



AVICANNA

**ANNUAL INFORMATION FORM  
FOR THE PERIOD ENDED DECEMBER 31, 2024**

**Dated: April 11, 2025**

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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 exclusive 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*”.

“**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.

“**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.

“**Board of Directors**” or “**Board**” means the board of directors of the Corporation.

“**Bondue**” means Inmobiliaria Bondue S.A.S.

“**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 y 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 cannabimol.

“**CBPMs**” means cannabis based cannabis based products for medicinal use.

“**CDSA**” has the meaning ascribed thereto under “*Regulatory Overview – Canada – Background*”.

“**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.

“**Criminal Code**” has the meaning ascribed thereto under “*Regulatory Framework – Colombia*”.

“**CSA**” has the meaning ascribed thereto under “*Regulatory Framework – United States of America*”.

“**DEA**” has the meaning ascribed thereto under “*Regulatory Framework – United States of America*”.

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

“**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.

“**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*”.

“**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*”

“**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 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)”*.

**“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”** has the meaning ascribed thereto under *“Regulatory Framework – Uruguay”*.

**“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)”*.

**“MDA”** has the meaning ascribed thereto under *“Regulatory Framework – United Kingdom”*.

**“MDR”** has the meaning ascribed thereto under *“Regulatory Framework – United Kingdom”*.

**“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.

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

“**OBCA**” means the *Business Corporations Act* (Ontario).

“**ODC**” has the meaning ascribed thereto under “*Regulatory Framework – Australia*”.

“**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.

“**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.

“**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.

“**Restricted Share Units**” means the restricted share units of the Corporation granted pursuant to the LTIP.

“**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*”.

“**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](http://www.sedar.com)., and “**SEDAR+**” means the new, secure web-based system used by all market participants to file, disclose and search for information on Canada’s capital markets (the Canadian Securities Administrators consolidated and replaced SEDAR with SEDAR+ on July 25, 2023) accessible at [www.sedarplus.ca](http://www.sedarplus.ca)

“**SENASA**” has the meaning ascribed thereto under “*Regulatory Framework – Argentina*”.

“**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.

“**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.

“**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.

“**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.

“**Warrant**” means a common share purchase warrant in the capital of the Corporation.

“**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 or enhancements of existing products, including, without limitation, our expectations and intentions regarding pharmaceuticals, phyto-therapeutics, lifestyle, derma-cosmetics 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 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;
- 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 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, Colombia, United States, Europe, and South America;
- 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

References to "\$" or "dollars" are to Canadian dollars, which is Avicanna's functional currency, unless otherwise noted. Fiscal year end of all entities within Avicanna's corporate structure is December 31. Avicanna's consolidated financial statements ("**financial statements**") are prepared in accordance with International Financial Reporting Standards ("**IFRS**").

### EXCHANGE RATE INFORMATION

This AIF contains reference to Canadian dollars, referred to herein as "\$", and also to 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.

	2024	2023	2022
High	0.7510	0.7617	0.8011
Low	0.6937	0.7207	0.7218
Average	0.7302	0.7410	0.7370
Closing	0.6950	0.7383	0.7652

### 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	Jurisdiction
2516167 Ontario Inc. (dba MyCannabis)	100%	Ontario, Canada
Avicanna LATAM S.A.S.	100%	Colombia
Santa Marta Golden Hemp S.A.S.	51% <sup>(1)</sup>	Colombia
Sigma Magdalena Canada Inc.	60% <sup>(2)</sup>	Ontario, Canada
Sigma Analytical Magdalena SAS	60% <sup>(2)</sup>	Colombia
Avicanna (UK) Limited	100%	United Kingdom
Avicanna USA Inc.	100%	Delaware, USA

**Notes:**

- (1) The remaining 49% is owned by Inmobiliaria Bondue SAS (“**Bondue**”). Bondue is owned and controlled by Mr. Giancarlo Davila Char, one of the Company’s directors.
- (2) The remaining 40% is owned by Sigma Expansion One Inc.

## GENERAL DEVELOPMENT OF THE BUSINESS

### Three Year History

#### *Fiscal Year 2022 (January 1, 2022 to December 31, 2022)*

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

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

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.

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.

In connection with the January 2022 Offering, 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**").

In connection with the January 2022 Offering, 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.

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

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.

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.

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

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.

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

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.

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.

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

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

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.

### ***Fiscal Year 2023 (January 1, 2023 to December 31, 2023)***

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 ("**Original Maturity Date**") and 1,056,210 January 2022 Warrants, to

amend the terms of the January 2022 Debentures and the January 2022 Warrants (“**January 2023 Amending Agreements**”). An aggregate of \$250,000 of January 2022 Debentures and 136,250 January 2022 Warrants (“**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 (“**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 (“**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 (“**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.

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.

March 28, 2023, the Corporation announced Shoppers Drug Mart® selected Avicanna as its partner to transition its Medical Cannabis by Shoppers business. Shoppers would continue to support patients throughout the transfer of assets and services to Avicanna, was anticipated to take place over the next three months.

May 4, 2023, the Corporation announced that it entered into a Master Service Agreement with Northern Green Canada Inc., a federally licensed EU GMP-certified cannabis producer, to operationalize the MyMedi.ca medical cannabis care platform.

May 29, 2023, the Corporation announced the execution of the definitive Asset Purchase Agreement between Shoppers Drug Mart® and Avicanna Inc. for Avicanna's acquisition of assets of the Medical

Cannabis by Shoppers business with a final closing date set for July 31, 2023.

August 1, 2023, the Corporation announced it closed the closed of the previously announced acquisition of the Medical Cannabis by Shoppers business from Shoppers Drug Mart® and the launch of an all-new medical cannabis care platform, MyMedi.ca.

September 1, 2023, the Corporation announced the retirement of Chandra Panchal, PhD as Chairman of the Board of Directors and that the Corporation would initiate a search for a new director.

November 13, 2023, the Corporation announced Paul Fornazzari, LL.B., LL.M., was appointed as a new director to the Corporation's Board of Directors.

December 4, 2023, the Corporation announced that it has closed a non-brokered private placement offering of 2,537,508 units of the Company (the "**Units**") at a price of \$0.35 per Unit for aggregate gross proceeds of \$888,127.80 ("**Offering**"). Each Unit is comprised of one common share in the capital of the Company (each, a "**Unit Share**") and one-half of one (0.5) common share purchase warrant of the Company (each whole warrant, a "**Warrant**"); and, each Warrant shall entitle the holder thereof to acquire one (1) common share in the capital of the Company at an exercise price of \$0.41 per share, subject to adjustment in certain events, until December 4, 2026. The Company has paid an aggregate total of \$29,977.50 in cash finders' fees and issued an aggregate total of 85,650 finder's warrants (each a "**Finder Warrant**") in connection with the Offering to certain finders in connection with subscriptions for Units made by purchasers introduced to the Company by such finders. Each Finder Warrant entitles the holder thereof to acquire one common share in the capital of the Company at an exercise price of \$0.41 per share, subject to adjustment in certain events, until December 4, 2026.

#### ***Fiscal Year 2024 (January 1, 2024 to December 31, 2024)***

January 30, 2024, the Corporation announced the Brazilian Health Regulatory Agency (*Agencia Nacional de Vigilância Sanitária*, "**ANVISA**") granted commercialization approval of Ease Labs Pharma ("**Ease Labs**") pharmaceutical preparation produced in Brazil containing Avicanna's Aureus branded active pharmaceutical ingredient ("**API**") to commercialize a pharmaceutical preparation product containing 2.5% of CBD and up-to 0.2% THC, which was the first product containing THC granted sanitary authorization under the RDC 327 and GMP certified manufacturing standards in Brazil. Ease Labs expected the product to be available in pharmacies with a medical prescription by March 2024.

February 5, 2024, the Corporation announced an exclusive supply agreement for two of the Corporation's proprietary topical products with a multinational pharmaceutical company representing an expansion of the Corporation's proprietary topical product offerings in Europe and facilitating expansion into several international markets.

February 13, 2024, the Corporation announced Trunerox™ received drug approval in Colombia from the Colombian National Institute of Drug and Food Surveillance (El Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA). Trunerox™ was approved by INVIMA in Colombia as a drug for the treatment for severe seizures related to Lennox-Gastaut Syndrome and Dravet Syndrome. Trunerox™ has not been approved as a drug in Canada by Health Canada. Trunerox is Avicanna's proprietary oral formulation with 10% cannabidiol ("CBD") and is manufactured with good manufacturing practices at Altea Farmacéutica in Bogota, Colombia utilizing CBD manufactured at the Avicanna's majority-owned subsidiary Santa Marta Golden Hemp SAS.

February 15, 2024, the Corporation announced a research and collaboration agreement with a multinational European based pharmaceutical company. The research collaboration to initially assess the Corporation's proprietary SEDDS technology in combination with Collaborator's various drug delivery and pharmaceutical formats. The research collaboration may subsequently assess the possibility of further preclinical research and clinical development.

April 18, 2024, the Corporation announced that it closed a non-brokered private placement offering of 5,313,959 units of the Company ("**Units**") at a price of \$0.40 per Unit for aggregate gross proceeds of approximately of \$2,125,000 ("**Offering**"). Each Unit is comprised of one common share in the capital of the Corporation (each, a "**Unit Share**") and one-half of one (0.5) common share purchase warrant of the Corporation (each whole warrant, a "**Warrant**"); and, each Warrant shall entitle the holder thereof to acquire one (1) common share in the capital of the Corporation at an exercise price of \$0.55 per share, subject to adjustment in certain events, until April 18, 2027. The Corporation paid an aggregate total of \$31,499.98 in cash finders' fees and issued an aggregate total of 78,750 finder's warrants (each a "**Finder Warrant**") in connection with the Offering to certain finders in connection with subscriptions for Units made by purchasers introduced to the Corporation by such finders. Each Finder Warrant entitles the holder thereof to acquire one common share in the capital of the Corporation at an exercise price of \$0.55 per share, subject to adjustment in certain events, until April 18, 2027.

June 19, 2024, the United States Patent and Trademark Office ("**USPTO**") issued Patent No. US 11,998,632 B2 to the Corporation that covers self-emulsifying drug delivery system ("**SEDDS**") oral cannabinoid composition and methods of treating neuropathic pain.

July 10, 2024, the Corporation announced that it held its annual general meeting of shareholders, at which members of the Board of Directors were elected, including the re-election of Aras Azadian, Giancarlo Davila Char, Paul Fornazzari, Eileen McCormack, and John McVicar. In addition, the Corporation's shareholders approved: reappointment of Kingston Ross Pasnak LLP as the Corporation's auditors for the ensuing year; authorized the board of directors to fix the auditors' remuneration; and, the unallocated awards under the omnibus long-term incentive plan of the Corporation.

August 2, 2024, the Corporation announced a change of auditors from Kingston Ross Pasnak LLP ("**Former Auditor**") to Ramirez Jimenez International CPAs ("**Successor Auditor**") effective August 2, 2024 until the next Annual General Meeting of Shareholders of the Corporation. There were no reservations or modified opinions contained in the Former Auditor's reports on any of the Corporation's audited financial statements; and, there were no reportable events including disagreements, consultations, or unresolved issues as defined in National Instrument 51-102 – Continuous Disclosure Obligations ("**NI 51-102**") (Part 4.11) between the Corporation and the Former Auditor, during the period that the Former Auditor acted as the Corporation's auditor. In accordance with NI 51-102, the Notice of Change of Auditors, together with the required letters from the Former Auditor and the Successor Auditor, were reviewed by the Corporation's audit committee and board of directors, filed on SEDAR+.

August 27, 2024, the United States Patent and Trademark Office ("**USPTO**") issued Patent No. US 12,064,461 B2 to the Corporation that covers deep penetrating topical cannabinoid composition and methods for treating musculoskeletal inflammation and pain.

August 28, 2024, the Corporation announced it closed a non-brokered private placement offering of 6,620,692 units of the Company (the "**Units**") at a price of \$0.30 per Unit for aggregate gross proceeds of \$1,986,207 (the "**Offering**"). Each Unit is comprised of one common share in the capital of the Corporation (each, a "**Unit Share**") and one-half of one (0.5) common share purchase warrant of the Corporation (each whole warrant, a "**Warrant**"); and, each 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 August 28, 2027. The Corporation has paid an aggregate total of \$58,503 in cash finders' fees and issued an aggregate total of 195,010 finders' warrants (each a "**Finder Warrant**") in connection with the Offering to certain finders in connection with subscriptions for Units made by purchasers introduced to the Company by such finders. Each Finder Warrant entitles the holder thereof to acquire one common share in the capital of the Company at an exercise price of \$0.40 per share, subject to adjustment in certain events, until August 28, 2027.

November 4, 2024, the Corporation announced it closed a non-brokered private placement offering of 2,666,701 units of the Company (the "**Units**") at a price of \$0.30 per Unit for aggregate gross proceeds of \$800,010 (the "**Offering**"). Each Unit is comprised of one common share in the capital of the Company (each, a "**Unit Share**") and one-half of one (0.5) common share purchase warrant of the Company (each whole warrant, a "Warrant"); and, each Warrant shall entitle the holder thereof to acquire one (1) common share in the capital of the Company at an exercise price of \$0.40 per share, subject to adjustment in certain events, until November 4, 2027. The Corporation paid an aggregate total of \$22,500 in cash finders' fees and issued an aggregate total of 75,000 finder's warrants (each a "**Finder Warrant**") in connection with the Offering to certain finders in connection with subscriptions for Units made by purchasers introduced to the Company by such finders. Each Finder Warrant entitles the holder thereof to acquire one common share in the capital of the Company at an exercise price of \$0.40 per share, subject to adjustment in certain events, until November 4, 2027.

## DESCRIPTION OF THE BUSINESS

### Summary

Avicanna is a commercial-stage international biopharmaceutical company focused on the advancement and commercialization of evidence-based cannabinoid-based products and formulations for the global medical and pharmaceutical market segments. Avicanna has an established scientific platform including R&D and clinical development leading to the commercialization of more than thirty proprietary, evidence-based finished products and supporting four commercial stage business pillars.

**Medical Cannabis formulary (RHO Phyto™):** The formulary offers a diverse range of proprietary products including oral, sublingual, topical, and transdermal deliveries with varying ratios of cannabinoids, supported by ongoing patient, and medical community education. RHO Phyto is an established brand in Canada currently available nationwide across several channels and expanding into new international markets.

**Medical cannabis care platform (MyMedi.ca):** MyMedi.ca is a medical cannabis care platform formed with the aim to better serve medical cannabis patients' needs and enhance the medical cannabis patients' journey. MyMedi.ca is operated by Northern Green Canada Inc. and features a diverse portfolio of products and bilingual pharmacist-led patient support programs. MyMedi.ca also provides specialty services to distinct patient groups such as veterans and collaborates with public and private payers for adjudication and reimbursement. MyMedi.ca provides educational resources to the medical community to facilitate the incorporation of medical cannabis into health care regimens.

**Pharmaceutical pipeline:** Leveraging Avicanna's scientific platform, vertical integration, and real-world evidence, Avicanna has developed a pipeline of proprietary, indication-specific cannabinoid-based candidates that are in various stages of clinical development. These cannabinoid-based drug candidates aim to address unmet medical needs in the areas of dermatology, chronic pain, and various neurological disorders.



**Active pharmaceutical ingredients (Aureus Santa Marta™):** Active pharmaceutical ingredients (“API”) supplied by the Company’s majority owned subsidiary Santa Marta Golden Hemp SAS (“SMGH”) is a commercial-stage business dedicated to providing a various forms high-quality CBD, THC and CBG to the Company’s international partners for use in the development and production of food, cosmetics, medical, and pharmaceutical products. The business unit also forms part of the Company’s supply chain and is a source of reliable input products for its consumer retail, medical cannabis, and pharmaceutical products for globally.

## Products and Services

Our products and services are grouped into four main categories:

- (i) Medical cannabis products;
- (ii) MyMedi.ca medical cannabis platform
- (iii) Pharmaceutical pipeline; and,
- (iv) Active pharmaceutical ingredients

## Canada

The Canadian market continues to be the core of the Company’s operations and most significant revenue driver where the Company has now established the infrastructure and proof of concept for its intellectual property and business units which can then be expanded internationally. The Company has established its commercial platform and operates an asset-light model where its 27 proprietary products are manufactured through 6 specialized licensed producers. The Company continues to demonstrate growth in products sales, active SKUs, and commercial listings with a predominant focus on medical, where patients have access to Avicanna products on 7 different medical platforms, including MyMedi.ca, Spectrum and Canna Farms. Across all channels, total commercial listings are up to 133 listings, for which 81 listings are on medical platforms and 52 listings are in adult-use channels (including in Ontario, Alberta, Saskatchewan, Manitoba, and New Brunswick). Total wholesale units of finished goods sold were 188,972 for the year-ended December 31, 2024, an increase of 52% over the total wholesale units sold in the prior year.

The launch of the MyMedi.ca medical cannabis care platform solidified the Company’s position as a leader in the medical cannabis category in Canada, with the goal to offer to patients and the medical community a comprehensive medical cannabis care platform that includes proprietary products and patient support programs. The Company generated \$13 million of revenue from MyMedi.ca during 2024. MyMedi.ca also resulted in increased awareness of Company and its products in addition to improving access to the Company’s products for patients which resulted in an increase in the Company’s product sales mainly through new listings, improved access, increased education, and inventory management efficiencies with the Company’s SKUs. MyMedi.ca also provides a platform for enhanced education and collaboration with the medical community and hospitals such as Sunnybrook Cancer Centre that directly dispense the Company’s RHO Phyto products, and various private and public insurance providers including 8 worker safety boards including WSIB (Ontario).

## International

At an international level, the Company has prioritized and optimized its operations to focus on the Company’s long term pharmaceutical pipeline and the expanding medical cannabis segment. The Company’s international operations are focused on the production and manufacturing of the Company’s proprietary finished products across cosmetics and pharmaceuticals designations including Trunerox™. Trunerox™ received drug approval, in Colombia, from the Colombian National Institute of Drug and Food Surveillance (El Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA) for the treatment for severe seizures related to Lennox-Gastaut Syndrome and Dravet Syndrome. Trunerox™ is Avicanna’s proprietary oral formulation with 10% cannabidiol (“CBD”) and is manufactured with good manufacturing

practices at Altea Farmacéutica in Bogota, Colombia utilizing CBD manufactured at the Avicanna's majority-owned subsidiary Santa Marta Golden Hemp SAS. Trunerox™ has not been approved as a drug in Canada by Health Canada.

Additionally, the Company's international efforts have been focused on the Aureus™ branded active pharmaceutical ingredients. The Company continues to expand its international footprint through strategic agreements and has completed commercial transactions in 22 countries.

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Years ended December 31,			
	2024	2023	2022
<b>Revenue</b>			
Service revenues	\$	\$ 121,227	\$ 120,631
License revenue		415,933	1,106,120
Product sales		16,254,323	2,806,737
	<b>\$</b>	<b>\$ 16,791,483</b>	<b>\$ 4,033,488</b>

## RHO Phyto™ Overview

The formulary of proprietary medical cannabis products marketed are under the RHO Phyto™ brand and offer a range of scientifically driven formulations in a variety of products including oral, sublingual, topical, and transdermal deliveries with varying ratios of cannabinoids. In Canada, the RHO Phyto™ products are the Company's flag ship medical cannabis products and are available through the MyMedi.ca platform in addition to other medical cannabis platforms such as Spectrum and Canna Farms, may also be available for dispensing in some Canadian hospitals including the Sunnybrook Cancer Center and provincial retail channels. Internationally, the RHO Phyto™ products are available in Barbados and Cayman Islands and the Company has plans for further expansion.

## RHO Phyto™ Formulations

- **Micro Drops:** The Micro Drops are orange flavoured and utilize Avicanna's inverted emulsion technology aimed to provide absorption and shelf-life stability. The product is administered with metered dosing using an oral syringe that is designed 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 designed for ease of use, and designed to deliver 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 Ultra 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.
- **Water-soluble formulations:** The nano-emulsion technology designed for instant dispersion and dissolution of cannabinoids which can be utilized for titration in drug delivery and beverages.

## MyMedi.ca Overview

MyMedi.ca is a medical cannabis care platform formed with the aim to better serve medical cannabis patients' needs and enhance the patient journey. MyMedi.ca is operated by Northern Green Canada Inc., and features a diverse portfolio of products and pharmacist-led patient support programs. MyMedi.ca also provides specialty services to distinct patient groups such as veterans and collaborates with public and private providers for adjudication and reimbursement. MyMedi.ca provides educational resources to facilitate the incorporation of medical cannabis into health care regimens.

Launched August 1, 2023, MyMedi.ca was established upon the closing of the Company's successful acquisition of the Medical Cannabis by Shoppers business, a subsidiary of Shoppers Drug Mart®. The MyMedi.ca cannabis care platform facilitates medical cannabis access and support nationwide in Canada

to tens of thousands of patients who have obtained medical cannabis authorization from a healthcare provider.

### **MyMedi.ca - Unique Features**

- Offers and emphasizes a multi-brand platform with 200+ SKUs from over 50 leading medical cannabis brands – in contrast with the approach of most other medical cannabis platforms that predominantly emphasize and limit offerings to only their own products.
- Offers training, medical education, products and services, and resources to facilitate the incorporation of medical cannabis into health care regimens including the Company's Avicenna Academy and also the Canadian Consortium for the Investigation of Cannabinoid Syllabus.
- Offers pharmacist led and bi-lingual patient support programs and specialty care services for distinct patient groups.
- Offers services to Canada's veterans with dedicated programs including adjudication services and good faith coverage for pre-approved patients.
- Offers a developed infrastructure that includes insurance reimbursement services for patients through 15 private insurance providers and public institutions including eight provincial worker safety boards.

### ***Pharmaceutical Pipeline***

#### **Pharmaceutical Products and Pipeline Overview**

The Company's pipeline of pharmaceutical preparations and indication specific drug candidates are currently in various stages of clinical development and registration. The pipeline of indication specific drug candidates are designed to address unmet needs in various areas, including neurology, depression, sleep, dermatology. The drug candidates are supported by the Company's scientific research and development and ongoing clinical trials including real world evidence studies. Certain pharmaceutical preparations and certain drug candidates are currently in various stages of submission-application-registration across several Latin American countries.

Potential marketing authorization and commercial pathways:

- Short term focus: Pharmaceutical approvals (South America and Central America).
- Long term vision: Pharmaceutical submissions seeking approvals including Health Canada and the FDA.

### **Trunerox™**

Trunerox™ is the Company's first indication-specific drug approved in Colombia. Trunerox™ is the Company's 10% CBD (THC free) formulation. Trunerox™ received drug approval in Colombia, in February 2024, from the Colombian National Institute of Drug and Food Surveillance (El Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA). Trunerox™ is approved by INVIMA in Colombia as a drug for the treatment for severe seizures related to Lennox-Gastaut Syndrome (LGS) and Dravet Syndrome (DS). Trunerox™ has not been approved as a drug in Canada by Health Canada.

INVIMA approval allows Avicanna to manufacture and commercialize Trunerox® in Colombia for the approved indications associated to the treatment for seizures related to LGS and DS. LGS and DS are two of the various, rare epileptic disorders classified as epileptic encephalopathies. Trunerox™ is manufactured with good manufacturing practices GMP at Altea Farmacéutica in Bogota, Colombia utilizing CBD manufactured at the Avicanna's majority-owned subsidiary Santa Marta Golden Hemp SAS. Around 50 million people worldwide have epilepsy, a common neurological condition globally where nearly 139 per 100,000 people are impacted. The Company anticipates Trunerox™ to be commercialized in several other Central American, South American and Caribbean countries in an expedited manner based upon INVIMA's certification by the Pan American Health Organization.

## ***Cannabinoid Raw Materials***

Under the Aureus brand, Avicanna offers premium flower, resins or whole plant crude oils, cannabinoid distillates, and isolated cannabinoids. 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.

- *Premium Flower* – offered as THC, CBD and CBG dominant dried flower is offered with GACP Good Agricultural and Collection Practices and USDA National Organic Program organic certifications.
- *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.
  - *Resins or plant crude oils* – typically, 30-60% purity of the target compounds.
  - *Cannabinoid distillates* – typically, 60-90% purity of the target compounds.
  - *Isolated cannabinoids* – typically, above 95% purity of the target compounds.

To date, through SMGH, we have distributed seeds, raw materials (Isolates and resins) and bulk formulations in 19 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, Uruguay, Singapore, Denmark, Switzerland and Paraguay. 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 9+ years of R&D, preclinical and clinical development on cannabinoids, Avicanna has established a cannabinoid-based scientific platform and continues to develop its 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 30+ commercial products from its scientific platform including cosmetics, medical cannabis now its first pharmaceutical product. Avicanna owns all related intellectual property including formulations, trademarks, and all associated methodologies.**

### **Pre-Clinical and Clinical Development**

Avicanna continues to collaborate with various leading university and hospital partners on various preclinical and clinical projects. In collaboration with researchers, we have successfully obtained eight peer-reviewed government grants supporting our research projects over the past few years. All the formulations developed, and data generated in collaboration with researchers are Avicanna’s intellectual property.

## The Real-World Evidence Studies on RHO Phyto formulations

The commercial availability of RHO Phyto™ products in Canada has led to the inclusion of these medical cannabis products in several real-world evidence (“RWE”) trials on specific therapeutic indications and patient populations. Data derived from RWE trials in Canada is expected to be a component of an overarching imperative of minimizing risk and maximizing efficacy from research and development, optimization of formulations, enhancement of clinical protocols, prioritization of pharmaceutical trials, and educational materials for the medical community.

- **University Health Network’s Medical (UHN) Medical Cannabis Real World Evidence Study through MyMedi.ca:** The prospective, non-interventional, observational study is aimed to enroll 1,000 patients across the country to understand the potential therapeutic use of medical cannabis and potential impact of medical cannabis on pain, sleep, anxiety, depression, and epilepsy. The study is led by Dr. Hance Clarke President of The Canadian Pain Society and the Canadian Consortium of the Investigation of Cannabinoids and being conducted with the support of the MyMedi.ca Patient Support Team. The study was originally initiated by Medical Cannabis by Shoppers and was part of Avicanna’s commitment to provide continuation of care to the platforms’ patients but also the advancement of medical research. Avicanna’s medical cannabis care platform MyMedi.ca will be providing the necessary infrastructure, patient support, and education for all participating HCPs nationwide. Utilizing validated questionnaires, the study seeks to understand the potential impact of various medical cannabis products and evaluate the change in use of concomitant medication over a 24-week duration. Participating patients will have access to the platform’s products including Avicanna’s own RHO Phyto formulation in addition to products from select licensed producers that are supporting the study.
- **Hospital for Sick Children - epidermolysis bullosa:** Avicanna’s dermatology drug candidate has been commercialized under medical cannabis legislation in Canada and the RHO Phyto brand. 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. The study is expected to be completed at the end of Q1 2024.
- **Santé Cannabis - Musculoskeletal pain and inflammation:** The real-world evidence focused on the RHO Phyto CBG Transdermal gel in patients with arthritis including osteoarthritis, rheumatoid arthritis, fibromyalgia, muscle and joint pain, localized pain, post-surgical pain, muscular and/or structural injuries. The completion of the study and data analysis will inform Avicanna’s direction on the RHO Phyto CBG Transdermal gel.

## 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 yet dry 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 focuses 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, currently operates cultivation facilities that include 300,000 square feet of cultivation space.

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 completed using proprietary 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 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 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,
- (i) 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;
- (i) to cultivate -under the modality of scientific purposes- 800 plants for R&D purposes, pursuant to resolution 279 of March 26, 2021;
- (i) 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;
- (i) 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;

(i) to cultivate -under the modality of scientific purposes- 801 plants for R&D purposes, pursuant to resolution 1547 of October 8, 2021;

(b) for the 2022-2023 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,

(i) 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:

- (c) 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.
  - (i) 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.
- (d) For the 2022-2023 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.
- (e) For the 2024 calendar year,
  - (i) for the SMGH lab to receive 4,464.5 kilograms (dry weight) of cannabis flower from the non-psychoactive genetic “NN-AV011” and 9,722.3 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 736 granted on December 17, 2024.

- *Registration of Psychoactive and Non-Psychoactive Cannabis Genetics*

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

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### **Cultivation Operations – Summary**

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

<b>SMGH Site</b>	<b>Status and Activities</b>
<b>Laboratory</b>	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.
<b>Analytical Equipment</b>	High performance liquid chromatography equipment is in place on site to allow for cannabinoid profiling.
<b>Shade house and Greenhouse Capacity</b>	We currently have 340,000 square feet of shade house and outdoor space plus 20,000 square feet of high-tech greenhouses.
<b>Genetic Registration / Quota Status</b>	Achieved genetic registration of 8 non-psychoactive varieties and 21 psychoactive varieties.  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.
<b>Cultivation Activities</b>	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-license any patent related to our products.

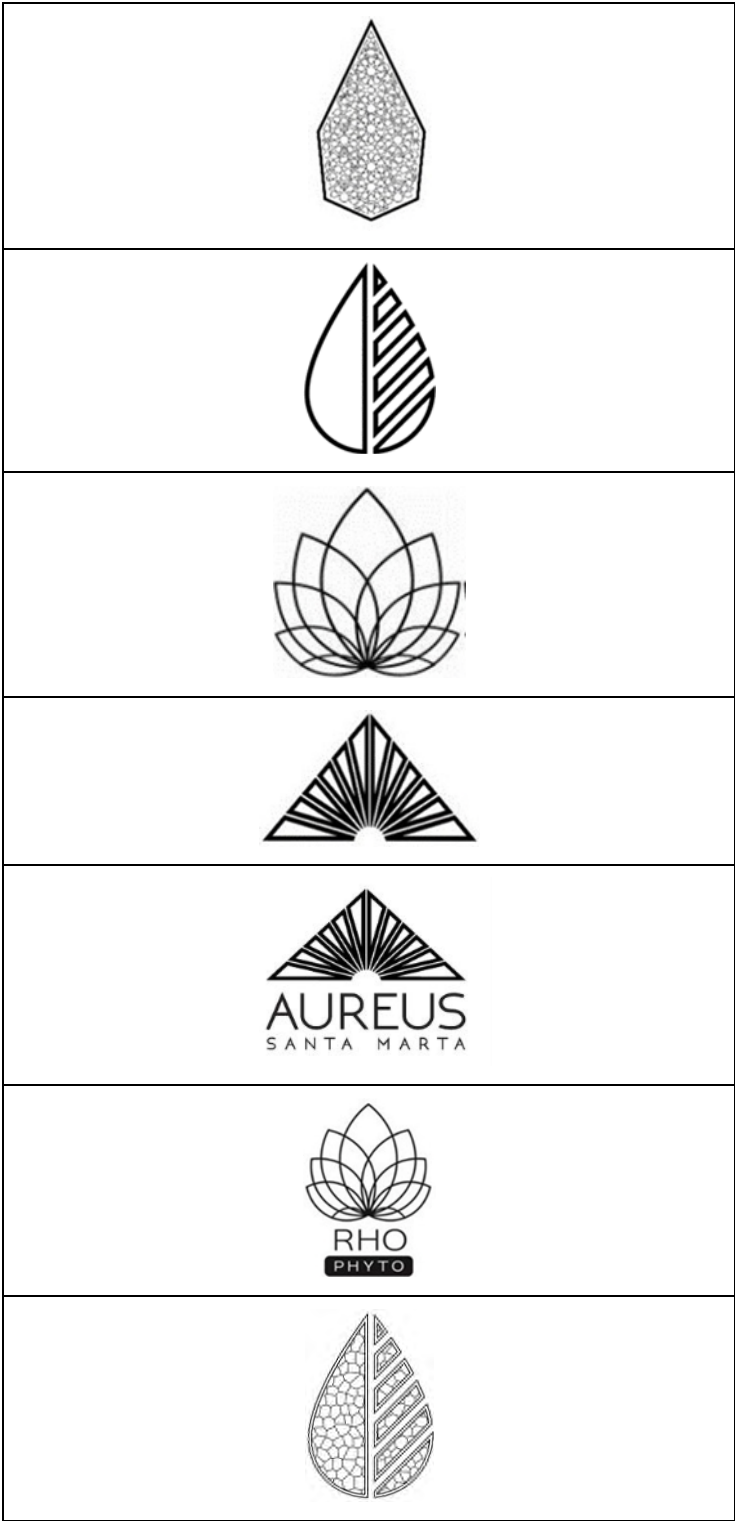
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Our patent portfolio currently includes:

<b>TITLE</b>	<b>ABSTRACT</b>	<b>APPLICATION NO.</b>	<b>STATUS</b>
Topical Cannabinoid Compositions and Methods for Treating Skin Diseases	Topical compositions comprising cannabinoids in combination with one or more humectants and one or more penetration enhancers are provided. Also provided are methods comprising applying a topical cannabinoid composition provided herein to the skin of a subject and uses of a topical cannabinoid formulation provided herein for the treatment of a skin disease or condition in a subject.	US18/549,878 CA3211573	Pending Pending
Topical cannabinoid compositions for clear skin	Topical composition comprising cannabinoids in combination with one or more antioxidants, one or more anti-microbial agents, one or more anti-inflammatory agents and one or more skin conditioning agents are provided. Also provided are methods comprising applying a topical composition provided herein to the skin of a subject and uses of a topical composition for promoting hydration and clear skin.	US17/075,764	Pending
Oral cannabinoid compositions and methods for treating neurological diseases and disorders	Self-emulsifying drug delivery compositions are provided for oral delivery of cannabinoids. The cannabinoids are dissolved in a solubilizer together with at least one stabilizer to improve dissolution and stability. The cannabinoids are also gelled in a standardized matrix to control the release upon contact with aqueous media. Also provided are methods comprising uses of oral cannabinoid compositions for the treatment of a neurological disease and/or disorder in a subject.	US18/716,049 CA3239914 WOIB2022/061666	Pending Pending Pending
Oral cannabinoid compositions and methods for treating neuropathic pain	Self-emulsifying drug delivery systems are provided for oral delivery of cannabinoids. The cannabinoids are dissolved in an oily medium (e.g. medium chain triglycerides) together with at least one surfactant to improve dissolution, stability, and bioavailability. Also provided are methods comprising uses of an oral cannabinoid compositions for the treatment of neuropathic pain in a subject.	US17/012,366	GRANTED* * US Patent No. 11,998,632 B2
Methods for reducing or eliminating incidence of seizures and sudden unexpected death in epilepsy	Methods of reducing the incidence and/or severity of seizures in a subject previously diagnosed with epilepsy or epileptic encephalopathy using a cannabinoid or a combination of cannabinoids as 5-HT1A receptor agonists are provided. Also provided are methods of treating epilepsy or epileptic encephalopathy, and/or reducing, ameliorating, or eliminating incidence of Sudden Unexpected Death in Epilepsy (SUDEP) by administering a cannabinoid or a combination of cannabinoids to a subject in need thereof.	WOIB2022/058932	Pending
Deep penetrating topical cannabinoid compositions and methods for treating musculoskeletal inflammation and pain	Topical compositions comprising cannabinoids in combination with one or more humectants and one or more penetration enhancers are provided. Also provided are methods comprising applying a topical cannabinoid composition provided herein to the skin areas of a subject affected by inflammation and/or pain associated with musculoskeletal disease or condition and uses of a topical cannabinoid formulation provided herein for the treatment of inflammation and/or pain associated with musculoskeletal disease or condition in a subject.	US17/811,972	GRANTED* * US Patent No. 12,064,461 B2

Our trademark portfolio (logos, word marks, design marks) currently includes:

<b>TRADEMARKS</b>
AVICANNA
RHO PHYTO
AUREUS
PURA ELEMENTS
PURA EARTH
PURA H&W
ELEVATING NATURE THROUGH SCIENCE
PURA H&W
TRUNEROX
RHO PHYTOTHERAPEUTICS



## **Employees, Specialized Skill and Knowledge**

As at the date of this AIF, Avicanna has 38 employees located in Canada and 4 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 11 employees and 3 independent contractors, all of which are located in Colombia; (ii) SMGH has 37 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 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, a small proportion of 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 one of the biggest 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 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 four to six weeks. 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 license holder's site is adequately secured and safeguarded at all times to protect public safety and to minimize the risks of diversion. Each license holder is responsible for understanding and complying with required physical security measures that apply to their license, 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, and SMGH. 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 Agricultural and Collection Practices (“**GACP**”) 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
Decree 811 of 2021 substitutes Title 11 of Part 8 of Book 2 of Decree 780 of 2016 (replaces and/or modifies the provisions of Decree 613)	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
Resolution 227 of 2022 from the Ministry of Justice, Ministry of Health and Ministry of Agriculture and Rural Development	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.
Resolution 539 of 2022 from the Ministry of Justice, Ministry of Health and Ministry of Commerce, Industry and Tourism	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.
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;
License to manufacture Cannabis Derivatives for a) national use, b) Scientific Research and c) export	Obtained	Ministry of Health	Keeping up-to-date records;
Registration as a non-psychoactive and psychoactive cannabis plant breeding unit	Obtained	ICA	Amending license within 30 days of occurrence of certain fundamental changes;
Registration to Export non-psychoactive and psychoactive cannabis seeds	Obtained	ICA	Filing import and export 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
Registration to produce non-psychoactive and psychoactive cannabis seeds	Obtained	Res. 31425 of 2018 as amended by Res. 7016 of 2019

*Drug Approval*

Avicanna LATAM obtained its first indication-specific drug registration for Trunerox™ in Colombia issued by INVIMA, the Health Authority of Colombia.

In accordance with Decree 677 of 1995 drugs, including pharmaceutical preparations based on natural resources, require for their production, importation, processing, packaging, labeling, dispensing, and commercialization, a drug approval issued by the INVIMA or its equivalent, or by the delegated health authority, following compliance with the technical-scientific, health, and quality requirements provided in the same decree.

Therefore after a detailed process of verification of all legal, technical, and pharmacological requirements were fulfilled in accordance with Decree 677 of 1995 INVIMA granted a drug approval (Registro Sanitario como medicamento) for Trunerox TM to Avicanna LATAM,. The approval allows Avicanna to manufacture and commercialize Trunerox in Colombia with approved indications and claims associated to the treatment for seizures related to Lennox-Gastaut Syndrome (LGS) and Dravet Syndrome (DS). Lennox-Gastaut Syndrome (LGS) and Dravet Syndrome (DS) are two of the various, rare epileptic disorders classified as epileptic encephalopathies.

Avicanna LATAM requires to manufacture the products in a Good Manufacturing Practices (GMP) facility and therefore the products will be manufactured in Altea Farmaceutica S.A. in accordance with Decree 677 of 1995

#### *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 . 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

	Strain ID	Status
27	AV034	Registered
28	AV033	Registered
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 (Notificación Sanitaria Obligatoria or 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, 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 obtained the NSO in the following table:

Product Name	NSO
GEL CORPORAL REFRESCANTE (CBD)	NSOC09287-21CO
GEL REFRESCANTE CORPORAL (CBD/CBG)	NSOC12454-22CO

## 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 licensees 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>1</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>2</sup>

#### *United States Federal Regulation of Hemp*

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.

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<sup>1</sup> 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>2</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](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 Cannabis-derived 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>3</sup>

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<sup>3</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.<sup>4</sup> 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>5</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

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<sup>4</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>5</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.<sup>6</sup> 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.<sup>7</sup> 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>8</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>6</sup> Ky. Rev. Stat. §§ 260.850-.858.

<sup>7</sup> U.S. Food and Drug Administration, Mission Statement: <https://www.fda.gov/about-fda/what-we-do#mission>.

<sup>8</sup> U.S. Food and Drug Administration, “FDA Regulation of Cannabis and Cannabis-Derived Products, Including Cannabidiol (CBD), Questions and Answers,” <https://www.fda.gov/news-events/public-health-focus/fda-regulation-cannabis-and-cannabis-derived-products-including-cannabidiol-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.<sup>9</sup> 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[.]”<sup>10</sup> FDA “is committed to evaluating the regulatory frameworks for non-drug uses, including products marketed as foods and dietary supplements[.]”<sup>11</sup> 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

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<sup>9</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>10</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), <https://www.fda.gov/news-events/fda-voices/fda-committed-sound-science-based-policy-cbd>.

<sup>11</sup> *Id.*

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.”<sup>12</sup>

As it continues down this path, the FDA is “[l]istening to and learning from stakeholders[.]”<sup>13</sup> 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.<sup>14</sup> 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.<sup>15</sup> 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.<sup>16</sup> 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.”<sup>17</sup>

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 developing brain and on the unborn child and breastfed newborn. The report acknowledges that the FDA

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<sup>12</sup> Id.

<sup>13</sup> Id.

<sup>14</sup> Id.

<sup>15</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>16</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>17</sup> Id.

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>18</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>19</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.

#### *Rescheduling*

Although there has been recent discussions and steps to potential rescheduling of cannabis from Schedule I to Schedule III, the timing (or even likelihood) of such remains speculative and uncertain at the

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<sup>18</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>19</sup> H.R. 8179, 116th Cong. (2020).

the present time. Cannabis (or marijuana) is currently categorized as a Schedule I controlled substance. By way of brief overview: in 1970, marijuana was placed and categorized as a Schedule I controlled substance. Marijuana, generally defined by the CSA to mean the plant *Cannabis sativa* L., whether growing or not: the seeds thereof; the resin extracted from any part of such plant; and every compound, manufacturer, salt, derivative, mixture, or preparation of such plant, its seeds or resins; in 2016, DEA and HHS examined rescheduling and DEA denied petitions to reschedule marijuana; however, significantly, in August 2023 HHS recommended to DEA to reschedule marijuana from Schedule I to Schedule III, and subsequently in May 2024 DEA proposed rulemaking to reschedule from Schedule I to Schedule III. Hearings for rescheduling were initially set to take place in December 2024 but later deferred until 2025.

## **Argentina**

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 legal and appropriate labels and packaging based on the target country's requirements. The Corporation intends that all products distributed to locations within the European Union 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 be 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 pharmaceutical (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 DIGEMID for the product to not be considered as a controlled substance and therefore not require an 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 is 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 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 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 7% 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 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 number 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 web-based 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.

### ***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 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 92,287,937 Common Shares issued and outstanding. In addition, as of the date of this AIF, there were 2,963,538 Common Shares issuable on the exercise of Stock Options, 25,388,437 Common Shares issuable on the exercise of Warrants, 1,768,902 Common Shares issuable on the vesting of Restricted Stock Units.

Holder 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, 2024 as well as the periods up to March 31, 2025:

Period	High Trading Price	Low Trading Price	Volume
January 2024	\$0.36	\$0.30	942,800
February 2024	\$0.48	\$0.31	1,408,800
March 2024	\$0.60	\$0.43	2,520,700
April 2024	\$0.53	\$0.34	3,064,900
May 2024	\$0.38	\$0.25	3,363,300
June 2024	\$0.40	\$0.24	3,852,000
July 2024	\$0.49	\$0.30	3,023,900
August 2024	\$0.41	\$0.29	1,624,000
September 2024	\$0.44	\$0.33	3,077,700
October 2024	\$0.40	\$0.28	5,465,400
November 2024	\$0.36	\$0.24	2,146,100
December 2024	\$0.40	\$0.30	1,331,300
January 2025	\$0.34	\$0.26	3,093,400
February 2025	\$0.32	\$0.24	4,157,300
March 2025	\$0.38	\$0.28	3,144,900

**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 marketplace that have been issued during the financial year ended December 31, 2024 as well as the periods up to April 11, 2025.

Date	Type of Security	Issue/Exercise Price	Number of Securities
February 26, 2024	Options <sup>(1)</sup>	\$0.38	450,000
February 26, 2024	Restricted Stock Units <sup>(1)</sup>	\$0.30	1,408,035
March 1, 2024	Options <sup>(1)</sup>	\$0.39	2,000,000
April 18, 2024	Warrants <sup>(2)</sup>	\$0.55	2,656,979
April 18, 2024	Broker Warrants <sup>(2)</sup>	\$0.55	78,750
June 21, 2024	Options <sup>(1)</sup>	\$0.33	2,137,500
June 21, 2024	Restricted Stock Units <sup>(1)</sup>	\$0.26	2,580,527
August 28, 2024	Warrants <sup>(3)</sup>	\$0.40	3,310,346
August 28, 2024	Broker Warrants <sup>(3)</sup>	\$0.40	195,010
November 4, 2024	Warrants <sup>(4)</sup>	\$0.40	1,333,350
November 4, 2024	Broker Warrants <sup>(4)</sup>	\$0.40	75,000
November 21, 2024	Options <sup>(1)</sup>	\$0.24	75,000
November 21, 2024	Restricted Stock Units <sup>(1)</sup>	\$0.30	300,000
February 25, 2025	Options <sup>(1)</sup>	\$0.26	1,611,274
February 25, 2025	Restricted Stock Units <sup>(1)</sup>	\$0.33	535,000

**Notes:**

- (1) Issued pursuant to the Corporation's Omnibus long-term incentive program
- (2) Issued in connection with the April 18, 2024 offering.
- (3) Issued in connection with the August 28, 2024 offering.
- (4) Issued in connection with the November 4, 2024 offering.

## DIRECTORS AND OFFICERS

The following table sets forth the name, province/state 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, Giancarlo Davila Char, Eileen McCormack, and Paul Fornazzari. 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.

<b>Name Jurisdiction of Residence</b>	<b>Positions with Corporation</b>	<b>Date First Appointment</b>	<b>Principal Occupation Preceding Five Years</b>
AZADIAN, Aras Ontario, Canada	Chief Executive Officer, and Director	November 25, 2016	Chief Executive Officer of Corporation (2016- Present)
CARDELLA, Phillip Ontario, Canada	Chief Financial Officer	December 21, 2022	Chief Financial Officer, Interim Chief Financial Officer, SVP Finance of Corporation (2021-Present); Assurance Manager, MNP LLP (2015-2021)
DAVILA CHAR, Giancarlo Florida, USA	Director	October 22, 2018	Commercial Manager of Caribbean Eco Soaps U.I.B.S. (2017-Present)
FORNAZZARI, Paul Ontario, Canada	Director <sup>(1)(2)(3)</sup>	November 13, 2024	Counsel (2025-Present), Partner (2015-2024) Fasken
McCORMACK, Eileen	Director <sup>(1)(2)(3)</sup>	January 4, 2022	Part-Time Consultant (2018- Present); Head of New Product Planning and Business Development at AstraZeneca USA (2014-2017)
McVICAR, John Ontario, Canada	Director <sup>(1)(2)(3)</sup>	June 24, 2021	Part-Time Executive and Director (2020-Present); Partner, Ernst & Young LLP (2002-2020).

**Notes:**

- (1) Member of Audit Committee. Mr. McVicar is Chair of Audit Committee.
- (2) Member of Compensation Committee. Mr. Fornazzari is Chair of Compensation Committee.
- (3) Member of Nominating & Corporate Governance Committee. Ms. McCormack is Chair of 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, 8,119,103 Common Shares, representing approximately 9% 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 49% 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 a Management Cease Trade Order (“MCTO”) with the Ontario Securities Commission 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, the Cease Trade Order (“CTO”) was issued effective June 11, 2021. The CTO was revoked on September 10, 2021.

### ***Bankruptcies***

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.

### ***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.

## 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, 2024, 2023, and 2022, the fees expected to be billed by our external auditor are set out in the table below:

	<b>Audit Fees<sup>(1)</sup></b>	<b>Tax Fees<sup>(2)</sup></b>	<b>All Other Fees<sup>(3)</sup></b>	<b>Total</b>
<b>Year ended December 31, 2024</b>	\$460,000	\$60,000	\$nil	\$510,000
<b>Year ended December 31, 2023</b>	\$400,000	\$60,000	\$30,000	\$490,000
<b>Year ended December 31, 2022</b>	\$400,000	\$60,000	\$nil	\$460,000

Notes:

- (1) "Audit Fees" are the fees necessary to perform the audit of the Corporation's financial statements for the period ended December 31, 2022, December 31, 2023, and December 31, 2024, 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.
- (3) "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, Ms. Eileen McCormack, and Mr. Paul Fornazzari. Each of Mr. McVicar, Ms. McCormack, and Mr. Fornazzari 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*".

<b>Audit Committee Member</b>	<b>Relevant Education and Experience</b>
John McVicar	M.B.A., Duke University B.Com., Queen's University CPA and CA designation holder (Former) Partner, Ernst & Young LLP



Eileen McCormack

M.Sc., University of Guelph  
B.Sc., University of Guelph  
(Former) Head, New Product Planning and Business Development,  
AstraZeneca USA

Paul Fornazzari

LL.M., Osgoode Hall Law School, York University  
LL.B., University of Windsor  
Counsel (and Former Partner), Fasken Martineau DuMoulin LLP

### ***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 intellectual property licensing and royalty agreement dated February 3, 2021 between the Corporation and Harrington Wellness Inc..

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 non-psychoactive 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 Ramirez Jimenez International CPAs. Ramirez Jimenez International CPAs 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) and the American Institute of Certified Public Accountants.

#### **ADDITIONAL INFORMATION**

Additional information regarding the Corporation may be found under the Corporation’s profile on SEDAR+ at [www.sedarplus.ca](http://www.sedarplus.ca) and on the Corporation’s website at [www.avicanna.com](http://www.avicanna.com).

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 31,2024.

**Schedule "A"**  
**AUDIT COMMITTEE CHARTER**