



**Nuvo Pharmaceuticals[®] Inc.
d/b/a Miravo Healthcare[™]**

ANNUAL INFORMATION FORM

March 5, 2021

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CERTAIN REFERENCES

Unless otherwise noted, the information contained in this Annual Information Form (AIF) is provided as at or for the year ended December 31, 2020, as applicable.

For an explanation of key terms, please refer to the “Glossary of Terms” at the end of this AIF. Unless otherwise noted, or indicated by context, “Miravo Healthcare”, “Miravo”, and the “Company” refers to Nuvo Pharmaceuticals Inc. doing business as (d/b/a) Miravo Healthcare (Miravo) and its subsidiaries, unless the context requires otherwise.

All dollar amounts are expressed in Canadian dollars unless otherwise noted.

FORWARD-LOOKING INFORMATION

This AIF contains “forward-looking information” as defined under Canadian securities laws (collectively, “forward-looking statements”). This document should be read in conjunction with the Company’s other publicly filed documents. Forward-looking statements appear in this AIF and include, but are not limited to, statements which reflect management’s expectations regarding objectives, plans, goals, strategies, future growth, results of operations, performance, business prospects, opportunities and macroeconomic and industry trends.

The words “plans”, “expects”, “does not expect”, “goals”, “seek”, “strategy”, “future”, “estimates”, “intends”, “anticipates”, “does not anticipate”, “projected”, “believes” or variations of such words and phrases or statements to the effect that certain actions, events or results “may”, “will”, “could”, “would”, “should”, “might”, “likely”, “occur”, “be achieved” or “continue” and similar expressions identify forward-looking statements. In addition, any statements that refer to expectations, intentions, projections or other characterizations of future events or circumstances contain forward-looking statements. Forward-looking statements are not historical facts but instead represent management’s expectations, estimates and projections regarding future events or circumstances. Some of the specific forward-looking statements in this AIF include, but are not limited to, statements with respect to the following:

- the ability of the Company to execute its growth strategies;
- the ability of the Company to meet its debt commitments;
- the Company’s competitive position within its industry;
- expectations regarding laws, rules and regulations applicable to the Company and the drug development process in general;
- expectations regarding ongoing litigation with respect to the Company’s and competitors’ products;
- expectations regarding industry and demographic trends applicable to the Company;
- expectations regarding the receipt of regulatory decisions applicable to the Company’s or competitors’ products;
- expectations regarding the receipt of milestone and royalty payments in respect of the Company’s products; and

- the expected impact of COVID-19 on the operations, business and financial results of the Company.

Such forward-looking statements are qualified in their entirety by the inherent risks, uncertainties and changes in circumstances surrounding future expectations which are difficult to predict and many of which are beyond the control of the Company.

Forward-looking statements are necessarily based on a number of estimates and assumptions that, while considered reasonable by management of the Company as of the date of this AIF, are inherently subject to significant business, economic and competitive uncertainties and contingencies. The Company's estimates, beliefs and assumptions, which may prove to be incorrect, include the various assumptions set forth herein, including, but not limited to, the Company's future growth potential, results of operations, future prospects and opportunities, industry trends, legislative or regulatory matters, future levels of indebtedness, availability of capital and current economic conditions.

When relying on forward-looking statements to make decisions, the Company cautions readers not to place undue reliance on these statements, as forward-looking statements involve significant risks and uncertainties. Forward-looking statements should not be read as guarantees of future performance or results and will not necessarily be accurate indications of whether or not the times at or by which such performance or results will be achieved. A number of factors could cause actual results to differ, possibly materially, from the results discussed in the forward-looking statements, including, but not limited to:

- the impact of changing conditions in the regulatory environment and drug development processes;
- increasing competition in the industries in which the Company operates;
- the inability of the Company to meet its debt commitments;
- the impact of unexpected product liability matters;
- the impact of ongoing litigation involving the Company and/or its products;
- the impact of changes in relationships with customers and suppliers;
- the degree of intellectual property protection currently afforded to the Company's products;
- the conditions applicable to the Company's milestone and royalty payments being met or unmet;
- the degree of market acceptance of the Company's products;
- changes in prevailing economic conditions;
- developments and changes in applicable laws and regulations;
- the impact of COVID-19 on the operations, business and financial results of the Company; and
- such other factors discussed under "Risk Factors" in this AIF.

If any risks or uncertainties with respect to the above materialize, or if the opinions, estimates or assumptions underlying the forward-looking statements prove incorrect, actual results or future events might vary materially from those anticipated in the forward-looking statements. The opinions, estimates or assumptions referred to above and described in greater detail under “Risk Factors” in this AIF should be considered carefully by readers. Although management has attempted to identify important risk factors that could cause actual results to differ materially from those contained in forward-looking statements, there may be other risk factors not presently known that management believes are not material that could also cause actual results or future events to differ materially from those expressed in such forward-looking statements.

All forward-looking statements are based only on information currently available to the Company and are made as of the date of this AIF. Except as expressly required by applicable Canadian securities law, the Company assumes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All forward-looking statements in this AIF are qualified by these cautionary statements.

MARKET AND INDUSTRY INFORMATION AND DATA

This AIF includes certain market and industry information and data obtained from third-party sources, industry publications and publicly available information as well as industry information and data prepared by management on the basis of its knowledge of the industry in which the Company operates (including management’s estimates and assumptions relating to the industry based on that knowledge). Management’s knowledge of the healthcare industry has been developed through its experience and participation in the industry. Management believes that the industry information and data presented is accurate and that its estimates and assumptions are reasonable, but there can be no assurance as to the accuracy or completeness of this data. Third-party sources generally state that the information contained therein has been obtained from sources believed to be reliable, but there can be no assurance as to the accuracy or completeness of included information. Although management believes it to be reliable, the Company has not independently verified any of the data from management or third-party sources referred to in this AIF, or analyzed or verified the underlying studies or surveys relied upon or referred to by such sources, or ascertained the underlying economic assumptions relied upon by such sources.

NUVO PHARMACEUTICALS INC. STRUCTURE

Corporate Structure

Nuvo Pharmaceuticals Inc. (Nuvo) was incorporated under the *Business Corporations Act* (Ontario) on August 22, 1983 under the laws of the Province of Ontario as Clark Pharmaceutical Laboratories Ltd. On November 14, 1990, the articles were amended to change the name of the Company from Clark Pharmaceutical Laboratories Ltd. to Dimethaid Research Inc. On September 30, 2005, the articles were further amended to change the name of the Company from Dimethaid Research Inc. to Nuvo Research Inc. On March 1, 2016, the articles were amended to change the name of the Company from Nuvo Research Inc. to Nuvo Pharmaceuticals Inc. On December 18, 2020, Nuvo announced it would be rebranding and would begin d/b/a Miravo Healthcare. The Company did not change its legal name or those of its wholly owned subsidiaries, but has registered the business name “Miravo Healthcare” in the jurisdictions in which it operates.

The Company's registered office and principal place of business is located at 6733 Mississauga Road, Unit 800, Mississauga, Ontario, Canada, L5N 6J5. Miravo's international operations are headquartered in Dublin, Ireland and its U.S. Food and Drug Administration (FDA), Health Canada and E.U. approved manufacturing facility is located in Varennes, Québec, Canada.

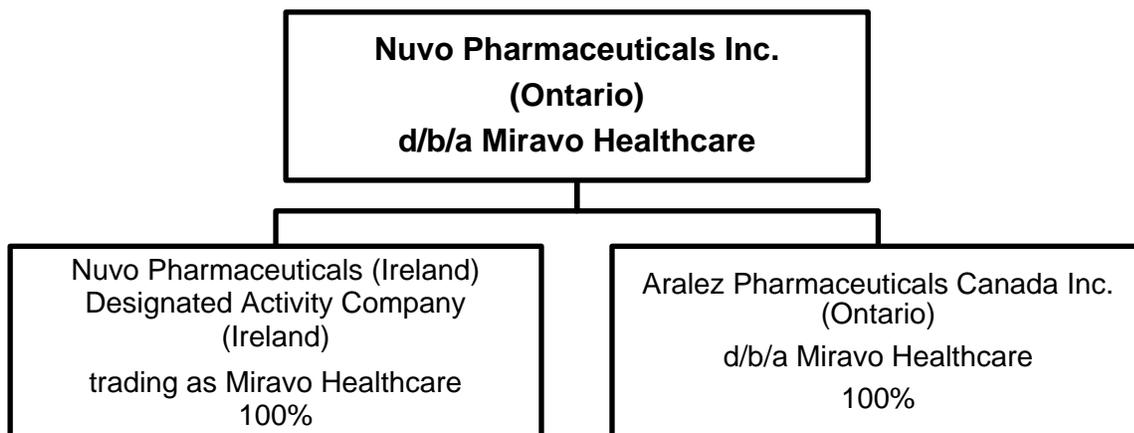
The Aralez Transaction

On December 31, 2018, the Company announced the acquisition of a portfolio of more than 20 revenue-generating products from Aralez Pharmaceuticals Inc. (Aralez) (the Aralez Transaction). The Aralez Transaction included the acquisition of Aralez Pharmaceuticals Canada Inc. (Aralez Canada), a growing business that includes the products Cambia[®], Blexten[®], as well as the Canadian distribution rights to Resultz[®], and provides a platform for the Company to acquire and launch additional commercial products in Canada. The Company also acquired the worldwide rights and royalties from licensees for Vimovo, Yosprala and Suvexx[®]/Treximet.

The aggregate purchase price paid by the Company to Aralez for the Aralez Transaction was \$146.4 million (US\$110 million, subject to certain working capital and indebtedness adjustments). The Company satisfied the purchase price through funding provided by certain funds managed by Deerfield Management Company, L.P. (Deerfield), a global, healthcare-specialized investor (the Deerfield Financing). See "General Development of the Business – Significant Acquisitions – The Aralez Transaction".

Organizational Chart

The following chart illustrates Nuvo's relationship to its subsidiaries, its respective jurisdictions of incorporation, as well as the percentage ownership as at December 31, 2020.



Nuvo Pharmaceuticals (Ireland) Designated Activity Company

In 2017, Nuvo Pharmaceuticals (Ireland) Limited was incorporated as an Irish limited liability company. In December 2018, Nuvo Pharmaceuticals (Ireland) Limited was re-registered as an Irish Designated Activity Company (DAC) and the company was renamed Nuvo Pharmaceuticals (Ireland) DAC. As of December 18, 2020, Nuvo Pharmaceuticals (Ireland) DAC began trading as Miravo Healthcare (Miravo Ireland). Miravo Ireland is a wholly owned subsidiary

of Nuvo Pharmaceuticals Inc. and holds (i) the worldwide (except Canada) product rights and intellectual property for Resultz, and (ii) following the Aralez Transaction (as described in further detail below), the worldwide product rights and royalties from licensees for Vimovo, Yosprala and Suvexx (except Canada) which is currently commercialized in the U.S. as Treximet.

Aralez Pharmaceuticals Canada, Inc.

In connection with the Aralez Transaction (as described in further detail below), Nuvo acquired all of the shares of Aralez's Canadian specialty pharmaceutical business, Aralez Canada, which was formerly known as Tribute Pharmaceuticals Canada Inc. (Tribute Pharmaceuticals). Aralez Canada is now a wholly owned subsidiary of Nuvo and is d/b/a Miravo Healthcare (Miravo). Miravo owns the Canadian distribution rights to Cambia, Blexten and Resultz along with a portfolio of 14 additional legacy brands.

GENERAL DEVELOPMENT OF THE BUSINESS

Nuvo Pharmaceuticals Inc. d/b/a Miravo Healthcare is a publicly traded, Canadian focused, healthcare company with global reach and a diversified portfolio of commercial products. The Company's products target several therapeutic areas, including pain, neurology, allergy and dermatology. The Company's strategy is to in-license and acquire growth-oriented, complementary products for Canadian and international markets. For a description of the Company's portfolio of products, see "Narrative Description of the Business".

The following is a summary of the general development of the Company's business over the past three years.

Three Year History of the Business

Fiscal 2021

Exclusive License Agreement with The Mentholatum Company to Market Resultz in the U.S.

In February 2021, Miravo Ireland entered into an exclusive license and supply agreement (the License Agreement) with The Mentholatum Company for the exclusive right to commercialize the Resultz formula and technology in the United States under the Mentholatum® brand. Miravo Ireland will earn revenue from The Mentholatum Company pursuant to the License Agreement. It is anticipated that The Mentholatum Company will launch Resultz during the summer of 2021. Resultz is currently manufactured by the Company's contract manufacturing partner in Europe.

Pennsaid 2% Launched in Switzerland

In January 2021, the Company's exclusive partner for Pennsaid 2% in Switzerland, Gebro Pharma AG (Gebro Pharma), launched the product into the Swiss market. The Company will begin to earn royalty revenue on net sales of Pennsaid 2% in Switzerland beginning in the first quarter of 2021.

Canadian Commercial Launch of NeoVisc®+ and NeoVisc® ONE

In January 2021, the Company launched NeoVisc+ 2 mL and NeoVisc ONE 4 mL in Canada. Both NeoVisc+ and NeoVisc ONE were issued a Medical Device License by Health Canada in September 2020 for the treatment of pain and improvement of joint functionality in patients affected by degenerative (age-related changes) or mechanical arthropathy (related to overuse) of the knee.

Fiscal 2020***Exclusive Agreement with Orion Corporation to Market Suvexx in Select E.U. Markets***

In December 2020, the Company's wholly owned subsidiary, Miravo Ireland entered into an exclusive license and supply agreement with Orion Corporation (Orion) for the right to package, distribute, market and sell Suvexx in Finland, Sweden, Denmark, Norway, Poland, Hungary, Latvia, Lithuania and Estonia (the Territory). Orion will be responsible for obtaining and maintaining the marketing authorizations for Suvexx in the Territory and will also manage all Territory specific commercial activities. Miravo Ireland will receive up to €1.7 million in upfront consideration, regulatory and sales-based milestone payments, as well as royalties on net sales of Suvexx in the Territory and revenue pursuant to the supply of product. Suvexx is currently manufactured by the Company's contract manufacturing partner in the United States.

Nuvo Pharmaceuticals Rebrands as Miravo Healthcare

In December 2020, Nuvo announced it would begin d/b/a Miravo Healthcare. The Company did not change its legal name or those of its wholly owned subsidiaries. The corporate rebranding reflects Nuvo's evolution into a growing, multi-asset Company which was transformed by the acquisition of the Aralez Canada business at the end of 2018. Miravo consolidates the Nuvo and Aralez brands under one common name.

Medical Device License Granted for Two New Line Extensions of NeoVisc in Canada

In September 2020, Miravo received notice that Health Canada had issued a medical device license for two new line extensions of NeoVisc. NeoVisc is a viscosupplement used to replenish the synovial fluid in the joints of patients with osteoarthritis. NeoVisc One is a low single-dose injection volume (only 4ml) viscosupplement. NeoVisc+ consists of a three injection dosing system that is administered to a patient over the course of a few weeks. In some patients, a three dose treatment may provide longer relief.

Suvexx Launched in Canada

In September 2020, Miravo launched Suvexx into the approximately \$130 million Canadian prescription acute migraine market. Suvexx (sumatriptan succinate and naproxen sodium tablets) is a fixed-dose combination prescription medication, indicated for the acute treatment of migraine attacks with or without aura in adults. Suvexx helps patients manage acute migraine attacks using a combination of sumatriptan succinate and naproxen sodium in a single tablet.

Blexten Pediatric Dossier Accepted for Review by Health Canada

In August 2020, the Blexten pediatric dossier was accepted for review by Health Canada. The original license agreement for Blexten included Canadian rights for the pediatric dosage formats. If approved, Blexten pediatric will be available in both an oral syrup formulation (2.5mg/ml) and an orally dispersible tablet formulation (10mg tablets). A regulatory decision from Health Canada is anticipated by late summer 2021.

Milestone Payment Received from Takeda Related to Approval of Cabpirin in Japan

In March 2020, Miravo Ireland received notice from Takeda Pharmaceutical Co., Ltd. (Takeda), that Japan's Ministry of Health, Labor and Welfare (the MHLW) approved Cabpirin tablets, a combination of the potassium-competitive acid blocker (P-CAB) vonoprazan fumarate and low-dose aspirin that will be co-promoted in Japan by Takeda and its co-promotion partner Otsuka Pharmaceutical Co., Ltd. Takeda holds a non-exclusive license to Miravo Ireland's Japanese patent no. 4756823 which covers the Cabpirin formulation. The MHLW approval triggered two milestone payments due to Miravo Ireland of \$2.8 million (US\$2.0 million) each. Miravo Ireland received the first \$2.8 million (US\$2.0 million) milestone payment in May 2020 and is contractually entitled to receive the second milestone payment no later than May 31, 2022, provided the licensed intellectual property remains valid and enforceable. Miravo Ireland is entitled to retain 50% of all royalty and milestone revenues generated from the Yosprala intellectual property with the remaining 50% to be paid to the estate of POZEN, Inc. (POZEN).

Dr. Reddy's Laboratories Launched Generic Version of Vimovo in the United States

In March 2020, Dr. Reddy's Laboratories Inc. (Dr. Reddy's) launched its generic version of Vimovo in the United States. As a result of an entry of a generic version of Vimovo in the U.S., Miravo Ireland's US\$7.5 million annual minimum royalty from its partner has ceased. The royalty rate for 2020 was calculated as 10% of net U.S. sales of Vimovo, subject to certain step-down provisions upon achievement of generic market share thresholds. As described in more detail below in the section entitled "Legal Proceedings and Regulatory Actions - Vimovo", there is ongoing patent litigation against Dr. Reddy's. In the event, Dr. Reddy's is found to infringe one of Miravo's patents, Miravo Ireland and Horizon could seek damages from Dr. Reddy's.

Pennsaid 2% Marketing Authorization Issued in Switzerland

In January 2020, the Company was informed by its licensee in Switzerland and Lichtenstein, Gebro Pharma that the marketing authorization for Pennsaid 2% was issued by Swissmedic. Gebro Pharma launched Pennsaid 2% in Switzerland in January 2021.

Repayment of Bridge Loan to Deerfield

In January 2020, the Company repaid the US\$6.0 million Bridge Loan (as defined below) (12.5% per annum) to Deerfield, ahead of its June 2020 maturity date. The Bridge Loan was one component of the financing provided by Deerfield in support of the acquisition of Aralez Canada, the U.S. and International rights to Vimovo and other related assets. The Company's remaining loans of US\$52.5 million and US\$60.0 million carry coupon interest rates of 3.5% per annum. See "General Development of the Business – Recent Financings – The Deerfield Financing".

Fiscal 2019

United States Court of Appeals Denied a Motion for Summary Judgment for Vimovo '996 patent and '920 patent

In November 2019, the United States District Court for the District of New Jersey (New Jersey District Court) denied a motion for summary judgment filed by Dr. Reddy's Laboratories Inc. (Dr. Reddy's). As a result, the patent infringement litigation against Dr. Reddy's, involving Miravo Ireland U.S. Patent Nos. 8,858,996 (the '996 patent) and 9,161,920 (the '920 patent), will continue.

Received an Application for an Industry-wide Class Action

On October 30, 2019, the Company received an application for an industry-wide class action in the Superior Court of Québec. In the application, the Company was named as a defendant, along with 33 other defendants, which includes a group of companies that manufacture, market, and/or distribute opioids in Québec. The claim is for \$30,000, plus interest, for compensatory damages for each class member, \$25.0 million from each defendant for punitive damages and pecuniary damages for each class member. The Company believes the claim is without merit and intends to vigorously defend itself.

Validity of Pennsaid 2% '913 patent

In October 2019, the United States Court of Appeals for the Federal Circuit (Court of Appeals) issued a ruling affirming the New Jersey District Court's decision upholding the validity of a certain claim of U.S. Patent No. 9,066,913 (the '913 patent) which covers Pennsaid 2%. Pursuant to this decision, but subject to any appeal rights, Actavis Laboratories UT, Inc., formerly known as Watson Laboratories, Inc., Actavis, Inc. and Actavis plc (collectively Actavis) is blocked from launching its generic version of Pennsaid 2% in the U.S. until the '913 patent expires on October 17, 2027. Miravo is the exclusive manufacturer of Pennsaid 2% for Horizon Therapeutics plc, who owns the Pennsaid 2% intellectual property rights in the U.S.

Pensaid 2% Approved in India to be Marketed by Sayre Therapeutics

In September 2019, the Company received notice from Sayre Therapeutics PVT Ltd (Sayre Therapeutics), that the Drug Controller General of India had approved the sale of Pennsaid 2% in India. Sayre Therapeutics has the exclusive rights to distribute, market and sell Pennsaid 2% in India, Sri Lanka, Bangladesh and Nepal. The Company and Sayre are evaluating commercial launch options in India as a result of changing market conditions, including increased competition and lower market pricing.

Validity of Vimovo '907 patent and '285 patent

In July 2019, the Court of Appeals denied the Company's *en banc* request to the Court of Appeals, to have the court reconsider the May 2019 decision involving U.S. Patent Nos. 6,926,907 (the '907 patent) and 8,557,285 (the '285 patent). In May 2019, the Company had received notice that the Court of Appeals reversed the decision by the New Jersey District Court related to certain Vimovo patents. This ruling reverses the decision made on July 10, 2017 involving the validity of the '907 patent and the '285 patent.

On February 18, 2020, one of Dr. Reddy's Abbreviated New Drug Applications (ANDAs) for Vimovo in the U.S. received FDA approval and a generic version of Vimovo launched in the U.S. in March 2020.

Amendment to the Financing Agreement with Deerfield

In June 2019, the Company agreed to an amendment to the Deerfield Facility Agreement to provide, among other things, for a payment deferral mechanism in the event that Vimovo U.S. market exclusivity is lost and an extension of the maturity date in respect of the Company's US\$6.0 million Bridge Loan by 6 months to December 31, 2020. The amendment will allow the Company to defer a portion of the mandatory minimum quarterly principal repayments by the difference between one quarter of the existing US\$7.5 million minimum annual royalty due from Vimovo sales in the U.S. and the actual amount of royalties received in the applicable quarter in the event Vimovo U.S. market exclusivity is lost earlier than had been expected prior to the Court of Appeals decision. The amount of any principal repayment deferred would, in accordance with the amendment, be subject to an interest rate of 12.5% per annum.

U.S. Court of Appeals for the Federal Circuit Reverses District Court's Decision Related to the '907 patent and the '285 patent

In May 2019, the Court of Appeals reversed the decision by the New Jersey District Court related to certain Vimovo patents. This ruling reverses the decision made on July 10, 2017 involving the '907 patent and the '285 patent.

Registration Dossier for Suvexx Accepted for Formal Review with Health Canada

In May 2019, the Suvexx registration dossier passed screening with Health Canada and went under formal review. Suvexx is a patent protected, fixed dose combination of naproxen sodium and sumatriptan. Suvexx was originally developed by Glaxo Group Limited, d/b/a GSK (GSK) and Aralez (POZEN) and is currently sold in the U.S. as Treximet. Treximet, approved by the FDA in April 2008, is indicated for the acute treatment of migraine with or without aura. The Company received Health Canada approval for Suvexx in the first quarter of 2020 and the product was commercially launched in Canada in September 2020. The Company owns global product and intellectual property rights to Suvexx, which were acquired in the Aralez Transaction (described below) on December 31, 2018.

Marketing Authorization for Pennsaid 2% Accepted by AGES

In April 2019, the Company announced the marketing authorization application for Pennsaid 2% cutaneous solution (Pennsaid 2%) had been accepted for review by the Austrian Agency for Health and Food Safety (AGES) acting as the reference member state (RMS). Included in this decentralized extension procedure are the local health authorities in Greece and Portugal. As of December 31, 2020, the Company has withdrawn the marketing authorization application for Pennsaid 2% for commercial reasons.

Obtained Shareholder Consents to Issue Common Shares Related to the Aralez Transaction

On March 11, 2019, the Company announced that it had obtained consents from shareholders of the Company holding, in the aggregate, more than 50% of the Company's issued

and outstanding Common Shares, approving the issuance by the Company of Common Shares pursuant to the conversion of convertible notes and the exercise of warrants (Warrants), which were issued to certain funds managed by Deerfield in connection with the previously announced closing of the Aralez Transaction.

Fiscal 2018

The Aralez Transaction

On December 31, 2018, the Company announced it had completed the acquisition of a portfolio of more than 20 revenue-generating products from Aralez, including Cambia, Blexten and the Canadian distribution rights to Resultz, that will create a platform for Miravo to acquire and launch additional commercial products in Canada. Miravo has also acquired the worldwide rights and royalties from licensees for Vimovo, Yosprala and the ex-U.S. product rights to Treximet. The Company satisfied the purchase price through funding provided by certain funds managed by Deerfield, a global, healthcare-specialized investor. See “General Development of the Business – Significant Acquisitions – The Aralez Transaction”.

License and Distribution Agreement for Resultz with Heumann

In December 2018, Miravo Ireland entered into a license and supply agreement with Heumann Pharma GmbH & Co. Generica KG (Heumann) which grants Heumann the exclusive right to distribute, market and sell Resultz in Germany. Heumann is headquartered in Nuremberg, Germany, and is part of the Torrent Pharma Group which has an international presence across 40 countries. Resultz is approved in Germany as a class one medical device for the human treatment of head lice infestation. Miravo Ireland received upfront consideration, is eligible to receive milestone payments and royalties on net sales of Resultz in Germany and will earn revenue from Heumann pursuant to an exclusive supply agreement. Heumann launched Resultz in Germany in October 2020. Resultz is currently manufactured by the Company's contract manufacturing partner in Europe.

Termination of Normal Course Issuer Bid

On December 3, 2018, the Company's normal course issuer bid, which permitted the Company to begin purchasing Common Shares on or about December 4, 2017, terminated. During the term of the normal course issuer bid, the Company purchased 235,543 Common Shares with available cash on hand for a total cost of \$748,000 or an average cost of \$3.18 per share. The Common Shares acquired by Miravo were cancelled.

License and Distribution Agreement for Resultz with Fagron

In July 2018, Miravo Ireland entered into a license and supply agreement with Fagron Belgium NV (Fagron) for Resultz granting Fagron the commercialization rights to Resultz in Belgium, the Netherlands and Luxembourg (BeNeLux) as a class one medical device for the human treatment of head lice infestation. Resultz is already cleared for marketing in BeNeLux. Miravo Ireland received upfront consideration, is eligible to receive royalties on net sales of Resultz in BeNeLux and will earn revenue from Fagron pursuant to an exclusive supply agreement. Fagron launched Resultz in BeNeLux in the second half of 2018. Resultz is currently manufactured by the Company's contract manufacturing partner in Europe. Miravo Ireland immediately began to earn royalty revenue under this agreement with Fagron.

Expiration of Shareholders' Rights Plan

In May 2018, the Company's Shareholders' rights plan expired. The Shareholders' rights plan was instituted in 1992 to provide the Board of Directors with sufficient time to consider and, if appropriate, to explore and develop alternatives for maximizing shareholder value if a takeover bid was made for the Company, and to provide every shareholder with an equal opportunity to participate in such a bid.

Resultz U.S. Asset Purchase

In January 2018, Miravo Ireland acquired the U.S. rights to Resultz from Piedmont Pharmaceuticals LLC (Piedmont). The acquisition included all U.S. product and intellectual property rights. See "General Development of the Business – Significant Acquisitions – Resultz U.S. Asset Purchase".

Significant Acquisitions

The Aralez Transaction

On September 19, 2018, the Company announced the signing of a definitive binding asset purchase agreement (the Asset Purchase Agreement) and a definitive binding share purchase agreement (the Share Purchase Agreement, and together with the Asset Purchase Agreement, the Purchase Agreements) with Aralez to acquire a portfolio of more than 20 revenue-generating products, as well as the associated personnel and infrastructure to continue the products' management and growth.

On August 10, 2018, Aralez, along with its Canadian subsidiary, Aralez Canada, commenced voluntary proceedings under Canada's *Companies' Creditors Arrangement Act* (the CCAA) in the Ontario Superior Court of Justice (the Ontario Court). In addition, certain other subsidiaries of Aralez voluntarily filed petitions under Chapter 11 of the United States Bankruptcy Code in the U.S. Bankruptcy Court for the Southern District of New York (together with the Ontario Court, the Courts) (the Bankruptcy Proceedings).

As part of the Bankruptcy Proceedings, Aralez and its subsidiaries conducted a sale process in accordance with bidding procedures approved by the Courts to pursue a sale or sales of their respective assets in accordance with the bidding procedures. The Purchase Agreements served as "stalking horse" bids in the sale process and entitled Miravo to a customary termination fee and expense reimbursement if it was not ultimately the successful bidder in the process. On November 29, 2018, Miravo was informed by Aralez that its bids pursuant to the terms of the Purchase Agreements were determined to be the successful bids under the Court approved bidding procedures. The Courts approved the Aralez Transaction in December 2018.

On December 31, 2018, the Company announced the closing of the Aralez Transaction. The Aralez Transaction included the acquisition of Aralez Canada, a growing business that includes the products Cambia, Blexten, and the Canadian distribution rights to Resultz, and will create a platform for the Company to acquire and launch additional commercial products in Canada. The Company also acquired the worldwide rights and royalties from licensees for Vimovo, Yosprala and the ex-U.S. product rights to Suvexx. In connection with the closing of the Aralez Transaction, the CCAA proceedings of Aralez Canada were terminated pursuant to an order of the Ontario Court.

The aggregate purchase price paid by the Company to Aralez at closing of the Aralez Transaction was US\$110 million (less a US\$4.4 million deposit previously paid and subject to certain working capital and indebtedness adjustments). The Company satisfied the purchase price through funding provided by certain funds managed by Deerfield, a global, healthcare-specialized investor. See “General Development of the Business – Recent Financings – The Deerfield Financing”.

In connection with the closing of the Aralez Transaction, the Company obtained representation and warranty insurance to cover any potential breach of the representations and warranties provided to the Company under the Purchase Agreements, as the Purchase Agreements did not include indemnification provisions given that the Aralez Transaction occurred in connection with the Bankruptcy Proceedings. The representation and warranties insurance policy (the RWI Policy) provides coverage of up to \$10.0 million and a deductible of \$1.1 million, which drops to \$550,000 after 12 months under certain circumstances, and is subject to certain exclusions.

The Company filed a Form 51-102F4 (Business Acquisition Report) with respect to the Aralez Transaction on SEDAR at www.sedar.com (under Nuvo Pharmaceuticals Inc.).

Resultz U.S. Asset Purchase

In January 2018, Miravo Ireland acquired the U.S. rights to Resultz from Piedmont. The acquisition included all U.S. product and intellectual property rights. Resultz was cleared as a Class 1 medical device by the FDA in May 2017 and has not yet been commercially launched in the U.S. Miravo has initiated discussions with potential licensees to commercialize Resultz in the U.S. Under the terms of the agreement, US\$1.5 million (CDN\$1.9 million) was paid to Piedmont. The transaction included a single-digit royalty payable by Miravo Ireland on net sales through 2034. Miravo, through Miravo Ireland, also obtained a right of first refusal to license or acquire certain related assets from Piedmont targeting other human indications. The Company filed a Form 51-102F4 (Business Acquisition Report) with respect to this acquisition on SEDAR at www.sedar.com (under Nuvo Pharmaceuticals Inc.).

Resultz ex-U.S. Asset Purchase

In December 2017, the Company acquired the global, ex-U.S. product and intellectual property rights to Resultz from Piedmont. The transaction included existing royalty streams in France, Spain, Portugal, Belgium, Ireland and the United Kingdom, Canada, Russia, Australia and Israel (collectively the Royalty Markets), generated from a network of existing global licensees and license agreements that were assumed by Miravo. Under the terms of the agreement, Miravo paid US\$7.0 million (CDN\$8.8 million) to Piedmont on closing. The transaction also included a single-digit royalty payable by Miravo on net sales generated from non-Royalty Markets through 2023 and potential added future consideration in the form of payments for achieving certain aggregate annual net sales-based milestones. The Company filed a Form 51-102F4 (Business Acquisition Report) with respect to this acquisition on SEDAR at www.sedar.com (under Nuvo Pharmaceuticals Inc.).

In January 2018, the Company transferred the worldwide (except Canada) Resultz product and intellectual property rights to Miravo Ireland pursuant to an asset transfer agreement. Together, the Company and Miravo Ireland hold the worldwide intellectual property rights to Resultz.

Recent Financings

In the past three years, the Company has not raised cash from the issuance of equity. The Company continuously monitors its cash flow requirements and will explore appropriate financing opportunities in order to support future corporate initiatives.

The Deerfield Financing

On December 31, 2018, the Company and Miravo Ireland, as borrowers, and Aralez Canada, as guarantor, entered the Deerfield Facility Agreement with Deerfield Private Design Fund III, L.P., as agent (the Agent) and certain funds managed by Deerfield, as lenders (collectively, the Lenders) to fund the purchase price of the Aralez Transaction.

The Deerfield Financing consists of (i) a 6-year, amortizing loan made available to Miravo Ireland in the principal amount of US\$60 million with an interest rate of 3.5% per annum (the Amortization Loan), (ii) an 18-month Bridge Loan made available to the Company in the principal amount of US\$6.0 million with an interest rate of 12.5% per annum (the Bridge Loan), (iii) a 6-year, convertible loan made available to the Company in the principal amount of US\$52.5 million with an interest rate of 3.5% per annum, initially convertible into 19,444,444 Common Shares of the Company at a conversion price of US\$2.70 (the Convertible Notes) (the Convertible Loan and, together with the Amortization Loan and the Bridge Loan, the Deerfield Loans), and (iv) 25,555,556 million common share purchase warrants, each such warrant initially exercisable for one Common Share of the Company for a period of six years from the date of issuance at an exercise price of \$3.53 per share (the Warrants).

The Amortization Loan proceeds were used by Miravo Ireland to fund the purchase price under the Asset Purchase Agreement and the transaction expenses related thereto. Pursuant to the Deerfield Facility Agreement, the loan notes issued to the Lenders in relation to the Amortization Loan were admitted to listing on a recognized stock exchange and be quoted “Eurobonds” within the meaning of section 64(1) of the *Tax Consolidation Act 1997* (Ireland) in March 2019. The proceeds of the Convertible Loan and a portion of the proceeds from the issuance of the Warrants were used by the Company to fund the purchase price under the Share Purchase Agreement and the transaction expenses related thereto. The proceeds of the Bridge Loan and the balance of the proceeds from the issuance of the Warrants are available to fund the Company’s working capital and general corporate purposes, including transactional expenses. In connection with the closing of the Deerfield Financing, the Company’s existing undrawn RBC Operating Facility was terminated.

The issuance of Common Shares of the Company upon the conversion of the Convertible Notes and the exercise of the Warrants was subject to Shareholder approval under the rules of the TSX. Pursuant to the rules of the TSX, the Company obtained written consents from shareholders holding, in the aggregate, more than 50% of the Company’s issued and outstanding Common Shares approving the issuance of such Common Shares upon the conversion of the Convertible Notes and exercise of the Warrants.

The Deerfield Facility Agreement contains customary representations and warranties and affirmative and negative covenants, including, among other things, limitations on asset sales, mergers and acquisitions, indebtedness, liens and dividends. In addition, the Company is subject to an annual financial covenant based on minimum levels of net sales per fiscal year and a mandatory quarterly repayment requirement under the Amortization Loan and the Bridge Loan

equal to the greater of (i) 50% of excess cash flow (as defined in the Deerfield Facility Agreement) for such quarter, and (ii) US\$2.5 million, commencing with the quarter ended March 31, 2019, provided that, solely with respect to the first four fiscal quarters after the closing date, the US\$2.5 million quarterly minimum is not applicable so long as US\$10.0 million in principal repayments have been made over such four fiscal quarters. The mandatory quarterly principal repayments are first applied to the Bridge Loan, which is at a higher interest rate than the Amortization Loan. The Company agreed to an amendment to the Deerfield Facility Agreement dated June 25, 2019, to provide, among other things, for a payment deferral mechanism in the event that Vimovo U.S. market exclusivity is lost and an extension of the maturity date in respect of the Company's US\$6.0 million Bridge Loan by 6 months to December 31, 2020. The amendment will allow the Company to defer a portion of the mandatory minimum quarterly principal repayments by the difference between one quarter of the existing US\$7.5 million minimum annual royalty due from Vimovo sales in the U.S. and the actual amount of royalties received in the applicable quarter in the event Vimovo U.S. market exclusivity is lost earlier than had been expected prior to the Court of Appeals decision. The amount of any deferred principal repayment would, until repaid in accordance with the amendment, be subject to an interest rate of 12.5% per annum. In January 2020, the Company received the full US\$7.5 million minimum annual royalty payment due from the 2019 sales of Vimovo in the U.S. and repaid the Bridge Loan of US\$6.0 million.

The Deerfield Loans are guaranteed by Aralez Canada and cross-guaranteed by each of the Company and Miravo Ireland as to each other's obligations, and are secured by a first ranking charge over substantially all property of each of the Company, Miravo Ireland and Aralez Canada.

The Deerfield Facility Agreement contains customary events of default, including an event of default upon certain circumstances constituting a change of control of, or other fundamental transactions relating to the Company, subject to specific exceptions and as more specifically set out in the Deerfield Facility Agreement. Failure to comply with the terms of the Deerfield Facility Agreement would entitle the Agent and the Lenders to accelerate all amounts outstanding under the Deerfield Loans, and upon such acceleration, the Agent and the Lenders would be entitled to enforce on the security granted by each of the Company, Miravo Ireland and Aralez Canada. The Lenders would then be repaid in full from the proceeds of all available assets prior to the repayment of claims of any unsecured creditors or equity holders.

In connection with the Deerfield Financing, the Company entered into a registration rights agreement with Deerfield (the Registration Rights Agreement), pursuant to which the Company has agreed to provide Deerfield with certain demand registration rights and piggy-back registration rights with respect to a sale of securities of the Company.

NARRATIVE DESCRIPTION OF THE BUSINESS

Nuvo Pharmaceuticals Inc. d/b/a Miravo Healthcare is a publicly traded, Canadian focused, healthcare company with global reach and a diversified portfolio of commercial products. The Company's products target several therapeutic areas, including pain, neurology allergy and dermatology. The Company's strategy is to in-license and acquire growth-oriented, complementary products for Canadian and international markets. Certain of the Company's main products are described below.

Products

Commercial Business

Products Commercialized by Miravo in Canada

The Commercial Business segment is comprised of products commercialized by the Company in Canada. This segment includes the Company's promoted products - Blexten, Cambia, Suvexx, NeoVisc and the Canadian business for Resultz, as well as a number of mature assets. The Company sells its products to wholesalers who in turn supply retail and hospital pharmacies across Canada. During the year ended December 31, 2020, the Company's Commercial Business segment contributed \$39.4 million or 53% of the Company's total revenue [\$35.6 million or 51% of the Company's total revenue for the year ended December 31, 2019].

The Company's promoted products are primarily prescribed by Canadian healthcare professionals, including neurologists, pain and migraine specialists, dermatologists, allergists, primary care physicians, prescribing pharmacists and nurse practitioners, which the Company's in-house commercial team calls on and supports through various educational and product detailing activities. The mature assets are prescribed to treat patients across a broad range of therapeutic areas, including pain management, cardiology, gastroenterology, antihyperlipidemic/metabolic agents, dermatology and various non-prescription medicines. These mature assets receive no or minimal promotional support, and in some cases, have lost market exclusivity and now compete with generic alternatives.

The Company's approved products related to the Commercial Business segment:

Distributed by Miravo in Canada			
Product	Description	Product	Description
	Second-generation antihistamine for the treatment of seasonal allergies and urticaria (hives)		Treatment of mild to moderate acute migraine with or without aura in adults 18 years and older.
	Treatment of moderate to severe acute migraine with or without aura in adults.		Viscosupplementation for knee osteoarthritis
	Pesticide-free topical treatment of head lice infestations.		Once daily treatment for patients with high cholesterol or high levels of triglycerides.
	Relief for tension-type headaches.		Antihypertensive agent
	Indicated for the cleansing of the colon in preparation for colonoscopy.		Instillation for the treatment of mild to severe GAG layer damage of the urinary bladder.
	Laxative for the treatment of occasional constipation and irregularity.		Once daily treatment for psoriasis and other keratinization disorders.
	Probiotic for the management and relief of chronic constipation and associated abdominal pain and cramps		Fully resorbable, antibiotic, collagen "haemostat" for surgical implantation during surgery to reduce the risk of surgical site infections.
	Iron supplement for the prevention and treatment of iron deficiency.		

¹: Products are available in Canada and not promoted in any capacity.

Blexten

Blexten is a second-generation antihistamine drug for the symptomatic relief of allergic rhinitis and chronic spontaneous urticaria. Blexten exerts its effect through its highly selective inhibition of peripheral histamine H1 receptors and has an efficacy comparable to cetirizine and desloratadine. In comparative studies, Blexten demonstrated somnolence rates similar to placebo representing a potentially non-sedating effect at therapeutic doses. It was developed in Spain by Faes Farma, S.A. (Faes). Bilastine, (the active ingredient in Blexten), is approved in Canada and over 100 countries worldwide, including Japan and most European countries. In 2014, Miravo entered into an exclusive license and supply agreement with Faes for the exclusive right to sell bilastine in Canada, which is sold under the brand name Blexten. The exclusive license is inclusive of prescription and non-prescription rights for Blexten, as well as adult and pediatric presentations in Canada.

In April 2016, Health Canada approved Blexten (bilastine 20 mg oral tablet) for the treatment of the symptoms of seasonal allergic rhinitis and chronic spontaneous urticaria (such as itchiness and hives). Blexten was commercially launched in Canada in December 2016. Miravo is contracted to pay additional milestone payments of approximately €0.3 million and \$0.8 million to Faes if certain sales targets or other milestone events are achieved over the life of the license and supply agreement term.

Blexten is an in-licensed product that is entitled to data exclusivity for having been a new molecule introduced to Canada upon Health Canada approval in 2016. Blexten's data exclusivity extends through October 2024.

Competitors

The competitive market for Blexten, includes diphenhydramine (Benedryl), hydroxyzine (Atarax), cetirizine (Reactine), desloratadine (Aerius), fexofenadine (Allegra), loratadine (Claritin) and Rupall (rupatadine).

Cambia

Cambia (diclofenac potassium for oral solution) is a patent protected, nonsteroidal anti-inflammatory drug (NSAID) and is currently the only prescription NSAID approved and available in Canada for the acute treatment of migraine with or without aura in adults 18 years of age or older. In 2010, Miravo signed a license agreement with Nautilus Neurosciences, Inc. (Nautilus) for the exclusive rights to develop, register, promote, manufacture, use, distribute, market and sell Cambia in Canada. Since 2011, three separate amendments to the license agreement have been executed. The license was assigned by Nautilus to Depomed, Inc. (Depomed) in December 2013. Depomed has subsequently been renamed Assertio Therapeutics Inc. The Company pays a tiered royalty on net sales of Cambia and future sales-based milestone payments of up to US\$5.3 million may be payable over time.

Cambia was approved by Health Canada in March 2012 and was commercially launched to specialists in Canada in October 2012 and broadly to all primary care physicians in February 2013.

As at March 5, 2021, Miravo in-licensed two Canadian patents expiring June 16, 2026, that provide protection for Cambia and/or its use.

Competitors

The competitive market for Cambia, includes the triptan class of drugs or 5-HT1 receptor agonists as they are known, which include sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), almotriptan (Axert), naratriptan (Amerge), eletriptan (Relpax) and frovatriptan (Frova).

Suvexx

Suvexx, (sumatriptan/naproxen sodium), is a patent protected migraine medicine that was developed by Aralez's wholly owned subsidiary POZEN in collaboration with Glaxo Group Limited, d/b/a GSK (GSK). The product is formulated with POZEN's patented technology (now owned by Miravo) of combining a triptan, sumatriptan 85 mg, with an NSAID, naproxen sodium 500 mg and GSK's RT Technology in a single tablet. The Company received Health Canada approval for Suvexx in the first quarter of 2020 and the product was commercially launched in Canada in September 2020.

As at March 5, 2021, Miravo owns one Canadian patent that covers Suvexx and/or its use expiring December 22, 2023.

Competitors

The competitive market for Suvexx, includes the triptan class of drugs also known as 5-HT1 receptor agonists, which include sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), almotriptan (Axert), naratriptan (Amerge), eletriptan (Relpax) and frovatriptan (Frova).

NeoVisc Line Extension

In January 2020, Miravo closed a licensing transaction bringing new line extensions to the NeoVisc Canadian business. NeoVisc is an injectable viscosupplement used by orthopedic surgeons, sports medicine physicians and healthcare practitioners to replenish synovial fluid in the joints of patients with osteoarthritis. NeoVisc One is a low single-dose injection volume (only 4ml) viscosupplement. The reduction of injection volume makes administration of NeoVisc One easier for healthcare professionals and more comfortable for patients. Neovisc+ consists of a three (2 ml) injection dosing system that is administered to a patient over the course of a few weeks. In some patients, a three dose treatment may provide longer relief. Both NeoVisc+ and NeoVisc ONE were issued a Medical Device License by Health Canada in September 2020. The new and improved NeoVisc formats launched in Canada in January 2021.

Competitors

The competitive market for NeoVisc, includes Synvisc, Monovisc, Orthovisc, Cingal, and Durolane.

Other Commercialized Products in Canada

The Company also markets: Resultz[®], Bezalip[®] SR, Proferrin[®], Fiorinal^{®1}, Fiorinal[®] C1, Viskazide[®], Visken[®], Collatamp[®] G, PegaLAX[®], Mutaflor[®], MoviPrep[®], Uracyst[®] and Soriatane[™].

¹. Products are available in Canada and not promoted in any capacity.

Production and Service Business

The Production and Service Business segment includes revenue from the sale of products manufactured by Miravo from its manufacturing facility in Varennes, Québec or contracted by Miravo Ireland from its international headquarters in Dublin, Ireland, as well as service revenue for testing, development and related quality assurance and quality control services provided by the Company. Key revenue streams in this segment, include Pennsaid 2%, Pennsaid and the bulk drug product for the Heated Lidocaine/Tetracaine (HLT) Patch, as well as ad hoc service agreements for testing, development and related quality assurance/quality control services. During the year ended December 31, 2020, the Company's Production and Service Business segment contributed \$12.8 million or 17% of the Company's total revenue [\$18.2 million or 26% for the year ended December 31, 2019].

The Company currently supplies Pennsaid 2% to Horizon for the U.S. market and Gebro Pharma for the Swiss market and is actively engaged in ongoing partnering efforts for Pennsaid 2% in the rest of the world. The Company will continue to focus on identifying license partners for Resultz in key unpartnered territories around the world, which could result in production revenue. Miravo believes its Production and Service Business segment has continued growth potential, as Miravo has the in-house capabilities and capacity to produce Pennsaid 2% and Resultz for new license partners.

Licensing and Royalty Business

The Licensing and Royalty Business segment includes the revenue generated from the licensing of the intellectual property and the ongoing royalties received under these exclusive licensing agreements. The Company's Licensing and Royalty Business segment revenue is primarily generated from:

- Net sales of Vimovo in the U.S. through the Company's partner Horizon;
- Net sales of Vimovo in various ex-U.S. markets, including Europe, Canada and South America by the Company's partner Grunenthal GmbH (Grunenthal);
- Net sales of Resultz in select European markets by the Company's various European license partners (See table below for full details); and
- Net sales of Cabpirin related to the licensing of the Company's Yosprala intellectual property in the Japanese market.

During the year ended December 31, 2020, the Company's Licensing and Royalty Business segment contributed \$21.5 million or 29% of the Company's total revenue [\$15.8 million or 23% for the year ended December 31, 2019].

The Company's out-licensing efforts for Pennsaid 2%, Resultz, Suvexx and Yosprala are targeted on all markets that remain unlicensed with a particular focus on Europe, the Middle East and Asia. The Company enters into exclusive, long-term licensing agreements with strategic partners in specific geographies. Miravo believes its Licensing and Royalty Business segment has continued growth potential, as Pennsaid 2%, Resultz and Suvexx products are protected by patents that provide licensees with market exclusivity and protection from generic competition, as well as favourable product profiles (See "Narrative Description of the Business – Products – Commercial Products").

The Company's approved products related to the Production and Service Business and Licensing and Royalty Business are segmented as follows:

Product	Description	Segments	Licensee or Distributor	Territories
Resultz[®] FullMarks LAUSBUB[®]	Pesticide-free topical treatment of head lice infestations.	Production and Service Business Licensing and Royalty Business	Fagron Belgium NV Heumann Pharma GmbH & Co. Generica KG Reckitt Benckiser (Brands) Limited Sato Pharmaceutical Co., Ltd. The Mentholatum Company	
Treximet[®] <small>sumatriptan / naproxen sodium</small> Suvexx[®]	Treatment of acute migraine	Licensing and Royalty Business	Currax Holdings USA LLC Orion Corporation	
PENNSAID[®] <small>(diclofenac sodium topical solution) 2% w/w</small>	Topical treatment of osteoarthritic pain in a more convenient format.	Production and Service Business Licensing and Royalty Business	Horizon Therapeutics plc Paladin Labs Inc. Sayre Therapeutics PVT Ltd Gebro Pharma AG	
PENNSAID[®]	Topical treatment of osteoarthritic pain.	Production and Service Business Licensing and Royalty Business	Paladin Labs Inc. Vianex S.A. Recordati S.p.A.	
VIMOVO[®]	Oral treatment for relief of arthritis symptoms with a reduced risk of developing gastric ulcers.	Licensing and Royalty Business	Horizon Therapeutics plc Grunenthal GmbH	
SYNERA[®] <small>(lidocaine and tetracaine) Topical Patch</small> RAPYDAN	Topical patch used to help prevent pain associated with needle sticks and other superficial skin procedures.	Licensing and Royalty Business Production and Service Business	Galen US Incorporated Eurocept International B.V.	
Yosprala[™] <small>(aspirin and omeprazole)</small>	Once daily treatment to help in the prevention of heart attacks and strokes with a reduced risk of developing gastric ulcers.	Licensing and Royalty Business	Genus Lifesciences Inc. Takeda Pharmaceutical Company Limited	
URACYST[®]	Instillation for the treatment of mild to severe GAG layer damage of the urinary bladder.	Licensing and Royalty Business	Aspire Pharmaceuticals	

Products Out-licensed and/or Manufactured by Miravo

Pennsaid 2%

Pennsaid 2% is a follow-on product to original Pennsaid (described below). Pennsaid 2% is a topical pain product that combines a dimethyl sulfoxide (DMSO) based transdermal carrier with 2% diclofenac sodium, a leading NSAID, compared to 1.5% for original Pennsaid. Pennsaid 2% is more viscous, is supplied in a metered dose pump bottle and has been approved in the U.S. for twice daily dosing compared to four times a day for Pennsaid. This provides Pennsaid 2% with potential advantages over Pennsaid and other competitor products and with patent protection. Miravo owns the worldwide rights to Pennsaid 2%, excluding the U.S. rights owned by Horizon.

United States

Pennsaid 2% was approved on January 16, 2014 in the U.S. and launched by the Company's then U.S. Pennsaid and Pennsaid 2% licensee, Mallinckrodt Inc. (Mallinckrodt) in February 2014 for the treatment of pain of osteoarthritis (OA) of the knee. In September 2014, the Company reached a settlement related to its litigation with Mallinckrodt. Under the terms of the settlement agreement, Mallinckrodt returned the U.S. sales and marketing rights to Pennsaid and Pennsaid 2% to Miravo. In October 2014, Miravo sold the U.S. rights to Pennsaid 2% to Horizon for US\$45.0 million. Under the terms of this agreement, the Company earns revenue from the manufacturing and sale of Pennsaid 2% to Horizon.

Miravo records revenue from Horizon when it ships Pennsaid 2% commercial bottles and product samples to Horizon for the U.S. market. The Company earns product revenue from Horizon pursuant to a long-term, exclusive supply agreement, as well as contract service revenue.

As of March 5, 2021, 19 U.S. patents have been listed in the FDA's Orange Book that provide protection for Pennsaid 2% and/or its use.

Rest of World

Gebro Pharma has the exclusive rights to register, distribute, market and sell Pennsaid 2% in Switzerland and Liechtenstein. In January 2020, Gebro Pharma received marketing authorization for Pennsaid 2% from Swissmedic, the overseeing Swiss regulatory authority. Gebro Pharma launched Pennsaid 2% in Switzerland in January 2021. The Company is eligible to receive milestone payments and royalties on net sales of Pennsaid 2% in Switzerland and Liechtenstein and will earn product revenue from the supply of Pennsaid 2% to Gebro Pharma on an exclusive basis from its manufacturing facility in Varennes, Québec.

Sayre Therapeutics has the exclusive rights to distribute, market and sell Pennsaid 2% in India, Sri Lanka, Bangladesh and Nepal. Sayre Therapeutics filed their application for regulatory approval with the Drug Controller General of India in December 2017. In September 2019, the Company received notice that the Drug Controller General of India had approved the sale of Pennsaid 2% as a prescription medication. The Company and Sayre are evaluating commercial launch options in India as a result of changing market conditions, including increased competition and lower market pricing. The Company is eligible to receive milestone payments and royalties on net sales of Pennsaid 2% in India, Sri Lanka, Bangladesh and Nepal and will earn product revenue from the supply of Pennsaid 2% to Sayre Therapeutics on an exclusive basis from its manufacturing facility in Varennes, Québec, if Pennsaid 2% is launched in these territories.

Paladin Labs Inc. (Paladin) has exclusive rights to market and sell Pennsaid 2% in Canada. Pennsaid 2% has not been submitted for approval and is not commercially launched in Canada.

Unlicensed Territories

The Company is pursuing Pennsaid 2% registrations in select European territories that will accept the existing clinical and technical data package. In 2019, the Company submitted its regulatory dossier for Pennsaid 2% to the Austrian Agency for Health and Food Safety acting as the Reference Member State (RMS). As of December 31, 2020, the Company has withdrawn the marketing authorization application for Pennsaid 2% for commercial reasons.

As of March 5, 2021, Miravo owns 9 patents which have been granted in 9 countries outside the U.S. that provide protection for Pennsaid 2% and/or its use.

Miravo is actively seeking commercialization partners for Pennsaid 2% in all remaining global markets where commercial opportunities exist.

Competitors

A number of existing pharmaceutical products treat the pain associated with OA. The goal, according to the American College of Rheumatology, is “control of pain and improvement in function and health-related quality of life, with avoidance, if possible, of toxic effects of therapy”. There are many products available to address this condition and those available in the U.S. generally fall into one of the following categories:

- oral analgesics and NSAIDs, intraarticular injections such as hyaluronic acid, steroids and platelet rich plasma and topical NSAIDs treatment and over-the-counter (OTC) oral medications that are accessible without a doctor’s prescription, such as acetaminophen (Tylenol) and low-dose NSAIDs such as ibuprofen (Advil, Motrin) and naproxen (Aleve), glucosamine and chondroitin;
- oral, full-dose, NSAIDs which are available by prescription only;
- oral, full-dose, NSAIDs combined with proton pump inhibitors (PPI) to reduce certain side effects common to NSAIDs, such as Vimovo which combines naproxen, an NSAID, with esomeprazole magnesium, a PPI, which are available by prescription only;
- topical NSAIDs, which are available with or without prescription;
- oral COX-2 selective NSAIDs which are available by prescription only; and
- oral opioid analgesics which are available by prescription only.

Pennsaid 2% faces competition in the U.S. from at least two other topically applied diclofenac drug products that were approved for marketing by the FDA, as well as numerous OTC products. The FLECTOR Patch, which contains the NSAID diclofenac epolamine was approved by the FDA for the topical treatment of acute pain due to minor strains, sprains and contusions and is marketed by Pfizer Inc. The second drug product, containing the NSAID diclofenac sodium is GlaxoSmithKline’s (GSK’s) Voltaren Gel which was approved by the FDA for the relief of the pain of OA of joints amenable to topical treatment, such as the knees and those of the hand and is marketed by GSK Consumer Health.

Pennsaid

Pennsaid, the Company’s first commercialized topical pain product, is used to treat the signs and symptoms of OA of the knee. Pennsaid is a combination of a DMSO-based transdermal carrier and 1.5% diclofenac sodium and delivers the active drug through the skin at the site of pain. While conventional oral NSAIDs expose patients to potentially serious systemic side effects such as gastrointestinal bleeding and cardiovascular risks, Miravo’s clinical trials suggest that some of these systemic side effects occur less frequently with topically applied Pennsaid. Pennsaid is currently sold in Canada by Paladin, in Italy by Recordati S.p.A. and in Greece by Vianex S.A.

In Canada, there are six generic versions of Pennsaid approved in the market. The first generic was launched in 2014. In addition, the Company's partner launched an authorized generic to protect market share. Additionally, a topical diclofenac product, GSK's Voltaren Emulgel (1.16% w/w diclofenac diethylamine) has been available in Canada as an OTC since October 2008. In August 2014, Voltaren Emulgel Extra Strength (2.32% w/w diclofenac diethylamine) was approved in Canada as an OTC product and was launched by GSK in October 2014. In the E.U., several major pharmaceutical companies market oral and topical NSAIDs that compete against Pennsaid in countries where it is marketed.

Resultz

United States

The Company acquired the U.S. product and intellectual property rights from Piedmont Pharmaceuticals LLC (Piedmont) in January 2018. See "General Development of the Business – Significant Acquisitions – Resultz U.S. Asset Purchase". The Company acquired the U.S. product and intellectual property rights from Piedmont Pharmaceuticals LLC (Piedmont) in January 2018. Resultz was cleared as a 510 (k) Exempt class 1 medical device for the treatment of lice by the FDA in May 2017 and has not yet been commercially launched in the U.S.

In February 2021, Miravo Ireland entered into an exclusive License Agreement with The Mentholatum Company for the exclusive right to commercialize the Resultz formula and technology in the United States under the Mentholatum® brand. Miravo Ireland will earn revenue from The Mentholatum Company pursuant to the License Agreement. It is anticipated that The Mentholatum Company will launch Resultz during the summer of 2021. The COVID-19 pandemic has created some uncertainty regarding the traditional seasonal demand for head lice treatments. Due to physical distancing regulations currently being enforced, many children in the U.S. are not physically attending school or daycare and are not able to participate in group activities, the traditional environments where head lice outbreaks occur. The License Agreement has been structured with an 18-month term, which will allow both parties to reassess market dynamics related to the COVID-19 pandemic and to determine if a longer-term agreement is warranted in a post-pandemic commercial environment. Resultz is currently manufactured by the Company's contract manufacturing partner in Europe.

As of March 5, 2021, Miravo Ireland owns 2 patents which have been granted in the U.S. that cover Resultz and/or its use, the latest patent expiring in 2024.

Rest of World (excluding U.S. and Canada)

The Company acquired the global, ex-U.S. product and intellectual property rights from Piedmont in December 2017. See "General Development of the Business – Significant Acquisitions – Resultz ex-U.S. Asset Purchase". Resultz is approved and marketed in France, Spain, Portugal, Belgium, Netherlands, Germany, Ireland, the United Kingdom, Russia and Australia through a network of existing license agreements and global licensees which include Reckitt Benckiser, Fagron and Heumann. Resultz is also pending registration in Japan, where the local license is held by Sato Pharmaceutical Co. Ltd. Resultz is a CE marked, Class I medical device for the treatment of lice, which does not require a prescription.

Fagron has the exclusive rights to register, distribute, market and sell Resultz in Belgium, the Netherlands and Luxembourg (BeNeLux) as a Class I medical device for the

human treatment of head lice infestation. Resultz is cleared for marketing in BeNeLux. Miravo Ireland received upfront consideration, is eligible to receive royalties on net sales of Resultz in BeNeLux and will earn revenue from Fagron pursuant to an exclusive supply agreement. Fagron launched Resultz in BeNeLux in the second half of 2018. Resultz is currently manufactured by the Company's contract manufacturing partner in Europe.

Heumann has the exclusive rights to distribute, market and sell Resultz in Germany. Resultz is considered a Class I medical device in Germany. Miravo Ireland received upfront consideration, is eligible to receive milestone payments and royalties on net sales of Resultz in Germany and will earn revenue from Heumann pursuant to an exclusive supply agreement. Heumann launched Resultz in Germany in October 2020. Resultz is currently manufactured by the Company's contract manufacturing partner in Europe.

As of March 5, 2021, 30 ex-US patents that cover the Resultz product and/or its use, have been granted in 20 countries. These patents provide protection through June 2028 (Brazil) and April 2023 (rest of world). The Canadian Resultz patent is owned by the Company and the remainder of the ex-U.S. patents are owned by Miravo Ireland.

Competitors

Resultz faces competition in all markets from other topically applied head lice solutions such as pesticide-based products (including pyrethrin, permethrin, malathion etc.), non-pesticide-based products (including dimethicone or other siloxanes) and homeopathic remedies (including tea tree oil, coconut oil and other naturally sourced ingredients). Key pesticide-based brands are Rid (Bayer), Nix (Prestige Brands), Sklice (Arbor), and Ovide (Taro). Key non-pesticide brands are Nix Ultra (Prestige Brands), Nyda (Pohl Boshkamp), Hedrin (Stada), Linicin (Meda) and Paranix (Omega). Key homeopathic remedies are Vamousse (Alliance Pharmaceuticals Ltd.).

Vimovo

Vimovo (naproxen/esomeprazole magnesium) is the brand name for a proprietary fixed-dose combination of enteric-coated naproxen, a pain-relieving NSAID, and immediate-release esomeprazole magnesium, a proton pump inhibitor, in a single delayed-release tablet. POZEN developed Vimovo in collaboration with AstraZeneca. On April 30, 2010, the FDA approved Vimovo for the relief of the signs and symptoms of OA, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. Vimovo is currently commercialized in the U.S. by Horizon and by Grunenthal in various rest of world territories, including Canada, Europe and select additional countries.

Rest of World (excluding the U.S)

Grunenthal holds the rights to commercialize Vimovo outside of the U.S. and Japan and pays Miravo Ireland a 10% royalty on net sales. Grunenthal's royalty payment obligation with respect to Vimovo expires on a country-by-country basis upon the later of (a) expiration of the last-to-expire of certain patent rights related to Vimovo in that country, and (b) ten years after the first commercial sale of Vimovo in such country. The royalty rate may be reduced to the mid-single digits in the event of a loss of market share as a result of certain competing products. Canada is the only country where a generic naproxen/esomeprazole magnesium product has

been approved and commercialized dating back to 2017 prior to the Company purchasing this royalty stream.

United States

Under the terms of the license agreement with Horizon, Miravo Ireland currently receives a 10% royalty on net sales of Vimovo sold in the U.S. A guaranteed minimum annual royalty payment of US\$7.5 million (US\$1.9 million per quarter) ceased when Dr. Reddy's launched a generic version of Vimovo in the U.S. during the first quarter of 2020. Horizon's royalty payment obligation with respect to Vimovo expires on the later of (a) the last to expire of certain patents covering Vimovo, and (b) ten years after the first commercial sale of Vimovo in the U.S. which occurred in 2010. The 10% royalty on net sales of Vimovo by its U.S. partner is subject to a step-down provision in the event that generic competition achieves a certain market share. Miravo Ireland and its U.S. partner have entered into settlement agreements with certain other generic Vimovo applicants, which permits them to enter the U.S. market now that Dr. Reddy's has launched its generic product. Consequently, these other generic companies may be able to market the product in the U.S. at any time once they receive FDA approval. There is on-going patent litigation in the U.S. (See "Legal Proceedings and Regulatory Actions – Vimovo"). In the event, Dr. Reddy's is found to infringe one of Miravo's patents, Miravo Ireland and Horizon could seek damages from Dr. Reddy's. When the Company acquired the Vimovo patents as part of the Aralez Transaction, the Company anticipated that the US\$7.5 million (US\$1.9 million per quarter) annual minimum royalty payments would cease in 2022.

Miravo Ireland's revenues from sales of Vimovo outside of the U.S. are unaffected by any ruling made by the U.S. courts.

As of March 5, 2021, Miravo Ireland owns 35 patents that cover the Vimovo product and/or its use, which have been granted in 19 countries, the latest patent expiring in 2031.

Suvexx/Treximet

United States

Suvexx/Treximet (sumatriptan/naproxen sodium) is a migraine medicine that was developed by the Aralez wholly owned subsidiary POZEN in collaboration with GSK. The product is formulated with POZEN's patented technology (now owned by Miravo) of combining a triptan, sumatriptan 85 mg, with an NSAID, naproxen sodium 500 mg and GSK's RT Technology in a single tablet. In 2008, the FDA approved Treximet (the U.S. brand name) for the acute treatment of migraine attacks, with or without aura, in adults. Treximet is currently commercialized in the U.S. by Currax Holdings USA LLC.

As of March 5, 2021, Miravo Ireland owns one U.S. patent expiring October 2, 2025 which covers Suvexx/Treximet.

Rest of World (excluding the U.S)

Orion holds the exclusive license and supply agreement for the right to package, distribute, market and sell Suvexx in Finland, Sweden, Denmark, Norway, Poland, Hungary, Latvia, Lithuania and Estonia (the Territory). Orion will be responsible for obtaining and maintaining the marketing authorizations for Suvexx in the Territory and will also manage all Territory specific

commercial activities. Miravo Ireland will receive up to EUR 1.7 million in upfront consideration, regulatory and sales-based milestone payments, as well as royalties on net sales of Suvexx in the Territory and revenue pursuant to the supply of product. Suvexx is currently manufactured by the Company's contract manufacturing partner in the United States.

As of March 5, 2021, 24 ex-US patents that cover the Suvexx product and/or its use have been granted in 24 countries, expiring December 22, 2023. The Canadian Suvexx patent is owned by Miravo and the remainder of the patents are owned by Miravo Ireland.

Competitors

The competitive market for Suvexx includes the triptan class of drugs also known as 5-HT₁ receptor agonists, which include sumatriptan (Imitrex), rizatriptan (Maxalt), zolmitriptan (Zomig), almotriptan (Axert), naratriptan (Amerge), eletriptan (Relpax) and frovatriptan (Frova).

Yosprala

Yosprala is currently the only prescription fixed-dose combination of aspirin (acetylsalicylic acid), an anti-platelet agent, and omeprazole, a proton-pump inhibitor, in the U.S. It is indicated for patients who require aspirin for secondary prevention of cardiovascular and cerebrovascular events and who are at risk of developing aspirin associated gastric ulcers. Yosprala is designed to support both cardio- and gastro-protection for at-risk patients through the proprietary Intelli-COAT system, which is formulated to sequentially deliver immediate-release omeprazole (40 mg) followed by a delayed-release, enteric-coated aspirin core in either 81 mg or 325 mg dose strengths. Yosprala was approved by the FDA in September 2016 and was commercially launched in the U.S. in October 2016. Yosprala is currently commercialized in the U.S. by Genus Lifesciences Inc. (Genus). The Company will receive a single-digit royalty on net sales in the U.S. by Genus until July 2023.

The intellectual property related to Yosprala was licensed to Takeda in May 2017, on a non-exclusive basis for the Japanese market. In March 2020, Miravo Ireland received notice from Takeda that Japan's Ministry of Health, Labor and Welfare (the MHLW) approved Cabpirin. Cabpirin is a fixed dose combination of vonoprazan fumarate and low-dose aspirin which is protected by Miravo Ireland's Japanese patent for the Yosprala formulation. In the year ended December 31, 2020, Miravo Ireland received \$2.5 million (US\$1.8 million), in milestone payments, net of withholding tax of 10%, triggered by the MHLW approval. Miravo Ireland is also contractually entitled to receive a second US\$1.8 million milestone payment, net of withholding tax of 10% on May 31, 2022 provided the licensed intellectual property remains valid and enforceable. Miravo Ireland will receive a single-digit royalty on net sales of Cabpirin in Japan until patent expiry on May 31, 2022.

Miravo Ireland is entitled to retain 50% of all royalty and milestone revenues generated from the Yosprala intellectual property on a global basis, with the remaining 50% to be paid to the estate of POZEN.

As of March 5, 2021, Miravo Ireland owns 23 patents that cover the Yosprala product and/or its use, which have been granted in 19 countries, the latest patent expiring in 2026.

Competitors

The competition for PPI-aspirin (PA) products, such as Yosprala, may come from aspirin itself, other aspirin-combination products that may be introduced, as well as other anti-platelet products used for secondary prevention of cardiovascular and cerebrovascular events.

HLT Patch

The HLT Patch is a topical patch that combines lidocaine, tetracaine and heat, using Miravo's proprietary Controlled Heat-Assisted Drug Delivery (CHADD™) technology. The CHADD unit generates gentle heating of the skin and in a well-controlled clinical trial has demonstrated that it contributes to the efficacy of the HLT Patch by improving the flux rate of lidocaine and tetracaine through the skin. The HLT Patch resembles a small adhesive bandage in appearance and for its currently approved indication is applied to the skin 20 to 30 minutes prior to painful medical procedures, such as venous access, blood draws, needle injections and minor dermatologic surgical procedures. The HLT Patch is marketed in the U.S. by Galen US Incorporated (Galen) under the brand name Synera. In Europe, the HLT Patch is marketed by the Company's European-based licensee, Eurocept International B.V. (Eurocept) under the brand name Rapydan. The HLT Patch is manufactured by a third-party contract manufacturing organization (CMO) for Galen and Eurocept. Currently, Miravo manufactures the bulk drug product for both parties.

Competitors

The HLT Patch faces competition in all markets from other topically applied local anaesthetic drug products such as compounded anaesthetic creams that are available from certain pharmacies, EMLA Cream (a eutectic mixture of lidocaine 2.5% and prilocaine 2.5%), and L.M.X 4 and L.M.X.5 Anorectal Creams that are available OTC.

Pipeline Products

Products	Phase 2	Phase 3	Regulatory Submission Preparation	Regulatory Submission	Approved
Blexten Pediatric					
Suvexx in the Nordics					

Blexten Pediatric

Miravo's original license agreement for Blexten included Canadian rights for the pediatric dosage formats. Blexten pediatric dosing consists of either an oral syrup formulation (2.5mg/ml) and an orally dispersible tablet formulation (10mg tablets). Miravo filed the pediatric dossier to Health Canada during the second quarter of 2020 and the dossier was accepted for review during the fourth quarter. A regulatory decision from Health Canada is anticipated by late summer 2021.

Blexten Ophthalmic

In April 2018, Aralez executed an amendment to add an ophthalmic formulation of Blexten, currently under development, to the portfolio. The ophthalmic version of Blexten provides physicians the ability to treat patients suffering from ocular symptoms such as itchy, watery or red eyes related to seasonal allergies with a highly effective, non-drowsy and long-lasting formulation. The Company is examining the dossier for its suitability for filing a New Drug Submission for Blexten ophthalmic with Health Canada.

Seasonality of Business

Certain products within the Company's product portfolio are subject to seasonal buying patterns and seasonal prescribing patterns. The Company is subject to and affected by the business and prescribing practices of its customers. Inventory practices, such as safety stock levels, of our partners may subject the Company to product sales fluctuations quarter-to-quarter or year-over-year. The Company's net sales and quarterly growth comparisons may also be affected by fluctuations in the buying patterns of retail chains, mail order distributors, wholesalers, and other trade buyers, resulting from seasonality.

Sales and Marketing

The Company's sales and marketing strategy is focused on the organic growth of existing promoted products in Canada - Blexten, Cambia, Suvexx, NeoVisc and the Canadian business for Resultz through several key activities. First, the Company's analytics team seeks to ensure that its sales force engages with appropriate prescribers of the Company's medications or medications that compete with its products. The Company creates demand by calling on and providing healthcare professionals with reliable and trustworthy information, supported by its clinical trials and data from other credible sources, and by coordinating and facilitating continuing health education events in targeted areas. Second, the Company supports its products by providing physicians and other healthcare practitioners with quality patient care materials. Third, the Company endeavours to ensure that its products are accessible through all major wholesalers and distributors in Canada and manages its supply chain efficiently to ensure that it can meet demand. The Company considers its sales force to be very experienced and well trained. Additionally, the Company offers its representatives a competitive incentive plan based on the achievement of results.

Manufacturing

The Company has a manufacturing facility in Varennes, Québec that produces Pennsaid 2%, Pennsaid and the bulk drug product for the HLT Patch. The Company manufactures these products for all of its global partners for markets where the products are sold. The facility is in compliance with current Good Manufacturing Practices (GMP). This manufacturing facility was last inspected by the FDA in July 2018, and remains compliant based on the last Health Canada inspection in May 2017 and will undergo inspection again in 2021.

The Company outsources the manufacturing of certain of its products to pharmaceutical manufacturing facilities operated by third-party contractors or authorized, third-party, CMOs in various places throughout the world. These facilities comply with the FDA's current GMP regulations, applicable Health Canada GMP regulations and European Union GMP regulations. The Company's manufacturers are all approved fabricators of pharmaceutical products according

to the FDA, Health Canada and European Union, as applicable. The Company believes these facilities have sufficient excess capacity at present to meet its short and long-term objectives. Some of the Company's products are packaged by third-party contract manufacturers.

Intellectual Property

The value of the Company's operations and commercial and drug development candidates, and their future prospects, depends heavily on establishing and protecting valid intellectual property rights. See "Risk Factors – Patents, Trademarks and Proprietary Technology".

Patents

Products Out-Licensed and/or Manufactured by Miravo

Pennsaid 2%

The following table summarizes where the Company's partners have commercialized Pennsaid 2% or are working to obtain regulatory approval:

Brand	Therapeutic Area	Licensee or Distributor	Licensed Territories	Intellectual Property
Pennsaid 2%	Osteoarthritis of the knee	Horizon Therapeutics plc	United States	Nineteen granted U.S. patents listed in the FDA's Orange Book with latest expiry in 2030.
		Paladin Labs Inc. ⁽¹⁾	Canada	One patent granted in Canada expiring in 2027. Pending patent application through 2033.
		Sayre Therapeutics PVT Ltd	India, Sri Lanka, Bangladesh and Nepal	One patent granted in India expiring in 2027.
		Gebro Pharma AG	Switzerland and Liechtenstein	One patent granted in Switzerland expiring in 2027. Pending patent applications in Europe through 2033.

⁽¹⁾ Regulatory approval not yet received in territory.

Resultz

The following table summarizes where Miravo Ireland's partners have commercialized Resultz or are working to obtain regulatory approval:

Brand	Therapeutic Area	Licensee or Distributor	Licensed Territories	Intellectual Property
Resultz	Treatment of Head Lice	Miravo	Canada	Two patents granted in Canada expiring in 2023.
		The Mentholatum Company	United States	Two patents granted in the U.S., the latest expiring in 2024
		Fagron Belgium NV	Belgium, Netherlands, Luxembourg	Two patents granted in Belgium expiring in 2023. One patent granted in each of the Netherlands and Luxembourg expiring in 2023.
		Heumann Pharma GmbH & Co. Generica KG	Germany	Two patents granted in Germany expiring in 2023
		Reckitt Benckiser (Brands) Limited	United Kingdom, Ireland, France, Spain, Russia, Belarus, Portugal, Australia, New Zealand	Two patents granted in each of the United Kingdom, Ireland, France, Spain, Portugal, and Australia expiring in 2023. One New Zealand patent expiring 2023.
Sato Pharmaceutical Co., Ltd.(1)	Japan	One patent granted in Japan expiring in 2023.		

(1) Partner is working to obtain regulatory approval in licensed territory.

HLT Patch

The following table summarizes where the Company's partners have commercialized the HLT Patch or are working to obtain regulatory approval:

Brand	Therapeutic Area	Licensee or Distributor	Licensed Territories	Intellectual Property
Synera ⁽¹⁾	Local Dermal Analgesia (Patch)	Galen US Incorporated	United States	Trademark protection for Synera owned by Galen.
Rapydan ⁽¹⁾		Eurocept B.V.	Europe, Russia ⁽²⁾ , Turkey ⁽²⁾ , Israel ⁽²⁾ and People's Republic of China ⁽²⁾	

(1) Synera and Rapydan are the brand names for the HLT Patch in their respective jurisdiction.

(2) Partner is responsible for obtaining regulatory approval in licensed territory.

Suvexx/Treximet

The following table summarizes where Miravo Ireland has partnered Suvexx/Treximet or are working to obtain regulatory approval:

Brand	Therapeutic Area	Licensee or Distributor	Licensed Territories	Intellectual Property
Suvexx	Migraine Headaches	Miravo	Canada	One patent granted in Canada to 2023.
Treximet		Currax Holdings LLC	U.S.	One patent granted in U.S. to 2025.

Vimovo

The following table summarizes where Miravo Ireland's partner has commercialized Vimovo or are working to obtain regulatory approval:

Brand	Therapeutic Area	Licensee or Distributor	Licensed Territories	Intellectual Property
Vimovo	Osteoarthritis/ Rheumatoid Arthritis Pain Relief	Horizon Therapeutics plc	U.S.	There are granted U.S. patents listed in the FDA's Orange Book with latest expiry in 2031. ⁽¹⁾
		Grunenthal GmbH	Worldwide (except U.S. and Japan)	Three granted Canadian patents with latest expiry in 2030. European patents granted in AT, BE, CH, DE, DK(1), ES, FI, FR, GB, GR, IE, IT, LU(1), NL, PT, SE, and NO expiring 2022. supplementary protection certificates are pending or granted to 2025/26 in AT, BE, CH, DE, DK(1), ES, FI, GB, GR, IE, IT, LU(1), NL, PT, SE and NO. One patent granted in Mexico ⁽¹⁾ to 2022. Three patents granted in Australia with latest expiry in 2026. Pending Brazilian applications through 2030.

⁽¹⁾ See "Legal Proceedings and Regulatory Actions - Vimovo" for additional detail on the ongoing litigation involving the '996 and '920 patents.

⁽²⁾ Miravo has transferred ownership of patents and supplementary protection certificates in DK and LU to Grunenthal; Miravo has transferred ownership of Mexican patent to Grunenthal.

Yosprala

The following table summarizes where Miravo Ireland's partners has commercialized Yosprala or are working to obtain regulatory approval:

Brand	Therapeutic Areas	Licensee or Distributor	Licensed Territories	Intellectual Property
Yosprala	Secondary prevention of cardiovascular and cerebrovascular events	Genus Lifesciences Inc. Takeda Pharmaceutical Company Limited	U.S.	Three patents granted in U.S. latest expiring 2023. ⁽¹⁾ One patent granted in Japan expiring 2022.

⁽¹⁾ Genus owns additional U.S. patents or patent applications covering Yosprala.

Products Commercialized by Miravo in Canada

Blexten

The following table summarizes the intellectual property Miravo has rights to under its license:

Brand	Therapeutic Areas	Licensee or Distributor	Licensed Territory	Intellectual Property
Blexten ⁽¹⁾	Allergies/ Urticaria	Miravo	Canada	Trademark protection for Blexten owned by Faes.

⁽¹⁾ Data exclusivity until October 21, 2024.

Cambia

The following table summarizes the intellectual property Miravo has rights to under its license:

Brand	Therapeutic Area	Licensee or Distributor	Licensed Territory	Intellectual Property
Cambia	Migraine Headaches	Miravo	Canada	Two patents granted in Canada to 2026. ⁽¹⁾

⁽¹⁾ In-licensed Patent.

Foam Technology

The Company owns three U.S. patents with the latest patent expiring November 22, 2031, and an issued patent in Canada expiring March 10, 2031 covering DMSO-based foamable formulations. The purchase agreement relating to the foam technology also included a commitment to remit a small portion of royalty payments, milestone payments or upfront payments received by the Company for out-licensing of products using the foam technology until the end of the applicable patent term, provided the out-licensed products continue to be covered by a valid claim.

Trademarks

The Company holds certain registered trademarks and trademark applications that will cover its pipeline and commercial products.

Confidential Information and Trade Secrets

In addition to patent protection, the confidential nature of the Company's expertise and its trade secrets will provide a period of exclusivity with respect to processes or products developed by, or for, the Company and its exclusive benefit. The Company believes it has taken the necessary steps to protect the confidentiality of its commercially sensitive activities.

Employees

As at December 31, 2020, the Company had 99 full-time employees. Miravo employees are not subject to any collective bargaining agreements and are not unionized.

Specialized Skill and Knowledge

The Company specializes in the licensing or acquisition of and the sales and marketing of prescription, non-prescription and medical device products in Canada through a direct commercial presence and around the world through distribution partners. The company also has specialized skill in manufacturing non-sterile semi-solid and liquid pharmaceutical-grade compounds at its GMP facility in Varennes, Québec.

The Company is experienced in drug development and navigating the clinical and regulatory pathways in Canada, the U.S. and Europe to out-license its existing products and to in-license new products. The Company from time-to-time will enlist the support of experienced clinical trial, regulatory and legal consultants and will use this and its own expert knowledge to assist in the successful development of its products and the protection of its intellectual property.

Covid-19 Impact and Mitigation

The Company has implemented the following measures during the 2020 fiscal year based on requirements and recommendations from local governments, as well as internal risk mitigation assessments:

- The Company has implemented policies to minimize COVID exposure, including limiting the number of workers at the Company offices, promoting physical distancing with markings and prohibiting visitors (except as legally required) to enter the Company's offices or manufacturing facility;
- The Company has implemented a contact tracing procedure and COVID screening protocol for all employees entering the workplace;
- The Company provides employees with personal protective equipment to allow them to carry out their day-to-day activities in the workplace. Enhanced cleaning protocols for high touch surfaces have been implemented along with reduced capacity limits in public meeting areas within the workplace;
- All non-manufacturing employees have the necessary equipment to work from home and are encouraged to work from home;

- Field-based sales representatives are not authorized to visit healthcare provider (HCP) offices, unless such visits are permitted in accordance with local health regulations and provided the HCP has requested the visit; and
- No international or inter-provincial business travel on behalf of the Company is currently permitted.

As of December 31, 2020, the Company has recorded \$1.2 million in government assistance resulting from the Canada Emergency Wage Subsidy, for which \$1.1 million was received prior to December 31, 2020.

Regulatory Environment and Drug Development Process

The research, development, manufacture and marketing of pharmaceutical products are subject to regulation by the FDA in the U.S., the Therapeutic Products Directorate (TPD) (a branch of Health Canada) in Canada, the European Medicines Agency (EMA) in Europe and comparable regulatory authorities in other foreign countries. These agencies and other federal, state, provincial and local entities will regulate the testing, manufacture, safety and promotion and sale of the Company's products.

For a pharmaceutical company to launch a new prescription or non-prescription drug, whether innovative (original) or a generic version of a known drug, it must demonstrate to the national regulatory authorities in the countries in which it intends to market the new drug that the drug is effective, safe and of sufficient quality for its intended use and population. Depending upon the circumstances surrounding the clinical evaluation of a drug candidate, the Company may undertake clinical and non-clinical animal studies, contract clinical trial activities to contract research organizations or rely upon future partners for such development. Approval of a product by one regulatory authority does not necessarily imply that it can or will be approved by a regulatory authority responsible for a different jurisdiction.

Although only the jurisdictions of the U.S., the E.U. and Canada are discussed in this section, the Company also intends to seek regulatory approval in other jurisdictions.

Canada

In Canada, all drugs are regulated under the *Food and Drugs Act* (Canada) and are enforced by the Health Products and Food Branch Inspectorate (HPFB) under the auspices of Health Canada. Activities that are regulated include all non-clinical and clinical trials used in support of marketing approval. In addition, the regulations state that GMPs must be adhered to during production of all products intended for human use and to some degree during the development process. The regulatory pathway for a potential drug candidate begins by conducting initial proof-of-concept and preliminary safety studies both in the laboratory and in animals (preclinical studies). After the preclinical studies are completed, applications to conduct human clinical trials with the drug candidate must be submitted to the TPD. This application is referred to as a Clinical Trial Application (CTA). The CTA includes information about the methods of manufacture of the drug and controls associated therewith, and preclinical studies demonstrating safety and potential efficacy of the drug candidate. The TPD has 30 days in which to notify a company if the application is satisfactory by issuance of a No Objection Letter (NOL), after which a company may proceed with clinical trials. In addition, before a clinical trial can commence at each participating clinical trial site, the site's institutional review board (the IRB) must approve the clinical trial protocol and other related documents.

After completing all required preclinical and clinical trials, and prior to selling a novel drug in Canada, a company will be required to submit an NDS to the TPD and receive a Notice of Compliance (NOC) to sell the drug. The information contained within the NDS describes the new drug, including the drug's generic and proposed names under which it will be sold, a list describing the quantities and qualities of the ingredients, the method of manufacturing, processing and packaging of the drug, controls in place during the manufacturing operations to determine safety, potency and purity, stability information, results of non-clinical and clinical trials, intended indications for use of the new drug and the efficacy of the new drug when used as intended. If, upon review of the NDS by the TPD, the NDS meets the requirements of the *Food and Drugs Act* (Canada) and the regulations thereunder, the TPD will issue the NOC. The TPD has the authority to impose certain post-approval requirements, such as post-market surveillance clinical trials. TPD approval can be withdrawn for failure to comply with any post-marketing requirements or for other reasons, such as the discovery of significant adverse effects.

United States

In the U.S., all drugs are regulated under the Code of Federal Regulations which is enforced by the FDA. The regulations require that non-clinical and clinical studies be conducted to demonstrate the safety and effectiveness of products before marketing and that the manufacturing be conducted according to GMPs. Subsequent to the completion of certain preclinical studies, the application to conduct human clinical trials with the drug candidate is submitted to the FDA. It is referred to as an investigational new drug application (IND) application. This application contains similar information to the Canadian CTA, and the FDA has 30 days in which to notify a company if the application is unsatisfactory. If the application is not deemed unsatisfactory, then a company may proceed with administering the medication to humans in clinical studies. As in Canada, before any clinical trial can commence at each participating clinical trial site, the site's IRB/REB must approve the clinical protocol and other related documents.

After completing all required preclinical and clinical trials, and prior to selling a drug in the U.S., a company must also comply with New Drug Application (NDA) procedures required by the FDA. The NDA procedure includes the submission of a package containing similar information to that required in the NDS in Canada to indicate safety and efficacy of the drug and describe the manufacturing processes and controls. FDA approval of the submission is required prior to commercial sale or shipment of the product in the U.S. Pre-and/or post-approval inspections of manufacturing and testing facilities are necessary. The FDA may also conduct inspections of the clinical trial sites and the preclinical laboratories conducting pivotal safety studies to ensure compliance with Good Clinical Practice (GCP) and Good Laboratory Practice (GLP) requirements, respectively. Similar to the TPD, the FDA has the authority to impose certain post-marketing requirements, such as post-market surveillance clinical and preclinical trials. In addition, FDA approval can be withdrawn for failure to comply with any post-marketing requirements or for other reasons, such as the discovery of significant adverse effects that change the benefit/risk profile of the drug.

Europe

In Europe, the evaluation of applications for new medicinal products submitted for European approval is coordinated by the EMA, a body of the E.U. The regulations are similar to those in Canada and the U.S. and require that preclinical and clinical studies be conducted to demonstrate the safety and effectiveness of products before marketing and that the manufacturing will be conducted according to GMPs. Subsequent to the preclinical studies and

prior to conducting human clinical trials, a CTA must be submitted to the competent authority in the country where the clinical trial will be conducted. This application contains similar information to the Canadian CTA and U.S. IND. In Europe, clinical trials are regulated by the European Clinical Trial Directive (Directive 2001/20/EC of April 4, 2001). As in Canada and the U.S., before a clinical trial can commence at each participating clinical trial site, the site's IRB/REB must approve the clinical protocol and other related documents.

A major difference in Europe, when compared to Canada and the U.S., is with the approval process. In Europe, there are two different procedures that can be used to gain marketing authorization in the E.U. The first procedure is referred to as the Centralized Procedure and requires that a single application be submitted to the EMA which, if approved, allows marketing in all countries of the E.U. The second procedure has two options: the first is referred to as the Mutual Recognition Procedure and requires that approval is gained from one Member State after which a request is made to the other Member States to mutually recognize the approval and the second is referred to as the Decentralized Procedure which requires a member state to act as the Reference Member State through a simultaneous application made to other member states.

Drug Development Process

A potential new drug must first be tested in the laboratory and in several animal species (preclinical or non-clinical studies) before being evaluated in humans (clinical studies). Preclinical studies primarily involve in vitro evaluations of the therapeutic activity of the drug and in vivo evaluations of the PK, metabolic and toxic effects of the drug in selected animal species. Ultimately, based on data generated during preclinical studies, extrapolations will be made to evaluate the potential risks versus the potential benefits of use of the drug in humans under specific conditions of use. Upon successful completion of the preclinical studies, the drug typically undergoes a series of evaluations in humans, including healthy volunteers and patients with the targeted disease.

The activities which are typically completed prior to obtaining approval for marketing a new drug product in Canada, the U.S. and E.U. may be summarized as follows:

- A. **Preclinical Studies**: In the preclinical stage of drug development, an investigational drug must be tested extensively in the laboratory to ensure it will be safe to administer to humans. Testing at this stage must provide data showing that the drug is reasonably safe for use in initial, small-scale, clinical studies. Depending on whether the compound has been studied or marketed previously, the sponsor may have several options for fulfilling this requirement including:
 - (a) compiling existing non-clinical data from past in vitro laboratory or animal studies on the compound;
 - (b) compiling data from previous clinical testing or marketing of the drug in a country whose population is relevant to the target population; or
 - (c) undertaking new preclinical studies designed to provide the evidence necessary to support the safety of administering the compound to humans.

During preclinical drug development, a sponsor evaluates the drug's toxic and pharmacologic effects through in vitro and in vivo laboratory animal testing.

Genotoxicity screening is performed, as well as investigations on drug absorption, metabolism, the toxicity of the drug's metabolites and the speed with which the drug and its metabolites are excreted from the body. In North America, sponsors are generally asked prior to first in human studies, at a minimum, to:

- (a) develop a pharmacological profile of the drug;
 - (b) determine the acute toxicity of the drug in at least two species of animals; and
 - (c) conduct short-term toxicity studies ranging from 2 weeks to 3 months, depending on the proposed duration of use of the substance in the proposed clinical studies.
- B. Filing of an IND or CTA: The formulation development and preclinical data are submitted to the FDA, TPD or other applicable regulatory body, for review prior to testing in humans.
- C. Clinical Trials: Clinical trials involve the administration of the drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted in compliance with federal, state and local regulations and requirements, under protocols detailing, for example, the objectives of the trial, the parameters to be used in monitoring safety and the efficacy criteria to be evaluated. Clinical trials to support NDAs or NDSs for marketing approval are typically conducted in three sequential phases, but the phases may overlap.

Phase 1 Trials: Phase 1 trials include the initial introduction of an investigational new drug into humans. These studies are closely monitored and may be conducted in patients, but are usually conducted in healthy volunteer subjects. These studies are designed to determine the metabolic and pharmacologic actions of the drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness. During Phase 1, sufficient information about the drug's PKs and pharmacological effects should be obtained to permit the design of well-controlled, scientifically valid, Phase 2 studies. In cases where the Phase 1 studies are conducted on patients and not on healthy volunteers, it is possible that these studies may show evidence of efficacy typically not obtained until Phase 2 studies. These are referred to as Phase 1/2 trials.

Phase 2 Trials: Phase 2 trials are controlled clinical studies conducted to obtain some preliminary data on the effectiveness and safety of the drug for a particular indication or indications in patients with the disease or condition. This phase of testing also helps determine dosage levels, common short-term side effects and risks associated with the drug.

Phase 3 Trials: Phase 3 trials are large controlled and uncontrolled trials. These trials are performed after preliminary evidence suggesting effectiveness and safety of the drug has been obtained in the Phase 2 trials and are intended to gather additional information about effectiveness and safety that is needed to evaluate the overall risk-benefit relationship of the drug. These studies provide an adequate basis for extrapolating the results to the general population and transmitting that information in the physician labelling.

Filing of an NDA or NDS: An NDA or NDS filing with the relevant regulatory authority in the U.S., Canada, E.U. or other pertinent jurisdiction documents the safety and efficacy of the IND and contains all the information collected during the drug development process including the preclinical studies, chemistry, manufacturing and controls (CMC) and the clinical trials. At the conclusion of successful preclinical, CMC and clinical testing, this series of documents is submitted to the regulatory authority. The application must present substantial evidence that the drug will have the effect it is represented to have when people use it or under the conditions for which it is prescribed, recommended or suggested in the labelling. Obtaining approval to market a new drug typically takes between ten months and two years after submission of an application to the applicable regulatory authority.

Once the data is reviewed and approved by the appropriate regulatory authorities, such as the TPD, FDA or EMA, the drug is deemed ready for sale. These authorities and other applicable regulatory bodies will determine whether the drug will be a prescription or non-prescription product based on factors such as the age and history of the drug, the number of patients having reported adverse effects and how well the drug is documented with respect to safety and efficacy. Given that innovative drugs have no long-term history of public use, it is unlikely that an innovative drug would be approved in the first instance as a non-prescription product.

After marketing approval for a drug has been obtained, further studies and clinical trials may be required or requested by the regulatory authorities. The FDA refers to these as Post-marketing Requirements (PMRs) and Commitments. Post-marketing trials may provide additional data about a product's safety, efficacy or optimal use. Some of the studies and clinical trials may be required; others may be studies or clinical trials a sponsor has committed to conduct. PMRs include studies and clinical trials that sponsors are required to conduct under one or more statutes or regulations. Some post-marketing commitments are studies or clinical trials that a sponsor has agreed to conduct, but that are not required by a statute or regulation. Failure to conduct or comply with an established timetable for completing PMRs may result in enforcement actions by the FDA that could include charges or civil monetary penalties. In addition, the FDA may prevent the marketing of the product in the U.S.

RISK FACTORS

The Company faces a variety of significant and diverse risks, many of which are inherent in the business conducted by the Company. Described below are certain risks that could materially affect the Company. Other risks and uncertainties that the Company does not presently consider to be material, or of which the Company is not presently aware, may become important factors that affect the Company's future financial condition and operating results. The occurrence of any of the risks discussed below could materially and adversely affect the Company's business, prospects, financial condition, operating results, cash flow or market value of the Common Shares.

Risks Related to the Business of the Company

Disease Outbreaks

The occurrence of an illness that leads, or is anticipated to lead, to a local, regional, or national outbreak or epidemic, or to an international outbreak or pandemic, such as Middle East Respiratory Syndrome (MERS-CoV), Severe Acute Respiratory Syndrome (SARS), Ebola (EVD),

H1N1 influenza virus, avian flu, or most notably the ongoing COVID-19 pandemic, or any similar illness or mutations thereof, could affect the Company's business as a result of a general or acute short or medium-term decline in economic activity affecting the Company's supply chain, the markets for its products, production capacity and staffing levels, and could lead to increased government regulation, quarantine measures, as well as restrictions on travel and the movement of persons or goods. Each of these risk factors has the potential to have a material adverse impact on the Company's business, financial condition and results of operations.

Inability to Meet Debt Commitments

As of December 31, 2020, the Company had total liabilities of \$131.4 million, including \$103.7 million of debt outstanding under the Deerfield Facility Agreement.

The Company has significant debt commitments to Deerfield, which may have adverse consequences, including:

- requiring a substantial portion of cash flow from operations to be dedicated to servicing the Company's indebtedness, thereby reducing the ability to use cash flow from its operations to fund operations, capital expenditures, and future business opportunities;
- the Deerfield Facility Agreement is secured by the assets of the Company and its subsidiaries;
- limiting the ability to obtain additional financing for working capital, capital expenditures, product and service development, debt service requirements, acquisitions, and general corporate or other purposes at reasonable rates, which is vital to the Company's business;
- increasing the risks of adverse consequences resulting from a breach of any indebtedness agreement, including, for example, a failure to make required payments of principal or interest due to failure of the Company's business to perform as expected;
- increasing vulnerability to general economic and industry conditions;
- restricting the ability to make strategic acquisitions or requiring non-strategic divestitures;
- subjecting the Company's operations to restrictive covenants that may limit operating flexibility; and
- placing the Company's operations at a competitive disadvantage compared to competitors that are less highly leveraged.

The Company's ability to satisfy its debt obligations will depend principally upon its future operating performance. As a result, prevailing economic conditions and financial, business and other factors, many of which are beyond the Company's control, may affect the Company's ability to make payments on its debt. If the Company does not generate sufficient cash flow to satisfy its debt service obligations, the Company may have to undertake alternative financing plans, such as refinancing or restructuring its debt, cost savings initiatives, proceeds-generating transactions, reducing or delaying capital investments or seeking to raise additional capital. The Company's ability to restructure or refinance its debt will depend on the capital markets and the Company's

financial condition at such time. Any refinancing of the Company's debt could be at higher interest rates and may require it to comply with more onerous covenants, which could further restrict the Company's business operations. The Company's inability to generate sufficient cash flow to satisfy its debt service obligations or to refinance its obligations on commercially reasonable terms could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

The Deerfield Facility Agreement imposes various covenants that limit the Company's ability and/or its subsidiaries' ability to, among other things:

- consolidate or merge with or into another person;
- enter into certain transactions with affiliates;
- pay dividends or distributions;
- create, incur or suffer to exist liens;
- create, incur, assume, guarantee or be liable with respect to indebtedness;
- acquire assets or transfer products or material assets; and
- issue equity securities senior to its Common Shares or convertible or exercisable for equity securities senior to its Common Shares.

The covenants imposed by the Deerfield Facility Agreement and the Company's obligations to service its outstanding debt:

- limit the Company's ability to borrow additional funds for working capital, capital expenditures, acquisitions or other general business purposes;
- limit the Company's ability to use its cash flow or obtain additional financing for future working capital, capital expenditures, acquisitions or other general business purposes;
- may require the Company to use a substantial portion of its cash flow from operations to make debt service payments;
- limit the Company's flexibility to plan for, or react to, changes in its business and industry;
- place the Company at a competitive disadvantage compared to its less leveraged competitors; and
- increase the Company's vulnerability to the impact of adverse economic and industry conditions.

If the Company is unable to successfully manage the limitations and decreased flexibility on its business due to its debt obligations, the Company may not be able to capitalize on strategic opportunities or grow its business to the extent the Company would be able to without these limitations. The Company's failure to comply with any of the covenants could result in a default under the Deerfield Facility Agreement, which could permit the lenders to declare all or part of

any outstanding loans to be immediately due and payable. If the Company is unable to pay the outstanding loans when due, then Deerfield could realize on its security, which encompasses the assets of Company and its subsidiaries.

In addition, pursuant to the Deerfield Financing, if a Major Transaction (as defined in the Deerfield Facility Agreement) occurs, such as a change of control transaction involving the Company, Deerfield is entitled, subject to the terms of the Deerfield Financing, to convert or exercise its Convertible Notes or Warrants, as applicable, such that Deerfield ultimately receives the cash, securities or other assets, as applicable, in exchange for such Common Shares on the same terms as other holders of Common Shares. This could materially adversely impact the anticipated results, or deter the entering into, of such a Major Transaction. In addition, Deerfield, in relation to certain Major Transactions or events of default, is entitled to be issued additional Common Shares. See the Deerfield Facility Agreement and the forms of Convertible Notes and Warrants filed under the Company's profile on SEDAR www.sedar.com (under Nuvo Pharmaceuticals Inc.).

Unexpected Costs or Liabilities Related to the Aralez Transaction

Although the Company conducted due diligence in connection with the acquisition of Aralez Canada, an unavoidable level of risk remains regarding any undisclosed or unknown liabilities of, or issues concerning, Aralez Canada and its business. The Company may discover that it has acquired substantial undisclosed liabilities. In such circumstances, the Company will not be able to fully claim indemnification from the sellers of Aralez Canada, as the Purchase Agreements did not include indemnification provisions given that Aralez Canada and related assets were purchased pursuant to the Bankruptcy Proceedings. The Company did obtain the RWI Policy to cover any potential liability under the Purchase Agreements, with coverage of up to \$10 million and a deductible of \$1.1 million, which drops to \$550,000 after 12 months under certain circumstances. However, the RWI Policy is subject to certain exclusions. In addition, there may be circumstances for which the insurer may elect to limit such coverage or refuse to indemnify the Company or situations for which the coverage provided under the RWI Policy may not be sufficient or applicable. The existence of any undisclosed liabilities and the Company's inability to claim indemnification could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

Economic Environment

Economic conditions may limit the Company's ability to access capital or may cause the Company's suppliers to increase their prices, reduce their output or change their terms of sale. If the operating or financial performance of the Company's customers or suppliers deteriorates or if they are unable to make scheduled payments or obtain credit, its customers may not be able to pay or may delay payment of accounts receivable owed and its suppliers may restrict credit or impose different payment terms. Any inability of customers to pay the Company for its products or any demands by suppliers for different payment terms, could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

The Company has no control over changes in inflation and interest rates, foreign currency exchange rates and controls or other economic factors affecting its business nor does it have control over the possibility of political unrest and legal and regulatory changes in jurisdictions in

which the Company operates. These factors could negatively affect the Company's future results of operations in those markets.

Potential Product Liability

The Company may be subject to product liability claims associated with the use of certain of its products either after their approval or during clinical trials and there can be no assurance that the Company's liability insurance will continue to be available on commercially reasonable terms or at all. Product liability claims might also exceed the amounts or fall outside of such coverage. Product liability claims against the Company, regardless of their merit or potential outcome, could be costly and divert management's attention from other business matters or adversely affect the Company's reputation and the demand for its products. There can be no assurance that a product liability claim or series of claims brought against the Company would not materially adversely impact the Company's business, financial condition or operating results.

In addition, certain drug retailers and distributors require minimum liability insurance as a condition of purchasing or accepting products for retail or wholesale distribution. Failure to satisfy such insurance requirements could impede the ability of the Company or its potential partners in achieving broad retail distribution of its products, which could materially adversely impact the Company.

Limited Product Shelf Life

Each of the Company's products has a limited shelf life. Accordingly, any product which exceeds the appropriate age limits may not be sold, may result in product returns and must be destroyed, which would in turn have an adverse financial impact on the Company associated with the cost of writing-off obsolete inventory.

Unexpected Product Safety or Efficacy Concerns

Unexpected safety or efficacy concerns can arise with respect to marketed products, whether or not scientifically justified, leading to product recalls, withdrawals or declining sales, as well as potential product liability, consumer fraud or other claims. Any of such occurrences could materially adversely impact the Company's business, financial condition or operating results.

Patents, Trademarks and Proprietary Technology

There can be no assurance as to the breadth or degree of protection that existing or future patents or patent applications may afford the Company or that any patent applications will result in issued patents or that the Company's patents or trademarks will be upheld if challenged. It is possible that the Company's existing patent or trademark rights may be deemed invalid. Although the Company believes that its products do not, and will not, infringe valid patents or trademarks or violate the proprietary rights of others, it is possible that use, sale or manufacture of its products may infringe on existing or future patent, trademark or proprietary rights of others. If the Company's products infringe the patent, trademark or proprietary rights of others, the Company may be required to stop selling or making certain of its products, may be required to modify or rename certain of its products or may have to obtain licenses to continue using, making or selling such products. There can be no assurance that the Company will be able to do so in a timely manner, upon acceptable terms and conditions, or at all. The failure to do any of the foregoing could materially adversely impact the Company. Moreover, if the Company's products infringe

patents, trademarks or proprietary rights of others, the Company could, under certain circumstances, become liable for substantial damages which could materially adversely impact the Company.

Patent litigation is very complex and expensive. Further, the discovery, trial and appeals process in patent litigation can take several years. Should the Company commence a lawsuit against a third party for patent infringement or should there be a lawsuit commenced against the Company with respect to the validity of its patents or any alleged patent infringement by the Company, the cost of such litigation, as well as the ultimate outcome of such litigation, whether or not the Company is successful, could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline. Moreover, there can be no assurance that the Company will have sufficient financial or other resources to enforce or defend a patent infringement or proprietary rights violation action.

Regardless of the validity of the Company's patents, there can be no assurance that others will be unable to obtain patents or develop competitive non-infringing products or processes that permit such parties to compete with the Company. The Company may not be able to protect its intellectual property rights throughout the world as filing, prosecuting and defending patents and trademarks on all of the Company's product candidates, products and product names, when and if they exist, in every jurisdiction would be prohibitively expensive and could take several years. Competitors may manufacture, sell or use the Company's technologies and use its trademarks in jurisdictions where the Company or its partners have not obtained patent and trademark protection. These products may compete with the Company's products, when and if it has any, and may not be covered by any of its or its partners' patent claims or other intellectual property rights.

The laws of some countries do not protect intellectual property rights to the same extent as the laws of Canada and the U.S. and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favour the enforcement of patents, trademarks and other intellectual property protection, particularly those protections relating to biotechnology and pharmaceuticals, which could make it difficult for the Company to stop the infringement of its patents. Proceedings to enforce patent rights in foreign jurisdictions could result in substantial cost and divert efforts and attention from other aspects of the Company's business.

Further, the strength of patents in the pharmaceutical field involves complex legal and scientific questions and, in the U.S., Canada and many foreign jurisdictions, patent policy also continues to evolve, and the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. This uncertainty is also a result of possible changes to the patent laws through either legislative action to change statutory patent law or court action that may reinterpret existing law in ways affecting the scope or validity of granted patents, or both. Particularly in recent years in the U.S., there have been several major legislative developments and court decisions that have affected patent laws in significant ways and there may be more developments in the future that may weaken or undermine our ability to obtain new patents or to enforce existing and future patents owned or licensed.

Ability to Protect Know How and Trade Secrets

The ability of the Company to maintain the confidentiality of its expertise and trade secrets is essential to its success. Disclosure and use of the Company's expertise and trade secrets, not otherwise protected by patents, are generally controlled under agreements with the parties involved. There can be no assurance however, that all confidentiality agreements are legally enforceable or will be honoured, that others will not independently develop equivalent or competing technology, that disputes will not arise over the ownership of intellectual property or that disclosure of the Company's trade secrets will not occur. To the extent that consultants or other research collaborators use intellectual property owned by others while working with the Company, disputes may also arise over the rights to related or resulting expertise or inventions.

Personnel

The Company's success depends upon certain key members of its sales and marketing, legal, business development, scientific, technical, manufacturing and management teams. The loss of any of these individuals could materially adversely impact the Company. The Company does not maintain key-man insurance coverage with respect to any of its employees.

The Company's success also depends, in large part, on its ability to continue to attract and retain qualified sales and marketing, legal, business development, scientific, technical, manufacturing and management personnel. The Company faces intense competition for such personnel. Highly skilled employees with the education and training required, especially employees with significant experience and expertise in drug delivery systems, are in high demand and may be hired by the Company's competitors. The Company may not be able to attract and retain such personnel in the future which could have a material adverse impact on the success of the Company.

The Company must also provide significant training for its employees due to the highly specialized nature of pharmaceutical products. With respect to its sales force, the Company is required to expend significant time and resources on training to establish credible, compliant and persuasive individuals in educating physicians to prescribe and pharmacists to dispense the Company's products. In addition, the Company must train its sales force to ensure that a consistent and appropriate message about its products is being delivered to its potential customers. If the Company is unable to effectively train its sales force and equip them with effective materials its efforts to successfully commercialize its products could be put in jeopardy, which could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

Further, the Company expects that its growth and potential expansion into specific areas and activities requiring new or additional expertise, such as in the areas of alliance management, product development, CMC work, clinical trials and regulatory approvals may place additional requirements on management, and the Company's operational and financial resources. Such demands could require an increase in the number of management and scientific personnel and development of additional expertise by existing personnel. The failure to attract and retain such personnel, or to develop such expertise, could materially adversely impact the Company. In addition, to attract qualified personnel, the Company may be required to establish offices in different locations. The failure of personnel in different locations to work effectively together could materially adversely impact the Company's success.

Dependence on a Small Number of Customers

The Company sells certain of its products in Canada, the U.S. and E.U. to a limited number of distributors. Under this distribution model, the distributors generally take physical delivery of the product and generally sell the product directly to pharmacies or patients. In addition, certain of the Company's products may be highly dependent on a small number of customers. The Company expects this significant distributor/customer concentration to continue for the foreseeable future. The Company's ability to generate and grow sales of its products will depend, in part, on the extent to which its distributors are able to provide adequate distribution of its products on pricing terms that are favorable to it. Although the Company believes it can find additional or replacement distributors, if necessary, the pricing terms of such arrangements may not be as favourable to the Company, its revenue during any period of disruption could suffer and the Company might incur additional costs. In addition, these distributors/customers are responsible for a significant portion of the Company's net trade accounts receivable balances. The loss of any large distributor/customer, a significant reduction in sales the Company make to them, any cancellation of orders they have made with the Company, or any failure to pay for the products the Company has shipped to them could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

Dependence on Third-Party Partnerships for Sales, Marketing, Customer Service, Distribution, Warehousing, Logistics, Invoicing and Accounts Receivables and Regulatory Services

Regarding products commercialized by Miravo, the Company relies on third-party arrangements, to provide customer service, distribution, warehousing, logistics, invoicing, accounts receivables and some regulatory services where it lacks the necessary resources or expertise. If the third parties cease to be able to provide the Company with these services or do not provide these services in a timely or professional manner, or in accordance with the applicable regulatory requirements or if contracts with such third parties are terminated for any reason, the Company may not be able to successfully manage the logistics associated with distributing and selling its products.

Regarding products out-licensed by the Company, or products manufactured for third parties under contract, the Company relies on marketing arrangements, including licensing or other third-party arrangements, to provide sales, marketing, distribution, logistics, invoicing and regulatory services including warehousing of finished products, accounts receivable management, billing, collection, record keeping and processing of invoices (including with insurance companies) for its products in jurisdictions where it lacks the necessary resources or expertise. If the third parties cease to be able to provide the Company with these services or do not provide these services in a timely or professional manner, or in accordance with the applicable regulatory requirements or if contracts with such third parties are terminated for any reason, the Company may not be able to successfully manage the logistics associated with distributing and selling its products.

In either case, this could result in a delay or interruption in delivering products to customers and could impact product sales and revenues or the Company's ability to integrate new products into its business, any of which could materially adversely impact the Company's business, financial condition, operating results or royalties earned. In addition, under these arrangements, disputes may arise with respect to payments that the Company or its partners believe are due, a

partner or distributor may develop or distribute products that compete with the Company's products or they may terminate the relationship. Further, disagreements with the Company's third-party partners could require or result in litigation or arbitration, which could be time consuming and expensive for the Company.

The Company has no influence in sales and marketing activities for products that are sold by third parties in the markets in which they are currently available. Decisions impacting sales and marketing efforts are made by the Company's partners in their respective territories. If one of the Company's partners is unable to successfully sell or stops selling its respective product, for any reason, it could have an adverse effect on the Company's product sales and cash resources, as well as royalties earned.

Loss of Licenses

The Company has licensed certain assets used in a substantial part of the Company's business, including certain intellectual property, marketing authorizations and related data, and commercial and technical medical information. The Company believes it is currently in material compliance with all requirements of such licenses. In certain cases, the Company does not control the filing, prosecution or maintenance of the patent rights underlying a license and may rely upon the Company's licensors to prosecute infringement of those rights. Such license agreements may be terminated by the licensor if the Company is in breach of its obligations thereunder and fails to cure that breach. If a license agreement is terminated, then the Company may lose its rights to utilize the intellectual property and other assets covered by such agreement in order to manufacture, market, promote, distribute and sell the licensed products, which may prevent the Company from continuing a substantial part of the Company's business. This could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

Timing of Milestone and Royalty Payments

The Company is party to various agreements pursuant to which the Company is obligated to make milestone payments or pay royalties to third parties. The Company may become obligated to make a milestone or other payment at a time when the Company does not have sufficient funds to make such payment, or at a time that would otherwise require it to use funds needed to continue to operate its business, which could curtail its operations, necessitate a scaling back of its commercialization and marketing efforts or cause the Company to seek funds to meet these obligations on terms unfavorable to it.

Manufacturing, Warehousing and Supply Risks

The Company's current internal manufacturing capabilities are limited to its site in Varennes, Québec, which is the sole manufacturing site of Pennsaid 2%, Pennsaid and the bulk drug product for the HLT Patch for all markets. The Company has never achieved full capacity utilization in this facility. The Company is exposed to the following manufacturing and supply risks, any of which could delay or prevent the commercialization of certain of its products, result in higher costs or deprive it of potential product revenues:

- The Company may encounter difficulties in achieving volume production, quality control and quality assurance, as well as relating to shortages of qualified personnel, which may lead to insufficient quantities to commercialize certain of its customer needs;

- The Company's manufacturing facilities are required to undergo satisfactory current GMP inspections prior to regulatory approval and are obliged to operate in accordance with FDA, E.U. and other nationally mandated GMP, which govern manufacturing processes, stability testing, record keeping and quality standards. Failure to establish and follow GMPs and to document adherence to such practices, may lead to significant delays in the availability of material for customer orders; and
- Changing manufacturing locations would be difficult and the number of potential manufacturers is limited. Changing manufacturers generally requires re-validation of the manufacturing processes and procedures in accordance with FDA, E.U. and other nationally mandated GMPs. Such re-validation may be costly and would be time consuming. It would be difficult or impossible to quickly find replacement manufacturers on acceptable terms, if at all.

The Company's manufacturing facility is subject to ongoing periodic unannounced inspection by the FDA and corresponding agencies, including E.U. and Canadian agencies, and may be subject to inspection by local, state, provincial and federal authorities from various jurisdictions to ensure strict compliance with GMPs and other government regulations. Failure by the Company to comply with applicable regulations could result in sanctions being imposed on it, including fines, injunctions, civil penalties, failure of the government to grant review of submissions or market approval of drugs, delays, suspension or withdrawal of approvals, seizures or recalls of product, operating restrictions, facility closures and criminal prosecutions, any of which could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

The Company may encounter manufacturing or warehousing and logistical failures that could impede or delay commercial production of its products. Any failure in the Company's manufacturing or warehousing and logistical operations could cause the Company to be unable to meet the demand for its products and lose potential revenue and harm its reputation. The Company's manufacturing and warehousing and logistical operations may encounter difficulties involving, among other things, production yields, regulatory compliance, quality control and quality assurance and shortages of qualified personnel.

With the exception of Pennsaid 2%, Pennsaid and the bulk drug product for the HLT Patch, the Company relies on several contract manufacturers for the supply of products. There are risks that could affect the ability of the Company's contract manufacturers to meet the Company's delivery time requirements or provide adequate amounts of material to meet the Company's needs. In addition to the manufacture of certain of the Company's products, the Company may have additional manufacturing requirements related to the technology required for any of the Company's products. In some cases, the delivery technology the Company utilizes is highly specialized or proprietary and for technical and legal reasons, the Company may have access to only one or a limited number of potential manufacturers for such delivery technology. Failure by these manufacturers to properly formulate the Company's products or licensed products for delivery could also result in unusable product and cause delays in the Company's discovery and development process, as well as additional expense to the Company.

The manufacturing process for products where the Company uses a contract manufacturer are based on technologies that the Company or its partners may develop and are subject to regulatory approvals from regulatory authorities, including the FDA, Health Canada, EMA, state and local regulations and other regulatory agencies as well as compliance with

ongoing regulatory requirements. Together with the Company's partners, the Company needs to contract with manufacturers who can meet all applicable regulatory guidelines and requirements. In addition, if the Company receives the necessary regulatory approval for any product candidate, it also expects to rely on third parties, including its commercial partners, to produce materials required for commercial supply. The Company may experience difficulty in obtaining adequate manufacturing capacity for its needs. If the Company is unable to obtain or maintain contract manufacturing for its product candidates, products or licensed products, or to do so on commercially reasonable terms, the Company may not be able to successfully develop and commercialize its products or licensed products. If a third-party manufacturer with whom the Company contracts fails to perform its obligations, the Company may be forced to manufacture the materials itself, which the Company may not have the necessary capabilities or resources for or enter into an agreement with a different third-party manufacturer, which the Company may not be able to do on equally favourable terms, within acceptable timelines or that complies with quality standards and with all applicable regulations and guidelines.

In the case of many of the Company's products, there is a single supplier for raw materials used in such products. If the relationships with any of the single-sourced suppliers is discontinued or if any manufacturer is unable to supply or produce required quantities of product on a timely basis, or at all, or if a supplier ceases production of an ingredient or component, the Company's operations would be negatively impacted and the business would be harmed.

In addition, the FDA and other regulatory agencies require that raw material manufacturers comply with all applicable regulations and standards pertaining to the manufacture, control, testing and use of the raw materials as appropriate. For the active pharmaceutical ingredients (API) or critical raw materials depending on the drug product, this means compliance with current GMPs for APIs and submission of all data related to the manufacture, control and testing of the API for quality, purity, identity and stability, as well as a complete description of the process, equipment, controls and standards used for the production of the API. This is usually submitted to the FDA in the form of a Drug Master File (DMF) by the manufacturer and referenced by the sponsor of the NDA. The DMF information and data is reviewed by the FDA as a critical component of the approvability of the NDA. As a result, in the case where only one supplier of a particular API or critical raw material meets all of the FDA's (or other regulatory agencies) requirements and has a DMF (or similar filing) on file with the FDA, the Company is at risk should a supplier violate GMP, fail an FDA inspection, terminate access to its DMF, be unable to manufacture product, choose not to supply the Company or decide to increase prices.

In addition, the Company could be subject to various import duties applicable to both finished products and raw materials and it may be affected by other import and export restrictions, as well as developments with an impact on international trade. Under certain circumstances, these international trade factors could affect manufacturing costs, which could in turn, affect the Company's margins, as well as the wholesale and retail prices of manufactured products.

Failure to Achieve Anticipated Benefits From Strategic Acquisitions

A significant part of the Company's business strategy includes acquiring and integrating complementary businesses, products, technologies or other assets, and forming strategic alliances and other business combinations, to help drive future growth. The Company may also in-license new products or compounds. Acquisitions or similar arrangements may be complex, time-consuming and expensive, and the process of negotiating the acquisition and integrating an acquired product, drug candidate, technology, business or company might result in operating

difficulties and expenditures and might require significant management attention that would otherwise be available for ongoing development of the Company's business, whether or not any such transaction is ever completed. Moreover, the Company may never realize the anticipated benefits of any acquisition or forecasted sales may not materialize.

In addition, the Company may explore, pursue and/or negotiate transactions that are not ultimately completed and there are a number of risks, costs and uncertainties relating thereto. For example, the market price of the Company's Common Shares may reflect a market assumption that such transactions will occur, and a failure to complete such transactions could result in a negative perception by the market of the Company generally and a decline in the price of its Common Shares. In addition, many costs relating to such transactions may be payable by the Company whether or not such transactions are completed.

If an acquisition is completed, the integration of the acquired business, product or other assets into the Company may also be complex and time-consuming and, if such businesses, products and assets are not successfully integrated, the Company may not achieve the anticipated benefits, cost-savings or growth opportunities. Potential difficulties that may be encountered in the integration process include the following:

- disruption of the Company's business and diversion of management's and employees' time and attention from operations;
- integrating personnel, operations, manufacturing technology and systems, while maintaining focus on selling and promoting existing and newly-acquired products;
- coordinating geographically dispersed organizations;
- motivating key employees of the acquired businesses;
- retaining existing customers and attracting new customers;
- maintaining the business relationships of the acquired company or that the company that previously owned such product has established, including with healthcare providers, third-party payers and distributors; and
- managing inefficiencies associated with integrating the operations of the Company.

The Company has incurred, and may incur in the future, restructuring and integration costs and a number of non-recurring transaction costs associated with these acquisitions. Non-recurring transaction costs include, but are not limited to, fees paid to legal, financial, regulatory, manufacturing and accounting advisors, filing fees, transfer and other transaction-related taxes and printing costs. Additional unanticipated costs may be incurred in the integration of the businesses of the Company and the acquired business. There can be no assurance that the elimination of certain duplicative costs, as well as the realization of other efficiencies related to the integration of the acquired business, will offset the incremental transaction-related costs over time. Therefore, any net benefit may not be achieved in the near term, the long term or at all.

Finally, these acquisitions and other arrangements, even if successfully integrated, may fail to further the Company's business strategy as anticipated or to achieve anticipated benefits and success, expose it to increased competition or challenges with respect to its products or

geographic markets, and expose it to additional or unexpected liabilities associated with an acquired business, product, technology or other asset or arrangement. Any one of these challenges or risks could impair the Company's ability to realize any benefit from an acquisition or arrangement after the Company has expended resources on them.

Failure to Acquire, License, Develop and Market Additional Product Candidates or Approved Products

As part of its strategy, the Company may acquire, license or develop and market additional products and product candidates. The product candidates where the Company allocates its resources may not be successful. In addition, because its internal research capabilities are limited, the Company may depend upon pharmaceutical, biotechnology and other researchers to sell or license products or technology. The success of this strategy depends partly upon the Company's ability to identify, select, license and/or acquire promising pharmaceutical or other healthcare product candidates and approved products for Canada, the U.S. and the rest of the world. Failure of this strategy could impair the Company's ability to grow. The process of proposing, negotiating and implementing a license or acquisition of a product candidate or approved product is lengthy and complex. Other companies, including some with substantially greater financial, marketing and sales resources, may compete with the Company for the license or acquisition of product candidates and approved products. The Company may devote resources to potential acquisitions or in-licensing opportunities that are never completed, or the Company may fail to realize the anticipated benefits of such efforts. The Company may not be able to acquire the rights to additional product candidates or approved products on terms that the Company find acceptable, or at all.

Further, any unapproved product candidate that the Company acquires may require additional development efforts prior to commercial sale, including extensive clinical testing and approval by applicable regulatory authorities. With all product candidates there are risks of failure typical of pharmaceutical product development, including the possibility that a product candidate will not be shown to be sufficiently safe and effective for approval by applicable regulatory authorities and thus will never make it to market. If such risks were to materialize, they could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

Hazardous Materials and the Environment

The Company's products involve the use of potentially hazardous materials, and as a result, it is exposed to potential liability claims and costs associated with complying with laws regulating hazardous waste. R&D and manufacturing activities involve the use of hazardous materials, including chemicals, and are subject to federal, provincial and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous materials and waste products. However, accidental injury or contamination from these materials may occur. In the event of an accident, the Company could be held liable for any damages, which could exceed its available financial resources. In addition, the Company may be required to incur significant costs to comply with environmental laws and regulations in the future.

Losses Due to Foreign Currency Fluctuations

The Company anticipates that a high percentage of the revenue from commercialization of its product candidates may be in currencies other than Canadian dollars. Fluctuation in the

exchange rate of the Canadian dollar relative to these other currencies could result in the Company realizing a lower profit margin on sales of its product candidates than anticipated at the time of entering into such commercial agreements. Adverse movements in exchange rates could materially adversely impact the Company's business, financial condition or operating results.

Taxes

Significant judgment is required in determining the Company's provision for income taxes and claims for investment tax credits (ITCs) related to qualifying Scientific Research and Experimental Development (SR&ED) expenditures in Canada. As noted below, various internal and external factors may have favourable or unfavourable effects on future provisions for income taxes and the Company's effective income tax rate. These factors include, but are not limited to, changes in tax laws, regulations and/or rates, results of audits by tax authorities, changing interpretations of existing tax laws or regulations, changes in estimates of prior years' items, future levels of R&D spending and changes in overall levels of income before taxes. Furthermore, new accounting pronouncements or new interpretation of existing accounting pronouncements could materially adversely impact the Company's effective income tax rate.

The Company and its subsidiaries have operations in various countries that have differing tax laws and rates. The Company's and its subsidiaries' tax reporting is subject to current domestic tax laws in the countries in which the Company and its subsidiaries operate, including transfer pricing laws and regulations between many of these jurisdictions, and the application of tax treaties between the various countries in which the Company and its subsidiaries operate. The Company's and its subsidiaries' income tax reporting is subject to audit by domestic and foreign authorities. Tax laws, regulations, and administrative practices in various jurisdictions may be subject to significant change, with or without notice, due to economic, political, and other conditions.

The amount of income tax and withholding tax required to be paid by the Company and/or its subsidiaries will be affected by many factors, including the amount of net income earned in the relevant operating jurisdictions, the structure of its operations, the availability of benefits under tax treaties, and the rates of taxes payable in respect of that income. The Company must make estimates and judgments, as well as take tax filing positions, based on its knowledge and understanding of applicable tax laws and tax treaties, and the application of those tax laws and tax treaties to its business. The final outcome of any audits by taxation authorities may differ from the estimates, assumptions and filing positions used in determining the tax treatment by the Company and/or its subsidiaries, and such outcome could lead to additional taxes, penalties and interest.

The Company was subject to withholding taxes on certain of its revenue streams. The withholding tax rates that were used were based on the interpretation of specific tax acts and related treaties. If a tax authority has a different interpretation from the Company's, it could potentially impose additional taxes, penalties or fines. This would potentially reduce the amounts of revenue ultimately received by the Company.

The Company, from time-to-time, has executed multiple reorganization transactions impacting its tax structure. If a tax authority has a different interpretation from the Company's, it could potentially impose additional taxes, penalties or interest.

International Scope of Operations

The Company's international operations and any future international operations may expose it to risks that could negatively impact its future results. The risks that the Company may be exposed to in these cases include, but are not limited to:

- tariffs and trade barriers;
- currency fluctuations, which could decrease the Company's revenues or increase its costs;
- regulations related to customs and import/export matters;
- tax issues, such as tax law changes, variations in tax laws, withholding tax obligations and claims by foreign tax authorities;
- limited access to qualified staff;
- inadequate infrastructure;
- cultural and language differences;
- inadequate banking systems;
- different and/or more stringent environmental laws and regulations;
- restrictions on the repatriation of profits or payment of dividends;
- crime, strikes, riots, civil disturbances, terrorist attacks or wars;
- nationalization or expropriation of property;
- law enforcement authorities and courts that are weak or inexperienced in commercial matters; and
- deterioration of political relations among countries.

Similarly, adverse economic conditions impacting the Company's customers in international countries or uncertainty about global economic conditions could cause purchases of its products to decline, which would adversely affect the Company's revenues and operating results. Any of these factors, or any other international factors, could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

Accumulated Deficit

The Company had an accumulated deficit of \$180.6 million as at December 31, 2020. The Company's inability to remain profitable could depress the market price of its shares and could impair its ability to raise capital, expand its business, expand its product pipeline or continue its operations.

Information Technology Infrastructure

Despite the implementation of security measures, the Company's information systems and those of the Company's contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruption to the Company's operations. The Company's business depends on the efficient and uninterrupted operation of computer and communications systems and networks, hardware and software systems and other information technology. If systems were to fail or the Company was unable to successfully expand the capacity of these systems, back up its data or was unable to integrate new technologies into its existing systems, its operations and financial results could suffer.

Security and Cyber Security Breaches

The Company has implemented security protocols and systems with the intent of maintaining the physical and electronic security of its operations and protecting its confidential information and information related to identifiable individuals against unauthorized access. Despite such efforts, the Company may be subject to security breaches, which could result in unauthorized access to its facilities or the information that the Company is trying to protect. Unauthorized physical access to one of the Company's facilities or electronic access to its information systems could result in, among other things, unfavorable publicity, litigation by affected parties, damage to sources of competitive advantage, disruptions to its operations, loss of proprietary information, customer information, financial obligations for damages related to the theft or misuse of such information and costs to remediate such security vulnerabilities, any of which could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

Management of Growth

The Company's future growth, if any, may cause a significant strain on management, operational, financial and other resources. The ability to effectively manage growth will require the Company to improve and/or expand its scientific, operational, financial and management information systems and to train, manage and motivate its employees. These demands may require the addition of new management personnel and the development of additional expertise by management. Any increase in resources devoted to research, product and business development without a corresponding increase in scientific, operational, financial and management information systems could materially adversely impact the Company's performance. The failure of the Company's management team to effectively manage growth could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

Risks Related to the Industry in which the Company Operates

Products May Fail to Achieve Market Acceptance

Any products successfully developed, acquired or licensed by the Company may not achieve market acceptance and, as a result, may not generate significant revenues. Market acceptance of the Company's products by physicians or patients will depend on a number of factors, including:

- availability, cost and effectiveness of products when compared to competing products and alternative treatments;
- relative convenience and ease of administration;
- the prevalence and severity of any adverse side effects;
- the acceptance of competing products;
- pricing, which may be subject to regulatory control;
- effectiveness of marketing and distribution partners' sales and marketing strategies; and
- the ability to obtain sufficient third-party insurance coverage or reimbursement.

If any product commercialized by the Company does not provide a treatment regimen that is as beneficial as the current standard of care or otherwise does not provide patient benefits, there is the potential that it will not achieve market acceptance. This may result in a shortfall in revenues and an inability to achieve or maintain profitability.

Laws and Regulations

Pharmaceutical and biotechnology companies have faced lawsuits and investigations pertaining to violations of healthcare "fraud and abuse" laws, such as the federal *False Claims Act*, the federal *Anti-Kickback Statute*, the United States *Foreign Corrupt Practices Act* (the FCPA) and other federal, state, territorial and provincial laws and regulations. The Company also faces increasingly strict data privacy and security laws in the U.S., Canada, the E.U. and other countries, the violation of which could result in fines and other sanctions. Certain countries have compliance programs and disclose certain payments made to healthcare providers or funds spent on the marketing and promotion of drug products. While the Company has developed a corporate compliance program, there can be no assurance it, or its employees or agents, are or will be in compliance with all applicable federal, state, provincial, territorial or foreign regulations and laws. If the Company is in violation of any of these requirements or any such actions are instituted against it, and the Company is not successful in defending or asserting its rights, those actions could have a significant impact on the Company's business, including the imposition of significant fines, exclusion from federal healthcare programs or other sanctions.

The FCPA, the Canadian *Corruption of Foreign Public Officials Act* (the CFPOA) and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to officials for the purpose of obtaining or retaining business. Although the Company requires its employees to consult with its legal department prior to making any payment or gift thought to be exempt under applicable law, there is no assurance that such policies or procedures will work effectively all of the time or protect the Company against liability under the FCPA and/or the CFPOA for actions taken by its employees and other intermediaries with respect to the Company's business or any businesses that the Company may acquire. The Company may operate in parts of the world that have experienced governmental corruption to some degree and, in certain circumstances, strict compliance with anti-bribery laws may conflict with local customs and practices or may require the Company to interact with doctors and hospitals, some of which may be state controlled, in a manner that is different from the U.S. and Canada. The Company cannot assure that its internal control policies and procedures will protect

it from reckless or criminal acts committed by its employees or agents. Violations of these laws, or allegations of such violations, could disrupt the Company's business and result in criminal or civil penalties or remedial measures, any of which could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

The Company is also subject to various privacy and security regulations. In the U.S., the Company is subject to the *Health Insurance Portability and Accountability Act of 1996*, as amended by the *Health Information Technology for Economic and Clinical Health Act of 2009* (as amended, HIPAA). HIPAA mandates, among other things, the adoption of uniform standards for the electronic exchange of information in common healthcare transactions (e.g., healthcare claims information and plan eligibility, referral certification and authorization, claims status, plan enrollment, coordination of benefits and related information), as well as standards relating to the privacy and security of individually identifiable health information, which require the adoption of administrative, physical and technical safeguards to protect such information. In addition, many states have enacted comparable laws addressing the privacy and security of health information, some of which are more stringent than HIPAA. Failure to comply with these laws can result in the imposition of significant civil and criminal penalties.

Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. Canada has adopted the *Personal Information Protection and Electronic Documents Act* (PIPEDA) which governs how private sector organizations collect, use and disclose personal information in the course of commercial business and which imposes significant compliance obligations. The E.U. and other jurisdictions have adopted data protection laws and regulations which also impose significant compliance obligations, including the E.U. Data Protection Directive, as implemented into national laws by the E.U. member states, which imposes strict obligations and restrictions on the ability to collect, analyze, and transfer personal data, including health data from clinical trials and adverse event reporting. Data protection authorities from different E.U. member states have interpreted the privacy laws differently, which adds to the complexity of processing personal data in the E.U. and guidance on implementation and compliance practices are often updated or otherwise revised. Any failure to comply with applicable information privacy laws could lead to supervisory authority enforcement actions, reputational damage and significant penalties adversely impacting Company operating results.

The E.U. General Data Protection Regulation (GDPR), came into effect on May 25, 2018 to expand data protection obligations, including by imposing more stringent conditions for consent from data subjects, strengthening the rights of individuals, including the right to have personal data deleted upon request, continuing to restrict the trans-border flow of such data, requiring mandatory data breach reporting and notification, increasing penalties for non-compliance and increasing the enforcement powers of the national data protection authorities. The GDPR mandate harmonizes E.U. data protection laws and is intended to make it easier for multinational companies operating across the E.U. to comply with their data protection obligations. Therefore, GDPR increases the Company's responsibility and liability in relation to processing personal data internationally. Along with the Company's existing controls, it is in the process of putting in place additional mechanisms to ensure compliance with GDPR. The costs of compliance with these laws and the potential liability associated with the failure to comply with these laws could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

Legislative or Regulatory Reform of the Healthcare System

In the U.S. and certain state and foreign jurisdictions, there have been a number of legislative and regulatory proposals to change the healthcare system in ways that could impact the ability of certain of the Company's products to be sold profitably. The *Patient Protection and Affordable Care Act* (the ACA) may affect the operational results of companies in the pharmaceutical industry, including the Company, and other healthcare-related industries by imposing additional costs and compliance burdens.

The Company is unable to predict the future course of federal or state healthcare legislation. A variety of federal and state agencies are in the process of implementing the ACA, including through the issuance of rules, regulations or guidance that materially affect the Company's business. The risk of the Company being found in violation of these rules and regulations is increased by the fact that many of them have not been fully interpreted by applicable regulatory authorities or the courts, and their provisions are open to a variety of interpretations. In addition, there is substantial uncertainty regarding the future of the ACA as there is continued interest to repeal and/or replace all or certain aspects of such laws. The outcome of such efforts could have a substantial impact on the Company's business. Further changes to healthcare laws or regulatory framework that reduce the Company's revenues or increase its compliance or other costs could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

In addition, pharmaceutical product pricing is subject to enhanced government and public scrutiny and calls for reform. Efforts by government officials or legislators to implement measures to regulate prices or payment for pharmaceutical products could adversely affect the Company's business if implemented.

In Canada, patented drug products are subjected to regulation by the Patented Medicine Prices Review Board (the PMPRB) pursuant to the Patent Act (Canada) and the Patented Medicines Regulations. The PMPRB does not approve prices for drug products in advance of their introduction to the market, and therefore, there may be risk involved in the determination of an allowable price selected by the Company for a patented drug product at the time of introduction to the market. If the PMPRB does not agree with the pricing assumptions chosen by the Company at any time during the patent life of a product, the price chosen could be challenged by the PMPRB, and if it is determined that the price charged is excessive, the price of the product may be reduced and a fine may be levied against the Company. Drug products that have no valid patents are not subject to the PMPRB's jurisdiction. Miravo currently has patent protected products in Canada (e.g. Cambia and Suvexx). Changes to the PMPRB regulations are scheduled to come into effect on July 1, 2021, with enforcement to begin on January 1, 2022. Final guidelines on how these changes will be implemented have been published and are not anticipated to negatively impact the Company's business. Subsequent changes to these guidelines or the regulations could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

Formularies

Third-party payers try to negotiate the pricing of medical services and products to control their costs. Pharmacy benefit managers typically develop formularies to reduce their cost for medications. Due to their lower costs, generic products are often favoured. The breadth of the products covered by formularies varies considerably from one managed care organization to

another, and many formularies include alternative and competitive products for treatment of particular medical conditions. Failure to be included on such formularies, failure to achieve favourable formulary status, restrictions on drugs included on formularies such as prior authorizations, step edits or other limitations, or delays in implementing changes to formulary status, may negatively impact the utilization of the Company's products. If the Company's products are not included within an adequate number of formularies or adequate reimbursement levels are not provided, or if those policies increasingly favour generic products, its market share which could materially adversely impact the Company's business, financial condition or operating results.

Competition

The pharmaceutical industry is characterized by evolving technology and intense competition. The Company is engaged in areas of research where developments are expected to continue at a rapid pace. Many companies, including major pharmaceutical and specialized biotechnology companies, are engaged in activities focused on medical conditions that are the same as or similar to those targeted by the Company. The Company's success depends upon maintaining its competitive position and the successful commercialization of its products. Competition from pharmaceutical and biotechnology companies, as well as universities and research institutes, is intense and is expected to increase. Many of these organizations have substantially greater R&D, manufacturing, marketing, financial and managerial experience and resources. If the Company fails to compete successfully in any of these areas, this could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

The intensely competitive environment in which the Company operates requires an ongoing, extensive search for medical and technological innovations and the ability to market products effectively, including the ability to communicate the effectiveness, safety and value of the Company's products for their intended uses to healthcare professionals in private practice, group practices and managed care organizations. There can be no assurance that the Company and its drug development partners will be able to successfully develop medical or technological innovations or that the Company and its licensing partners will be able to effectively market the Company's existing products or any future products.

Additionally, the Company competes to acquire the intellectual property assets that are required to continue to broaden its product portfolio. The Company seeks to acquire rights to new intellectual property through corporate acquisitions, asset acquisitions, licensing and joint venture arrangements. Competitors with greater resources may acquire assets that the Company seeks, and even if the Company is successful, competition may increase the acquisition price of such assets. If the Company fails to compete successfully, its growth may be limited.

Generic Drug Manufacturers and Litigation

Regulatory approval for competing generic drugs can be obtained without investing in the same level of costly and time-consuming clinical trials that the Company has conducted or might conduct in the future. Due to the substantially reduced development costs, generic drug manufacturers are often able to charge much lower prices for their products than the original developer. Where available, generic versions may be required or encouraged in preference to branded version under third-party reimbursement programs or substituted by pharmacies for branded versions by law. The Company faces competition from manufacturers of generic drug

versions of some of its products that are commercial, since a number of the Company's patents have expired, or if not yet expired, may be ignored by generic drug manufacturers who choose to launch their products "at risk" of a possible patent infringement lawsuit brought by the Company or its licensing partners. Generic competition may impact the prices at which the Company's products are sold, the royalty rates the Company receives and the volume of product sold which may substantially reduce the Company's overall revenues and market share. Such competition could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

In the U.S., under the *Hatch-Waxman Act*, the FDA can approve an ANDA for a generic version of a branded drug or a variation of an existing branded drug, without undertaking the clinical testing necessary to obtain approval to market a new drug. This is referred to as the "ANDA process". In place of such clinical studies, an ANDA applicant usually needs to submit data and information demonstrating that its product has the same active ingredient(s) and is bioequivalent to the branded product, in addition to, for example, any data necessary to establish that any difference in inactive ingredients does not result in different safety or efficacy profiles, as compared to the reference drug. The Hatch-Waxman Act, in addition to providing brand-name drug manufacturers with periods of marketing exclusivity, such as three-year "new clinical investigation" exclusivity, requires an applicant for a drug that relies, at least in part, on the FDA's findings of safety or effectiveness for a branded drug, to notify the sponsor of the branded drug of their application and potential infringement of any patents listed in the FDA Orange Book. Upon receipt of this notice, the sponsor of the branded drug has 45 days to bring a patent infringement suit in federal district court against the applicant seeking approval of a product covered by the patent. If such a suit is commenced and the ANDA was filed after the patent had been listed in the FDA Orange Book, then the FDA is generally prohibited from granting approval of the ANDA or Section 505(b)(2) NDA, a type of NDA that relies on information for which the applicant does not have a right of reference, until the earliest of 30 months from the date the FDA accepted the application for filing (the 30-Month Stay), or the conclusion of patent infringement litigation in the generic's favour or expiration of the patent. If an ANDA was filed before the patent had been listed in the FDA Orange Book, the 30-Month Stay does not apply and it is possible that the ANDA holder may launch its generic product "at risk" of patent infringement proceedings initiated by the innovator drug company. If the litigation is resolved in favour of the applicant or the challenged patent expires during the 30-month stay period, the stay is terminated and the FDA may thereafter approve the application based on the standards for approval of ANDAs and Section 505(b)(2) NDAs. Frequently, the unpredictable nature and significant costs of patent litigation leads the parties to settle out of court. Settlement agreements between branded companies and generic applicants may allow, among other things, a generic product to enter the market prior to the expiration of any or all of the applicable patents covering the branded product, either through the introduction of an authorized generic or by providing a license to the patents in suit. Comparable procedures and data exclusivity rights exist in Canada under the Patented Medicines (Notice of Compliance) Regulations and the Food and Drug Regulations, respectively.

In the U.S., Pennsaid 2% and Vimovo are protected by multiple patents listed in the FDA Orange Book. The approval or launch of generic versions of Pennsaid 2% or Vimovo in the U.S. market, or timely and expensive litigation costs associated with protecting the patents for these products, could materially adversely impact the Company's future revenue from product sales. A generic version of Vimovo launched in the U.S. market in 2020 as discussed above.

General Litigation and Class Action Litigation

The Company operates in a highly litigious environment. From time-to-time, the Company is or may be threatened with, or is or could be named as a defendant in, various legal proceedings, including lawsuits based upon product liability, patent infringement, personal injury, breach of contract and lost profits or other consequential damage claims. Such actions can include class action based on drugs with unanticipated side effects. In addition, the Company may be forced to litigate to enforce or defend its intellectual property rights, to protect its trade secrets or to determine the validity and scope of other parties' proprietary rights.

A significant judgment against the Company or the imposition of a significant fine or penalty or a finding that the Company has failed to comply with laws or regulations or a failure to settle any dispute on satisfactory terms could have a significant adverse impact on the financial and operational results of the Company as well as the Company's reputation. Additionally, lawsuits and investigations can be expensive to defend, whether or not the lawsuit or investigation has merit, and the defense of these actions may divert the attention of the Company's management and other resources that would otherwise be engaged in running the Company's business.

As more particularly described herein, the Company, along with other defendants, is currently defending a class action filed in the Superior Court of Québec with respect to the manufacturing, marketing, and/or distribution of opioids in Québec. The claim is for \$30,000, plus interest for compensatory damages for each class member, \$25.0 million from each defendant for punitive damages and pecuniary damages for each class member. The Company believes that the claim against the Company is without merit, and intends to vigorously defend itself. However, there can be no assurance about the outcome of this litigation, including the amount of any judgment or settlement against the Company or possible reputational damage. Even if the Company is successful in defending this claim, the Company could incur significant costs in defending itself. The amount of any judgement or settlement and/or the cost of defending the claim could have a significant adverse impact on the financial and operational results of the Company. See "Legal Proceedings and Regulatory Actions".

Obtaining Government and Regulatory Approvals

The research, testing, manufacturing, packaging, labeling, approval, storage, selling, marketing and distribution of drug products are subject to extensive regulation in the U.S. by the FDA, in Canada by the TPD and by similar regulatory authorities in the E.U., Japan and elsewhere, and regulations and requirements differ from country-to-country. Despite the time and expense exerted by the Company, failure can occur at any stage in the regulatory approval process.

The process of completing a drug development program and obtaining regulatory approval for a drug can be long and may involve significant delays, despite the Company's best efforts, and can require substantial cash and resources. Even after initial approval has been obtained, further research, including post-marketing studies, may be required to expand indications covered under the product approvals and labelling. Also, regulatory agencies require post-marketing surveillance programs to monitor side effects. Results of post-marketing programs may limit or expand additional marketing of the drug. Moreover, regulations are rigorous, time consuming and costly and the Company cannot predict the extent to which it may be affected by changes in regulatory developments and its ability to meet such regulations. There is also a risk that the

Company's products may be withdrawn from the market and the required approvals suspended as a result of non-compliance with regulatory requirements. Furthermore, there can be no assurance that the regulators will not require modification to any submissions, which may result in delays or failure to obtain regulatory approvals. There can also be no assurance that the Company's products will prove to be safe and effective in clinical trials.

In addition to the regulatory approval process, pharmaceutical companies are subject to regulations under local, provincial, state and federal law, including requirements regarding occupational safety, laboratory practices, environmental protection and hazardous substance control and may be subject to other present and future local, provincial, state, federal and foreign regulations, including possible future regulations of the pharmaceutical industry.

Failure to obtain or a delay in obtaining necessary regulatory approvals, the restriction, suspension or revocation of existing approvals or any other failure to comply with regulatory requirements, could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

United States Regulation

The FDA has substantial discretion in the drug approval process. The FDA may delay, limit or deny approval of a drug candidate for many reasons including:

- a drug candidate may not be deemed safe or effective;
- the FDA may find the data from preclinical studies, CMC and clinical trials insufficient;
- the FDA may change its approval policies or adopt new regulations; or
- third-party products may enter the market and change approval requirements.

Even once drug candidates are approved, these approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. The FDA may require further testing and surveillance programs to monitor the pharmaceutical product that has been commercialized. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, injunction actions and criminal prosecutions.

The process of receiving FDA approval has become more complex with the requirement to submit a Risk Evaluation and Mitigation Strategy (REMS) as part of the drug application for certain classes of drugs and some individual drug products. In addition, the FDA may require REMS after approving a covered application, including applications approved before the REMS program was initiated.

The FDA has the authority to regulate the claims the Company's partners make in marketing its prescription drug products to ensure that such claims are true, not misleading, supported by scientific evidence and consistent with the product's approved labelling. Failure to comply with FDA requirements in this regard could result in, among other things, suspensions or withdrawal of approvals, product seizures and injunctions against the manufacture, holding, distribution, marketing and sale of certain of the Company's products, and civil or criminal sanctions.

Canadian Regulation

The TPD may deny issuance of a NOC for an NDS if applicable regulatory criteria are not satisfied or may require additional testing. Product approvals may be withdrawn if compliance with regulatory standards is not maintained or if problems occur after the product reaches the market. The TPD may require further testing and surveillance programs to monitor a pharmaceutical product which has been commercialized. Non-compliance with applicable requirements can result in fines and other judicially imposed sanctions, including product seizures, injunction actions and criminal prosecutions against the Company.

Additional Regulatory Considerations

There is no assurance that problems will not arise that could delay or prevent the commercialization of the Company's products currently under development or that the TPD, FDA or other foreign regulatory agencies will be satisfied with the information submitted by the Company, including results of clinical trials, to approve the marketing of such products. The Company cannot predict the time required for regulatory approval or the extent of clinical testing and documentation that is required by regulatory authorities. Any delays in obtaining, or failure to obtain regulatory approvals in Canada, the U.S., the E.U. or other foreign countries, would significantly delay the development of the Company's markets and the receipt of revenues from the sale of its products.

Demand Fluctuations

In general, the Company's marketing partners are required to provide 12 to 24 month rolling forecasts of their demand on a quarterly basis, and are also required to place firm purchase orders based on the near-term portion of those forecasts. If wholesaler or market demand for certain of the Company's products is lower than forecasted, the Company's marketing partners or their wholesaler customers may accumulate excess inventory. If such conditions persist, the Company's marketing partners may sharply reduce subsequent purchase orders for a sustained period of time until such excess inventory is consumed, if ever. Significant and unplanned reductions in the Company's manufacturing orders have occurred in the past and the Company's results of operations were adversely affected. If such reductions occur again in the future, the Company's revenues will be negatively impacted, economies of scale will be lost, and revenues may be insufficient to fully absorb overhead costs, which could result in net losses. Conversely, if the Company's marketing partners promote significantly increased demand, the Company may not be able to manufacture such unplanned increases in a timely manner, especially following prolonged periods of reduced demand. As the Company has no control over these factors, purchase orders could fluctuate significantly from quarter-to-quarter, and the Company's results of operations could fluctuate accordingly.

Natural Disasters, Climate-Change or Other Events That Disrupt Business Operations

The Company's manufacturing facility is located in Varennes, Québec, where natural disasters or similar events, like blizzards, fires or explosions or large-scale accidents or power outages, could severely disrupt the Company's operations, and materially adversely impact its business, results of operations, financial condition and prospects. If a disaster, power outage or other event occurred that prevented the Company from using all or a significant portion of this facility, that damaged critical infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for the Company to continue its business for a substantial

period of time, which could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

Additionally, the Company and its manufacturers or suppliers may be exposed to climate change risk from natural disasters, changes in weather patterns and severe weather, that may result in physical damage to the Company's manufacturing facility or those of the Company's manufacturers and suppliers. Such damage may result in disrupted operations, and it may be difficult for the Company to continue its business for a substantial period of time, which could materially adversely impact the Company's business, financial condition or operating results and could cause the market value of its Common Shares to decline.

In addition, climate change has continued to attract the focus of governments, the scientific community and the general public as an important threat, given the emission of greenhouse gases and other activities continue to negatively impact the planet. The Company faces the risk that its operations or those of the Company's manufacturers and suppliers will be subject to government initiatives aimed at countering climate change, which could impose constraints on its operational flexibility.

Rapid Technological Change

Pharmaceutical technologies are subject to rapid and significant technological change. The Company expects its competitors will develop new technologies and products that may render the Company's products and drug delivery technologies uncompetitive or obsolete. The products and drug delivery technologies of its competitors may be more effective than the products and drug delivery technologies developed by the Company. As a result, the Company's products may become obsolete before it recovers expenses incurred in connection with their development or realizes revenues from any commercialized products, which could materially adversely impact the Company.

Prolonged Development Time

It takes considerable time to develop new prescription or over the counter drug products, to obtain the necessary regulatory approvals permitting sales, to establish appropriate distribution channels and market acceptance and to obtain insurer reimbursement approvals. This time period is generally from five to more than ten years and it exposes the Company to significant risks, including the development of competing products, loss of investor interest, shifting consumer preferences, changes in personnel and new regulatory requirements. During this lengthy period, the Company often incurs significant development-related costs without generating offsetting revenues.

Publications of Negative Study or Clinical Trial Results

The publication of negative results of studies or clinical trials related to the Company's products, or the therapeutic areas in which its products compete, may adversely affect sales, the prescription trends for the products, the reputation of the products and the market value of the Company's Common Shares. From time-to-time, studies or clinical trials on various aspects of pharmaceutical products are conducted by the Company, academics or others, including government agencies. The results of these studies or trials, when published, may have a dramatic effect on the market for the pharmaceutical product that is the subject of the study. In the event of the publication of negative results of studies or clinical trials related to the Company's marketed

products or the therapeutic areas in which these products compete, there could be a material adverse impact on the Company's business, financial condition or operating results and the market value of its Common Shares could decline.

Risks Related to the Ownership of Securities of the Company

Volatility of Share Price

Market prices for pharmaceutical related securities, including those of the Company, have been historically volatile and subject to substantial fluctuations. The stock market, from time-to-time, experiences significant price and volume fluctuations unrelated to the underlying value of the Company's business or its operating performance. The market price of Common Shares cannot be predicted. Future announcements concerning the Company or its competitors, including announcements regarding the results of testing, technological innovations, new commercial products, marketing arrangements, government regulations, developments concerning regulatory actions affecting the Company's products and its competitors' products in any jurisdiction, developments concerning proprietary rights, litigation, additions or departures of key personnel, cash flow, public concerns about the safety of the Company's products and economic conditions and political factors in the U.S., E.U., Canada or other jurisdictions may have a significant impact on the market price of the Common Shares. To the extent that other companies within the Company's industry experience declines in their stock price, the share price of the Common Shares may decline as well. In addition, there can be no assurance that the Common Shares will continue to be listed on the TSX or OTCQX.

In addition, when the market price of a company's shares drops significantly, shareholders may institute securities class action against the company. A lawsuit against the Company could result in substantial costs and could divert the time and attention of the Company's management and other resources.

Potential Dilution

As a result of the Deerfield Financing, Deerfield now holds the Warrants initially exercisable for 25,555,556 fully paid and non-assessable Common Shares, and the Convertible Notes, initially convertible into 19,444,444 fully paid and non-assessable Common Shares. The Common Shares underlying the Warrants and the Convertible Notes represent approximately 395.14% of the Company's 11,388,282 issued and outstanding Common Shares on a non-diluted basis as of December 31, 2020. If the Warrants and Convertible Notes were to be fully exercised, Deerfield would own approximately 79.8% of the issued and outstanding Common Shares. However, Deerfield does not have the right to convert or exercise such securities if doing so would result in Deerfield and its affiliates and joint actors beneficially owning more than 4.985% of the number of Common Shares (on a non-diluted basis) outstanding immediately after giving effect to such conversion or exercise (the 4.985% Cap). Accordingly, Deerfield is unable to exercise a sufficient number of Warrants or Convertible Notes to materially affect control of the Company.

Deerfield may seek to sell some of their Common Shares upon exercise or conversion of the Warrants and Convertible Notes pursuant to the Registration Rights Agreement. No prediction can be made as to the effect, if any, a future sale of Common Shares by Deerfield will have on the market value of the Common Shares prevailing from time to time. However, the future sale of a substantial number of Common Shares by Deerfield, or the perception that such sale could occur, could adversely affect the market value of the Common Shares.

The potential concentration of the Company's issued and outstanding Common Shares in the hands of one shareholder may discourage an unsolicited bid for the Common Shares, and this may adversely impact the value and trading price of the Common Shares.

The Company may consider issuing debt or equity securities in the future to fund potential acquisitions or for general corporate purposes. If the Company raises additional funding or completes an acquisition or merger by issuing additional equity securities, such issuance may substantially dilute the interests of shareholders of the Company and reduce the value of their investment. The market price of the Common Shares could decline as a result of issuances of new shares or sales by existing shareholders of Common Shares in the market or the perception that such sales could occur. Sales by shareholders might also make it more difficult for the Company itself to sell equity securities at a time and price that it deems appropriate. If the Company incurs debt, it may increase its leverage relative to its earnings or to its equity capitalization, requiring the Company to pay interest expenses. The Company may not be able to market such issuances on favourable terms, or at all, in which case, the Company may not be able to execute its business plan.

Absence of Dividends

The Company has not paid dividends on its Common Shares and does not anticipate declaring any dividends in the near future. As a result, the return on an investment in the Common Shares will depend upon any future appreciation in value. There is no guarantee that the Common Shares will appreciate in value or even maintain the price at which they were purchased.

Active Trading Market for Common Shares

The Company's Common Shares are listed for trading on the TSX and the OTCQX. There can be no assurance that an active trading market in the Company's Common Shares on the TSX and the OTCQX will be sustained.

Securities Industry Analyst Research Reports

The trading market for the Company's Common Shares is influenced by the research and reports that industry or securities analysts publish about the Company or any of its partners. If covered, a decision by an analyst to cease coverage of the Company or failure to regularly publish reports on the Company, could cause the Company to lose visibility in the financial markets, which in turn could cause the stock price or trading volume to decline. Moreover, if an analyst who covers the Company or any of its partners downgrades its or its partner's stock or if operating results do not meet analysts' expectations, the stock price could decline. Currently, to the Company's knowledge, there is one analyst who publishes research reports about the Company. The Company and its products have also been discussed in analyst research reports published about its partners and competitors.

Quarterly Fluctuations

The Company's quarterly and annual operating results are likely to fluctuate in the future. These fluctuations could cause the market value of the Company's Common Shares to decline. The nature of the Company's business involves variable factors, such as the timing of launch and market acceptance of the Company's products, the timing and costs associated with the research, development and regulatory submissions of the Company's products in development, the costs

of maintaining manufacturing facilities operating below capacity and the costs associated with public company and other regulatory compliance. As a result, in some future quarters or years, the Company's clinical, financial or operating results may not meet the expectations of securities analysts and investors which could result in a decline in the price of the Company's Common Shares.

Compliance with Laws and Regulations Affecting Public Companies

Any future changes to the laws and regulations affecting public companies, compliance with existing provisions of Multilateral Instrument 52-109 – *Certification of Disclosure in Issuer's Annual and Interim Filings* of the Canadian Securities Administrators and the other applicable Canadian securities laws, regulations and related rules and policies, may cause the Company to incur increased costs as it evaluates the implications of new rules and implements any new requirements. Delays or a failure to comply with the new laws, rules and regulations could result in enforcement actions, the assessment of penalties or civil suits.

Any new laws and regulations may make it more expensive for the Company to provide indemnities to the Company's officers and directors and may make it more difficult to obtain certain types of insurance, including liability insurance for directors and officers. Accordingly, the Company may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for the Company to attract and retain qualified persons to serve on its Board of Directors or as executive officers. The Company may be required to hire additional personnel and utilize additional outside legal, accounting and advisory services, all of which could cause general and administrative costs to increase beyond what the Company currently has planned. The Company is continuously evaluating and monitoring developments with respect to these laws, rules and regulations and it cannot predict or estimate the amount of the additional costs it may incur or the timing of such costs.

The Company is required annually to review and report on the effectiveness of its internal control over financial reporting in accordance with Multilateral Instrument 52-109 – *Certification of Disclosure in Issuer's Annual and Interim Filings*. The results of this review are reported in the Company's Annual Report and in its Management's Discussion and Analysis of Results of Operations and Financial Condition. The Company's Chief Executive Officer and Chief Financial Officer are required to report on the effectiveness of the Company's internal control over financial reporting.

Management's review is designed to provide reasonable assurance, not absolute assurance, that all material weaknesses existing within the Company's internal controls are identified. Material weaknesses represent deficiencies existing in the Company's internal controls that may not prevent or detect a misstatement occurring which could have a material adverse effect on the quarterly or annual financial statements of the Company. In addition, management cannot provide assurance that the remedial actions being taken by the Company to address any material weaknesses identified will be successful, nor can management provide assurance that no further material weaknesses will be identified within its internal controls over financial reporting in future years.

If the Company fails to maintain effective internal controls over its financial reporting, there is the possibility of errors or omissions occurring or misrepresentations in the Company's

disclosures which could materially adversely impact the Company's business, its financial statements and the market value of the Common Shares.

Public Company Requirements May Strain Resources

As a public company, the Company is subject to the reporting requirements of the *Securities Act* (Ontario), as amended, the regulations and rules thereto, including the national and multilateral instruments adopted as rules, decisions, rulings and orders promulgated under the *Securities Act* (Ontario) and the published policy statements issued by the Ontario Securities Commission (OSC) and the listing requirements of the TSX. The ever-increasing obligations of operating as a public company will require significant expenditures and will place additional demands on management as the Company complies with the reporting requirements of a public company. The Company may need to hire additional accounting, financial and legal staff with appropriate public company experience and technical accounting and regulatory knowledge.

In addition, actions that may be taken by significant stockholders may divert the time and attention of the Company's Board of Directors and management from its business operations. Campaigns by significant investors to effect changes at publicly traded companies have increased in recent years. If a proxy contest were to be pursued by any of the Company's stockholders, it could result in substantial expense to the Company and consume significant attention of management and the Board of Directors. In addition, there can be no assurance that any stockholder will not pursue actions to effect changes in the management and strategic direction of the Company, including through the solicitation of proxies from the Company's stockholders.

DIVIDENDS

Dividends are payable on the Common Shares if and when declared by Miravo's Board of Directors. The Company has never paid dividends on the Common Shares and does not expect to do so in the near future.

Pursuant to the terms of the Deerfield Facility Agreement and the Warrants, during the terms thereof, the Company is prohibited from declaring or paying any dividends or other distribution on the Company's capital stock.

DESCRIPTION OF CAPITAL STRUCTURE

The Company's authorized share capital consists of an unlimited number of Common Shares and an unlimited number of first and second preferred shares, issuable in series, of which 11,388,282 Common Shares and no preferred shares were outstanding as of December 31, 2020.

The following is a description of the material characteristics of the Company's Common Shares and preferred shares including descriptions of other instruments that are convertible or exercisable into Common Shares.

Common Shares

The holders of Common Shares are entitled to receive notice of any meeting of the Company's shareholders and to attend and vote thereat, excepting those meetings at which only those holding another class of shares or a particular series are entitled to vote. Each Common Share entitles its holder to one vote. Subject to the rights of those holding preferred shares, the

holders of Common Shares are entitled to receive on a *pro rata* basis such dividends as the Board of Directors of the Company may declare out of funds legally available. In the event of the dissolution, liquidation, winding-up or other distribution of the Company's assets, such holders are entitled to receive on a *pro rata* basis, all the Company's remaining assets after payment of all liabilities, subject to the rights of the holders of the preferred shares. The Common Shares carry no pre-emptive or conversion rights. The preceding was a summary of the principal characteristics of the Common Shares. A full description of the Common Shares can be found in the Company's Restated Articles of Incorporation dated March 1, 2016. The Restated Articles of Incorporation are available on SEDAR at www.sedar.com (under Nuvo Pharmaceuticals Inc.).

Preferred Shares

Under the Company's Restated Articles of Incorporation, preferred shares may be issued in one or more series, the number, designation, rights, privileges, restrictions and conditions of which are to be determined by the Board of Directors. The preferred shares are entitled to priority over the Common Shares with respect to the payment of dividends and distributions in the event of the dissolution, liquidation or winding-up of the Company. Except as required by law, the holders of first preferred shares as a class, and holders of second preferred shares as a class, are not entitled to receive notice of, attend or vote at any meeting of the Company's shareholders. Pursuant to the Deerfield Facility Agreement, the Company is not permitted to issue preferred shares.

The preceding was a summary of the principal characteristics of the preferred shares. A full description of the preferred shares can be found in the Company's Restated Articles of Incorporation dated March 1, 2016. The Restated Articles of Incorporation are available on SEDAR at www.sedar.com (under Nuvo Pharmaceuticals Inc.).

Securities Convertible or Exercisable into Common Shares

Warrants

The Warrants are exercisable into Common Shares commencing on the date that Shareholder approval was obtained for the underlying issuance of Common Shares, being March 11, 2019. Prior to the exercise of the Warrants into Common Shares, the holder is not entitled to any rights as a Shareholder including with respect to voting, participation or comparable rights. If, as and when exercised, the Common Shares issued to such holder will entitle such holder to one vote per Common Share. Upon any exercise of the Warrants, the Company will deliver Common Shares on the basis of one Warrant for one Common Share.

Any holder of the Warrants shall be obligated to exercise the Warrants through cash payment of the exercise price. The exercise price of the Warrants is CDN\$3.53.

The Warrants are subject to the 4.985% Cap. That is, any holder of the Warrants will not have the right to exercise the Warrants if doing so would result in such holder and its affiliates and joint actors beneficially owning more than 4.985% of the number of Common Shares (on a non-diluted basis) outstanding immediately after giving effect to such exercise.

Following a Major Transaction (as defined in the Warrants), subject to certain conditions, the Warrants will become exercisable for an additional number of Common Shares determined in accordance with the terms of the Warrants, subject to continued application of the 4.985% Cap,

except that in the case of certain Major Transactions involving the conversion of the Common Shares into the right to receive cash, securities or other assets (either under the Major Transaction or a subsequent liquidation of the Company), a holder of Warrants is permitted to exercise the Warrants (without the application of the 4.985% Cap) for the additional number of Common Shares described above immediately prior to and conditional upon completion of the Major Transaction, such that the holder ultimately receives the cash, securities or other assets, as applicable, in exchange for such Common Shares on the same terms as other holders of Common Shares.

If the Company shall at any time effect any subdivision of outstanding Common Shares (by any share split, share dividend, recapitalization or otherwise), combination of outstanding Common Shares (by consolidation, combination, reverse share split or otherwise), reclassification or other similar transaction of such character that Common Shares shall be changed into or become exchangeable for a larger or smaller number of shares (a Stock Event), then upon the effective date thereof, the aggregate number of Common Shares which the holder is entitled to purchase upon exercise of the Warrants shall be increased or decreased, as the case may be, in direct proportion to the increase or decrease in the number of Common Shares by reason of such Stock Event, and the exercise price shall be, in the case of an increase in the number of shares, proportionally decreased and, in the case of decrease in the number of shares, proportionally increased.

The Warrants are not transferrable to a person or entity engaged directly in the operation of a healthcare or pharmaceutical business without the consent of the Company.

Convertible Notes

The Convertible Notes are convertible into Common Shares commencing the date that Shareholder approval was obtained for the underlying issuance of Common Shares, being March 11, 2019. Prior to the conversion of the Convertible Notes into Common Shares, the holder is not entitled to any rights as a shareholder including with respect to voting, participation or comparable rights. If, as and when converted, the Common Shares issued to such holder will entitle such holder to one vote per Common Share.

The term of the Convertible Notes is six years, with 3.5% interest per annum, payable quarterly in arrears. Upon the expiration of the term, any outstanding Convertible Notes shall be repaid by the Company in cash to the holder thereof. The Convertible Notes shall convert into Common Shares at the conversion price of US\$2.70 per share.

The Convertible Notes are subject to the 4.985% Cap. That is, any holder of the Convertible Notes will not have the right to convert the Convertible Notes if doing so would result in such holder and its affiliates and joint actors beneficially owning more than 4.985% of the number of Common Shares (on a non-diluted basis) outstanding immediately after giving effect to such conversion.

Following a Major Transaction (as defined in the Convertible Notes), subject to certain conditions, the Convertible Notes will become convertible into (i) the number of Common Shares into which they were convertible prior to the Major Transaction, and (ii) an additional number of Common Shares, based on a calculation set forth in the Convertible Notes, subject to continued application of the 4.985% Cap following the Major Transaction, except that in the case of certain Major Transactions involving the conversion of the Common Shares into the right to receive cash,

securities or other assets (either under the Major Transaction or a subsequent liquidation of the Company), a holder of Convertible Notes is permitted to convert Convertible Notes (without the application of the 4.985% Cap) into the additional number of Common Shares described above immediately prior to and conditional upon completion of the Major Transaction, such that the holder ultimately receives the cash, securities or other assets, as applicable, in exchange for such Common Shares on the same terms as other holders of Common Shares.

If the Company shall at any time effect any Stock Event, then upon the effective date thereof, or, if applicable, the record date therefor, the conversion price in effect on such date shall be adjusted in direct proportion to the adjustment to the number of Common Shares resulting from such Stock Event, such that in the case of an increase in the number of Common Shares, the conversion price shall be proportionally decreased, and in the case of an increase in the number of Common Shares, the conversion price shall be proportionally decreased.

The Convertible Notes are not transferrable to a person or entity engaged directly in the operation of a healthcare or pharmaceutical business without the consent of the Company.

The preceding was a summary of the principal characteristics of the Warrants and Convertible Notes. The forms of the Warrants and Convertible Notes are available on SEDAR at www.sedar.com (under Nuvo Pharmaceuticals Inc.).

MARKET FOR SECURITIES

The Common Shares are listed and posted for trading on the TSX under the symbol “MRV”. The Common Shares are also traded in the U.S. on the OTCQX as “MRVFF” and on the Unofficial Regulated Markets of many German stock exchanges including the Frankfurt Stock Exchange, the Berlin Stock Exchange, the Munich Stock Exchange and the XETRA electronic trading system of the Deutsche Börse.

The following table provides information on the monthly price range and trading volume for the Common Shares on the TSX during the year ended December 31, 2020:

Month	Low	High	Volume
	\$	\$	
January 2020	0.47	0.60	516,687
February 2020	0.57	1.14	483,742
March 2020	0.55	0.96	401,113
April 2020	0.45	1.00	499,562
May 2020	0.67	0.91	356,356
June 2020	0.73	0.81	220,488
July 2020	0.65	0.79	140,863
August 2020	0.68	0.79	602,394
September 2020	0.72	0.92	213,413
October 2020	0.80	0.95	260,600
November 2020	0.78	0.90	357,600
December 2020	0.81	0.95	285,500

As part of the Deerfield Financing, the Company's subsidiary, Miravo Ireland, issued certain loan notes to Deerfield in relation to the Amortization Loan in the aggregate amount of US\$60 million, which loan notes were admitted to listing on a recognized stock exchange in March 2019 pursuant to the Deerfield Facility Agreement. The Company has guaranteed the loan notes and each of the loan notes will be a quoted "Eurobond" within the meaning of Section 64(1) of the *Tax Consolidation Act 1997* (Ireland). See "General Development of the Business – Recent Financings – The Deerfield Financing".

DIRECTORS AND OFFICERS

The following table sets forth the name, municipality of residence, position with the Company and principal occupation of each director and executive officer of the Company. Directors of the Company hold office until the next annual Shareholders' meeting or until successors are duly elected or appointed.

Name and Residence	Principal Occupation	Director Since	Number of Common Shares Beneficially Owned
Robert Harris ⁽¹⁾⁽⁷⁾ Ontario, Canada	Executive Chairman of Miravo	May 11, 2017	75,000
John C. London ⁽²⁾⁽⁵⁾⁽⁶⁾ Ontario, Canada	Vice Chairman of Miravo	September 21, 2004	155,786
Daniel N. Chicoine ⁽³⁾⁽⁴⁾⁽⁵⁾ Ontario, Canada	Executive Chairman, Crescita Therapeutics Inc.	September 21, 2004	235,784
David A. Copeland ⁽⁶⁾⁽⁹⁾⁽¹⁰⁾ Ontario, Canada	Private Business Investor	September 21, 2004	57,692
Anthony E. Dobranowski ⁽⁴⁾⁽⁸⁾ Ontario, Canada	Private Business Investor	September 21, 2004	52,819
Jesse F. Ledger ⁽¹¹⁾ Ontario, Canada	President & Chief Executive Officer of Miravo	N/A	98,886
Mary-Jane E. Burkett ^{(12) (13)} Ontario, Canada	Vice President & Chief Financial Officer of Miravo	N/A	10,390
Katina K. Loucaides Ontario, Canada	Vice President, Secretary and General Counsel of Miravo	N/A	23,126
Kelly A. Demerino Ontario, Canada	Interim Chief Financial Officer	N/A	1,200

(1) Robert Harris was appointed Executive Chairman January 1, 2019.

(2) John London was appointed Vice Chairman January 1, 2019. He had previously held the positions of Executive Chairman and Chief Executive Officer.

- (3) Daniel N. Chicoine is the Executive Chairman of Crescita Therapeutics Inc. The principal business of Crescita Therapeutics Inc. is a portfolio of dermatology prescription and non-prescription products.
- (4) Member of the Audit Committee.
- (5) Member of the Compensation, Corporate Governance & Nominating Committee.
- (6) Member of the Transaction Committee.
- (7) Chairman of the Transaction Committee
- (8) Chairman of the Compensation, Corporate Governance & Nominating Committee.
- (9) Chairman of the Audit Committee.
- (10) Lead Director.
- (11) Jesse Ledger was appointed President & Chief Executive Officer in November 2017. He had previously held the position of President and joined Miravo in April 2016 in the role of Vice President, Business Development.
- (12) Mary-Jane Burkett joined Miravo in December 2012 and was appointed Vice President & Chief Financial Officer in September 2016.
- (13) Maternity leave as of March 2020.

Each of the directors and executive officers of the Company has been engaged for more than five years in his or her present principal occupation or in other capacities with the corporation or organization (or predecessor thereof) in which he or she currently holds his or her principal occupation, with the exception of the following: Mr. Ledger was the Vice President, Business Development & International Business of Tribute Pharmaceuticals prior to joining Miravo in April 2016. Mr. Harris was the President & Chief Executive Officer of Tribute Pharmaceuticals until he retired in 2016.

As at December 31, 2020, the directors and executive officers of Miravo, as a group, beneficially owned, directly or indirectly, or exercised control or direction of 710,683 Common Shares, 6% of the Company's Common Shares, or 1% assuming all potentially dilutive instruments were exercised or converted.

Individual Bankruptcies

None of the Company's existing directors or executive officers, and to the best of the Company's knowledge, no Shareholder holding a sufficient number of securities to affect materially the control of the Company, has, within the ten years prior to the date of this AIF, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or become 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 that individual.

Corporate Cease Trade Orders and Bankruptcies

Except as disclosed below, none of the Company's existing directors or executive officers, and to the best of the Company's knowledge, no Shareholder holding a sufficient number of securities to affect materially the control of the Company is, as at the date of this AIF, or has been within the ten years before the date of this AIF, (i) a director, chief executive officer or chief financial officer of any company that was subject to an order that was issued while the existing director or executive officer was acting in the capacity as director, chief executive officer or chief financial officer, or (ii) was subject to an order that was issued after the existing 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, or (iii) a director or executive officer of any company that, while that person was acting in that 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. For the purposes of this paragraph, "order" means a cease trade order, an order similar to a cease trade

order or an order that denied the relevant company access to any exemption under securities legislation, in each case, that was in effect for a period of more than 30 consecutive days.

Rob Harris was a director of Aralez until his resignation in August 2018. Aralez commenced voluntary proceedings under the CCAA in Canada and Chapter 11 in the U.S. in August 2018.

Penalties or Sanctions

None of the Company's directors or executive offices, and to the best of the Company's knowledge, no shareholder holding a sufficient number of securities to affect materially the control of the Company, has been subject to 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 has been subject to any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor making an investment decision.

Conflicts of Interest

Certain directors and officers of Miravo or its subsidiaries are, and may continue to be, directors, officers or shareholders of other companies whose operations may, from time-to-time, be in direct competition with those of Miravo or with entities which may, from time-to-time, provide financing to, or make equity investments in competitors of Miravo. In accordance with the *Business Corporations Act* (Ontario), such directors and officers will be required to disclose all conflicts of interest as such conflicts arise. If a conflict of interest arises at a meeting of the Board of Directors, any director in a conflict will disclose his or her interest and abstain from voting on such matter.

LEGAL PROCEEDINGS AND REGULATORY ACTIONS

The Company, or the intellectual property in respect of certain of its products, has been involved in the following legal proceedings during the last financial year, all in the normal course of business and relating to patent claims. While it is not possible to determine the outcome of these matters, in the event of an adverse outcome or outcomes, the Company's business could be materially harmed.

Vimovo

Pursuant to the Aralez Transaction, on December 31, 2018, Miravo Ireland acquired the worldwide rights and royalties from licensees for Vimovo from POZEN. See "General Development of the Business – Significant Acquisitions – The Aralez Transaction".

In the U.S., Horizon has control over and is responsible for the patent litigation related to Vimovo pursuant to the amended and restated collaboration and license agreement between the parties. Further, Horizon has certain rights to settle such litigation without Miravo Ireland's consent in certain circumstances.

Currently, there is one active patent litigation matter in the U.S. against Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. (collectively, Dr. Reddy's) involving U.S. the

'996 and '920 Patents in the New Jersey District Court. This case is list in the following table and summarized below.

Name	Number	District	Filed
Horizon Pharma, Inc. et al v. Dr. Reddy's Laboratories, Inc. et al	2-15-cv-03324	NJD	May 13, 2015

Horizon and Miravo Ireland reached litigation settlements with five other generic companies: (i) Teva Pharmaceuticals Industries Limited (formerly known as Actavis Laboratories FL, Inc., which itself was formerly known as Watson Laboratories, Inc. - Florida) and Actavis Pharma, Inc. (collectively, Actavis Pharma) (ii) Lupin; (iii) Mylan Pharmaceuticals Inc., Mylan Laboratories Limited, and Mylan Inc. (collectively, Mylan); Ajanta Pharma Ltd. and Ajanta Pharma USA, Inc. (collectively, Ajanta); and Anchen Pharmaceuticals, Inc. (Anchen). Certain of these settlement agreements include provisions allowing generic versions of Vimovo to enter the U.S. market as a consequence of Dr. Reddy's launching their generic version of Vimovo in March 2020.

Historical Litigation - '907 and '285 Patents

In May 2019, the U.S. Court of Appeals for the Federal Circuit (Court of Appeals) reversed a decision made in June 2017 by the New Jersey District Court. As a result, the '907 and '285 Patents owned by Miravo Ireland and licensed to Horizon covering Vimovo in the U.S were invalidated. On June 15, 2019, Miravo Ireland and Horizon filed an *en banc* request to the Court of Appeals seeking to have the court reconsider the May 2019 decision. On July 30, 2019, the Court of Appeals denied the request to reconsider their decision invalidating the two patents. Miravo Ireland and Horizon filed a petition to the Supreme Court of the United States (Supreme Court) in October 2019 to request to have the decision of the Court of Appeals reconsidered. The Supreme Court denied that petition on January 13, 2020. On February 18, 2020, Dr. Reddy's second-filed ANDA for Vimovo in the U.S. received FDA approval. Dr. Reddy's launched a generic version of Vimovo in the U.S. in March 2020. As discussed above, Horizon and Miravo Ireland have entered into litigation settlements with a number of generic companies and certain of these agreements include provisions allowing generic versions of Vimovo to enter the U.S. market as a consequence of Dr. Reddy's launching its generic version of Vimovo in March 2020. Pursuant to the agreement with Horizon, if, and when, a competitor generic version of Vimovo enters the U.S. market, Miravo Ireland will continue to receive a 10% royalty on net sales of Vimovo in the U.S., subject to a step-down provision in the event that generic competition achieves a certain market share. As of December 31, 2020, generic competition did not achieve the quantum of the market share to trigger the step-down provision. Miravo Ireland's US\$7.5 million minimum annual royalty due for Vimovo net sales in the U.S. ceased with the launch of a generic Vimovo in the U.S.

Pending Litigation - '996 and '920 Patents

Miravo Ireland has other patents to protect Vimovo in the U.S. and, as mentioned above, there is ongoing patent litigation against Dr. Reddy's with respect to the '996 and '920 Patents in the New Jersey District Court. As a result, Dr. Reddy's launch of a generic Vimovo is considered to be an "at risk" launch. If Miravo Ireland's other patents are found by the New Jersey District Court to be infringed and not invalid in the ongoing litigation, Miravo Ireland and Horizon could seek damages from Dr. Reddy's.

Dr. Reddy's filed a motion for summary judgment in the New Jersey District Court in August 2019 asserting that the '996 and '920 Patents were invalid as a result of the decision of the Court of Appeals that invalidated the '907 and '285 Patents. The New Jersey District Court denied this motion in November 2019, and the litigation against Dr. Reddy's involving '996 and '920 Patents continued.

Miravo Ireland and its partner filed a motion for a preliminary injunction in the New Jersey District Court in November 2019 requesting that Dr. Reddy's be preliminarily enjoined from infringing the '996 and '920 Patents. In December 2019, the New Jersey District Court denied this motion. Miravo Ireland and Horizon moved for reconsideration of the decision and the Court denied this motion on February 4, 2020.

Dr. Reddy's filed a second motion for summary judgement in the New Jersey District Court in October 2020 asserting that the '996 and '920 Patents are invalid as a result of the Court of Appeals decision that invalidated the '907 and '285 Patents, this time in view of the district court's August 2020 claim construction decision. In February 2021, the New Jersey District Court denied this motion, and as a result the pending litigation against Dr. Reddy's involving the '996 and '920 Patents continues.

Vimovo is protected by multiple patents listed in the FDA Orange Book. While Horizon is responsible for this litigation, including the costs of same, the Company nevertheless will have to incur additional expenses in connection with the lawsuits relating to Vimovo, which may be substantial and could materially adversely impact the Company's future revenue from Vimovo royalties. Moreover, responding to and defending pending litigation results in a significant diversion of management's attention.

Fiorinal

On October 30, 2019, Aralez Canada received an amended application for authorization to institute a class action against a group of 34 defendants, including Aralez Canada, that manufacture, market, and/or distribute opioids in Québec. The claim is for \$30,000, plus interest for compensatory damages for each class member, \$25.0 million from each defendant for punitive damages and pecuniary damages for each class member. The proposed class is all natural persons in Québec who have been prescribed and consumed any one or more of the opioids manufactured, marketed, distributed and/or sold by the defendants between 1996 and the present day and who suffer or have suffered from opioid use disorder. The proposed class includes any direct heirs of any deceased persons who met the above-description and excludes certain persons subject to a prior settlement agreement. The amended application is currently pending before the Superior Court in the Province of Québec. The Company has never promoted or made any claims outside of the approved Health Canada label and believes that the claim is without merit and intends to vigorously defend the matter. See "Risk Factors – General Litigation and Class Action Litigation".

INTERESTS OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Other than as set out below and elsewhere in this AIF, none of the following persons has any material interest, direct or indirect, in any transaction within the three most recently completed financial years or during the current financial year that has materially affected or will materially affect the Company:

- (a) a director or executive officer of the Company;
- (b) a person or company that is the direct or indirect beneficial owner of, or who exercises control or direction over, more than 10% of any class or series of the Company's outstanding voting securities; and
- (c) an associate or affiliate of any of the persons or companies referred to in paragraphs (a) or (b).

TRANSFER AGENT

The transfer agent and registrar for the Common Shares is AST Trust Company at its office in Toronto, Ontario, Canada.

AUDIT COMMITTEE

Charter of the Audit Committee

The Audit Committee of the Company's Board of Directors has developed its Charter, the text of which is set forth in Appendix I to this AIF.

Composition of the Audit Committee

The Audit Committee is comprised of three members: David A. Copeland, Anthony E. Dobranowski and Daniel N. Chicoine. Each member is independent and financially literate as defined in Multilateral Instrument 52-110 - *Audit Committees*.

Relevant Education and Experience of Audit Committee Members

In addition to each member's general business experience, the education and experience relevant to the performance of Audit Committee responsibilities are set forth below.

David A Copeland

Mr. Copeland has been Miravo's Lead Director and member of the Audit Committee since 2004. He was the Chair of Miravo's Audit Committee until February 2016 and assumed this role again in May 2017. He is also a member of the Transaction Committee. Mr. Copeland was the former President and Chief Operating Officer of Triam Automotive Inc., an automobile parts supplier. From 1984 to 1992, Mr. Copeland held a number of senior management positions at Magna International Inc. (Magna), a global automotive parts supplier, including Chief Financial Officer of Magna and Chief Executive Officer of the Cosma Group of Magna. Mr. Copeland has been an advisor, investor and director in a number of private early stage companies since 1998. His background includes a focus on business valuation and mergers and acquisitions (M&A). Since March 2016, Mr. Copeland has been a director and a member of the Audit Committee and the Compensation, Corporate Governance & Nominating Committee of Crescita Therapeutics Inc. (Crescita). Mr. Copeland is a Chartered Professional Accountant and a Chartered Accountant and holds a Bachelor of Mathematics degree from the University of Waterloo.

Anthony E. Dobranowski

Mr. Dobranowski has been a Miravo director and member of the Audit Committee and the Compensation, Corporate Governance & Nominating Committee since 2004. He assumed the role of Chair of the Compensation, Corporate Governance & Nominating Committee in 2018. Mr. Dobranowski retired from Magna in 2007. During his employment with Magna, Mr. Dobranowski was most recently a Vice President, and prior to that held various executive positions (Vice Chairman, President and Chief Financial Officer) at Tesma International Inc. (Tesma), a publicly traded Magna subsidiary. He was instrumental in the initial public offering of Tesma in 1995, and was involved in all aspects of Tesma's growth, with particular emphasis on financing, investor relations and M&A activity. Previous to that, Mr. Dobranowski held various senior management positions with other Magna companies. Since March 2016, Mr. Dobranowski has been the Lead Director, the Chair of the Corporate Governance, Compensation & Nominating Committee and a member of the Audit Committee of Crescita. Mr. Dobranowski is a Chartered Professional Accountant and a Chartered Accountant and holds Bachelor of Science and Masters of Business Administration degrees from the University of Toronto.

Daniel N. Chicoine

Mr. Chicoine has been a Miravo Director since March 2016 and has been a member of the Audit Committee since March 1, 2019. Previously, Mr. Chicoine served as Miravo's Chairman and Co-CEO and was actively involved in its day-to-day operations since 2004. In March 2016, Mr. Chicoine was appointed the Chairman & Chief Executive Officer of Crescita. Since April 2018, he has served as Crescita's Executive Chairman. Since July 2020, Mr. Chicoine has served as a Director and Chair of the Audit Committee at NeuPath Health Inc. From 2001 to 2004, Mr. Chicoine served as the Chief Financial Officer at Cosma International, Magna's body and chassis systems group. Mr. Chicoine served as the President of PowerCart Systems Inc., a Markham-based private company that designs and manufactures battery-equipped workstations that power devices with wireless communication capability. Previously, Mr. Chicoine served as Vice Chairman in charge of sales at Triam Automotive Inc. From 1982 to 1993, Mr. Chicoine held various positions at the Magna group of companies, including President and Chief Executive Officer of Atoma International Inc. Mr. Chicoine is a graduate of the University of Toronto in commerce and is a Chartered Professional Accountant.

Audit Fees

The following table outlines the fees paid or payable to Ernst & Young LLP, the Company's auditors, for the years ended December 31, 2020 and December 31, 2019.

Fees	Year ended December 31, 2020 \$	Year ended December 31, 2019 \$
Audit Fees ⁽¹⁾	482,728	568,247
Tax Fees ⁽²⁾	48,385	59,790
TOTAL	531,113	628,037

- (1) Audit fees include fees for the quarterly interim reviews, the annual audit and statutory audit fees for a subsidiary within the scope of the consolidated audit.
- (2) Tax fees include fees incurred for tax planning and tax advice for the Company's Canadian and Irish operations.

MATERIAL CONTRACTS

The only material contracts entered into by the Company during the recently completed financial year or prior to the most recently completed financial year (but after January 1, 2002) that are still in effect, other than in the ordinary course of business, are as follows:

- Facility Agreement among Nuvo Pharmaceuticals Inc., Nuvo Pharmaceuticals (Ireland) Designated Activity Company, Deerfield Private Design Fund III, L.P., and Cortland Capital Market Services LLC, dated December 31, 2018 as amended. See “General Development of the Business – Recent Financings – The Deerfield Financing”.
- License Agreement between Aralez Pharmaceuticals Canada Inc. and Assertio Therapeutics, Inc. dated November 9, 2010, as amended by Amendment No. 1 dated August 11, 2011, as amended by Amendment No. 2 dated September 30, 2012 and as amended by Amendment No. 3 dated February 12, 2019, and Letter Agreement between Assertio Therapeutics, Inc. and Nuvo Pharmaceuticals Inc. dated November 16, 2018. See “General Development of the Business – Products Commercialized by Miravo in Canada – Cambia”.
- Bilastine License and Supply Agreement between Aralez Pharmaceuticals Canada Inc. and Faes Farma, S.A. dated May 13, 2014, as amended on April 17, 2018 and January 18, 2019, and Letter Agreement among Faes Farma, S.A., Aralez Pharmaceuticals Inc. and Nuvo Pharmaceuticals Inc. dated October 29, 2018. See “General Development of the Business – Products Commercialized by Miravo in Canada – Blexten”.
- Share Purchase Agreement among Nuvo Pharmaceuticals Inc., Aralez Pharmaceuticals Inc., and Aralez Pharmaceuticals Canada Inc. dated September 18, 2018. See “General Development of the Business – Significant Acquisitions – The Aralez Transaction”.
- Asset Purchase Agreement among Nuvo Pharmaceuticals (Ireland) Designated Activity Company, POZEN Inc. and Aralez Pharmaceuticals Trading DAC dated September 18, 2018. See “General Development of the Business – Significant Acquisitions – The Aralez Transaction”.
- Amended and Restated Collaboration and License Agreement for the U.S. between Nuvo Pharmaceuticals (Ireland) Designated Activity Company and Horizon Pharma USA, Inc. dated November 18, 2013, as amended pursuant to Amendment No. 1 dated November 18, 2013 and Amendment No.2 dated February 22, 2018, and Three Party Letter Agreement dated November 18, 2013. See “General Development of the Business – Products Out-Licensed and/or Manufactured by Miravo – Vimovo”.
- Amended and Restated Collaboration and License Agreement for Rest of World, between Nuvo Pharmaceuticals (Ireland) Designated Activity Company and AstraZeneca AB dated as of November 18, 2013, and as assigned to Grünenthal GmbH on December 3, 2018, and Three Party Letter Agreement dated November 18, 2013. See “General Development of the Business – Products Out-Licensed and/or Manufactured by Miravo – Vimovo”.

- Asset Transfer Agreement between Nuvo Pharmaceuticals Inc. and Nuvo Pharmaceuticals (Ireland) DAC dated January 11, 2018. See “General Development of the Business – Significant Acquisitions – Resultz ex-U.S. Asset Purchase”.
- The U.S. Asset Purchase Agreement between Nuvo Pharmaceuticals (Ireland) DAC and Piedmont Pharmaceuticals LLC dated January 12, 2018. See “General Development of the Business – Significant Acquisitions – Resultz U.S. Asset Purchase”.
- The Supply Agreement between the Company and Horizon Pharma Ireland Limited dated October 17, 2014, as amended by Amendment No. 1 to Supply Agreement, dated as of February 4, 2016, Amendment No. 2 to Supply Agreement, dated as of January 1, 2017, and Amendment No. 3 to Supply Agreement, dated as of February 12, 2018.

EXPERTS

The Company’s Consolidated Financial Statements for the year ended December 31, 2020 were audited by Ernst & Young LLP (EY), independent auditors appointed by the shareholders of the Company upon the recommendation of the Board of Directors. EY has confirmed that it is independent with respect to the Company within the context of the CPA Code of Professional Conduct of the Chartered Professional Accountants of Ontario. A copy of the consolidated annual financial statements of the Trust, including the external auditor’s report thereon, is available at www.sedar.com (under Nuvo Pharmaceuticals Inc.).

ADDITIONAL INFORMATION

Additional information regarding the Company can be found at www.sedar.com (under Nuvo Pharmaceuticals Inc.). Additional information on Miravo, including directors’ and officers’ remuneration and indebtedness, principal holders of the Company’s securities, options to purchase securities and interests of insiders in material transactions is contained in the Company’s Management Information Circular for its most recent annual meeting of Shareholders involving the election of directors. Additional financial information is provided in the Company’s Consolidated Financial Statements and Notes to the Consolidated Financial Statements and Management’s Discussion and Analysis for the year ended December 31, 2020.

Copies of the Company’s Report to Shareholders, including its Consolidated Financial Statements and Notes to the Consolidated Financial Statements and Management’s Discussion and Analysis for the year ended December 31, 2020, and this AIF may be obtained upon request from the Company’s Investor Relations Department or on the Company’s website: www.miravohealthcare.com.

GLOSSARY OF TERMS

Abbreviated New Drug Application	An Abbreviated New Drug Application (ANDA) contains data that, when submitted to the FDA provides for the review and ultimate approval of a generic drug product. Generic drug applications are called “abbreviated” because they are generally not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, a generic applicant must scientifically demonstrate that its product is bioequivalent (i.e. performs in the same manner as the innovator drug).
Active Pharmaceutical Ingredient	An Active Pharmaceutical Ingredient (API) is any substance or mixture of substances intended to be used in the manufacture of a drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure and function of the body.
Blexten	Blexten is a second generation antihistamine drug for the symptomatic relief of allergic rhinitis and chronic spontaneous urticaria
Cambia	Cambia (diclofenac potassium for oral solution) is an NSAID and is currently the only prescription NSAID approved in Canada for the acute treatment of migraine attacks with or without aura in adults 18 years of age or older.
Companies' Creditors Arrangement Act	Companies' Creditors Arrangement Act (CCAA) has the meaning ascribed thereto in “Significant Acquisitions – Aralez Transaction”.
Chemistry, Manufacturing and Controls	Chemistry, Manufacturing and Controls (CMC) constitutes that part of pharmaceutical development that deals with the nature of the drug substance (API) and drug product, the manner in which both are made, and the manner by which the manufacturing process is shown to be in control. CMC considerations include formulation development, manufacturing process and equipment, container-closure system (packaging), stability evaluation and shelf life (storage condition) and specifications for raw materials/components and the finished drug product.
Clinical Trials	The regulated process by which new drugs proceed after discovery through to acceptance for marketing to patients. The term most correctly refers to the period during which new compounds are tested in human subjects and encompasses the several phases as outlined under “Narrative Description of Business – Regulatory Environment and Drug Development Process”.
Common Shares	Common Shares means the Common Shares in the capital of the Company.

Contract Manufacturing Organization	A Contract Manufacturing Organization (CMO) manufactures products under contract for other companies.
Contract Research Organization	A Contract Research Organization (CRO) is a company that conducts research on behalf of a pharmaceutical or biotechnology company.
Corruption of Foreign Public Officials Act	Corruption of Foreign Public Officials Act (CFPOA) has the meaning ascribed thereto in "Risk Factors – Risk Related to the Industry in which the Company Operates – Laws and Regulations".
Controlled Heat-Assisted Drug Delivery	A Controlled Heat-Assisted Drug Delivery (CHADD) unit contains a heat-generating powder that consists of a proprietary mixture of several non-toxic ingredients which produce heat when exposed to air.
Clinical Trial Application	A Clinical Trial Application (CTA) that must be submitted to Health Canada and deemed acceptable prior to the initiation of conducting a clinical trial using a new drug involving human subjects.
Diclofenac sodium	An NSAID that is the API in Pennsaid 2% and Pennsaid.
DMSO	Dimethyl sulfoxide (DMSO) is the molecular penetration enhancer used in Pennsaid 2% and Pennsaid.
Drug Master File	A Drug Master File (DMF) is a submission to the FDA that may be used to provide confidential, detailed information about facilities, processes or articles employed in the manufacturing, processing, packaging, and storing of one or more human drugs. Neither law nor FDA regulations require the submission of a DMF. A DMF is submitted solely at the discretion of the holder. The DMF holder provides the written authorization to the FDA that allows the review of the Master File to support other regulatory applications. The information contained in a DMF may be used to support an Investigational New Drug Application (IND), a New Drug Application (NDA), an Abbreviated New Drug Application, another DMF, an Export Application or amendments to any of these. DMF's are generally created to allow a party other than the holder of the DMF to reference material without disclosing to that party the contents of the file.
Efficacy	Capacity for producing a desired result or effect.
European Medicines Agency	The European Medicines Agency (EMA) regulates the research, development, manufacture and marketing of pharmaceutical products
FCPA	FCPA has the meaning ascribed thereto in "Risk Factors – Risk Related to the Industry in which the Company Operates – Laws and Regulations".
Food and Drug Administration	The U.S. Food and Drug Administration (FDA), an agency within the Department of Health and Human Services, the U.S. government's principal agency for protecting the health of all

	Americans, which is among other responsibilities charged with regulating pharmaceutical products in the U.S.
Food and Drug Administration Orange Book	Food and Drug Administration (FDA) Orange Book means the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations.
Good Clinical Practices and Good Laboratory Practices	Good Clinical Practices (GCP) and Good Laboratory Practices (GLP) are standards for the conduct of clinical trials (including laboratory studies) the data from which are expected to be submitted to a regulatory agency such as the FDA. In the case of GLP these practices are defined by regulation. GCP have arisen from general accepted clinical practices within the industry.
General Data Protection Regulation	General Data Protection Regulation (GDPR) has the meaning ascribed thereto in "Risk Factors – Risk Related to the Industry in which the Company Operates – Laws and Regulations".
Good Manufacturing Practices	Good Manufacturing Practices (GMP), i.e. guidelines established by the governments of various countries, including Canada and the U.S., to be used as a standard in accordance with the World Health Organization's Certification Scheme on the quality of pharmaceutical products.
Heated Lidocaine/Tetracaine Patch	The HLT Patch is a topical patch that combines lidocaine, tetracaine and heat, using Miravo's proprietary Controlled Heat-Assisted Drug Delivery (CHADD™) technology.
Investigational New Drug	An investigational New Drug application (IND) which must be filed and accepted by the FDA before human clinical trials may begin.
Isopropyl myristate	Isopropyl myristate is a polar emollient and is used in cosmetic and topical medicinal preparations where good absorption into the skin is desired.
Lidocaine	A common local anesthetic drug, when used topically, relieves pain by blocking signals at the nerve endings in skin and underlying tissues.
New Drug Application	New Drug Application (NDA), a document containing preclinical, clinical and chemistry, manufacturing and control data collected on a drug. An NDA is submitted to the FDA in order to obtain approval to market a prescription drug in the U.S.
Naproxen	An anti-inflammatory drug often used in the treatment of headache and arthritis.
New Drug Submission	A New Drug Submission (NDS) is an application submitted to Health Canada containing information on a drug's safety, effectiveness and quality in order to obtain approval to market the drug in Canada.
Notice of Compliance	A notification, issued by Health Canada, indicating that a manufacturer has complied with relevant sections of the Food and Drug Regulations following the satisfactory review of a

	submission (NOC). This notification serves as the marketing authorization for a new drug in Canada.
No Objection Letter	A notification, issued by Health Canada, indicating that an application for a clinical trial application is deemed acceptable (NOL).
Patient Protection and Affordable Care Act	ACA has the meaning ascribed thereto in “Risk Factors – Risk Related to the Industry in which the Company Operates – Legislative or Regulatory Reform of the Healthcare System”.
Osteoarthritis	Osteoarthritis (OA) is a type of arthritis that is caused by the breakdown and eventual loss of the cartilage of one or more joints. Cartilage is a connective tissue that serves as a “cushion” between the bones of the joints.
OTCQX	OTCQX means the OTCQX over the counter market provided and operated by the OTC Market Group.
Pennsaid	Pennsaid is used to treat the signs and symptoms of osteoarthritis of the knee. Pennsaid is a combination of a DMSO-based transdermal carrier and 1.5% diclofenac sodium and delivers the active drug through the skin at the site of pain.
Pennsaid 2%	Pennsaid 2% is a topical pain product that combines a dimethyl sulfoxide (DMSO) based transdermal carrier with 2% diclofenac sodium, a leading NSAID, compared to 1.5% for original Pennsaid. Pennsaid 2% is more viscous, is supplied in a metered dose pump bottle and has been approved in the U.S. for twice daily dosing compared to four times a day for Pennsaid.
Pesticide	A substance used for destroying insects or other organisms harmful to cultivated plants or to animals.
PIPEDA	Has the meaning ascribed thereto in “Risk Factors – Risk Related to the Industry in which the Company Operates – Laws and Regulations”.
Placebo	An inactive substance administered to a group of patients in a clinical study in order to form a control group against which the results obtained from patients receiving an active substance can be measured.
Patented Medicine Prices Review Board	Patented Medicine Prices Review Board (PMPRB) has the meaning ascribed thereto in “Risk Factors – Risk Related to the Industry in which the Company Operates – Legislative or Regulatory Reform of the Healthcare System”.
Patent Trial and Appeal Board	Patent Trial and Appeal Board (PTAB) has the meaning ascribed thereto in “Legal Proceedings and Regulatory Actions – Vimovo”.
Preclinical studies	Those studies generally completed prior to human clinical trials.
Preferred Shares	Preferred Shares means the preferred shares in the capital of the Company.
Proton-pump inhibitors	Proton-pump inhibitors (PPI) are a group of drugs whose main action is a long-lasting reduction in the production of stomach acid.

Resultz	Resultz is a commercial-stage, OTC product intended to kill head lice and remove their eggs from hair with as little as a 5-minute treatment. It is a pesticide-free, topical solution that contains only two common cosmetic ingredients - 50% isopropyl myristate and 50% cyclomethicone D5.
Risk Evaluation and Mitigation Strategy	A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage a known or potential serious risk associated with a drug. A REMS may be required by the FDA and can include a Medication Guide, Patient Package Insert, a communication plan, an education plan, and even restricted marketing, to assure safe use of the drug.
RWI Policy	RWI Policy has the meaning ascribed thereto in "Significant Acquisitions – Aralez Transaction".
Sumatriptan	A serotonin-agonist drug used for the acute treatment of migraines.
Tetracaine	A local anesthetic drug that can be administered by local injection or by topical application to conjunctiva, mucosae and skin. When used topically, relieves pain by blocking signals at the nerve endings in skin and underlying tissues.
Therapeutic Products Directorate	The Therapeutic Products Directorate (TPD) is the division within Health Canada that reviews New Drug Submissions.
Suvexx/Treximet	Suvexx/Treximet (sumatriptan/naproxen sodium) is a migraine medicine that was developed by Aralez's wholly owned subsidiary POZEN, Inc. in collaboration with Glaxo Group Limited, d/b/a GSK. The product is formulated with POZEN's patented technology (now owned by Miravo) of combining a triptan, sumatriptan 85 mg, with an NSAID, naproxen sodium 500 mg and GSK's RT Technology in a single tablet.
Vimovo	Vimovo (naproxen/esomeprazole magnesium) is the brand name for a proprietary fixed-dose combination of enteric-coated naproxen, a pain-relieving NSAID, and immediate-release esomeprazole magnesium, a proton pump inhibitor (PPI), in a single delayed-release tablet.
Yosprala	Yosprala is currently the only prescription fixed-dose combination of aspirin (acetylsalicylic acid), an anti-platelet agent, and omeprazole, a proton-pump inhibitor (PPI), in the U.S.

APPENDIX I – AUDIT COMMITTEE CHARTER

NUVO PHARMACEUTICALS INC.
d/b/a
MIRAVO HEALTHCARE
(the “Corporation”)

AUDIT COMMITTEE CHARTER

PURPOSE

The purpose of the Audit Committee (the “Committee”) is to assist the board of directors of the Corporation (the “Board”) in fulfilling its responsibilities of oversight and supervision of the accounting and financial reporting practices and procedures, the adequacy of internal accounting controls and procedures and the quality and integrity of the consolidated financial statements of the Corporation and its affiliates. The Committee is also responsible for the audit process.

More specifically the purpose of the Committee is to satisfy itself that:

- A. The Corporation’s annual financial statements are fairly presented in accordance with International Financial Reporting Standards (“IFRS”) and to recommend to the Board whether the annual financial statements should be approved.
- B. The information contained in the Corporation’s quarterly financial statements, annual report and other financial publications, such as management’s discussion and analysis is complete and accurate in all material respects and to recommend to the Board whether these materials should be approved.
- C. The Corporation has appropriate systems of internal control over the safeguarding of assets and financial reporting to ensure compliance with legal and regulatory requirements.
- D. The external audit functions have been effectively carried out and that any matter which the independent auditors wish to bring to the attention of the Board has been addressed. The Committee will also review the qualifications and independence of the external auditors, and recommend to the Board the re-appointment or appointment of external auditors and their remuneration.

COMPOSITION AND TERMS OF OFFICE

- A. Following each annual meeting of the Corporation, the Board shall appoint three or more directors to serve on the Committee. Such appointees shall not be officers or employees of either the Corporation or its affiliates. Each member of the Committee must be “independent” as defined by National Instrument 52-110 – *Audit Committees*, as it may be amended or replaced from time to time (“NI 52-110”) and free of any relationship that could, or could reasonably be perceived to, in the opinion of the Board, interfere with the exercise of independent judgment as a member of the Committee. All members of the Committee must be financially literate and be able to read and understand fundamental financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of the issues that can

reasonably be expected to be raised by the Corporation's financial statements, including the Corporation's balance sheet, income statement and cash flow statement, or develop that capability within a reasonable time after appointment.

- B. The chair of Committee (the "**Chair**") shall be appointed by the Board and shall not be an officer or employee of the Corporation or its affiliates. The Chair shall be "financially literate" within meaning of NI 52-110, having an understanding of IFRS and financial statements, internal controls and procedures for financial reporting and, if possible, shall have served as the principal financial officer for another business entity.
- C. No members of the Committee shall receive, other than for service on the Board or the Committee or other committees of the Board, any consulting, advisory, or other compensatory fee from the Corporation or its affiliates.
- D. Any member of the Committee may be removed or replaced at any time by the Board and shall cease to be a member upon ceasing to be a director of the Corporation. Each member of the Committee shall hold office until the close of the next annual meeting of the Corporation or until the member resigns or is replaced, whichever first occurs. The Board may fill vacancies on the Committee by election from among the Board. If and whenever a vacancy shall exist on the Committee, the remaining members may exercise all powers of the Committee so long as a quorum remains.
- E. The Committee will meet at least four times per year. The meetings will be scheduled to permit timely review of the interim and annual financial statements of the Corporation and its affiliates. Additional meetings may be held as deemed necessary by the Chair or as requested by any member of the Committee or by the external auditors.
- F. Meetings of the Committee shall be held from time to time and at such place as any member of the Committee shall determine upon prior notice to each of the other Committee members. If all members consent, and proper notice has been given or waived, a member or members of the Committee may participate in a meeting of the Committee by means of telephone, electronic or other such communication facilities as to permit all persons participating in the meeting to communicate adequately with each other, and a member participating in such a meeting by any such means is deemed to be present at that meeting.
- G. A quorum for the transaction of business at all meetings of the Committee shall be a majority of the members of the Committee. Questions arising at any meeting shall be determined by a majority of votes of the members of the Committee present, and in case of an equality of votes the Chair shall have a second casting vote.
- H. The Committee may invite such directors, officers and employees of the Corporation as it may see fit from time to time to attend meetings of the Committee and assist in the discussion and consideration of the business of the Committee, but without voting rights.
- I. The Committee shall keep regular minutes of proceedings and shall cause them to be recorded in books kept for that purpose, and shall report the same to the Board at such times as the Board may, from time to time, require.
- J. Supporting schedules and information reviewed by the Committee will be available for examination by any director upon request to the Secretary of the Committee.

- K. The Committee shall choose as its secretary such person as it deems appropriate.
- L. The external auditors shall be given notice of, and have the right to appear before and to be heard at, every meeting of the Committee, and shall appear before the Committee when requested to do so by the Committee.

LIMITATIONS ON COMMITTEE'S DUTIES

In contributing to the Committee's discharge of its duties, each member of the Committee shall be obliged only to exercise the care, diligence and skill that a reasonably prudent person would exercise in comparable circumstances. Nothing in this Charter is intended or may be construed as imposing on any member of the Committee a standard of care or diligence that is in any way more onerous or extensive than the standard to which any member of the Board may be otherwise subject.

Members of the Committee are entitled to rely, absent actual knowledge to the contrary, on (i) the integrity of the persons and organizations from whom they receive information, (ii) the accuracy and completeness of the information provided, (iii) representations made by management of the Corporation as to the non-audit services provided to the Corporation by the external auditor, (iv) financial statements of the Corporation represented to them by a member of management or in a written report of the external auditors to present fairly the financial position of the Corporation in accordance with applicable generally accepted accounting principles, and (v) any report of a lawyer, accountant, engineer, appraiser or other person whose profession lends credibility to a statement made by any such person.

RESPONSIBILITIES

Subject to the powers and duties of the Board, the Board hereby delegates to the Committee the following powers and duties to be performed by the Committee on behalf of and for the Board:

Financial Reporting Control

The Committee shall:

- (a) review reports from senior officers of the Corporation, outlining any significant changes in financial risks facing the Corporation;
- (b) review the management letter of the external auditors and responses to suggestions made;
- (c) annually review this Charter and the performance of the Committee itself;
- (d) review any new appointments to senior positions of the Corporation or its affiliates, with financial reporting responsibilities;
- (e) obtain assurance the external auditors regarding the overall control environment and the adequacy of accounting system controls; and
- (f) assess the overall effectiveness of the internal control and risk management frameworks through discussions with management and the external auditors and assess whether

recommendations made by the external auditors have been implemented by management.

Interim Financial Statements

The Committee shall:

- (a) review interim financial statements with officers of the Corporation prior to their release and recommend their approval to the Board. This will include a detailed review of quarterly and year-to-date results; and
- (b) review the Corporation's management's discussion and analysis and press releases accompanying interim financial statements.

Annual Financial Statements and Other Financial Information

The Committee shall:

- (a) review any changes in accounting policies or financial reporting requirements that may affect the current year's financial statements;
- (b) obtain summaries of significant transactions and other potentially difficult matters whose treatment in the annual financial statements merit advance consideration;
- (c) obtain draft annual financial statements in advance of the Committee meeting and assess, on a preliminary basis, the reasonableness of the financial statements in light of the analyses provided by officers of the Corporation;
- (d) review any material pending or threatened litigation, claims and assessments that could have a material effect upon the financial position or operating results of the Corporation and the appropriateness of the disclosure thereof in the documents reviewed by the Committee;
- (e) discuss the annual financial statements and the auditors' report thereon in detail with officers of the Corporation and its auditors;
- (f) review the annual report and other annual financial reporting documents, including management's discussion and analysis and press release;
- (g) provide to the Board a recommendation as to whether the annual financial statements should be approved;
- (h) review insurance coverage including directors' and officers' liability coverage ; and
- (i) review the Corporation's Annual Information Form and ensure compliance with Form 52-110F1 – *Audit Committee Information Required in an AIF*.

External Audit Terms of Reference, Reports, Planning and Appointment

The Committee shall:

- (a) ensure that the external auditor explicitly acknowledges that they are ultimately and directly accountable to the Board and the Committee as representatives of the shareholders;
- (b) review the audit plan with the external auditors;
- (c) specify its expectations of the external auditors, including the expected relationship between the external auditors and the Committee;
- (d) discuss in private with the external auditors matters affecting the conduct of their audit and other corporate matters, including:
 - the quality (not only acceptability) of IFRS accounting principles;
 - the quality of internal controls;
 - the appropriateness of financial statement disclosures;
 - the relationships between the external auditors and the Corporation, its management or employees;
 - the risks or exposures facing the Corporation; and
 - any other matters the external auditors may wish to bring to the attention of the Committee.
- (e) recommend to the Board each year the retention or replacement of the external auditors. This process shall include establishment of criteria for and an ongoing assessment of the continued independence of the external auditor. If there is a plan to change auditors, review all issues related to the change and the steps planned for an orderly transition;
- (f) where there are significant unsettled issues between management and the external auditor that do not affect the audited financial statements, ensure that there is an agreed course of action leading to the resolution of such matters; and
- (g) annually review and recommend for approval to the Board the terms of engagement and the remuneration of the external auditors.

Other Matters

The Committee shall:

- (a) pre-approve all non-audit services to be provided to the Corporation or its subsidiary entities by the issuer's external auditor or delegate such pre-approval of non-audit services to a member or certain members of the Committee, provided that these member or members shall notify the Committee at each Committee meeting of the non-audit services they approved since the last Committee meeting;

- (b) review periodically management reports assessing the adequacy and effectiveness of the Corporation's disclosure controls and procedures;
- (c) establish procedures for the review of the Corporation's public disclosure of financial information extracted or derived from the Corporation's financial statements and the related management's discussion and analysis;
- (d) establish procedures for the receipt, retention and treatment of complaints received by the issuer regarding accounting, internal accounting controls, or auditing matters; and
- (e) establish procedures for the confidential, anonymous submission by employees of the issuer of concerns regarding questionable accounting or auditing matters.

MEETINGS

The Committee shall meet at least four times per year and more frequently as circumstances require. All members of the Committee should strive to be at all meetings. The Committee shall meet separately, periodically, with senior management and may request any member of the Corporation's senior management or the Corporation's outside counsel to attend meetings of the Committee or with any members of, or advisors to, the Committee. The Committee will also meet in camera at each of its regularly scheduled meetings.

Quorum for the transaction of business at any meeting of the Committee shall be a majority of the number of members of the Committee or such greater number as the Committee shall by resolution determine. The powers of the Committee may be exercised at a meeting at which a quorum of the Committee is present in person or by telephone or other electronic means or by a resolution signed by all members entitled to vote on that resolution at a meeting of the Committee. Each member (including the Chair) is entitled to one (but only one) vote in Committee proceedings. The Committee shall keep minutes of each meeting of the Committee.

Meetings of the Committee shall be held from time to time and at such place as a member of the Committee may request upon 48 hours prior notice. The notice period may be waived by a quorum of the Committee.

The Committee may delegate authority to individual members and subcommittees of its members where the Committee determines it is appropriate to do so.

INDEPENDENT ADVICE

In discharging its mandate, the Committee shall have the authority to retain, at the expense of the Corporation, special advisors as the Committee determines to be necessary to permit it to carry out its duties.

ACCOUNTABILITY

- A. The Committee shall report to the Board at its next regular meeting all such action it has taken since the previous report.
- B. The Committee is empowered to investigate any activity of the Corporation and all employees are to co-operate as requested by the Committee. The Committee may retain persons having special expertise to assist it in fulfilling its responsibilities.

- C. The Committee is authorized to request the presence at any meeting, but without voting rights, of a representative from the external auditors, senior management, legal counsel or anyone else who could contribute substantively to the subject of the meeting and assist in the discussion and consideration of the business of the Committee, including directors, officers and employees of the Corporation.

NO RIGHTS CREATED

This Charter is a broad policy statement and is intended to be part of the Committee's flexible governance framework. While this Charter should comply with all applicable law and the Corporation's constituting documents, this Charter does not create any legally binding obligations on the Committee, the Board, any director or the Corporation.

March 5, 2021