panchal resigned as a director of Pure Global and Farber & Partners Inc. was appointed as receiver pursuant to the *Bankruptcy and Insolvency Act* and the *Courts of Justice Act*.

#### Penalties or Sanctions

To the knowledge of the Corporation, no director or executive officer of the Corporation (nor any personal holding corporation of any of such persons), or shareholder holding a sufficient number of securities of the Corporation to affect materially the control of the Corporation, has been subject to: (a) any penalties or sanctions imposed by a court relating to securities legislation or by a securities regulatory authority or has entered into a settlement agreement with a securities regulatory authority; or (b) any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

#### **CONFLICTS OF INTEREST**

To the knowledge of the Corporation, there are no known existing or potential conflicts of interest between the Corporation and its directors or officers as a result of their outside business interests except that certain of the Corporation's directors and officers serve as directors and officers of other companies, and therefore it is possible that a conflict may arise between their duties to the Corporation and their duties as a director or officer of such other companies.

#### LEGAL PROCEEDINGS AND REGULATORY ACTIONS

In the course of the Corporation's business, the Corporation may from time to time have access to confidential or proprietary information of third parties, and these parties could bring a claim against the Corporation asserting that it has misappropriated their technologies and improperly incorporated such technologies into its products. Due to these factors, there remains a constant risk of intellectual property litigation affecting the Corporation's business. In the future, the Corporation may be made a party to litigation involving intellectual property matters and such actions, if determined adversely, could have a material adverse effect on the Corporation.

On November 12, 2021, Setu Purohit filed a lawsuit in the Ontario Superior Court of Justice against Avicanna Inc. seeking approximately \$1,462,500 for wrongful dismissal, damages, costs, and damages. Avicanna Inc. intends, and will, defend itself vigorously against the lawsuit.

#### **AUDIT COMMITTEE DISCLOSURE**

#### **Audit Committee Charter**

In accordance with applicable Canadian securities legislation and, in particular, NI 52-110, information with respect to the Corporation's Audit Committee is contained below. The full draft text of the Audit Committee Charter is attached to this AIF as Schedule "A". The Audit Committee is responsible for overseeing the integrity of the Corporation's financial statements, reviewing financial reports and other financial information, recommending the appointment and reviewing and appraising the audit efforts of the

Corporation's external auditors, overseeing and monitoring the Corporation's financial reporting processes and internal controls, the Corporation's processes to manage business and financial risk and its compliance with legal, ethical and regulatory requirements and encouraging improvement of, and adherence to, the Corporation's policies, procedures and practices.

The Audit Committee assists the Board in discharging its oversight of:

- the quality and integrity of our financial statements and related information;
- the independence, qualifications and appointment of our external auditor;
- the monitoring and periodic review of our Corporate Disclosure Policy, our disclosure controls and procedures, internal control over financial reporting and management's responsibility for assessing and reporting on the effectiveness of such controls;
- our risk management processes;
- the monitoring and periodic review of our Whistle Blowing Policy;
- the monitoring and periodic review of our Related Party Transactions Policy and transactions with our related parties; and
- the monitoring and periodic review of our Code of Business Conduct and Ethics and our assessment of management's processes to ensure compliance with the Code of Business Conduct and Ethics.

The Audit Committee has access to all of our books, records, facilities and personnel and may request any information about the Corporation as it may deem appropriate. It also has the authority, in its sole discretion and at the Corporation's expense, to retain and set the compensation of outside legal, accounting or other advisors as necessary to assist in the performance of its duties and responsibilities. The Audit Committee will also have direct communication channels with the Chief Financial Officer and the Corporation's external auditors to discuss and review such issues as the Audit Committee may deem appropriate.

#### **Audit Fees**

For the years ended December 31, 2020, December 31, 2021, and December 31, 2022 the fees expected to be billed by our external auditor are set out in the table below:

	Audit Fees <sup>(1)</sup>	Tax Fees <sup>(2)</sup>	All Other Fees <sup>(3)</sup>	Total
Year ended December 31, 2022	\$400,000	\$60,000	\$nil	\$460,000
Year ended December 31, 2021	\$340,000	\$7,000	\$25,000	\$372,000
Year ended December 31, 2020	\$575,000	\$nil	\$150,000	\$725,000

# Notes:

- "Audit Fees" are the fees necessary to perform the audit of the Corporation's financial statements for the period ended December 31, 2020, December 31, 2021 and December 31, 2022 including accounting consultations, a review of matters reflected in the financial statements and audit or other services required by legislation or regulation, such as comfort letters, consents and reviews of securities filings.
- (2) "Tax Fees" are fees other than those included in Audit Fees for tax services, including preparation of the annual tax returns for Canada, Colombia, United Kingdom, and the USA and fees related to advisory services related to the Corporation's structure and related tax issues in new jurisdictions.
- "All Other Fees" include all other non-audit services and non-tax related services. These services were provided in connection with the MCTO issued on April 9, 2021 and include but are not limited to: review of documents submitted to regulatory authorities and the time dedicated to meetings and calls as needed.

# **Composition of the Audit Committee**

The Audit Committee currently consists of three directors, namely, Mr. John McVicar, Dr. Chandrakant Panchal, Chairman of the Board, and Ms. Eileen McCormack. Each of Mr. McVicar, Dr. Panchal, and Ms. McCormack are persons determined by the Board to be independent directors within the meaning of NI 52-110. Each of the Audit Committee members is financially literate in accordance with NI 52-110 and has an understanding of the accounting principles used to prepare financial statements and varied experience as to the general application of such accounting principles, as well as an understanding of the internal controls and procedures necessary for financial reporting. For additional details regarding the relevant education and experience of each member of the Audit Committee, see also "Directors and Executive Officers — Management".

Audit Committee Member	M.B.A., Duke University B.Com., Queen's University CPA and CA designation holder (Former) Partner, Ernst & Young LLP		
John McVicar			
Dr. Chandrakant Panchal	Ph.D, Biochemical Engineering, University of Western Ontario Director, Canadian Oil Recovery & Remediation Enterprises Ltd. Director, Medicenna Therapeutic Corp.		
Eileen McCormack	M.Sc., University of Guelph B.Sc., University of Guelph (Former) Head, New Product Planning and Business Development, AstraZeneca USA		

#### Reliance on Certain Exemptions

At no time since the commencement of the Corporation's most recently completed financial year has the Corporation relied on any exemption provided by Part 3 or Part 8 of NI 52-110.

#### **Audit Committee Oversight**

At no time since the commencement of the Corporation's most recently completed financial year was a recommendation of the Audit Committee to nominate or compensate an external auditor not adopted by the Board.

#### Pre-Approval Policies and Procedures

The Corporation has not yet adopted any specific policies or procedures for the engagement of non-audit services. Such matters are the subject of review and pre-approval by the Audit Committee.

#### INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Except as described herein with respect to SMGH (and Mr. Davila Char's relationship with Bondue), no insider, director or executive officer of the Corporation and no associate of any director, executive officer, or insider has any material interest, direct or indirect, in any transaction within the three years before the date of this AIF that has materially affected or is reasonably expected to materially affect the Corporation.

#### **REGISTRAR AND TRANSFER AGENT**

The registrar and transfer agent of the Corporation is Odyssey Trust Company at its principal office at 323 - 409 Granville St. Vancouver, British Columbia, V6C 1T2.

#### **MATERIAL CONTRACTS**

Except for contracts entered into in the ordinary course of business, the only material contracts of the Corporation entered into within the most recently completed financial year, or before the most recently completed financial year that are still in effect that are required to be filed by the Corporation, are as follows:

- the SMGH shareholder's agreement dated August 14, 2018 between Avicanna Inc., Lucas Echeverri Robledo, Santa Mara Golden Hemp S.A.S., and Inmobiliaria Bondue S.A.S.;
- the Altea Manufacturing Agreement, dated as of December 11, 2018, between the Corporation and Altea, as more particularly described under "Our Products – Manufacturing and Selling Phytotherapeutics in Colombia";
- the U of T Sponsored Research and Collaboration Agreement, dated as of November 20, 2017, between the Corporation and the University of Toronto, as more particularly described under "Research and Development – U of T Sponsored Research and Collaboration Agreement";

- the License Agreement, dated as of November 26, 2019 between the Corporation, and LC 2019, as more particularly described under "General Development of the Business Three Year History Fiscal Year 2019 (January 1, 2019 to December 31, 2019)".
- the SDM Agreement, dated as of January 7, 2020 between the Corporation and Medical Cannabis by Shoppers Drug Mart Inc. as more particularly described under "General Development of the Business Three Year History Recent Developments (January 1, 2020 to March 31, 2020)".
- the Valens Agreement dated as February 7, 2020 between the Corporation and Valens Agritech Ltd. as more particularly described under "General Development of the Business Three Year History Recent Developments (January 1, 2020 to March 31, 2020)".
- The intellectual property licensing and royalty agreement dated February 3, 2021 between the Corporation and Harrington Wellness Inc. as more particularly described under "General Development of the Business Three Year History Recent Developments (January 1, 2021 to December 31, 2021)".

To the extent that cannabis-related licenses could also be considered to be material contracts, the following licences, registrations or quotas, as applicable, are in effect:

#### granted to SMGH:

- Resolution 973 issued on November 24, 2017 and expiring on November 23, 2022, which
  authorizes the cultivation of psychoactive cannabis and permits SMGH to conduct the
  following activities: (i) seed production for sowing; (ii) production of grain; and (iii) the
  manufacture of cannabis derivatives;
- Resolution 472 issued on June 1, 2018 and expiring on November 23, 2020, which amends Resolution 973 and adds the permitted activity to cultivate psychoactive cannabis for scientific purposes;
- Resolution 4282 issued on October 27, 2017 and expiring on October 26, 2023, which
  authorizes the manufacturing of psychoactive cannabis derivatives for the purposes of
  distribution nationally (Colombia) and for exportation;
- Resolution 3466 issued on August 17, 2018 and expiring on the same day as Resolution 4282 which is October 26, 2023, which amends Resolution 4282 and adds the permitted activity to manufacture cannabis derivatives for scientific purposes;
- Resolution 463 issued on May 29, 2018, which authorizes the cultivation of nonpsychoactive cannabis and permits SMGH to conduct the following activities: (i) seed production for sowing; (ii) production of grain; (iii) the manufacture of cannabis derivatives; and (iv) to cultivate for scientific purposes;

- Resolution 763 issued on December 26, 2017 and expiring on December 25, 2022, which
  is a registration with National Narcotics Fund of Colombia for the activity of manufacturing
  cannabis derivatives for the purposes of distribution nationally (Colombia) and for
  exportation;
- Resolution 639 issued on September 14, 2018 and expiring on December 25, 2022, which amends Resolution 763 and adds the permitted activity to manufacture cannabis derivatives for scientific purposes;
- Resolution 30924 granted by ICA on August 27, 2018 which registers SMGH as a Plant Breeding Unit of psychoactive and non-psychoactive cannabis plants;
- Resolution 31425 granted by ICA on September 3, 2018 which permits SMGH to produce sexual cannabis seeds;
- Resolution 7016 granted by ICA on May 26, 2019 which permits SMGH to produce asexual cannabis seeds;
- Resolution 6149 issued on May 9, 2019, which is a registration of the psychoactive genetic "GYPSSY KUSH – AV019";
- Resolution 6152 issued on May 9, 2019, which is a registration of the psychoactive genetic "TROPICANNA – AV008";
- Resolution 6153 issued on May 9, 2019, which is a registration of the psychoactive genetic "COMA KUSH – AV030";
- Resolution 6148 issued on May 9, 2019, which is a registration of the non-psychoactive genetic "NN-AV011";

# **INTEREST OF EXPERTS**

Our current independent auditor is Kingston Ross Pasnak LLP. Kingston Ross Pasnak LLP has confirmed that it is independent of the Corporation within the meaning of the Code of Professional Conduct of the Chartered Professional Accountants of (Ontario).

# **ADDITIONAL INFORMATION**

Additional information regarding the Corporation may be found under the Corporation's profile on SEDAR at <a href="https://www.sedar.com">www.sedar.com</a> and on the Corporation's website at <a href="https://www.avicanna.com">www.avicanna.com</a>.

Additional information, including the remuneration and indebtedness of the directors and executive officers of the Corporation, principal holders of the Corporation's securities and the securities authorized for issuance under equity compensation plans, will be contained in the Corporation's information circular for its upcoming annual meeting of security holders that will involve the election of directors.

Additional financial information relating to the Corporation is provided in the Corporation's financial statements and management's discussion and analysis for the financial year ended December 31, 2022.

# Schedule "A" AUDIT COMMITTEE CHARTER

#### AVICANNA INC.

#### AUDIT COMMITTEE CHARTER

#### I. GENERAL

# 1. Mandate and Purpose of the Committee

The purpose of the Audit Committee (the "**Committee**") is to assist the board of directors (the "**Board**") of Avicanna Inc. (the "**Company**") in fulfilling its oversight responsibilities relating to:

- (a) the integrity of the Company's financial statements;
- (b) the Company's compliance with legal and regulatory requirements, as they relate to the Company's financial statements;
- (c) the qualifications, independence and performance of the external auditor;
- (d) internal controls and disclosure controls;
- (e) the performance of the Company's internal audit function; and
- (f) performing the additional duties set out in this Charter or otherwise delegated to the Committee by the Board.

# 2. Authority of the Committee

- (a) The Committee has the authority to:
  - (i) engage independent counsel and other advisors as it determines necessary to carry out its duties;
  - (ii) set and pay the compensation for any advisors employed by the Committee; and
  - (iii) communicate directly with the internal and external auditors.
- (b) The Committee has the authority to delegate to individual members or subcommittees of the Committee.

#### II. PROCEDURAL MATTERS

#### 1. Composition

The Committee will be composed of a minimum of three members.

#### 2. Member Qualifications

Members of the Committee must state whether or not they are (i) "independent" as defined in National Instrument 52-110 – Audit Committees and (ii) "financially literate" as defined in National Instrument 52-110 – Audit Committees.

#### 3. Member Appointment and Removal

Members of the Committee will hold office until the next annual meeting of the shareholders.

#### 4. Committee Structure and Operations

# (a) Chair

Each year, the Board will appoint one member of the Committee to act as Chair of the Committee. The Chair of the Committee may be removed at any time at the discretion of the Board. If, in any year, the Board does not appoint a Chair, the incumbent Chair will continue in office until a successor is appointed.

If the Chair of the Committee is absent from any meeting, the Committee will select one of the other members of the Committee to preside at that meeting.

#### (b) Meetings

The Chair of the Committee will be responsible for developing and setting the agenda for Committee meetings. The Chair, in consultation with the Committee members, will determine the schedule and frequency of the Committee meetings. However, the Committee will meet at least four times per year.

#### (c) Notice

- (i) Notice of the time and place of every meeting will be given by email or by phone to each member of the Committee at least 24 hours before the time fixed for that meeting.
- (ii) The external auditor of the Company will be given notice of every meeting of the Committee and, at the expense of the Company, will be entitled to attend and be heard at that meeting.
- (iii) If requested by a member of the Committee, the external auditor will attend every meeting of the Committee held during the term of office of the external auditor.

# (d) Quorum

A majority of the Committee will constitute a quorum. No business may be transacted by the Committee except at a meeting of its members at which a quorum of the Committee is present in person or by means of such telephonic, electronic or other communications facilities as permit all persons participating in the meeting to communicate with each other simultaneously and instantaneously.

#### (e) Attendees

The Committee may invite any of the directors, officers and employees of the Company and any advisors as it sees fit to attend meetings of the Committee.

During each meeting of the Committee, the Committee will meet with only Committee members present in person or by other permitted means.

# (f) Secretary

Unless otherwise determined by resolution of the Board, the corporate secretary of the Company, or his or her nominee, will act as the Secretary to the Committee.

# (g) Records

Minutes of meetings of the Committee will be recorded and maintained by the Secretary to the Committee and will be subsequently presented to the Committee for review and approval.

#### (h) Liaison

The Chief Financial Officer will act as management liaison with the Committee.

#### 5. Committee and Charter Review

The Committee will conduct an annual review and assessment of its performance, effectiveness and contribution, including a review of its compliance with this Charter, in accordance with the process developed by the Board. The Committee will conduct that review and assessment in such manner as it deems appropriate and report the results to the Board.

The Committee will also review and assess the adequacy of this Charter on an annual basis, taking into account all legislative and regulatory requirements applicable to the Committee, as well as any best practice guidelines recommended by regulators or an applicable stock exchange, and will recommend any required or desirable changes to the Board.

#### 6. Reporting to the Board

The Committee will report to the Board in a timely manner with respect to each of its meetings held. This report may take the form of circulating copies of the minutes of each meeting held.

#### III. RESPONSIBILITIES

#### 1. Financial Reporting

- (a) The Committee is responsible for reviewing and recommending approval to the Board of:
  - (i) the Company's financial statements, MD&A and annual and interim profit or loss news releases; and

- (ii) prospectus type documents.
- (b) The Committee is also responsible for:
  - (i) discussing with management and the external auditor the quality of generally accepted accounting principles ("**GAAP**"), not just the acceptability of GAAP;
  - (ii) discussing with management any significant variances between comparative reporting periods and across comparable business units;
  - in the course of discussion with management and the external auditor, identifying problems or areas of concern and ensuring those matters are satisfactorily resolved;
  - (iv) engaging the external auditor to perform a review of the interim financial reports and reviewing their findings, however, no formal report from the external auditor will be required;
  - (v) reviewing the financial statements of the Company's subsidiaries, as well as the consolidated financial statements and financial statements for the Company pension plans, joint ventures and the like;
  - (vi) requiring a representation letter from management similar to that provided by the external auditor; and
  - (vii) reviewing all financial information and earnings guidance provided to analysts and rating agencies.

#### 2. External Auditor

- (a) The Company's external auditor is required to report directly to the Committee.
- (b) The Committee is responsible for recommending to the Board:
  - the external auditor to be nominated for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company; and
  - (ii) the compensation of the external auditor.
- (c) The Committee is directly responsible for overseeing the work of the external auditor engaged for the purpose of preparing or issuing an auditor's report or performing other audit, review or attest services for the Company, including the resolution of disagreements between management and the external auditor regarding financial reporting.

# 3. Relationship with the External Auditor

(a) The Committee is responsible for reviewing the proposed audit plan and the proposed audit fees (to ensure fee containment).

- (b) The Committee is also responsible for:
  - establishing effective communication processes with management and the external auditor so that it can objectively monitor the quality and effectiveness of the external auditor's relationship with management and the Committee;
  - receiving and reviewing regular reports from the external auditor on the progress against the approved audit plan, important findings, recommendations for improvements and the auditors' final report;
  - (iii) reviewing, at least annually, a report from the external auditor on all relationships and engagements for non-audit services that may reasonably be thought to bear on the independence of the auditor;
  - (iv) meeting regularly in private with the external auditor; and
  - (v) receiving at least annually a report by the external auditor on the audit firm's internal quality control.

# 4. Accounting Policies

The Committee is responsible for:

- (a) reviewing the Company's accounting policy note to ensure completeness and acceptability with GAAP as part of the approval of the financial statements;
- (b) proactively discussing and reviewing the impact of proposed changes in accounting standards or securities policies or regulations;
- (c) reviewing with management and the external auditor any proposed changes in major accounting policies and key estimates and judgments that may be material to financial reporting;
- (d) ensuring by discussion with management and the external auditor that the underlying accounting policies, disclosures and key estimates and judgments are considered to be the most appropriate in the circumstances (within the range of acceptable options and alternatives);
- (e) discussing with management and the external auditor the clarity and completeness of the Company's financial disclosures made under continuous disclosure requirements; and
- (f) reviewing benchmarks of the Company's accounting policies to those followed in its industry.

# 5. Risk and Uncertainty

(a) The Committee is responsible for reviewing, as part of its approval of the financial statements, uncertainty notes and disclosures.

- (b) The Committee, in consultation with management, will identify the principal business risks and decide on the Company's "appetite" for risk. The Committee is responsible for reviewing related risk management policies and recommending those policies for approval by the Board. The Committee is then responsible for communicating and assigning to the applicable Board committee those policies for implementation and ongoing monitoring.
- (c) The Committee is responsible for requesting the external auditor's opinion of management's assessment of significant risks facing the Company and how effectively they are being managed or controlled.

#### 6. Controls and Control Deviations

- (a) The Committee is responsible for reviewing:
  - the plan and scope of the annual audit with respect to planned reliance and testing of controls; and
  - (ii) major points contained in the auditor's management letter resulting from control evaluation and testing.
- (b) The Committee is also responsible for:
  - (i) receiving reports from management when significant control deviations occur;
  - (ii) establishing a Company-wide culture that conveys basic values of ethical integrity as well as legal compliance and strong financial reporting and control;
  - reviewing plans of the internal and external auditors to ensure the combined evaluation and testing of control is comprehensive, well-coordinated, cost effective and appropriate to risks, business activities and changing circumstances;
  - (iv) participating in the review and appointment of key people involved in financial reporting (i.e., the Chief Financial Officer, the manager of internal audit, etc.);
  - (v) reviewing Chief Executive Officer and Chief Financial Officer certification matters including matters relating to disclosure controls and procedures;
  - (vi) reviewing annually a formal report prepared by management on the effectiveness of the Company's control systems;
  - (vii) reviewing fraud prevention policies and programs and monitoring their implementation; and
  - (viii) examining whether extension of its oversight of control systems into non-financial areas (e.g., operations) is appropriate.

# 7. Compliance with Laws and Regulations

- (a) The Committee is responsible for discussing the Company's compliance with tax and financial reporting laws and regulations, if and when issues arise.
- (b) The Committee is responsible for reviewing regular reports from management and others (e.g., internal and external auditors) concerning the Company's compliance with financial related laws and regulations, such as:
  - (i) tax and financial reporting laws and regulations;
  - (ii) legal withholdings requirements;
  - (iii) environmental protection laws; and
  - (iv) other matters for which directors face liability exposure.
- (c) The Committee is responsible for providing input to and reviewing the Company's Code of Business Conduct and Ethics.
- (d) The Committee is responsible for expanding its review to include a broader set of laws and regulations that must be complied with (e.g., compliance with privacy laws in electronic commerce systems).
- (e) The Committee with other Board committees is responsible for annually reviewing reports from other Board committees on management's processes to ensure compliance with the Company's Code of Business Conduct and Ethics.

#### 8. Relationship with the Internal Auditor

- (a) The Committee is responsible for reviewing:
  - (i) the appointment of the internal auditor;
  - (ii) the internal auditor's terms of reference;
  - (iii) the overall scope of the internal audit;
  - (iv) the majority of reports issued by the internal auditor; and
  - (v) management's response to the internal auditor's reports.
- (b) The Committee is responsible for approving the reporting relationship of the internal auditor to ensure appropriate segregation of duties is maintained and the internal auditor has direct access to the Committee.
- (c) The Committee is responsible for ensuring that the internal auditor's involvement with financial reporting is coordinated with the activities of the external auditor.

(d) If no internal audit function exists, the Committee is responsible for regularly reviewing the need for such a function.

#### 9. Other Responsibilities and Issues

- (a) The Chair of the Committee is responsible for ensuring the information received by the Committee is responsive to important performance measures and to the key risks the Committee oversees.
- (b) The Committee is responsible for the investigation of any matters that fall within the Committee's responsibilities and has the explicit authority to do so.
- (c) The Committee is responsible for receiving and reviewing reports from the internal and external auditors on their review of the officer and senior executive expense accounts.
- (d) The Committee is responsible for approving policies on political donations and commissions paid to suppliers or customers and for receiving reports from the internal and/or external auditors on their review of those donations and commissions.
- (e) The Committee is responsible for reviewing and providing management with its views on funding matters, financing strategies, capital structure etc., as well as appropriate accounting and presentation issues related thereto.

# 10. Pre-Approval of Non-Audit Services

The Committee is responsible for pre-approving all non-audit services to be provided to the Company or its subsidiary entities by the Company's external auditor.

#### 11. Review of Public Disclosure

The Committee will review the following disclosures in advance of their public release by the Company:

- (a) the Company's financial statements, MD&A and annual and interim profit or loss news releases;
- (b) earnings guidance; and
- (c) financial outlooks and future-oriented financial information;

The Committee is responsible for being satisfied that adequate procedures are in place for the review of the Company's public disclosure of financial information extracted or derived from the Company's financial statements and must periodically assess the adequacy of those procedures.

#### 12. Submission Systems and Treatment of Complaints

The Committee is responsible for establishing procedures for:

(a) the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls, or auditing matters; and

(b) the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters.

# 13. Hiring Policies

The Committee is responsible for reviewing and approving the Company's hiring policies regarding partners, employees and former partners and employees of the present and former external auditor of the Company.

Approval Date: July 8, 2019